GILEAD SCIENCES INC
Form 10-Q
May 05, 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 March 31, 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**

(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
333 Lakeside Drive, Foster City, California	**94404**

(Address of principal executive offices) (Zip Code)

650-574-3000
Registrant s telephone number, including area code

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

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

Number of shares outstanding of the issuer s common stock, par value $.001 per share, as of April 30, 2004: 214,322,265

GILEAD SCIENCES, INC.

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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 . 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)

	March 31, 2004 (unaudited)	December 31, 2003 (Note)
Assets		
Current assets:		
Cash and cash equivalents	$ 155,585	$ 194,719
Marketable securities	682,057	512,281
Accounts receivable	257,491	235,217
Inventories	101,252	98,102
Deferred tax assets	162,847	197,567
Prepaid expenses and other	35,782	28,012
Total current assets	1,395,014	1,265,898
Property, plant and equipment, net	198,951	198,200
Noncurrent deferred tax assets	43,994	52,494
Other noncurrent assets	37,563	38,130
	$ 1,675,522	$ 1,554,722
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 28,105	$ 35,649
Accrued clinical and preclinical expenses	14,605	11,859
Accrued compensation and employee benefits	31,561	35,772
Income taxes payable	14,544	13,305
Other accrued liabilities	74,617	83,836
Deferred revenue	12,357	5,474
Total current liabilities	175,789	185,895
Long-term deferred revenue	22,305	20,530
Long-term obligations	331	323
Convertible senior debt	345,000	345,000
Commitments and contingencies		
Stockholders equity:		
	214	213

Common stock, par value $.001 per share; 500,000 shares authorized; 213,940 and 213,253 shares issued and outstanding at March 31, 2004 and December 31, 2003, respectively				
Additional paid-in capital		1,464,119		1,453,203
Deferred compensation		(1,013)		(1,306)
Accumulated other comprehensive income		7,992		4,507
Accumulated deficit		(339,215)		(453,643)
Total stockholders equity		1,132,097		1,002,974
	$	1,675,522	$	1,554,722

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 March 31,	
	2004	**2003**
Revenues:		
Product sales	$ 276,585	$ 155,964
Royalty and contract revenue	32,542	9,141
Total revenues	309,127	165,105
Costs and expenses:		
Cost of goods sold	34,949	21,372
Research and development	53,678	41,140
Selling, general and administrative	76,077	47,591
Purchased in-process research and development		488,599
Total costs and expenses	164,704	598,702
Income (loss) from operations	144,423	(433,597)
Gain on equity investment	20,576	
Interest and other income, net	2,928	3,817
Interest expense	(2,089)	(5,614)
Income (loss) before provision for income taxes	165,838	(435,394)
Provision for income taxes	51,410	2,660
Net income (loss)	$ 114,428	$ (438,054)
Net income (loss) per share - basic	$ 0.54	$ (2.21)
Net income (loss) per share - diluted	$ 0.50	$ (2.21)
Shares used in per share calculation - basic	213,634	198,328
Shares used in per share calculation - diluted	230,201	198,328

See accompanying notes.

GILEAD SCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)

	Three Months Ended March 31,	
	2004	2003
OPERATING ACTIVITIES:		
Net income (loss)	$ 114,428	$ (438,054)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation and amortization	5,850	4,599
Purchased in-process research and development		488,599
Gain on equity investment	(20,576)	
Deferred tax assets	43,220	
Other non-cash transactions	3,470	377
Changes in assets and liabilities:		
Accounts receivable	(27,391)	(20,973)
Inventories	(3,150)	(4,892)
Prepaid expenses and other assets	(9,345)	(1,603)
Accounts payable	(7,544)	(5,409)
Accrued liabilities	(9,414)	1,423
Deferred revenue	8,658	(3,125)
Net cash provided by operating activities	98,206	20,942
INVESTING ACTIVITIES:		
Purchases of marketable securities	(365,206)	(307,130)
Sales of marketable securities	149,688	124,824
Maturities of marketable securities	68,365	12,130
Acquisition of Triangle net assets, net of cash acquired		(375,507)
Capital expenditures	(5,355)	(2,670)
Net cash used in investing activities	(152,508)	(548,353)
FINANCING ACTIVITIES:		
Proceeds from issuances of common stock	10,917	26,359
Repayments of long-term debt	(23)	(1,760)
Net cash provided by financing activities	10,894	24,599
Effect of exchange rates on cash	4,274	3,358
Net decrease in cash and cash equivalents	(39,134)	(499,454)
Cash and cash equivalents at beginning of period	194,719	616,931
Cash and cash equivalents at end of period	$ 155,585	$ 117,477

See accompanying notes.

GILEAD SCIENCES, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
March 31, 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 fair presentation 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 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).

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 common shares outstanding during the period. For the three months ended March 31, 2004, diluted net income per share includes the effect of options to purchase 9.2 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 4.2 million shares of common stock were outstanding during the three months ended March 31, 2004, but were not included in the computation of diluted earnings per share because the options exercise price was greater than the average market price of our common stock during this period, therefore, their effect is antidilutive. Diluted net loss per share for the three months ended March 31, 2003 does not include the effect of options to purchase 10.0 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, or the effect of the $345.0 million 2% convertible senior debt as their effect was 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* (SFAS 123), we have elected to continue to follow Accounting Principles Board Opinion (APB) No. 25, *Accounting for Stock Issued to Employees*, and Financial Accounting Standards Board Interpretation No. 44 (FIN 44), *Accounting for Certain Transactions Involving Stock Compensation an Interpretation of APB Opinion No. 25,* 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 March 31,	
	2004	2003
Net income (loss) as reported	$ 114,428	$ (438,054)
Add: Stock-based employee compensation expense included in reported net income (loss), net of related tax effects	179	46
Deduct: Total stock-based employee compensation expense determined under the fair value based method for all awards, net of related tax effects	(16,894)	(18,824)
Pro forma net income (loss)	$ 97,713	$ (456,832)
Net income (loss) per share:		
Basic - as reported	$ 0.54	$ (2.21)
Basic - pro forma	$ 0.46	$ (2.30)
Diluted - as reported	$ 0.50	$ (2.21)
Diluted - pro forma	$ 0.43	$ (2.30)

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 March 31,	
	2004	2003
Expected life in years (from vesting date):		
Stock options	1.84	1.84
ESPP	1.63	1.52
Discount rate:		
Stock options	2.9%	2.4%
ESPP	1.7%	2.5%

Volatility		51	%	81	%
Expected dividend yield		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. An approximate two-year time period was used 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):

	March 31, 2004	December 31, 2003
Raw materials	$ 64,873	$ 54,178
Work in process	7,719	11,775
Finished goods	28,660	32,149
Total inventories	$ 101,252	$ 98,102

3. Comprehensive Income (Loss)

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

	Three Months Ended March 31,	
	2004	2003
Net income (loss)	$ 114,428	$ (438,054)
Net foreign currency translation gain (loss)	(712)	3,194
Net unrealized gain (loss) on available-for-sale securities	839	(789)
Net unrealized gain on cash flow hedges	3,358	1,021
Comprehensive income (loss)	$ 117,913	$ (434,628)

4. Gain on Equity Investment

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 included in our condensed consolidated statement of operations. 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 net exercised the warrant and now hold 646,841 shares of Eyetech common stock included within marketable securities on the accompanying balance sheet. The net exercise feature of the warrant enabled a cashless exercise which utilized shares of Eyetech common stock as consideration. The shares are subject to a 180-day lockup period, which will expire during the third quarter of 2004. In accordance with SFAS No. 115, the shares will be reported at their fair market value with the unrealized gain or loss, if any, recorded to accumulated other comprehensive income on the condensed consolidated balance sheet until such time as they are sold when the gain or loss would be realized in our condensed consolidated statement of operations.

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 is currently evaluating its supply and sales strategy with respect to DaunoXome as we have decided to continue selling this product. 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.

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 90% of sales in 2003 and 89% of sales in the quarter ended March 31, 2004, have similar economic and other characteristics, including the nature of the products and production processes, type of customers, distribution methods, and regulatory environment.

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 month periods ended March 31, 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.

Product sales consisted of the following (in thousands):

	Three Months Ended March 31,	
	2004	2003
Viread	$ 193,096	$ 107,272
AmBisome	51,873	41,058
Other	31,616	7,634
Total product sales	$ 276,585	$ 155,964

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

	Three Months Ended March 31,	
	2004	2003
United States	$ 143,077	$ 79,186
Switzerland	29,618	5,175
France	30,912	17,851
Spain	26,147	15,877
United Kingdom	17,470	12,219
Italy	16,376	9,027
Germany	11,947	6,970
Other European countries	23,554	15,872
Other countries	10,026	2,928
Total revenues	$ 309,127	$ 165,105

For the three months ended March 31, 2004, product sales to two distributors accounted for approximately 13% and 17% of total revenues. For the three months ended March 31, 2003, product sales to three distributors accounted for approximately 11%, 11% and 15% of total revenues.

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 revenues from six 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) and Emtriva (emtricitabine) 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, based on new facts and circumstances described in Footnote 5, we have decided to continue to sell DaunoXome in certain markets around the world. 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 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. Also, as Viread and AmBisome are used over longer periods of time, new safety issues may arise which could reduce our revenues. In addition, as these products mature, private insurers and government reimbursers may reduce the amount they will reimburse patients, which will increase pressure on us to reduce prices.

New Products and New Indications. If we do not introduce new products or increase revenues from our existing products, we may 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. If Hepsera does not continue to demonstrate a superior resistance profile compared to lamivudine, which is its primary advantage over this competitor, sales of Hepsera may decline. In addition, we may not be able to develop a co-formulation of tenofovir (Viread) with emtricitabine (Emtriva) that will support regulatory approval. If we fail to increase our sales of Hepsera or if we do not successfully market a co-formulation of emtricitabine and tenofovir, we may not be able to increase revenues and expand our research and development efforts.

Safety. As our products, including Viread, AmBisome, Hepsera, and Emtriva, 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. For example, while we did not observe clinically significant kidney toxicity in our clinical trials of Viread, kidney toxicity has been reported with post-approval use of Viread and the Viread label has been updated to include this warning. 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 and Emtriva 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. For example, on August 7, 2003, the FDA issued a written warning concerning our promotional practices of Viread. If we fail to comply with applicable regulatory requirements, we could be subject to penalties including fines or suspensions of regulatory approvals.

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.

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

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.

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, a substantial portion of our product sales in the United States is conducted with three distributors, Amerisource Bergen Corp., McKesson Corp. and Cardinal Health, Inc. Inventory levels held by these and other wholesalers may fluctuate significantly which could cause our sales to them and as a result, our operating results, to fluctuate unexpectedly 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 have agreed to 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 must be 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.

Compulsory Licenses. 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 make their HIV drugs available at a low cost, their patents might not be enforceable to prevent generic competition. If certain countries do not permit enforcement of our patents, sales of our products 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 our products in those countries, thereby reducing our sales, or we could respond to governmental concerns by reducing prices for our products. In addition, compulsory licenses may increase the risk of

counterfeiting, as we would no longer have control over manufacturing and distribution in those markets. In addition, countries such as Canada are considering amending their patent laws to permit export of otherwise patented products to countries in the developing world.

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 and Viread will also depend largely on obtaining and maintaining government reimbursement because in many European countries, including the United Kingdom and France, patients are reluctant to 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 product liability insurance, a successful product liability claim against us may not be covered by our insurance or could require us to pay amounts beyond that provided by our insurance, either of which could impair our financial condition and our ability to clinically test and to market our products.

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

Our operating results for the first quarter of 2004 in comparison to the first quarter of 2003 were characterized by solid growth in our key HIV drug, Viread, leading to a record quarter for total product revenues. Based on independent third party data, Viread has now become the most widely prescribed antiretroviral in its class of drugs, achieving more new and total prescriptions than competing drugs in the nucleotide/nucleoside reverse transcriptase inhibitor (NRTI) market. As a result of the growth of Viread sales, leading to strong growth in operating income, we have generated a significant increase in cash flow from operations, with an increase to $98.2 million in the first quarter of 2004 from $20.9 million in the first quarter of 2003, or 369% year over year growth. 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 both Viread and Emtriva (acquired from Triangle) now provide physicians the ability to construct once-daily regimens.

Total revenues

We had total revenues of $309.1 million for the quarter ended March 31, 2004 compared with $165.1 million for the quarter ended March 31, 2003. Included in total revenues are product sales, 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 March 31, 2004	Change		Three Months Ended March 31, 2003
Viread	$	193,096	80%	$	107,272
AmBisome		51,873	26%		41,058
Other		31,616	314%		7,634
Total product sales	$	276,585	77%	$	155,964

The increase in product sales is primarily due to the significant 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 and has since become an antiretroviral therapy widely prescribed by physicians. Sales of Viread in the first quarter of 2004 were 70% of total product sales, compared to 69% of total product sales in the same period of 2003. Of the Viread sales in the first quarter of 2004, $115.9 million were U.S. sales, an increase of 68% compared to the first quarter of 2003, and $77.2 million were international sales, an increase of 101% compared to the same period in 2003. International sales in 2004 were positively impacted by $9.8 million due to a more favorable currency environment compared to the first quarter of 2003. With the continued market expansion of Viread, we expect Viread sales in 2004 to grow approximately 30% to 35% and be in the range of $725 million to $775 million for the year.

Sales of AmBisome accounted for 19% of product sales in the quarter ended March 31, 2004 compared to 26% of product sales in the quarter ended March 31, 2003. AmBisome sales in the first quarter of 2004 were $7.3 million higher due to the favorable currency environment compared to the same quarter last year. On a volume basis, AmBisome sales increased by 6% in Europe compared to the first quarter of 2003 due to stronger than expected demand. With an expected increase in competition, we believe 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 $18.9 million during the quarter ended March 31, 2004, an increase of 226% compared to the first quarter of 2003. This increase was primarily driven by prescription growth in both the U.S. and Europe. Sales of Emtriva totaled $12.0 million for the quarter ended March 31, 2004. Emtriva was approved for marketing in the U.S. in July 2003 and in the European Union in October 2003.

Royalty and contract revenue

Royalty and contract revenue was $32.5 million for the first quarter of 2004 compared with $9.1 million for the comparable quarter in 2003. The most significant source of royalty and contract revenue recorded in the first quarters of 2004 and 2003 was from worldwide sales of Tamiflu by Roche, which generated royalties of $27.4 million and $4.3 million, respectively. The significant year over year increase in Tamiflu royalty was due primarily to the severe U.S. flu season in the fourth quarter of 2003. We record royalties from Roche in the quarter following the quarter in which the related Tamiflu sales occur.

Cost of Goods Sold

Cost of goods sold was $34.9 million in the first quarter of 2004, compared with $21.4 million in the first quarter of 2003. The increase from 2003 to 2004 can primarily be attributed to increases in the volume of Viread sold, which grew 80% versus the same period last year.

Gross Margins

Product gross margins were 87.4% in the first quarter of 2004, compared with 86.3% in the same period of 2003. The improvement from 2003 to 2004 is primarily driven by product mix as Viread and Hepsera, both higher margin products, contributed more significantly to net product sales in the first quarter of 2004 compared to the same period in 2003.

Foreign exchange also 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 first quarter of 2004, gross margins were positively impacted by the weakening U.S. dollar compared to the first quarter 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 $53.7 million for the first quarter of 2004, up 30% from $41.1 million for the first quarter of 2003. The increase in R&D expenses for the first quarter 2004 is primarily attributable to increased headcount, costs associated with the development of the co-formulation of Viread and Emtriva, and research spending on prodrug technology. Based on current budgeted programs, we expect R&D expenses for the 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 the fixed-dose combination of Viread and Emtriva.

Selling, General and Administrative Expenses

Selling, general and administrative (SG&A) expenses were $76.1 million for the first quarter of 2004 compared to $47.6 million for the first quarter of 2003. The 60% increase is 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 $310 million to $330 million, or 25% to 30% higher than 2003 levels, primarily due to the increase in marketing activities associated with the continued promotion of Viread, Emtriva, Hepsera and AmBisome.

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. 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 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 successfully 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 exhibited in patients with HIV infection.	Phase 2 trials at acquisition date. Effective January 28, 2004, we announced our intent to terminate the licensing agreement with Emory University and the University of Georgia Research Foundation, Inc. and development will be discontinued.	$ 114.8
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 remaining efforts for completion of Triangle s research and development projects primarily consist of clinical trials, the cost, length and success of which are extremely difficult to predict. Numerous risks and uncertainties exist that could prevent completion of development, including the ability to enroll patients in clinical trials, the possibility of unfavorable results of our clinical trials, and the risk of failing to obtain FDA and other regulatory body approvals. 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, purchased from Triangle, will be approved in the U.S. or the European Union or whether marketing approvals will have significant limitations on its use. We have terminated our rights with respect to the other potential products that we acquired with the acquisition of Triangle. We also do not yet have approval of the fixed-dose combination product containing tenofovir DF and emtricitabine. Future discussions with regulatory agencies will determine the amount of data needed and timelines for review, which may differ materially from current projections. The acquired products under development may never be successfully commercialized. Emtriva, for example, is a product with many similarities to other existing products. As a result, it may be difficult to successfully penetrate the market and to achieve significant revenues. In addition, 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, if we believe commercialization will be difficult relative to other opportunities in our pipeline. If these programs cannot be completed on a timely basis or at all, then our prospects for future revenue growth would be adversely impacted.

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.

Gain on Equity Investment

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. 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 net exercised the warrant and now hold 646,841 shares of Eyetech common stock included within marketable securities on the accompanying balance sheet. The net exercise feature of the warrant enabled a cashless exercise which utilized shares of Eyetech common stock as consideration. These shares are subject to a 180-day lockup period that expires during the third quarter of 2004. In accordance with SFAS No. 115, the shares will be reported at their fair market value with the unrealized gain or loss, if any, recorded to accumulated other comprehensive income on the condensed consolidated balance sheet until such time as they are sold when the gain or loss would be realized in our condensed consolidated statement of operations.

Interest and Other Income, net

We reported interest and other income of $2.9 million for the quarter ended March 31, 2004, down from $3.8 million for the quarter ended March 31, 2003. This decrease is attributable to the decline in interest rates over the past year.

Interest Expense

Interest expense was $2.1 million for the quarter ended March 31, 2004 and $5.6 million for the quarter ended March 31, 2003. This decrease 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 quarter 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 first quarter of 2004. Our provision for income taxes for the first quarter of 2004 was $51.4 million compared to $2.7 million for the first quarter of 2003. The provision in the first quarter of 2003 was primarily associated with income earned by our foreign subsidiaries and federal alternative minimum tax. The effective tax rate for the first quarter 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 first quarter of 2004 as a result of the strengthening Euro versus the comparable period last year was a positive $10.6 million. This includes the impact from revenues, international spending as well as hedging activity.

Liquidity and Capital Resources

Cash, cash equivalents and marketable securities totaled $837.6 million at March 31, 2004, up from $707.0 million at December 31, 2003. The increase of $130.6 million was primarily due to net cash provided by operations of $98.2 million and proceeds from issuances of stock under employee stock plans of $10.9 million. In addition, we now hold marketable equity securities worth approximately $21.5 million at March 31, 2004 as a result of our net exercise of the warrant to purchase Eyetech stock, which completed an initial public offering during the quarter. These shares are subject to a 180-day lockup period that expires during the third quarter of 2004. In accordance with SFAS No. 115, the shares will be reported at their fair market value with the unrealized gain or loss, if any, recorded to accumulated other comprehensive income on the condensed consolidated balance sheet until such time as they are sold when the gain or loss would be realized in our condensed consolidated statement of operations.

Working capital at March 31, 2004 was $1,219.2 million compared to $1,080.0 million at December 31, 2003. Significant changes in working capital during the first quarter of 2004 included a $27.4 million increase in accounts receivable, a $34.7 million decrease in current deferred tax assets, a $7.5 million decrease in accounts payable and a $9.4 million decrease in accrued liabilities. The accounts receivable increase was primarily due to increased sales of Viread in the U.S. and Europe. The $34.7 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. Significant changes in current liabilities during the first quarter of 2004 included the decrease in accounts payable which is primarily due to the timing of payments to vendors as well as slightly lower operating expense levels compared to the fourth quarter of 2003. The $9.4 million decrease in accrued liabilities is 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 quarter of 2004.

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 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 costs associated with our no-profit Global Access program for least developed nations,

the possibility of acquiring manufacturing capabilities or office facilities,

the possibility of acquiring other companies or new products, 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, 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 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

As of March 31, 2004, our $345.0 million convertible senior notes had a fair value of $457.1 million. In addition, we now hold marketable equity securities worth approximately $21.5 million at March 31, 2004 as a result of our net exercise of the warrant to purchase Eyetech stock, which completed an initial public offering during the quarter. In accordance with SFAS No. 115, the shares will be reported at their fair market value with the unrealized gain or loss, if any, recorded to accumulated other comprehensive income on the condensed consolidated balance sheet. 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 March 31, 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 March 31, 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 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits

No. 10.74 Employment Agreement, dated April 26, 2004, by and between Gilead Sciences, Inc. and Mark L. Perry

No. 31.1 Certification

No. 31.2 Certification

No. 32 Certification

(b) Reports on Form 8-K

On January 29, 2004, the Company filed an 8-K announcing the earnings of the Company for the fourth quarter and year ended December 31, 2003.

SIGNATURES

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

GILEAD SCIENCES, INC.
(Registrant)

Date: May 4, 2004

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

Date: May 4, 2004

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

Exhibit Index

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