

GILEAD SCIENCES INC
Form 10-Q
May 03, 2006
Table of Contents

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

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended March 31, 2006

or

.. TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

Commission File Number 0-19731

GILEAD SCIENCES, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

94-3047598
(I.R.S. Employer
Identification No.)

333 Lakeside Drive, Foster City, California

94404

Edgar Filing: GILEAD SCIENCES INC - Form 10-Q

(Address of Principal Executive Offices)

650-574-3000

(Zip Code)

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 a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

Number of shares outstanding of the issuer's common stock, par value \$0.001 per share, as of April 28, 2006: 455,016,054

Table of Contents

GILEAD SCIENCES, INC.

INDEX

PART I. FINANCIAL INFORMATION

Item 1.	<u>Condensed Consolidated Financial Statements:</u>	
	<u>Condensed Consolidated Balance Sheets at March 31, 2006 and December 31, 2005</u>	3
	<u>Condensed Consolidated Statements of Income for the Three Months Ended March 31, 2006 and 2005</u>	4
	<u>Condensed Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2006 and 2005</u>	5
	<u>Notes to Condensed Consolidated Financial Statements</u>	6
Item 2.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	16
Item 3.	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	23
Item 4.	<u>Controls and Procedures</u>	23

PART II. OTHER INFORMATION

Item 1.	<u>Legal Proceedings</u>	23
Item 1A.	<u>Risk Factors</u>	23
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	27
Item 6.	<u>Exhibits</u>	28

SIGNATURES

29

We own or have rights to various trademarks, copyrights and trade names used in our business including the following: GILEAD SCIENCES®, HEPSERA®, VIREAD®, VISTIDE®, DAUNOXOME®, AMBISOME®, EMTRIVA® and TRUVADA®. MACUGEN® is a registered trademark belonging to OSI Pharmaceuticals, Inc. SUSTIVA® is a registered trademark and BARACLUDE™ is a trademark of Bristol-Myers Squibb Company. TAMIFLU® is a registered trademark belonging to F. Hoffmann-La Roche Ltd. This report also includes other trademarks, service marks and trade names of other companies.

Table of Contents**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, 2006 (unaudited)	December 31, 2005 (1)
Assets		
Current assets:		
Cash and cash equivalents	\$ 268,677	\$ 707,913
Marketable securities	2,270,944	1,603,120
Accounts receivable, net	433,633	396,125
Inventories	224,372	216,903
Deferred tax assets	97,905	84,839
Prepaid expenses	39,105	48,383
Other current assets	40,769	34,925
Total current assets	3,375,405	3,092,208
Property, plant and equipment, net	240,587	242,568
Noncurrent portion of prepaid royalties	328,332	333,582
Noncurrent deferred tax assets	60,163	66,893
Other noncurrent assets	32,047	29,400
	\$ 4,036,534	\$ 3,764,651
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	\$ 60,209	\$ 61,083
Accrued clinical and preclinical expenses	10,260	10,514
Accrued compensation and employee benefits	52,604	59,927
Income taxes payable	73,710	95,739
Other accrued liabilities	151,865	149,516
Deferred revenue	12,881	18,353
Current portion of long-term debt	60,000	60,000
Current portion of other long-term obligations	374	206
Total current liabilities	421,903	455,338
Long-term deferred revenue	31,787	32,725
Long-term debt	184,000	240,000
Other long-term obligations	382	650
Minority interest in joint venture	10,049	8,160
Commitments and contingencies		
Stockholders equity:		
Common stock, par value \$0.001 per share; 700,000 shares authorized; 462,850 and 459,726 shares issued and outstanding at March 31, 2006 and December 31, 2005, respectively	463	460
Additional paid-in capital	2,318,077	2,206,228
Accumulated other comprehensive income (loss)	(2,473)	11,578

Edgar Filing: GILEAD SCIENCES INC - Form 10-Q

Deferred stock compensation		(130)
Retained earnings	1,072,346	809,642
Total stockholders' equity	3,388,413	3,027,778
	\$ 4,036,534	\$ 3,764,651

(1) The Condensed Consolidated Balance Sheet at December 31, 2005 has been derived from audited consolidated financial statements at that date but does not include all of the information and footnotes required by United States generally accepted accounting principles for complete financial statements.

See accompanying notes.

Table of Contents**GILEAD SCIENCES, INC.****CONDENSED CONSOLIDATED STATEMENTS OF INCOME**

(unaudited)

(in thousands, except per share amounts)

	Three Months Ended March 31,	
	2006	2005
Revenues:		
Product sales	\$ 559,353	\$ 400,211
Royalty and contract revenue	133,525	30,203
Total revenues	692,878	430,414
Costs and expenses:		
Cost of goods sold	90,357	57,415
Research and development	88,400	70,434
Selling, general and administrative	142,469	79,088
Total costs and expenses	321,226	206,937
Income from operations	371,652	223,477
Interest and other income, net	28,525	7,319
Interest expense	(3,724)	(9)
Minority interest in joint venture	994	261
Income before provision for income taxes	397,447	231,048
Provision for income taxes	134,743	73,935
Net income	\$ 262,704	\$ 157,113
Net income per share basic	\$ 0.57	\$ 0.35
Net income per share diluted	\$ 0.55	\$ 0.34
Shares used in per share calculation basic	461,425	449,549
Shares used in per share calculation diluted	481,802	467,619

See accompanying notes.

Table of Contents**GILEAD SCIENCES, INC.****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(unaudited)

(in thousands)

	Three Months Ended March 31,	
	2006	2005
OPERATING ACTIVITIES:		
Net income	\$ 262,704	\$ 157,113
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	11,243	6,137
Stock-based compensation expense	29,632	151
Excess tax benefits from stock-based compensation	(37,380)	
Deferred tax assets	(626)	30,579
Asset disposal	7,883	
Write-down of inventory	6,820	
Minority interest in joint venture	1,889	115
Other non-cash transactions	4,881	455
Changes in operating assets and liabilities:		
Accounts receivable, net	(41,329)	(223)
Inventories	(13,104)	485
Prepaid expenses and other assets	(5,832)	(14,996)
Accounts payable	(874)	(11,690)
Income taxes payable	9,642	29,576
Accrued liabilities	(7,245)	25,758
Deferred revenue	(6,410)	(634)
Net cash provided by operating activities	221,894	222,826
INVESTING ACTIVITIES:		
Purchases of marketable securities	(1,044,377)	(491,449)
Proceeds from sales of marketable securities	278,201	203,970
Proceeds from maturities of marketable securities	90,440	73,247
Capital expenditures and other	(14,258)	(8,875)
Net cash used in investing activities	(689,994)	(223,107)
FINANCING ACTIVITIES:		
Proceeds from issuances of common stock	43,529	17,031
Repayments of long-term debt and other obligations	(56,132)	120
Excess tax benefits from stock-based compensation	37,380	
Net cash provided by financing activities	24,777	17,151
Effect of exchange rate changes on cash	4,087	(15,838)
Net increase (decrease) in cash and cash equivalents	(439,236)	1,032
Cash and cash equivalents at beginning of period	707,913	280,909
Cash and cash equivalents at end of period	\$ 268,677	\$ 281,941

See accompanying notes.

Table of Contents

GILEAD SCIENCES, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2006

(unaudited)

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles for interim financial information. The financial statements include all adjustments (consisting only of normal recurring adjustments) that the management of Gilead Sciences, Inc. (Gilead, the Company or we) believes 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. On an on-going basis, management evaluates its estimates, including those related to revenue recognition, allowance for doubtful accounts, inventories, prepaid royalties, clinical trial accruals, our income tax provision and stock-based compensation. Actual results may differ from these estimates. The accompanying condensed consolidated financial statements include the accounts of the Company, its wholly owned subsidiaries and its joint venture with Bristol-Myers Squibb Company (BMS), for which Gilead is the primary beneficiary as determined under Financial Accounting Standards Board (FASB) Interpretation No. 46, *Consolidation of Variable Interest Entities* (FIN 46R). Minority interest is recorded for BMS's interest in the joint venture. Significant intercompany transactions have been eliminated.

During the three months ended March 31, 2006, we began reporting net foreign exchange transaction gains or losses as well as fair value changes on derivative instruments not designated as hedges, in interest and other income, net, in our Condensed Consolidated Statements of Income. These amounts, which were previously reported as selling, general and administrative (SG&A) expenses, were reclassified to conform to the current period presentation. Additionally, we began classifying interest receivable related to our marketable securities from marketable securities into other current assets in our Condensed Consolidated Balance Sheets to conform to the current period presentation. This reclassification had the effect of increasing other current assets and decreasing marketable securities by \$12.9 million as of December 31, 2005. On our Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2005, this reclassification had the effect of decreasing net cash used in investing activities and decreasing net cash provided by operating activities by \$4.4 million. This reclassification did not affect our Condensed Consolidated Statements of Income.

The accompanying financial information should be read in conjunction with the audited consolidated financial statements for the year ended December 31, 2005, included in our Annual Report on Form 10-K as filed with the Securities and Exchange Commission (SEC).

Earnings Per Share

Basic earnings per share is calculated based on the weighted-average number of shares of common stock outstanding during the period. Diluted earnings per share is calculated based on the weighted-average number of shares of common stock and other dilutive securities outstanding during the period. Potential dilutive shares of common stock resulting from the assumed exercise of outstanding stock options and equivalents are determined based on the treasury stock method.

Table of Contents

The following table is a reconciliation of the numerator and denominator used in the calculation of basic and diluted earnings per share (in thousands):

	Three Months Ended March 31,	
	2006	2005
Numerator:		
Net income used in calculation of diluted earnings per share	\$ 262,704	\$ 157,113
Denominator:		
Weighted-average shares of common stock outstanding used in calculation of basic earnings per share	461,425	449,549
Effect of dilutive securities:		
Stock options and equivalents	20,377	18,070
Weighted-average shares of common stock outstanding used in calculation of diluted earnings per share	481,802	467,619

Options to purchase approximately 4.9 million and 2.5 million shares of common stock were also outstanding during the three months ended March 31, 2006 and 2005, respectively, 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 was antidilutive.

Stock-Based Compensation

In December 2004, the FASB issued Statement of Financial Accounting Standards (SFAS) No. 123 (revised 2004), *Share-Based Payment* (SFAS 123R), a revision of SFAS No. 123, *Accounting for Stock-Based Compensation* (SFAS 123), which requires that all share-based payments to employees and directors, including grants of stock options, be recognized in the income statement based on their fair values, beginning with the first quarterly period after June 15, 2005, with early adoption permitted. SFAS 123R also requires the benefit of tax deductions in excess of recognized compensation cost to be reported in the statement of cash flows as a financing cash flow, rather than as an operating cash flow. SFAS 123R supersedes Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25) and amends SFAS No. 95, *Statement of Cash Flows*. On January 1, 2006, we adopted SFAS 123R using the modified prospective method, one of the adoption methods permitted under SFAS 123R (see Note 9).

2. INVENTORIES

Inventories are summarized as follows (in thousands):

	March 31, 2006	December 31, 2005
Raw materials	\$ 138,802	\$ 147,950
Work in process	31,132	25,061
Finished goods	54,438	43,892
Total inventories	\$ 224,372	\$ 216,903

Based on our current assessment of Gilead Access Program forecasted sales and existing pricing, we do not believe that we will fully recover the capitalized manufacturing costs associated with our existing Gilead Access Program inventory as of March 31, 2006. Accordingly, during the quarter ended March 31, 2006, we recorded \$6.8 million in cost of goods sold to write-down this inventory to its estimated net realizable value.

3. ASSET DISPOSAL

In March 2006, we received local city approval to proceed with the demolition of two of our owned buildings in Foster City, California, and to begin construction. We included the charge associated with the write-off of these buildings, equal to their aggregate net book value of \$7.9

million, in SG&A expenses.

4. EUROPEAN HEADQUARTERS RELOCATION

In June 2005, Gilead announced that the commercial, medical and administrative groups of its European headquarters, based in Paris, France, would be relocated to the London area in the United Kingdom. The European headquarters for our

Table of Contents

regulatory, safety and information technology groups are currently located in the Cambridge area in the United Kingdom. We believe that this relocation will enable us to achieve efficiencies through the closer proximity of the groups as Gilead positions itself to compete with the large pharmaceutical companies at a global level. Gilead's French subsidiary will continue to occupy Gilead's existing Paris facilities as we will continue to maintain and expand our sales and marketing presence in France.

In the third quarter of 2005, when the relocation plans were finalized, Gilead accrued a charge of \$8.4 million, primarily consisting of employee severance costs and termination benefits, which was included in SG&A expenses. As of March 31, 2006, approximately \$4.4 million has been charged against the accrual that is included in accrued compensation and employee benefits in the Condensed Consolidated Balance Sheet. The remaining payments are expected to be made during the second quarter of 2006. Additional costs relating to the new headquarters in the United Kingdom, including recruitment costs, legal expenses, capital expenditures and other related costs are being expensed as incurred. Based upon the most current information available, we believe that the aggregate severance, relocation and recruiting costs resulting from the relocation of our European headquarters continues to be in the range of \$10 million to \$13 million.

5. JAPAN TOBACCO

In March 2005, we entered into a licensing agreement with Japan Tobacco Inc. (Japan Tobacco), under which Japan Tobacco granted Gilead exclusive rights to develop and commercialize a novel HIV integrase inhibitor, GS 9137 (formerly called JTK-303), in all countries of the world, excluding Japan, where Japan Tobacco will retain such rights. Under the terms of the agreement, we incurred an upfront license fee of \$15.0 million which was included in research and development (R&D) expenses in the first quarter of 2005 as there was no future alternative use for this technology. In March 2006, we recorded \$5.0 million in R&D expenses related to a milestone we incurred as a result of dosing of the first patient in a Phase 2 clinical study. We are obligated to make additional payments upon the achievement of other milestones as well as pay royalties based on any future net product sales in the territories where we may market the drug.

6. JOINT VENTURE WITH BRISTOL-MYERS SQUIBB

In December 2004, we entered into a collaboration with BMS to develop and commercialize the single tablet regimen of Gilead's Truvada and BMS's Sustiva® (efavirenz) in the United States. Structured as a joint venture, Gilead and BMS formed the limited liability company, Bristol-Myers Squibb & Gilead Sciences, LLC. Under the terms of the collaboration, Gilead and BMS granted royalty-free sublicenses to the joint venture for the use of their respective company-owned technologies and, in return, were granted a license by the joint venture to use any intellectual property that results from the collaboration. The ownership interests of the joint venture by Gilead and BMS, which reflect their respective economic interests, are based on the fraction of the estimated net selling price of the single tablet regimen attributable to Truvada and Sustiva, respectively, and will be adjusted on an annual basis. Since the net selling price for Truvada may change over time relative to the net selling price of Sustiva, both Gilead's and BMS's respective economic interests in the joint venture may vary annually.

Gilead has primary responsibility for clinical development activities and regulatory filings relating to any new products resulting from the collaboration, and BMS and Gilead will share marketing and sales efforts (both parties will provide equivalent sales force efforts for a minimum number of years). The daily operations of the joint venture are governed by four primary joint committees. Gilead is responsible for accounting, financial reporting and product distribution for the joint venture. Both parties agreed to provide their respective bulk active pharmaceutical ingredients to the joint venture at their approximate market values. As of March 31, 2006 and December 31, 2005, the joint venture held approximately \$30.2 million and \$26.5 million, respectively, of the active pharmaceutical ingredient in Sustiva which it purchased from BMS at BMS's estimated net selling price of Sustiva in the U.S. market. In April 2006, the joint venture filed a New Drug Application with the U.S. Food and Drug Administration for approval of the single tablet regimen.

The joint venture's total equity investment at risk is not expected to be sufficient to allow it to finance its operational activities without the ongoing funding of Gilead and BMS. Although we are the primary beneficiary, the legal structure of the joint venture limits the recourse that its creditors will have over the general credit or assets of Gilead. As explained in Note 1, our condensed consolidated financial statements include the results of our joint venture with BMS and reflect BMS's minority interest in the joint venture.

7. CREDIT FACILITIES

In December 2005, we entered into an agreement with a syndicate of banks, to provide for a five-year \$500.0 million senior credit facility. The \$500.0 million facility consisted of an uncollateralized \$300.0 million term loan, which was entered into by Gilead Biopharmaceutics Ireland Corporation (GBIC), one of our wholly-owned Irish subsidiaries, and an

Table of Contents

uncollateralized \$200.0 million revolving credit facility, which was entered into by the U.S. parent company, Gilead Sciences, Inc. The proceeds from the term loan were used by GBIC in December 2005 to facilitate a cash dividend distribution of \$280.0 million to the parent company as part of the repatriation of our qualified foreign earnings under the provisions of the American Jobs Creation Act.

Under the terms of our term loan, the minimum amount of the principal payment that is required to be repaid at the end of each calendar quarter, beginning on March 31, 2006, is \$15.0 million. Interest is accrued at a rate of LIBOR plus a tiered contractual rate of up to 62.5 basis points, and is payable in arrears at the end of each quarter. GBIC can prepay the term loan at any time in whole or in part, together with accrued interest on the prepaid principal, without penalty or premium. During the three months ended March 31, 2006, \$56.0 million of the term loan was repaid. Any outstanding interest or principal at December 2010 is payable on demand. The U.S. parent company and another wholly-owned subsidiary, Gilead Vintage Park, LLC, are guarantors. As of March 31, 2006, the outstanding principal on the term loan was \$244.0 million.

Under the terms of the revolving credit facility, interest is accrued and payable at a rate of LIBOR plus a tiered contractual rate of up to 50 basis points, and is payable in arrears at the end of each quarter. The parent company can prepay any outstanding borrowings at any time in whole or in part, together with accrued interest on the prepaid principal, without penalty or premium. Any outstanding interest or principal at December 2010 is payable on demand. The capacity of the revolving credit facility will increase to a maximum of \$500.0 million as the term loan is repaid. We have the ability to irrevocably cancel any unutilized portion of the revolving credit facility, in whole or in part. Any proceeds obtained under the revolving credit facility are expected to be used for working capital, capital expenditures and other general corporate purposes, including the issuance of letters of credit up to \$25.0 million. Gilead Vintage Park, LLC is the guarantor. In March 2006, the revolving credit facility was increased to \$256.0 million as a result of a \$56.0 million repayment we made under the term loan. As of March 31, 2006, we did not have any borrowings under the revolving credit facility.

8. CONTINGENCIES

Legal Proceedings

A number of states, counties and municipalities have filed complaints alleging that a large number of pharmaceutical defendants, including in some instances Gilead, reported inaccurate prices for their products, causing the governmental entity named as the plaintiff to overpay for pharmaceutical products furnished to participants in the Medicaid program. Separate actions filed by New York City and numerous New York counties were consolidated in a multi-district litigation proceeding before the United States District Court for the District of Massachusetts. On August 23, 2005, these cases were voluntarily dismissed with respect to Gilead. To its knowledge, Gilead has been named in three additional cases, (1) State of Alabama v. Abbott Laboratories, Inc. et al., currently pending in the Circuit Court of Montgomery County, Alabama; (2) County of Erie v. Abbott Laboratories, Inc. et al., currently pending in the Supreme Court of the State of New York, County of Erie and (3) State of Mississippi v. Abbott Laboratories, Inc., et al., currently pending in the Chancery Court of the First Judicial District of Hinds County, Mississippi. The complaints assert claims under state law and seek damages (and, in the State of Alabama case, treble damages) and attorneys' fees. We intend to defend the cases vigorously. The cases are all at a preliminary stage and it is not possible to predict the outcome. As such, no amounts have been accrued related to the outcome of these cases.

A purported class action complaint was filed on November 10, 2003, in the United States District Court for the Northern District of California against Gilead and our Company's Chief Executive Officer, Chief Financial Officer, former Executive Vice President of Operations (and current Senior Business Advisor), Executive Vice President of Research and Development, Senior Vice President of Manufacturing and Senior Vice President of Research. The complaint alleges that the defendants violated federal securities laws, specifically Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 of the Securities and Exchange Commission, by making certain alleged false and misleading statements. The plaintiffs seek unspecified damages on behalf of a purported class of purchasers of Gilead's securities during the period from July 14, 2003 through October 28, 2003. Other similar actions were subsequently filed and the court issued an order consolidating the lawsuits into a single action on December 22, 2003. On February 9, 2004, the court issued an order appointing lead plaintiffs in the consolidated action. On April 30, 2004, the lead plaintiffs, on behalf of the purported class, filed their consolidated amended complaint. On June 21, 2004, the Company and individual defendants filed their motion to dismiss the consolidated amended complaint. On January 4, 2005, the court granted the defendants' motion to dismiss with leave to amend. Plaintiffs filed a second amended complaint on February 25, 2005 and a third amended complaint on March 11, 2005. On October 11, 2005, the court granted the defendants' motion to dismiss the third amended complaint with leave to amend. On December 2, 2005, the plaintiffs filed a fourth consolidated amended complaint. The court heard defendants' motion to dismiss on February 21, 2006, took the matter under submission and has yet to render its decision. We intend to defend the cases vigorously. As the outcome cannot be predicted at this time, no amount has been accrued related to the outcome of this matter.

Table of Contents

We are also a party to various other legal actions that arose in the ordinary course of our business. We do not believe that any of these other legal actions will have a material adverse impact on our business, results of operations or financial position.

Other Matters

In March 2006, as part of an initiative to evaluate our European distribution framework outside of our five largest European markets, we began contacting certain of our European distributors regarding our current distribution terms with them and our intent to ultimately terminate these distribution relationships. This process will entail lengthy negotiations between us and these distributors. Although it is probable that we will incur contract termination costs, we are currently unable to reasonably estimate such costs in accordance with SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities* and as such, no amount has been accrued related to the outcome of these negotiations.

9. STOCK-BASED COMPENSATION

On January 1, 2006, we adopted the provisions of SFAS 123R which requires that the fair value of all share-based payments to employees and directors, including grants of stock options, be recognized in our Condensed Consolidated Statements of Income. We applied the modified prospective method, one of the adoption methods permitted under SFAS 123R, which requires that compensation expense be recorded for all nonvested stock options and other stock-based awards at the beginning of the first quarter of adoption of SFAS 123R. In accordance with the modified prospective method, no prior period amounts have been restated to reflect our adoption of SFAS 123R.

Pro Forma Information Under SFAS 123

Prior to the adoption of SFAS 123R, in accordance with the provisions of SFAS 123, as amended by SFAS No. 148, *Accounting for Stock-Based Compensation-Transition and Disclosure*, we elected to follow APB 25, and FASB Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation - an Interpretation of APB Opinion No. 25*, in accounting for our employee stock-based plans. Under APB 25, if the exercise price of Gilead's employee and director stock options was equal to or greater than the fair value of the underlying stock on the date of grant, no compensation expense was recognized in our Condensed Consolidated Statements of Income.

The table below presents net income and basic and diluted net income per share as if compensation cost for the Company's stock option plans and 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, 2005
Net income as reported	\$ 157,113
Add: Stock-based employee compensation expense included in reported net income, net of related tax effects	92
Deduct: Total stock-based employee compensation expense determined under the fair value based method for all awards, net of related tax effects	(19,433)
Pro forma net income	\$ 137,772
Net income per share:	
Basic - as reported	\$ 0.35
Basic - pro forma	\$ 0.31
Diluted - as reported	\$ 0.34
Diluted - pro forma	\$ 0.29

Adoption of SFAS 123R

Edgar Filing: GILEAD SCIENCES INC - Form 10-Q

Stock-based compensation is recognized as expense over the requisite service periods in our Condensed Consolidated Statements of Income using a graded vesting expense attribution approach for unvested stock option awards granted prior to the adoption of SFAS 123R and using the straight-line expense attribution approach for stock option awards granted after the adoption of SFAS 123R. As stock-based compensation expense related to stock option awards recognized on adoption of SFAS 123R is based on awards ultimately expected to vest, gross expense has been reduced for estimated forfeitures. SFAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. We estimated forfeitures based on our historical experience. Prior to the adoption of SFAS 123R, pro forma information required under SFAS 123 included forfeitures as they occurred.

Table of Contents

In November 2005, the FASB issued FASB Staff Position No. 123R-3, *Transition Election Related to Accounting for the Tax Effects of Share-Based Payment Awards*. We adopted the simplified method to calculate the beginning balance of the additional paid-in-capital (APIC) pool of the excess tax benefit, and to determine the subsequent impact on the APIC pool and Condensed Consolidated Statements of Cash Flows of the tax effects of employee stock-based compensation awards that were outstanding upon our adoption of SFAS 123R.

The table below summarizes the impact of adopting SFAS 123R effective January 1, 2006 (in thousands, except per share amounts):

	Three Months Ended March 31, 2006	
Cost of goods sold	\$	3,187
Research and development expenses		11,949
Selling, general and administrative expenses		14,496
Stock-based compensation expense included in total costs and expenses		29,632
Tax benefit related to stock-based compensation expense		6,129
Stock-based compensation expense included in net income	\$	23,503
Stock-based compensation expense included in net income per share:		
Basic	\$	0.05
Diluted	\$	0.05

During the three months ended March 31, 2006, we capitalized \$2.5 million of stock-based compensation costs into inventory. The total fair value of stock options that vested during the three months ended March 31, 2006 was \$36.6 million. As of March 31, 2006, we had stock-based compensation expense of \$245.8 million related to nonvested stock option awards not yet recognized, which is expected to be recognized over an estimated weighted average period of 2.5 years.

Valuation Assumptions

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 expected volatility and expected life. In connection with our adoption of SFAS 123R, we refined the methodologies used to derive our valuation model assumptions. To calculate the estimated fair value of the awards, we used the following assumptions:

	Three Months Ended March 31, 2006		2005
Expected Volatility:			
Stock options	39%		47%
ESPP	34%		47%
Expected life in years:			
Stock options	5.3		4.8
ESPP	1.3		1.4
Risk-free interest rate:			
Stock options	4.6%		3.7%
ESPP	4.7%		2.5%
Expected dividend yield	0%		0%

The fair value of stock option awards granted prior to the adoption of SFAS 123R was calculated using the multiple option approach while the fair value of stock option awards granted beginning January 1, 2006 was calculated using the single option approach.

Table of Contents

Prior to the adoption of SFAS 123R, we used historical stock price volatility. In connection with our adoption of SFAS 123R, we determined that a blend of historical volatility along with implied volatility for traded options on Gilead's stock is a better reflection of market activity and expected volatility.

The expected life of stock-based awards represents the weighted-average period the stock awards are expected to remain outstanding. We estimate the weighted-average expected life based on historical cancellation and historical exercise data related to our stock option awards as well as the contractual term and vesting terms of the awards.

The risk-free interest rate is based upon observed interest rates appropriate for the term of the stock-based awards. The dividend yield is based on our history and expectation of dividend payouts.

Other Stock-Based Compensation Information

In May 2004, Gilead's stockholders approved and we adopted the 2004 Equity Incentive Plan (2004 Plan). Stock options under the NeXstar and Triangle stock option plans, which we assumed as a result of the merger with NeXstar and the acquisition of Triangle, have been converted into Gilead options effective with the merger or acquisition. The 2004 Plan is a broad-based, incentive plan that allows for the awards to be granted to employees, directors and consultants of Gilead. Generally, few grants have been made to consultants and currently there are no grants outstanding to consultants. The 2004 Plan provides for option grants designated as either nonqualified or incentive stock options. Prior to January 1, 2006, Gilead granted both nonqualified and incentive stock options while after January 1, 2006, all stock options granted are nonqualified stock options. Under the 2004 Plan, employee stock options generally vest over five years, are exercisable over a period not to exceed the contractual term of ten years from the date the stock options are issued and are granted at prices not less than the fair value of our common stock on the grant date. Stock option exercises are settled with newly issued common stock from the plan's previously authorized and available pool of shares. As of March 31, 2006, there were 14,873,616 shares remaining and available for future grant under the 2004 Plan.

Under Gilead's ESPP, employees can purchase shares of Gilead common stock based on a percentage of their compensation. The purchase price per share is equal to the lower of 85% of the fair value of our common stock on the offering date or the purchase date. A two-year look-back feature in our ESPP causes the offering period to reset if the fair value of our common stock on the purchase date is less than that on the original offering date. ESPP purchases by employees are settled with newly issued common stock from the plan's previously authorized and available pool of shares. As of March 31, 2006, there were 1,725,683 shares remaining and available for issuance under the ESPP.

The following table summarizes activity under all Gilead, NeXstar and Triangle stock option plans. All option grants presented in the table had exercise prices not less than the fair value of the underlying stock on the grant date (shares in thousands):

	Three Months Ended March 31, 2006 Weighted Average Exercise		Year Ended December 31, 2005 Weighted Average Exercise	
	Shares	Price	Shares	Price
Outstanding, beginning of period	45,920	\$22.60	49,413	\$18.10
Granted	5,714	\$58.17	8,930	\$36.39
Forfeited	(817)	\$28.14	(1,997)	\$26.05
Exercised	(3,123)	\$13.94	(10,426)	\$12.45
Outstanding, end of period	47,694	\$27.33	45,920	\$22.60
Exercisable, end of period	22,037	\$17.06	22,237	\$15.56
Weighted average grant-date fair value		\$24.93		\$15.79

Table of Contents

The following is a summary of Gilead stock options outstanding and stock options exercisable at March 31, 2006 (options and aggregate intrinsic value in thousands):

Range of Exercise Prices	Options Outstanding Weighted				Options Exercisable			
	Options Outstanding	Weighted Average Remaining Contractual Life in Years	Average Exercise Price	Aggregate Intrinsic Value	Options Exercisable	Weighted Average Remaining Contractual Life in Years	Weighted Average Exercise Price	Aggregate Intrinsic Value
\$ 2.25 - \$16.43	9,834	4.0	\$8.03	\$ 532,946	9,454	3.9	\$7.79	\$ 514,586
\$16.44 - \$17.89	9,934	6.4	\$17.12	448,049	6,140	6.3	\$17.06	277,275
\$17.90 - \$30.53	9,913	7.8	\$28.53	333,956	3,659	7.7	\$28.19	124,520
\$30.84 - \$38.87	9,888	8.5	\$33.01	288,812	2,623	8.3	\$33.04	76,550
\$39.15 - \$70.47	8,125	9.6	\$54.79	60,433	161	3.4	\$48.63	2,286
Total	47,694	7.2	\$27.33	\$ 1,664,196	22,037	5.7	\$17.06	\$ 995,217

The following is a summary of the activity relating to Gilead's nonvested stock options for the three months ended March 31, 2006 (shares in thousands):

	Shares	Weighted Average Grant-Date Fair Value
Nonvested, January 1, 2006	23,683	\$14.32
Granted	5,714	\$24.93
Forfeited	(817)	\$14.04
Vested	(2,923)	\$12.53
Nonvested, March 31, 2006	25,657	\$16.89

10. STOCKHOLDERS EQUITY

Stock Repurchase Program

In March 2006, Gilead's Board of Directors authorized a program for the repurchase of Gilead common stock in an amount up to \$1.0 billion over a two-year period. Stock repurchases under this program may be made through open market and private block transactions pursuant to Rule 10b5-1 plans or privately negotiated purchases or other means, including accelerated share repurchase transactions or similar arrangements. The timing and actual number of shares repurchased will depend on a variety of factors including price, corporate and regulatory requirements and other market conditions. During the three months ended March 31, 2006, we did not repurchase any common stock under this program.

In April 2006, Gilead repurchased and retired 8.4 million shares of Gilead common stock at \$65.13 per share, or \$545.0 million. The remaining authorized amount of stock repurchases that may be made under this program which terminates in March 2008 is \$455.0 million.

Comprehensive Income

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

	Three Months Ended March 31,	
	2006	2005
Net income	\$ 262,704	\$ 157,113
Net foreign currency translation loss	(109)	(1,861)
Net unrealized gain (loss) on cash flow hedges, net of related tax effects	(6,263)	22,089
Net unrealized loss on available-for-sale securities, net of related tax effects	(7,679)	(2,042)
Comprehensive income	\$ 248,653	\$ 175,299

Table of Contents**11. SEGMENT INFORMATION**

Gilead operates in one business segment, which primarily focuses on the development and commercialization of human therapeutics for infectious diseases. All products are included in one segment because our major products have similar economic and other characteristics, including the nature of the products and production processes, type of customers, distribution methods and regulatory environment.

Product sales consist of the following (in thousands):

	Three Months Ended March 31,	
	2006	2005
HIV Products:		
Truvada	\$ 248,946	\$ 91,167
Viread	191,775	197,843
Emtriva	9,962	12,446
Total HIV products	450,683	301,456
AmBisome	53,800	54,214
Hepsera	52,655	42,665
Vistide	1,794	1,595
DaunoXome	421	281
Total product sales	\$ 559,353	\$ 400,211

Product sales and product-related contract revenue are attributed to countries based on ship-to location. Royalty and non-product related contract revenue are attributed to countries based on the location of the collaboration partner. Certain revenue amounts for 2005 have been reclassified between geographic regions to conform to the current period presentation. The following table summarizes total revenues from external customers and collaboration partners by geographic region (in thousands):

	Three Months Ended March 31,	
	2006	2005
United States	\$ 300,594	\$ 229,547
Outside of the United States:		
Switzerland	118,945	14,959
France	48,315	39,112
Italy	35,215	25,652
Spain	35,145	30,365
United Kingdom	35,043	23,938
Germany	28,914	26,401
Other European countries	48,055	25,177
Other countries	42,652	15,263
Total revenues outside of the United States	392,284	200,867
Total revenues	\$ 692,878	\$ 430,414

The following table summarizes revenues from our customers who individually account for 10% or more of our total revenues (as a % of total revenues):

Edgar Filing: GILEAD SCIENCES INC - Form 10-Q

	Three Months Ended	
	March 31,	
	2006	2005
Cardinal Health, Inc.	16%	20%
McKesson Corp.	11%	12%
AmerisourceBergen Corp.	10%	12%

Table of Contents**12. SUBSEQUENT EVENTS****Convertible Senior Notes**

In April 2006, we issued \$650.0 million principal amount of convertible senior notes due in 2011 (2011 Notes) and \$650.0 million principal amount of convertible senior notes due in 2013 (2013 Notes) (collectively, the Notes) in a private placement pursuant to Rule 144A. The 2011 Notes and the 2013 Notes were issued at par bearing interest rates of 0.50% and 0.625%, respectively. The aggregate principal amount of the Notes sold reflects the full exercise by the initial purchasers of their option to purchase additional Notes to cover over-allotments. The 2011 Notes may be convertible based on an initial conversion rate of 12.9024 shares per \$1,000 principal amount of notes (which represents an initial conversion price of approximately \$77.50 per share). The 2013 Notes may be convertible based on an initial conversion rate of 13.1230 shares per \$1,000 principal amount of notes (which represents an initial conversion price of approximately \$76.20 per share). The Notes may be converted, subject to adjustment, only under the following circumstances: 1) during any calendar quarter beginning after September 30, 2006 if the closing price of our common stock for at least 20 trading days in the 30 consecutive trading days of the previous quarter is more than 130% of the applicable conversion price per share, 2) if we make specified distributions to holders of our common stock or specified corporate transactions occur, or 3) during the last month prior to maturity of the applicable Notes. Upon conversion, a holder would receive an amount in cash equal to the lesser of (i) the principal amount of the Note or (ii) the conversion value, as defined. If the conversion value exceeds \$1,000, we will also deliver, at our option, cash or common stock or a combination of cash and common stock for the conversion value in excess of \$1,000. If the Notes are converted in connection with a change in control, as defined, we may be required to provide a make-whole premium in the form of an increase in the conversion rate, subject to a stated maximum amount. In addition, in the event of a change in control, the holders may require us to purchase all or a portion of their Notes at a purchase price equal to 100% of the principal amount of Notes, plus accrued and unpaid interest, if any.

Concurrent with the issuance of the Notes, we purchased convertible note hedges in private transactions at a cost of \$379.1 million to cover, subject to customary anti-dilution adjustments, 16.9 million shares of our common stock at strike prices which correspond to the initial conversion prices of the Notes. If the market value per share of our common stock at the time of conversion of the Notes is above the strike price of the applicable convertible note hedges, we are entitled to receive from the counterparties of the transactions cash or common stock or a combination of cash and common stock for the excess of the then current market price of the common stock over the strike price of the convertible note hedges. We also sold warrants in private transactions and received net proceeds of \$235.5 million to acquire 16.9 million shares of our common stock, subject to customary anti-dilution adjustments. If the market value of our common stock at the time of the exercise of the applicable warrants exceeds their respective strike prices, we will be required to net settle with the respective counterparties for the value of the warrants in excess of the warrant strike prices. The warrants have strike prices of \$101.60 per share (for the warrants expiring in 2011) and \$107.79 per share (for the warrants expiring in 2013) and are exercisable only on the respective expiration dates. Taken together, the convertible note hedges and warrants are intended to reduce the potential dilution upon future conversions of the Notes by effectively increasing the initial conversion price to \$101.60 per share for the 2011 Notes and \$107.79 per share for the 2013 Notes. The net cost of \$143.7 million of the convertible note hedge and warrant transactions will be recorded in stockholders' equity. We will also record a tax benefit of approximately \$147 million in stockholders' equity from the deferred tax assets that we will recognize related to the convertible note hedges.

Contemporaneously with the closing of the sale of the Notes, a portion of the net proceeds from the Notes issuances and the proceeds of the warrant transactions were used to repurchase \$544.9 million or 8.4 million shares of our common stock under our stock repurchase program.

Investment in Corus Pharma

In April 2006, we purchased \$25.0 million of Series C preferred stock of Corus Pharma, Inc. (Corus), a privately-held Seattle, Washington-based company focused on the development of novel drugs for respiratory diseases. The Series C preferred stock is convertible into Corus' common stock on a one-to-one basis, which may be adjusted for future stock issuances by Corus and certain other events. In connection with the purchase of Corus' Series C preferred stock, we also entered into an agreement whereby we will have an exclusive option to acquire all of Corus' remaining stock at a pre-specified price through December 31, 2006. We will record our investment in Corus in other noncurrent assets and currently do not expect to consolidate Corus.

Table of Contents**ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS****Executive Summary**

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 nine approved products and marketing operations in eleven countries. We focus our research and clinical programs on anti-infectives. Currently, we market Viread® (tenofovir disoproxil fumarate), Truvada® (tenofovir disoproxil fumarate and emtricitabine) and Emtriva® (emtricitabine) for the treatment of human immunodeficiency virus (HIV) infection; Hepsera® (adefovir dipivoxil) for the treatment of chronic hepatitis B; AmBisome® (amphotericin B) liposome for injection for the treatment of fungal infection; and Vistide® (cidofovir injection) for the treatment of cytomegalovirus (CMV) retinitis. F. Hoffmann-La Roche Ltd (Roche) currently markets Tamiflu® (oseltamivir phosphate) for the treatment and prevention of influenza under a royalty-paying development and license agreement with us. Eyetech Pharmaceuticals, Inc. (Eyetech) markets Macugen® (pegaptanib sodium injection) in the United States for the treatment of neovascular age-related macular degeneration under a royalty-paying collaborative agreement with us. We began recording royalties from Eyetech during the second quarter of 2005.

Our operating results for the first quarter of 2006 were led by strong net product sales of \$559.4 million including HIV product sales (Viread, Truvada and Emtriva) of \$450.7 million. A 50% increase in HIV product sales in the first quarter of 2006 over the first quarter of 2005 served as a key driver in increasing total product sales by 40% over the comparable period in 2005. In the United States, Truvada sales were up 20% sequentially from the fourth quarter of 2005 and represented 69% of our U.S. HIV product sales. Outside of the United States, higher HIV product sales as compared to the first quarter of 2005 were primarily because the launch of Truvada in certain European countries began in the first three months of 2005. Additionally, Viread sales volume continued to increase, particularly in Europe, Australia and Canada, as well as in Brazil, where individual orders tend to be large and ordering patterns tend to be unpredictable. AmBisome product sales in the first quarter of 2006 decreased by 1% compared to the first quarter of 2005, as a result of the dynamics of the competitive European antifungal market. Hepsera product sales for the first quarter of 2006 increased 23% from the first quarter of 2005 driven primarily by significant volume growth in both the United States and Europe, which increased by 15% and 30%, respectively, compared to the same quarter last year. On the collaborative front, the Company recognized \$129.4 million in royalty revenue of which \$115.3 million related to royalties received from fourth quarter 2005 sales of Tamiflu by F. Hoffmann-La Roche Ltd (Roche). Tamiflu royalties increased due to strong sales of Tamiflu by Roche as well as the elimination of the contractual cost of goods adjustment.

During the first quarter of 2006, we adopted the provisions of Statement of Financial Accounting Standards (SFAS) No. 123 (revised 2004), *Share-Based Payment* (SFAS 123R) and began expensing the fair value of stock-based compensation cost. As a result, stock-based compensation expense is a significant component of the increase in our operating expenses for the quarter ended March 31, 2006 as compared to the prior year. Further discussion is included in *Critical Accounting Policies and Estimates* below.

During the quarter, we continued to make progress in our HIV, hepatitis B virus (HBV) and hepatitis C virus (HCV) programs. We achieved bioequivalence on a formulation of the single tablet regimen of Truvada and Bristol-Myers Squibb Company's (BMS) Sustiva (the single tablet regimen) earlier this year, and filed a New Drug Application (NDA) in April 2006. In our integrase inhibitor programs, we dosed our first patient in a Phase 2 clinical study related to our novel integrase inhibitor for HIV, GS 9137, which we licensed from Japan Tobacco. This event triggered a \$5.0 million milestone payment which we recorded in research and development expenses. Our internally developed integrase inhibitor, GS 9160, did not demonstrate a desired level of bioavailability and therefore, we decided to discontinue development of GS 9160 and turn our focus to a back-up integrase inhibitor, GS 9224. In the HBV area, we continued to enroll patients into our two pivotal Phase 3 studies of Viread for chronic hepatitis B and in HCV, and we are expecting to begin Phase 1/2 viral dynamics clinical studies in the second or third quarters of 2006 on GS 9132 in collaboration with Achillion Pharmaceuticals.

In April 2006, our exploration into new therapeutic areas was marked by a \$25.0 million Series C preferred stock investment in Corus Pharma, Inc., a privately-held Seattle, Washington-based company focused on the development of novel drugs for respiratory diseases. Concurrent with the investment, we also have an exclusive option to purchase all of the remaining shares of Corus at a pre-specified price through December 31, 2006.

Our cash, cash equivalents and marketable securities continued to grow by \$228.6 million primarily funded by our first quarter operating cash flows. In April 2006, we issued \$1.30 billion principal amount of convertible senior notes and concurrently we repurchased \$544.9 million of our common stock under our stock repurchase program, purchased convertible note hedges at a cost of \$379.1 million as well as sold warrants for proceeds of \$235.5 million. Together with our existing cash, cash equivalents and marketable securities, the net proceeds of these transactions of \$587.6 million, after deducting the initial purchasers' discount and the estimated offering expenses, will allow us to further our corporate development initiatives, including licensing opportunities and potential acquisitions, as well as to meet our ongoing working capital and infrastructure needs.

Table of Contents

Critical Accounting Policies and Estimates

Reference is made to Critical Accounting Policies and Estimates included in our Annual Report on Form 10-K for the year ended December 31, 2005.

Stock-based Compensation

In December 2004, the Financial Accounting Standards Board (FASB) issued SFAS 123R, a revision of SFAS No. 123, *Accounting for Stock-Based Compensation* (SFAS 123), which requires that all share-based payments to employees and directors, including grants of stock options be recognized in the income statement based on their fair values. SFAS 123R supersedes Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25) and amends SFAS No. 95, *Statement of Cash Flows*. On January 1, 2006, we adopted SFAS 123R using the modified prospective method of adoption as permitted under SFAS 123R which requires that compensation expense be recorded for all nonvested stock options and other stock-based awards as of the beginning of the first quarter of adoption. In accordance with the modified prospective method, no prior period amounts have been restated to reflect the provisions of SFAS 123R.

Prior to the adoption of SFAS 123R, in accordance with the provisions of SFAS 123, we elected to follow APB 25, and FASB Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation - an Interpretation of APB Opinion No. 25*, in accounting for our employee stock-based plans. Under APB 25, if the exercise price of Gilead's employee and director stock options was equal to or greater than the fair value of the underlying stock on the date of grant, no compensation expense was recognized. However, as required by SFAS 123, the pro forma impact of expensing the fair value of our stock option awards and employee stock purchase plan was disclosed in the notes to our condensed consolidated financial statements.

In connection with our adoption of SFAS 123R, we refined our valuation assumptions and the methodologies used to derive those assumptions; however, we elected to continue using the Black-Scholes option valuation model. The fair value of stock option awards granted prior to the adoption of SFAS 123R was calculated using the multiple option approach while the fair value of stock option awards granted beginning January 1, 2006 was calculated using the single option approach. Concurrent with our adoption of SFAS 123R, we determined that a blend of historical volatility along with implied volatility for traded options on Gilead's stock would be a better measure of market conditions and expected volatility. Previously, we used historical stock price volatility as it was the most reliable source of volatility data. We estimate the weighted-average expected life of our stock-option awards based on historical cancellation and exercise data related to our stock-based awards as well as the contractual term and vesting terms of the awards. We allocate stock-based compensation expense using a graded vesting expense attribution approach for unvested stock option awards granted prior to the adoption of SFAS 123R consistent with the expense attribution approach used in our historical SFAS 123 disclosures and using a straight-line expense attribution approach for stock-based awards granted after the adoption of SFAS 123R. We currently believe that the straight-line expense attribution approach better reflects the level of service to be provided over the vesting period of our awards. Stock-based compensation expense related to stock options is recognized net of estimated forfeitures. We estimated forfeitures based on our historical experience.

During the quarter ended March 31, 2006, we recognized stock-based compensation expense of \$23.5 million, net of tax, and capitalized \$2.5 million into inventory. As of March 31, 2006, we had unrecognized stock-based compensation of \$245.8 million related to nonvested stock options awards, which is expected to be recognized over an estimated weighted average period of 2.5 years.

Results of Operations

Total Revenues

We had total revenues of \$692.9 million for the quarter ended March 31, 2006 compared with \$430.4 million for the quarter ended March 31, 2005. Included in total revenues are product sales and royalty and contract revenue, including revenue earned from manufacturing collaborations.

Table of Contents*Product Sales*

Product sales consisted of the following (in thousands):

	Three Months Ended March 31,		Change
	2006	2005	
HIV Products:			
Truvada	\$ 248,946	\$ 91,167	173%
Viread	191,775	197,843	(3)%
Emtriva	9,962	12,446	(20)%
Total HIV products	450,683	301,456	50%
AmBisome	53,800	54,214	(1)%
Hepsera	52,655	42,665	23%
Other	2,215	1,876	18%
Total product sales	\$ 559,353	\$ 400,211	40%

Total product sales increased 40% in the first quarter of 2006 compared to the first quarter of 2005. This growth is driven primarily by our HIV product franchise, including higher product sales for Truvada, as well as higher product sales of Hepsera.

HIV Products

HIV product sales for the first quarter of 2006 were \$450.7 million, of which \$259.6 million were U.S. sales, an increase of 36% compared to the first quarter of 2005, and \$191.0 million were sales outside of the United States, an increase of 72% compared to the same period in 2005. We continued to see steady prescription gains for our HIV product portfolio and as of the week ended March 31, 2006, according to a third-party market research firm, our HIV products collectively held approximately 40% of both new and total prescriptions in the nucleoside reverse transcriptase market.

Truvada

Truvada sales were \$248.9 million for the first quarter of 2006, an increase of 173% from Truvada sales in the first quarter of 2005. Sales of Truvada commenced in the United States in the third quarter of 2004 and in certain European countries during 2005. We observed strong uptake of Truvada in France, Italy and Spain since the respective product launches in 2005, partly due to data included in our product label from our clinical studies.

Viread

Viread sales were \$191.8 million in the first quarter of 2006, a 3% decrease from \$197.8 million in the first quarter of 2005. The decrease from certain patients switching from a Viread-containing regimen to one containing Truvada, was offset by strong sales in countries outside of the United States where the product is marketed, particularly in those countries in which Truvada has recently launched or has not yet launched.

Emtriva

Emtriva sales were \$10.0 million for the first quarter of 2006, a decrease of 20% from the first quarter of 2005. This decrease was primarily driven by certain patients switching from an Emtriva-containing regimen to one containing Truvada in countries where Truvada is available.

Edgar Filing: GILEAD SCIENCES INC - Form 10-Q

For the full year 2006, we expect sales from our HIV products to be in the range of \$1.825 billion to \$1.875 billion. This does not include future product sales, if any, that may result should the single tablet regimen of Truvada and BMS's Sustiva be approved for commercial sale in the United States, as we cannot predict whether or when the single tablet regimen will be approved by the U.S. Food and Drug Administration (FDA).

Table of Contents*AmBisome*

AmBisome sales for the first quarter of 2006 were \$53.8 million, a decrease of 1% compared to the first quarter of 2005, primarily due to a sales volume decrease of 2% in Europe. The decrease in sales volume was primarily due to the dynamics of the competitive European antifungal market. For the full year 2006, we expect AmBisome sales to be in the range of \$205.0 million to \$215.0 million.

Hepsera

Hepsera sales totaled \$52.7 million for the first quarter of 2006, a 23% increase from \$42.7 million in the first quarter of 2005. The increase in sales for the first quarter of 2006 was primarily driven by sales volume growth in the United States and Europe of 15% and 30%, respectively. Hepsera sales volume also increased with respect to our sales of Hepsera to GlaxoSmithKline (GSK), which we sell at cost, in connection with their distribution activities in Asia. For the full year 2006, we expect Hepsera sales to be in the range of \$205.0 million to \$215.0 million.

Royalty and Contract Revenue

For the first quarter of 2006, royalty and contract revenue resulting from collaborations with corporate partners totaled \$133.5 million, an increase of \$103.3 million from the first quarter of 2005. The increase in the first quarter of 2006 was primarily driven by the recognition of Tamiflu royalties from Roche of \$115.3 million. This amount was significantly higher than the Tamiflu royalties of \$11.9 million recognized in the first quarter of 2005. The increase was primarily due to the significantly higher Tamiflu sales recorded by Roche during the fourth quarter of 2005 compared to the same period in 2004 as well as the elimination of a contractual cost of goods adjustment that had historically reduced the amount of Tamiflu royalties we received.

Cost of Goods Sold and Product Gross Margin Percentage

The following table summarizes the period over period changes in our cost of goods sold (in thousands) and product gross margin percentages:

	Three Months Ended		
	March 31,		
	2006	2005	Change
Total product sales	\$ 559,353	\$ 400,211	40%
Cost of goods sold	\$ 90,357	\$ 57,415	57%
Product gross margin percentage	84%	86%	

Our product gross margin percentage for the first quarter of 2006 was 84%, compared to 86% for the same quarter of 2005. The lower gross margin percentage is primarily due to product mix changes as switches continue to occur from Viread, a higher margin product, to Truvada, the inclusion of stock-based compensation expense of \$3.2 million from our adoption of SFAS 123R during the first quarter of 2006 and a \$6.8 million charge to cost of goods sold in the first quarter of 2006 to write-down the inventory for our Gilead Access Program to its estimated net realizable value.

We expect our product gross margin in 2006 to be in the range of 85% to 86%. This includes the impact of our adoption of SFAS 123R but excludes the impact of the potential launch of the single tablet regimen as we cannot predict whether or when the single tablet regimen will be approved by the FDA. We expect any launch of the single tablet regimen would decrease our product gross margin percentage, but without a corresponding impact to our net profit. This is due to the fact that as the majority owner of our joint venture with BMS, we will consolidate 100% of the single tablet regimen revenue. We will earn the full product margin of the Truvada portion of the single tablet regimen but earn zero product gross margin on the Sustiva portion of the single tablet regimen that the joint venture purchases from BMS at BMS's estimated net selling price of Sustive in the U.S. market.

Table of Contents*Research and Development Expenses*

The following table summarizes the period over period changes in our research and development (R&D) expenses into these major components (in thousands):

	Three Months Ended		
	March 31,		
	2006	2005	Change
Research	\$ 18,365	\$ 12,347	49%
Clinical development	55,519	49,508	12%
Pharmaceutical development	14,516	8,579	69%
Total research and development expenses	\$ 88,400	\$ 70,434	26%

R&D expenses for the first quarter of 2006 were \$88.4 million compared to \$70.4 million for the same quarter in 2005. R&D expenses for the first quarter of 2006 were higher due to stock-based compensation expense of \$11.9 million from our adoption of SFAS 123R on January 1, 2006, increased clinical study expenses of \$5.7 million relating to our HIV, HBV and HCV programs and increased compensation and benefits of \$4.5 million due largely to higher headcount. In general, significant collaboration payments during a quarter can cause our R&D expenses to fluctuate. During the first quarter of 2006, we incurred a milestone payment of \$5.0 million related to the dosing of the first patient in Phase II study for our lead integrase inhibitor, GS 9137, under our HIV integrase license agreement with Japan Tobacco. In comparison, in the first quarter of 2005, we incurred an upfront payment of \$15.0 million to Japan Tobacco related to the signing of the same agreement.

For the full year 2006, we expect our R&D expenses to be in the range of \$345.0 million to \$370.0 million. This includes the impact of our adoption of SFAS 123R. This does not include any additional R&D expenses for potential new collaborations or product licensing activity.

Selling, General and Administrative Expenses

The following summarizes the period over period changes in our selling, general and administrative (SG&A) expenses (in thousands):

	Three Months Ended		
	March 31,		
	2006	2005	Change
Selling, general and administrative expenses	\$ 142,469	\$ 79,088	80%

SG&A expenses for the first quarter of 2006 were \$142.5 million compared to \$79.1 million for the same quarter in 2005. The higher SG&A expenses in the first quarter of 2006 as compared to the first quarter of 2005 were primarily due to stock-based compensation expense of \$14.5 million from our adoption of SFAS 123R on January 1, 2006, the \$7.9 million write-off of certain capital assets related to campus renovations, increased promotional program spending of \$7.7 million, as well as increased compensation and benefits of \$7.6 million due largely to higher headcount. The remainder of the increased SG&A expenses was due to an expansion of our sales and marketing activities worldwide. During the three months ended March 31, 2006, we began reporting net foreign exchange transaction gains or losses as well as fair value changes on derivative instruments not designated as hedges in interest and other income, net. These amounts, which were previously reported as SG&A expenses, were reclassified to enhance the comparability of our financial statements with those of other companies. Prior year amounts which were insignificant have been reclassified to be consistent with the current year presentation.

In March 2006, as part of an initiative to evaluate our European distribution framework outside of our five largest European markets, we began contacting certain of our European distributors regarding our current distribution terms with them and our intent to ultimately terminate these distribution relationships. This process will entail lengthy negotiations between us and these distributors. Although it is probable that we will incur contract termination costs, we are currently unable to reasonably estimate such costs in accordance with SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities* and as such, no amount has been accrued related to the outcome of these negotiations. When the amounts become estimable, we will record such costs in SG&A expenses.

For the full year 2006, we expect our SG&A expenses to be in the range of \$500.0 million to \$530.0 million. This includes the impact of our adoption of SFAS 123R, the anticipated costs associated with launching and supporting Truvada in various countries, as well as costs related to

our ongoing investment in our global commercial organization through hiring

Table of Contents

and promotional programs, but excludes the distribution agreement termination costs mentioned above as well as the impact of the potential launch of the single tablet regimen as we cannot predict whether or when the single tablet regimen will be approved by the FDA.

Interest and Other Income, net

Interest and other income, net, was \$28.5 million for the first quarter of 2006, up from \$7.3 million for the first quarter of 2005, which includes the reclassification mentioned above. The increase in the first quarter of 2006 compared to the same period in 2005 was primarily due to higher investment balances and interest rates during the first quarter of 2006.

Interest Expense

Interest expense for the first quarter of 2006 of \$3.7 million was due primarily to the interest under our term loan which we entered into in December 2005.

Minority Interest in Joint Venture

The minority interest reflects BMS's interest in the operating results of our joint venture with BMS in the United States. The operations of the joint venture commenced in 2005 with activities primarily focusing on the co-formulation of the single tablet regimen and achieving bioequivalence with the various co-formulations. We achieved bioequivalence on a formulation of the single tablet regimen at the end of 2005, and we filed a NDA for the single tablet regimen in April 2006. If the single tablet regimen is approved and commercialized, we expect a significant increase in the activities of the joint venture.

Provision for Income Taxes

Our effective income tax rate was 33.9% for the first quarter of 2006. Our effective income tax rate was 32.0% for the first quarter of 2005. Our provision for income taxes for the first quarter of 2006 was \$134.7 million compared to \$73.9 million for the first quarter of 2005. The effective tax rate for the first quarter of 2006 varied from the statutory rate primarily as a result of permanently reinvested earnings of our foreign operations and the tax impact of stock-based compensation expensing under SFAS 123R. We do not provide for U.S. income taxes on undistributed earnings of our foreign operations that are intended to be permanently reinvested.

For the full year 2006, we expect our effective income tax rate to be in the range of 33% to 35%, which includes the impact of our adoption of SFAS 123R. Various factors may have favorable or unfavorable effects on our effective income tax rate during the remainder of 2006 and in subsequent years. These factors include, but are not limited to, changes in tax laws and rates, changes in the interpretations of these laws, changes in accounting rules, future levels of research and development spending, future levels of capital expenditures, changes in the mix of earnings in the various tax jurisdictions in which we operate, changes in overall levels of pre-tax earnings and changes in stock-based compensation.

Liquidity and Capital Resources

The following table summarizes our cash, cash equivalents and marketable securities, our working capital, and our statements of cash flows (in thousands):

	March 31, 2006	December 31, 2005
Cash, cash equivalents and marketable securities	\$ 2,539,621	\$ 2,311,033
Working capital	\$ 2,953,502	\$ 2,636,870
	Three Months ended	
	March 31,	2005
	2006	2005
Cash provided by (used in):		
Operating activities	\$ 221,894	\$ 222,826

Edgar Filing: GILEAD SCIENCES INC - Form 10-Q

Investing activities	\$ (689,994)	\$ (223,107)
Financing activities	\$ 24,777	\$ 17,151

Cash, Cash Equivalents and Marketable Securities

Cash, cash equivalents and marketable securities totaled \$2.54 billion at March 31, 2006, an increase of 10% from December 31, 2005. The increase of \$228.6 million was primarily due to net cash provided by operations of \$221.9 million, partially offset by a \$56.0 million financing cash outflow related to a pay-down of our term loan.

Table of Contents

Working Capital

Working capital at March 31, 2006 was \$2.95 billion compared to \$2.64 billion at December 31, 2005. The increase of \$316.6 million was primarily due to the following:

\$228.6 million increase in cash, cash equivalents and marketable securities;

\$37.5 million increase in accounts receivable primarily due to increased sales in the first quarter of 2006, partially offset by collection activity;

\$22.0 million decrease in income taxes payable due to payment of income taxes in the first quarter of 2006; and

\$13.1 million increase in deferred tax assets due to our adoption of SFAS 123R and changes in unrealized losses related to certain hedge contracts and available-for-sale securities in the first quarter of 2006.

Cash Provided by Operating Activities

Cash provided by operating activities was comprised primarily of net income of \$262.7 million, non-cash depreciation and amortization of \$11.2 million, and non-cash stock-based compensation expense of \$29.6 million, partially offset by a \$65.2 million net cash outflow related to changes in operating assets and liabilities. Operating cash flows also included a non-cash outflow of \$37.4 million related to excess tax benefits from stock option exercises which is now classified under cash provided by financing activities in accordance with SFAS 123R. Cash provided by operating activities during the quarter ended March 31, 2005 included \$157.1 million of net income, a non-cash change in deferred tax assets of \$30.6 million and a \$28.3 million net cash inflow related to changes in operating assets and liabilities.

Cash Used in Investing Activities

Cash used in investing activities primarily related to purchases, sales and maturities of available-for-sale securities. We used \$690.0 million of cash for investing activities during the first quarter of 2006, compared to \$223.1 million during the first quarter of 2005. The increase in cash used in investing activities was primarily due to a significant increase in our cash and cash equivalents balances.

Capital expenditures made in the first quarter of 2006 related to expanding certain aspects of our manufacturing capabilities, upgrading our facilities, as well as additional spending on computer and laboratory equipment to accommodate our growth.

Cash Provided by Financing Activities

Cash provided by financing activities in the first quarter of 2006 primarily related to activity under our employee stock option plans and our term loan. During the first quarter of 2006, we received proceeds from employee stock option exercises of \$43.5 million and made a \$56.0 million principal repayment of our term loan. As a result of our adoption of SFAS 123R, we also classified \$37.4 million of excess tax benefits from stock option exercises under cash provided by financing activities.

Other Information

As of March 31, 2006, we had an uncollateralized revolving credit facility of \$256.0 million of which there were no outstanding amounts. The capacity of the revolving credit facility will continue to increase to a maximum of \$500.0 million commensurate with the principal repayments of our term loan.

In April 2006, we issued \$1.30 billion principal amount of convertible senior notes in a private placement. The net proceeds from the convertible note issuances of \$1.28 billion, after deducting the initial purchasers' discount and the estimated offering expenses, were used to repurchase \$544.9 million of our common stock. Concurrent with the issuance of the notes, we purchased convertible note hedges in private transactions at a cost of \$379.1 million. We also sold warrants to acquire 16.9 million shares of our common stock in private transactions and received net

Edgar Filing: GILEAD SCIENCES INC - Form 10-Q

proceeds of \$235.5 million. Taken together, the convertible note hedges and warrants are intended to reduce the potential dilution upon future conversions of the notes by effectively increasing the initial conversion price of the notes.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that are currently material or reasonably likely to be material to our financial position or results of operations.

Table of Contents

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There have been no significant changes in our market risk as of March 31, 2006 compared to the disclosures in Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2005 (2005 10-K).

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

An evaluation as of March 31, 2006 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 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 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 Control 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, 2006, 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 1. LEGAL PROCEEDINGS

Information pertaining to legal proceedings can be found in Item 1. Condensed Consolidated Financial Statements Note 8. Contingencies to the interim condensed consolidated financial statements, and is incorporated by reference herein.

ITEM 1A. RISK FACTORS

This Form 10-Q contains forward-looking statements based on our current expectations. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Because our actual results may differ materially from any forward-looking statements made by us or on our behalf, you should also read the Risk Factors included in our 2005 10-K for more detailed information regarding these and other risks and uncertainties that can affect our actual financial and operating results. Given these risks and uncertainties, you are cautioned not to place undue reliance on forward-looking statements. The forward-looking statements included in this report are made only as of the date hereof. Except as required under federal securities laws and the rules and regulations of the SEC, we do not undertake and specifically decline any obligation to update publicly any forward-looking statements after the distribution of this report, whether as a result of new information, future events, changes in assumptions or otherwise. The Company notes these factors for investors as permitted by the Private Securities Litigation Reform Act of 1995. It is not possible to predict or identify all such factors and, therefore, you should not consider any of the above risks or the risks set forth in our 2005 10-K to be a complete statement of all the potential risks or uncertainties that we face.

Edgar Filing: GILEAD SCIENCES INC - Form 10-Q

Dependence on our HIV products. We are currently dependent on sales of our HIV products, especially Viread and Truvada, to support our existing operations. Our HIV products are exclusively of the nucleoside class of antiviral therapeutics. Were the treatment paradigm for HIV to change, causing nucleoside-based therapeutics to fall out of favor, or if we are unable to continue increasing our HIV product sales, our results of operations would likely suffer and we would likely need to scale

Table of Contents

back our operations, including our spending on research and development efforts. HIV product sales for the three months ended March 31, 2006 were \$450.7 million, or 65% of our total revenues, and sales of Truvada and Viread comprised 55% and 43%, respectively, of total HIV product sales in the first quarter of 2006. Our sales of HIV products and other products may decline for many of the reasons described in the Risk Factors set forth in our 2005 10-K and this section.

New Products and Growth of Existing Product Revenues. If we do not introduce new products or increase revenues from our existing products, we will not be able to increase our total revenues. Each new product commercialization effort will face the risks outlined in the Risk Factors set forth in our 2005 10-K and this section. If we fail to increase our sales of our HIV products, we may not be able to increase revenues and expand our research and development efforts. We may face difficulties in our collaboration efforts with BMS to commercialize the single tablet regimen of Truvada and Sustiva. For example, regulatory approval for the New Drug Application (NDA) that filed with the FDA in April 2006 may not be granted on a timely basis, or at all.

Significant Competition. We face significant competition from businesses that have substantially greater resources than we do. In addition, our competitors have more products and have operated in the fields in which we compete for longer than we have. Our HIV products compete primarily with products from GlaxoSmithKline (GSK), which markets fixed-dosed combination products that compete with Truvada. For AmBisome, we are encountering significant competition from new products produced by Merck & Co., Inc. and Pfizer Inc. (Pfizer). In addition, we are aware of reports of at least three lipid formulations that claim similarity to AmBisome becoming available outside of the United States, including the anticipated entry of one such formulation in Greece. These formulations may reduce market demand for AmBisome and if any of these formations are later found to be unsafe, sales of AmBisome may also be negatively impacted as well. For Hepsera, we have encountered increased competition with the launch of BMS's Baraclude[®] (entecavir), and there is the potential for future competition from telbivudine, developed by Novartis Pharmaceuticals Corporation and Idenix Pharmaceuticals Limited, which is awaiting approval in the United States and Europe. These companies have substantially greater resources than we do and may significantly impede our ability to be successful with our antiviral products and AmBisome.

Product Profiles and Safety. As our products, including Viread, Truvada, Emtriva, AmBisome and Hepsera, are used over longer periods of time by many patients taking numerous other medicines, we have found and expect to continue to find new issues such as safety, resistance or drug interaction issues, which may require us to provide additional warnings on our labels or narrow our approved indications, each of which could reduce the market acceptance of these products. Safety and efficacy studies of Viread and Emtriva, dosed as separate products, are ongoing and have been underway for a longer period of time than the safety and efficacy studies of Truvada, which are also underway. If serious safety, resistance or interaction issues arise with our marketed products, sales of these products could be limited or 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, once approved, are subject to extensive regulation by FDA and comparable regulatory agencies in other countries. We are continuing clinical trials for Viread, Truvada, Emtriva, AmBisome and Hepsera for currently approved and additional uses. We anticipate that we will file for marketing approval in additional countries and for additional products over the next several years. These products may fail to receive marketing approval on a timely basis, or at all. In addition, our marketed products and how we manufacture and sell these products are subject to extensive continued regulation and review.

Dependence on Contract Research Organizations. We extensively outsource our clinical trial activities and usually perform only a small portion of the start-up activities in-house. We rely on third party contract research organizations (CROs) to perform most of our clinical studies, including document preparation, site identification, screening and preparation, pre-study visits, training and program management. If there is any dispute or disruption in our relationship with our CROs, our clinical trials may be delayed.

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 fails to achieve its 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 new safety issues for our existing products, which could in turn reduce our revenues.

Manufacturing. We depend on third parties to perform manufacturing activities effectively and on a timely basis for most of our products. We depend on third party manufacturers to manufacture Viread, Truvada, Emtriva, Hepsera and Vistide, including the Truvada and Viread made available to physicians and treatment programs at no-profit prices in developing countries under our Access Program. We rely on these third parties for the manufacture of both the active pharmaceutical ingredient and final drug product for clinical and commercial purposes. In addition, Roche, either by itself or through third parties, is responsible for manufacturing Tamiflu. If these third parties fail to perform as required, this could impair our

Table of Contents

ability to deliver our products on a timely basis or receive royalties or cause delays in our clinical trials and applications for regulatory approval, and these events could harm our competitive position. These third-party manufacturers may develop problems over which we have no control, and these problems may adversely affect our business.

We manufacture AmBisome and Macugen at our facilities in San Dimas, California. These are our only formulation and manufacturing facilities in the United States. We own a manufacturing facility in Ireland that conducts quality control testing, labeling and packaging. In addition, we use third parties as alternate contract suppliers to fill and freeze dry certain batches of product. In the event of a natural disaster, including an earthquake, equipment failure, strike or other difficulty, we may be unable to replace this manufacturing capacity in a timely manner and may be unable to manufacture AmBisome and Macugen 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 Astellas Pharma, Inc. (created through the merger of Yamanouchi Pharmaceutical Co. Ltd. and Fujisawa Pharmaceutical Co., Ltd.) and Dainippon Sumitomo Pharma Co., Ltd. for AmBisome, GSK for Hepsera, Roche for Tamiflu, Pfizer for Vistide, OSI and Pfizer for Macugen and Japan Tobacco for Viread, Truvada and Emtriva in Japan and our joint venture with BMS to develop and commercialize the single tablet regimen of Truvada and Sustiva. In many countries, we rely on international distributors for sales of Viread, Truvada, Emtriva, AmBisome and Hepsera outside the United States. Some of these relationships also involve the clinical development of these products by our partners. Reliance on collaborative relationships poses a number of risks, including the risk that we are not able to control the resources our partners devote to our programs or products, disputes may arise with respect to the ownership of rights to technology, disagreements could cause delays in or termination of projects or result in litigation or arbitration, contracts may fail to provide significant 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 collaborative efforts. If these efforts fail, our product development or commercialization of new products could be delayed or revenue from existing products could decline.

Fluctuations in Operating Results. The clinical trials required for regulatory approval of our products, as well as clinical trials we are required to conduct after approval, 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. During the first quarter of 2006, approximately 90% of our product sales in the United States were to three wholesalers, AmerisourceBergen Corp., Cardinal Health, Inc. and McKesson Corp. Inventory levels held by those wholesalers can cause our operating results to fluctuate unexpectedly if our sales to wholesalers do not match end user demand. The U.S. wholesalers with whom we have entered into inventory management agreements may not be completely effective in matching inventory levels to end user demand, as they make estimates to determine end user demand. The non-retail sector in the United States, which includes government institutions, correctional facilities and large health maintenance organizations, which currently contributes to approximately 25% to 30% of our HIV business, tends to be less consistent in terms of buying patterns, and often results in quarter over quarter fluctuations that do not necessarily mirror the growth patterns that can be seen in the retail prescription data. The unpredictable variability of Tamiflu sales and the strong relationship between this revenue and global pandemic planning and supply also cause our operating results to fluctuate from quarter to quarter.

Patents and Proprietary Rights. Our success will depend to a significant degree on our ability to protect our patents and other intellectual property rights both domestically and internationally. We have a number of patents, patent applications and rights to patents related to the compounds in our products, but we cannot be certain that issued patents will be enforceable or provide adequate protection or that pending patent applications will result in issued patents. Competitors may have filed patent applications or received patents and may obtain additional patents and proprietary rights that block or compete with our patents. If competitors file patent applications covering our technology, we may have to participate in interference proceedings or litigation to determine the right to a patent. Litigation and interference proceedings are expensive even if we are ultimately successful.

Patents do not cover the active ingredients in AmBisome. In addition, we do not have patent filings in China or certain other Asian countries covering all forms of adefovir dipivoxil, the active ingredient in Hepsera. Asia is a major market for therapies for HBV, the indication for which Hepsera has been developed.

As part of the approval process of some of our products, the FDA has determined that the products would be granted an exclusivity period during which other manufacturer's applications for approval of our products will not be granted. Generic manufacturers often wait to challenge the patents protecting products until one year prior to the end of the exclusivity period. From time to time, we have received notices from manufacturers indicating that they intend to import chemical intermediates possibly for use in making our products. It is, therefore, possible that generic manufacturers are considering attempts to seek FDA approval for a similar or identical drug through an Abbreviated NDA, which is the application form typically used by manufacturers seeking approval of a generic drug. If our patents are subject to challenges, we may need to spend significant resources to defend such challenges and we may not be able to defend our patents successfully.

Table of Contents

Foreign Currency Risk. A significant percentage of our product sales are denominated in foreign currencies, primarily the Euro. Increases in the value of the U.S. dollar against 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 use foreign currency forward contracts to hedge a percentage of our forecasted international sales, primarily those denominated in the Euro currency. We also hedge a portion of our accounts receivable balances denominated in foreign currencies, which reduces but does not eliminate our exposure to currency fluctuations between the date a sale is recorded and the date that cash is collected. Our hedging program only hedges a portion of our total exposure, significant foreign exchange rate fluctuations within a short period of time could still 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, Italy, Portugal and Spain are subject to significant payment delays due to government funding and reimbursement practices. Historically, receivables tended to accumulate over a period of time and then be settled through large lump sum payments as government funding became available. 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 results of operations would be adversely affected.

Imports. Prices for our products are based on local market economics and competition and sometimes differ from country to country. Our sales in countries with relatively higher prices may be reduced if products can be imported into those or other 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 re-sold at much higher prices. If this happens with our products, particularly Viread and Truvada, which we have agreed to make available at no-profit prices to 97 countries participating in our Access Program, 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 products, 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. 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, thereby reducing our product sales. Certain offices of the government of Brazil have expressed concern over the affordability of our HIV products and declared that they are considering issuing compulsory licenses to permit the manufacture of otherwise patented products for HIV infection, including Viread. We are currently engaged in discussions with the Brazilian government regarding the affordability of our HIV products. In addition, concerns over the cost and availability of Tamiflu as fear grows about a potential avian flu pandemic have generated international discussions over potential compulsory licensing of our Tamiflu patents. Furthermore, Roche may issue voluntary licenses to permit third party manufacturing of Tamiflu. For example, Roche has granted a sublicense to Shanghai Pharmaceutical (Group) Co., Ltd. for China and a sublicense to India's Hetero Drugs Limited for India and certain developing countries. Should one or more compulsory licenses be issued permitting generic manufacturing to override Gilead's Tamiflu patents, or should Roche issue additional voluntary licenses to permit third party manufacturing of Tamiflu, those developments could reduce royalties received from Roche's sales of Tamiflu. Certain countries do not permit enforcement of our patents, and manufacturers are able to sell generic versions of our products in those countries. Compulsory licenses or sales of generic versions of our products could significantly reduce our sales and adversely affect our results of operations, particularly if generic versions of our products are imported into territories where we have existing commercial sales.

Pharmaceutical Pricing and Reimbursement Pressures. Successful commercialization of our products depends, in part, on the availability of governmental and third-party payor reimbursement for the cost of such products and related treatments. Government authorities and third-party payors increasingly are challenging the price of medical products and services, particularly for innovative new products and therapies. This has resulted in lower average sales prices. For example, a majority of our sales of AmBisome and Vistide, and a majority of our sales of Truvada, Viread and Hepsera, are subject to reimbursement by government agencies, resulting in significant discounts from list price and rebate obligations. Our business may be adversely affected by an increase in U.S. or international pricing pressures. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and health care reform, pharmaceutical reimbursement policies and pricing in general.

In Europe, the success of Viread, Truvada, Emtriva, Hepsera, AmBisome and Tamiflu will also depend largely on obtaining and maintaining government reimbursement because in many European countries, including the United Kingdom and France, patients are unlikely to use prescription drugs that are not reimbursed by their governments. In addition,

Table of Contents

negotiating prices with governmental authorities can delay commercialization by twelve months or more. We also expect that the success of our products in development, particularly in Europe, will depend on the ability to obtain reimbursement. Even if reimbursement is available, reimbursement policies may adversely affect our ability to sell our products on a profitable basis. For example, in Europe as in many international markets, governments control the prices of prescription pharmaceuticals and expect prices of prescription pharmaceuticals to decline over the life of the product or as volumes increase. As new drugs come to market, we may face significant price decreases for our products across much of Europe. We believe that this will continue into the foreseeable future as governments struggle with escalating health care spending. As a result of these pricing practices, it may become difficult to maintain our historic levels of profitability or to achieve expected rates of growth.

Insurance Coverage. The testing, manufacturing, marketing and use of our commercial products, as well as products in development, involve substantial risk of product liability claims. These claims may be made directly by consumers, healthcare providers, pharmaceutical companies or others. Our product liability insurance may not cover a successful product liability claim against us and we could be required 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.

Litigation. We are named as a defendant in lawsuits regarding the use of average wholesale price and reimbursement rates under Medicaid. We have also been named as a defendant in a lawsuit alleging violations of the federal securities laws. Adverse results from these lawsuits could result in material damages that could significantly reduce our earnings and cash flows.

Tax Rate. Various factors may have favorable or unfavorable effects on our effective income tax rate. These factors include, but are not limited to, interpretations of existing tax laws, our adoption of SFAS 123R relating to the accounting for stock options and other share-based payments, changes in tax laws and rates, future levels of research and development spending, changes in accounting standards, 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. The impact on our income tax provision resulting from the above-mentioned factors may be significant and could have a negative impact on our net income.

Recently Adopted Changes in Accounting for Stock-Based Compensation. We adopted SFAS 123R on January 1, 2006, under which we are required to record additional compensation expense related to stock options and other share-based payments in 2006 and beyond. The impact on our earnings resulting from this new standard will have a significant negative impact on our reported results of operations compared to the results we have reported under prior accounting standards on stock options and other share-based payments.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

Table of Contents

ITEM 6. EXHIBITS

- 3.1 Restated Certificate of Incorporation of the Registrant, as amended.⁽¹⁾
- 3.2 Bylaws of the Registrant, as amended and restated March 30, 1999.⁽²⁾
- 3.3 Certificate of Designation of Series A Junior Participating Preferred Stock of the Registrant.⁽³⁾
- 10.1* Amended and Restated Agreement dated as of June 10, 2004 by and between Astellas Pharma Inc., as successor to Fujisawa Healthcare, Inc., and Gilead Sciences, Inc.
- 10.2 2006 Corporate Bonus Plan.⁽⁴⁾
- 10.3 Code Section 162(m) Bonus Plan.⁽⁴⁾
- 10.4 Gilead Sciences, Inc. Severance Plan, as amended through May 9, 2005.⁽⁴⁾
- 31.1 Certification of Chief Executive Officer, as required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.
- 31.2 Certification of Chief Financial Officer, as required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.
- 32** Certification of Chief Executive Officer and Chief Financial Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350)

⁽¹⁾ Filed as an exhibit to Registrant's Registration Statement on Form S-8 (No. 333-117480) filed on July 19, 2004, and incorporated herein by reference.

⁽²⁾ Filed as an exhibit to Registrant's Annual Report on Form 10-K/A for the fiscal year ended December 31, 1998, and incorporated herein by reference.

⁽³⁾ Filed as an exhibit to Registrant's Current Report on Form 8-K filed with the SEC on November 21, 1994 and incorporated herein by reference.

⁽⁴⁾ Filed as an exhibit to Registrant's Current Report on Form 8-K filed with the SEC on February 22, 2006 and incorporated herein by reference.

* Certain confidential portions of this Exhibit were omitted by means of marking such portions with an asterisk (the Mark). This Exhibit has been filed separately with the Secretary of the SEC without the Mark pursuant to the Registrant's Application Requesting Confidential Treatment under Rule 24b-2 under the Securities Exchange Act of 1934.

** This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

Table of Contents

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 3, 2006

/s/ John C. Martin
John C. Martin

President and Chief Executive Officer

Date: May 3, 2006

/s/ John F. Milligan
John F. Milligan

Executive Vice President and Chief Financial Officer

(Principal Financial and Accounting Officer)

Table of Contents

Exhibit Index

(a) Exhibits

- 3.1 Restated Certificate of Incorporation of the Registrant, as amended.⁽¹⁾
- 3.2 Bylaws of the Registrant, as amended and restated March 30, 1999.⁽²⁾
- 3.3 Certificate of Designation of Series A Junior Participating Preferred Stock of the Registrant.⁽³⁾
- 10.1* Amended and Restated Agreement dated as of June 10, 2004 by and between Astellas Pharma Inc., as successor to Fujisawa Healthcare, Inc., and Gilead Sciences, Inc.
- 10.2 2006 Corporate Bonus Plan.⁽⁴⁾
- 10.3 Code Section 162(m) Bonus Plan.⁽⁴⁾
- 10.4 Gilead Sciences, Inc. Severance Plan, as amended through May 9, 2005.⁽⁴⁾
- 31.1 Certification of Chief Executive Officer, as required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.
- 31.2 Certification of Chief Financial Officer, as required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.
- 32** Certification of Chief Executive Officer and Chief Financial Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350)

⁽¹⁾ Filed as an exhibit to Registrant's Registration Statement on Form S-8 (No. 333-117480) filed on July 19, 2004, and incorporated herein by reference.

⁽²⁾ Filed as an exhibit to Registrant's Annual Report on Form 10-K/A for the fiscal year ended December 31, 1998, and incorporated herein by reference.

⁽³⁾ Filed as an exhibit to Registrant's Current Report on Form 8-K filed with the SEC on November 21, 1994 and incorporated herein by reference.

⁽⁴⁾ Filed as an exhibit to Registrant's Current Report on Form 8-K filed with the SEC on February 22, 2006 and incorporated herein by reference.

* Certain confidential portions of this Exhibit were omitted by means of marking such portions with an asterisk (the Mark). This Exhibit has been filed separately with the Secretary of the SEC without the Mark pursuant to the Registrant's Application Requesting Confidential Treatment pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

** This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.