

GILEAD SCIENCES INC  
Form 10-Q  
May 07, 2009  
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, 2009

or

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

Commission File No. 0-19731

**GILEAD SCIENCES, INC.**

(Exact Name of Registrant as Specified in Its Charter)

Edgar Filing: GILEAD SCIENCES INC - Form 10-Q

**Delaware**  
(State or Other Jurisdiction of

**94-3047598**  
(IRS Employer

**Incorporation or Organization)**

**Identification No.)**

**333 Lakeside Drive, Foster City, California**  
(Address of principal executive offices)

**94404**  
(Zip Code)

**650-574-3000**

**Registrant's Telephone Number, Including Area Code**

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company)

Smaller reporting company

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 30, 2009: 906,395,631

**Table of Contents****GILEAD SCIENCES, INC.****INDEX**

<b>PART I.</b>	<b><u>FINANCIAL INFORMATION</u></b>	<b>3</b>
Item 1.	<u>Condensed Consolidated Financial Statements</u>	3
	<u>Condensed Consolidated Balance Sheets at March 31, 2009 and December 31, 2008</u>	3
	<u>Condensed Consolidated Statements of Income for the Three Months Ended March 31, 2009 and 2008</u>	4
	<u>Condensed Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2009 and 2008</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>	17
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	27
Item 4.	<u>Controls and Procedures</u>	28
<b>PART II.</b>	<b><u>OTHER INFORMATION</u></b>	<b>29</b>
Item 1.	<u>Legal Proceedings</u>	29
Item 1A.	<u>Risk Factors</u>	29
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	45
Item 3.	<u>Defaults Upon Senior Securities</u>	45
Item 4.	<u>Submission of Matters to a Vote of Security Holders</u>	45
Item 5.	<u>Other Information</u>	45
Item 6.	<u>Exhibits</u>	46
	<b><u>SIGNATURES</u></b>	<b>52</b>

We own or have rights to various trademarks, copyrights and trade names used in our business, including the following: GILEAD®, GILEAD SCIENCES®, TRUVADA®, VIREAD®, EMTRIVA®, HEPSERA®, AMBISOME®, VISTIDE®, LETAIRIS® and VOLIBRIS®. ATRIPLA® is a registered trademark belonging to Bristol-Myers Squibb & Gilead Sciences, LLC. MACUGEN® is a registered trademark belonging to OSI Pharmaceuticals, Inc. SUSTIVA® is a registered trademark of Bristol-Myers Squibb Pharma Company. TAMIFLU® is a registered trademark belonging to Hoffmann-La Roche Inc. 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)

	<b>March 31, 2009 (unaudited)</b>	<b>December 31, 2008 (1)</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 1,663,646	\$ 1,459,302
Short-term marketable securities	396,648	330,760
Accounts receivable, net	1,068,000	1,023,397
Inventories	936,727	927,868
Deferred tax assets	135,612	140,882
Prepaid taxes	179,612	198,318
Prepaid expenses	70,741	71,815
Other current assets	164,929	126,066
<b>Total current assets</b>	<b>4,615,915</b>	<b>4,278,408</b>
Property, plant and equipment, net	679,437	528,799
Noncurrent portion of prepaid royalties	248,959	257,208
Noncurrent deferred tax assets	220,693	226,728
Long-term marketable securities	1,548,595	1,449,577
Other noncurrent assets	206,315	196,111
<b>Total assets</b>	<b>\$ 7,519,914</b>	<b>\$ 6,936,831</b>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 578,362	\$ 601,200
Accrued government rebates	189,096	176,939
Accrued compensation and employee benefits	88,404	103,840
Income taxes payable	95,362	44,757
Other accrued liabilities	256,660	245,662
Deferred revenues	48,300	42,963
Current portion of other long-term obligations	5,613	5,631
<b>Total current liabilities</b>	<b>1,261,797</b>	<b>1,220,992</b>
Long-term deferred revenues	51,285	74,181
Convertible senior notes, net	1,111,866	1,098,025
Long-term income taxes payable	56,588	56,588
Other long-term obligations	21,095	21,462
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock, par value \$0.001 per share; 5,000 shares authorized; none outstanding		
Common stock, par value \$0.001 per share; 2,800,000 shares authorized; 906,489 and 909,819 shares issued and outstanding at March 31, 2009 and December 31, 2008, respectively	906	910
Additional paid-in capital	4,018,583	3,930,109
Accumulated other comprehensive income	111,644	41,240
Retained earnings	672,956	300,314
<b>Total Gilead stockholders' equity</b>	<b>4,804,089</b>	<b>4,272,573</b>
Noncontrolling interest	213,194	193,010
<b>Total stockholders' equity</b>	<b>5,017,283</b>	<b>4,465,583</b>

## Edgar Filing: GILEAD SCIENCES INC - Form 10-Q

Total liabilities and stockholders' equity	\$ 7,519,914	\$ 6,936,831
--	--------------	--------------

- (1) The condensed consolidated balance sheet at December 31, 2008 has been derived from audited consolidated financial statements at that date, revised for retrospective application of FASB Staff Position Accounting Principles Board Opinion No. 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)* (FSP APB 14-1) and Statement of Financial Accounting Standards (SFAS) No. 160, *Noncontrolling Interests in Consolidated Financial Statements, an amendment of Accounting Research Bulletin No. 51, Consolidated Financial Statements* (SFAS 160), but does not include all of the information and footnotes required by U.S. generally accepted accounting principles for complete financial statements. See Note 1 Summary of Significant Accounting Policies .

See accompanying notes.

**Table of Contents****GILEAD SCIENCES, INC.****Condensed Consolidated Statements of Income**

(unaudited)

(in thousands, except per share amounts)

	<b>Three Months Ended March 31,</b>	
	<b>2009</b>	<b>2008 (1)</b>
<b>Revenues:</b>		
Product sales	\$ 1,447,580	\$ 1,141,306
Royalty revenues	53,042	109,452
Contract and other revenues	29,838	7,394
<b>Total revenues</b>	<b>1,530,460</b>	<b>1,258,152</b>
<b>Costs and expenses:</b>		
Cost of goods sold	329,414	239,848
Research and development	188,779	155,301
Selling, general and administrative	203,951	194,957
<b>Total costs and expenses</b>	<b>722,144</b>	<b>590,106</b>
<b>Income from operations</b>	<b>808,316</b>	<b>668,046</b>
Interest and other income, net	4,158	22,700
Interest expense	(16,671)	(16,001)
<b>Income before provision for income taxes</b>	<b>795,803</b>	<b>674,745</b>
<b>Provision for income taxes</b>	<b>209,227</b>	<b>188,320</b>
<b>Net income</b>	<b>586,576</b>	<b>486,425</b>
<b>Net loss attributable to noncontrolling interest</b>	<b>2,536</b>	<b>1,875</b>
<b>Net income attributable to Gilead</b>	<b>\$ 589,112</b>	<b>\$ 488,300</b>
<b>Net income per share attributable to Gilead common stockholders basic</b>	<b>\$ 0.65</b>	<b>\$ 0.53</b>
<b>Shares used in per share calculation basic</b>	<b>909,780</b>	<b>928,104</b>
<b>Net income per share attributable to Gilead common stockholders diluted</b>	<b>\$ 0.63</b>	<b>\$ 0.51</b>
<b>Shares used in per share calculation diluted</b>	<b>942,479</b>	<b>966,554</b>

(1) The condensed consolidated statement of income for the three months ended March 31, 2008 has been revised for the retrospective application of FSP APB 14-1 and SFAS 160. See Note 1 Summary of Significant Accounting Policies .  
See accompanying notes.



**Table of Contents****GILEAD SCIENCES, INC.****Condensed Consolidated Statements of Cash Flows**

(unaudited)

(in thousands)

	<b>Three Months Ended March 31,</b>	
	<b>2009</b>	<b>2008 (1)</b>
<b>Operating Activities:</b>		
Net income	\$ 586,576	\$ 486,425
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation	13,720	10,709
Amortization	25,428	18,926
Stock-based compensation expense	41,045	36,136
Excess tax benefits from stock-based compensation	(20,693)	(89,244)
Tax benefits from employee stock plans	23,604	93,533
Deferred income taxes	11,305	4,263
Other non-cash transactions	39,366	(13,354)
Changes in operating assets and liabilities:		
Accounts receivable, net	(89,073)	(141,022)
Inventories	(11,895)	(58,120)
Prepaid expenses and other assets	(102)	58,516
Accounts payable	(20,999)	104,674
Income taxes payable	50,605	14,590
Accrued liabilities	10,002	70,104
Deferred revenues	(17,559)	9,375
<b>Net cash provided by operating activities</b>	<b>641,330</b>	<b>605,511</b>
<b>Investing Activities:</b>		
Purchases of marketable securities	(879,439)	(658,962)
Proceeds from sales of marketable securities	587,427	531,995
Proceeds from maturities of marketable securities	127,694	20,500
Capital expenditures and other	(164,071)	(16,749)
<b>Net cash used in investing activities</b>	<b>(328,389)</b>	<b>(123,216)</b>
<b>Financing Activities:</b>		
Proceeds from issuances of common stock	40,947	65,480
Repurchases of common stock	(230,065)	(815,936)
Repayments of long-term debt and other obligations	(36)	(97)
Excess tax benefits from stock-based compensation	20,693	89,244
Contributions from (distributions to) noncontrolling interest	22,720	(28,413)
<b>Net cash used in financing activities</b>	<b>(145,741)</b>	<b>(689,722)</b>
<b>Effect of exchange rate changes on cash</b>	<b>37,144</b>	<b>(37,775)</b>
<b>Net change in cash and cash equivalents</b>	<b>204,344</b>	<b>(245,202)</b>
<b>Cash and cash equivalents at beginning of period</b>	<b>1,459,302</b>	<b>968,086</b>



Edgar Filing: GILEAD SCIENCES INC - Form 10-Q

Cash and cash equivalents at end of period	\$ 1,663,646	\$ 722,884
--	--------------	------------

- (1) The condensed consolidated statement of cash flows for the three months ended March 31, 2008 has been revised for the retrospective application of FSP APB 14-1 and SFAS 160. See Note 1 Summary of Significant Accounting Policies .  
See accompanying notes.

**Table of Contents**

**GILEAD SCIENCES, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

(unaudited)

**1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Basis of Presentation**

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared in accordance with U.S. 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, we or our) believes are necessary for a fair presentation of the periods presented. These interim financial results are not necessarily indicative of results expected for the full fiscal year or for any subsequent interim period.

The preparation of these Condensed Consolidated Financial Statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosures. On an ongoing basis, management evaluates its estimates, including critical accounting policies or estimates related to revenue recognition, allowance for doubtful accounts, prepaid royalties, clinical trial accruals, our tax provision and stock-based compensation. We base our estimates on historical experience and on various other market specific and other relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ significantly from these estimates.

The accompanying Condensed Consolidated Financial Statements include the accounts of Gilead, our wholly-owned subsidiaries and our joint ventures with Bristol-Myers Squibb Company (BMS), for which we are the primary beneficiary as determined under Financial Accounting Standards Board (FASB) Interpretation No. 46 (revised December 2003), *Consolidation of Variable Interest Entities*. We record a noncontrolling interest in our Condensed Consolidated Financial Statements to reflect BMS' s interest in the joint ventures. Significant intercompany transactions have been eliminated. The Condensed Consolidated Financial Statements include the results of companies acquired by us from the date of each acquisition.

The accompanying Condensed Consolidated Financial Statements and related financial information should be read in conjunction with the audited Consolidated Financial Statements and the related notes thereto for the year ended December 31, 2008, included in our Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission.

*Convertible Senior Notes*

In May 2008, the FASB issued FASB Staff Position (FSP) Accounting Principles Board Opinion No. 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)* (FSP APB 14-1). FSP APB 14-1 addresses instruments commonly referred to as Instrument C from Emerging Issues Task Force (EITF) Issue No. 90-19, *Convertible Bonds with Issuer Option to Settle for Cash upon Conversion*, which requires the issuer to settle the principal amount in cash and the conversion spread in cash or net shares at the issuer' s option. FSP APB 14-1 requires that issuers of these instruments account for their liability and equity components separately by bifurcating the conversion option from the debt instrument, classifying the conversion option in equity and then accreting the resulting discount on the debt as additional interest expense over the expected life of the debt. FSP APB 14-1 is effective for fiscal years beginning after December 15, 2008 and interim periods within those fiscal years and requires retrospective application to all periods presented.

On January 1, 2009, we adopted the provisions of FSP APB 14-1 on a retrospective basis and reflected additional interest expense and a related benefit from income taxes of \$12.9 million and \$5.1 million, respectively, for the three months ended March 31, 2008 in our Condensed Consolidated Statement of Income,

**Table of Contents**

and recorded additional interest expense and a related benefit from income taxes of \$13.6 million and \$5.3 million, respectively, for the three months ended March 31, 2009. In addition, the retrospective adoption of FSP APB 14-1 decreased deferred tax assets and debt issuance costs included in other assets by an aggregate of \$81.7 million, decreased convertible senior notes, net included in long-term liabilities by \$201.8 million, and increased total stockholders' equity by \$120.1 million after a charge of \$82.6 million to retained earnings on our Condensed Consolidated Balance Sheet as of December 31, 2008.

*Noncontrolling Interest*

In December 2007, the FASB issued Statement of Financial Accounting Standards (SFAS) No. 160, *Noncontrolling Interests in Consolidated Financial Statements, an amendment of Accounting Research Bulletin No. 51, Consolidated Financial Statements* (SFAS 160). SFAS 160 establishes accounting and reporting standards for ownership interests in subsidiaries held by parties other than the parent, the amount of consolidated net income (loss) attributable to the parent and to the noncontrolling interests, changes in a parent's ownership interest and the valuation of retained noncontrolling equity investments when a subsidiary is deconsolidated. SFAS 160 also establishes additional reporting requirements that identify and distinguish between the ownership interest of the parent and the interest of the noncontrolling owners. SFAS 160 is effective for interim periods and fiscal years beginning after December 15, 2008. On January 1, 2009, we adopted the provisions of SFAS 160 and reclassified the noncontrolling interest (formerly minority interest) from liabilities to stockholders' equity on our Condensed Consolidated Balance Sheets on a retrospective basis, which resulted in the reclassification of the change in noncontrolling interest from net cash provided by operating activities to net cash used in financing activities on our Condensed Consolidated Statements of Cash Flows. We also presented the noncontrolling interest on our Condensed Consolidated Statements of Income as net loss attributable to noncontrolling interest, a component of consolidated net income, on a retrospective basis.

**Net Income Per Share attributable to Gilead Common Stockholders**

Basic net income per share attributable to Gilead common stockholders is calculated based on the weighted-average number of shares of our common stock outstanding during the period. Diluted net income per share attributable to Gilead common stockholders is calculated based on the weighted-average number of shares of our common stock outstanding and other dilutive securities outstanding during the period. The potential dilutive shares of our common stock resulting from the assumed exercise of outstanding stock options and equivalents (consisting primarily of performance shares) and the assumed exercise of warrants relating to the convertible senior notes due in 2011 (2011 Notes) and the convertible senior notes due in 2013 (2013 Notes) (collectively, the Notes) are determined under the treasury stock method.

Because the principal amount of the Notes will be settled in cash, only the conversion spread relating to the Notes is included in our calculation of diluted net income per share attributable to Gilead common stockholders. The potential dilutive shares of our common stock resulting from the assumed settlement of the conversion spread of the Notes are determined under the guidance set forth in SFAS No. 128, *Earnings Per Share*, EITF Issue No. 04-8, *The Effect of Contingently Convertible Instruments on Diluted Earnings Per Share*, and EITF Topic No. D-72, *Effect of Contracts That May Be Settled in Stock or Cash on the Computation of Diluted Earnings Per Share*. Under such guidance, the settlement of the conversion spread of the Notes has a dilutive effect when the average market price of our common stock during the period exceeds \$38.75 and \$38.10 for the 2011 Notes and 2013 Notes, respectively. The average market price of our common stock during the three months ended March 31, 2009 and 2008 exceeded both of the conversion prices of the Notes and their dilutive effect is included in the table below.

Warrants relating to the 2011 Notes and 2013 Notes have a dilutive effect when the average market price of our common stock during the period exceeds the warrants' exercise prices of \$50.80 and \$53.90, respectively. The average market price of our common stock during each of the three months ended March 31, 2009 and 2008 did not exceed the warrants' exercise prices relating to the Notes.

**Table of Contents**

Stock options to purchase approximately 15.4 million and 9.5 million weighted-average shares of our common stock were outstanding during the three months ended March 31, 2009 and 2008, respectively, but were not included in the computation of diluted net income per share attributable to Gilead common stockholders because the options' exercise prices were greater than the average market price of our common stock during these periods; therefore, their effect was antidilutive.

The following table is a reconciliation of the numerator and denominator used in the calculation of basic and diluted net income per share attributable to Gilead common stockholders (in thousands):

	<b>Three Months Ended March 31,</b>	
	<b>2009</b>	<b>2008</b>
<b>Numerator:</b>		
Net income attributable to Gilead	\$ 589,112	\$ 488,300
<b>Denominator:</b>		
Weighted-average shares of common stock outstanding used in calculation of basic net income per share attributable to Gilead common stockholders	909,780	928,104
<b>Effect of dilutive securities:</b>		
Stock options and equivalents	26,074	32,562
Conversion spread related to 2011 convertible senior notes	3,169	2,801
Conversion spread related to 2013 convertible senior notes	3,456	3,087
Weighted-average shares of common stock outstanding used in calculation of diluted net income per share attributable to Gilead common stockholders	942,479	966,554

**Fair Value**

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* (SFAS 157). SFAS 157 defines fair value, establishes a framework for measuring fair value and expands the disclosure requirements regarding fair value measurements. SFAS 157 is effective for fiscal years beginning after November 15, 2007 for financial assets and liabilities as well as for non-financial assets and liabilities that are recognized or disclosed at fair value on a recurring basis in the financial statements. In accordance with FSP No. 157-2, *Effective Date of FASB Statement No. 157* (FSP 157-2), for all other non-financial assets and liabilities, SFAS 157 is effective for fiscal years beginning after November 15, 2008. In October 2008, the FASB issued FSP No. 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset is Not Active* (FSP 157-3), that clarifies the application of SFAS 157 for financial assets in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. FSP 157-3 is applicable to the valuation of auction rate securities held by us for which there was no active market as of March 31, 2009.

On January 1, 2009, in accordance with FSP 157-2, we adopted the provisions of SFAS 157 on a prospective basis for our non-financial assets and liabilities that are not recognized or disclosed at fair value on a recurring basis. SFAS 157 requires that we determine the fair value of financial and non-financial assets and liabilities using the fair value hierarchy established in SFAS 157 and describes three levels of inputs that may be used to measure fair value, as follows:

Level 1 inputs which include quoted prices in active markets for identical assets or liabilities;

Level 2 inputs which include observable inputs other than Level 1 inputs, such as quoted prices for similar assets or liabilities; quoted prices for identical or similar assets or liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the asset or liability; and

**Table of Contents**

Level 3 inputs which include unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the underlying asset or liability. Level 3 assets and liabilities include those whose fair value measurements are determined using pricing models, discounted cash flow methodologies or similar valuation techniques, as well as significant management judgment or estimation.

The adoption of SFAS 157 for our non-financial assets and liabilities that are not recognized or disclosed at fair value on a recurring basis had no effect on our consolidated net income for the three months ended March 31, 2009.

The following table summarizes, for each major category of assets or liabilities, the respective fair value and the classification by level of input within the fair value hierarchy defined in SFAS 157 (in thousands):

	March 31, 2009				December 31, 2008			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
<b>Assets:</b>								
Cash equivalents	\$	\$ 42,098	\$	\$ 42,098	\$ 2,500	\$ 179,847	\$	\$ 182,347
Marketable securities	205,585	1,637,065	102,593	1,945,243	200,502	1,477,202	102,633	1,780,337
Derivatives		126,552		126,552		90,870		90,870
	\$ 205,585	\$ 1,805,715	\$ 102,593	\$ 2,113,893	\$ 203,002	\$ 1,747,919	\$ 102,633	\$ 2,053,554
<b>Liabilities:</b>								
Derivatives	\$	\$ 352	\$	\$ 352	\$	\$ 150	\$	\$ 150

The following table is a reconciliation of marketable securities measured at fair value using significant unobservable inputs (Level 3) (in thousands):

	Three Months Ended March 31,	
	2009	2008
Balance, beginning of period	\$ 102,633	\$ 7,258
Total realized and unrealized gains (losses) included in		
Interest and other income, net	(29)	(1,898)
Other comprehensive income, net	2,495	(8,710)
Sales of marketable securities	(2,506)	(14,064)
Transfers into Level 3		157,699
Balance, end of period	\$ 102,593	\$ 140,285

Total losses for the three months ended March 31, 2009 included in earnings attributable to the change in unrealized losses relating to assets still held at the reporting date

	\$ (29)	\$ (1,898)
--	---------	------------

Marketable securities, measured at fair value using Level 3 inputs, are substantially comprised of auction rate securities within our available-for-sale investment portfolio. The underlying assets of our auction rate securities are comprised of student loans. Although auction rate securities would typically be measured using Level 2 inputs, the failure of auctions and the lack of market activity and liquidity experienced since the beginning of 2008 required that these securities be measured using Level 3 inputs. The fair value of our auction rate securities was determined using a discounted cash flow model that considered projected cash flows for the issuing trusts, underlying collateral and expected yields. Projected cash flows were estimated based on the underlying loan principal, bonds outstanding and payout formulas. The weighted-average life over which the cash flows were projected considered the collateral composition of the securities and related historical and projected prepayments. The underlying student loans have a weighted-average expected life of three to nine years. The discount rates used in our discounted cash flow model were based on market conditions for comparable or similar term asset-backed securities as well as other fixed income securities adjusted for an



**Table of Contents**

illiquidity discount resulting in a discount rate of 4.7%. Our auction rate securities reset every seven to 35 days with maturity dates ranging from 2023 through 2041 and have interest rates ranging from 1.0% to 1.3%. As of March 31, 2009, our auction rate securities continued to earn interest.

Our auction rate securities were recorded in long-term marketable securities on our Condensed Consolidated Balance Sheet at March 31, 2009. Although there continued to be failed auctions as well as lack of market activity and liquidity in 2009, based on our assessment of the underlying collateral, the creditworthiness of the issuers of the securities and our ability and intent to hold these securities until anticipated recovery, which could be at final maturity, we had no other-than-temporary impairments on these securities as of March 31, 2009.

**2. DERIVATIVE FINANCIAL INSTRUMENTS**

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities, an amendment of SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities* (SFAS 161). SFAS 161 is intended to improve financial reporting of derivative instruments and hedging activities by requiring enhanced qualitative and quantitative disclosures to enable financial statement users to better understand the effects of derivatives and hedging on an entity's financial position, financial performance and cash flows in the context of an entity's risk exposures. SFAS 161 is effective for interim periods and fiscal years beginning after November 15, 2008. On January 1, 2009, we adopted the provisions of SFAS 161 on a prospective basis for our derivative instruments.

We operate in foreign countries which exposes us to market risk associated with foreign currency exchange rate fluctuations between the U.S. dollar and various foreign currencies, the most significant of which is the Euro. In order to manage the risk related to changes in foreign currency exchange rates, we hedge certain of our foreign currency exposures related to outstanding monetary assets and liabilities and forecasted product sales with foreign currency exchange forward contracts and foreign currency exchange option contracts. In general, the market risks of our foreign currency exchange contracts are offset by corresponding gains and losses on the transactions being hedged. Our exposure to credit risk from these contracts is a function of changes in interest and currency exchange rates and, therefore, varies over time. We limit the risk that counterparties to these contracts may be unable to perform by transacting only with major banks, all of which we monitor closely in the context of current market conditions. We also limit risk of loss by entering into contracts that provide for net settlement at maturity. Therefore, our overall risk of loss in the event of a counterparty default is limited to the amount of any unrecognized gains on outstanding contracts (i.e., those contracts that have a positive fair value) at the date of default. We do not enter into derivative financial contracts for trading purposes. We do not hedge our net investment in any of our foreign subsidiaries.

We enter into foreign currency exchange contracts to hedge our market risk exposure associated with foreign currency exchange rate fluctuations for certain monetary assets and liabilities of our foreign subsidiaries that are denominated in a non-functional currency. As these derivative instruments are not designated as hedges under SFAS Nos. 133 and 138, *Accounting for Derivative Instruments and Hedging Activities* (collectively referred to as SFAS 133), we record the changes in the fair value of such instruments in interest and other income, net on our Condensed Consolidated Statements of Income.

Foreign currency exchange contracts used to hedge forecasted product sales are designated as cash flow hedges under SFAS 133. These derivative instruments are employed to eliminate or minimize certain foreign currency exposures that can be confidently identified and quantified, all with maturities of 18 months or less. At the inception of a hedging relationship and on a quarterly basis, we perform a regression analysis taking the change in cash flow of the underlying contract and regressing it against the change in cash flow of the hedge instrument (excluding time value) to assess the effectiveness of the hedging relationship. We assess hedge effectiveness on a retrospective basis using a dollar offset approach monthly. We exclude time value from our effectiveness testing and recognize changes in the time value of the hedge in interest and other income, net. The effective component of the hedge is recorded in accumulated other comprehensive income (OCI) or loss within

**Table of Contents**

stockholders' equity as an unrealized gain or loss on the hedging instrument. When the hedged forecasted transactions occur, the hedges are de-designated and the unrealized gains and losses are reclassified into product sales. Substantially all values related to the hedged forecasted transactions reported in accumulated OCI at March 31, 2009 will be reclassified to product sales within 12 months.

We had notional amounts on foreign currency exchange forward and option contracts outstanding of \$2.37 billion and \$2.39 billion at March 31, 2009 and December 31, 2008, respectively.

The following table summarizes information about the fair values of derivative instruments on our Condensed Consolidated Balance Sheet as of March 31, 2009 (in thousands):

	Location of Asset Derivatives	Fair Value	Location of Liability Derivatives	Fair Value
<b>Derivatives designated as hedges under SFAS 133:</b>				
Foreign currency exchange contracts	Other current assets	\$ 116,165	Other accrued liabilities	\$ 290
Foreign currency exchange contracts	Other noncurrent assets	10,386	Other long-term obligations	52
Total derivatives designated as hedges under SFAS 133		126,551		342
<b>Derivatives not designated as hedges under SFAS 133:</b>				
Foreign currency exchange contracts	Other current assets	1	Other accrued liabilities	10
Total derivatives not designated as hedges under SFAS 133		1		10
Total derivatives		\$ 126,552		\$ 352

The following table summarizes the effect of our derivative instruments on our Condensed Consolidated Statement of Income for the three months ended March 31, 2009 (in thousands):

Derivatives in SFAS 133 Cash Flow Hedging Relationships	Amount of Net Gain Recognized in OCI on Derivative (Effective Portion)	Location of		Net Loss Recognized in Income on Derivative (Ineffective Portion and Amount Excluded from Effectiveness Testing)	Net Loss Recognized in Income on Derivative (Ineffective Portion and Amount Excluded from Effectiveness Testing)
		Net Gain Reclassified from Accumulated OCI into Income (Effective Portion)	Net Gain Reclassified from Accumulated OCI into Income (Effective Portion)		
Foreign currency exchange contracts	\$109,114	Product sales	\$ 37,818	Interest and other income, net	\$ (16,119)



Edgar Filing: GILEAD SCIENCES INC - Form 10-Q

	<b>Location of Net</b>	<b>Amount of Net</b>
<b>Derivatives Not</b>	<b>Gain Recognized</b>	<b>Gain Recognized in</b>
<b>Designated as Hedges</b>	<b>in Income on</b>	<b>Income on</b>
<b>under SFAS 133</b>	<b>Derivative</b>	<b>Derivative</b>
Foreign currency exchange contracts	Interest and other income, net	\$56,362

**Table of Contents****3. ACQUISITION OF REAL ESTATE**

In January 2009, we completed the purchase of an office building and approximately 30 acres of land located in Foster City, California, for an aggregate purchase price of \$140.1 million. The purchase price was allocated primarily based on the estimated relative fair values to land of \$71.6 million, building of \$64.3 million, land improvements of \$2.7 million and office furniture and equipment of \$1.1 million.

**4. INVENTORIES**

Inventories are summarized as follows (in thousands):

	March 31, 2009	December 31, 2008
Raw materials	\$ 482,070	\$ 505,106
Work in process	140,369	140,333
Finished goods	314,288	282,429
Total inventories	\$ 936,727	\$ 927,868

As of March 31, 2009 and December 31, 2008, the joint ventures formed by Gilead and BMS, which are included in our Condensed Consolidated Financial Statements, held \$604.5 million and \$607.7 million in inventory, respectively, of efavirenz active pharmaceutical ingredient, purchased from BMS at BMS's estimated net selling price of Sustiva.

**5. COMMITMENTS AND CONTINGENCIES****Legal Proceedings**

On May 12, 2006, the United States District Court for the Northern District of California executed orders dismissing in its entirety and with prejudice the fourth consolidated amended complaint associated with a purported class action lawsuit against us and our Chief Executive Officer; President and Chief Operating Officer; former Executive Vice President of Operations; Executive Vice President of Research and Development and Chief Scientific Officer; Senior Vice President of Manufacturing; and Senior Vice President of Research, alleging 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 promulgated by the Securities Exchange Commission, by making certain alleged false and misleading statements. The plaintiffs have appealed the dismissal. On August 11, 2008, the United States Court of Appeals for the Ninth Circuit reversed the district court's decision and remanded the case to the district court. On February 6, 2009, we filed a petition for a writ of certiorari with the Supreme Court of the United States, requesting that the court review the judgment of the court of appeals. In April 2009, the Supreme Court of the United States denied our petition. The case continues before the district court. On February 13, 2009, we filed a further motion to dismiss the fourth consolidated amended complaint on alternative grounds. It is not possible to predict the outcome of this case, and as such, no amounts have been accrued related to the outcome of this case.

On November 29, 2006, we received a subpoena from the United States Attorney's Office in San Francisco requesting documents regarding our marketing and medical education programs for Truvada, Viread and Emtriva. Since that time, we have cooperated with the government's investigation. On March 2, 2009, the United States Department of Justice (DOJ) notified the United States District Court for the Northern District of California of its decision not to intervene in a lawsuit filed by one of our former employees under the *qui tam* provisions of the federal False Claims Act. The DOJ has also notified us of its decision to decline to intervene in two additional False Claims Act lawsuits. Following the DOJ's decision, the plaintiffs in all three of these cases have voluntarily dismissed their allegations against us.

On March 12 and March 19, 2009, two class action complaints were filed in Santa Clara County Superior Court against us, CV Therapeutics, Inc. (CV Therapeutics), a company we acquired in April 2009, and members

**Table of Contents**

of CV Therapeutics' board of directors arising out of the merger agreement between CV Therapeutics and Gilead. The two matters were consolidated on April 1, 2009, and a consolidated complaint was filed on April 1, 2009, alleging that CV Therapeutics and its board of directors breached their fiduciary duties to CV Therapeutics' stockholders and Gilead aided and abetted the purported breach of fiduciary duty. The consolidated complaint sought compensatory and/or rescissory damages as well as attorney and other fees and costs. The plaintiffs filed a motion for preliminary injunction to halt the consummation of the tender offer, which motion was denied by the court on April 13, 2009. On May 6, 2009, the parties filed a stipulation to dismiss the suit with prejudice.

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, consolidated results of operations or financial position.

**6. STOCK-BASED COMPENSATION EXPENSE**

The following table summarizes the stock-based compensation expense included in our Condensed Consolidated Statements of Income (in thousands):

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2009</b>	<b>2008</b>
Cost of goods sold	\$ 3,254	\$ 1,694
Research and development expenses	16,955	16,895
Selling, general and administrative expenses	20,836	17,547
Stock-based compensation expense included in total costs and expenses	41,045	36,136
Income tax effect	(10,757)	(10,135)
Stock-based compensation expense included in net income	\$ 30,288	\$ 26,001

**7. STOCKHOLDERS' EQUITY****Stock Repurchase Programs**

In October 2008, we entered into an accelerated share repurchase agreement with a financial institution to repurchase \$750.0 million of our common stock on an accelerated basis. This accelerated share repurchase was part of the \$3.00 billion stock repurchase program authorized by our board of directors in October 2007. Under the terms of the accelerated share repurchase agreement, we paid \$750.0 million to settle the initial purchase transaction and received 14,874,519 shares of our common stock at an initial price of \$50.42 per share. In March 2009, upon termination of the agreement and in accordance with the share delivery provisions of the agreement, we received an additional 1,356,337 shares of our common stock based on the average of the daily volume weighted-average prices of our common stock during a specified period less a predetermined discount per share. As a result, the total number of shares repurchased and retired under this accelerated share repurchase agreement was 16,230,856 shares at an average purchase price of \$46.21 per share.

During the three months ended March 31, 2009, in addition to the additional shares that we received under the terms of the accelerated share repurchase transaction, we repurchased and retired 5,008,447 shares of our common stock at an average purchase price of \$45.92 per share, for an aggregate purchase price of \$230.0 million through open market transactions. As of March 31, 2009, the remaining authorized amount of stock repurchases that may be made under our \$3.00 billion stock repurchase program which expires in December 2010 was \$768.1 million.

We use the par value method of accounting for our stock repurchases. Under the par value method, common stock is first charged with the par value of the shares involved. The excess of the cost of shares acquired over the par value is allocated to APIC based on an estimated average sales price per issued share with the excess amounts

**Table of Contents**

charged to retained earnings. As a result of our open market stock repurchases during the three months ended March 31, 2009, we reduced common stock and APIC by an aggregate of \$16.5 million and charged \$213.5 million to retained earnings.

**Comprehensive Income**

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

	<b>Three Months Ended March 31,</b>	
	<b>2009</b>	<b>2008</b>
Net income	\$ 586,576	\$ 486,425
Other comprehensive income (loss):		
Net foreign currency translation gain (loss)	(3,466)	4,316
Net unrealized gain on available-for-sale securities, net of related tax effects	2,574	2,900
Net unrealized gain (loss) on cash flow hedges, net of related tax effects	71,296	(10,783)
Total other comprehensive income (loss)	70,404	(3,567)
Comprehensive income	656,980	482,858
Comprehensive loss attributable to noncontrolling interest	2,536	1,875
Comprehensive income attributable to Gilead	\$ 659,516	\$ 484,733

**8. SEGMENT INFORMATION**

We operate in one business segment, which primarily focuses on the development and commercialization of human therapeutics for life threatening diseases. All products are included in one segment, because our major products, Truvada, Atripla, Viread, Hepsera, Emtriva and AmBisome, which together accounted for substantially all of our total product sales for the three months ended March 31, 2009 and 2008, 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 consisted of the following (in thousands):

	<b>Three Months Ended March 31,</b>	
	<b>2009</b>	<b>2008</b>
Antiviral products:		
Truvada	\$ 590,353	\$ 479,385
Atripla	509,883	324,217
Viread	160,605	152,667
Hepsera	72,714	83,022
Emtriva	7,234	8,389
Total antiviral products	1,340,789	1,047,680
AmBisome	64,271	71,028
Letairis	39,580	20,337
Other	2,940	2,261
Total product sales	\$ 1,447,580	\$ 1,141,306



**Table of Contents**

The following table summarizes total revenues from external customers and collaboration partners by geographic region (in thousands). Product sales and product related contract revenues are attributed to countries based on ship-to location. Royalty and non-product related contract revenues are attributed to countries based on the location of the collaboration partner.

	Three Months Ended March 31,	
	2009	2008
United States	\$ 803,160	\$ 669,576
Outside of the United States:		
United Kingdom	98,652	63,489
Spain	98,071	77,724
France	93,528	92,346
Italy	79,886	69,591
Germany	77,208	39,482
Switzerland	44,710	102,892
Other European countries	141,123	65,560
Other countries	94,122	77,492
<b>Total revenues outside of the United States</b>	<b>727,300</b>	<b>588,576</b>
<b>Total revenues</b>	<b>\$ 1,530,460</b>	<b>\$ 1,258,152</b>

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

	Three Months Ended March 31,	
	2009	2008
Cardinal Health, Inc.	21%	22%
McKesson Corp.	14%	16%
AmerisourceBergen Corp.	11%	12%

**9. INCOME TAXES**

Our income tax rate of 26.3% for the three months ended March 31, 2009 differed from the U.S. federal statutory rate of 35% primarily due to tax credits and certain operating earnings from non-U.S. subsidiaries that are considered indefinitely invested outside the United States, partially offset by state taxes. We do not provide for U.S. income taxes on undistributed earnings of our foreign operations that are intended to be permanently reinvested.

As of March 31, 2009, we believe it is reasonably possible that our unrecognized tax benefits will decrease by approximately \$50 million in the next 12 months as we expect to have clarification from the Internal Revenue Service (IRS) around some of our uncertain tax positions. With respect to the remaining unrecognized tax benefits, we are currently unable to make a reasonable estimate as to the period of cash settlement, if any, with the respective taxing authorities.

We file federal, state and foreign income tax returns in many jurisdictions in the United States and abroad. For U.S. federal and California income tax purposes, the statute of limitations remains open for all years from inception due to our utilization of net operating losses relating to prior years.

Our income tax returns are audited by federal, state and foreign tax authorities. We are currently under examination by the IRS for the 2003 and 2004 tax years and by various state and foreign jurisdictions. There are differing interpretations of tax laws and regulations, and as a result, significant disputes may arise with these tax



## **Table of Contents**

authorities involving issues of the timing and amount of deductions and allocations of income among various tax jurisdictions. We periodically evaluate our exposures associated with our tax filing positions.

We record liabilities related to uncertain tax positions in accordance with FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes, an interpretation of SFAS No. 109, Accounting for Income Taxes*. We do not believe any such uncertain tax positions currently pending will have a material adverse effect on our Condensed Consolidated Financial Statements, although an adverse resolution of one or more of these uncertain tax positions in any period could have a material impact on the results of operations for that period.

## **10. SUBSEQUENT EVENTS**

In March 2009, we signed an agreement to acquire CV Therapeutics for \$20.00 per share. This transaction, valued at approximately \$1.4 billion, closed on April 17, 2009, at which time CV Therapeutics became a wholly-owned subsidiary of Gilead. CV Therapeutics was a publicly held biopharmaceutical company based in Palo Alto, California, primarily focused on applying molecular cardiology to the discovery, development and commercialization of small molecule drugs for the treatment of cardiovascular diseases. CV Therapeutics has two marketed products, Ranexa® (ranolazine) for the treatment of chronic angina and Lexiscan® (regadenoson) injection for use as a pharmacologic stress agent in radionuclide myocardial perfusion imaging in patients unable to undergo adequate exercise stress. CV Therapeutics also has several product candidates currently being evaluated for the treatment of atrial fibrillation, pulmonary diseases and diabetes. We believe the acquisition will provide us with an opportunity to further expand into the cardiovascular therapeutic area. We will be applying the provisions of SFAS No. 141 (revised 2007), *Business Combinations*, to account for this acquisition.

In April 2009, in connection with the acquisition of CV Therapeutics, we borrowed \$400.0 million under our amended and restated credit agreement to partially fund the acquisition. Under the credit agreement, we, along with our wholly-owned subsidiary, Gilead Biopharmaceutics Ireland Corporation (GBIC), may borrow up to an aggregate of \$1.25 billion in revolving credit loans at an interest rate of either (i) LIBOR plus a margin ranging from 0.20 percent to 0.32 percent or (ii) the base rate, as defined in the credit agreement. The credit agreement will terminate and all outstanding amounts owing thereunder shall be due and payable on December 17, 2012. We and GBIC may reduce the commitments and may prepay loans under the credit agreement in whole or in part at any time without penalty, subject to certain conditions. We intend to repay the loan using cash flow generated from operations. As of May 6, 2009, the amount available under this credit facility was approximately \$850 million.



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

*This Quarterly Report on Form 10-Q contains forward-looking statements based on our current expectations. The forward-looking statements are contained principally in this section entitled Management's Discussion and Analysis of Financial Condition and Results of Operations and Risk Factors. Words such as expect, anticipate, target, goal, project, intend, plan, could, should, might, believe, seek, estimate, continue, may, variations of such words and similar expressions are intended to identify such forward-looking statements. In addition, any statements that refer to projections of our future financial performance, our anticipated trends in our businesses and other characterizations of future events or circumstances are forward-looking statements. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Our actual results may differ materially from those suggested by these forward-looking statements for various reasons, including those identified below under Risk Factors. 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 Securities and Exchange Commission, we do not undertake 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. In evaluating our business, you should carefully consider the risks described in the section entitled Risk Factors under Part II, Item 1A below, in addition to the other information in this Quarterly Report on Form 10-Q. Any of the risks contained herein could materially and adversely affect our business, results of operations and financial condition.*

You should read the following management's discussion and analysis of our financial condition and results of operations in conjunction with our audited Consolidated Financial Statements and related notes thereto included as part of our Annual Report on Form 10-K for the year ended December 31, 2008 and our unaudited Condensed Consolidated Financial Statements for the three months ended March 31, 2009 and other disclosures (including the disclosures under Part II, Item 1A, Risk Factors) included in this Quarterly Report on Form 10-Q. Our Condensed Consolidated Financial Statements have been prepared in accordance with U.S. generally accepted accounting principles and are presented in U.S. dollars.

**Management Overview**

We are a biopharmaceutical company that discovers, develops and commercializes innovative therapeutics in areas of unmet medical need. Our mission is to advance the care of patients suffering from life threatening diseases worldwide. Headquartered in Foster City, California, we have operations in North America, Europe and Australia. We market Truvada® (emtricitabine/tenofovir disoproxil fumarate), Atripla® (efavirenz 600 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg), Viread® (tenofovir disoproxil fumarate) and Emtriva® (emtricitabine) for the treatment of human immunodeficiency virus (HIV) infection; Hepsara® (adefovir dipivoxil) and Viread for the treatment of chronic hepatitis B virus (HBV); AmBisome® (amphotericin B) liposome for injection for the treatment of severe fungal infections; Letairis® (ambrisentan) for the treatment of pulmonary arterial hypertension (PAH); and Vistide® (cidofovir injection) for the treatment of cytomegalovirus infection. F. Hoffmann-La Roche Ltd (together with Hoffmann-La Roche Inc., Roche) markets Tamiflu® (oseltamivir phosphate) for the treatment and prevention of influenza under a royalty-paying collaborative agreement with us. OSI Pharmaceuticals, Inc. markets Macugen® (pegaptanib sodium injection) in the United States and Europe for the treatment of neovascular age-related macular degeneration under a royalty-paying collaborative agreement with us. GlaxoSmithKline Inc. (GSK) markets Volibris® (ambrisentan) outside of the United States for the treatment of PAH under a royalty-paying collaborative agreement with us.

*Business Highlights*

In March 2009, we signed an agreement to acquire CV Therapeutics, Inc. (CV Therapeutics) for \$20.00 per share. This transaction, valued at approximately \$1.4 billion, closed on April 17, 2009, at which time CV Therapeutics became our wholly-owned subsidiary. The results of operations of CV Therapeutics are not

---

## **Table of Contents**

included in our Condensed Consolidated Financial Statements as of and for the three months ended March 31, 2009. CV Therapeutics was a publicly held biopharmaceutical company based in Palo Alto, California, primarily focused on applying molecular cardiology to the discovery, development and commercialization of small molecule drugs for the treatment of cardiovascular diseases. CV Therapeutics has two marketed products as well as several product candidates currently being evaluated for the treatment of atrial fibrillation, pulmonary diseases and diabetes. We believe the acquisition will provide us with an opportunity to further expand into the cardiovascular therapeutic area.

In January 2009, we completed the purchase of an office building and approximately 30 acres of land located in Foster City, California, for an aggregate purchase price of \$140.1 million.

With regard to our antiviral research and development (R&D) efforts, in February 2009, we presented the data and results from two Phase 1 studies for GS 9350, our pharmacoenhancer that is in development as a boosting agent for certain HIV medicines. In April 2009, we initiated a Phase 2 study of the complete single-tablet fixed-dose regimen containing elvitegravir, GS 9350 and Truvada in treatment-naïve patients, and anticipate the study to be fully enrolled by the second quarter of 2009.

In the cardiovascular area, in March 2009, we began enrolling patients in a Phase 2 clinical trial of cicletanine hydrochloride, an oral agent in development for the treatment of PAH. In April 2009, we announced preliminary data from DAR-311 (DORADO), a Phase 3 study for darusentan for the treatment of resistant hypertension.

With regard to our respiratory efforts, in February 2009, we received a response from the U.S. Food and Drug Administration (FDA) to our appeal, submitted under the formal dispute resolution process, regarding the agency's complete response letter for our new drug application (NDA) for aztreonam for inhalation solution for the treatment of cystic fibrosis (CF) in the United States. Following its review under the dispute resolution process, the FDA reiterated its position outlined in the complete response letter, including the need for us to conduct an additional clinical study of aztreonam for inhalation solution before we can resubmit our NDA. In March 2009, the Committee for Medicinal Products for Human Use (CHMP), the scientific committee of the European Medicines Agency (EMA), notified us that it had adopted a negative opinion on our Marketing Authorisation Application (MAA) for aztreonam for inhalation solution for the treatment of CF in the European Union. We are conferring with both regulatory bodies to determine what further studies would be required to address their concerns and support approval of this product.

### *Financial Highlights*

Our operating results for the three months ended March 31, 2009 were led by total product sales of \$1.45 billion. Antiviral product sales (Truvada, Atripla, Viread, Hepsera and Emtriva) increased 28% to \$1.34 billion in the three months ended March 31, 2009 from the three months ended March 31, 2008, and were the key drivers for total product sales growth of 27% for the three months ended March 31, 2009 as compared to the three months ended March 31, 2008. Atripla contributed \$509.9 million, or 38%, to our first quarter 2009 antiviral product sales. The growth of Atripla product sales and its increased proportion relative to our overall product sales caused our product gross margin to decrease to 77.2% for the three months ended March 31, 2009 from 79.0% in the same period of 2008, due primarily to the efavirenz component of Atripla sales which is recorded at zero gross margin. Truvada product sales for the three months ended March 31, 2009 comprised \$590.4 million, or 44% of our first quarter 2009 antiviral product sales. Truvada product sales for the three months ended March 31, 2009 increased 23% from the three months ended March 31, 2008 primarily due to continued sales volume growth in the United States and Europe. Foreign currency fluctuations for the three months ended March 31, 2009 had an unfavorable impact of approximately \$22.3 million on total revenues and \$11.7 million on pre-tax income when compared to the three months ended March 31, 2008.

Royalty, contract and other revenues that we recognized from our collaborations with corporate partners were \$82.9 million for the three months ended March 31, 2009, a decrease of 29% from the three months ended

## **Table of Contents**

March 31, 2008. The decrease was driven primarily by lower Tamiflu royalties from Roche of \$33.2 million for the three months ended March 31, 2009 compared to Tamiflu royalties of \$93.4 million in the same period in 2008 due to decreased sales related to pandemic planning initiatives worldwide. This decrease was partially offset by the recognition of approximately \$24.0 million of previously deferred collaboration payments from a corporate partner as we no longer have substantive ongoing performance obligations.

Operating expenses which include R&D and selling, general and administrative (SG&A) expenses increased \$42.5 million for the three months ended March 31, 2009, or 12%, compared to the three months ended March 31, 2008, reflecting the higher headcount required to support the continued growth of our business as well as the increased research and clinical study activity in our development pipeline. We expect to incur acquisition-related costs in 2009 for the acquisition of CV Therapeutics.

Cash, cash equivalents and marketable securities increased by \$369.3 million during the three months ended March 31, 2009, driven primarily by our operating cash flows of \$641.3 million, partially offset by repurchases under the \$3.00 billion stock repurchase program authorized by our Board of Directors (Board) in October 2007, which expires in December 2010. During the three months ended March 31, 2009, we received an additional 1.4 million shares of our common stock, bringing the total number of shares repurchased and retired under the accelerated share repurchase agreement entered into in October 2008 to 16.2 million shares at an average purchase price of \$46.21 per share. In addition, we repurchased a total of \$230.0 million of our common stock through open market purchases, or approximately 5.0 million shares. As of March 31, 2009, the remaining authorized amount of stock repurchases that may be made under our Board authorized stock repurchase program was \$768.1 million.

## **Critical Accounting Policies, Estimates and Judgments**

There have been no material changes in our critical accounting policies, estimates and judgments during the three months ended March 31, 2009 compared to the disclosures in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2008.

## **Adoption of New Accounting Pronouncements**

On January 1, 2009, we adopted the provisions of Financial Accounting Standards Board Staff Position Accounting Principles Board Opinion No. 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)* (FSP APB 14-1) on a retrospective basis for our convertible senior notes. FSP APB 14-1 requires us to account for the liability and equity components of our convertible senior notes separately by bifurcating the conversion option from the debt instrument, classifying the conversion option in equity and then accreting the resulting discount on the debt as additional interest expense over the expected life of the debt. Accordingly, we reflected additional interest expense and a related benefit from income taxes of \$12.9 million and \$5.1 million, respectively, for the three months ended March 31, 2008 in our Condensed Consolidated Statement of Income, and recorded additional interest expense and a related benefit from income taxes of \$13.6 million and \$5.3 million, respectively, for the three months ended March 31, 2009. In addition, the retrospective adoption of FSP APB 14-1 decreased deferred tax assets and debt issuance costs included in other assets by an aggregate of \$81.7 million, decreased convertible senior notes, net included in long-term liabilities by \$201.8 million, and increased total stockholders' equity by \$120.1 million after a charge of \$82.6 million to retained earnings on our Condensed Consolidated Balance Sheet as of December 31, 2008.

On January 1, 2009, we adopted the provisions of Statement of Financial Accounting Standards (SFAS) No. 160, *Noncontrolling Interests in Consolidated Financial Statements, an amendment of Accounting Research Bulletin No. 51, Consolidated Financial Statements* (SFAS 160). Accordingly, we reclassified the noncontrolling interest (formerly minority interest) from liabilities to stockholders' equity on our Condensed Consolidated Balance Sheets on a retrospective basis, which resulted in the reclassification of the change in noncontrolling

**Table of Contents**

interest from net cash provided by operating activities to net cash used in financing activities on our Condensed Consolidated Statements of Cash Flows. We also presented the noncontrolling interest on our Condensed Consolidated Statements of Income as net loss attributable to noncontrolling interest, a component of consolidated net income, on a retrospective basis.

**Results of Operations***Total Revenues*

We had total revenues of \$1.53 billion for the three months ended March 31, 2009 compared to \$1.26 billion for the same period in 2008. Included in total revenues were product sales, royalty revenues and contract and other revenues.

*Product Sales*

The following table summarizes the period over period changes in our product sales (in thousands):

	Three Months Ended March 31,		Change
	2009	2008	
<b>Antiviral products:</b>			
Truvada	\$ 590,353	\$ 479,385	23%
Atripla	509,883	324,217	57%
Viread	160,605	152,667	5%
Hepsera	72,714	83,022	(12)%
Emtriva	7,234	8,389	(14)%
<b>Total antiviral products</b>	<b>1,340,789</b>	<b>1,047,680</b>	<b>28%</b>
AmBisome	64,271	71,028	(10)%
Letairis	39,580	20,337	95%
Other	2,940	2,261	30%
<b>Total product sales</b>	<b>\$ 1,447,580</b>	<b>\$ 1,141,306</b>	<b>27%</b>

Total product sales increased by 27% for the three months ended March 31, 2009 compared to the same period in 2008, due primarily to an overall increase in our antiviral product sales, including the strong growth in sales of Atripla and Truvada. A significant percentage of our product sales continued to be denominated in foreign currencies. We used foreign currency exchange forward and option contracts to hedge a percentage of our forecasted international sales, primarily those denominated in Euro. This reduced, but did not eliminate, fluctuations in sales due to changes in foreign currency exchange rates.

*Antiviral Products*

Antiviral product sales increased by 28% for the three months ended March 31, 2009 compared to the same period in 2008, driven primarily by sales volume growth of Atripla and Truvada.

*Truvada*

Truvada sales increased by 23% for the three months ended March 31, 2009 compared to the same period in 2008, driven primarily by sales volume growth in the United States and Europe. Truvada sales accounted for 44% of our total antiviral product sales for the three months ended March 31, 2009.

*Atripla*

Atripla sales increased by 57% for the three months ended March 31, 2009 compared to the same period in 2008, driven primarily by its continued uptake in the United States and Europe. We consolidate 100% of Atripla product sales because we are the primary beneficiary of our joint venture with Bristol-Myers Squibb Company (BMS) in the United States. Outside of the United States, we also

**Table of Contents**

recognize 100% of Atripla product sales. The efavirenz portion of our Atripla sales was approximately \$187.5 million and \$119.6 million for the three months ended March 31, 2009 and 2008, respectively. Atripla sales accounted for 38% of our total antiviral product sales for the three months ended March 31, 2009.

*Other Antiviral Products*

Other antiviral product sales, which include product sales of Viread, Hepsera and Emtriva, decreased by 1% for the three months ended March 31, 2009 compared to the same period in 2008, driven primarily by increased Viread sales volume growth, offset by sales volume decreases in Hepsera product sales.

*Letairis*

Sales of Letairis for the treatment of PAH increased 95% for the three months ended March 31, 2009 compared to the same period in 2008, driven primarily by sales volume growth in the United States.

*Royalty Revenues*

The following table summarizes the period over period change in our royalty revenues (in thousands):

	Three Months Ended		
	March 31,		
	2009	2008	Change
Royalty revenues	\$ 53,042	\$ 109,452	(52)%

Our most significant source of royalty revenues for the three months ended March 31, 2009 and 2008 was from sales of Tamiflu by Roche.

Royalty revenues for the three months ended March 31, 2009 were \$53.0 million, a decrease of 52% compared to the same period in 2008, driven primarily by the recognition of Tamiflu royalties from Roche of \$33.2 million in the three months ended March 31, 2009 compared to Tamiflu royalties from Roche of \$93.4 million recognized in the same period in 2008. The lower Tamiflu royalties were due primarily to decreased Roche sales related to pandemic planning initiatives worldwide. We recognize royalties on Tamiflu sales by Roche in the quarter following the quarter in which Tamiflu is sold.

*Cost of Goods Sold and Product Gross Margin*

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

	Three Months Ended		
	March 31,		
	2009	2008	Change
Total product sales	\$ 1,447,580	\$ 1,141,306	27%
Cost of goods sold	\$ 329,414	\$ 239,848	37%
Product gross margin	77.2%	79.0%	

Our product gross margin for the three months ended March 31, 2009 was 77.2%, compared to 79.0% for the same period in 2008. The decrease in our product gross margin was due primarily to the higher proportion of Atripla sales, which include the efavirenz component at zero product gross margin.

A higher mix of Atripla product sales decreases our overall product gross margin. Although we record 100% of Atripla product sales, we only benefit from the product gross margin on the Truvada portion of Atripla sales. The efavirenz portion of Atripla sales carries a zero product gross profit and gross margin since we purchase efavirenz from BMS at BMS's net selling price of efavirenz.



**Table of Contents***Research and Development Expenses*

The following table summarizes the period over period change in the major components of our R&D expenses (in thousands):

	<b>Three Months Ended March 31,</b>		<b>Change</b>
	<b>2009</b>	<b>2008</b>	
Research	\$ 43,998	\$ 34,509	27%
Clinical development	115,072	94,768	21%
Pharmaceutical development	29,709	26,024	14%
Total research and development	\$ 188,779	\$ 155,301	22%

R&D expenses consist primarily of personnel costs, including salaries, benefits and stock-based compensation, clinical studies performed by contract research organizations, materials and supplies, license fees and overhead allocations consisting of various support and facilities related costs. Our R&D activities are separated into three main categories: research, clinical development and pharmaceutical development. Research costs typically consist of preclinical and toxicology costs. Clinical development costs include costs for Phase 1, 2, 3 and 4 clinical trials. Pharmaceutical development expenses consist of costs for product formulation and chemical analysis.

R&D expenses for the three months ended March 31, 2009 increased by \$33.5 million, or 22%, compared to the same period in 2008, due primarily to increased compensation and benefit expenses of \$13.8 million due largely to higher headcount, as well as increased clinical study expenses of \$10.0 million driven primarily by the growth in our business.

*Selling, General and Administrative Expenses*

The following summarizes the period over period change in our SG&A expenses (in thousands):

	<b>Three Months Ended March 31,</b>		<b>Change</b>
	<b>2009</b>	<b>2008</b>	
Selling, general and administrative	\$ 203,951	\$ 194,957	5%

SG&A expenses for the three months ended March 31, 2009 increased by \$9.0 million, or 5%, compared to the same period in 2008, due primarily to increased compensation and benefit expenses of \$12.6 million driven largely by higher headcount.

*Purchased In-process Research and Development Expenses*

In connection with our acquisitions of Myogen Inc. (Myogen) and Corus Pharma, Inc. (Corus) in 2006, we recorded purchased in-process research and development (IPR&D) expenses of \$2.06 billion and \$335.6 million, respectively, during the year ended December 31, 2006.



**Table of Contents**

The purchased IPR&D expense for Myogen represented the estimated fair value of Myogen's incomplete R&D programs that had not yet reached technological feasibility and had no alternative future uses as of the acquisition date and, therefore, was expensed upon acquisition. A summary of these programs at the acquisition date, updated for subsequent changes in status of development, is as follows:

<b>Program</b>	<b>Description</b>	<b>Status of Development</b>	<b>Estimated Acquisition Date Fair Value (in millions)</b>
Ambrisentan	An orally active, non-sulfonamide, propanoic acid-class, endothelin receptor antagonist (ERA) for the treatment of PAH.	Phase 3 clinical trials were completed prior to the acquisition date. We filed an NDA with the FDA in December 2006 and, in June 2007, the FDA approved Letairis for the treatment of PAH in the United States. Additionally, in March 2007, the EMEA validated the marketing authorization application for ambrisentan for the treatment of PAH, filed by our collaboration partner, GSK. In April 2008, the European Commission granted GSK marketing authorization for ambrisentan for the treatment of PAH, which is marketed under the name Volibris by GSK.	\$ 1,413.7
Darusentan	An orally active ETA-selective ERA for the treatment of resistant hypertension.	In Phase 3 clinical development as of the acquisition date and the date of this filing.	\$ 644.5

The remaining efforts for completing the darusentan IPR&D program consist primarily of clinical trials, the cost, length and success of which are extremely difficult to predict, and obtaining necessary regulatory approvals. Numerous risks and uncertainties exist that could prevent completion of development, including the possibility of unfavorable results of our clinical trials and the risk of failing to obtain FDA and other regulatory body approvals. Feedback from regulatory authorities or results from clinical trials might require modifications to or delays in later stage clinical trials or additional trials to be performed. We cannot be certain that darusentan for the treatment of resistant hypertension will be approved in the United States or in countries outside of the United States or whether marketing approvals will have significant limitations on its use. Future discussions with regulatory agencies will determine the amount of data needed and timelines for review, which may differ materially from current projections. Darusentan may never be successfully commercialized. As a result, we may make a strategic decision to discontinue development of darusentan if, for example, we believe commercialization will be difficult relative to other opportunities in our pipeline. If this program cannot be completed on a timely basis or at all, then our prospects for future revenue growth may be adversely impacted. No assurance can be given that the underlying assumptions used to forecast the above cash flows or the timely and successful completion of this project will materialize as estimated. For these reasons, among others, actual results may vary significantly from estimated results.

**Table of Contents**

The purchased IPR&D expense for Corus represented the estimated fair value of Corus' incomplete aztreonam for inhalation solution for CF R&D program that had not yet reached technological feasibility and had no alternative future use as of the acquisition date and, therefore, was expensed upon acquisition. A description of this program at the acquisition date, updated for subsequent changes in status of development, is as follows:

<b>Program</b>	<b>Description</b>	<b>Status of Development</b>	<b>Estimated Acquisition Date Fair Value (in millions)</b>
Aztreonam for inhalation solution for the treatment of CF	Aztreonam formulation for inhalation to be used against Gram-negative bacteria that cause lung infections in patients with CF.	In Phase 3 clinical trials as of the acquisition date. We filed an NDA with the FDA in November 2007. In September 2008, we received a complete response letter from the FDA informing us that the FDA will not approve our NDA for aztreonam for inhalation solution for the treatment of CF in its current form and requesting we conduct an additional Phase 3 clinical study. In November 2008, we filed a request for a formal dispute resolution with the FDA. In February 2009, in response to our appeal, the FDA notified us that it was reiterating its position that we will need to conduct another clinical study of aztreonam for inhalation solution before we can resubmit our NDA. In March 2008, we also submitted a MAA in the European Union and received notice of acceptance and priority review by Health Canada for approval in Canada. In March 2009, the CHMP of the EMEA notified us that it adopted a negative opinion on our MAA. We are conferring with the European regulatory bodies to determine appropriate options to address the issues outlined in the CHMP opinion.	\$ 335.6

The remaining efforts for completing Corus' IPR&D program consist primarily of clinical trials, the cost, length and success of which are extremely difficult to predict. Numerous risks and uncertainties exist that could prevent completion of development, including the possibility of unfavorable results of our clinical trial and the risk of failing to obtain FDA and other regulatory body approvals. We cannot be certain that aztreonam for inhalation solution for the treatment of CF will be approved in the United States or in countries outside of the United States or whether marketing approvals will have significant limitations on its use. Aztreonam for inhalation solution for the treatment of CF may never be successfully commercialized. As a result, we may make a strategic decision to discontinue development of aztreonam for inhalation solution for the treatment of CF if, for example, we believe commercialization will be difficult relative to other opportunities in our pipeline. If this program cannot be completed on a timely basis or at all, then our prospects for future revenue growth may be adversely impacted. No assurance can be given that the underlying assumptions used to forecast the above cash flows or the timely and successful completion of the project will materialize as estimated. For these reasons, among others, actual results may vary significantly from estimated results.

**Table of Contents***Interest and Other Income, Net*

We recorded interest and other income, net, of \$4.2 million for the three months ended March 31, 2009, a decrease of \$18.5 million from the same period in 2008. The decrease was due primarily to increased costs related to our hedging activities of \$15.0 million, decreased interest income of \$13.3 million due primarily to a reduction in the average yield of our investment portfolio as a result of lower interest rates, partially offset by net foreign currency exchange gains of \$6.6 million.

*Provision for Income Taxes*

Our income tax rate was 26.3% for the three months ended March 31, 2009, compared to 27.9% for the same period in 2008. Our provision for income taxes for the three months ended March 31, 2009 was \$209.2 million compared to \$188.3 million for the same period in 2008. The tax rate for the three months ended March 31, 2009 differed from the U.S. federal statutory rate of 35% due primarily to tax credits, certain operating earnings from non-U.S. subsidiaries that are considered indefinitely invested outside the United States, partially offset by state taxes. We do not provide for U.S. income taxes on undistributed earnings of our foreign operations that are intended to be permanently reinvested.

As a result of the retrospective application of FSP APB 14-1, we reflected a decrease in our provision for income taxes of \$5.1 million for the three months ended March 31, 2008.

**Liquidity and Capital Resources**

The following table summarizes our cash, cash equivalents and marketable securities, our working capital, and our cash flow activity (in thousands):

	As of March 31, 2009	As of December 31, 2008
Cash, cash equivalents and marketable securities	\$ 3,608,889	\$ 3,239,639
Working capital	\$ 3,354,118	\$ 3,057,416
	<b>Three Months Ended March 31,</b>	
	<b>2009</b>	<b>2008</b>
Cash provided by (used in):		
Operating activities	\$ 641,330	\$ 605,511
Investing activities	\$ (328,389)	\$ (123,216)
Financing activities	\$ (145,741)	\$ (689,722)

*Cash, Cash Equivalents and Marketable Securities*

Cash, cash equivalents and marketable securities totaled \$3.61 billion at March 31, 2009, an increase of \$369.3 million or 11% from December 31, 2008. The increase was primarily attributable to net cash provided by operations of \$641.3 million, partially offset by our repurchase of \$230.1 million of our common stock under our stock repurchase program and capital expenditures and other of \$164.1 million related primarily to the purchase of an office building and approximately 30 acres of land located in Foster City, California.

*Working Capital*

Working capital was \$3.35 billion at March 31, 2009, an increase of \$296.7 million or 10% from December 31, 2008. The increase was primarily attributable to:

an increase of \$270.2 million in cash, cash equivalents and short-term marketable securities; and

Edgar Filing: GILEAD SCIENCES INC - Form 10-Q

an increase of \$44.6 million in accounts receivable, net, primarily driven by increased product sales.

## **Table of Contents**

This increase was partially offset by a \$50.6 million increase in income taxes payable, primarily due to the increase in provision for income taxes driven by higher income.

As a result of the retrospective application of FSP APB 14-1, our current portion of deferred tax asset was reduced by \$21.9 million as of December 31, 2008 to reflect the basis difference associated with the liability component that represents a temporary difference under SFAS No. 109, *Accounting for Income Taxes*.

### *Cash Provided by Operating Activities*

Cash provided by operating activities of \$641.3 million for the three months ended March 31, 2009 related primarily to net income of \$586.6 million which was adjusted for non-cash items such as \$41.0 million of stock-based compensation expense, \$39.1 million of depreciation and amortization and \$23.6 million of tax benefits from employee stock plans. This was partially offset by \$79.0 million of cash outflow related to changes in operating assets and liabilities and \$20.7 million of excess tax benefits from stock option exercises which we reclassified to cash used in financing activities in accordance with SFAS No. 123 (revised 2004), *Share-Based Payment*.

Cash provided by operating activities of \$605.5 million for the three months ended March 31, 2008 was comprised primarily of net income of \$486.4 million adjusted for non-cash items, such as \$93.5 million of tax benefits from employee stock plans, \$58.1 million of cash inflow related to changes in operating assets and liabilities and \$36.1 million of stock-based compensation expense. This was partially offset by \$89.2 million of excess tax benefits from stock option exercises. Our operating cash flows for the three months ended March 31, 2008 has been revised for our retrospective application of SFAS 160 on January 1, 2009 and the resulting reclassification of the change in noncontrolling interest from cash provided by operating activities to cash used in financing activities.

### *Cash Used in Investing Activities*

Cash used in investing activities for the three months ended March 31, 2009 and 2008 primarily related to purchases, sales and maturities of available-for-sale securities as well as capital expenditures.

We used \$328.4 million of cash in investing activities in the three months ended March 31, 2009, compared to \$123.2 million during the three months ended March 31, 2008. The increase was due primarily to increased capital expenditures and a higher level of activity in purchases, sales and maturities of marketable securities in the three months ended March 31, 2009 compared to the same period in 2008. Capital expenditures and other of \$164.1 million made in the three months ended March 31, 2009 related primarily to the purchase of an office building and approximately 30 acres of land located in Foster City, California.

### *Cash Used in Financing Activities*

Cash used in financing activities for the three months ended March 31, 2009 was \$145.7 million, driven primarily by the \$230.1 million used to repurchase our common stock under our stock repurchase program. The cash outflows were partially offset by proceeds of \$40.9 million that we received from issuances of stock under our employee stock plans and \$20.7 million of excess tax benefits from stock option exercises.

Cash used in financing activities for the three months ended March 31, 2008 was \$689.7 million, driven primarily by the \$815.9 million used to repurchase our common stock under our stock repurchase program. The cash outflows were partially offset by \$89.2 million of excess tax benefits from stock option exercises, as well as proceeds of \$65.5 million that we received from issuances of stock under our employee stock plans.

As a result of our adoption of SFAS 160, we reclassified the changes in noncontrolling interest from cash provided by operating activities to cash used in financing activities, as discussed above.

---

## **Table of Contents**

In October 2008, we entered into an accelerated share repurchase agreement with a financial institution to repurchase \$750.0 million of our common stock on an accelerated basis. Under the terms of this accelerated share repurchase agreement, we paid \$750.0 million to settle the initial purchase transaction and received 14,874,519 shares of our common stock at a price of \$50.42 per share. In March 2009, upon termination of the agreement and in accordance with the share delivery provisions of the agreement, we received an additional 1,356,337 shares of our common stock based on the average of the daily volume weighted-average prices of our common stock during a specified period less a predetermined discount per share. As a result, the total number of shares repurchased and retired under this transaction was 16,230,856 shares at an average purchase price of \$46.21 per share. The accounting for this accelerated share repurchase was consistent with that of our previous accelerated share repurchase.

As of March 31, 2009, the remaining authorized amount of stock repurchases that may be made under our \$3.00 billion stock repurchase program which expires in December 2010 was \$768.1 million.

### *Other Information*

As of March 31, 2009, approximately \$1.25 billion was available under our amended and restated credit agreement. In April 2009, we borrowed \$400.0 million under our credit agreement to partially fund the acquisition of CV Therapeutics. Under the credit agreement, we, along with our wholly-owned subsidiary, Gilead Biopharmaceutics Ireland Corporation (GBIC), may borrow up to an aggregate of \$1.25 billion in revolving credit loans at an interest rate of either (i) LIBOR plus a margin ranging from 0.20 percent to 0.32 percent or (ii) the base rate, as defined in the credit agreement. The credit agreement will terminate and all amounts owing thereunder shall be due and payable on December 17, 2012. We and GBIC may reduce the commitments and may prepay loans under the credit agreement in whole or in part at any time without penalty, subject to certain conditions. We intend to repay the loan using cash flow generated from operations. As of May 6, 2009, the amount available under this credit facility was approximately \$850 million.

### **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 consolidated financial position or results of operations.

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

There have been no material changes in our market risk during the three months ended March 31, 2009 compared to the disclosures in Part II, Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2008.

A portion of our marketable securities are held in auction rate securities. During the three months ended March 31, 2008, we began observing the failed auctions for our auction rate securities for which the underlying assets are comprised of student loans. Most of our auction rate securities, including those subject to the failed auctions, are currently rated AAA, consistent with the high quality rating required by our investment policy, are supported by the federal government as part of the Federal Family Education Loan Program, and are over-collateralized. Our auction rate securities reset every seven to 35 days with maturity dates ranging from 2023 through 2041 and have interest rates ranging from 1.0% to 1.3%. As of March 31, 2009, our auction rate securities continued to earn interest.

If auctions continue to fail for securities in which we have invested, we may be unable to liquidate some or all of our auction rate securities at par, should we need or desire to access the funds invested in those securities. However, based on our total cash and marketable securities position, our expected operating cash flows as well as access to funds through our credit facility, we believe that we will be able to hold these securities until there is a

## **Table of Contents**

recovery in the auction market and the related securities, which may be at final maturity. As a result, we do not anticipate that the current illiquidity of these auction rate securities will have a material effect on our cash requirements or working capital.

In light of the volatility and developments that we have seen in the financial markets, we continue to review our cash equivalents and marketable securities carefully and strive to invest prudently. We believe that maintaining the primary goals of our investment policy, safety and preservation of principal and diversification of risk, as well as liquidity, has protected us from many of the risks in the credit markets while allowing us to continue to meet our operating cash flow requirements as well as execute on other strategic opportunities such as the acquisition of CV Therapeutics.

### **ITEM 4. CONTROLS AND PROCEDURES**

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

An evaluation as of March 31, 2009 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 our disclosure controls and procedures, which are defined under Securities and Exchange Commission (SEC) rules as controls and other procedures of a company that are designed to ensure that the information required to be disclosed by a company in the reports that it files or submits under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at March 31, 2009.

#### **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, 2009, 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.

**Table of Contents****PART II. OTHER INFORMATION****ITEM 1. LEGAL PROCEEDINGS**

In November 2008, we received notice that Teva Pharmaceuticals (Teva) submitted an abbreviated new drug application (ANDA) to the U.S. Food and Drug Administration (FDA) requesting permission to manufacture and market a generic version of Truvada. In the notice, Teva alleges that two of the patents associated with emtricitabine, U.S. Patent Numbers 6,642,245 and 6,703,396, owned by Emory University and licensed exclusively to us, are invalid, unenforceable and/or will not be infringed by Teva's manufacture, use or sale of a generic version of Truvada. In December 2008, we filed a lawsuit in U.S. District Court in New York against Teva for infringement of the two emtricitabine patents. In March 2009, we received notice that Teva Pharmaceuticals submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Atripla. In the notice, Teva alleges that the same two emtricitabine patents are invalid, unenforceable and/or will not be infringed by Teva's manufacture, use or sale of a generic version of Atripla. We expect to file a lawsuit in U.S. District Court in New York against Teva for infringement of the two emtricitabine patents. We cannot predict the ultimate outcome of these actions, and we may spend significant resources defending these patents. If we are unsuccessful in these lawsuits, some or all of our original claims in the patents may be narrowed or invalidated, and the patent protection for Truvada and Atripla in the United States would be shortened to expire in 2017 instead of 2021.

Information pertaining to certain of our other legal proceedings can be found in Part I. Item 1. Condensed Consolidated Financial Statements Notes to Condensed Consolidated Financial Statements Note 5. Commitments and Contingencies to the interim Condensed Consolidated Financial Statements, and is incorporated by reference herein.

**ITEM 1A. RISK FACTORS**

*In evaluating our business, you should carefully consider the following risks in addition to the other information in this Quarterly Report on Form 10-Q. A manifestation of any of the following risks could materially and adversely affect our business, results of operations and financial condition. We note 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 the following risks to be a complete statement of all the potential risks or uncertainties that we face.*

**A substantial portion of our revenues is derived from sales of Truvada and Atripla. If we are unable to maintain or continue increasing sales of Truvada and Atripla, our results of operations may be adversely affected.**

We are currently dependent on sales of our products for the treatment of HIV, especially Truvada and Atripla, to support our existing operations. Our HIV products contain tenofovir disoproxil fumarate and/or emtricitabine, which belong to 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 were unable to continue increasing our HIV product sales, our results of operations would likely suffer and we would likely need to scale back our operations, including our spending on research and development (R&D) efforts. For the three months ended March 31, 2009, Truvada and Atripla product sales were \$1.10 billion, or 72% of our total revenues. We may not be able to sustain the growth rate of sales of our HIV products, especially Truvada and Atripla, for the reasons stated in this risk factor, including:

As our HIV products are used over a longer period of time in many patients and in combination with other products, and additional studies are conducted, new issues with respect to safety, resistance and interactions with other drugs may arise, which could cause us to provide additional warnings or contraindications on our labels, narrow our approved indications or halt sales of a product, each of which could reduce our revenues.



---

**Table of Contents**

As our HIV products mature, private insurers and government reimbursers often reduce the amount they will reimburse patients for these products, which increases pressure on us to reduce prices.

A large part of the market for our HIV products consists of patients who are already taking other HIV drugs. If we are not successful in encouraging physicians to change patients' regimens to include our HIV products, the sales of our HIV products will be limited.

As generic HIV products are introduced into major markets, our ability to maintain pricing and market share may be affected. **Our inability to accurately estimate demand for our products, as well as sales fluctuations as a result of inventory levels held by wholesalers, pharmacies and non-retail customers make it difficult for us to accurately forecast sales and may cause our earnings to fluctuate, which could adversely affect our financial results and our stock price.**

During the three months ended March 31, 2009, approximately 88% of our product sales in the United States were to three wholesalers, Cardinal Health, Inc., McKesson Corp. and AmerisourceBergen Corp. The U.S. wholesalers with whom we have entered into inventory management agreements make estimates to determine end user demand and may not be completely effective in matching their inventory levels to actual end user demand. As a result, changes in inventory levels held by those wholesalers can cause our operating results to fluctuate unexpectedly if our sales to these wholesalers do not match end user demand. In addition, inventory is held at retail pharmacies and other non-wholesale locations with whom we have no inventory management agreements and no control over buying patterns. Adverse changes in economic conditions or other factors may cause retail pharmacies to reduce their inventories of our products, which would reduce their orders from wholesalers and, consequently, the wholesalers' orders from us, even though end user demand has not changed. For example, in the fourth quarter of 2008, strong prescription demand for Truvada and Atripla was not fully reflected in our revenues for the fourth quarter. We believe this is because inventories were drawn down within the retail distribution channel during the quarter. As inventory in the distribution channel fluctuates from quarter to quarter, we may continue to see a mismatch between prescription demand for our products and our revenues. In addition, the non-retail sector in the United States, which includes government institutions, including state AIDS Drug Assistance Programs (ADAP), correctional facilities and large health maintenance organizations, tends to be even less consistent in terms of buying patterns, and often causes quarter over quarter fluctuations that do not necessarily mirror the purchasing patterns that can be seen within the retail sector. For example, in the first quarter of 2008, we observed large non-retail purchases by a small number of state ADAPs that purchase centrally and have significant warehousing capacity. We believe such purchases were driven by the grant cycle for federal ADAP funds rather than current patient demand, which tempered orders and our associated product sales, revenues and earnings in the second quarter of 2008 as these organizations depleted their increased inventory levels established during the first quarter of 2008. We expect to continue to experience fluctuations in the purchasing patterns of our non-retail customers which may result in fluctuations in our product sales, revenues and earnings in the future.

We estimate the future demand for our products, consider the shelf life of our inventory and regularly review the realizability of our inventory. If actual demand is less than our estimated demand, we could be required to record inventory write-downs, which would have an adverse impact on our results of operations and our stock price.

**If we fail to commercialize new products or expand the indications for existing products, our prospects for future revenues may be adversely affected.**

If we do not introduce new products to market or increase sales of our existing products, we will not be able to increase or maintain our total revenues and continue to expand our R&D efforts. For example, the new drug application (NDA) submitted by us for aztreonam for inhalation solution for the treatment of cystic fibrosis (CF) in the United States was delayed when we received a complete response letter from the FDA informing us that the FDA will not approve the NDA in its current form and requesting we conduct an additional Phase 3 clinical

**Table of Contents**

study. In November 2008, we filed a request for dispute resolution with the FDA to determine whether further analyses of the existing data could lead to approval or whether we will need to conduct an additional study. In February 2009, in response to our appeal, the FDA notified us that it is reiterating its position that we will need to conduct another clinical study of aztreonam for inhalation solution before we can resubmit our NDA. In March 2009, the Committee for Medicinal Products for Human Use (CHMP), the scientific committee of the European Medicines Agency, notified us that it adopted a negative opinion on the our marketing authorization application for aztreonam for inhalation solution in the European Union. We are conferring with European regulatory bodies to determine appropriate options to address the issues outlined in the CHMP opinion. Existing data from any ongoing or from any additional clinical trial that we may commence to satisfy FDA or CHMP concerns may not support the approval of aztreonam for inhalation solution in the United States or the European Union, which may cause us considerable expense and may lead to further delays or cause us to abandon further development of the product. There are also risks that health authorities in other countries where marketing authorization applications are pending will undertake similar additional reviews which would compound the risks described above. As a result, aztreonam for inhalation solution may never be successfully commercialized. Further, we may make a strategic decision to discontinue development of such product candidate if, for example, we believe commercialization will be difficult relative to other opportunities in our pipeline. If this program and others in our pipeline cannot be completed on a timely basis or at all, then our prospects for future revenue growth may be adversely impacted.

**A significant portion of our product sales occur outside the United States, and currency fluctuations as well as hedging expenses may cause our earnings to fluctuate, which could adversely affect our stock price.**

Because a significant percentage of our product sales are denominated in foreign currencies, primarily the Euro, we face exposure to adverse movements in foreign currency exchange rates. When the U.S. dollar strengthens against these foreign currencies, the relative value of sales made in the respective foreign currency decreases. Conversely, when the U.S. dollar weakens against these currencies, the relative value of such sales increases. Overall, we are a net receiver of foreign currencies and, therefore, benefit from a weaker U.S. dollar and are adversely affected by a stronger U.S. dollar relative to those foreign currencies in which we transact significant amounts of business.

We use foreign currency exchange forward and option contracts to hedge a percentage of our forecasted international sales, primarily those denominated in the Euro. We also hedge certain monetary assets and liabilities denominated in foreign currencies, which reduces but does not eliminate our exposure to currency fluctuations between the date a transaction is recorded and the date that cash is collected or paid. We cannot predict future fluctuations in the foreign currency exchange rate of the U.S. dollar. If the U.S. dollar appreciates significantly against certain currencies and our hedging program does not sufficiently offset the effects of such appreciation, our results of operations will be adversely affected and our stock price may decline.

Additionally, the expenses that we recognize in relation to our hedging activities can also cause our earnings to fluctuate. The level of hedging expenses that we recognize in a particular period is impacted by the changes in interest rate spreads between the foreign currencies that we hedge and the U.S. dollar.

**We face significant competition.**

We face significant competition from large pharmaceutical and biotechnology companies, most of whom 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 Inc. (GSK), which markets fixed dose combination products that compete with Truvada and Atripla. GSK and Pfizer Inc. (Pfizer) recently announced that they are combining their HIV drug businesses into a single, jointly owned company that will focus solely on competing in the HIV market. For Hepsara and Viread for treatment of chronic hepatitis B, we compete primarily with products produced by GSK, Bristol-Myers Squibb Company (BMS) and Novartis Pharmaceuticals Corporation (Novartis) in the United States, the European Union and China. For AmBisome, we compete primarily with products produced by

---

## **Table of Contents**

Merck & Co., Inc. (Merck) and Pfizer. In addition, we are aware of at least two lipid formulations that claim similarity to AmBisome becoming available outside of the United States, including the possible entry of one such formulation in Greece. These formulations may reduce market demand for AmBisome. Furthermore, the manufacture of lipid formulations of amphotericin B is very complex and if any of these formulations are found to be unsafe, sales of AmBisome may be negatively impacted by association. Letairis competes directly with Actelion Pharmaceuticals US, Inc. (Actelion) and indirectly with PAH products from United Therapeutics Corporation and Pfizer. Tamiflu competes with products sold by GSK and generic competitors. Aztreonam for inhalation solution for the treatment of CF, if approved for marketing, will compete with a product marketed by Novartis.

In addition, a number of companies are pursuing the development of technologies which are competitive with our existing products or research programs. These competing companies include specialized pharmaceutical firms and large pharmaceutical companies acting either independently or together with other pharmaceutical companies. Furthermore, academic institutions, government agencies and other public and private organizations conducting research may seek patent protection and may establish collaborative arrangements for competitive products or programs.

**If significant safety issues arise for our marketed products or our product candidates, our future sales may be reduced, which would adversely affect our results of operations.**

The data supporting the marketing approvals for our products and forming the basis for the safety warnings in our product labels were obtained in controlled clinical trials of limited duration and, in some cases, from post-approval use. As our products are used over longer periods of time by many patients with underlying health problems, taking numerous other medicines, we expect to continue to find new issues such as safety, resistance or drug interaction issues, which may require us to provide additional warnings or contraindications on our labels or narrow our approved indications, each of which could reduce the market acceptance of these products.

Our product Letairis, which was approved by the FDA in June 2007, is a member of a class of compounds called endothelin receptor antagonists which pose specific risks, including serious risks of liver injury and birth defects. Because of these risks, Letairis is available only through the Letairis Education and Access Program (LEAP), a restricted distribution program intended to help physicians and patients learn about the risks associated with the product and assure appropriate use of the product. As the product is used by additional patients, we may discover new risks associated with Letairis which may result in changes to the distribution program and additional restrictions on the use of Letairis which may decrease demand for the product. For example, since the launch of Letairis, cases of edema in certain patients taking Letairis have been reported. This information has recently been added to the product label, which may negatively impact demand for the product.

If serious safety, resistance or drug interaction issues arise with our marketed products, including Letairis, sales of these products could be limited or halted by us or by regulatory authorities and our results of operations would be adversely affected.

**Our operations depend on compliance with complex FDA and comparable international regulations. Failure to obtain broad approvals on a timely basis or to maintain compliance could delay or halt commercialization of our products.**

The products we develop must be approved for marketing and sale by regulatory authorities and, once approved, are subject to extensive regulation by the FDA and comparable regulatory agencies in other countries. We are continuing clinical trials for Truvada, Atripla, Viread, Hepsera, Emtriva, AmBisome and Letairis for currently approved and additional uses. We anticipate that we will file for marketing approval in additional countries and for additional indications and products over the next several years. These products may fail to receive such marketing approvals on a timely basis, or at all.

---

**Table of Contents**

In September 2008, we received a complete response letter from the FDA informing us that the FDA will not approve our NDA for aztreonam for inhalation solution for treatment of CF in its current form and requesting we conduct an additional Phase 3 clinical study. In November 2008, we filed a request for dispute resolution with the FDA to determine whether further analyses of the existing data could lead to approval or whether we will need to conduct an additional study. In February 2009, in response to our appeal, the FDA notified us that it is reiterating its position that we will need to conduct another clinical study of aztreonam for inhalation solution before we can resubmit our NDA. In March 2009, the CHMP notified us that it adopted a negative opinion on our marketing authorization application for aztreonam for inhalation solution in the European Union. We are conferring with European regulatory bodies to determine appropriate options to address the issues outlined in the CHMP opinion. Existing data from any ongoing clinical trials or any additional clinical trial that we may commence to satisfy FDA or CHMP concerns may not support the approval of aztreonam for inhalation solution in the United States or the European Union, which may cause us considerable expense and may lead to further delays or cause us to abandon further development of the product. There are also risks that health authorities in other countries where marketing authorization applications are pending will undertake similar additional reviews which would compound the risks described above.

In addition, our marketed products and how we manufacture and sell these products are subject to extensive regulation and review. Discovery of previously unknown problems with our marketed products or problems with our manufacturing or promotional activities may result in restrictions on our products, including withdrawal of the products from the market. If we fail to comply with applicable regulatory requirements, we could be subject to penalties including fines, suspensions of regulatory approvals, product recalls, seizure of products and criminal prosecution.

On September 27, 2007, President Bush signed into law the Food and Drug Administration Amendments Act of 2007, which significantly expanded the FDA's authority, including, among other things, to:

require sponsors of marketed products to conduct post-approval clinical studies to assess a known serious risk, signals of serious risk or to identify an unexpected serious risk;

mandate labeling changes to products, at any point in a product's lifecycle, based on new safety information; and

require sponsors to implement a Risk Evaluation and Mitigation Strategy for a product which could include a medication guide, patient package insert, a communication plan to healthcare providers or other elements as the FDA deems are necessary to assure safe use of the drug, which could include imposing certain restrictions on distribution or use of a product.

Failure to comply with these or other requirements, if imposed on a sponsor by the FDA, could result in significant civil monetary penalties.

**The results and anticipated timelines of our clinical trials are uncertain and may not support continued development of a product pipeline, which would adversely affect our prospects for future revenue growth.**

We are required to demonstrate the safety and efficacy of products that we develop for 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 product candidates fails to achieve its primary endpoint in clinical trials, if safety issues arise or if the results from our clinical trials are otherwise inadequate to support regulatory approval of our product candidates, commercialization of that product candidate could be delayed or halted. We may also face challenges in clinical trial protocol design. If the clinical trials for any of the product candidates in our pipeline are delayed or terminated, our prospects for future revenue growth would be adversely impacted. For example, we face numerous risks and uncertainties with our product candidates, including elvitegravir, our novel HIV integrase inhibitor; darusentan for the treatment of resistant hypertension;

---

**Table of Contents**

and ambrisentan for the treatment of idiopathic pulmonary fibrosis (IPF), each currently in Phase 3 clinical trials that could prevent completion of development of these product candidates. These risks include our ability to enroll patients in clinical trials, the possibility of unfavorable results of our clinical trials, the need to modify or delay our clinical trials or to perform additional trials and the risk of failing to obtain FDA and other regulatory body approvals. As a result, our product candidates may never be successfully commercialized. Further, we may make a strategic decision to discontinue development of our product candidates if, for example, we believe commercialization will be difficult relative to other opportunities in our pipeline. If these programs and others in our pipeline cannot be completed on a timely basis or at all, then our prospects for future revenue growth may be adversely impacted. In addition, clinical trials involving our commercial products could raise new safety issues for our existing products, which could in turn decrease our revenues and harm our business.

**Due to our reliance on third party contract research organizations to conduct our clinical trials, we are unable to directly control the timing, conduct, expense and quality of our clinical trials.**

We extensively outsource our clinical trial activities and usually perform only a small portion of the start-up activities in-house. We rely on independent third party contract research organizations (CROs), over which we do not have control, to perform most of our clinical studies, including document preparation, site identification, screening and preparation, pre-study visits, training, program management and bioanalytical analysis. If there is any dispute or disruption in our relationship with our CROs, our clinical trials may be delayed. Moreover, in our regulatory submissions, we rely on the quality and validity of the clinical work performed by third party CROs. If any of our CROs' processes, methodologies or results were determined to be invalid or inadequate, our own clinical data and results and related regulatory approvals could be adversely impacted.

**We depend on relationships with other companies for sales and marketing performance and revenues. Failure to maintain these relationships, poor performance by these companies or disputes with these companies could negatively impact our business.**

We rely on a number of significant collaborative relationships with major pharmaceutical companies for our sales and marketing performance in certain territories. These include collaborations with BMS for Atripla in the United States, Europe and Canada; Roche for Tamiflu; and GSK for ambrisentan in territories outside of the United States. In some countries, we rely on international distributors for sales of Truvada, Viread, Hepsera, Emtriva and AmBisome. 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 unable to control the resources our corporate partners devote to our programs or products;

disputes may arise with respect to the ownership of rights to technology developed with our corporate partners;

disagreements with our corporate partners could cause delays in, or termination of, the research, development or commercialization of product candidates or result in litigation or arbitration;

contracts with our corporate partners may fail to provide significant protection or may fail to be effectively enforced if one of these partners fails to perform;

our corporate partners have considerable discretion in electing whether to pursue the development of any additional products and may pursue alternative technologies or products either on their own or in collaboration with our competitors;

our corporate partners with marketing rights may choose to pursue competing technologies or to devote fewer resources to the marketing of our products than they do to products of their own development; and

our distributors and our corporate partners may be unable to pay us, particularly in light of current economic conditions.



---

**Table of Contents**

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 revenues from products could decline.

Under our April 2002 licensing agreement with GSK, we gave GSK the right to control clinical and regulatory development and commercialization of Hepsera in territories in Asia, Africa and Latin America. These include major markets for Hepsera, such as China, Japan, Taiwan and South Korea. The success of Hepsera in these territories depends almost entirely on the efforts of GSK. In this regard, GSK promotes Epivir-HBV/Zeffix, a product that competes with Hepsera. Consequently, GSK's marketing strategy for Hepsera may be influenced by its promotion of Epivir-HBV/Zeffix. We receive royalties from GSK equal to a percentage of GSK's net sales of Hepsera as well as net sales of GSK's Epivir-HBV/Zeffix. If GSK fails to devote sufficient resources to, or does not succeed in developing or commercializing Hepsera in its territories, our potential revenues from sales of Hepsera from these territories may be substantially reduced.

In addition, Letairis is distributed through third party specialty pharmacies, which are pharmacies specializing in the dispensing of medications for complex or chronic conditions that may require a high level of patient education and ongoing counseling. The use of specialty pharmacies requires significant coordination with our sales and marketing, medical affairs, regulatory affairs, legal and finance organizations and involves risks, including but not limited to risks that these specialty pharmacies will:

not provide us with accurate or timely information regarding their inventories, patient data or safety complaints;

not effectively sell or support Letairis;

not devote the resources necessary to sell Letairis in the volumes and within the time frames that we expect;

not be able to satisfy their financial obligations to us or others; or

cease operations.

We also rely on a third party to administer LEAP, the restricted distribution program designed to support Letairis. This third party provides information and education to prescribers and patients on the risks of Letairis, confirms insurance coverage and investigates alternative sources of reimbursement or assistance, ensures fulfillment of the risk management requirements mandated for Letairis by the FDA and coordinates and controls dispensing to patients through the third party specialty pharmacies. Failure of this third party or the specialty pharmacies that distribute Letairis to perform as expected may result in regulatory action from the FDA or decreased Letairis sales, either of which would harm our business.

Further, we will be dependent on the supplier of the inhalation device that delivers aztreonam for inhalation solution, if and when regulatory approval is obtained, to distribute the device through specialty pharmacies or other distribution channels, and we will not have control over many key aspects related to the device. For example, the supplier could encounter issues with regulatory agencies related to the device or be unable to supply sufficient quantities of this device at the time of a commercial launch or following a commercial launch. Moreover, because this device will be subject to a separate reimbursement approval process, in the event our supplier is unable to obtain reimbursement approval or receives approval at a lower-than-expected price, sales of aztreonam for inhalation solution may be adversely affected. In addition, we may not be able to obtain adequate supplies of inhalation devices from our supplier. Any of the previously described issues may limit or further delay the commercial launch of aztreonam for inhalation solution, which would adversely affect our financial results.

---

**Table of Contents****Our existing products are subject to reimbursement from government agencies and other third parties. Pharmaceutical pricing and reimbursement pressures may reduce profitability.**

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 health administration authorities, private health insurers and other organizations generally provide reimbursement. In the United States, the European Union and other significant or potentially significant markets for our products and product candidates, government authorities and third party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. For example, a significant portion of our sales of the majority of our products are subject to significant discounts from list price and rebate obligations. In addition, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the European Union will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our product revenues and profitability. 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 our commercialized products, and any other product candidates we may develop, will depend largely on obtaining and maintaining government reimbursement, because in many European countries patients are unlikely to use prescription drugs that are not reimbursed by their governments. In addition, negotiating prices with governmental authorities can delay commercialization by 12 months or more. Reimbursement policies may adversely affect our ability to sell our products on a profitable basis. In many international markets, governments control the prices of prescription pharmaceuticals, including through the implementation of reference pricing, price cuts, rebates, retrospective taxes and profit control, and expect prices of prescription pharmaceuticals to decline over the life of the product or as volumes increase. In recent years, many countries in the European Union have increased the amount of discounts required on our products, and we expect this to continue as countries attempt to manage health care expenditures, especially in light of the global economic downturn. As new drugs come to market, we may face significant price decreases for our products across most of the European countries. 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.

**Our results of operations could be adversely affected by current and future health care reforms.**

Legislative and regulatory changes to government prescription drug procurement and reimbursement programs occur relatively frequently in the United States and foreign jurisdictions. There have been significant changes to the federal Medicare system in recent years in the United States that could impact the pricing of our products. Under the Medicare Prescription Drug Improvement and Modernization Act of 2003, Medicare beneficiaries are able to elect coverage for prescription drugs under Medicare Part D. The prescription drug program began on January 1, 2006 and although we have benefited from patients transitioning from Medicaid to Medicare Part D since 2006, the longer term impact of Medicare Part D on our business is not yet clear to us, and the impact will depend in part on specific decisions regarding the level of coverage provided for the therapeutic categories in which our products are included, the terms on which such coverage is provided, and the extent to which preference is given to selected products in a category. Third party payors providing Medicare Part D coverage have attempted to negotiate price concessions from pharmaceutical manufacturers. In addition, discussions are taking place at the federal level to pass legislation that would either allow or require the federal government to directly negotiate price concessions from pharmaceutical manufacturers or set minimum requirements for Medicare pricing. The increasing pressure to lower prescription drug prices may limit drug access for Medicare Part D enrollees. Further, Medicare patients have to pay co-insurance, which may influence which products are recommended by physicians and selected by patients. Our results of operations could be materially adversely affected by the reimbursement changes emerging from Medicare prescription drug coverage legislation. In addition to federal Medicare proposals, state Medicaid drug payment changes could also lower payment for our products. To the extent that private insurers or managed care programs follow Medicaid



---

## **Table of Contents**

coverage and payment developments, the adverse effects may be magnified by private insurers adopting lower payment schedules. Additionally, any additional statutory or regulatory changes, including potential changes to Medicare Part D, and health care reform at both the federal and state levels could adversely affect payment for our drugs and demand for our product. At this time, a few states have already enacted health care reform legislation, and the federal government and individual state governments continue to consider health care reform policies and legislation. The pricing and reimbursement environment for our products may change in the future and become more challenging due to, among other reasons, new policies of the new presidential administration or new health care legislation passed by Congress.

The Ryan White Program, the largest federal program designed to provide care and support services for people living with HIV in the United States, provides funding for our HIV products through state ADAPs to many patients who are uninsured or underinsured. Federal funding is appropriated by Congress each year and is provided to cities, states, providers and other organizations. In addition to federal funding, some states and localities provide additional funding for Ryan White Program services. The program is up for reauthorization again by September 2009 unless otherwise extended by Congress, and there may be changes to the program which would change or decrease the funding available for our HIV products. For example, if appropriations for the Ryan White Program are held at the same amount as in previous years and more people access our HIV drugs through ADAP, then it is likely that we will face pressures to provide even greater discounts for drugs purchased through the program. In addition, falling state revenues and budget cuts may result in reduction of state or local funding for the Ryan White Program, which could lead to increased demand on our patient assistance programs, under which we offer our HIV products free of charge to eligible patients.

### **Expenses associated with clinical trials may cause our earnings to fluctuate, which could adversely affect our stock price.**

The clinical trials required for regulatory approval of our products, as well as clinical trials we are required to conduct after approval, are very expensive. It is difficult to accurately predict or control the amount or timing of these expenses from quarter to quarter, and the FDA may require more clinical testing than we originally anticipated. For example, the FDA has recently reiterated its position that we will need to conduct another Phase 3 clinical study of aztreonam for inhalation solution before we can resubmit our NDA. Uneven and unexpected spending on these programs may cause our operating results to fluctuate from quarter to quarter, and our stock price may decline.

### **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 may not be able to obtain effective patents to protect our technologies from use by competitors and patents of other companies could require us to stop using or pay for the use of required technology.**

Patents and other proprietary rights are very important to our business. Our success will depend to a significant degree on our ability to:

obtain patents and licenses to patent rights;

preserve trade secrets; and

operate without infringing on the proprietary rights of others.

If we have a properly designed and enforceable patent, it can be more difficult for our competitors to use our technology to create competitive products and more difficult for our competitors to obtain a patent that prevents us from using technology we create. As part of our business strategy, we actively seek patent protection both in the United States and internationally and file additional patent applications, when appropriate, to cover improvements in our compounds, products and technology.

We have a number of U.S. and foreign patents, patent applications and rights to patents related to our compounds, products and technology, but we cannot be certain that issued patents will be enforceable or provide

## **Table of Contents**

adequate protection or that pending patent applications will result in issued patents. Patent applications are confidential for a period of time until a patent is issued. As a result, we may not know if our competitors filed patent applications for technology covered by our pending applications or if we were the first to invent the technology that is the subject of our patent applications. Competitors may have filed patent applications or received patents and may obtain additional patents and proprietary rights that block or compete with our patents. In addition, 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, such that, even if we are ultimately successful, our results of operations may be adversely affected by such events.

From time to time, certain individuals or entities may challenge our patents. For example, in 2007, the Public Patent Foundation filed requests for re-examination with the United States Patent and Trademark Office (PTO) challenging four of our patents related to tenofovir disoproxil fumarate, which is an active ingredient in Truvada, Atripla and Viread. The PTO granted these requests and issued non-final rejections for the four patents, which is a step common in a proceeding to initiate the re-examination process. In 2008, the PTO confirmed the patentability of all four patents.

Although we were successful in responding to the PTO office actions in the instance above, similar organizations may still challenge our patents in foreign jurisdictions. For example, in April 2008, the Brazilian Health Ministry, citing the U.S. patent re-examination proceedings as grounds for rejection, requested that the Brazilian patent authority issue a decision that is not supportive of our patent application for tenofovir disoproxil fumarate in Brazil. In August 2008, an examiner in the Brazilian patent authority issued a final rejection of our fumarate salt patent application, the only patent application for tenofovir disoproxil fumarate we have filed in Brazil. We have filed an appeal within the patent authority responding to the questions raised in the rejection. We cannot predict the outcome of this proceeding on our tenofovir disoproxil fumarate patent application. If we are unable to successfully appeal the decision by the patent authority in the courts, the Brazilian patent authority will reject the tenofovir DF patent application. If the tenofovir disoproxil fumarate patent application is rejected by the Brazilian patent authority, the Brazilian government would likely purchase generic tenofovir disoproxil fumarate, which would significantly reduce our sales of HIV products in Brazil.

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 Hepsara. Asia is a major market for therapies for hepatitis B infection, the indication for which Hepsara has been developed. Flolan's patent and market exclusivity protection has expired. As a result, one or more generic pharmaceutical companies may launch a generic version of Flolan in the United States.

We may obtain patents for certain products many years before marketing approval is obtained for those products. Because patents have a limited life, which may begin to run prior to the commercial sale of the related product, the commercial value of the patent may be limited. However, we may be able to apply for patent term extensions.

As part of the approval process of some of our products, the FDA granted an exclusivity period during which other manufacturers' applications for approval of generic versions of our product will not be granted. Generic manufacturers often wait to challenge the patents protecting products that have been granted exclusivity 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 new drug application (ANDA), 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. For example, in November 2008, we received notice that Teva Pharmaceuticals (Teva) submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Truvada. In the notice, Teva alleges that two of the patents associated with emtricitabine, owned by Emory University and licensed

---

**Table of Contents**

exclusively to us, are invalid, unenforceable and/or will not be infringed by Teva's manufacture, use or sale of a generic version of Truvada. In December 2008, we filed a lawsuit in U.S. District Court in New York against Teva for infringement of the two emtricitabine patents. In March 2009, we received notice that Teva Pharmaceuticals submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Atripla. In the notice, Teva alleges that the same two emtricitabine patents are invalid, unenforceable and/or will not be infringed by Teva's manufacture, use or sale of a generic version of Atripla. We expect to file a lawsuit in U.S. District Court in New York against Teva for infringement of the two emtricitabine patents. We cannot predict the ultimate outcome of these actions and we may spend significant resources defending these patents. If we are unsuccessful in these lawsuits, some or all of our original claims in the patents may be narrowed or invalidated and the patent protection for Truvada and Atripla in the United States would be shortened to expire in 2017 instead of 2021.

In August 2007, the PTO adopted new rules which were scheduled to become effective on November 1, 2007. In October 2007, GSK successfully obtained a preliminary injunction against implementation of these rules, and in April 2008, the court ruled in support of GSK's challenge to the rules and obtained a permanent injunction against their implementation. The rules would have restricted the number of claims permitted in a patent application and the number of continuing patent applications that can be filed. Following the court's ruling, the PTO filed a notice of appeal to the Court of Appeals for the Federal Circuit. In March 2009, the Court of Appeals for the Federal Circuit affirmed one of the rules, vacated one of the rules, and remanded the case to the district court. The rule restricting the number of claims permitted in a patent application was held to be a legitimate exercise of the PTO's authority. The rule restricting the number of continuing patent applications that can be filed was held to be beyond the authority of the PTO. The case was remanded to the district court to resolve other issues, including whether the rules are impermissibly vague and retroactive and if they are inconsistent with federal patent law. In the remanded action at the district court, if GSK is unsuccessful in challenging the implementation of the rules and the rules are implemented, we may be limited in our ability to obtain broad patent coverage for our products and product candidates, which may allow competitors to market products very similar to ours or to obtain patent coverage for closely related products.

**Our success depends in large part on our ability to operate without infringing upon the patents or other proprietary rights of third parties.**

If we infringe the patents of others, we may be prevented from commercializing products or may be required to obtain licenses from these third parties. We may not be able to obtain alternative technologies or any required license on reasonable terms or at all. If we fail to obtain these licenses or alternative technologies, we may be unable to develop or commercialize some or all of our products. For example, we are aware of a body of patents that may relate to our operation of LEAP, our restricted distribution program designed to support Letairis. In addition, Actelion, which markets Tracleer, has applied for a patent that claims a method of use for endothelin receptor antagonists (ERAs) for the treatment of IPF. If issued, this patent may interfere with our efforts to commercialize our own ERA, ambrisentan, for the treatment of IPF.

Furthermore, we use significant proprietary technology and rely on unpatented trade secrets and proprietary know-how to protect certain aspects of our production and other technologies. Our trade secrets may become known or independently discovered by our competitors.

**We may not be able to successfully integrate our existing business with the business of CV Therapeutics, Inc. or any other business or assets we acquire.**

Integrating the business of CV Therapeutics, Inc. (CV Therapeutics) with our existing business will be a complex and time-consuming process. Until recently, CV Therapeutics operated independently of us, with its own business, corporate culture, locations, employees and systems. As a result of this acquisition, we will have to operate our existing business, along with the business of CV Therapeutics, as one combined organization utilizing common information and communication systems, operating procedures, financial controls and human resources practices, including benefits, training and professional development programs. There may be

## **Table of Contents**

substantial difficulties, costs and delays involved in the integration of our business with CV Therapeutics and the integration of our business with any other company or assets that we may from time to time acquire. The failure to successfully integrate our business with CV Therapeutics, or any other assets or companies we may acquire, may have a material adverse effect on our business, financial condition and results of operations.

### **Manufacturing problems could delay product shipments and regulatory approvals, which may adversely affect our results of operations.**

We depend on third parties to perform manufacturing activities effectively and on a timely basis for the majority of our solid dose products. In addition, Roche, either by itself or through third parties, is responsible for manufacturing Tamiflu. The manufacturing process for pharmaceutical products is highly regulated and regulators may shut down manufacturing facilities that they believe do not comply with regulations. We, our third party manufacturers and our corporate partners are subject to the FDA's current Good Manufacturing Practices (GMP), which are extensive regulations governing manufacturing processes, stability testing, record keeping and quality standards. Similar regulations are in effect in other countries. Our manufacturing operations are also subject to routine inspections by regulatory agencies. Additionally, these third party manufacturers and corporate partners are independent entities who are subject to their own unique operational and financial risks which are out of our control. If we or any of these third party manufacturers or corporate partners fail to perform as required, this could impair our ability to deliver our products on a timely basis or receive royalties or cause delays in our clinical trials and applications for regulatory approval. To the extent these risks materialize and affect their performance obligations to us, our financial results may be adversely affected.

### **Our ability to successfully manufacture and commercialize aztreonam for inhalation solution, if approved, will depend upon our ability to manufacture in a multi-product facility.**

Aztreonam is a mono-bactam Gram-negative antibiotic that we currently plan to manufacture, by ourselves or through third parties, in multi-product manufacturing facilities. Historically, the FDA has permitted the manufacture of mono-bactams in multi-product manufacturing facilities; however, there can be no assurance that the FDA will continue to allow this practice. We do not currently have a single-product facility that can be dedicated to the manufacture of aztreonam for inhalation solution nor have we engaged a contract manufacturer with a single-product facility for aztreonam for inhalation solution. If the FDA prohibits the manufacture of mono-bactam antibiotics, like aztreonam for inhalation solution, in multi-product manufacturing facilities in the future, we may not be able to procure a single-product manufacturing facility in a timely manner, which would adversely affect our commercial supplies of aztreonam for inhalation solution and our anticipated financial results attributable to such product, if approved.

### **We may not be able to obtain materials or supplies necessary to conduct clinical trials or to manufacture and sell our products, which would limit our ability to generate revenues.**

We need access to certain supplies and products to conduct our clinical trials and to manufacture our products. In light of the economic downturn, we have had increased difficulty in purchasing certain of the raw materials used in our manufacturing process. If we are unable to purchase sufficient quantities of these materials or find suitable alternate materials in a timely manner, our development efforts for our product candidates may be delayed or our ability to manufacture our products would be limited, which would limit our ability to generate revenues.

Suppliers of key components and materials must be named in an NDA filed with the FDA for any product candidate for which we are seeking FDA approval, and significant delays can occur if the qualification of a new supplier is required. Even after a manufacturer is qualified by the FDA, the manufacturer must continue to expend time, money and effort in the area of production and quality control to ensure full compliance with GMP. Manufacturers are subject to regular, periodic inspections by the FDA following initial approval. If, as a result of these inspections, the FDA determines that the equipment, facilities, laboratories or processes do not comply with applicable FDA regulations and conditions of product approval, the FDA may suspend the manufacturing

---

## **Table of Contents**

operations. If the manufacturing operations of any of the single suppliers for our products are suspended, we may be unable to generate sufficient quantities of commercial or clinical supplies of product to meet market demand, which would in turn decrease our revenues and harm our business.

In addition, if delivery of material from our suppliers were interrupted for any reason, we may be unable to ship certain of our products for commercial supply or to supply our products in development for clinical trials. In addition, some of our products and the materials that we utilize in our operations are made at only one facility. For example, we manufacture AmBisome and fill and finish Macugen exclusively at our facilities in San Dimas, California. In the event of a natural disaster, including an earthquake, equipment failure or other difficulty, we may be unable to replace this manufacturing capacity in a timely manner and may be unable to manufacture AmBisome and Macugen to meet market needs.

Our product candidate, aztreonam for inhalation solution, which is pending FDA approval, is dependent on four different single-source suppliers. First, aztreonam, the active pharmaceutical ingredient in aztreonam for inhalation solution, is manufactured by a single supplier at a single site. Second, it is administered to the lungs of patients through a device that is made by a single supplier at a single site. Third, the FDA recently approved our facilities in San Dimas to manufacture aztreonam for inhalation solution, subject to FDA approval of the product and delivery device. The San Dimas facility is the only manufacturing site authorized to manufacture aztreonam for inhalation solution, although we are pursuing FDA approval of a third party supplier. Fourth, the diluent for aztreonam for inhalation solution will be manufactured by a single manufacturer at a single site.

In addition, we depend on a single supplier for high quality cholesterol, which is used in the manufacture of AmBisome. We also depend on single suppliers for the active pharmaceutical ingredient and for the tableting of Letairis. Problems with any of the single suppliers we depend on may negatively impact our development and commercialization efforts.

### **We face credit risks from our European customers that may adversely affect our results of operations.**

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. This has resulted and may continue to result in an increase in days sales outstanding due to the average length of time that we have accounts receivable outstanding. Our accounts receivable in these countries totaled approximately \$555.5 million as of March 31, 2009, of which \$179.5 million was more than 120 days past due. Historically, receivables balances with certain government owned hospitals accumulated over a period of time and were then subsequently settled as large lump sum payments. If significant changes were to occur in the reimbursement practices of these 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.

### **Our product revenues and gross margin could be reduced by imports from countries where our products are available at lower prices.**

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 other 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 Truvada and Viread, which we have agreed to make available at substantially reduced prices to more than 125 countries participating in our Gilead Access Program, or Atripla, which Merck distributes at substantially reduced prices to HIV infected patients in developing countries under our August 2006 agreement, our revenues would be adversely affected. In addition, we have established partnerships with ten Indian generic manufacturers to distribute high-quality, low-cost generic versions of tenofovir disoproxil fumarate to 95 developing world countries, including India. If generic versions of our medications under these licenses are then re-exported to the United States, Europe or other markets outside of these 95 countries, our revenues would be adversely affected.

---

**Table of Contents**

In addition, purchases of our products in countries where our selling prices are relatively low for resale in countries in which our selling prices are relatively high may adversely impact our revenues and gross margin and may cause our sales to fluctuate from quarter to quarter. For example, in the European Union, we are required to permit products purchased in one country to be sold in another country. Purchases of our products in countries where our selling prices are relatively low for resale in countries in which our selling prices are relatively high affect the inventory level held by our wholesalers and can cause the relative sales levels in the various countries to fluctuate from quarter to quarter and be more difficult to forecast. In addition, wholesalers may attempt to arbitrage the pricing differential between countries by purchasing excessive quantities of our products. These activities may result in fluctuating quarterly sales in certain countries which do not reflect the actual demand for our products from customers. Such quarterly fluctuations may impact our earnings, which could adversely affect our stock price. For example, during 2007, we experienced increased sales of our HIV products in France. We believe a portion of these products was being re-exported to other countries and resold at higher prices. Our sales of Truvada and Viread in France and any countries to or from which sales have been re-exported may continue to fluctuate. Although we established an order management system in France in December 2007 to manage Truvada and Viread sales to facilitate the adequate and appropriate supply of those products commensurate with market demand in France, there can be no assurance that this management system will be effective or that these re-exporting activities will not continue in France, other European countries or elsewhere, and as a result, our results of operations could be adversely affected.

**In some countries, we may be required to grant compulsory licenses for our products or face generic competition for our products.**

In a number of developing countries, government officials and other interested groups have suggested that pharmaceutical companies should make drugs for HIV infection available at low cost. Alternatively, governments in those developing 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. For example, in the past, certain offices of the government of Brazil have expressed concern over the affordability of our HIV products and declared that they were considering issuing compulsory licenses to permit the manufacture of otherwise patented products for HIV infection, including Viread. In May 2006, we reached agreement with the Brazilian Health Ministry to reduce the price of Viread in Brazil by approximately 50%. In addition, concerns over the cost and availability of Tamiflu related to a potential avian flu pandemic have generated international discussions over compulsory licensing of our Tamiflu patents. For example, the Canadian government may allow Canadian manufacturers to manufacture and export the active ingredient in Tamiflu to eligible developing and least developed countries under Canada's Access to Medicines Regime. Furthermore, Roche has issued 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 our Tamiflu patents, or should Roche issue additional voluntary licenses to permit third party manufacturing of Tamiflu, those developments could reduce royalties we receive from Roche's sales of Tamiflu. Certain countries do not permit enforcement of our patents, and third party 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.

**We may face significant liability resulting from our products that may not be covered by insurance and successful claims could materially reduce our earnings.**

The testing, manufacturing, marketing and use of our commercial products, as well as product candidates in development, involve substantial risk of product liability claims. These claims may be made directly by consumers, healthcare providers, pharmaceutical companies or others. In recent years, coverage and availability of product liability insurance has decreased. In addition, the cost to defend lawsuits or pay damages for product liability claims may exceed our coverage. If we are unable to maintain adequate coverage or if claims exceed our

---

**Table of Contents**

coverage, our financial condition and our ability to clinically test our product candidates and to market our products will be adversely impacted. In addition, negative publicity associated with any claims, regardless of their merit, may decrease the future demand for our products and impair our financial condition.

**Our assumptions used to determine our self-insurance levels could be wrong and materially impact our business.**

We continually evaluate our levels of self-insurance based on historical claims experience, demographic factors, severity factors and other actuarial assumptions. However, if future occurrences and claims differ from these assumptions and historical trends, our business, financial results and financial condition could be materially impacted by claims and other expenses.

**Expensive litigation and government investigations may reduce our earnings.**

In November 2008, we received notice that Teva submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Truvada. In the notice, Teva alleges that two of the patents associated with emtricitabine, owned by Emory University and licensed exclusively to us, are invalid, unenforceable and/or will not be infringed by Teva's manufacture, use or sale of a generic version of Truvada. In December 2008, we filed a lawsuit in U.S. District Court in New York against Teva for infringement of the two emtricitabine patents. In March 2009, we received notice that Teva Pharmaceuticals submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Atripla. In the notice, Teva alleges that the same two emtricitabine patents are invalid, unenforceable and/or will not be infringed by Teva's manufacture, use or sale of a generic version of Atripla. We expect to file a lawsuit in U.S. District Court in New York against Teva for infringement of the two emtricitabine patents. We cannot predict the ultimate outcome of these actions, and we may spend significant resources defending these patents. If we are unsuccessful in these lawsuits, some or all of our original claims in the patents may be narrowed or invalidated, and the patent protection for Truvada and Atripla in the United States would be shortened to expire in 2017 instead of 2021.

In addition, we, along with certain of our officers and a former officer, were named as defendants in a class action lawsuit alleging violations of federal securities laws. The lawsuit was dismissed by the United States District Court for the Northern District of California, but in August 2008 the United States Court of Appeals for the Ninth Circuit reversed the dismissal and remanded the case to the district court. In February 2009, we filed a petition for a writ of certiorari with the Supreme Court of the United States, requesting that the Supreme Court review the judgment of the court of appeals. In April 2009, the U.S. Supreme Court denied our petition. The case continues before the district court. In February 2009, we filed a further motion to dismiss the fourth consolidated amended complaint on alternative grounds.

**Changes in our effective income tax rate could reduce our earnings.**

Various factors may have favorable or unfavorable effects on our income tax rate. These factors include, but are not limited to, interpretations of existing tax laws, changes in tax laws and rates, the accounting for stock options and other share-based payments, mergers and acquisitions, future levels of R&D spending, changes in accounting standards, changes in the mix of earnings in the various tax jurisdictions in which we operate, changes in overall levels of pre-tax earnings and finalization of federal, state and foreign income tax audits. 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. For example, California recently passed legislation which may potentially reduce our California income tax commencing in 2011. In response to the legislation, we have evaluated certain tax planning strategies. If the tax planning strategies are not implemented, we may need to revalue certain of our tax assets. Any required revaluation may impact our income tax provision which could have a negative impact on our earnings.

## **Table of Contents**

Our income tax returns are audited by federal, state and foreign tax authorities. We are currently under examination by the Internal Revenue Service for the 2003 and 2004 tax years and by various state and foreign jurisdictions. There are differing interpretations of tax laws and regulations, and as a result, significant disputes may arise with these tax authorities involving issues of the timing and amount of deductions and allocations of income among various tax jurisdictions. Resolution of one or more of these exposures in any reporting period could have a material impact on the results of operations for that period.

### **Changes in accounting may affect our financial position and results of operations.**

U.S. generally accepted accounting principles and related implementation guidelines and interpretations can be highly complex and involve subjective judgments. Changes in these rules or their interpretation, the adoption of new pronouncements or the application of existing pronouncements to changes in our business could significantly affect our financial position and results of operations.

For example, in December 2007, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 141 (revised 2007), *Business Combinations* (SFAS 141R). SFAS 141R establishes principles and requirements for recognizing and measuring assets acquired, liabilities assumed and any noncontrolling interests in the acquiree in a business combination. SFAS 141R also provides guidance for recognizing and measuring goodwill acquired in a business combination; requires purchased in-process research and development to be capitalized at fair value as intangible assets at the time of acquisition; requires acquisition-related expenses and restructuring costs to be recognized separately from the business combination; expands the definition of what constitutes a business; and requires the acquirer to disclose information that users may need to evaluate and understand the financial effect of the business combination. SFAS 141R is effective on a prospective basis and impacts business combination transactions for which the acquisition date occurs in fiscal years beginning after December 15, 2008. We adopted SFAS 141R on January 1, 2009 and will be applying the provisions of SFAS 141R to account for the CV Therapeutics acquisition.

### **If we fail to attract and retain highly qualified personnel, we may be unable to successfully develop new product candidates, conduct our clinical trials and commercialize our product candidates.**

Our future success will depend in large part on our continued ability to attract and retain highly qualified scientific, technical and management personnel, as well as personnel with expertise in clinical testing, governmental regulation and commercialization. We face competition for personnel from other companies, universities, public and private research institutions, government entities and other organizations. Competition for qualified personnel in the biopharmaceutical field is intense, and there is a limited pool of qualified potential employees to recruit. We may not be able to attract and retain quality personnel on acceptable terms. If we are unsuccessful in our recruitment and retention efforts, our business may be harmed.



**Table of Contents****ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

The table below summarizes our stock repurchase activity for the quarter ended March 31, 2009 (in thousands, except per share amounts):

		Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Programs	Maximum Fair Value of Shares that May Yet Be Purchased Under the Program
January 1	January 31, 2009		\$		\$ 998,057
February 1	February 28, 2009	1,512	\$ 49.38	1,512	\$ 923,389
March 1	March 31, 2009	4,918	\$ 44.91	4,853	\$ 768,092
Total		6,430(1)(2)	\$ 45.96	6,365(1)(2)	

- (1) In October 2008, we entered into an accelerated share repurchase agreement with a financial institution to repurchase \$750.0 million of our common stock on an accelerated basis. This accelerated share repurchase is part of the \$3.00 billion stock repurchase program authorized by our Board of Directors in October 2007, announced in October 2007 and expiring in December 2010. Under the terms of the accelerated share repurchase agreement, we paid \$750.0 million to settle the initial purchase transaction and received 14,874,519 shares of our common stock at a price of \$50.42 per share. In March 2009, upon termination of the agreement and in accordance with the share delivery provisions of the agreement, we received an additional 1,356,337 shares of our common stock based on the average of the daily volume weighted-average prices of our common stock during a specified period less a predetermined discount per share. As a result, the total number of shares retired under this accelerated share repurchase agreement was 16,230,856 shares at an average purchase price of \$46.21 per share. In addition to the additional shares that we received under the terms of the accelerated share repurchase transaction, we repurchased and retired 5,008,447 shares of our common stock at an average purchase price of \$45.92 per share, for an aggregate purchase price of \$230.0 million through open market transactions during the three months ended March 31, 2009. The accounting for this accelerated share repurchase was consistent with that of our previous accelerated share repurchase.
- (2) The difference between the total number of shares purchased and the total number of shares purchased as part of publicly announced programs is due to shares of common stock withheld by us from employee restricted stock awards in order to satisfy our applicable tax withholding obligations.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

Not applicable.

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

None.

**ITEM 5. OTHER INFORMATION**

Not applicable.

**Table of Contents****ITEM 6. EXHIBITS**

<b>Exhibit Footnote</b>	<b>Exhibit Number</b>	<b>Description of Document</b>
(1)	2.1	Agreement and Plan of Merger among Registrant, Apex Merger Sub, Inc. and CV Therapeutics, Inc., dated as of March 12, 2009
(1)	2.2	Stockholder Agreement by and between Registrant and Louis G. Lange, dated as of March 12, 2009
(2)	3.1	Restated Certificate of Incorporation of the Registrant
(3)	3.2	Certificate of Designation of the Series A Junior Participating Preferred Stock of Registrant
(4)	3.3	Certificate of Amendment to Certificate of Designation of the Series A Junior Participating Preferred Stock of Registrant
(5)	3.4	Amended and Restated Bylaws of the Registrant, as amended and restated on October 24, 2008
	4.1	Reference is made to Exhibit 3.1, Exhibit 3.2, Exhibit 3.3 and Exhibit 3.4
(6)	4.2	Amended and Restated Rights Agreement between the Registrant and ChaseMellon Shareholder Services, LLC, dated October 21, 1999
(7)	4.3	First Amendment to Amended and Restated Rights Agreement between the Registrant and Mellon Investor Services, LLC (formerly known as ChaseMellon Shareholder Services, LLC), dated October 29, 2003
(8)	4.4	Second Amendment to Amended and Restated Rights Agreement between the Registrant and Mellon Investor Services, LLC (formerly known as ChaseMellon Shareholder Services, LLC), dated May 11, 2006
(9)	4.5	Indenture related to the Convertible Senior Notes, due 2011, between Registrant and Wells Fargo Bank, National Association, as trustee (including form of 0.50% Convertible Senior Note due 2011), dated April 25, 2006
(9)	4.6	Indenture related to the Convertible Senior Notes, due 2013, between Registrant and Wells Fargo Bank, National Association, as trustee (including form of 0.625% Convertible Senior Note due 2013), dated April 25, 2006
(10)	10.1	Confirmation of OTC Convertible Note Hedge related to 2011 Notes, dated April 19, 2006, as amended and restated as of April 24, 2006, between Registrant and Bank of America, N.A.
(10)	10.2	Confirmation of OTC Convertible Note Hedge related to 2013 Notes, dated April 19, 2006, as amended and restated as of April 24, 2006, between Registrant and Bank of America, N.A.
(10)	10.3	Confirmation of OTC Warrant Transaction, dated April 19, 2006, as amended and restated as of April 24, 2006, between Registrant and Bank of America, N.A. for warrants expiring in 2011
(10)	10.4	Confirmation of OTC Warrant Transaction, dated April 19, 2006, as amended and restated as of April 24, 2006, between Registrant and Bank of America, N.A. for warrants expiring in 2013

**Table of Contents**

<b>Exhibit</b>		
<b>Footnote</b>	<b>Exhibit Number</b>	<b>Description of Document</b>
(11)	10.5	Amended and Restated Credit Agreement among Registrant, Gilead Biopharmaceutics Ireland Corporation, the lenders parties thereto and Bank of America, N.A., as Administrative Agent, Swing Line Lender and L/C Issuer, dated as of December 18, 2007
(11)	10.6	Parent Guaranty Agreement, dated as of December 18, 2007, by Registrant
(12)	10.7	Master Confirmation by and between Registrant and Citibank N.A., together with the Supplemental Confirmation, dated as of October 21, 2008
*(13)	10.8	Gilead Sciences, Inc. 1991 Stock Option Plan, as amended through January 29, 2003
*(14)	10.9	Form of option agreements used under the 1991 Stock Option Plan
*(13)	10.10	Gilead Sciences, Inc. 1995 Non-Employee Directors Stock Option Plan, as amended through January 30, 2002
*(15)	10.11	Form of option agreement used under the Gilead Sciences, Inc. 1995 Non-Employee Directors Stock Option Plan
*(16)	10.12	Gilead Sciences, Inc. 2004 Equity Incentive Plan, as amended through May 8, 2008
*(17)	10.13	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants prior to February 2008)
*(18)	10.14	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants commencing in February 2008)
*(17)	10.15	Form of non-employee director stock option agreement used under 2004 Equity Incentive Plan (for grants prior to 2008)
*(18)	10.16	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for initial grants commencing in 2008)
*(18)	10.17	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for annual grants commencing in May 2008)
*(19)	10.18	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for grants in 2007)
*(20)	10.19	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for grants commencing in 2008)
*(21)	10.20	Form of restricted award agreement used under 2004 Equity Incentive Plan (for grants prior to 2008)
*(22)	10.21	Form of restricted stock unit issuance agreement used under the 2004 Equity Incentive Plan (for grants commencing in 2008)
*(23)	10.22	Gilead Sciences, Inc. Employee Stock Purchase Plan, as amended through May 9, 2007
*(24)	10.23	Gilead Sciences, Inc. Deferred Compensation Plan Basic Plan Document
*(24)	10.24	Gilead Sciences, Inc. Deferred Compensation Plan Adoption Agreement
*(24)	10.25	Addendum to the Gilead Sciences, Inc. Deferred Compensation Plan

**Table of Contents**

<b>Footnote</b>	<b>Exhibit Number</b>	<b>Description of Document</b>
*(35)	10.26	Gilead Sciences, Inc. 2005 Deferred Compensation Plan, as amended and restated on October 23, 2008
*(35)	10.27	Gilead Sciences, Inc. Severance Plan, as amended on December 15, 2008
*(17)	10.28	Gilead Sciences, Inc. Corporate Bonus Plan
*(17)	10.29	Gilead Sciences, Inc. Code Section 162(m) Bonus Plan
*(25)	10.30	2009 Base Salaries for the Named Executive Officers
*(16)	10.31	Offer Letter dated April 16, 2008 between Registrant and Robin Washington
*(14)	10.32	Form of Indemnity Agreement entered into between the Registrant and its directors and executive officers
*(14)	10.33	Form of Employee Proprietary Information and Invention Agreement entered into between Registrant and certain of its officers and key employees
*(19)	10.34	Form of Employee Proprietary Information and Invention Agreement entered into between Registrant and certain of its officers and key employees (revised in September 2006)
+(21)	10.35	Amended and Restated Collaboration Agreement by and among Registrant, Gilead Holdings, LLC, Bristol-Myers Squibb Company, E.R. Squibb & Sons, L.L.C., and Bristol-Myers Squibb & Gilead Sciences, LLC, dated September 28, 2006
+(18)	10.36	Commercialization Agreement by and between Gilead Sciences Limited and Bristol-Myers Squibb Company, dated December 10, 2007
+(14)	10.37	Letter Agreement between Registrant and Institute of Organic Chemistry and Biochemistry of the Academy of Sciences of the Czech Republic (IOCB) and REGA Stichting v.z.w. (REGA, and together with IOCB, IOCB/REGA), dated September 23, 1991
+(26)	10.38	Amendment Agreement between Registrant and IOCB/REGA, dated October 25, 1993
(27)	10.39	Amendment Agreement between Registrant and IOCB/REGA, dated December 27, 2000
(21)	10.40	Sixth Amendment Agreement to the License Agreement, between the IOCB and the K. U. Leuven Research and Development and Registrant, dated August 18, 2006
+(21)	10.41	Development and License Agreement among Registrant and F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc., dated September 27, 1996
+(28)	10.42	First Amendment and Supplement dated November 15, 2005 to the Development and Licensing Agreement between Registrant, F. Hoffmann-La Roche Ltd and Hoffman-La Roche Inc. dated September 27, 1996
+(29)	10.43	Exclusive License Agreement between Registrant (as successor to Triangle Pharmaceuticals, Inc.), Glaxo Group Limited, The Wellcome Foundation Limited, Glaxo Wellcome Inc. and Emory University, dated May 6, 1999
+(30)	10.44	Royalty Sale Agreement by and among Registrant, Emory University and Investors Trust & Custodial Services (Ireland) Limited, solely in its capacity as Trustee of Royalty Pharma, dated July 18, 2005

**Table of Contents**

<b>Exhibit</b>	<b>Exhibit</b>	<b>Description of Document</b>
<b>Footnote</b>	<b>Number</b>	
+(30)	10.45	Amended and Restated License Agreement between Registrant, Emory University and Investors Trust & Custodial Services (Ireland) Limited, solely in its capacity as Trustee of Royalty Pharma, dated July 21, 2005.
+(31)	10.46	License Agreement between Japan Tobacco Inc. and Registrant, dated March 22, 2005
+(32)	10.47	License Agreement between Registrant (as successor to Myogen, Inc.) and Abbott Deutschland Holding GmbH dated October 8, 2001
+(32)	10.48	License Agreement between Registrant (as successor to Myogen, Inc.) and Abbott Laboratories, dated June 30, 2003
+(33)	10.49	Master Clinical and Commercial Supply Agreement between Gilead World Markets, Limited, Registrant and Patheon Inc., dated January 1, 2003
+(30)	10.50	Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Gilead Sciences Limited and PharmaChem Technologies (Grand Bahama), Ltd., dated July 17, 2003
+(34)	10.51	Addendum to Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Gilead Sciences Limited and PharmaChem Technologies (Grand Bahama) Ltd., dated May 10, 2007
+(35)	10.52	Addendum to Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Gilead Sciences Limited and PharmaChem Technologies (Grand Bahama) Ltd., dated December 5, 2008
+(20)	10.53	Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Registrant and Ampac Fine Chemicals LLC, dated March 6, 2008
+(28)	10.54	Restated and Amended Toll Manufacturing Agreement between Gilead Sciences Limited, Registrant and ALTANA Pharma Oranienburg GmbH, dated November 7, 2005
+(11)	10.55	Emtricitabine Manufacturing Supply Agreement between Gilead Sciences Limited and Degussa AG, dated June 6, 2006
(35)	10.56	Purchase and Sale Agreement and Escrow Instructions between Electronics for Imaging, Inc. and Registrant, dated October 23, 2008
	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
	32.1**	Certifications 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 Current Report on Form 8-K filed on March 12, 2009, and incorporated herein by reference.

(2) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on May 9, 2008, and incorporated herein by reference.

**Table of Contents**

- (3) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on November 22, 1994, and incorporated herein by reference.
- (4) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on May 11, 2006, and incorporated herein by reference.
- (5) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on October 28, 2008, and incorporated herein by reference.
- (6) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on October 22, 1999, and incorporated herein by reference.
- (7) Filed as an exhibit to the Registrant's Current Report on Form 8-K filed on October 31, 2003, and incorporated herein by reference.
- (8) Filed as an exhibit to Registrant's Registration Statement on Form S-8 (No. 333-135412) filed on June 28, 2006, and incorporated herein by reference.
- (9) Filed as an exhibit to the Registrant's Current Report on Form 8-K filed on April 25, 2006, and incorporated herein by reference.
- (10) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2006, and incorporated herein by reference.
- (11) Filed as an exhibit to Registrant's Current Report on Form 8-K also filed on December 19, 2007, and incorporated herein by reference.
- (12) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on October 21, 2008, and incorporated herein by reference.
- (13) Filed as an exhibit to Registrant's Registration Statement on Form S-8 (No. 333-102912) filed on January 31, 2003, and incorporated herein by reference.
- (14) Filed as an exhibit to Registrant's Registration Statement on Form S-1 (No. 33-55680), as amended, and incorporated herein by reference.
- (15) 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.
- (16) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008, and incorporated herein by reference.
- (17) Filed as an exhibit to Registrant's Current Report on Form 8-K/A filed on February 22, 2006, and incorporated herein by reference.
- (18) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2007, and incorporated herein by reference.

## Edgar Filing: GILEAD SCIENCES INC - Form 10-Q

- (19) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2006, and incorporated herein by reference.
- (20) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2008, and incorporated herein by reference.
- (21) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2006, and incorporated herein by reference.
- (22) Filed as an exhibit to Registrant's Current Report on Form 8-K first filed on December 19, 2007, and incorporated herein by reference.
- (23) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on May 11, 2007, and incorporated herein by reference.

**Table of Contents**

- (24) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2001, and incorporated herein by reference.
- (25) Information is included in Registrant's Current Report on Form 8-K filed on January 27, 2009, and incorporated herein by reference.
- (26) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended March 31, 1994, and incorporated herein by reference.
- (27) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2000, and incorporated herein by reference.
- (28) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2005, and incorporated herein by reference.
- (29) Filed as an exhibit to Triangle Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q/A filed on November 3, 1999, and incorporated herein by reference.
- (30) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2005, and incorporated herein by reference.
- (31) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2005, and incorporated herein by reference.
- (32) Filed as an exhibit to Myogen, Inc.'s Registration Statement on Form S-1 (No. 333-108301), as amended, originally filed on August 28, 2003, and incorporated herein by reference.
- (33) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2003, and incorporated herein by reference.
- (34) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on August 7, 2007, and incorporated herein by reference.
- (35) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2008, and incorporated herein by reference.

\* Management contract or compensatory plan or arrangement.

\*\* 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 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.



- + 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 Registrant's Application Requesting Confidential Treatment under Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

**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 7, 2009

/s/ JOHN C. MARTIN  
**John C. Martin, Ph.D.**

**Chairman and Chief Executive Officer**

**(Principal Executive Officer)**

Date: May 7, 2009

/s/ ROBIN L. WASHINGTON  
**Robin L. Washington**

**Senior Vice President and Chief Financial Officer**

**(Principal Financial and Accounting Officer)**

**Table of Contents****Exhibit Index**

## (a) Exhibits

<b>Footnote</b>	<b>Exhibit Number</b>	<b>Description of Document</b>
(1)	2.1	Agreement and Plan of Merger among Registrant, Apex Merger Sub, Inc. and CV Therapeutics, Inc. dated as of March 12, 2009
(1)	2.2	Stockholder Agreement by and between Registrant and Louis G. Lange, dated as of March 12, 2009
(2)	3.1	Restated Certificate of Incorporation of the Registrant
(3)	3.2	Certificate of Designation of the Series A Junior Participating Preferred Stock of Registrant
(4)	3.3	Certificate of Amendment to Certificate of Designation of the Series A Junior Participating Preferred Stock of Registrant
(5)	3.4	Amended and Restated Bylaws of the Registrant, as amended and restated on October 24, 2008
	4.1	Reference is made to Exhibit 3.1, Exhibit 3.2, Exhibit 3.3 and Exhibit 3.4
(6)	4.2	Amended and Restated Rights Agreement between the Registrant and ChaseMellon Shareholder Services, LLC, dated October 21, 1999
(7)	4.3	First Amendment to Amended and Restated Rights Agreement between the Registrant and Mellon Investor Services, LLC (formerly known as ChaseMellon Shareholder Services, LLC), dated October 29, 2003
(8)	4.4	Second Amendment to Amended and Restated Rights Agreement between the Registrant and Mellon Investor Services, LLC (formerly known as ChaseMellon Shareholder Services, LLC), dated May 11, 2006
(9)	4.5	Indenture related to the Convertible Senior Notes, due 2011, between Registrant and Wells Fargo Bank, National Association, as trustee (including form of 0.50% Convertible Senior Note due 2011), dated April 25, 2006
(9)	4.6	Indenture related to the Convertible Senior Notes, due 2013, between Registrant and Wells Fargo Bank, National Association, as trustee (including form of 0.625% Convertible Senior Note due 2013), dated April 25, 2006
(10)	10.1	Confirmation of OTC Convertible Note Hedge related to 2011 Notes, dated April 19, 2006, as amended and restated as of April 24, 2006, between Registrant and Bank of America, N.A.
(10)	10.2	Confirmation of OTC Convertible Note Hedge related to 2013 Notes, dated April 19, 2006, as amended and restated as of April 24, 2006, between Registrant and Bank of America, N.A.
(10)	10.3	Confirmation of OTC Warrant Transaction, dated April 19, 2006, as amended and restated as of April 24, 2006, between Registrant and Bank of America, N.A. for warrants expiring in 2011
(10)	10.4	Confirmation of OTC Warrant Transaction, dated April 19, 2006, as amended and restated as of April 24, 2006, between Registrant and Bank of America, N.A. for warrants expiring in 2013

**Table of Contents**

<b>Exhibit</b>	<b>Exhibit</b>	<b>Description of Document</b>
<b>Footnote</b>	<b>Number</b>	
(11)	10.5	Amended and Restated Credit Agreement among Registrant, Gilead Biopharmaceutics Ireland Corporation, the lenders parties thereto and Bank of America, N.A., as Administrative Agent, Swing Line Lender and L/C Issuer, dated as of December 18, 2007
(11)	10.6	Parent Guaranty Agreement, dated as of December 18, 2007, by Registrant
(12)	10.7	Master Confirmation by and between Registrant and Citibank N.A., together with the Supplemental Confirmation, dated as of October 21, 2008
*(13)	10.8	Gilead Sciences, Inc. 1991 Stock Option Plan, as amended through January 29, 2003
*(14)	10.9	Form of option agreements used under the 1991 Stock Option Plan
*(13)	10.10	Gilead Sciences, Inc. 1995 Non-Employee Directors Stock Option Plan, as amended through January 30, 2002
*(15)	10.11	Form of option agreement used under the Gilead Sciences, Inc. 1995 Non-Employee Directors Stock Option Plan
*(16)	10.12	Gilead Sciences, Inc. 2004 Equity Incentive Plan, as amended through May 8, 2008
*(17)	10.13	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants prior to February 2008)
*(18)	10.14	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants commencing in February 2008)
*(17)	10.15	Form of non-employee director stock option agreement used under 2004 Equity Incentive Plan (for grants prior to 2008)
*(18)	10.16	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for initial grants commencing in 2008)
*(18)	10.17	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for annual grants commencing in May 2008)
*(19)	10.18	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for grants in 2007)
*(20)	10.19	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for grants commencing in 2008)
*(21)	10.20	Form of restricted award agreement used under 2004 Equity Incentive Plan (for grants prior to 2008)
*(22)	10.21	Form of restricted stock unit issuance agreement used under the 2004 Equity Incentive Plan (for grants commencing in 2008)
*(23)	10.22	Gilead Sciences, Inc. Employee Stock Purchase Plan, as amended through May 9, 2007
*(24)	10.23	Gilead Sciences, Inc. Deferred Compensation Plan Basic Plan Document
*(24)	10.24	Gilead Sciences, Inc. Deferred Compensation Plan Adoption Agreement
*(24)	10.25	Addendum to the Gilead Sciences, Inc. Deferred Compensation Plan

**Table of Contents**

<b>Exhibit</b>	<b>Exhibit</b>	<b>Description of Document</b>
<b>Footnote</b>	<b>Number</b>	
*(35)	10.26	Gilead Sciences, Inc. 2005 Deferred Compensation Plan, as amended and restated on October 23, 2008
*(35)	10.27	Gilead Sciences, Inc. Severance Plan, as amended on December 15, 2008
*(17)	10.28	Gilead Sciences, Inc. Corporate Bonus Plan
*(17)	10.29	Gilead Sciences, Inc. Code Section 162(m) Bonus Plan
*(25)	10.30	2009 Base Salaries for the Named Executive Officers
*(16)	10.31	Offer Letter dated April 16, 2008 between Registrant and Robin Washington
*(14)	10.32	Form of Indemnity Agreement entered into between the Registrant and its directors and executive officers
*(14)	10.33	Form of Employee Proprietary Information and Invention Agreement entered into between Registrant and certain of its officers and key employees
*(19)	10.34	Form of Employee Proprietary Information and Invention Agreement entered into between Registrant and certain of its officers and key employees (revised in September 2006)
+(21)	10.35	Amended and Restated Collaboration Agreement by and among Registrant, Gilead Holdings, LLC, Bristol-Myers Squibb Company, E.R. Squibb & Sons, L.L.C., and Bristol-Myers Squibb & Gilead Sciences, LLC, dated September 28, 2006
+(18)	10.36	Commercialization Agreement by and between Gilead Sciences Limited and Bristol-Myers Squibb Company, dated December 10, 2007
+(14)	10.37	Letter Agreement between Registrant and Institute of Organic Chemistry and Biochemistry of the Academy of Sciences of the Czech Republic (IOCB) and REGA Stichting v.z.w. (REGA, and together with IOCB, IOCB/REGA), dated September 23, 1991
+(26)	10.38	Amendment Agreement between Registrant and IOCB/REGA, dated October 25, 1993
(27)	10.39	Amendment Agreement between Registrant and IOCB/REGA, dated December 27, 2000
(21)	10.40	Sixth Amendment Agreement to the License Agreement, between the IOCB and the K. U. Leuven Research and Development and Registrant, dated August 18, 2006
+(21)	10.41	Development and License Agreement among Registrant and F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc., dated September 27, 1996
+(28)	10.42	First Amendment and Supplement dated November 15, 2005 to the Development and Licensing Agreement between Registrant, F. Hoffmann-La Roche Ltd and Hoffman-La Roche Inc. dated September 27, 1996
+(29)	10.43	Exclusive License Agreement between Registrant (as successor to Triangle Pharmaceuticals, Inc.), Glaxo Group Limited, The Wellcome Foundation Limited, Glaxo Wellcome Inc. and Emory University, dated May 6, 1999
+(30)	10.44	Royalty Sale Agreement by and among Registrant, Emory University and Investors Trust & Custodial Services (Ireland) Limited, solely in its capacity as Trustee of Royalty Pharma, dated July 18, 2005

**Table of Contents**

<b>Footnote</b>	<b>Exhibit Number</b>	<b>Description of Document</b>
+(30)	10.45	Amended and Restated License Agreement between Registrant, Emory University and Investors Trust & Custodial Services (Ireland) Limited, solely in its capacity as Trustee of Royalty Pharma, dated July 21, 2005.
+(31)	10.46	License Agreement between Japan Tobacco Inc. and Registrant, dated March 22, 2005
+(32)	10.47	License Agreement between Registrant (as successor to Myogen, Inc.) and Abbott Deutschland Holding GmbH dated October 8, 2001
+(32)	10.48	License Agreement between Registrant (as successor to Myogen, Inc.) and Abbott Laboratories, dated June 30, 2003
+(33)	10.49	Master Clinical and Commercial Supply Agreement between Gilead World Markets, Limited, Registrant and Patheon Inc., dated January 1, 2003
+(30)	10.50	Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Gilead Sciences Limited and PharmaChem Technologies (Grand Bahama), Ltd., dated July 17, 2003
+(34)	10.51	Addendum to Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Gilead Sciences Limited and PharmaChem Technologies (Grand Bahama) Ltd., dated May 10, 2007
+(35)	10.52	Addendum to Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Gilead Sciences Limited and PharmaChem Technologies (Grand Bahama) Ltd., dated December 5, 2008
+(20)	10.53	Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Registrant and Ampac Fine Chemicals LLC, dated March 6, 2008
+(28)	10.54	Restated and Amended Toll Manufacturing Agreement between Gilead Sciences Limited, Registrant and ALTANA Pharma Oranienburg GmbH, dated November 7, 2005
+(11)	10.55	Emtricitabine Manufacturing Supply Agreement between Gilead Sciences Limited and Degussa AG, dated June 6, 2006
(35)	10.56	Purchase and Sale Agreement and Escrow Instructions between Electronics for Imaging, Inc. and Registrant, dated October 23, 2008
	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
	32.1**	Certifications 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 Current Report on Form 8-K filed on March 12, 2009, and incorporated herein by reference.

(2) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on May 9, 2008, and incorporated herein by reference.

**Table of Contents**

- (3) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on November 22, 1994, and incorporated herein by reference.
- (4) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on May 11, 2006, and incorporated herein by reference.
- (5) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on October 28, 2008, and incorporated herein by reference.
- (6) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on October 22, 1999, and incorporated herein by reference.
- (7) Filed as an exhibit to the Registrant's Current Report on Form 8-K filed on October 31, 2003, and incorporated herein by reference.
- (8) Filed as an exhibit to Registrant's Registration Statement on Form S-8 (No. 333-135412) filed on June 28, 2006, and incorporated herein by reference.
- (9) Filed as an exhibit to the Registrant's Current Report on Form 8-K filed on April 25, 2006, and incorporated herein by reference.
- (10) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2006, and incorporated herein by reference.
- (11) Filed as an exhibit to Registrant's Current Report on Form 8-K also filed on December 19, 2007, and incorporated herein by reference.
- (12) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on October 21, 2008, and incorporated herein by reference.
- (13) Filed as an exhibit to Registrant's Registration Statement on Form S-8 (No. 333-102912) filed on January 31, 2003, and incorporated herein by reference.
- (14) Filed as an exhibit to Registrant's Registration Statement on Form S-1 (No. 33-55680), as amended, and incorporated herein by reference.
- (15) 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.
- (16) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008, and incorporated herein by reference.
- (17) Filed as an exhibit to Registrant's Current Report on Form 8-K/A filed on February 22, 2006, and incorporated herein by reference.
- (18) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2007, and incorporated herein by reference.

## Edgar Filing: GILEAD SCIENCES INC - Form 10-Q

- (19) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2006, and incorporated herein by reference.
- (20) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2008, and incorporated herein by reference.
- (21) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2006, and incorporated herein by reference.
- (22) Filed as an exhibit to Registrant's Current Report on Form 8-K first filed on December 19, 2007, and incorporated herein by reference.
- (23) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on May 11, 2007, and incorporated herein by reference.



**Table of Contents**

- (24) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2001, and incorporated herein by reference.
- (25) Information is included in Registrant's Current Report on Form 8-K filed on January 27, 2009, and incorporated herein by reference.
- (26) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended March 31, 1994, and incorporated herein by reference.
- (27) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2000, and incorporated herein by reference.
- (28) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2005, and incorporated herein by reference.
- (29) Filed as an exhibit to Triangle Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q/A filed on November 3, 1999, and incorporated herein by reference.
- (30) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2005, and incorporated herein by reference.
- (31) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2005, and incorporated herein by reference.
- (32) Filed as an exhibit to Myogen, Inc.'s Registration Statement on Form S-1 (No. 333-108301), as amended, originally filed on August 28, 2003, and incorporated herein by reference.
- (33) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2003, and incorporated herein by reference.
- (34) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on August 7, 2007, and incorporated herein by reference.
- (35) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2008, and incorporated herein by reference.

\* Management contract or compensatory plan or arrangement.

\*\* 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 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.

Edgar Filing: GILEAD SCIENCES INC - Form 10-Q

- + 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 Registrant's Application Requesting Confidential Treatment under Rule 24b-2 under the Securities Exchange Act of 1934, as amended.