GILEAD SCIENCES INC
Form 10-Q
November 05, 2009
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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 September 30, 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)

Delaware	**94-3047598**
(State or Other Jurisdiction of	**(IRS Employer**
Incorporation or Organization)	**Identification No.)**
333 Lakeside Drive, Foster City, California	**94404**
(Address of principal executive offices)	**(Zip Code)**

650-574-3000

Registrant s Telephone Number, Including Area Code

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x 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 x 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 x	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 x

Number of shares outstanding of the issuer s common stock, par value $0.001 per share, as of October 30, 2009: 899,925,051

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GILEAD SCIENCES, INC.

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We own or have rights to various trademarks, copyrights and trade names used in our business, including the following: GILEAD®, GILEAD SCIENCES®, TRUVADA®, VIREAD®, HEPSERA®, AMBISOME®, EMTRIVA®, VISTIDE®, LETAIRIS®, VOLIBRIS , RANEXA® and CAYSTON®. 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. LEXISCAN® is a registered trademark belonging to Astellas US LLC. This report also includes other trademarks, service marks and trade names of other companies.

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PART I. FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

GILEAD SCIENCES, INC.

Condensed Consolidated Balance Sheets

(unaudited)

(in thousands, except per share amounts)

	September 30, 2009	December 31, 2008
Assets		
Current assets:		
Cash and cash equivalents	$ 1,024,599	$ 1,459,302
Short-term marketable securities	330,713	330,760
Accounts receivable, net	1,339,165	1,023,397
Inventories	1,017,827	927,868
Deferred tax assets	192,701	140,882
Prepaid taxes	249,500	198,318
Prepaid expenses	83,391	71,815
Other current assets	59,714	126,066
Total current assets	4,297,610	4,278,408
Property, plant and equipment, net	701,371	528,799
Noncurrent portion of prepaid royalties	231,956	257,208
Noncurrent deferred tax assets	134,417	226,728
Long-term marketable securities	1,936,818	1,449,577
Intangible assets	1,555,602	123,008
Other noncurrent assets	79,206	73,103
Total assets	$ 8,936,980	$ 6,936,831
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 742,684	$ 601,200
Accrued government rebates	228,707	176,939
Accrued compensation and employee benefits	127,691	103,840
Income taxes payable	139,536	44,757
Other accrued liabilities	395,656	245,662
Deferred revenues	49,362	42,963
Current portion of other long-term obligations	205,613	5,631
Total current liabilities	1,889,249	1,220,992
Long-term deferred revenues	44,567	74,181
Convertible senior notes, net	1,140,887	1,098,025
Long-term income taxes payable	67,757	56,588
Other long-term obligations	42,363	21,462
Commitments and contingencies (Note 11)		
Stockholders equity:		
Preferred stock, par value $0.001 per share; 5,000 shares authorized; none outstanding		
	902	910

Common stock, par value $0.001 per share; 2,800,000 shares authorized; 901,816 and 909,819 shares issued and outstanding at September 30, 2009 and December 31, 2008, respectively		
Additional paid-in capital	4,264,222	3,930,109
Accumulated other comprehensive income (loss)	(39,199)	41,240
Retained earnings	1,420,613	300,314
Total Gilead stockholders equity	5,646,538	4,272,573
Noncontrolling interest	105,619	193,010
Total stockholders equity	5,752,157	4,465,583
Total liabilities and stockholders equity	$ 8,936,980	$ 6,936,831

See accompanying notes.

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GILEAD SCIENCES, INC.

Condensed Consolidated Statements of Income

(unaudited)

(in thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Revenues:				
Product sales	$ 1,648,955	$ 1,338,502	$ 4,664,913	$ 3,697,024
Royalty revenues	142,133	25,161	269,070	185,221
Contract and other revenues	10,301	7,605	45,021	25,300
Total revenues	1,801,389	1,371,268	4,979,004	3,907,545
Costs and expenses:				
Cost of goods sold	409,700	300,183	1,122,159	805,715
Research and development	269,856	188,062	700,273	519,905
Selling, general and administrative	227,427	189,189	692,789	603,679
Purchased in-process research and development				10,851
Total costs and expenses	906,983	677,434	2,515,221	1,940,150
Income from operations	894,406	693,834	2,463,783	1,967,395
Interest and other income, net	14,017	3,637	31,098	40,363
Interest expense	(17,217)	(16,382)	(52,372)	(48,811)
Income before provision for income taxes	891,206	681,089	2,442,509	1,958,947
Provision for income taxes	220,728	187,396	616,310	546,206
Net income	670,478	493,693	1,826,199	1,412,741
Net loss attributable to noncontrolling interest	2,555	2,160	7,344	6,195
Net income attributable to Gilead	$ 673,033	$ 495,853	$ 1,833,543	$ 1,418,936
Net income per share attributable to Gilead common stockholders basic	$ 0.75	$ 0.54	$ 2.02	$ 1.54
Shares used in per share calculation basic	903,319	920,807	906,213	923,894
Net income per share attributable to Gilead common stockholders diluted	$ 0.72	$ 0.52	$ 1.96	$ 1.47
Shares used in per share calculation diluted	932,424	960,585	936,530	964,267

See accompanying notes.

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GILEAD SCIENCES, INC.

Condensed Consolidated Statements of Cash Flows

(unaudited)

(in thousands)

	Nine Months Ended September 30,	
	2009	**2008**
Operating Activities:		
Net income	$ 1,826,199	$ 1,412,741
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation	44,312	37,548
Amortization	104,522	77,669
Purchased in-process research and development expense		10,851
Stock-based compensation expenses	138,860	114,605
Excess tax benefits from stock-based compensation	(59,268)	(155,723)
Tax benefits from employee stock plans	66,243	169,328
Deferred income taxes	11,339	18,498
Other non-cash transactions	46,015	9,912
Changes in operating assets and liabilities:		
Accounts receivable, net	(290,013)	(259,086)
Inventories	(40,020)	(298,382)
Prepaid expenses and other assets	(33,356)	(22,275)
Accounts payable	135,212	341,462
Income taxes payable	118,621	8,884
Accrued liabilities	79,327	94,770
Deferred revenues	(23,215)	4,295
Net cash provided by operating activities	2,124,778	1,565,097
Investing Activities:		
Purchases of marketable securities	(1,916,498)	(2,251,247)
Proceeds from sales of marketable securities	1,186,319	1,749,029
Proceeds from maturities of marketable securities	362,849	169,020
Acquisition of CV Therapeutics, net of cash acquired	(1,247,816)	
Acquisition of assets from Navitas		(10,851)
Capital expenditures and other	(203,070)	(73,345)
Net cash used in investing activities	(1,818,216)	(417,394)
Financing Activities:		
Proceeds from issuances of common stock	160,924	176,416
Proceeds from credit facility	400,000	
Repayments of credit facility	(200,000)	
Repurchases of common stock	(756,491)	(1,216,068)
Extinguishment of long-term debt	(305,406)	
Repayments of other long-term obligations	(5,607)	(3,749)
Excess tax benefits from stock-based compensation	59,268	155,723
Distributions to noncontrolling interest	(80,047)	(6,468)
Net cash used in financing activities	(727,359)	(894,146)

Effect of exchange rate changes on cash	(13,906)	(12,219)
Net change in cash and cash equivalents	(434,703)	241,338
Cash and cash equivalents at beginning of period	1,459,302	968,086
Cash and cash equivalents at end of period	$ 1,024,599	$ 1,209,424

See accompanying notes.

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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 and estimates related to revenue recognition, allowance for doubtful accounts, prepaid royalties, intangible assets, 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 the *Consolidation* Topic of the Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC). 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 operating results of companies acquired by us from the date of each acquisition for the applicable reporting periods.

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 (SEC). The condensed consolidated balance sheet at December 31, 2008 has been derived from audited consolidated financial statements at that date. Certain prior year amounts have been revised for the retrospective application of certain guidance in the *Debt* Topic and *Consolidation* Topic of the FASB ASC, as discussed below.

FASB Accounting Standards Codification

In June 2009, the FASB issued Statement of Financial Accounting Standards (SFAS) No. 168, *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles (GAAP) a replacement of SFAS No. 162* (SFAS 168), which establishes the FASB ASC as the source of authoritative U.S. GAAP recognized by the FASB to be applied by non-governmental entities. This guidance is effective for interim periods and fiscal years ending after September 15, 2009. On July 1, 2009, we adopted the provisions of this guidance and as a result, the majority of references to historically issued accounting pronouncements are now superseded by references to the FASB ASC. Certain accounting pronouncements, such as SFAS 168, will remain authoritative until they are integrated into the FASB ASC.

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Convertible Senior Notes

In May 2008, the FASB issued guidance in the *Debt* Topic of the FASB ASC which addresses instruments that require the issuer to settle the principal amount in cash and the conversion spread in cash or net shares at the issuer s option. This guidance 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. This guidance 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 this guidance on a retrospective basis for our convertible senior notes due in 2011 (2011 Notes) and the convertible senior notes due in 2013 (2013 Notes) (collectively, the Notes) and reflected additional interest expense of $13.4 million and $39.6 million, respectively, a related benefit from income taxes of $5.3 million and $15.6 million, respectively, and a decrease in net income per share attributable to Gilead common stockholders on a diluted basis of $0.01 and $0.03, respectively, for the three and nine months ended September 30, 2008 in our Condensed Consolidated Statements of Income. We recorded additional interest expense of $14.2 million and $41.9 million, respectively, a related benefit from income taxes of $5.5 million and $16.3 million, respectively, and a decrease in net income per share attributable to Gilead common stockholders on a diluted basis of $0.01 and $0.03, respectively, for the three and nine months ended September 30, 2009. In addition, the retrospective adoption of this guidance 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 in our Condensed Consolidated Balance Sheet as of December 31, 2008.

Noncontrolling Interest

In December 2007, the FASB issued guidance in the *Consolidation* Topic of the FASB ASC which 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. This guidance also establishes additional reporting requirements that identify and distinguish between the ownership interest of the parent and the interest of the noncontrolling owners. This guidance is effective for interim periods and fiscal years beginning after December 15, 2008 and requires retrospective application to all periods presented.

On January 1, 2009, we adopted the provisions of this guidance on a retrospective basis and reclassified the noncontrolling interest (formerly minority interest) from liabilities to stockholders equity on our Condensed Consolidated Balance Sheets. Our adoption of this guidance also 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 Notes are determined under the treasury stock method.

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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. In accordance with the guidance in the *Earnings Per Share* Topic of the FASB ASC, our common stock resulting from the assumed 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 the conversion prices of $38.75 and $38.10 for the 2011 Notes and 2013 Notes, respectively. The average market prices of our common stock during each of the three and nine months ended September 30, 2009 and 2008 exceeded both of the conversion prices of the Notes and the 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 prices of our common stock during the three and nine months ended September 30, 2009 and the nine months ended September 30, 2008 did not exceed the warrants exercise prices relating to the 2011 Notes. The average market prices of our common stock during the three and nine months ended September 30, 2009 and 2008 did not exceed the warrants exercise prices relating to the 2013 Notes. For the three months ended September 30, 2008, the dilutive effect of warrants related to the 2011 Notes is included in the table below.

Stock options to purchase approximately 16.9 million and 17.1 million weighted-average shares of our common stock were outstanding during the three and nine months ended September 30, 2009, 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. Stock options to purchase approximately 10.0 million and 9.9 million weighted-average shares of our common stock were outstanding during the three and nine months ended September 30, 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):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Numerator:				
Net income attributable to Gilead	$ 673,033	$ 495,853	$ 1,833,543	$ 1,418,936
Denominator:				
Weighted-average shares of common stock outstanding used in the calculation of basic net income per share attributable to Gilead common stockholders	903,319	920,807	906,213	923,894
Effect of dilutive securities:				
Stock options and equivalents	23,288	30,726	24,482	32,260
Conversion spread related to the 2011 Notes	2,765	4,223	2,774	3,914
Conversion spread related to the 2013 Notes	3,052	4,508	3,061	4,199
Warrants related to the Notes		321		
Weighted-average shares of common stock outstanding used in the calculation of diluted net income per share attributable to Gilead common stockholders	932,424	960,585	936,530	964,267

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Concentrations of Risk

We are subject to credit risk from our portfolio of cash equivalents and marketable securities. Under our investment policy, we limit amounts invested in such securities by duration, industry group, investment type and issuer, except for securities issued by the U.S. government. We are not exposed to any significant concentrations of credit risk from these financial instruments. The goals of our investment policy, in order of priority, are as follows: safety and preservation of principal and diversification of risk, liquidity of investments sufficient to meet cash flow requirements and a competitive after-tax rate of return.

We are also subject to credit risk from our accounts receivable related to our product sales. The majority of our trade accounts receivable arises from product sales in the United States and Europe. In certain countries where payments are typically slow, primarily Greece, Italy, Portugal and Spain, our aggregate accounts receivable balance is significant. In most cases, slow payment practices in these countries reflect the pace at which governmental entities reimburse our customers. This, in turn, may increase the financial risk related to certain of our customers. Sales to customers in these countries in Europe that tend to pay relatively slowly have increased and may continue to further increase, therefore increasing the average length of time that we have accounts receivable outstanding. At September 30, 2009, our aggregate accounts receivable in Greece, Italy, Portugal and Spain totaled $723.8 million, of which $247.4 million was more than 120 days past due. To date, we have not experienced significant losses with respect to the collection of our accounts receivable and believe that our past due accounts receivable, net of allowances, as reflected in our Condensed Consolidated Balance Sheets, are collectible. We perform credit evaluations of our customers financial conditions and generally have not required collateral.

2. FAIR VALUE

In April 2009, the FASB issued guidance in the *Financial Instruments* Topic of the FASB ASC which extends the disclosure requirements regarding the fair value of financial instruments to interim financial statements. This guidance is effective for interim periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. On April 1, 2009, we adopted the provisions of this guidance on a prospective basis for our financial instruments. Our financial instruments consist principally of cash and cash equivalents, marketable securities, accounts receivable, foreign currency exchange forward and option contracts, accounts payable and long-term debt. Cash and cash equivalents, marketable securities and foreign currency exchange contracts that hedge accounts receivable and forecasted sales are reported at their respective fair values on our Condensed Consolidated Balance Sheets. The carrying value and fair value of the Notes were $1.14 billion and $1.67 billion, respectively, as of September 30, 2009. The fair value of the Notes was measured using Level 2 inputs. The remaining financial instruments are reported on our Condensed Consolidated Balance Sheets at amounts that approximate current fair values.

In September 2006, the FASB issued guidance in the *Fair Value* Topic of the FASB ASC that defines fair value, establishes a framework for measuring fair value and expands the disclosure requirements regarding fair value measurements. This guidance 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 and is effective for fiscal years beginning after November 15, 2008 for all other non-financial assets and liabilities. On January 1, 2008, we adopted the provisions of this guidance on a prospective basis for our 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, and on January 1, 2009, we adopted the provisions of this guidance on a prospective basis for our non-financial assets and liabilities that are not recognized or disclosed at fair value on a recurring basis. The adoption of the guidance had no effect on our consolidated net income for the three and nine months ended September 30, 2009.

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The fair value guidance in the FASB ASC requires that we determine the fair value of financial and non-financial assets and liabilities using the fair value hierarchy established in the guidance 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

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 following table summarizes, for assets or liabilities recorded at fair value, the respective fair value and the classification by level of input within the fair value hierarchy defined above (in thousands):

	September 30, 2009				December 31, 2008			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Assets:								
Debt securities:								
U.S. treasury securities	$ 377,856	$	$	$ 377,856	$ 202,243	$	$	$ 202,243
U.S. government sponsored entity debt securities		829,411		829,411		681,774		681,774
Municipal debt securities		295,597		295,597		332,637		332,637
Corporate debt securities		688,133		688,133		450,730		450,730
Residential mortgage-backed securities		107,915		107,915		134,761		134,761
Student loan-backed securities			103,398	103,398			101,798	101,798
Other debt securities		60,617	812	61,429		57,147	835	57,982
Total debt securities	377,856	1,981,673	104,210	2,463,739	202,243	1,657,049	102,633	1,961,925
Equity securities	1,785			1,785	759			759
Derivatives		14,114		14,114		90,870		90,870
	$ 379,641	$ 1,995,787	$ 104,210	$ 2,479,638	$ 203,002	$ 1,747,919	$ 102,633	$ 2,053,554
Liabilities:								
Derivatives	$	$ 74,301	$	$ 74,301	$	$ 150	$	$ 150

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Balance, beginning of period	$ 102,898	$ 131,276	$ 102,633	$ 7,258
Total realized and unrealized gains (losses) included in:				
Interest and other income, net		325	(29)	(1,939)
Other comprehensive income, net	1,894	(6,244)	7,661	(14,932)
Sales of marketable securities	(582)	(3,207)	(6,055)	(25,936)
Transfers into Level 3				157,699
Balance, end of period	$ 104,210	$ 122,150	$ 104,210	$ 122,150
Total losses included in earnings attributable to the change in unrealized losses relating to assets still held at the reporting date	$	$	$ (29)	$ (2,264)

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 eight 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 illiquidity discount resulting in an annual discount rate of 2.7%. Our auction rate securities reset every seven to 35 days with maturity dates ranging from 2023 through 2041 and have annual interest rates ranging from 0.5% to 1.2%. As of September 30, 2009, our auction rate securities continued to earn interest.

In April 2009, the FASB also issued additional guidance on estimating fair value when the volume and level of activity for an asset or liability have significantly decreased in relation to normal market activity for the asset or liability and is applicable to the valuation of auction rate securities held by us for which there was no active market as of September 30, 2009.

Our auction rate securities were recorded in long-term marketable securities on our Condensed Consolidated Balance Sheets at September 30, 2009 and December 31, 2008. Although there continued to be failed auctions as well as lack of market activity and liquidity in 2009, we believe we had no other-than-temporary impairments on these securities as of September 30, 2009 because we do not intend to sell these securities and it is not more likely than not that we will be required to sell these securities before the recovery of their amortized cost basis.

3. AVAILABLE-FOR-SALE SECURITIES

In April 2009, the FASB issued guidance in the *Investments Debt and Equity Securities* Topic of the FASB ASC which addresses the recognition and presentation of other-than-temporary impairments, provides some new disclosure requirements as well as extends certain annual disclosure requirements to interim periods. This guidance is effective for interim periods and fiscal years ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. On April 1, 2009, we adopted the provisions of this guidance on a prospective basis for our available-for-sale securities.

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The following table is a summary of available-for-sale debt and equity securities recorded in cash equivalents or marketable securities in our Condensed Consolidated Balance Sheets. Estimated fair values of available-for-sale securities are generally based on prices obtained from commercial pricing services (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
September 30, 2009				
Debt securities:				
U.S. treasury securities	$ 376,177	$ 1,683	$ (4)	$ 377,856
U.S. government sponsored entity debt securities	818,921	10,533	(43)	829,411
Municipal debt securities	291,872	3,761	(36)	295,597
Corporate debt securities	676,086	12,085	(38)	688,133
Residential mortgage-backed securities	105,929	2,134	(148)	107,915
Student loan-backed securities	116,550		(13,152)	103,398
Other debt securities	60,569	911	(51)	61,429
Total debt securities	2,446,104	31,107	(13,472)	2,463,739
Equity securities	1,450	335		1,785
Total	$ 2,447,554	$ 31,442	$ (13,472)	$ 2,465,524
December 31, 2008				
Debt securities:				
U.S. treasury securities	$ 199,962	$ 2,281	$	$ 202,243
U.S. government sponsored entity debt securities	669,721	12,105	(52)	681,774
Municipal debt securities	328,776	3,987	(126)	332,637
Corporate debt securities	450,567	2,146	(1,983)	450,730
Residential mortgage-backed securities	134,409	926	(574)	134,761
Student loan-backed securities	122,400		(20,602)	101,798
Other debt securities	58,468	735	(1,221)	57,982
Total debt securities	1,964,303	22,180	(24,558)	1,961,925
Equity securities	1,451		(692)	759
Total	$ 1,965,754	$ 22,180	$ (25,250)	$ 1,962,684

As of September 30, 2009 and December 31, 2008, other debt securities consisted primarily of foreign government and agency securities as well as other asset-backed securities.

The following table summarizes the classification of the available-for-sale debt and equity securities on our Condensed Consolidated Balance Sheets (in thousands):

	September 30, 2009	December 31, 2008
Cash and cash equivalents	$ 197,993	$ 182,347
Short-term marketable securities	330,713	330,760
Long-term marketable securities	1,936,818	1,449,577
Total	$ 2,465,524	$ 1,962,684

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The following table summarizes our portfolio of available-for-sale debt securities by contractual maturity (in thousands):

	September 30, 2009		December 31, 2008	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
Less than one year	$ 525,649	$ 528,706	$ 510,983	$ 513,106
Greater than one year but less than five years	1,630,599	1,655,776	1,122,885	1,137,877
Greater than five years but less than ten years	42,702	43,653	43,239	43,994
Greater than ten years	247,154	235,604	287,196	266,948
Total	$ 2,446,104	$ 2,463,739	$ 1,964,303	$ 1,961,925

The following table summarizes the gross realized gains and losses related to sales of marketable securities (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Gross realized gains on sales	$ 1,734	$ 4,206	$ 9,108	$ 16,756
Gross realized losses on sales	$ (212)	$ (3,607)	$ (1,169)	$ (8,572)

The cost of securities sold was determined based on the specific identification method.

The following table summarizes our available-for-sale debt securities that were in a continuous unrealized loss position, but were not deemed to be other-than-temporarily impaired (in thousands):

	Less Than 12 Months		12 Months or Greater		Total	
	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value
September 30, 2009						
Debt securities:						
U.S. treasury securities	$ (4)	$ 104,123	$	$	$ (4)	$ 104,123
U.S. government sponsored entity debt securities	(43)	40,614			(43)	40,614
Municipal debt securities	(36)	36,322			(36)	36,322
Corporate debt securities	(26)	78,860	(12)	7,485	(38)	86,345
Residential mortgage-backed securities	(6)	1,550	(142)	1,424	(148)	2,974
Student loan-backed securities			(13,152)	103,398	(13,152)	103,398
Other debt securities	(17)	18,891	(34)	9,574	(51)	28,465
Total	$ (132)	$ 280,360	$ (13,340)	$ 121,881	$ (13,472)	$ 402,241
December 31, 2008						
Debt securities:						
U.S. treasury securities	$	$	$	$	$	$
U.S. government sponsored entity debt securities	(52)	46,944			(52)	46,944
Municipal debt securities	(126)	24,871			(126)	24,871
Corporate debt securities	(1,599)	138,726	(384)	9,887	(1,983)	148,613
Residential mortgage-backed securities	(217)	37,862	(357)	1,400	(574)	39,262
Student loan-backed securities	(20,602)	101,798			(20,602)	101,798
Other debt securities	(137)	6,789	(1,084)	12,837	(1,221)	19,626
Total	$ (22,733)	$ 356,990	$ (1,825)	$ 24,124	$ (24,558)	$ 381,114

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As of September 30, 2009 and December 31, 2008, the gross unrealized losses were primarily caused by an increase in the yield-to-maturity of the underlying securities, and approximately 18% and 29%, respectively, of the total number of our investments were in unrealized loss positions. In the case of auction rate securities, gross unrealized losses were caused by a higher discount rate used in the valuation of these securities as compared to the coupon rates of these securities. No significant facts or circumstances have arisen to indicate that there has been any deterioration in the creditworthiness of the issuers of these securities. Based on our review of these securities, we believe we had no other-than-temporary impairments on these securities as of September 30, 2009 and December 31, 2008 because we do not intend to sell these securities and it is not more likely than not that we will be required to sell these securities before the recovery of their amortized cost basis.

During the three and nine months ended September 30, 2009, the net unrealized gains on available-for-sale securities included in accumulated other comprehensive income (OCI) were $8.3 million and $21.7 million, respectively, and gains of $1.0 million and $5.1 million, respectively, were reclassified out of accumulated OCI into interest and other income, net.

4. DERIVATIVE FINANCIAL INSTRUMENTS

In March 2008, the FASB issued guidance in the *Derivatives and Hedging* Topic of the FASB ASC 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. This guidance is effective for interim periods and fiscal years beginning after November 15, 2008. On January 1, 2009, we adopted the provisions of this guidance 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 the *Derivatives and Hedging* Topic of the FASB ASC, 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 the *Derivatives and Hedging* Topic of the FASB ASC. 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 assess hedge effectiveness on a prospective basis by performing 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. We assess hedge effectiveness on a retrospective basis using a dollar offset approach monthly. We exclude time

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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 or loss within 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 September 30, 2009 will be reclassified to product sales within 12 months.

We had notional amounts on foreign currency exchange forward and option contracts outstanding of $3.14 billion and $2.39 billion at September 30, 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 September 30, 2009 (in thousands):

	Asset Derivatives		Liability Derivatives	
	Location	Fair Value	Location	Fair Value
Derivatives designated as hedges:				
Foreign currency exchange contracts	Other current assets	$ 11,718	Other accrued liabilities	$ 65,796
Foreign currency exchange contracts	Other noncurrent assets	2,394	Other long-term obligations	8,467
Total derivatives designated as hedges		14,112		74,263
Derivatives not designated as hedges:				
Foreign currency exchange contracts	Other current assets	2	Other accrued liabilities	38
Total derivatives not designated as hedges		2		38
Total derivatives		$ 14,114		$ 74,301

The following table summarizes the effect of our foreign currency exchange contracts on our Condensed Consolidated Statements of Income (in thousands):

	Three Months Ended September 30, 2009	Nine Months Ended September 30, 2009
Derivatives designated as hedges:		
Net losses recognized in OCI (effective portion)	$ (55,640)	$ (17,003)
Net gains reclassified from accumulated OCI into product sales (effective portion)	$ 16,714	$ 89,771
Net gains (losses) recognized in interest and other income, net (ineffective portion and amounts excluded from effectiveness testing)	$ 806	$ (14,726)
Derivatives not designated as hedges:		
Net losses recognized in interest and other income, net	$ (37,519)	$ (28,479)

The net unrealized losses related to our cash flow hedges included in accumulated OCI, net of taxes, were $51.9 million at September 30, 2009. Net unrealized gains related to our cash flow hedges included in accumulated OCI, net of taxes, were $54.9 million at December 31, 2008.

5. ACQUISITION OF CV THERAPEUTICS, INC.

In December 2007, the FASB issued guidance in the *Business Combinations* Topic of the FASB ASC which establishes principles and requirements for recognizing and measuring assets acquired, liabilities assumed and any noncontrolling interests in the acquiree in a business

combination. This guidance also provides clarification for recognizing and measuring goodwill acquired in a business combination; requires purchased in-process research and development (IPR&D) to be capitalized at fair value as intangible assets at the time of acquisition;

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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. This guidance is effective for business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. On January 1, 2009, we adopted the provisions of this guidance on a prospective basis and applied it to our acquisition of CV Therapeutics, Inc. (CV Therapeutics) as discussed below.

On April 15, 2009, we acquired CV Therapeutics through a cash tender offer under the terms of an agreement and plan of merger entered into in March 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 had two marketed products, Ranexa for the treatment of chronic angina and Lexiscan injection for use as a pharmacologic stress agent in radionuclide myocardial perfusion imaging in patients unable to undergo adequate exercise stress. CV Therapeutics also had several product candidates in clinical development for the treatment of pulmonary and cardiovascular diseases. We believe the acquisition will provide us with an opportunity to further expand into the cardiovascular therapeutic area.

The CV Therapeutics acquisition was accounted for as a business combination in accordance with the guidance in the *Business Combinations* Topic of the FASB ASC. The results of operations of CV Therapeutics since April 15, 2009 have been included in our Condensed Consolidated Statement of Operations, and were not significant. The acquisition date was determined to be April 15, 2009 as that is the date on which we acquired approximately 89% of the outstanding shares of common stock of CV Therapeutics and obtained effective control of the company. The acquisition was completed two days later on April 17, 2009, at which time CV Therapeutics became a wholly-owned subsidiary.

The aggregate consideration transferred to acquire CV Therapeutics was $1.39 billion, and consisted of cash paid for common stock and other equity instruments at or prior to closing of $1.38 billion and the fair value of vested stock options assumed of $15.7 million.

In accordance with the acquisition merger agreement, the number of Gilead stock options and restricted stock units into which assumed CV Therapeutics stock options and restricted stock units were converted was determined based on the option conversion ratio. This conversion ratio was calculated by taking the per share acquisition price of $20.00 and dividing it by the average closing price of our common stock for the five consecutive trading days immediately preceding (but not including) the closing date of April 17, 2009, which was $46.24 per share. The fair value of stock options assumed was calculated using a Black-Scholes valuation model with the following assumptions: market price of $44.54 per share, which was the closing price of our common stock on the acquisition date; expected term ranging from 0.1 to 5.2 years; risk-free interest rate ranging from 0.1% to 1.7%; expected volatility ranging from 37.4% to 43.2%; and no dividend yield. The fair value of restricted stock units assumed was calculated using the acquisition-date closing price of $44.54 per share for our common stock.

We included the fair value of vested stock options assumed by us of $15.7 million in the consideration transferred for the acquisition. There were no vested restricted stock units assumed by us. The estimated fair value of unvested stock options and restricted stock units assumed by us of $11.2 million was not included in the consideration transferred and is being recognized as stock-based compensation expense over the remaining future vesting period of the awards.

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The following table summarizes the assets acquired and liabilities assumed at April 15, 2009 (in thousands):

Intangible assets marketed products	$ 951,200
Intangible assets IPR&D	180,100
Goodwill	316,818
Deferred tax assets	413,816
Deferred tax liabilities	(442,969)
Other assets/liabilities	
Cash and cash equivalents	129,087
Marketable securities	116,363
Accounts receivable	9,136
Inventories	50,455
Prepaids and other current assets	60,671
Property, plant and equipment	11,672
Other assets	20,162
Accounts payable	(5,089)
Accrued and other current liabilities	(87,898)
Convertible senior notes	(303,060)
Other liabilities	(27,906)
Total other net liabilities	(26,407)
Total consideration transferred	$ 1,392,558

Intangible Assets

A substantial portion of the assets acquired consisted of intangible assets related to CV Therapeutics two marketed products, Ranexa and Lexiscan, and CV Therapeutics IPR&D projects. Management determined that the estimated acquisition-date fair values of the intangible assets related to the marketed products and IPR&D projects were $951.2 million and $180.1 million, respectively.

Of the $951.2 million of intangible assets related to the marketed products, $688.4 million related to Ranexa and $262.8 million related to Lexiscan. In accordance with the guidance in the *Intangibles Goodwill and Other* Topic of the FASB ASC, we have determined that these intangible assets have finite useful lives and will be amortized over their respective useful lives, which we estimated to be the periods over which the associated product patents will expire as those are the periods over which the intangible assets are expected to contribute to the future cash flows of the related products.

Of the $180.1 million of intangible assets related to the IPR&D projects, $93.4 million related to CVT-3619, a product candidate in Phase 1 clinical studies for the treatment of hypertriglyceridemia. The remaining balance of the intangible assets related to IPR&D projects represented various other in-process projects with no single project comprising a significant portion of the total value. In accordance with the guidance in the *Intangibles Goodwill and Other* Topic of the FASB ASC, intangible assets related to IPR&D projects are considered to be indefinite-lived until the completion or abandonment of the associated research and development (R&D) efforts. During the period the assets are considered indefinite-lived, they will not be amortized but will be tested for impairment on an annual basis and between annual tests if we become aware of any events occurring or changes in circumstances that would indicate a reduction in the fair value of the IPR&D projects below their respective carrying amounts. If and when development is complete, which generally occurs if and when regulatory approval to market a product is obtained, the associated assets would be deemed finite-lived and would then be amortized based on their respective estimated useful lives at that point in time.

The estimated fair value of the intangible assets related to the marketed products and IPR&D projects was determined using the income approach, which discounts expected future cash flows to present value. We

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estimated the fair value of these intangible assets using a present value discount rate of 9%, which is based on the estimated weighted-average cost of capital for companies with profiles substantially similar to that of CV Therapeutics. This is comparable to the estimated internal rate of return for CV Therapeutics operations and represents the rate that market participants would use to value the intangible assets. For the intangible assets related to the IPR&D projects, we compensated for the differing phases of development of each project by probability-adjusting our estimation of the expected future cash flows associated with each project. We then determined the present value of the expected future cash flows using the discount rate of 9%. The projected cash flows from the IPR&D projects were based on key assumptions such as estimates of revenues and operating profits related to the projects considering their stages of development; the time and resources needed to complete the development and approval of the related product candidates; the life of the potential commercialized products and associated risks, including the inherent difficulties and uncertainties in developing a drug compound such as obtaining marketing approval from the U.S. Food and Drug Administration (FDA) and other regulatory agencies; and risks related to the viability of and potential alternative treatments in any future target markets.

We are amortizing the intangible asset related to Ranexa over its estimated useful life using an amortization rate derived from our forecasted future product sales for Ranexa. We are amortizing the intangible asset related to Lexiscan over its estimated useful life on a straight-line basis. Given that current Lexiscan revenues consist of royalties received from a collaboration partner and we will have limited ongoing access and visibility into that partner s future sales forecasts, we cannot make a reasonable estimate of the amortization rate utilizing a forecasted product sales approach. The weighted-average amortization period for these intangible assets is approximately 10 years.

Deferred Tax Assets and Deferred Tax Liabilities

The $413.8 million of deferred tax assets resulting from the acquisition was primarily related to federal and state net operating loss and tax credit carryforwards. The $443.0 million of deferred tax liabilities resulting from the acquisition was primarily related to the difference between the book basis and tax basis of the intangible assets related to the marketed products and IPR&D projects. We have concluded, based on the guidance set forth in the *Income Taxes* Topic of the FASB ASC, that it is more likely than not that we will not realize the benefit from deferred tax assets related to certain state net operating loss carryforwards. As a result, a valuation allowance of $15.1 million was recorded related to those deferred tax assets. For presentation purposes, the $443.0 million of deferred tax liabilities, all of which is of a noncurrent nature, has been netted against noncurrent deferred tax assets on our Condensed Consolidated Balance Sheet.

Convertible Senior Notes

As a result of the acquisition, we assumed convertible notes from CV Therapeutics consisting of 2.75% senior subordinated convertible notes due 2012, 3.25% senior subordinated convertible notes due 2013 and 2.0% senior subordinated convertible debentures due 2023. In accordance with the guidance in the *Business Combinations* Topic of the FASB ASC, all of these convertible notes were recognized at their fair values at the acquisition date. In May 2009, we offered to repurchase these convertible notes in consideration for their par value plus accrued interest, as required under the terms of the respective convertible note agreements following the occurrence of a change in control or fundamental change as defined in the agreements. As of September 30, 2009, substantially all of these convertible notes have been extinguished.

Goodwill

The excess of the consideration transferred over the fair values assigned to the assets acquired and liabilities assumed was $316.8 million, which represents the goodwill amount resulting from the acquisition. Management believes that the goodwill mainly represents the synergies and economies of scale expected from combining the operations of Gilead and CV Therapeutics. None of the goodwill is expected to be deductible for income tax purposes. We recorded the goodwill as an intangible asset in our Condensed Consolidated Balance Sheet as of

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the acquisition date. In accordance with the guidance in the *Intangibles Goodwill and Other* Topic of the FASB ASC, goodwill is tested for impairment on an annual basis and between annual tests if we become aware of any events occurring or changes in circumstances that would indicate a reduction in the fair value of the goodwill below its carrying amount.

Acquisition-Related Transaction Costs and Restructuring Expenses

We recognized $8.4 million of acquisition-related transaction costs in selling, general and administrative (SG&A) expenses for the nine months ended September 30, 2009, which consisted primarily of investment banker fees, legal and accounting costs related to the acquisition. In addition, during the three months ended June 30, 2009, we approved a plan to realize certain synergies between us and CV Therapeutics, re-align our cardiovascular operations and eliminate certain redundancies. The restructuring plan includes the consolidation and re-alignment of the cardiovascular R&D organization, the exit from certain of our facilities and the termination of certain contractual obligations. As a result of this restructuring plan, we recorded $2.6 million and $5.8 million in SG&A expenses and R&D expenses, respectively, for the three months ended September 30, 2009, primarily related to employee severance and termination benefits costs. For the nine months ended September 30, 2009, we recorded $15.5 million and $17.0 million in SG&A expenses and R&D expenses, respectively, primarily related to employee severance and termination benefits costs. These costs were recorded in accordance with the guidance in the *Exit or Disposal Cost Obligations* Topic of the FASB ASC. We expect the total amount to be incurred in connection with the significant activities of our restructuring plan to be approximately $34 million for employee severance and termination benefits, $22 million for facilities-related costs and $6 million for employee relocation costs. These costs are expected to be incurred through 2010 with the majority of the expenses to be incurred by the end of 2009.

The following table summarizes the restructuring liabilities accrued for employee severance and termination benefits and changes in those amounts during the period (in thousands):

Balance at March 31, 2009	$
Costs incurred during the period	21,575
Costs paid or settled during the period	(11,448)
Balance at June 30, 2009	10,127
Costs incurred during the period	8,400
Costs paid or settled during the period	(11,181)
Balance at September 30, 2009	$ 7,346

Pro Forma Information

The following unaudited pro forma information presents the combined results of operations of Gilead and CV Therapeutics for the three and nine months ended September 30, 2009 and 2008 as if the acquisition of CV Therapeutics had been completed on January 1, 2009 and 2008, respectively, with adjustments to give effect to pro forma events that are directly attributable to the acquisition. The unaudited pro forma results do not reflect any operating efficiencies or potential cost savings which may result from the consolidation of the operations of Gilead and CV Therapeutics. Accordingly, these unaudited pro forma results are presented for illustrative purposes and are not intended to represent or be indicative of the actual results of operations of the combined company that would have been achieved had the acquisition occurred at the beginning of each period presented, nor are they intended to represent or be indicative of future results of operations.

The following table summarizes the unaudited pro forma results of operations (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Total revenues	$ 1,801,389	$ 1,405,980	$ 5,022,720	$ 4,014,068
Net income attributable to Gilead	$ 673,033	$ 454,899	$ 1,734,860	$ 1,285,586

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6. 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. Based on the estimated relative fair values, the purchase price was allocated primarily 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.

7. INVENTORIES

Inventories are summarized as follows (in thousands):

	September 30, 2009	December 31, 2008
Raw materials	$ 402,161	$ 505,106
Work in process	256,583	140,333
Finished goods	359,083	282,429
Total inventories	$ 1,017,827	$ 927,868

As of September 30, 2009 and December 31, 2008, the joint ventures formed by Gilead and BMS, which are included in our Condensed Consolidated Financial Statements, held $660.8 million and $607.7 million in inventory, respectively, of efavirenz active pharmaceutical ingredient purchased from BMS at BMS s estimated net selling price of efavirenz.

8. GOODWILL AND OTHER INTANGIBLE ASSETS

The following table summarizes the changes in the carrying amount of goodwill (in thousands):

Balance at December 31, 2008	$ 120,648
Goodwill resulting from the acquisition of CV Therapeutics	316,818
Balance at September 30, 2009	$ 437,466

The following table summarizes our finite-lived intangible assets (in thousands):

	September 30, 2009		December 31, 2008	
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Intangible asset Ranexa	$ 688,400	$ 14,164	$	$
Intangible asset Lexiscan	262,800	11,799		
Other	22,095	9,296	8,942	6,582
Total	$ 973,295	$ 35,259	$ 8,942	$ 6,582

Amortization expense related to intangible assets was $15.2 million and $28.7 million for the three and nine months ended September 30, 2009, respectively, and was recorded primarily in cost of goods sold in our Condensed Consolidated Statements of Income. Amortization expense related to intangible assets was $0.7 million and $2.1 million for the three and nine months ended September 30, 2008, respectively, and was recorded primarily in SG&A expenses in our Condensed Consolidated Statements of Income.

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As of September 30, 2009, the estimated future amortization expense associated with our intangible assets for the remaining three months of 2009 and each of the five succeeding fiscal years are as follows (in thousands):

Fiscal Year	
2009 (remaining three months)	$ 14,718
2010	68,546
2011	77,626
2012	86,375
2013	92,883
2014	97,351
Total	$ 437,499

As of September 30, 2009 we had indefinite-lived intangible assets of $180.1 million related to purchased IPR&D from our acquisition of CV Therapeutics.

9. COLLABORATIVE ARRANGEMENTS

As a result of entering into strategic collaborations from time to time, we may hold investments in non-public companies. We review our interests in our investee companies for consolidation and/or appropriate disclosure based on the guidance in the *Consolidation* Topic of the FASB ASC. As of September 30, 2009, we determined that certain of our investee companies are variable interest entities; however, other than with respect to our joint ventures with BMS, we are not the primary beneficiary and therefore do not consolidate these investees.

Bristol-Myers Squibb Company

North America

In December 2004, we entered into a collaboration with BMS in the United States to develop and commercialize a single tablet regimen containing our Truvada and BMS s Sustiva (efavirenz), which we sell as Atripla. The collaboration is structured as a joint venture and operates as a limited liability company named Bristol-Myers Squibb & Gilead Sciences, LLC, which we consolidate. The ownership interests of the joint venture and thus the sharing of product revenue and costs reflect the respective economic interests of BMS and us and are based on the proportions of the net selling price of Atripla attributable to efavirenz and Truvada. Since the net selling price for Truvada may change over time relative to the net selling price of efavirenz, both BMS s and our respective economic interests in the joint venture may vary annually.

We share marketing and sales efforts with BMS and both parties are obligated to provide equivalent sales force efforts for a minimum number of years. We are responsible for accounting, financial reporting, tax reporting and product distribution for the joint venture. Both parties provide their respective bulk active pharmaceutical ingredients to the joint venture at their approximate market values. In July 2006, the joint venture received approval from the FDA to sell Atripla in the United States. In September 2006, we and BMS amended the joint venture s collaboration agreement to allow the joint venture to sell Atripla into Canada and in October 2007, the joint venture received approval from Health Canada to sell Atripla in Canada. As of September 30, 2009 and December 31, 2008, the joint venture held efavirenz active pharmaceutical ingredient which it purchased from BMS at BMS s estimated net selling price of efavirenz in the U.S. market. These amounts are included in inventories on our Consolidated Balance Sheets. As of September 30, 2009 and December 31, 2008, total assets held by the joint venture were $1.28 billion and $1.07 billion, respectively, and consisted primarily of cash and cash equivalents, accounts receivable (including intercompany receivables with Gilead) and inventories. As of September 30, 2009 and December 31, 2008, total liabilities held by the joint venture were $996.9 million and $548.0 million, respectively, and consisted primarily of accounts payable (including intercompany payables with Gilead) and other accrued expenses. These asset and liability amounts do not reflect the impact of

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intercompany eliminations that are included in the Condensed Consolidated Balance Sheets. Although we are the primary beneficiary of the joint venture, the legal structure of the joint venture limits the recourse that its creditors will have over our general credit or assets.

Europe

In December 2007, Gilead Sciences Limited (GSL), one of our wholly-owned subsidiaries in Ireland, and BMS entered into a collaboration arrangement to commercialize and distribute Atripla in the European Union, Norway, Iceland, Switzerland and Liechtenstein (the European Territory). The parties formed a limited liability company which we consolidate, to manufacture Atripla for distribution in the European Territory using efavirenz that it purchases from BMS at BMS s estimated net selling price of efavirenz in the European Territory. We are responsible for product distribution, inventory management and warehousing. Through our local subsidiaries, we have primary responsibility for order fulfillment, collection of receivables, customer relations and handling of sales returns in all the territories where we co-promote Atripla with BMS. We are also responsible for accounting, financial reporting and tax reporting for the collaboration. In December 2007, the European Commission approved Atripla for sale in the European Union. As of September 30, 2009 and December 31, 2008, efavirenz purchased from BMS at BMS s estimated net selling price of efavirenz in the European Territory is included in inventories on our Consolidated Balance Sheets.

The parties also formed a limited liability company to hold the marketing authorization for Atripla in Europe. We have primary responsibility for regulatory activities and we share marketing and sales efforts with BMS. In the major market countries, both parties have agreed to provide equivalent sales force efforts. Revenue and cost sharing is based on the relative ratio of the respective net selling prices of Truvada and efavirenz.

Tibotec Pharmaceuticals

In July 2009, GSL entered into a license and collaboration agreement with Tibotec Pharmaceuticals (Tibotec), a wholly-owned subsidiary of Johnson & Johnson, to develop and commercialize a new once-daily fixed-dose combination (the Combination Product) containing our Truvada and Tibotec s investigational non-nucleoside reverse transcriptase inhibitor, TMC278 (25 mg rilpivirine hydrochloride), which is currently in Phase 3 clinical trials. Under the agreement, Tibotec granted us an exclusive license to the Combination Product for administration to adults in a once daily, oral dosage form, worldwide excluding low-income countries and Japan. Neither party is restricted from combining its drug products with any other drugs.

In accordance with the terms of the agreement, we will reimburse up to 71.5 million (approximately $100.0 million) of development costs incurred by Tibotec for TMC278 through December 2011, and we are required to use commercially reasonable efforts to develop and formulate the Combination Product, including the completion of bioequivalence studies. For the three months ended September 30, 2009, we recorded $52.4 million in reimbursable R&D expenses incurred by Tibotec in the development of TMC278. Tibotec is required to use commercially reasonable efforts to develop TMC278 and obtain its approval in the United States and Europe. We will manufacture the Combination Product and assume the lead role in registration, distribution and, subject to regulatory approval, commercialization of the Combination Product in the licensed countries. Tibotec will have the right to detail the Combination Product in the licensed countries, and, at its option, can request that it be the distributor of the Combination Product in a limited number of such countries. The price of the Combination Product is expected to be the sum of the price of Truvada and the price of TMC278 purchased separately. We expect to recognize product sales revenue from future sales of the Combination Product if and when it is approved. The cost of TMC278 to be purchased by us from Tibotec for the Combination Product will approximate the market price of TMC278, less a specified percentage of up to 30%.

Either party may terminate the agreement if the Combination Product is withdrawn from the market, if a party materially breaches the agreement or if certain clinical or regulatory conditions are not met. We may terminate the agreement in the United States and Canada on or after the expiration of the last to expire patent for

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tenofovir disoproxil fumarate in the United States, and may terminate the agreement in any other country on or after the expiration of the last to expire patent for tenofovir disoproxil fumarate in a country of the European Union. Tibotec may terminate the agreement in the United States and Canada on or after the expiration of the last to expire patent for TMC278 in the United States, and may terminate the agreement in any other country on or after the expiration of the last to expire patent for TMC278 in a country of the European Union.

10. CREDIT FACILITY

Under our amended and restated credit agreement, we, along with our wholly-owned subsidiary, Gilead Biopharmaceutics Ireland Corporation, may borrow up to an aggregate of $1.25 billion in revolving credit loans. The credit agreement also includes a sub-facility for swing-line loans and letters of credit. Loans under the credit agreement bear interest at an interest rate of either LIBOR plus a margin ranging from 0.20 percent to 0.32 percent or the base rate, as defined in the credit agreement. In April 2009, in connection with the acquisition of CV Therapeutics, we borrowed $400.0 million under the credit agreement to partially fund the acquisition. As of September 30, 2009, we have repaid $200.0 million under this credit agreement and expect to repay the remaining $200.0 million in the fourth quarter of 2009 using cash flow generated from operations. The credit agreement will terminate and all amounts owing thereunder shall be due and payable on December 17, 2012. We 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. As of September 30, 2009, we had letters of credit outstanding under this credit facility of $3.8 million, and the amount available under the credit facility was approximately $1.05 billion. We are required to comply with certain covenants under this credit facility and as of September 30, 2009, we were in compliance with all such covenants.

11. 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 putative class action lawsuit against the Company and six current and former executives our Chairman and 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 SEC, by making certain alleged false and misleading statements. The plaintiffs 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 denied the 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. On June 3, 2009, the district court granted in part and denied in part our motion to dismiss and gave plaintiffs leave to amend the complaint. On July 10, 2009, plaintiffs filed a fifth consolidated amended complaint. We filed a motion to dismiss the fifth consolidated amended complaint, which the district court heard on October 9, 2009. In an order dated October 13, 2009, the court granted in part and denied in part our motion to dismiss. With respect to the Section 10(b) claim, the court denied the motion as to Gilead and two of the six individual defendants; the court granted the motion as to four of the individual defendants. As to the Section 20(a) claim, the court denied the motion as to all of the individual defendants; therefore, all defendants remain in the case. The court has ordered the defendants to file an answer to the complaint and has scheduled a case management conference for January 22, 2010. 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 August 12, 2009, we received a subpoena from the Office of the Inspector General of the U.S. Department of Health and Human Services requesting documents regarding the development, marketing and

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sales of Ranexa. We have been cooperating and will continue to cooperate with any related governmental inquiry. It is not possible to predict the outcome of this inquiry, and as such, no amounts have been accrued related to the outcome of this inquiry.

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.

12. STOCK-BASED COMPENSATION EXPENSES

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Cost of goods sold	$ 2,461	$ 2,592	$ 8,486	$ 7,134
Research and development expenses	21,916	17,680	63,192	49,945
Selling, general and administrative expenses	24,230	21,322	72,255	57,526
Stock-based compensation expenses included in total costs and expenses	48,607	41,594	143,933	114,605
Income tax effect	(12,389)	(11,513)	(37,466)	(32,114)
Stock-based compensation expenses included in net income	$ 36,218	$ 30,081	$ 106,467	$ 82,491

13. STOCKHOLDERS EQUITY

Stock Option Plan

In May 2009, our stockholders approved an amendment to the Gilead Sciences, Inc. 2004 Equity Incentive Plan (2004 Plan) to increase the number of shares authorized for issuance under the 2004 Plan by 20,000,000 shares of our common stock. As of September 30, 2009, there were 56,290,640 shares authorized and available for future grant under the 2004 Plan.

In connection with the acquisition of CV Therapeutics, we assumed CV Therapeutics 1994 Equity Incentive Plan, as amended and restated, Non-Employee Directors Stock Option Plan, as amended and restated, 2000 Equity Incentive Plan, as amended and restated, 2000 Nonstatutory Incentive Plan, as amended and restated and 2004 Employee Commencement Incentive Plan, as amended and restated (collectively, the CV Therapeutics Plans). The majority of options that were issued and outstanding under the CV Therapeutics Plans as of April 15, 2009 were converted into options to purchase approximately 1.8 million shares of our common stock and remain subject to their original terms and conditions. There are no shares available for future grant under the CV Therapeutics Plans.

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 (Board) 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

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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 and nine months ended September 30, 2009, in addition to the additional shares that we received under the terms of the accelerated share repurchase transaction completed in March 2009, we repurchased and retired 6,220,000 and 16,546,133 shares, respectively, of our common stock at an average purchase price of $46.32 and $45.70 per share, respectively, for an aggregate purchase price of $288.1 million and $756.2 million, respectively, through open market transactions. As of September 30, 2009, the remaining authorized amount of stock repurchases that may be made under our $3.00 billion Board-authorized stock repurchase program which expires in December 2010 was $241.9 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 additional paid-in capital (APIC) based on an estimated average sales price per issued share with the excess amounts charged to retained earnings. As a result of our open market stock repurchases during the nine months ended September 30, 2009, we reduced common stock and APIC by an aggregate of $47.3 million and charged $709.2 million to retained earnings.

Comprehensive Income

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Net income	$ 670,478	$ 493,693	$ 1,826,199	$ 1,412,741
Other comprehensive income (loss):				
Net foreign currency translation gain (loss)	2,520	(10,566)	9,735	(6,903)
Net unrealized gain (loss) on available-for-sale securities, net of related tax effects	7,343	(12,268)	16,601	(28,217)
Net unrealized gain (loss) on cash flow hedges, net of related tax effects	(72,355)	40,035	(106,775)	56,673
Total other comprehensive income (loss)	(62,492)	17,201	(80,439)	21,553
Comprehensive income	607,986	510,894	1,745,760	1,434,294
Comprehensive loss attributable to noncontrolling interest	2,555	2,160	7,344	6,195
Comprehensive income attributable to Gilead	$ 610,541	$ 513,054	$ 1,753,104	$ 1,440,489

14. 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 and nine months ended September 30, 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.

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Product sales consisted of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Antiviral products:				
Truvada	$ 620,564	$ 549,101	$ 1,818,996	$ 1,544,635
Atripla	605,299	427,623	1,684,324	1,106,941
Viread	169,711	155,958	489,241	459,306
Hepsera	67,928	91,217	207,716	264,604
Emtriva	6,729	7,634	21,001	24,111
Total antiviral products	1,470,231	1,231,533	4,221,278	3,399,597
AmBisome	77,064	72,884	214,645	213,680
Letairis	48,073	31,656	131,781	76,679
Ranexa	49,005		85,070	
Other	4,582	2,429	12,139	7,068
Total product sales	$ 1,648,955	$ 1,338,502	$ 4,664,913	$ 3,697,024

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 September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
United States	$ 918,477	$ 750,288	$ 2,592,910	$ 2,101,134
Outside of the United States:				
France	121,393	105,087	326,692	294,932
Spain	111,305	91,348	318,917	259,778
United Kingdom	99,663	81,028	283,893	217,180
Italy	79,235	64,946	239,434	209,171
Switzerland	127,763	18,151	237,354	167,071
Germany	70,092	71,429	207,249	175,013
Other European countries	137,004	98,139	416,469	214,397
Other countries	136,457	90,852	356,086	268,869
Total revenues outside of the United States	882,912	620,980	2,386,094	1,806,411
Total revenues	$ 1,801,389	$ 1,371,268	$ 4,979,004	$ 3,907,545

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 September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Cardinal Health, Inc.	19%	20%	19%	21%
McKesson Corp.	15%	16%	14%	15%

AmerisourceBergen Corp.	12%	11%	12%	11%

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15. INCOME TAXES

Our income tax rate of 24.8% and 25.2% for the three and nine months ended September 30, 2009, respectively, differed from the U.S. federal statutory rate of 35% due primarily to tax credits, the resolution of certain tax positions with tax authorities 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.

In May 2009, we reached agreement with the Internal Revenue Service (IRS) on several issues related to the examinations of our federal income tax returns for 2003 and 2004. We also amended our California income tax returns for 2003 through 2007 based on the resolution of certain tax positions with the IRS. As a result, we reduced our unrecognized tax benefits by $30.5 million in 2009.

As of September 30, 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 IRS and other tax authorities 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 tax 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 2005, 2006 and 2007 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. We periodically evaluate our exposures associated with our tax filing positions.

We record liabilities related to uncertain tax positions in accordance with the guidance in the *Income Tax* Topic of the FASB ASC. This guidance clarifies the accounting for uncertainty in income taxes recognized in an enterprise s financial statements by prescribing a minimum recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. 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.

16. SUBSEQUENT EVENTS

We evaluated all subsequent events that occurred after the balance sheet date through the date of filing these Condensed Consolidated Financial Statements on Form 10-Q with the SEC on November 5, 2009. There were no subsequent events requiring recognition or disclosure in these financial statements.

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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 business 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 and nine months ended September 30, 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 (GAAP) 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 infection; Hepsera® (adefovir dipivoxil) and Viread for the treatment of chronic hepatitis B virus; AmBisome® (amphotericin B) liposome for injection for the treatment of severe fungal infections; Letairis® (ambrisentan) for the treatment of pulmonary arterial hypertension (PAH); Ranexa® (ranolazine) for the treatment of chronic angina; 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. Menarini International Operations Luxembourg SA markets Ranexa outside of the United States under a royalty-paying collaborative agreement with us. Astellas Pharma US, Inc. markets Lexiscan® (regadenoson) injection in the United States for use as a pharmacologic stress agent in radionuclide myocardial perfusion imaging under a royalty-paying collaborative agreement with us.

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Business Highlights

In July 2009, we entered into a collaboration and license agreement with Tibotec Pharmaceuticals (Tibotec), a wholly-owned subsidiary of Johnson & Johnson, to develop and commercialize a new once-daily fixed-dose combination containing our Truvada and Tibotec s investigational non-nucleoside reverse transcriptase inhibitor, TMC278 (25 mg rilpivirine hydrochloride), which is currently in Phase 3 clinical trials. We will reimburse up to 71.5 million (approximately $100.0 million) of development costs incurred by Tibotec for TMC278 through December 2011. We expect to recognize product sales revenue from future sales of this new combination product if and when it is approved. The cost of TMC278 to be purchased by us from Tibotec for the combination product will approximate the market price of TMC278, less a specified percentage of up to 30%.

In the cardiovascular area, in September 2009, we announced the online publication in *The Lancet* of data from DAR-311 (DORADO), a Phase 3 clinical trial evaluating our once-daily oral endothelin receptor antagonist darusentan as an add-on treatment for resistant hypertension.

With regard to our respiratory efforts, in October 2009, we announced that the Anti-Infective Drugs Advisory Committee of the U.S. Food and Drug Administration (FDA) is scheduled to review aztreonam for inhalation solution for the treatment of infections due to *Pseudomonas aeruginosa (P. aeruginosa)* in patients with cystic fibrosis (CF) in December 2009. In September 2009, we announced that the European Commission had granted conditional marketing authorization for Cayston® 75 mg powder and solvent for nebuliser solution for the suppressive therapy of chronic pulmonary infections due to *P. aeruginosa* in patients with CF aged 18 years and older. Cayston will be made available in certain countries of the European Union, subject to the requirements of national authorities, beginning in early 2010. Also in September 2009, Cayston received conditional marketing approval in Canada.

Acquisition of CV Therapeutics, Inc. and Restructuring

In April 2009, we completed the acquisition of CV Therapeutics, Inc. (CV Therapeutics), 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 had two marketed products as well as several product candidates in clinical development for the treatment of pulmonary and cardiovascular diseases. We believe the acquisition will provide us with an opportunity to further expand into the cardiovascular therapeutic area. We adopted the guidance in the *Business Combinations* Topic of the Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) in recognizing the consideration transferred of $1.39 billion and recorded $951.2 million and $180.1 million in intangible assets relating to marketed products and in-process research and development (IPR&D) projects, respectively, which constituted a significant portion of the assets acquired from CV Therapeutics. The results of operations of CV Therapeutics beginning on April 15, 2009, the acquisition date, were included in our Condensed Consolidated Financial Statements for the three and nine months ended September 30, 2009.

During the three months ended June 30, 2009, we also approved a plan to realize certain synergies between us and CV Therapeutics, re-align our cardiovascular operations and eliminate certain redundancies. The restructuring plan included the consolidation and re-alignment of the cardiovascular research and development (R&D) organization, the exit from certain of our facilities and the termination of certain contractual obligations. As a result of this restructuring plan, we recorded an aggregate of $8.4 million and $32.5 million in expenses for the three and nine months ended September 30, 2009, primarily related to employee severance and termination benefits costs. We expect the total amount to be incurred in connection with the significant activities of our restructuring plan to be approximately $34 million for employee severance and termination benefits, $22 million for facilities-related costs and $6 million for employee relocation costs. These costs are expected to be incurred through 2010 with the majority of the expenses to be incurred by the end of 2009.

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Financial Highlights

Our operating results for the three months ended September 30, 2009 were led by total product sales of $1.65 billion. Antiviral product sales (Truvada, Atripla, Viread, Hepsera and Emtriva) increased 19% to $1.47 billion in the three months ended September 30, 2009 from the three months ended September 30, 2008, and were the key drivers for total product sales growth of 23% for the three months ended September 30, 2009 as compared to the three months ended September 30, 2008. Atripla contributed $605.3 million, or 41%, to our third quarter 2009 antiviral product sales. The growth of Atripla product sales and its increased proportion relative to our overall product sales contributed to the decrease in our product gross margin to 75% for the three months ended September 30, 2009 from 78% 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 September 30, 2009 comprised $620.6 million, or 42% of our third quarter 2009 antiviral product sales. Truvada product sales for the three months ended September 30, 2009 increased 13% from the three months ended September 30, 2008 due primarily to continued sales volume growth in the United States and Europe, partially offset by an unfavorable foreign currency exchange impact. Foreign currency fluctuations for the three months ended September 30, 2009 had an unfavorable impact of approximately $51.0 million on total revenues and $22.1 million on pre-tax income when compared to the three months ended September 30, 2008.

Royalty, contract and other revenues that we recognized from our collaborations with corporate partners were $152.4 million for the three months ended September 30, 2009, an increase of $119.7 million from the three months ended September 30, 2008. The increase was driven primarily by higher Tamiflu royalties from Roche of $113.5 million for the three months ended September 30, 2009 compared to Tamiflu royalties from Roche of $8.6 million in the same period in 2008 due to increased sales related primarily to pandemic planning initiatives worldwide.

Operating expenses which include R&D and selling, general and administrative (SG&A) expenses increased $120.0 million for the three months ended September 30, 2009, or 32%, compared to the three months ended September 30, 2008, reflecting the R&D expense reimbursement related to the Tibotec TMC278 collaboration, higher headcount required to support the continued growth of our business, severance and termination benefits costs incurred as a result of our restructuring activities, as well as other incremental operating expenses associated with the growth of our business and our acquisition of CV Therapeutics.

Cash, cash equivalents and marketable securities increased by $52.5 million during the nine months ended September 30, 2009, driven primarily by operating cash flows of $2.12 billion partially offset by cash used to acquire CV Therapeutics of $1.13 billion, net of cash, cash equivalents and marketable securities assumed from CV Therapeutics of $245.4 million, and $756.5 million used to repurchase approximately 16.5 million shares of our common stock through open market purchases. As of September 30, 2009, the remaining authorized amount of stock repurchases that may be made under our $3.00 billion Board-authorized stock repurchase program which expires in December 2010 was $241.9 million.

Critical Accounting Policies, Estimates and Judgments

Reference is made to Critical Accounting Policies, Estimates and Judgments included in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2008.

Intangible Assets

In conjunction with business combinations that we have completed, we have recorded intangible assets primarily related to marketed products, IPR&D projects and goodwill as part of our recognition and measurement of assets acquired and liabilities assumed in a business combination. Identifiable intangible assets such as those related to marketed products or IPR&D projects, are measured at their respective fair values as of the acquisition date. We have adopted the guidance under the *Business Combinations* Topic of the FASB ASC for measuring and recognizing intangible assets that were acquired after January 1, 2009. We believe the fair values assigned to

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our acquired intangible assets are based on reasonable estimates and assumptions given the available facts and circumstances as of the acquisition dates. Discounted cash flow models are used in valuing these intangible assets, and these models require the use of significant estimates and assumptions including but not limited to:

- estimates of revenues and operating profits related to the products or product candidates;
- the probability of success for unapproved product candidates considering their stages of development;
- the time and resources needed to complete the development and approval of product candidates;
- the life of the potential commercialized products and associated risks, including the inherent difficulties and uncertainties in developing a product candidate such as obtaining FDA and other regulatory approvals; and
- risks related to the viability of and potential alternative treatments in any future target markets.

Goodwill represents the excess of the consideration transferred over the estimated fair values of assets acquired and liabilities assumed in a business combination. In accordance with the guidance in the *Intangibles Goodwill and Other* Topic of the FASB ASC, goodwill and intangible assets determined to have indefinite useful lives are not amortized, but are required to be tested for impairment at least annually. We test goodwill and other indefinite-lived intangible assets for impairment on an annual basis and in between annual tests if we become aware of any events occurring or changes in circumstances that would indicate a reduction in the fair value of the assets below their carrying amounts. As of September 30, 2009, we had $617.6 million of indefinite-lived intangible assets consisting of $437.5 million of goodwill resulting from various business combinations and $180.1 million of intangible assets related to the IPR&D projects that we acquired from CV Therapeutics.

In accordance with the guidance in the *Intangibles Goodwill and Other* Topic of the FASB ASC, intangible assets with finite useful lives are amortized over their estimated useful lives and are reviewed for impairment when facts or circumstances suggest that the carrying value of these assets may not be recoverable. With respect to intangible assets related to the marketed products that we acquired from CV Therapeutics, we are amortizing the intangible asset related to Ranexa over its estimated useful life using an amortization rate derived from our forecasted future product sales for Ranexa. Our product sales forecasts are prepared annually and determined using our best estimates of future activity upon considering such factors as historical and expected future patient usage or uptake of our products, the introduction of complimentary or combination therapies or products and future product launch plans. If a previously unanticipated and significant change occurs to our sales forecasts, we will prospectively update the rate used to amortize our intangible asset related to Ranexa which may increase future cost of goods sold, as that is where we record the amortization expense. We are amortizing the intangible asset related to Lexiscan over its estimated useful life on a straight-line basis. Given that current Lexiscan revenues consist of royalties received from a collaboration partner and we will have limited ongoing access and visibility into that partner s future sales forecasts, we cannot make a reasonable estimate of the amortization rate utilizing a forecasted product sales approach. As of September 30, 2009, we had $938.0 million of net unamortized finite-lived intangible assets consisting primarily of intangible assets related to the marketed products that we acquired from CV Therapeutics.

Our judgment regarding the existence of impairment indicators is based on our historical and projected future operating results, our extent or manner of use of the acquired assets, legal and regulatory factors and events, our overall business strategy and market and economic trends. If events occur in the future that cause us to conclude that impairment indicators exist and that certain intangible assets are impaired, our financial condition and results of operations may be adversely impacted.

Other than as set forth herein, there have been no other material changes in our critical accounting policies, estimates and judgments during the three and nine months ended September 30, 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.

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Adoption of New Accounting Guidance

On July 1, 2009, we adopted the provisions of Statement of Financial Accounting Standards (SFAS) No. 168, *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles a replacement of SFAS No. 162* (SFAS 168), on a prospective basis. This guidance establishes the FASB ASC as the source of authoritative U.S. GAAP recognized by the FASB to be applied by non-governmental entities and is effective for interim periods and fiscal years ending after September 15, 2009. As a result of adopting this guidance, the majority of references to historically issued accounting pronouncements are now superseded by references to the FASB ASC. Certain accounting pronouncements, such as SFAS 168, will remain authoritative until they are integrated into the FASB ASC.

On April 1, 2009, we adopted guidance in the *Investments Debt and Equity Securities* Topic of the FASB ASC, which addresses the recognition and presentation of other-than-temporary impairments, provides some new disclosure requirements as well as extends certain annual disclosure requirements to interim periods. This guidance is effective for interim periods and fiscal years ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. We adopted the provisions of this guidance on a prospective basis for our available-for-sale securities.

On April 1, 2009, we adopted guidance in the *Financial Instruments* Topic of the FASB ASC, which extends the disclosure requirements regarding the fair value of financial instruments to interim financial statements. This guidance is effective for interim periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. We adopted the provisions of this guidance on a prospective basis for our financial instruments, which consist principally of cash and cash equivalents, marketable securities, accounts receivable, foreign currency exchange forward and option contracts, accounts payable and long-term debt.

On January 1, 2009, we adopted guidance in the *Business Combinations* Topic of the FASB ASC, which establishes principles and requirements for recognizing and measuring assets acquired, liabilities assumed and any noncontrolling interests in the acquiree in a business combination. This guidance also provides clarification for recognizing and measuring goodwill acquired in a business combination; requires purchased IPR&D 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. This guidance is effective for business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. We adopted the provisions of this guidance on a prospective basis and applied it to our acquisition of CV Therapeutics.

On January 1, 2009, we adopted guidance in the *Derivatives and Hedging* Topic of the FASB ASC that required 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. This guidance is effective for interim periods and fiscal years beginning after November 15, 2008. We adopted the provisions of this guidance on a prospective basis for our derivative instruments.

On January 1, 2009, we adopted guidance in the *Debt* Topic of the FASB ASC which addresses instruments that require the issuer to settle the principal amount in cash and the conversion spread in cash or net shares at the issuer s option. This guidance 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. This guidance 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. We adopted this guidance on a retrospective basis for our convertible senior notes. Accordingly, we reflected additional interest expense of $13.4 million and $39.6 million, respectively, a related benefit from income taxes

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of $5.3 million and $15.6 million, respectively, and a decrease in net income per share attributable to Gilead common stockholders on a diluted basis of $0.01 and $0.03, respectively, for the three and nine months ended September 30, 2008 in our Condensed Consolidated Statements of Income, and recorded additional interest expense of $14.2 million and $41.9 million, respectively, a related benefit from income taxes of $5.5 million and $16.3 million, respectively, and a decrease in net income per share attributable to Gilead common stockholders on a diluted basis of $0.01 and $0.03, respectively, for the three and nine months ended September 30, 2009. In addition, the retrospective adoption of this guidance 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 in our Condensed Consolidated Balance Sheet as of December 31, 2008.

On January 1, 2009, we adopted guidance in the *Consolidation* Topic of the FASB ASC which 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. This guidance also establishes additional reporting requirements that identify and distinguish between the ownership interest of the parent and the interest of the noncontrolling owners. This guidance is effective for interim periods and fiscal years beginning after December 15, 2008 and requires retrospective application to all periods presented. We adopted the provisions of this guidance on a retrospective basis and reclassified the noncontrolling interest (formerly minority interest) from liabilities to stockholders equity on our Condensed Consolidated Balance Sheets. Our adoption of this guidance also 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.

Results of Operations

Total Revenues

We had total revenues of $1.80 billion for the three months ended September 30, 2009 compared to $1.37 billion for the same period in 2008. We had total revenues of $4.98 billion for the nine months ended September 30, 2009 and $3.91 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, except percentages):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2009	2008	Change	2009	2008	Change
Antiviral products:						
Truvada	$ 620,564	$ 549,101	13%	$ 1,818,996	$ 1,544,635	18%
Atripla	605,299	427,623	42%	1,684,324	1,106,941	52%
Viread	169,711	155,958	9%	489,241	459,306	7%
Hepsera	67,928	91,217	(26)%	207,716	264,604	(21)%
Emtriva	6,729	7,634	(12)%	21,001	24,111	(13)%
Total antiviral products	1,470,231	1,231,533	19%	4,221,278	3,399,597	24%
AmBisome	77,064	72,884	6%	214,645	213,680	0%
Letairis	48,073	31,656	52%	131,781	76,679	72%
Ranexa	49,005		100%	85,070		100%
Other	4,582	2,429	89%	12,139	7,068	72%
Total product sales	$ 1,648,955	$ 1,338,502	23%	$ 4,664,913	$ 3,697,024	26%

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Total product sales increased by 23% and 26% for the three and nine months ended September 30, 2009, respectively, compared to the same periods in 2008, due primarily to an overall increase in our antiviral product sales, including the strong growth in sales of Atripla and continued growth in sales of 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 19% and 24% for the three and nine months ended September 30, 2009, respectively, compared to the same periods in 2008, driven primarily by sales volume growth of Atripla and Truvada.

Truvada

Truvada sales increased by 13% and 18% for the three and nine months ended September 30, 2009, respectively, compared to the same periods in 2008, driven primarily by sales volume growth in the United States and Europe, partially offset by an unfavorable foreign currency exchange impact. Truvada sales accounted for 42% and 43% of our total antiviral product sales for the three and nine months ended September 30, 2009, respectively.

Atripla

Atripla sales increased by 42% and 52% for the three and nine months ended September 30, 2009, respectively, compared to the same periods in 2008, driven primarily by sales volume growth in the United States and Europe including the launch of Atripla in France in the second quarter of 2009. Atripla sales include the efavirenz portion at zero product gross margin. The efavirenz portion of our Atripla sales was approximately $221.6 million and $617.1 million for the three and nine months ended September 30, 2009, respectively, and approximately $155.9 million and $406.0 million for the three and nine months ended September 30, 2008, respectively. Atripla sales accounted for 41% and 40% of our total antiviral product sales for the three and nine months ended September 30, 2009, respectively.

Other Antiviral Products

Other antiviral product sales, which include product sales of Viread, Hepsera and Emtriva decreased by four percent for both the three and nine months ended September 30, 2009 compared to the same periods in 2008, driven primarily by sales volume decreases in Hepsera, partially offset by sales volume increases in Viread.

Letairis

Sales of Letairis increased by 52% and 72% for the three and nine months ended September 30, 2009, respectively, compared to the same periods in 2008, driven primarily by sales volume growth in the United States.

Ranexa

Sales of Ranexa were $49.0 million for the three months ended September 30, 2009 and $85.1 million from April 15, 2009 (the date of our acquisition of CV Therapeutics) to September 30, 2009.

Royalty Revenues

The following table summarizes the period over period changes in our royalty revenues (in thousands, except percentages):

	Three Months Ended September 30,		Change	Nine Months Ended September 30,		Change

	2009	2008		2009	2008	
Royalty revenues	$ 142,133	$ 25,161	465%	$ 269,070	$ 185,221	45%

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Royalty revenues for the three months ended September 30, 2009 were $142.1 million, an increase of 465% compared to the same period in 2008, driven primarily by the recognition of Tamiflu royalties from Roche of $113.5 million in the three months ended September 30, 2009, compared to Tamiflu royalties from Roche of $8.6 million recognized in the same period in 2008. The higher Tamiflu royalties were due to increased Roche sales related primarily to pandemic planning initiatives worldwide. Royalty revenues for the nine months ended September 30, 2009 were $269.1 million, an increase of 45% compared to the same period in 2008, driven primarily by the recognition of Tamiflu royalties from Roche of $198.6 million in the nine months ended September 30, 2009 compared to Tamiflu royalties from Roche of $139.5 million recognized in the same period in 2008. The higher Tamiflu royalties were due to increased Roche sales related primarily to pandemic planning initiatives worldwide. We recognize royalties on Tamiflu sales by Roche in the quarter following the quarter in which the product 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 September 30,			Nine Months Ended September 30,		
	2009	2008	Change	2009	2008	Change
Total product sales	$ 1,648,955	$ 1,338,502	23%	$ 4,664,913	$ 3,697,024	26%
Cost of goods sold	$ 409,700	$ 300,183	36%	$ 1,122,159	$ 805,715	39%
Product gross margin	75%	78%		76%	78%	

Our product gross margin for the three and nine months ended September 30, 2009 was 75% and 76%, respectively, compared to 78% for both the three and nine months ended September 30, 2008. The lower product gross margins for the three and nine months ended September 30, 2009 compared to the same periods in 2008 were due primarily to the higher proportion of Atripla sales, which include the efavirenz portion at zero product gross margin as well as the amortization associated with the intangible assets related to the marketed products acquired in our acquisition of CV Therapeutics.

Restructuring

During the three months ended June 30, 2009, we approved a plan to realize certain synergies between us and CV Therapeutics, re-align our cardiovascular operations and eliminate certain redundancies. The restructuring plan includes the consolidation and re-alignment of the cardiovascular R&D organization, the exit from certain of our facilities and the termination of certain contractual obligations. As a result of this restructuring plan, we recorded $2.6 million and $5.8 million in SG&A expenses and R&D expenses, respectively, for the three months ended September 30, 2009, primarily related to employee severance and termination benefits costs. For the nine months ended September 30, 2009, we recorded $15.5 million and $17.0 million in SG&A expenses and R&D expenses, respectively, primarily related to employee severance and termination benefits costs. These costs were recorded in accordance with the guidance in the *Exit or Disposal Cost Obligations* Topic of the FASB ASC. We expect the total amount to be incurred in connection with the significant activities of our restructuring plan to be approximately $34 million for employee severance and termination benefits, $22 million for facilities-related costs and $6 million for employee relocation costs. These costs are expected to be incurred through 2010 with the majority of the expenses to be incurred by the end of 2009.

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Research and Development Expenses

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2009	2008	Change	2009	2008	Change
Research	$ 45,487	$ 44,344	3%	$ 137,749	$ 119,610	15%
Clinical development	188,168	116,377	62%	459,488	321,132	43%
Pharmaceutical development	36,201	27,341	32%	103,036	79,163	30%
Total research and development	$ 269,856	$ 188,062	43%	$ 700,273	$ 519,905	35%

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, licenses and 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 September 30, 2009 increased by $81.8 million, or 43%, compared to the same period in 2008, due primarily to the R&D expense reimbursement related to our Tibotec TMC278 collaboration of $52.4 million and increased compensation and benefit expenses of $21.8 million, driven primarily by higher headcount related to the growth of our business and the acquisition of CV Therapeutics, including severance and termination benefits associated with our restructuring activities. R&D expenses for the three months ended September 30, 2008 included a $7.0 million milestone payment made to Japan Tobacco related to the dosing of patients with elvitegravir in Phase 3 studies.

R&D expenses for the nine months ended September 30, 2009 increased by $180.4 million, or 35%, compared to the same period in 2008, due primarily to the R&D expense reimbursement related to our Tibotec TMC278 collaboration of $52.4 million, increased compensation and benefit expenses of $69.6 million, driven primarily by higher headcount related to the growth of our business and the acquisition of CV Therapeutics, including severance and termination benefits associated with our restructuring activities, and increased clinical study expenses of $22.4 million.

Selling, General and Administrative Expenses

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2009	2008	Change	2009	2008	Change
Selling, general and administrative	$ 227,427	$ 189,189	20%	$ 692,789	$ 603,679	15%

SG&A expenses for the three months ended September 30, 2009 increased by $38.2 million, or 20%, compared to the same period of 2008, due primarily to increased contract and professional services expenses of $16.3 million driven primarily by our increased sales and marketing activities and $5.8 million related to certain contract termination costs, and increased compensation and benefit expenses of $13.3 million driven primarily by higher headcount related to the growth of our business and the acquisition of CV Therapeutics.

SG&A expenses for the nine months ended September 30, 2009 increased by $89.1 million, or 15%, compared to the same period in 2008, due primarily to increased compensation and benefit expenses of $51.2 million, driven primarily by higher headcount related to the growth of our business and the acquisition of

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CV Therapeutics, including severance and termination benefits associated with our restructuring activities, and increased contract and professional services expenses of $34.2 million driven primarily by our expanding sales and marketing activities and $5.8 million related to certain contract termination costs. During the nine months ended September 30, 2008, we incurred costs of $12.4 million associated with certain employee termination-related disputes in our international operations.

Interest and Other Income, Net

Interest and other income, net, was $14.0 million and $31.1 million for the three and nine months ended September 30, 2009, respectively, an increase of $10.4 million and a decrease of $9.3 million from the same periods in 2008, respectively. The increase for the three months ended September 30, 2009 compared to the same period in 2008 was due primarily to increased net foreign currency exchange translation gains of $9.6 million and decreased costs related to our hedging activities of $7.8 million, partially offset by lower interest income of $7.2 million due primarily to a reduction in the average yield of our investment portfolio as a result of lower interest rates. The decrease for the nine months ended September 30, 2009 compared to the same period in 2008 was due primarily to decreased interest income of $26.7 million due primarily to a reduction in the average yield of our investment portfolio as a result of lower interest rates, partially offset by an increase in net foreign currency exchange gains of $18.9 million.

Provision for Income Taxes

Our income tax rate was 24.8% and 25.2% for the three and nine months ended September 30, 2009, respectively, compared to 27.5% and 27.9% for the same periods in 2008, respectively. Our provision for income taxes for the three and nine months ended September 30, 2009 was $220.7 million and $616.3 million, respectively, compared to $187.4 million and $546.2 million, respectively, for the same periods in 2008. The tax rates for the three and nine months ended September 30, 2009 differed from the U.S. federal statutory rate of 35% due primarily to tax credits, the resolution of certain tax positions with tax authorities 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.

Purchased In-process Research and Development

In connection with our acquisition of CV Therapeutics in April 2009, we recorded intangible assets of $180.1 million related to the IPR&D projects that we acquired from CV Therapeutics. Of the $180.1 million of intangible assets related to the IPR&D projects, $93.4 million related to CVT-3619, a product candidate in Phase 1 clinical studies for the treatment of hypertriglyceridemia. The remaining balance of the intangible assets related to IPR&D projects represented various other in-process projects with no single project comprising a significant portion of the total value. In accordance with the guidance in the *Intangibles Goodwill and Other* Topic of the FASB ASC, intangible assets related to IPR&D projects are considered to be indefinite-lived until the completion or abandonment of the associated R&D efforts. During the period the assets are considered indefinite-lived, they will not be amortized but will be tested for impairment on an annual basis and between annual tests if we become aware of any events occurring or changes in circumstances that would indicate a reduction in the fair value of the IPR&D projects below their respective carrying amounts. If and when development is complete, which generally occurs if and when regulatory approval to market a product is obtained, the associated assets would be deemed finite-lived and would then be amortized based on their respective estimated useful lives at that point in time.

The estimated fair value of the intangible assets related to the IPR&D projects acquired from CV Therapeutics was determined using the income approach, which discounts expected future cash flows to present value. We estimated the fair value of these intangible assets using a present value discount rate of 9%, which is based on the estimated weighted-average cost of capital for companies with profiles substantially similar to that

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of CV Therapeutics. This is comparable to the estimated internal rate of return for CV Therapeutics operations and represents the rate that market participants would use to value the intangible assets. We compensated for the differing phases of development of each project by probability-adjusting our estimation of the expected future cash flows associated with each project. We then determine the present value of the expected future cash flows using the discount rate of 9%. The projected cash flows from the IPR&D projects were based on key assumptions such as estimates of revenues and operating profits related to the projects considering their stages of development; the time and resources needed to complete the development and approval of the related product candidates; the life of the potential commercialized products and associated risks, including the inherent difficulties and uncertainties in developing a drug compound such as obtaining marketing approval from the FDA and other regulatory agencies; and risks related to the viability of and potential alternative treatments in any future target markets.

In connection with our acquisition of the cicletanine assets from Navitas in 2008, we recorded IPR&D expense of $10.9 million during the three months ended June 30, 2008 in accordance with SFAS No. 141, *Business Combination* (SFAS 141). As we do not consider the acquisition to be a material purchase, we have not made further disclosures regarding the related purchased IPR&D.

In connection with our acquisitions of Myogen Inc. (Myogen) and Corus Pharma, Inc. (Corus) in 2006, we recorded purchased IPR&D expenses of $2.06 billion and $335.6 million, respectively, during the year ended December 31, 2006 in accordance with SFAS 141.

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:

Program	Description	Status of Development	Estimated Acquisition Date Fair Value (in millions)
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 a new drug application (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 authorisation application (MAA) 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

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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.

The purchased IPR&D expense for Corus represented the estimated fair value of Corus s incomplete aztreonam for inhalation solution for CF IPR&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:

Program	Description	Status of Development	Estimated Acquisition Date Fair Value (in millions)
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 October 2009, we announced that the Anti-Infective Drugs Advisory Committee of the FDA is scheduled to review aztreonam for inhalation solution in December 2009. 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 September 2009, the European Commission granted conditional marketing authorization for Cayston for patients with CF aged 18 years and older. Also in September 2009, Cayston received conditional marketing approval in Canada.	$ 335.6

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The remaining efforts for completing Corus s 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.

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 September 30, 2009	As of December 31, 2008
Cash, cash equivalents and marketable securities	$ 3,292,130	$ 3,239,639
Working capital	$ 2,408,361	$ 3,057,416

	Nine Months Ended September 30,	
	2009	2008
Cash provided by (used in):		
Operating activities	$ 2,124,778	$ 1,565,097
Investing activities	$ (1,818,216)	$ (417,394)
Financing activities	$ (727,359)	$ (894,146)

Cash, Cash Equivalents and Marketable Securities

Cash, cash equivalents and marketable securities totaled $3.29 billion at September 30, 2009, an increase of $52.5 million or 2% from December 31, 2008. This increase was primarily attributable to:

net cash provided by operations of $2.12 billion;

proceeds from our credit facility of $400.0 million, partially offset by our repayments of $200.0 million; and

proceeds from issuances of common stock under our employee stock plans of $160.9 million.

This increase was partially offset by the following:

cash used to acquire CV Therapeutics of $1.13 billion, net of cash, cash equivalents and marketable securities assumed from CV Therapeutics of $245.4 million;

$756.5 million used to repurchase our common stock under our stock repurchase program; and

$305.4 million used to extinguish the convertible senior notes we assumed in our acquisition of CV Therapeutics.

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Working Capital

Working capital was $2.41 billion at September 30, 2009, a decrease of $649.1 million or 21% from working capital as of December 31, 2008. This decrease was primarily attributable to:

- a decrease of $434.8 million in cash, cash equivalents and short-term marketable securities;
- an increase of $400.0 million in the current portion of other long-term obligations driven by proceeds from our credit facility, partially offset by $200.0 million of repayments;
- an increase of $141.5 million in accounts payable due primarily to the purchases of efavirenz at its estimated market value from BMS; and
- an increase of $150.0 million in other accrued liabilities due primarily to an increase in the liability associated with the fair value of our foreign currency exchange forward contracts as well as the R&D expense reimbursement related to our Tibotec TMC278 collaboration.

This decrease was partially offset by an increase of $315.8 million in accounts receivable, net, primarily driven by increased product sales.

Cash Provided by Operating Activities

Cash provided by operating activities of $2.12 billion for the nine months ended September 30, 2009 primarily related to net income of $1.83 billion, adjusted for non-cash items such as $148.8 million of depreciation and amortization expenses and $138.9 million of stock-based compensation expenses, partially offset by $59.3 million of excess tax benefits from stock option exercises which we reclassified to cash used in financing activities, and $53.4 million of net cash outflow related to changes in operating assets and liabilities.

Cash provided by operating activities of $1.57 billion for the nine months ended September 30, 2008 was comprised primarily of $1.41 billion in net income, adjusted for non-cash items such as $169.3 million of tax benefits from employee stock plans, $115.2 million of depreciation and amortization expenses and $114.6 million of stock-based compensation expenses. This was partially offset by $155.7 million of excess tax benefits from stock option exercises which we reclassified to cash used in financing activities and $130.3 million of cash outflow related to changes in operating assets and liabilities. Our operating cash flows for the nine months ended September 30, 2008 has been revised for our retrospective application of the guidance in the *Consolidation* Topic of the FASB ASC on January 1, 2009, which required the 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 nine months ended September 30, 2009 primarily related to our acquisition of CV Therapeutics, purchases, sales and maturities of marketable securities as well as capital expenditures. Cash used in investing activities for the nine months ended September 30, 2008 primarily related to purchases, sales and maturities of marketable securities as well as capital expenditures.

We used $1.82 billion of cash in investing activities in the nine months ended September 30, 2009, compared to $417.4 million during the nine months ended September 30, 2008. The increase was due primarily to cash used in our acquisition of CV Therapeutics of $1.25 billion, net of cash and cash equivalents acquired and increased capital expenditures in the nine months ended September 30, 2009 compared to the same period in 2008. Capital expenditures and other items of $203.1 million made in the nine months ended September 30, 2009 related primarily to the purchase of an office building and approximately 30 acres of land located in Foster City, California.

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Cash Used in Financing Activities

Cash used in financing activities for the nine months ended September 30, 2009 was $727.4 million, driven primarily by the $756.5 million used to repurchase our common stock under our stock repurchase program and the $305.4 million used to extinguish the convertible senior notes assumed from the acquisition of CV Therapeutics. The cash outflows were partially offset by proceeds of $400.0 million that we borrowed under our existing revolving credit agreement to partially fund the acquisition of CV Therapeutics, of which $200.0 million has been repaid, and proceeds of $160.9 million from issuances of common stock under our employee stock plans.

Cash used in financing activities for the nine months ended September 30, 2008 was $894.1 million, driven primarily by the $1.22 billion used to repurchase our common stock under our stock repurchase program. The cash outflows were partially offset by proceeds of $176.4 million that we received from issuances of common stock under our employee stock plans, as well as $155.7 million of excess tax benefits from stock option exercises.

As a result of our adoption of the guidance in the *Consolidation* Topic of the FASB ASC, we reclassified the change in noncontrolling interest from cash provided by operating activities to cash used in financing activities, as discussed above.

Under our amended and restated credit agreement, we, along with our wholly-owned subsidiary, Gilead Biopharmaceutics Ireland Corporation, may borrow up to an aggregate of $1.25 billion in revolving credit loans. The credit agreement also includes a sub-facility for swing-line loans and letters of credit. Loans under the credit agreement bear interest at an interest rate of either LIBOR plus a margin ranging from 0.20 percent to 0.32 percent or the base rate, as defined in the credit agreement. In April 2009, in connection with the acquisition of CV Therapeutics, we borrowed $400.0 million under the credit agreement to partially fund the acquisition. As of September 30, 2009, we have repaid $200.0 million under this credit agreement and expect to repay the remaining $200.0 million in the fourth quarter of 2009 using cash flow generated from operations. The credit agreement will terminate and all amounts owing thereunder shall be due and payable on December 17, 2012. We 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. As of September 30, 2009, approximately $1.05 billion was available to be drawn down under this credit agreement.

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 accelerated share repurchase agreement 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 September 30, 2009, the remaining authorized amount of stock repurchases that may be made under our $3.00 billion Board-authorized stock repurchase program which expires in December 2010 was $241.9 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.

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ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There have been no material changes in our market risk during the nine months ended September 30, 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 0.5% to 1.2%. As of September 30, 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 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 September 30, 2009 was carried out under the supervision of 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 in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act), 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 Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC s rules and forms, and that such information is accumulated and communicated to the company s management, including its Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at September 30, 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 September 30, 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.

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Limitations on the Effectiveness of Controls

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

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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 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. In May 2009, we filed another lawsuit in U.S. District Court in New York against Teva for infringement of the two emtricitabine patents. In September 2009, the lawsuits were consolidated. We cannot predict the ultimate outcome of this litigation, and we may spend significant resources defending these patents. If we are unsuccessful in this litigation, 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 11. 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 our HIV products, particularly Truvada and Atripla. If we are unable to maintain or continue increasing sales of these products, our results of operations may be adversely affected.

We are currently dependent on sales of our products for the treatment of HIV, particularly 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

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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 September 30, 2009, Truvada and Atripla product sales together were $1.23 billion, or 68% 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 any number of reasons including, but not limited to, the following:

- 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.

- 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.

A portion of our pre-tax income is derived from royalty revenue recognized from sales of Tamiflu by Roche. If sales of Tamiflu were to decrease, our pre-tax income will be disproportionately and adversely affected.

F. Hoffmann-La Roche Ltd (together with Hoffmann-La Roche Inc., Roche) markets Tamiflu worldwide for the treatment and prevention of influenza under a royalty-paying collaborative agreement with us. We recognized $113.5 million in royalty revenue in the third quarter of 2009 related to royalties received from second quarter 2009 sales of Tamiflu by Roche. Although such royalty revenue represented less than 7% of our total revenues in the third quarter of 2009, it represented 13% of our pre-tax income during the period. Roche s Tamiflu sales have unpredictable variability due to their strong relationship with global pandemic planning efforts. Sales of Tamiflu increased sharply in the first three quarters of 2009 primarily as a result of pandemic planning initiatives worldwide. If sales of Tamiflu were to decrease, our royalty revenues will decrease and our pre-tax income will decrease disproportionately. Any such decrease could be material and could adversely impact our operating results.

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 nine months ended September 30, 2009, approximately 87% 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 if end user demand has not changed. For example, during the second quarter of 2009, the wholesalers increased their inventory levels for Atripla and Truvada, while inventory levels for Viread decreased. In the third quarter of 2009, the wholesalers drew down on their inventory such that inventory levels for Atripla and Truvada at the end of the third quarter were more

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consistent with the levels held during the first quarter of 2009. As inventory in the distribution channel fluctuates from quarter to quarter, we may continue to see fluctuations in our earnings and 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 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 was reiterating its position that we will need to conduct another clinical study of aztreonam for inhalation solution before we can resubmit our NDA. We are conferring with the FDA to determine what further studies would be required to address their concerns and support approval of this product candidate. Existing data from any ongoing or additional clinical trial that we may commence to satisfy FDA concerns may not support the approval of aztreonam for inhalation solution in the United States, 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, safety issues may arise or the results from the clinical study may be otherwise inadequate to support full regulatory approval of aztreonam for inhalation solution in jurisdictions where conditional marketing approval was granted, such as the European Union and Canada. 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 and 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

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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 Hepsera 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 Merck & Co., Inc. (Merck) and Pfizer. In addition, we are aware of generic versions of liposomal amphotericin B in India and at least two other 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. Ranexa competes predominantly with generic compounds from three distinct classes of drugs, beta-blockers, calcium channel blockers and long-acting nitrates for the treatment of chronic angina in the United States. 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

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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 (ERAs) 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, Letairis and Ranexa 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.

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 was reiterating its position that we will need to conduct another clinical study of aztreonam for inhalation solution before we can resubmit our NDA. We are conferring with the FDA to determine what further studies would be required to address their concerns and support approval of this product candidate. Existing data from any ongoing or from any additional clinical trial that we may commence to satisfy FDA concerns may not support the approval of aztreonam for inhalation solution in the United States, 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, safety issues may arise or the results from the clinical study may be otherwise inadequate to support full regulatory approval of aztreonam for inhalation solution in jurisdictions where conditional marketing approval was granted, such as the European Union and Canada.

Further, 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.

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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 and our operating results may be adversely affected.

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; 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), to perform most of our clinical studies, including document preparation, site identification, screening and preparation, pre-study visits, training, program management and bioanalytical analysis. Many important aspects of the services performed for us by the CROs are out of our direct control. 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.

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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 payers 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. 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 coverage and payment developments, the adverse effects may be magnified by private insurers adopting lower payment schedules.

Both President Obama s Administration and Congress have made healthcare reform a top priority and have proposed reforms to extend coverage to millions of uninsured Americans and to reduce the rate of growth in the costs of government-sponsored healthcare programs. Impending reform legislation in Congress may include reducing the coverage and reimbursement of our products and additional healthcare reform costs being borne by pharmaceutical and biotechnology companies, including us, which could have an adverse impact on our business.

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

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

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 related to 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.

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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 payer 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 payers 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, revenue-related taxes and profit control, and expect prices of prescription pharmaceuticals to decline over the life of the product or as volumes increase. Recently, 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.

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 that 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.

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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 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 then filed an appeal within the patent authority responding to the questions raised in the rejection. In July 2009, the Brazilian patent authority again rejected the application. This was the highest level of appeal available to us within the Brazilian patent authority. We intend to file a civil action in Brazilian federal court to further appeal the action of the Brazilian patent authority in the fourth quarter of 2009. 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 government would likely purchase generic tenofovir disoproxil fumarate, which would significantly reduce our sales of HIV products in Brazil. As another example, the Patent Office of India initially allowed our claims covering tenofovir disoproxil and tenofovir disoproxil fumarate. However, under Indian civil procedure, prior to the official grant of the allowed applications, several parties filed legal actions to protest the decision to grant the patents. In August 2009, the Indian Patent Office announced that it had decided these actions against us and would not therefore allow the patents to be granted. We intend to file an appeal within the Indian Patent Office. We cannot predict the outcome of these proceedings. If we are unable to successfully appeal these decisions, any further appeals will have to be pursued in the Indian court system, and may ultimately prove unsuccessful. In the meantime, any competitor is able to sell generic tenofovir disoproxil fumarate in India. In addition, if we are unable to successfully appeal any further negative decisions by the Indian Patent Office in the Indian courts, these competitors would be able to continue to sell generic tenofovir disoproxil fumarate, which could reduce the amount of royalties we receive from our Indian generic licenses.

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

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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 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 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. In May 2009, we filed another 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 either of these actions and we may spend significant resources defending these patents. If we are unsuccessful in one or both of 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.

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 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.

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

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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 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.

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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 of Letairis and Ranexa and for the tableting of Letairis. Astellas Pharma US, Inc., which markets Lexiscan in the United States, is responsible for the commercial manufacture and supply of product in United States and is dependent on a single supplier for the active pharmaceutical ingredient of Lexiscan. 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 $723.8 million as of September 30, 2009, of which $247.4 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.

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 not reflect the actual consumer demand in any given quarter. These quarterly fluctuations may impact our earnings, which could adversely affect our stock price and harm our business.

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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 July 2009, the Brazilian patent authority rejected our patent application for tenofovir disoproxil fumarate, the active pharmaceutical ingredient in Viread. We intend to file a civil action in Brazilian federal court to further appeal the action of the Brazilian patent authority. If we are unable to successfully appeal the decision by the patent authority in the courts, the Brazilian government would likely purchase generic tenofovir disoproxil fumarate, which would significantly reduce our sales of HIV products in Brazil. 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 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,

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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 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. In May 2009, we filed another 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 either of these actions, and we may spend significant resources defending these patents. If we are unsuccessful in one or both of 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, and our business will be harmed.

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. Further, in August 2009, we received a subpoena from the Office of the Inspector General of the U.S. Department of Health and Human Services requesting documents regarding the development, marketing and sales of Ranexa.

The outcome of the lawsuits above, any other lawsuits that may be brought against us, the investigation or any other such investigations brought against us, are inherently uncertain, and adverse developments or outcomes can result in significant expenses, monetary damages, penalties or injunctive relief against us that could significantly reduce our earnings and cash flows and harm our business.

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.

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 2005, 2006 and 2007 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 rules or policies 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 guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

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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.

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

In October 2007, our board of directors authorized a program for the repurchase of our common stock in an aggregate amount up to $3.00 billion through open market and private block transactions pursuant to Rule 10b5-1 plans, privately negotiated purchases or other means, including accelerated share repurchase transactions or similar arrangements. This stock repurchase program expires on December 31, 2010.

The table below summarizes our stock repurchase activity for the three months ended September 30, 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
July 1 July 31, 2009	2,054	$ 46.96	2,040	$ 434,245
August 1 August 31, 2009	2,082	$ 45.84	2,080	$ 338,889
September 1 September 30, 2009	2,100	$ 46.19	2,100	$ 241,897
Total	6,236(1)	$ 46.33	6,220(1)	

(1) 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.

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ITEM 6. EXHIBITS

Exhibit Footnote	Exhibit Number	Description of Document
(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, as amended through May 8, 2008
(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 Series A Junior Participating Preferred Stock of the 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
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(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
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(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
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*(14)	10.9	Form of option agreements used under the 1991 Stock Option Plan
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*(16)	10.12	Gilead Sciences, Inc. 2004 Equity Incentive Plan, as amended through May 6, 2009
*(17)	10.13	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants prior to February 2008)
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*(23)	10.27	Gilead Sciences, Inc. Employee Stock Purchase Plan, as amended through May 9, 2007
*(24)	10.28	Gilead Sciences, Inc. Deferred Compensation Plan Basic Plan Document
*(24)	10.29	Gilead Sciences, Inc. Deferred Compensation Plan Adoption Agreement
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*(14)	10.38	Form of Employee Proprietary Information and Invention Agreement entered into between Registrant and certain of its officers and key employees
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+(28)	10.40	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)	10.41	Commercialization Agreement by and between Gilead Sciences Limited and Bristol-Myers Squibb Company, dated December 10, 2007
+(29)	10.42	Amendment Agreement, dated October 25, 1993, between Registrant, the Institute of Organic Chemistry and Biochemistry (IOCB) and Rega Stichting v.z.w. (REGA), together with the following exhibits: the License Agreement, dated December 15, 1991, between Registrant, IOCB and REGA (the 1991 License Agreement), the License Agreement, dated October 15, 1992, between Registrant, IOCB and REGA (the October 1992 License Agreement) and the License Agreement, dated December 1, 1992, between Registrant, IOCB and REGA (the December 1992 License Agreement)
(30)	10.43	Amendment Agreement between Registrant and IOCB/REGA, dated December 27, 2000 amending the 1991 License Agreement and the December 1992 License Agreement

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(28)	10.44	Sixth Amendment Agreement to the License Agreement, between IOCB/REGA and Registrant, dated August 18, 2006 amending the October 1992 License Agreement and the December 1992 License Agreement
+(28)	10.45	Development and License Agreement among Registrant and F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc., dated September 27, 1996
+(31)	10.46	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
+(32)	10.47	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
+(33)	10.48	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
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+(35)	10.51	License Agreement between Registrant (as successor to Myogen, Inc.) and Abbott Deutschland Holding GmbH dated October 8, 2001
+(35)	10.52	License Agreement between Registrant (as successor to Myogen, Inc.) and Abbott Laboratories, dated June 30, 2003
+(36)	10.53	License Agreement between Registrant (as successor to CV Therapeutics, Inc.) and Syntex (U.S.A.) Inc., dated March 27, 1996
+(36)	10.54	First Amendment to License Agreement between Registrant (as successor to CV Therapeutics, Inc.) and Syntex (U.S.A.) Inc., dated July 3, 1997
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+(37)	10.56	Amendment No. 4 to Collaboration and License Agreement with Registrant (as successor to CV Therapeutics, Inc.) and Roche Palo Alto LLC, dated June 20, 2006
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+(39)	10.58	Master Clinical and Commercial Supply Agreement between Gilead World Markets, Limited, Registrant and Patheon Inc., dated January 1, 2003
+(33)	10.59	Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Gilead Sciences Limited and PharmaChem Technologies (Grand Bahama), Ltd., dated July 17, 2003
+(39)	10.60	Addendum to Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Gilead Sciences Limited and PharmaChem Technologies (Grand Bahama) Ltd., dated May 10, 2007

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+(25)	10.61	Addendum to Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Gilead Sciences Limited and PharmaChem Technologies (Grand Bahama) Ltd., dated December 5, 2008
+(21)	10.62	Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Registrant and Ampac Fine Chemicals LLC, dated March 6, 2008
+(31)	10.63	Restated and Amended Toll Manufacturing Agreement between Gilead Sciences Limited, Registrant and ALTANA Pharma Oranienburg GmbH, dated November 7, 2005
+(11)	10.64	Emtricitabine Manufacturing Supply Agreement between Gilead Sciences Limited and Degussa AG, dated June 6, 2006
(25)	10.65	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)
	101***	The following materials from Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2009, formatted in Extensible Business Reporting Language (XBRL) includes: (i) Condensed Consolidated Balance Sheets at September 30, 2009 and December 31, 2008, (ii) Condensed Consolidated Statements of Income for the Three and Nine Months Ended September 30, 2009 and 2008, (iii) Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2009 and 2008, and (iv) Notes to Condensed Consolidated Financial Statements, tagged as blocks of text.

(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.
(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.

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(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 Current Report on Form 8-K filed on May 11, 2009, 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.
(19) Filed as an exhibit to Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2009, and incorporated herein by reference.
(20) 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.
(21) 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.
(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.
(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) 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.
(26) Information is included in Registrant s Current Report on Form 8-K filed on January 27, 2009, and incorporated herein by reference.
(27) 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.
(28) 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.
(29) 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.
(30) 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.
(31) 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.
(32) 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.
(33) 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.
(34) 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.
(35) 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.

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(36) Filed as an exhibit to CV Therapeutics, Inc. s Registration Statement on Form S-3 (No. 333-59318), as amended, originally filed on April 20, 2001, and incorporated herein by reference.
(37) Filed as an exhibit to CV Therapeutics, Inc. s Quarterly Report on Form 10-Q for the quarter ended June 30, 2006, and incorporated herein by reference.
(38) 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.
(39) Filed as an exhibit to Registrant s Current Report on Form 8-K filed on August 7, 2007, 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.
*** XBRL information is furnished and not filed or a part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Exchange Act of 1933, as amended, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections.
\+ 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.

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SIGNATURES

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

GILEAD SCIENCES, INC.

(Registrant)

Date: November 5, 2009

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

Chairman and Chief Executive Officer

(Principal Executive Officer)

Date: November 5, 2009

/s/ ROBIN L. WASHINGTON
Robin L. Washington

Senior Vice President and Chief Financial Officer

(Principal Financial and Accounting Officer)

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Exhibit Index

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(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, as amended through May 8, 2008
(3)	3.2	Certificate of Designation of the Series A Junior Participating Preferred Stock of Registrant
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+(38)	10.58	Master Clinical and Commercial Supply Agreement between Gilead World Markets, Limited, Registrant and Patheon Inc., dated January 1, 2003
+(33)	10.59	Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Gilead Sciences Limited and PharmaChem Technologies (Grand Bahama), Ltd., dated July 17, 2003

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Exhibit Footnote	Exhibit Number	Description of Document
+(39)	10.60	Addendum to Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Gilead Sciences Limited and PharmaChem Technologies (Grand Bahama) Ltd., dated May 10, 2007
+(25)	10.61	Addendum to Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Gilead Sciences Limited and PharmaChem Technologies (Grand Bahama) Ltd., dated December 5, 2008
+(21)	10.62	Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Registrant and Ampac Fine Chemicals LLC, dated March 6, 2008
+(31)	10.63	Restated and Amended Toll Manufacturing Agreement between Gilead Sciences Limited, Registrant and ALTANA Pharma Oranienburg GmbH, dated November 7, 2005
+(11)	10.64	Emtricitabine Manufacturing Supply Agreement between Gilead Sciences Limited and Degussa AG, dated June 6, 2006
(25)	10.65	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)
	101***	The following materials from Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2009, formatted in Extensible Business Reporting Language (XBRL) includes: (i) Condensed Consolidated Balance Sheets at September 30, 2009 and December 31, 2008, (ii) Condensed Consolidated Statements of Income for the Three and Nine Months Ended September 30, 2009 and 2008, (iii) Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2009 and 2008, and (iv) Notes to Condensed Consolidated Financial Statements, tagged as blocks of text.

(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.
(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.

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(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 Current Report on Form 8-K filed on May 11, 2009, 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.
(19) Filed as an exhibit to Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2009, and incorporated herein by reference.
(20) 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.
(21) 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.
(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.
(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) 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.
(26) Information is included in Registrant s Current Report on Form 8-K filed on January 27, 2009, and incorporated herein by reference.
(27) 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.
(28) 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.
(29) 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.
(30) 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.
(31) 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.
(32) 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.
(33) 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.

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(34) 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.
(35) 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.
(36) Filed as an exhibit to CV Therapeutics, Inc. s Registration Statement on Form S-3 (No. 333-59318), as amended, originally filed on April 20, 2001, and incorporated herein by reference.
(37) Filed as an exhibit to CV Therapeutics, Inc. s Quarterly Report on Form 10-Q for the quarter ended June 30, 2006, and incorporated herein by reference.
(38) 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.
(39) Filed as an exhibit to Registrant s Current Report on Form 8-K filed on August 7, 2007, 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.
*** XBRL information is furnished and not filed or a part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Exchange Act of 1933, as amended, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections.
\+ 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.