

GILEAD SCIENCES INC  
Form 10-Q  
November 08, 2010  
[Table of Contents](#)

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

**FORM 10-Q**

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the quarterly period ended September 30, 2010

or

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

Commission File No. 0-19731

**GILEAD SCIENCES, INC.**

(Exact Name of Registrant as Specified in Its Charter)

Edgar Filing: GILEAD SCIENCES INC - Form 10-Q

<b>Delaware</b> (State or Other Jurisdiction of Incorporation or Organization)	<b>94-3047598</b> (IRS Employer Identification No.)
<b>333 Lakeside Drive, Foster City, California</b> (Address of principal executive offices)	<b>94404</b> (Zip Code)
<b>650-574-3000</b>	
<b>Registrant's Telephone Number, Including Area Code</b>	

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

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

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

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company

(Do not check if a smaller reporting company)

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

Number of shares outstanding of the issuer's common stock, par value \$0.001 per share, as of October 29, 2010: 811,867,667

**Table of Contents**

**GILEAD SCIENCES, INC.**

**INDEX**

PART I.	<b><u>FINANCIAL INFORMATION</u></b>	3
Item 1.	<u>Condensed Consolidated Financial Statements</u>	3
	<u>Condensed Consolidated Balance Sheets at September 30, 2010 and December 31, 2009</u>	3
	<u>Condensed Consolidated Statements of Income for the Three and Nine Months Ended September 30, 2010 and 2009</u>	4
	<u>Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2010 and 2009</u>	5
	<u>Notes to Condensed Consolidated Financial Statements</u>	6
Item 2.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	26
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	37
Item 4.	<u>Controls and Procedures</u>	37
PART II.	<b><u>OTHER INFORMATION</u></b>	38
Item 1.	<u>Legal Proceedings</u>	38
Item 1A.	<u>Risk Factors</u>	39
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	57
Item 3.	<u>Defaults Upon Senior Securities</u>	57
Item 4.	<u>Removed and Reserved</u>	57
Item 5.	<u>Other Information</u>	57
Item 6.	<u>Exhibits</u>	58
	<b><u>SIGNATURES</u></b>	67

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. LEXISCAN® is a registered trademark belonging to Astellas U.S. LLC. MACUGEN® is a registered trademark belonging to Eyetech Inc. SUSTIVA® is a registered trademark of Bristol-Myers Squibb Pharma Company. TAMIFLU® is a registered trademark belonging to Hoffmann-La Roche Inc. This report also includes other trademarks, service marks and trade names of other companies.

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

(in thousands, except per share amounts)

	September 30, 2010 (unaudited)	December 31, 2009
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 1,022,993	\$ 1,272,958
Short-term marketable securities	1,284,538	384,017
Accounts receivable, net	1,670,405	1,389,534
Inventories	1,273,389	1,051,771
Deferred tax assets	310,316	295,080
Prepaid taxes	279,956	274,196
Prepaid expenses	78,699	78,111
Other current assets	111,651	66,891
<b>Total current assets</b>	<b>6,031,947</b>	<b>4,812,558</b>
Property, plant and equipment, net	692,032	699,970
Noncurrent portion of prepaid royalties	203,649	226,250
Noncurrent deferred tax assets	95,291	101,498
Long-term marketable securities	2,744,150	2,247,871
Intangible assets	1,576,573	1,524,777
Other noncurrent assets	111,949	85,635
<b>Total assets</b>	<b>\$ 11,455,591</b>	<b>\$ 9,698,559</b>
<b>Liabilities and Stockholders Equity</b>		
Current liabilities:		
Accounts payable	\$ 950,813	\$ 810,544
Accrued government rebates	296,597	248,660
Accrued compensation and employee benefits	132,045	132,481
Income taxes payable	38,710	167,623
Other accrued liabilities	443,763	384,015
Deferred revenues	95,794	122,721
Current portion of convertible senior notes, net and other long-term obligations	632,386	5,587
<b>Total current liabilities</b>	<b>2,590,108</b>	<b>1,871,631</b>
Long-term deferred revenues	39,446	43,026
Convertible senior notes, net	2,818,708	1,155,443
Long-term income taxes payable	80,797	87,383
Other long-term obligations	47,760	35,918
Commitments and contingencies (Note 11)		
Stockholders equity:		
Preferred stock, par value \$0.001 per share; 5,000 shares authorized; none outstanding		

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

Common stock, par value \$0.001 per share; 2,800,000 shares authorized; 815,474 and 899,753 shares issued and outstanding at September 30, 2010 and December 31, 2009, respectively	815	900
Additional paid-in capital	4,575,984	4,376,651
Accumulated other comprehensive income (loss)	7,485	(5,758)
Retained earnings	1,122,030	1,995,272
Total Gilead stockholders' equity	5,706,314	6,367,065
Noncontrolling interest	172,458	138,093
Total stockholders' equity	5,878,772	6,505,158
Total liabilities and stockholders' equity	\$ 11,455,591	\$ 9,698,559

See accompanying notes.

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

(unaudited)

(in thousands, except per share amounts)

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2010</b>	<b>2009</b>	<b>2010</b>	<b>2009</b>
<b>Revenues:</b>				
Product sales	\$ 1,865,559	\$ 1,648,955	\$ 5,459,683	\$ 4,664,913
Royalty revenues	69,358	142,133	480,829	269,070
Contract and other revenues	2,739	10,301	10,221	45,021
<b>Total revenues</b>	<b>1,937,656</b>	<b>1,801,389</b>	<b>5,950,733</b>	<b>4,979,004</b>
<b>Costs and expenses:</b>				
Cost of goods sold	477,584	409,700	1,373,539	1,122,159
Research and development	230,440	269,856	680,170	700,273
Selling, general and administrative	250,559	227,427	764,183	692,789
<b>Total costs and expenses</b>	<b>958,583</b>	<b>906,983</b>	<b>2,817,892</b>	<b>2,515,221</b>
<b>Income from operations</b>	<b>979,073</b>	<b>894,406</b>	<b>3,132,841</b>	<b>2,463,783</b>
Interest and other income, net	15,593	14,017	49,523	31,098
Interest expense	(33,620)	(17,217)	(68,339)	(52,372)
<b>Income before provision for income taxes</b>	<b>961,046</b>	<b>891,206</b>	<b>3,114,025</b>	<b>2,442,509</b>
Provision for income taxes	258,883	220,728	850,641	616,310
<b>Net income</b>	<b>702,163</b>	<b>670,478</b>	<b>2,263,384</b>	<b>1,826,199</b>
Net loss attributable to noncontrolling interest	2,713	2,555	8,454	7,344
<b>Net income attributable to Gilead</b>	<b>\$ 704,876</b>	<b>\$ 673,033</b>	<b>\$ 2,271,838</b>	<b>\$ 1,833,543</b>
<b>Net income per share attributable to Gilead common stockholders basic</b>	<b>\$ 0.85</b>	<b>\$ 0.75</b>	<b>\$ 2.61</b>	<b>\$ 2.02</b>
Shares used in per share calculation basic	833,006	903,319	871,887	906,213
<b>Net income per share attributable to Gilead common stockholders diluted</b>	<b>\$ 0.83</b>	<b>\$ 0.72</b>	<b>\$ 2.55</b>	<b>\$ 1.96</b>
Shares used in per share calculation diluted	847,228	932,424	890,216	936,530

See accompanying notes.

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

(unaudited)

(in thousands)

	<b>Nine Months Ended September 30,</b>	
	<b>2010</b>	<b>2009</b>
<b>Operating Activities:</b>		
Net income	\$ 2,263,384	\$ 1,826,199
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation expense	49,375	44,312
Amortization expense	138,585	104,522
Stock-based compensation expenses	146,690	138,860
Excess tax benefits from stock-based compensation	(68,642)	(59,268)
Tax benefits from employee stock plans	69,940	66,243
Deferred income taxes	42,720	11,339
Other non-cash transactions	(19,621)	46,015
Changes in operating assets and liabilities:		
Accounts receivable, net	(352,081)	(290,013)
Inventories	(228,263)	(40,020)
Prepaid expenses and other assets	(5,818)	(33,356)
Accounts payable	141,692	135,212
Income taxes payable	(135,499)	118,621
Accrued liabilities	97,115	79,327
Deferred revenues	(30,507)	(23,215)
Net cash provided by operating activities	2,109,070	2,124,778
<b>Investing Activities:</b>		
Purchases of marketable securities	(3,800,280)	(1,916,498)
Proceeds from sales of marketable securities	1,808,222	1,186,319
Proceeds from maturities of marketable securities	591,646	362,849
Acquisitions, net of cash acquired	(91,000)	(1,247,816)
Capital expenditures and other	(38,523)	(203,070)
Net cash used in investing activities	(1,529,935)	(1,818,216)
<b>Financing Activities:</b>		
Proceeds from issuances of convertible notes, net of issuance costs	2,462,500	
Proceeds from sale of warrants	155,425	
Purchases of convertible note hedges	(362,622)	
Proceeds from issuances of common stock	166,826	160,924
Proceeds from credit facility	500,000	400,000
Repayments of credit facility	(500,000)	(200,000)
Repurchases of common stock	(3,407,055)	(756,491)
Extinguishment of long-term debt		(305,406)
Repayments of other long-term obligations	(5,589)	(5,607)
Excess tax benefits from stock-based compensation	68,642	59,268

Edgar Filing: GILEAD SCIENCES INC - Form 10-Q

Distributions from (to) noncontrolling interest	42,819	(80,047)
Net cash used in financing activities	(879,054)	(727,359)
Effect of exchange rate changes on cash	49,954	(13,906)
Net change in cash and cash equivalents	(249,965)	(434,703)
Cash and cash equivalents at beginning of period	1,272,958	1,459,302
Cash and cash equivalents at end of period	\$ 1,022,993	\$ 1,024,599

See accompanying notes.



**Table of Contents**

**GILEAD SCIENCES, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

(unaudited)

**1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Basis of Presentation**

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared in accordance with U.S. generally accepted accounting principles for interim financial information. The financial statements include all adjustments (consisting only of normal recurring adjustments) that the management of Gilead Sciences, Inc. (Gilead, we or us) 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, expenses, and related disclosures. On an ongoing basis, management evaluates its estimates, including critical accounting policies or estimates related to revenue recognition, intangible assets, allowance for doubtful accounts, prepaid royalties, clinical trial accruals, its 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. We record a noncontrolling interest in our Condensed Consolidated Financial Statements to reflect BMS' 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, 2009, included in our Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (SEC).

*Consolidation of Variable Interest Entities*

On January 1, 2010, we adopted amended guidance for the consolidation of variable interest entities. The amended guidance eliminates a mandatory quantitative approach to determine whether a variable interest gives the entity a controlling financial interest in a variable interest entity in favor of a qualitatively focused analysis. Additionally, the amended guidance requires an ongoing reassessment of whether the entity is a primary beneficiary. We adopted the provisions of this guidance on a prospective basis for our joint ventures with BMS, which we consolidate because we are the primary beneficiary. The adoption of this guidance did not have any impact on our Condensed Consolidated Financial Statements.

**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

**Table of Contents**

shares of our common stock resulting from the assumed exercise of outstanding stock options, restricted stock units and performance shares and the assumed exercise of warrants relating to the convertible senior notes due in 2011 (2011 Notes), 2013 (2013 Notes), 2014 (2014 Notes) and 2016 (2016 Notes) (collectively, the Notes) are determined under the treasury stock method.

Because the principal amount of the Notes will be settled in cash, only the conversion spread relating to the Notes is included in our calculation of diluted net income per share attributable to Gilead common stockholders. 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, \$38.10, \$45.08 and \$45.41 for the 2011 Notes, 2013 Notes, 2014 Notes and 2016 Notes, respectively. During the nine months ended September 30, 2010 and the three and nine months ended September 30, 2009, the average market prices of our common stock exceeded the conversion prices of the 2011 Notes and the 2013 Notes and the dilutive effects are included in the accompanying table.

Warrants relating to the 2011 Notes, 2013 Notes, 2014 Notes and 2016 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, \$53.90, \$56.76 and \$60.10, respectively. The average market prices of our common stock during each of the three and nine months ended September 30, 2010 and 2009 did not exceed the warrants' exercise prices relating to any of the Notes; therefore, these warrants did not have a dilutive effect on our net income per share for those periods.

Stock options to purchase approximately 27.1 million and 22.6 million weighted-average shares of our common stock were outstanding during the three and nine months ended September 30, 2010, 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 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.

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,	
	2010	2009	2010	2009
<b>Numerator:</b>				
Net income attributable to Gilead	\$ 704,876	\$ 673,033	\$ 2,271,838	\$ 1,833,543
<b>Denominator:</b>				
Weighted-average shares of common stock outstanding used in the calculation of basic net income per share attributable to Gilead common stockholders	833,006	903,319	871,887	906,213
<b>Effect of dilutive securities:</b>				
Stock options and equivalents	14,222	23,288	17,120	24,482
Conversion spread related to the 2011 Notes		2,765	461	2,774
Conversion spread related to the 2013 Notes		3,052	748	3,061
Weighted-average shares of common stock outstanding used in the calculation of diluted net income per share attributable to Gilead common stockholders	847,228	932,424	890,216	936,530

## **Table of Contents**

### **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 credit rating, maturity, 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. To date, we have not experienced significant losses with respect to the collection of our accounts receivable. We believe that our allowance for doubtful accounts was adequate at September 30, 2010.

### **Recent Accounting Pronouncements**

In October 2009, the Financial Accounting Standards Board issued new standards for revenue recognition for agreements with multiple deliverables. These new standards impact the determination of when the individual deliverables included in a multiple element arrangement may be treated as separate units of accounting. Additionally, these new standards modify the manner in which the transaction consideration is allocated across the separately identified deliverables by no longer permitting the residual method of allocating arrangement consideration. These new standards are effective for us beginning in the first quarter of 2011; however, early adoption is permitted. The adoption of these standards is not expected to have a material impact on our Condensed Consolidated Financial Statements.

## **2. FAIR VALUE MEASUREMENTS**

Our financial instruments consist principally of cash and cash equivalents, marketable securities, accounts receivable, foreign currency exchange forward and option contracts, accounts payable, short-term 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 \$3.45 billion and \$3.94 billion, respectively, as of September 30, 2010. The carrying value and fair value of the 2011 and 2013 Notes were \$1.16 billion and \$1.58 billion, respectively, as of December 31, 2009. The fair value of the Notes was based on their quoted market values. The remaining financial instruments are reported on our Condensed Consolidated Balance Sheets at amounts that approximate current fair values. Certain amounts within debt securities have been re-categorized in the accompanying tables to conform to the current presentation.

We determine the fair value of financial and non-financial assets and liabilities using the following fair value hierarchy, which establishes 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.

**Table of Contents**

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

	September 30, 2010				December 31, 2009			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
<b>Assets:</b>								
<b>Debt securities:</b>								
U.S. treasury securities	\$ 1,557,870	\$	\$	\$ 1,557,870	\$ 289,790	\$	\$	\$ 289,790
U.S. government agencies and FDIC guaranteed securities		1,430,945		1,430,945		1,086,082		1,086,082
Municipal debt securities		12,998		12,998		433,474		433,474
Non-U.S. government securities		251,260		251,260		75,524		75,524
Corporate debt securities		802,141		802,141		566,176		566,176
Residential mortgage and asset-backed securities		108,256		108,256		120,407	839	121,246
Student loan-backed securities			88,311	88,311			104,823	104,823
<b>Total debt securities</b>	<b>1,557,870</b>	<b>2,605,600</b>	<b>88,311</b>	<b>4,251,781</b>	<b>289,790</b>	<b>2,281,663</b>	<b>105,662</b>	<b>2,677,115</b>
Equity securities	3,370			3,370	3,470			3,470
Derivatives		51,873		51,873		26,198		26,198
	\$ 1,561,240	\$ 2,657,473	\$ 88,311	\$ 4,307,024	\$ 293,260	\$ 2,307,861	\$ 105,662	\$ 2,706,783
<b>Liabilities:</b>								
Contingent consideration	\$	\$	\$ 11,100	\$ 11,100	\$	\$	\$	\$
Derivatives		58,780		58,780		47,688		47,688
	\$	\$ 58,780	\$ 11,100	\$ 69,880	\$	\$ 47,688	\$	\$ 47,688

Marketable securities, measured at fair value using Level 2 inputs, are primarily comprised of U.S. government sponsored entity and corporate debt securities. We review trading activity and pricing for these investments as of the measurement date. When sufficient quoted pricing for identical securities is not available, we use market pricing and other observable market inputs for similar securities obtained from various third party data providers. These inputs represent quoted prices for similar assets in active markets or these inputs have been derived from observable market data. This approach results in the classification of these securities as Level 2 of the fair value hierarchy.

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

	Three Months Ended		Nine Months Ended	
	September 30, 2010	September 30, 2009	September 30, 2010	September 30, 2009
Balance, beginning of period	\$ 94,062	\$ 102,898	\$ 105,662	\$ 102,633
Total realized and unrealized gains (losses) included in:				
Interest and other income, net			115	(29)
Other comprehensive income, net	2,299	1,894	4,066	7,661
Sales of marketable securities	(8,050)	(582)	(21,532)	(6,055)
Transfers into Level 3				
<b>Balance, end of period</b>	<b>\$ 88,311</b>	<b>\$ 104,210</b>	<b>\$ 88,311</b>	<b>\$ 104,210</b>

Edgar Filing: GILEAD SCIENCES INC - Form 10-Q

Total losses included in interest and other income, net attributable to the change in unrealized losses relating to assets still held at the reporting date	\$	\$	\$	\$	(29)
---	----	----	----	----	------

**Table of Contents**

Our policy is to recognize transfers into or out of Level 3 classification as of the actual date of the event or change in circumstances that caused the transfer. 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 consist 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 four 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 and other fixed income securities, adjusted for an illiquidity discount. This resulted in an annual discount rate of 2.01%. Our auction rate securities reset every seven to 14 days with maturity dates ranging from 2023 through 2040 and have annual interest rates ranging from 0.44% to 1.19%. As of September 30, 2010, our auction rate securities continued to earn interest.

Our auction rate securities were recorded in long-term marketable securities on our Condensed Consolidated Balance Sheets at September 30, 2010 and December 31, 2009. Although there continued to be failed auctions as well as lack of market activity and liquidity in 2010, we believe we had no other-than-temporary impairments on these securities as of September 30, 2010 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.

**Table of Contents****3. AVAILABLE-FOR-SALE SECURITIES**

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
<b>September 30, 2010</b>				
Debt securities:				
U.S. treasury securities	\$ 1,547,252	\$ 10,623	\$ (5)	\$ 1,557,870
U.S. government agencies and FDIC guaranteed securities	1,414,099	16,851	(5)	1,430,945
Municipal debt securities	12,845	153		12,998
Non-U.S. government securities	248,865	2,497	(102)	251,260
Corporate debt securities	791,688	10,536	(83)	802,141
Residential mortgage and asset-backed securities	107,552	1,196	(492)	108,256
Student loan-backed securities	94,400		(6,089)	88,311
Total debt securities	4,216,701	41,856	(6,776)	4,251,781
Equity securities	1,451	1,919		3,370
Total	\$ 4,218,152	\$ 43,775	\$ (6,776)	\$ 4,255,151
<b>December 31, 2009</b>				
Debt securities:				
U.S. treasury securities	\$ 289,055	\$ 844	\$ (109)	\$ 289,790
U.S. government agencies and FDIC guaranteed securities	1,077,910	9,116	(944)	1,086,082
Municipal debt securities	429,583	3,986	(95)	433,474
Non-U.S. government securities	74,756	874	(106)	75,524
Corporate debt securities	557,116	9,563	(503)	566,176
Residential mortgage and asset-backed securities	119,308	2,048	(110)	121,246
Student loan-backed securities	115,400		(10,577)	104,823
Total debt securities	2,663,128	26,431	(12,444)	2,677,115
Equity securities	1,451	2,019		3,470
Total	\$ 2,664,579	\$ 28,450	\$ (12,444)	\$ 2,680,585

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, 2010	December 31, 2009
Cash and cash equivalents	\$ 226,463	\$ 48,697
Short-term marketable securities	1,284,538	384,017
Long-term marketable securities	2,744,150	2,247,871
Total	\$ 4,255,151	\$ 2,680,585





**Table of Contents**

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

	September 30, 2010		December 31, 2009	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
Less than one year	\$ 1,406,891	\$ 1,410,301	\$ 429,980	\$ 432,714
Greater than one year but less than five years	2,623,016	2,660,083	1,878,589	1,898,183
Greater than five years but less than ten years	25,806	26,489	56,895	57,585
Greater than ten years	160,988	154,908	297,664	288,633
<b>Total</b>	<b>\$ 4,216,701</b>	<b>\$ 4,251,781</b>	<b>\$ 2,663,128</b>	<b>\$ 2,677,115</b>

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,	
	2010	2009	2010	2009
Gross realized gains on sales	\$ 1,290	\$ 1,734	\$ 10,588	\$ 9,108
Gross realized losses on sales	\$ (260)	\$ (212)	\$ (2,434)	\$ (1,169)

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
<b>September 30, 2010</b>						
Debt securities:						
U.S. treasury securities	\$ (5)	\$ 240,430	\$	\$	\$ (5)	\$ 240,430
U.S. government agencies and FDIC guaranteed securities	(5)	41,994			(5)	41,994
Municipal debt securities						
Non-U.S. government securities	(102)	72,518			(102)	72,518
Corporate debt securities	(83)	134,831			(83)	134,831
Residential mortgage and asset-backed securities	(492)	33,855			(492)	33,855
Student loan-backed securities			(6,089)	88,311	(6,089)	88,311
<b>Total</b>	<b>\$ (687)</b>	<b>\$ 523,628</b>	<b>\$ (6,089)</b>	<b>\$ 88,311</b>	<b>\$ (6,776)</b>	<b>\$ 611,939</b>
<b>December 31, 2009</b>						
Debt securities:						
U.S. treasury securities	\$ (109)	\$ 97,871	\$	\$	\$ (109)	\$ 97,871
U.S. government agencies and FDIC guaranteed securities	(944)	223,901			(944)	223,901
Municipal debt securities	(95)	65,377			(95)	65,377
Non-U.S. government securities	(106)	30,924			(106)	30,924
Corporate debt securities	(503)	126,410			(503)	126,410
Residential mortgage and asset-backed securities	(110)	36,446			(110)	36,446
Student loan-backed securities			(10,577)	104,823	(10,577)	104,823

Edgar Filing: GILEAD SCIENCES INC - Form 10-Q

Total	\$ (1,867)	\$ 580,929	\$ (10,577)	\$ 104,823	\$ (12,444)	\$ 685,752
-------	------------	------------	-------------	------------	-------------	------------

**Table of Contents**

As of September 30, 2010 and December 31, 2009, approximately 12% and 32%, respectively, of the total number of securities were in an unrealized loss position. The gross unrealized losses for auction rate securities were caused by a higher discount rate used in the valuation of these securities as compared to the coupon rates of these securities. The gross unrealized losses for the other securities were primarily the result of an increase in the yield-to-maturity of the underlying 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, 2010 and December 31, 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.

During the three and nine months ended September 30, 2010, we recorded net unrealized gains on available-for-sale securities of \$9.7 million and \$18.4 million, respectively, in accumulated other comprehensive income (OCI). During the three and nine months ended September 30, 2010, gains of \$1.0 million and \$5.0 million, respectively, were reclassified out of accumulated OCI into interest and other income, net. Comparatively, during the three and nine months ended September 30, 2009, we recorded net unrealized gains on available-for-sale securities of \$8.3 million and \$21.7 million, respectively, in accumulated OCI. During the three and nine months ended September 30, 2009, 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**

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 a portion 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, 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. 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 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 OCI 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

**Table of Contents**

are reclassified into product sales. The majority of gains and losses related to the hedged forecasted transactions reported in accumulated OCI at September 30, 2010 will be reclassified to product sales within 12 months.

We had notional amounts on foreign currency exchange forward contracts outstanding of \$3.55 billion and \$3.45 billion at September 30, 2010 and December 31, 2009, respectively.

The following table summarizes information about the fair values of derivative instruments on our Condensed Consolidated Balance Sheets (in thousands):

	September 30, 2010			
	Asset Derivatives		Liability Derivatives	
	Location	Fair Value	Location	Fair Value
Derivatives designated as hedges:				
Foreign currency exchange contracts	Other current assets	\$ 51,746	Other accrued liabilities	\$ 38,579
Foreign currency exchange contracts	Other noncurrent assets		Other long-term obligations	20,178
Total derivatives designated as hedges		51,746		58,757
Derivatives not designated as hedges:				
Foreign currency exchange contracts	Other current assets	127	Other accrued liabilities	23
Total derivatives not designated as hedges		127		23
Total derivatives		\$ 51,873		\$ 58,780

	December 31, 2009			
	Asset Derivatives		Liability Derivatives	
	Location	Fair Value	Location	Fair Value
Derivatives designated as hedges:				
Foreign currency exchange contracts	Other current assets	\$ 16,183	Other accrued liabilities	\$ 45,482
Foreign currency exchange contracts	Other noncurrent assets	10,010	Other long-term obligations	2,180
Total derivatives designated as hedges		26,193		47,662
Derivatives not designated as hedges:				
Foreign currency exchange contracts	Other current assets	5	Other accrued liabilities	26
Total derivatives not designated as hedges		5		26
Total derivatives		\$ 26,198		\$ 47,688

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

	Three Months Ended		Nine Months Ended	
	September 30, 2010	2009	September 30, 2010	2009
Derivatives designated as hedges:				
Net gains (losses) recognized in OCI (effective portion)	\$ (174,321)	\$ (55,640)	\$ 76,023	\$ (17,003)
Net gains reclassified from accumulated OCI into product sales (effective portion)	\$ 31,526	\$ 16,714	\$ 69,080	\$ 89,771

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

Net gains (losses) recognized in interest and other income, net (ineffective portion and amounts excluded from effectiveness testing)	\$ 5,158	\$ 806	\$ 3,493	\$ (14,726)
Derivatives not designated as hedges:				
Net gains (losses) recognized in interest and other income, net	\$ (106,918)	\$ (37,519)	\$ 31,916	\$ (28,479)

**Table of Contents**

The net unrealized gains related to our cash flow hedges included in accumulated OCI, net of taxes, were \$12.9 million at September 30, 2010. Net unrealized losses related to our cash flow hedges included in accumulated OCI, net of taxes, were \$16.5 million at December 31, 2009.

**5. ACQUISITION OF CGI PHARMACEUTICALS, INC.**

In June 2010, we signed an agreement to acquire CGI Pharmaceuticals, Inc. (CGI) for up to \$120.0 million in cash, consisting of \$91.0 million as an upfront payment and up to \$29.0 million of contingent consideration payable based on the achievement of clinical development milestones. This transaction closed on July 8, 2010, at which time CGI became a wholly-owned subsidiary of Gilead. CGI was a privately-held development stage pharmaceutical company based in Branford, Connecticut, primarily focused on small molecule chemistry and protein kinase biology. The lead preclinical compound from CGI's library of proprietary small molecule kinase inhibitors targets spleen tyrosine kinase (Syk) and could have unique applications for the treatment of serious inflammatory diseases, including rheumatoid arthritis. We believe the acquisition will provide us with an opportunity to expand our research efforts in an interesting and promising area of drug discovery.

The CGI acquisition was accounted for as a business combination. The results of operations of CGI since July 8, 2010 have been included in our Condensed Consolidated Statements of Income and were not significant.

The acquisition-date fair value of the total consideration transferred to acquire CGI was \$102.1 million, and consisted of cash paid at or prior to closing of \$91.0 million and contingent consideration of \$11.1 million.

The following table summarizes the fair values of the assets acquired and liabilities assumed at July 8, 2010 (in thousands):

Intangible assets IPR&D	\$ 26,630
Goodwill	70,111
Deferred tax assets	12,656
Deferred tax liabilities	(6,313)
Other net liabilities assumed	(984)
 Total consideration transferred	 \$ 102,100

Intangible assets associated with in-process research and development (IPR&D) projects relate to the preclinical Syk product candidate. Management determined that the estimated acquisition-date fair value of intangible assets related to IPR&D was \$26.6 million. The estimated fair value was determined using the income approach, which discounts expected future cash flows to present value. We estimated the fair value using a present value discount rate of 18%, which is based on the estimated weighted-average cost of capital for companies with profiles substantially similar to that of CGI. This is comparable to the estimated internal rate of return for CGI's operations and represents the rate that market participants would use to value the intangible assets. The projected cash flows from the IPR&D project was based on key assumptions such as: estimates of revenues and operating profits related to the project considering its stage of development; the time and resources needed to complete the development and approval of the product candidate; the life of the potential commercialized product 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. 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 as well as 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.

## **Table of Contents**

The excess of the consideration transferred over the fair values assigned to the assets acquired and liabilities assumed is \$70.1 million, which represents the goodwill amount resulting from the CGI acquisition. Management believes that the goodwill mainly represents the synergies expected from combining our research and development operations as well as acquiring CGI's assembled workforce and other intangible assets that do not qualify for separate recognition. We recorded the goodwill as an intangible asset in our Condensed Consolidated Balance Sheet as of the acquisition date. Goodwill is tested for impairment on an annual basis as well as 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. As we have elected to treat the CGI acquisition as an asset acquisition for California state tax purposes, the goodwill resulting from the acquisition is deductible for California state income tax purposes, although such amounts are not deductible for federal income tax purposes.

We do not consider the CGI acquisition to be a material business combination and therefore have not disclosed the pro forma results of operations as required for material business combinations.

## **6. 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 the discovery, development and commercialization of small molecule drugs for the treatment of cardiovascular, metabolic and pulmonary diseases. CV Therapeutics had two marketed products as well as several product candidates in clinical development for the treatment of cardiovascular, metabolic and pulmonary diseases.

During the second quarter of 2009, we approved a plan to realize certain synergies between CV Therapeutics and us, re-align our cardiovascular operations and eliminate certain redundancies. The restructuring plan included consolidation and re-alignment of the cardiovascular research and development (R&D) organization, our exit from certain facilities and the termination of certain contractual obligations. During the three months ended September 30, 2010, we recorded \$0.4 million in R&D expenses, related to relocation and employee severance costs. During the nine months ended September 30, 2010, we recorded \$13.2 million and \$3.2 million of restructuring expenses in selling, general and administrative (SG&A) expenses and R&D expenses, respectively, related to lease termination costs, other facilities-related expenses, relocation and employee severance costs. As of September 30, 2010, we recorded approximately \$39.4 million and \$28.9 million in SG&A expenses and R&D expenses, respectively, related to employee severance, relocation, lease termination costs and other facilities-related expenses. We expect to incur an additional \$0.4 million in the fourth quarter of 2010 bringing the total amount to be incurred in connection with our restructuring plan to approximately \$36.3 million for employee severance and relocation and \$32.4 million for facilities-related expenses.

**Table of Contents**

The following table summarizes the restructuring liabilities accrued for and changes in those amounts during the period for the restructuring plan discussed above (in thousands):

	<b>Employee Severance and Termination Benefits</b>	<b>Facilities- Related Costs</b>
<b>Balance at December 31, 2008</b>	\$	\$
Costs incurred during the period	33,797	9,880
Costs paid or settled during the period	(24,108)	(545)
<b>Balance at December 31, 2009</b>	9,689	9,335
Costs incurred during the period	829	12,243
Costs paid or settled during the period	(8,513)	(1,431)
<b>Balance at March 31, 2010</b>	2,005	20,147
Costs incurred during the period	815	
Costs paid or settled during the period	(1,916)	(1,405)
<b>Balance at June 30, 2010</b>	904	18,742
Costs incurred during the period	438	
Costs paid or settled during the period	(677)	(91)
<b>Balance at September 30, 2010</b>	\$ 665	\$ 18,651

During the second quarter of 2010, we implemented a plan to close our operations in Durham, North Carolina and consolidate our liver disease work in Foster City, California. The restructuring plan includes consolidation of the liver disease R&D organization and our exit from certain facilities. We expect to complete this plan by the end of December 2010. During the three months ended September 30, 2010, we recorded \$1.1 million and \$5.6 million in SG&A expenses and R&D expenses, respectively, related to employee severance and facilities-related expenses. During the nine months ended September 30, 2010, we recorded \$1.4 million and \$7.0 million of restructuring expenses in SG&A expenses and R&D expenses, respectively, related to employee severance and facilities-related expenses. We expect to incur an additional \$13.5 million in the fourth quarter of 2010, bringing the total amount to be incurred in connection with this restructuring plan to approximately \$11.6 million for employee severance and \$10.3 million for facilities-related expenses.

**7. INVENTORIES**

Inventories are summarized as follows (in thousands):

	<b>September 30, 2010</b>	<b>December 31, 2009</b>
Raw materials	\$ 441,525	\$ 333,582
Work in process	392,541	392,042
Finished goods	439,323	326,147
Total	\$ 1,273,389	\$ 1,051,771

As of September 30, 2010 and December 31, 2009, the joint ventures formed by Gilead and BMS, which are included in our Condensed Consolidated Financial Statements, held \$891.3 million and \$667.8 million in inventory, respectively, of efavirenz active pharmaceutical ingredient purchased from BMS at BMS' estimated net selling price of efavirenz.





**Table of Contents****8. INTANGIBLE ASSETS**

The following table summarizes the carrying amount of our intangible assets (in thousands):

	September 30, 2010	December 31, 2009
Goodwill	\$ 532,669	\$ 462,558
Finite lived intangible assets	878,374	923,319
Indefinite lived intangible assets	165,530	138,900
Total	\$ 1,576,573	\$ 1,524,777

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

Balance at December 31, 2009	\$ 462,558
Goodwill resulting from the acquisition of CGI	70,111
Balance at September 30, 2010	\$ 532,669

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

	September 30, 2010		December 31, 2009	
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Intangible asset Ranexa	\$ 688,400	\$ 46,570	\$ 688,400	\$ 21,889
Intangible asset Lexiscan	262,800	37,543	262,800	18,235
Other	22,095	10,808	22,095	9,852
Total	\$ 973,295	\$ 94,921	\$ 973,295	\$ 49,976

Amortization expense related to intangible assets was \$14.9 million and \$44.9 million for the three and nine months ended September 30, 2010, respectively, and was recorded in cost of goods sold in our Condensed Consolidated Statements of Income. Comparatively, 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.

As of September 30, 2010, the estimated future amortization expense associated with our intangible assets for the remaining three months of 2010 and each of the five succeeding fiscal years are as follows (in thousands):

Fiscal Year	Amount
2010 (remaining three months)	\$ 14,981
2011	73,707
2012	86,627
2013	95,302
2014	99,790

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

2015	104,216
<b>Total</b>	<b>\$ 474,623</b>

As of September 30, 2010, we had indefinite-lived intangible assets of \$165.5 million, which consisted of \$26.6 million and \$138.9 million of purchased IPR&D from our acquisitions of CGI and CV Therapeutics, respectively. As of December 31, 2009, we had indefinite-lived intangible assets of \$138.9 million related to purchased IPR&D from our acquisition of CV Therapeutics.

**Table of Contents****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 applicable guidance. As of September 30, 2010, 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 arrangement with BMS in the United States to develop and commercialize a single tablet regimen containing our Truvada and BMS 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 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, manufacturing 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, 2010 and December 31, 2009, the joint venture held efavirenz active pharmaceutical ingredient which it purchased from BMS at BMS estimated net selling price of efavirenz in the U.S. market. These amounts are included in inventories on our Condensed Consolidated Balance Sheets. As of September 30, 2010 and December 31, 2009, total assets of the joint venture were \$1.57 billion and \$1.40 billion, respectively, and consisted primarily of cash and cash equivalents, accounts receivable (including intercompany receivables with Gilead) and inventories. As of September 30, 2010 and December 31, 2009, total liabilities of the joint venture were \$1.10 billion and \$1.03 billion, 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 intercompany eliminations that are included in our 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, Iceland, Liechtenstein, Norway and Switzerland (collectively, 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 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, 2010 and December 31, 2009, efavirenz purchased from BMS at BMS estimated net selling price of efavirenz in the European Territory is included in inventories on our Condensed Consolidated Balance Sheets.

**Table of Contents**

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.

**10. LONG TERM OBLIGATIONS***2014 and 2016 Convertible Senior Notes*

In July 2010, we issued \$1.25 billion of convertible senior notes due in 2014 and \$1.25 billion of convertible senior notes due in 2016 in a private placement pursuant to Rule 144A of the Securities Act of 1933, as amended. The 2014 Notes and the 2016 Notes were issued at par and bear interest rates of 1.00% and 1.625%, respectively. Debt issuance costs are primarily comprised of \$37.5 million in bankers' fees, the majority of which was recorded in other noncurrent assets and is being amortized to interest expense over the contractual terms of the Notes. The aggregate principal amount of the 2014 and 2016 Notes sold reflects the full exercise by the initial purchasers of their option to purchase additional Notes to cover over-allotments. The initial conversion rate for the 2014 Notes is 22.1845 shares per \$1,000 principal amount of 2014 Notes (which represents an initial conversion price of approximately \$45.08 per share), and the initial conversion rate for the 2016 Notes is 22.0214 shares per \$1,000 principal amount of 2016 Notes (which represents an initial conversion price of approximately \$45.41 per share). The conversion rates are subject to customary anti-dilution adjustments.

The 2014 and 2016 Notes may be converted prior to April 1, 2014 and April 1, 2016, respectively, only under the following circumstances: 1) during any calendar quarter commencing after September 30, 2010, if the closing price of the common stock for at least 20 trading days (whether or not consecutive) during the period of 30 consecutive trading days ending on the last trading day of the preceding calendar quarter is greater than 130% of the applicable conversion price on each applicable trading day, or, 2) during the five business day period after any measurement period of ten consecutive trading days in which, for each trading day of such period, the trading price per \$1,000 principal amount of notes was less than 98% of the product of the last reported sale price of Gilead common stock and the applicable conversion rate on such trading day, or 3) upon the occurrence of specified corporate transactions, such as the distribution of certain stock rights, cash amounts, or other assets to all Gilead shareholders or the occurrence of a change in control. On and after April 1, 2014, in the case of the 2014 Notes, and April 1, 2016, in the case of the 2016 Notes, holders may convert their Notes at any time, regardless of the foregoing circumstances. Generally, upon conversion, a holder would receive an amount in cash equal to the lesser of (i) the principal amount of the note or (ii) the conversion value for such note, as measured under the indenture governing the relevant notes. If the conversion value exceeds the principal amount, we may also deliver, at our option, cash or common stock or a combination of cash and common stock for the conversion value in excess of the principal amount. If the 2014 and 2016 Notes are converted in connection with a change in control, we may be required to provide a make whole premium in the form of an increase in the conversion rate, subject to a stated maximum amount. In addition, in the event of a change in control, the holders may require us to purchase all or a portion of their notes at a purchase price equal to 100% of their principal amount, plus accrued and unpaid interest, if any.

Concurrent with the issuance of the 2014 and 2016 Notes, we purchased convertible note hedges in private transactions at a cost of \$362.6 million, which is tax deductible over the life of the notes. We also sold warrants in private transactions and received net proceeds of \$155.4 million from the sale of the warrants. The convertible note hedges and warrants are intended to reduce the potential economic dilution upon future conversions of the 2014 and 2016 Notes by effectively increasing our conversion price to \$56.76 per share for the 2014 Notes and \$60.10 per share for the 2016 Notes. The net cost of \$207.2 million of the convertible note hedge and warrant transactions was recorded in stockholders equity.

The convertible note hedges cover, subject to customary anti-dilution adjustments, 55.3 million shares of our common stock at strike prices that initially correspond to the initial conversion prices of the 2014 and 2016

**Table of Contents**

Notes and are subject to adjustments similar to those applicable to the conversion price of the related notes. If the market value per share of our common stock at the time of conversion of the 2014 and 2016 Notes is above the strike price of the applicable convertible note hedges, we will be entitled to receive from the counterparties in the transactions shares of our common stock or, to the extent we have made a corresponding election with respect to the related convertible notes, cash or a combination of cash and shares of our common stock, at our option, for the excess of the market value of the common stock over the strike price of the convertible note hedges. The convertible note hedges will terminate upon the maturity of the 2014 and 2016 Notes or when none of the 2014 and 2016 Notes remain outstanding due to conversion or otherwise. There are 55.3 million shares of our common stock underlying the warrants, subject to customary anti-dilution adjustments. The warrants have strike prices of \$56.76 per share (for the warrants expiring in 2014) and \$60.10 per share (for the warrants expiring in 2016) and are exercisable only on their respective expiration dates. If the market value of our common stock at the time of the exercise of the applicable warrants exceeds their respective strike prices, we will be required to net settle in cash or shares of our common stock, at our option, with the respective counterparties for the value of the warrants in excess of the warrant strike prices.

As of September 30, 2010, we have used a portion of the net proceeds from the issuance of the convertible notes to repurchase \$1.18 billion of our common stock and repay the \$500.0 million borrowed under our credit facility. The remaining proceeds will be used to fund additional repurchases of our common stock and repay existing indebtedness.

*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 20 basis points to 32 basis points or the base rate, as described in the credit agreement. 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. The credit agreement will terminate in December 2012 and all unpaid borrowings thereunder shall be due and payable at that time. In May 2010, we borrowed \$500.0 million under the credit agreement to fund our stock repurchases. In August 2010, we repaid the \$500.0 million borrowed under this credit agreement using proceeds from our convertible senior notes issued in July 2010. As of September 30, 2010, we had \$4.5 million in letters of credit outstanding under the \$1.25 billion credit agreement. We are required to comply with certain covenants under the credit agreement and as of September 30, 2010, we were in compliance with all such covenants.

**11. COMMITMENTS AND CONTINGENCIES****Legal Proceedings**

Since November 2003, we have been defending a class action securities lawsuit purportedly brought on behalf of a class made up of all purchasers of our stock between July 14 and October 28, 2003. The lawsuit names Gilead and six current and former executives of Gilead as defendants. The lawsuit alleges that the defendants violated federal securities laws, specifically Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated by the SEC, by making certain alleged false and misleading statements. On May 12, 2006, the United States District Court for the Northern District of California (the District Court) executed orders dismissing in its entirety and with prejudice the fourth consolidated amended complaint. 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. 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

**Table of Contents**

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. On November 16, 2009, we filed an answer to the fifth consolidated amended complaint. In March 2010, we agreed to settle the dispute. Under the terms of the proposed settlement, the plaintiffs will dismiss the action and release all claims against Gilead and each of the individual defendants. In exchange, we agreed to pay \$8.25 million to the class members. The proposed settlement amount will be paid in full by our insurance carriers. Further, Gilead and the individual defendants continue to deny that they committed any act or omission giving rise to any liability and/or violation of law. On July 7, 2010, the District Court issued an order granting preliminary approval to the settlement. On November 5, 2010, the District Court granted final approval of the settlement.

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 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.

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 consolidated business, financial position or results of operations.

**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,	
	2010	2009	2010	2009
Cost of goods sold	\$ 2,728	\$ 2,461	\$ 8,548	\$ 8,486
Research and development expenses	20,946	21,916	62,536	63,192
Selling, general and administrative expenses	28,128	24,230	75,606	72,255
Stock-based compensation expenses included in total costs and expenses	51,802	48,607	146,690	143,933
Income tax effect	(13,990)	(12,389)	(40,070)	(37,466)
Stock-based compensation expenses included in net income	\$ 37,812	\$ 36,218	\$ 106,620	\$ 106,467

**13. STOCKHOLDERS EQUITY****Stock Repurchase Programs**

Under our current three-year, \$5.0 billion stock repurchase program authorized by our Board of Directors in May 2010, we repurchased \$2.41 billion of our common stock through September 30, 2010. As of September 30, 2010, the remaining authorized amount of stock repurchases that may be made under our \$5.0 billion repurchase program was \$2.59 billion. During the three and nine months ended September 30, 2010, we utilized \$1.55 billion and \$3.41 billion of cash to repurchase and retire 45.8 million and 93.6 million shares of our common stock, respectively, at average purchase prices of \$33.90 and \$36.40 per share.

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

**Table of Contents**

share with the excess amounts charged to retained earnings. As a result of our stock repurchases during the nine months ended September 30, 2010, we reduced common stock and APIC by an aggregate of \$271.3 million and charged \$3.15 billion 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,	
	2010	2009	2010	2009
Net income	\$ 702,163	\$ 670,478	\$ 2,263,384	\$ 1,826,199
Other comprehensive income (loss):				
Net foreign currency translation gain (loss)	8,025	2,520	(3,729)	9,735
Net unrealized gain on available-for-sale securities, net of related tax effects	8,813	7,343	13,441	16,601
Net unrealized gain (loss) on cash flow hedges, net of related tax effects	(198,977)	(72,355)	3,531	(106,775)
Total other comprehensive income (loss)	(182,139)	(62,492)	13,243	(80,439)
Comprehensive income	520,024	607,986	2,276,627	1,745,760
Comprehensive loss attributable to noncontrolling interest	2,713	2,555	8,454	7,344
Comprehensive income attributable to Gilead	\$ 522,737	\$ 610,541	\$ 2,285,081	\$ 1,753,104

**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, Atripla, Truvada and Viread, which together accounted for substantially all of our total product sales for the three and nine months ended September 30, 2010 and 2009, have similar economic and other characteristics, including the nature of the products and production processes, type of customers, distribution methods and regulatory environment.

Product sales consisted of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Antiviral products:				
Atripla	\$ 742,692	\$ 605,299	\$ 2,151,368	\$ 1,684,324
Truvada	668,741	620,564	1,968,222	1,818,996
Viread	184,263	169,711	541,121	489,241
Hepsera	47,519	67,928	156,977	207,716
Emtriva	6,696	6,729	20,597	21,001
Total antiviral products	1,649,911	1,470,231	4,838,285	4,221,278
AmBisome	75,132	77,064	230,355	214,645
Letairis	60,446	48,073	176,293	131,781
Ranexa	60,312	49,005	172,015	85,070
Other products	19,758	4,582	42,735	12,139
Total product sales	\$ 1,865,559	\$ 1,648,955	\$ 5,459,683	\$ 4,664,913





**Table of Contents**

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
United States	\$ 1,071,770	\$ 918,477	\$ 3,124,137	\$ 2,592,910
Outside of the United States:				
Switzerland	53,535	127,763	414,618	237,354
France	126,485	121,393	376,564	326,692
Spain	101,421	111,305	338,706	318,917
United Kingdom	105,186	99,663	322,885	283,893
Italy	78,395	79,235	261,519	239,434
Germany	70,077	70,092	195,084	207,249
Other European countries	177,356	137,004	509,050	416,469
Other countries	153,431	136,457	408,170	356,086
<b>Total revenues outside the United States</b>	<b>865,886</b>	<b>882,912</b>	<b>2,826,596</b>	<b>2,386,094</b>
<b>Total revenues</b>	<b>\$ 1,937,656</b>	<b>\$ 1,801,389</b>	<b>\$ 5,950,733</b>	<b>\$ 4,979,004</b>

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Cardinal Health, Inc.	17%	19%	17%	19%
McKesson Corp.	14%	15%	14%	14%
AmerisourceBergen Corp.	13%	12%	12%	12%

**15. INCOME TAXES**

Our income tax rate of 26.9% and 27.3% for the three and nine months ended September 30, 2010, respectively, differed from the U.S. federal statutory rate of 35% due primarily to 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.

We file federal, state and foreign income tax returns in many jurisdictions in the United States and abroad. For federal income tax purposes, the statute of limitations is open for 2003 and onwards. For certain acquired entities, the statute of limitations is open for all years from inception due to our utilization of their net operating losses and credits carried over from prior years. For California income tax purposes, the statute of limitations is open for 2002 and onwards.

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. We periodically evaluate our exposures associated with our tax filing positions.



**Table of Contents**

As of September 30, 2010, we believe it is reasonably possible that our unrecognized tax benefits will decrease by approximately \$4.0 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 record liabilities related to uncertain tax positions in accordance with the income tax guidance which 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.

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

*This Quarterly Report on Form 10-Q contains forward-looking statements regarding future events and our future results that are subject to the safe harbors created under the Securities Act of 1933, as amended (the Securities Act), and the Securities Exchange Act of 1934, as amended (the Exchange Act). 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, believe, seek, estimate, continue, may, could, should, might, variations of such words and similar expressions are intended to identify such forward-looking statements. In addition, any statements other than statements of historical fact are forward-looking statements, including statements regarding overall trends, operating cost and revenue trends, liquidity and capital needs and other statements of expectations, beliefs, future plans and strategies, anticipated events or trends and similar expressions. We have based these forward-looking statements on our current expectations about future events. 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, and specifically decline, any obligation to update any of these statements or to publicly announce the results of any revisions to 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, 2009 and our unaudited Condensed Consolidated Financial Statements for the three and nine months ended September 30, 2010 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 Asia Pacific. We market products in the HIV/AIDS, liver disease, respiratory and cardiovascular/metabolic therapeutic areas. Our product portfolio is comprised of Truvada<sup>®</sup> (emtricitabine and tenofovir disoproxil fumarate), Atripla<sup>®</sup> (efavirenz 600 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg), Viread<sup>®</sup> (tenofovir disoproxil fumarate) and Emtriva<sup>®</sup> (emtricitabine) for the treatment of human immunodeficiency virus (HIV) infection; Hepsera<sup>®</sup> (adefovir dipivoxil) and Viread for the treatment of chronic hepatitis B; AmBisome<sup>®</sup> (amphotericin B liposome for injection) for the treatment of severe fungal infections; Letairis<sup>®</sup> (ambrisentan) for the treatment of pulmonary arterial hypertension (PAH); Ranexa<sup>®</sup> (ranolazine) for the treatment of chronic angina; Vistide<sup>®</sup> (cidofovir injection) for the treatment of cytomegalovirus infection and Cayston<sup>®</sup> (aztreonam for inhalation solution) as a treatment to improve respiratory symptoms in cystic fibrosis (CF) patients with *Pseudomonas aeruginosa* (*P. aeruginosa*). In addition, we also sell and distribute certain products through our corporate partners under royalty-paying collaborative agreements. For example, F. Hoffmann-La Roche Ltd (together with Hoffmann-La Roche Inc., Roche) markets Tamiflu<sup>®</sup> (oseltamivir

---

**Table of Contents**

phosphate) for the treatment and prevention of influenza; GlaxoSmithKline Inc. (GSK) markets Hepsera for the treatment of chronic hepatitis B in certain territories outside of the United States; GSK also markets Volibris® (ambrisentan) outside of the United States for the treatment of PAH; Astellas Pharma US, Inc. markets AmBisome for the treatment of severe fungal infections in the United States and Canada; Astellas US LLC markets Lexiscan® (regadenoson) injection in the United States for use as a pharmacologic stress agent in radionuclide myocardial perfusion imaging; Raptiscan Pharma Solutions, Inc. markets regadenoson in certain territories outside of the United States for the inducement of pharmacological stress and/or vasodilation of the coronary vasculature strictly for purposes of diagnosing cardiovascular disease; Menarini International Operations Luxembourg SA markets Ranexa in certain territories outside of the United States for the treatment of chronic angina; and Japan Tobacco Inc. markets Truvada, Viread and Emtriva in Japan.

*Business Highlights*

In the HIV area, in September 2010, we announced that we had submitted a Marketing Authorization Application to the European Medicines Agency for marketing approval of the fixed-dose combination of Truvada and Tibotec Pharmaceuticals (Tibotec) investigational non-nucleoside reverse transcriptase inhibitor, TMC278 (rilpivirine), for the treatment of HIV-1 infection in adults. We anticipate submitting a New Drug Application to the U.S. Food and Drug Administration for the fixed-dose combination of Truvada and TMC278 in the fourth quarter of this year.

Also in the HIV area, in September 2010, we released positive 48-week results from two of our ongoing Phase 2 clinical studies in HIV-infected patients. The first were from the study of our investigational fixed-dose, single-tablet Quad regimen of elvitegravir, cobicistat and Truvada versus Atripla. The second were from the study of cobicistat-boosted atazanavir plus Truvada compared to ritonavir-boosted atazanavir plus Truvada. Results from both studies were presented at the 50th Annual Interscience Conference on Antimicrobial Agents and Chemotherapy in Boston.

In the liver disease area, in October 2010, we announced data from a Phase 2a study showing that our investigational compounds GS 9190 and GS 9256, used in conjunction with current standard of care therapies, produced substantial suppression of the hepatitis C virus (HCV) within 28 days of treatment. The findings were presented at the 61st annual meeting of the American Association for the Study of Liver Diseases in Boston. Our HCV pipeline now includes seven unique molecules spanning six therapeutic classes with different mechanisms of action. Five of these compounds are currently in clinical trials, and two are slated to enter human clinical studies early next year.

Also in the liver disease area, in October 2010, we announced new data from the open-label phase of two pivotal Phase 3 clinical trials (Studies 102 and 103) evaluating the four-year efficacy of Viread for the treatment of chronic hepatitis B virus (HBV) infection, which show that Viread maintains antiviral suppression with no development of resistance through four years of treatment. Data also show significant s antigen loss, a marker of the resolution of chronic HBV infection, in HBeAg-positive patients. These findings were also presented at the 61st annual meeting of the American Association for the Study of Liver Diseases in Boston.

In the respiratory area, in October 2010, we announced that our head-to-head Phase 3 clinical trial of Cayston versus tobramycin inhalation solution (TIS) in CF patients with *P. aeruginosa* achieved its co-primary endpoint of superiority of Cayston to TIS for mean actual change in forced expiratory volume in one second (FEV1, a measure of lung function) percent predicted across three treatment cycles (six months). These data were presented at the 24th Annual North American Cystic Fibrosis Conference in Baltimore.

*Financial Highlights*

Our operating results for the three months ended September 30, 2010 were led by total product sales of \$1.87 billion, an increase of 13% over total product sales of \$1.65 billion for the three months ended

---

**Table of Contents**

September 30, 2009. The increase in product sales was driven primarily by our antiviral franchise (Atripla, Truvada, Viread, Hepsera and Emtriva), due mainly to the strong growth in Atripla sales. Atripla contributed \$742.7 million, or 45%, to our third quarter 2010 antiviral product sales. Atripla product sales for the three months ended September 30, 2010 increased 23% from the same period in 2009 primarily due to sales volume growth in the United States and Europe. The growth of Atripla product sales and its increased proportion to overall product sales caused total product gross margin to decrease to 74% in the three months ended September 30, 2010 from 75% in the same period of 2009, due primarily to the efavirenz component of Atripla which has a gross margin of zero. Truvada product sales for the three months ended September 30, 2010 comprised \$668.7 million, or 41% of our third quarter 2010 antiviral product sales. Truvada product sales for the three months ended September 30, 2010 increased 8% from the three months ended September 30, 2009 primarily due to sales volume growth in the United States and Europe. Foreign currency exchange had an unfavorable impact of \$44.2 million and \$37.4 million on our third quarter 2010 revenues and pre-tax earnings, respectively, compared to the third quarter of 2009.

Product sales in the United States were driven primarily by our antiviral franchise but also reflected growth from our cardiovascular franchise. Antiviral product sales in the United States increased 15% in the third quarter of 2010 compared to the same quarter in 2009, resulting from the continued strong growth of patient and market share in the United States. Compared to the second quarter of 2010, antiviral product sales in the United States grew 4% in the third quarter due to strong demand for our antiviral products, despite the added impact of rebates to AIDS Drug Assistance Programs (ADAPs) and Public Health Service (PHS) entities as mandated by healthcare reform legislation adopted in the United States. With respect to our cardiovascular franchise, Ranexa sales in the United States were \$57.7 million in the third quarter of 2010, reflecting a continued growth in demand as Ranexa prescriptions have increased by 61% since our acquisition of CV Therapeutics in April 2009. Ranexa sales increased 28% from the third quarter of 2009 and were relatively flat compared to the second quarter of 2010. Furthermore, Letairis sales contributed \$60.4 million to our third quarter 2010 product sales in the United States, reflecting a 26% increase from the third quarter of 2009 and remaining relatively flat compared to the second quarter of 2010. Our newest product, Cayston, also contributed \$14.7 million in its second full quarter of sales, the majority of which was in the United States.

Product sales in Europe were driven by antiviral product sales, which increased 5% in the third quarter of 2010 compared to the same quarter in 2009, due to a strong continued growth in demand. Compared to the second quarter of 2010, antiviral product sales in Europe increased 2% in the third quarter of 2010. While we saw demand growth for our products in Europe, the effect was partially offset by recent mandatory price reductions in certain European countries and foreign currency exchange impact from a strengthening U.S. dollar relative to European currencies.

Royalty revenues recognized from our collaborations with corporate partners were \$69.4 million for the three months ended September 30, 2010, a decrease of \$72.8 million from royalty revenues of \$142.1 million for the three months ended September 30, 2009. The change in royalty revenues resulted primarily from decreased Tamiflu sales by Roche related to influenza pandemic planning initiatives worldwide. Compared to the second quarter of 2010, Tamiflu royalties in the third quarter of 2010 decreased significantly due to the fulfillment of many of the existing pandemic orders from governments and corporations. Based on Roche's reported sales of Tamiflu for the three months ended September 30, 2010, we expect Tamiflu royalties to further decrease to approximately \$21 million in the fourth quarter of 2010.

Our research and development (R&D) and selling, general and administrative (SG&A) expenses decreased by \$16.3 million, or 3%, for the three months ended September 30, 2010 compared to the same period in 2009. The decrease was due primarily to lower R&D expense reimbursement related to our collaboration with Tibotec. Also, in the second half of 2010, we experienced lower R&D expense due to delays in clinical trial expenditures which we expect to incur in future periods.

During the second quarter of 2010, we approved and communicated a plan to close our operations in Durham, North Carolina and consolidate our liver disease work in Foster City, California. We believe that this

---

## **Table of Contents**

plan will allow our employees across R&D to collaborate more effectively and further advance our programs in the liver disease area. For the three months ended September 30, 2010, we incurred \$6.7 million of restructuring expenses related to employee severance and facilities-related expenses. We expect to close our operations in Durham by the end of December 2010 and incur an additional \$13.5 million in pre-tax restructuring expenses during the fourth quarter of 2010, bringing the total restructuring cost to approximately \$21.9 million comprised of employee severance and facilities-related expenses.

Cash, cash equivalents and marketable securities increased by \$1.15 billion during the nine months ended September 30, 2010, driven primarily by our operating cash flows of \$2.11 billion and proceeds of \$2.46 billion from the issuance of convertible senior notes, net of issuance costs, partially offset by repurchases of our common stock under our stock repurchase programs. Under our current three-year, \$5.0 billion stock repurchase program, we repurchased \$2.41 billion of our common stock through September 30, 2010. During the nine months ended September 30, 2010, we utilized \$3.41 billion of cash to repurchase and retire 93.6 million shares of our common stock at an average purchase price of \$36.40 per share.

In July 2010, we issued \$2.50 billion of convertible senior notes in a private placement and purchased convertible note hedges as well as sold warrants for a net cost of \$207.2 million. The cost of the convertible note hedges will be tax deductible over the life of the notes. The convertible note hedges and warrants are intended to reduce the potential economic dilution upon future conversions of the notes by effectively increasing our conversion prices for the notes. Our interest expense for the three months ended September 30, 2010 increased by \$16.4 million compared to the same period in 2009, due primarily to increased interest expense related to our convertible notes. We expect to see the impact of a full quarter of interest expense related to these convertible notes in the fourth quarter of 2010.

As of September 30, 2010, we have used a portion of the net proceeds from the issuance of the convertible notes to repurchase \$1.18 billion of our common stock and repay the \$500.0 million borrowed under our credit facility. The remaining proceeds will be used to fund additional repurchases of our common stock and repay existing indebtedness.

### *Healthcare Reform*

In March 2010, healthcare reform legislation was adopted in the United States. As a result, we are required to further rebate or discount products reimbursed or paid for by various public payers, including Medicaid and other entities eligible to purchase discounted products through the 340B Drug Pricing Program under the Public Health Service Act, such as ADAPs. The discounts, rebates and fees in the legislation that will impact us include:

effective January 1, 2010, our minimum base rebate amount owed to Medicaid on products reimbursed by Medicaid has been increased by 8%, and the discounts or rebates we owe to ADAPs and other PHS entities which reimburse or purchase our products have also been increased by 8%;

effective March 23, 2010, we are required to extend rebates to patients receiving our products through Medicaid managed care organizations;

effective January 1, 2011, we will be required to provide a 50% discount on products sold to patients while they are in the Medicare Part D donut hole; and

effective 2011, we, along with other pharmaceutical manufacturers of branded drug products, will be required to pay a portion of a new industry fee (also known as the pharmaceutical excise tax), calculated based on select government sales during the 2010 calendar year as a percentage of total industry government sales.

Starting in 2014, as the number of people with access to healthcare coverage is expected to increase, we could experience a positive impact on the sales of our products. Further, the expansion of healthcare coverage may decrease the reliance of patients on state ADAPs that currently rely on the availability of federal and state funding.





**Table of Contents**

We estimate that the full impact of healthcare reform for 2010 will be a reduction of approximately \$200 million in U.S. net product sales, and that the majority of this impact began in the third quarter and will continue throughout the fourth quarter of 2010 since some of the new discount and rebate requirements take two quarters to fully implement. For 2011, excluding the impact of the new pharmaceutical excise tax, we estimate that the impact of healthcare reform on product sales will be similar to 2010 as a percentage of our U.S. net product sales.

Many of the specific determinations necessary to implement the healthcare reform legislation have yet to be decided and communicated by the federal government. For example, we do not know how many or how quickly patients receiving our product under the Medicare Part D program will reach the donut hole or how the pharmaceutical excise tax will be calculated and reflected in our financial results. Based on the information that we have to date, we estimate the 2011 impact of the pharmaceutical excise tax to be less than \$50 million, which will be classified as SG&A expense. The excise tax is not tax deductible. In calculating the anticipated financial impacts of healthcare reform described above, we have made several estimates and assumptions with respect to our expected payer mix, how the reforms will be implemented and the timing for implementing the various discounts, rebates and fees contained in the legislation.

**Critical Accounting Policies, Estimates and Judgments**

There have been no material changes in our critical accounting policies, estimates and judgments during the nine months ended September 30, 2010 compared to the disclosures in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2009.

**Results of Operations***Total Revenues*

Total revenues for the three months ended September 30, 2010 were \$1.94 billion, compared to \$1.80 billion for the same period in 2009. Total revenues for the nine months ended September 30, 2010 were \$5.95 billion, compared to \$4.98 billion for the same period in 2009. Included in total revenues were product sales, royalty revenues and contract and other revenues. A significant percentage of our product sales continued to be denominated in foreign currencies and we face exposure to adverse movements in foreign currency exchange rates. We used foreign currency exchange forward and option contracts to hedge a percentage of our forecasted international sales, primarily those denominated in Euro. Foreign currency exchange had an unfavorable impact of \$44.2 million on our third quarter 2010 revenues compared to the third quarter of 2009.

*Product Sales*

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2010	2009	Change	2010	2009	Change
<b>Antiviral products:</b>						
Atripla	\$ 742,692	\$ 605,299	23%	\$ 2,151,368	\$ 1,684,324	28%
Truvada	668,741	620,564	8%	1,968,222	1,818,996	8%
Viread	184,263	169,711	9%	541,121	489,241	11%
Hepsera	47,519	67,928	(30)%	156,977	207,716	(24)%
Emtriva	6,696	6,729	0%	20,597	21,001	(2)%
<b>Total antiviral products</b>	<b>1,649,911</b>	<b>1,470,231</b>	<b>12%</b>	<b>4,838,285</b>	<b>4,221,278</b>	<b>15%</b>
AmBisome	75,132	77,064	(3)%	230,355	214,645	7%
Letairis	60,446	48,073	26%	176,293	131,781	34%
Ranexa	60,312	49,005	23%	172,015	85,070	102%
Other products	19,758	4,582	331%	42,735	12,139	252%
<b>Total product sales</b>	<b>\$ 1,865,559</b>	<b>\$ 1,648,955</b>	<b>13%</b>	<b>\$ 5,459,683</b>	<b>\$ 4,664,913</b>	<b>17%</b>



## **Table of Contents**

Total product sales increased by 13% and 17% for the three and nine months ended September 30, 2010, respectively, compared to the same periods in 2009. This increase was due primarily to the strong growth of Atripla sales.

### *Antiviral Products*

Antiviral product sales increased by 12% and 15% for the three and nine months ended September 30, 2010, respectively, compared to the same periods in 2009.

#### *Atripla*

Atripla sales increased by 23% and 28% for the three and nine months ended September 30, 2010, respectively, compared to the same periods in 2009, driven primarily by sales volume growth in the United States and Europe. Atripla sales include the efavirenz component which has a gross margin of zero. The efavirenz portion of our Atripla sales was approximately \$273.5 million and \$791.9 million for the three and nine months ended September 30, 2010, respectively and approximately \$221.6 million and \$617.1 million for the three and nine months ended September 30, 2009, respectively. Atripla sales accounted for 45% and 44% of our total antiviral product sales for the three and nine months ended September 30, 2010, respectively.

#### *Truvada*

Truvada sales increased by 8% for both the three and nine months ended September 30, 2010, compared to the same periods in 2009, driven primarily by sales volume growth in the United States and Europe. Truvada sales accounted for 41% of our total antiviral product sales for both the three and nine months ended September 30, 2010.

#### *Other Antiviral Products*

Other antiviral product sales, which include product sales of Viread, Hepsara and Emtriva, were relatively flat for the three and nine months ended September 30, 2010, compared to the same periods in 2009, due primarily to higher Viread sales offset by sales volume decreases in Hepsara.

#### *AmBisome*

Sales of AmBisome decreased by 3% and increased by 7% for the three and nine months ended September 30, 2010, respectively, compared to the same periods in 2009. The decrease for the three months ended September 30, 2010 was due primarily to decreased pricing outside of the United States and foreign currency exchange fluctuations, partially offset by sales volume increases in certain markets outside of the United States. The increase in AmBisome sales for the nine months ended September 30, 2010 was driven primarily by sales volume growth in certain markets outside of the United States. AmBisome product sales in the United States and Canada relate solely to our sales of AmBisome to Astellas Pharma US, Inc. which are recorded at our manufacturing cost.

#### *Letairis*

Sales of Letairis increased by 26% and 34% for the three and nine months ended September 30, 2010, respectively, compared to the same periods in 2009, driven primarily by sales volume growth in the United States.

#### *Ranexa*

Sales of Ranexa increased by 23% and 102% for the three and nine months ended September 30, 2010, respectively, compared to the same periods in 2009, driven primarily by sales volume growth in the United States. Ranexa sales began on April 15, 2009, the date Gilead acquired CV Therapeutics.



**Table of Contents***Royalty Revenues*

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2010	2009	Change	2010	2009	Change
Royalty revenues	\$ 69,358	\$ 142,133	(51)%	\$ 480,829	\$ 269,070	79%

Our most significant source of royalty revenues for the three and nine months ended September 30, 2010 and 2009 was from sales of Tamiflu by Roche. We recognize royalties on Tamiflu sales by Roche in the quarter following the quarter in which Tamiflu is sold.

Royalty revenues for the three months ended September 30, 2010 were \$69.4 million, a decrease of 51% or \$72.8 million compared to the same period in 2009, primarily due to lower Tamiflu royalties from Roche of \$34.5 million in the three months ended September 30, 2010, compared to Tamiflu royalties from Roche of \$113.5 million in the same period in 2009. Compared to the second quarter of 2010, Tamiflu royalties decreased by \$49.3 million in the three months ended September 30, 2010 due to the fulfillment of many of the existing pandemic orders from governments and corporations.

Royalty revenues for the nine months ended September 30, 2010 were \$480.8 million, an increase of 79% or \$211.8 million compared to the same period in 2009, driven primarily by higher Tamiflu royalties from Roche of \$364.6 million in the nine months ended September 30, 2010, compared to Tamiflu royalties from Roche of \$198.6 million in the same period in 2009. These increases were primarily driven by increased Tamiflu royalties in the first quarter of 2010 related to influenza pandemic planning initiatives worldwide.

*Cost of Goods Sold and Product Gross Margin*

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2010	2009	Change	2010	2009	Change
Total product sales	\$ 1,865,559	\$ 1,648,955	13%	\$ 5,459,683	\$ 4,664,913	17%
Cost of goods sold	\$ 477,584	\$ 409,700	17%	\$ 1,373,539	\$ 1,122,159	22%
Product gross margin	74%	75%		75%	76%	

Our product gross margin for the three months ended September 30, 2010 was 74% compared to 75% for the same period in 2009. Our product gross margin for the nine months ended September 30, 2010 was 75% compared to 76% for the same period in 2009. The lower product gross margin for the three and nine months ended September 30, 2010 compared to the same periods in 2009 was due primarily to the higher proportion of Atripla sales, which has a gross margin of zero for the efavirenz component. For the nine months ended September 30, 2010, the decrease in product gross margin was partially offset by favorable product mix.

*Restructuring*

During the second quarter of 2010, we approved and communicated a plan to close our operations in Durham, North Carolina and consolidate our liver disease work in Foster City, California. We believe this plan will allow our employees across R&D to collaborate more effectively and further advance our programs in the liver disease area. We expect to close our operations in Durham by the end of December 2010. For the three months ended September 30, 2010, we recorded \$1.1 million and \$5.6 million in SG&A expenses and R&D expenses, respectively, related to employee severance and facilities-related expenses. For the nine months ended



**Table of Contents**

September 30, 2010, we recorded \$1.4 million and \$7.0 million of restructuring expenses in SG&A expenses and R&D expenses, respectively, related to employee severance and facilities-related expenses. We expect to incur an additional \$13.5 million in the fourth quarter of 2010, bringing the total amount to be incurred in connection with our restructuring plan to approximately \$11.6 million for employee severance and \$10.3 million for facilities-related expenses.

During the second quarter of 2009, we approved a plan to realize certain synergies between CV Therapeutics and us, re-align our cardiovascular operations and eliminate certain redundancies. For the three months ended September 30, 2010, we recorded \$0.4 million of restructuring expenses in R&D expenses related to relocation and employee severance costs. For the nine months ended September 30, 2010 we recorded \$13.2 million and \$3.2 million of restructuring expenses in SG&A expenses and R&D expenses, respectively, related to lease termination costs, other facilities-related expenses, relocation and employee severance costs. As of September 30, 2010, we recorded approximately \$39.4 million and \$28.9 million in SG&A expenses and R&D expenses, respectively, related to employee severance, relocation, lease termination costs and other facilities-related expenses. We expect to incur an additional \$0.4 million in the fourth quarter of 2010, bringing the total amount to be incurred in connection with this restructuring plan to approximately \$36.3 million for employee severance and relocation and \$32.4 million for facilities-related expenses.

*Research and Development Expenses*

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2010	2009	Change	2010	2009	Change
Research and development	\$ 230,440	\$ 269,856	(15)%	\$ 680,170	\$ 700,273	(3)%

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.

R&D expenses for the three months ended September 30, 2010 decreased by \$39.4 million, or 15%, compared to the same period in 2009, due primarily to a decrease of \$46.3 million in R&D expense reimbursements related to our collaboration with Tibotec.

R&D expenses for the nine months ended September 30, 2010 decreased by \$20.1 million, or 3%, compared to the same period in 2009, due primarily to a decrease of \$30.6 million in R&D expense reimbursements related to our collaboration with Tibotec, partially offset by increases in various other R&D expenses.

*Selling, General and Administrative Expenses*

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2010	2009	Change	2010	2009	Change
Selling, general and administrative	\$ 250,559	\$ 227,427	10%	\$ 764,183	\$ 692,789	10%

SG&A expenses for the three months ended September 30, 2010 increased by \$23.1 million, or 10%, compared to the same period in 2009. This was due primarily to increased compensation and benefits expenses of \$14.6 million as a result of higher headcount to support our expanding commercial activities.



**Table of Contents**

SG&A expenses for the nine months ended September 30, 2010 increased by \$71.4 million, or 10%, compared to the same period in 2009, due primarily to increased compensation and benefits expenses of \$20.2 million, increased promotional expenses of \$19.0 million driven primarily by our expanding sales and marketing activities and facilities-related expenses of \$18.9 million related primarily to lease termination costs associated with our restructuring activities.

*Interest and Other Income, Net*

Interest and other income, net for the three and nine months ended September 30, 2010 increased by \$1.6 million and \$18.4 million, respectively, compared to the same periods in 2009, due primarily to decreased costs related to our hedging activities.

*Interest Expense*

Interest expense for the three and nine months ended September 30, 2010 increased by \$16.4 million and \$16.0 million, respectively, compared to the same periods in 2009, due primarily to increased interest expense related to our convertible notes issued in July 2010.

*Provision for Income Taxes*

Our provision for income taxes was \$258.9 million and \$850.6 million for the three and nine months ended September 30, 2010, respectively, compared to \$220.7 million and \$616.3 million for the three and nine months ended September 30, 2009, respectively. Our effective tax rate was 26.9% and 27.3% for the three and nine months ended September 30, 2010, respectively, compared to our effective tax rate of 24.8% and 25.2% for the three and nine months ended September 30, 2009, respectively. The effective tax rates for the three and nine months ended September 30, 2010 were higher than the effective tax rates for the three and nine months ended September 30, 2009 as a result of lower earnings from non-U.S. subsidiaries that are considered indefinitely invested outside the United States as a percentage of total earnings, the expiration of the federal research tax credit as of December 31, 2009 and the resolution of certain tax positions with tax authorities in 2009.

The effective tax rate for the three and nine months ended September 30, 2010 differed from the U.S. federal statutory rate of 35% due primarily to 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.

**Liquidity and Capital Resources**

The following table summarizes our cash, cash equivalents and marketable securities, our working capital and our cash flow activities as of the end of, and for each of, the periods presented (in thousands):

	As of September 30, 2010	As of December 31, 2009
Cash, cash equivalents and marketable securities	\$ 5,051,681	\$ 3,904,846
Working capital	\$ 3,441,839	\$ 2,940,927
	Nine Months Ended September 30,	
	2010	2009
Cash provided by (used in):		
Operating activities	\$ 2,109,070	\$ 2,124,778
Investing activities	\$ (1,529,935)	\$ (1,818,216)
Financing activities	\$ (879,054)	\$ (727,359)

---

**Table of Contents**

*Cash, Cash Equivalents and Marketable Securities*

Cash, cash equivalents and marketable securities totaled \$5.05 billion at September 30, 2010, an increase of \$1.15 billion or 29% from December 31, 2009. This increase was primarily attributable to net cash provided by operations of \$2.11 billion and proceeds of \$2.46 billion from the issuance of convertible senior notes, net of issuance costs, partially offset by \$3.41 billion used to repurchase common stock under our stock repurchase programs.

*Working Capital*

Working capital was \$3.44 billion at September 30, 2010, an increase of \$500.9 million or 17%, from working capital as of December 31, 2009. This increase was primarily attributable to:

an increase of \$650.6 million in cash, cash equivalents and short-term marketable securities;

an increase of \$280.9 million in accounts receivable, net, primarily driven by increased product sales; and

an increase of \$221.6 million in inventories, due primarily to the purchase of efavirenz at its estimated net selling price from Bristol-Myers Squibb Company (BMS).

This increase was partially offset by:

an increase of \$626.8 million in the current portion of convertible senior notes, net and other long-term obligations, due to the reclassification of our convertible senior notes due in 2011 to current liabilities; and

an increase of \$140.3 million in accounts payable, due primarily to the purchases of efavirenz from BMS.

*Cash Provided by Operating Activities*

Cash provided by operating activities of \$2.11 billion for the nine months ended September 30, 2010 primarily related to net income of \$2.26 billion, adjusted for non-cash items such as \$146.7 million of stock-based compensation expenses, \$188.0 million of depreciation and amortization expenses and \$69.9 million of tax benefits from employee stock plans, partially offset by \$513.4 million of net cash outflow related to changes in operating assets and liabilities and \$68.6 million of excess tax benefits from stock option exercises which we reclassified to cash used in financing 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 Used in Investing Activities*

Cash used in investing activities for the nine months ended September 30, 2010 was \$1.53 billion, driven by a net use of \$1.40 billion in purchases of marketable securities, \$91.0 million used in our acquisition of CGI Pharmaceuticals, Inc., and \$38.5 million of capital expenditures.

Cash used in investing activities for the nine months ended September 30, 2009 was \$1.82 billion and related to cash used in our acquisition of CV Therapeutics of \$1.25 billion, net of cash and cash equivalents acquired, a net use of \$367.3 million in purchases of marketable securities as well as capital expenditures of \$203.1 million.



---

## **Table of Contents**

### *Cash Used in Financing Activities*

Cash used in financing activities for the nine months ended September 30, 2010 was \$879.1 million, driven primarily by the \$3.41 billion used to repurchase our common stock under our stock repurchase programs and \$362.6 million used to purchase note hedges related to our convertible senior notes due in 2014 and 2016. The cash outflows were partially offset by \$2.46 billion in proceeds from the issuance of convertible senior notes, net of issuance costs, \$155.4 million in proceeds from the sale of warrants related to our convertible senior notes, and \$166.8 million in proceeds from issuances of common stock under our employee stock plans.

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 net proceeds of \$200.0 million from borrowings under our credit facility to partially fund the acquisition of CV Therapeutics, and proceeds of \$160.9 million from issuances of common stock under our employee stock plans.

### *Other Information*

Under our current three-year, \$5.0 billion stock repurchase program authorized by our Board in May 2010, we repurchased \$2.41 billion of our common stock through September 30, 2010. As of September 30, 2010, the remaining authorized amount of stock repurchases that may be made under our \$5.0 billion repurchase program was \$2.59 billion. During the nine months ended September 30, 2010, we utilized \$3.41 billion of cash to repurchase and retire 93.6 million shares of our common stock at an average purchase price of \$36.40 per share.

During the three months ended September 30, 2010, we repaid the \$500.0 million revolving credit facility originally drawn down in May 2010 under our amended and restated credit agreement. Under that 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 20 basis points to 32 basis points or the base rate, as described in the credit agreement. The credit agreement will terminate in December 2012 and all unpaid borrowings thereunder shall be due and payable at that time. We may reduce the commitments and may prepay loans under the credit agreement in whole or in part without penalty, subject to certain conditions. As of September 30, 2010, approximately \$1.25 billion was available to be drawn down under this credit agreement.

In July 2010, we issued \$2.50 billion of convertible senior notes in a private placement and purchased convertible note hedges as well as sold warrants for a net cost of \$207.2 million. The cost of the convertible note hedges will be tax deductible over the life of the notes. The convertible note hedges and warrants are intended to reduce the potential economic dilution upon future conversions of the notes by effectively increasing our conversion prices for the notes.

As of September 30, 2010, we have used a portion of the net proceeds from the issuance of the convertible notes to repurchase \$1.18 billion of our common stock and repay the \$500.0 million borrowed under our credit facility. The remaining proceeds will be used to fund additional repurchases of our common stock and repay existing indebtedness.

### **Off Balance Sheet Arrangements**

We do not have any off balance sheet arrangements.

### **Recent Accounting Pronouncements**

In October 2009, the Financial Accounting Standards Board issued new standards for revenue recognition for agreements with multiple deliverables. These new standards impact the determination of when the individual

## **Table of Contents**

deliverables included in a multiple element arrangement may be treated as separate units of accounting. Additionally, these new standards modify the manner in which the transaction consideration is allocated across the separately identified deliverables by no longer permitting the residual method of allocating arrangement consideration. These new standards are effective for us beginning in the first quarter of 2011; however, early adoption is permitted. The adoption of these standards is not expected to have a material impact on our Condensed Consolidated Financial Statements.

### **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, 2010 compared to the disclosures in Part II, Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2009.

A portion of our marketable securities consist of auction rate securities. In 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 14 days with maturity dates ranging from 2023 through 2040 and have annual interest rates ranging from 0.44% to 1.19%. As of September 30, 2010, 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.

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

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

An evaluation as of September 30, 2010 was carried out under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures, which are defined 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, 2010.

#### **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, 2010, 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.

---

**Table of Contents**

**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 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 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 challenged the same two emtricitabine patents. In May 2009, we filed another lawsuit in U.S. District Court in New York against Teva for infringement of the two emtricitabine patents, and this lawsuit was consolidated with the lawsuit filed in December 2008. In January 2010, we received notice that Teva submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Viread. In the notice, Teva challenged four of the tenofovir disoproxil fumarate patents protecting Viread. In January 2010, we also received notices from Teva amending its ANDAs related to Truvada and Atripla. In the notice related to Truvada, Teva challenged four patents related to tenofovir disoproxil fumarate and two additional patents related to emtricitabine. In the notice related to Atripla, Teva challenged four patents related to tenofovir disoproxil fumarate, two additional patents related to emtricitabine and two patents related to efavirenz. In March 2010, we filed a lawsuit against Teva for infringement of the four Viread patents and two additional emtricitabine patents. In March 2010, BMS and Merck filed a lawsuit against Teva for infringement of the patents related to efavirenz.

In June 2010, we received notice that Lupin Limited (Lupin) submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Ranexa. In the notice, Lupin alleges that ten of the patents associated with Ranexa are invalid, unenforceable and/or will not be infringed by Lupin's manufacture, use or sale of a generic version of Ranexa. In July 2010, we filed a lawsuit in U.S. District Court in New Jersey against Lupin for infringement of our patents for Ranexa.

In August 2010, we received notice that Sigmapharm Labs (Sigmapharm) submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Hepsera. In the notice, Sigmapharm alleges that both of the patents associated with Hepsera are invalid, unenforceable and/or will not be infringed by Sigmapharm's manufacture, use or sale of a generic version of Hepsera. In September 2010, we filed a lawsuit against Sigmapharm for infringement of our patents for Hepsera.

One of the patents challenged by Sigmapharm is also being challenged by Ranbaxy, Inc. (Ranbaxy) pursuant to a notice received in October 2010. We are currently evaluating Ranbaxy's notice letter.

We cannot predict the ultimate outcome of these actions, and we may spend significant resources enforcing these patents. If we are unsuccessful in these lawsuits, some or all of our original claims in the patents may be narrowed or invalidated and the patent protection for Truvada, Atripla, Viread, Hepsera and Ranexa in the United

---

**Table of Contents**

States could be substantially shortened. Further, if all of the patents covering those products are invalidated, the FDA could approve the requests to manufacture a generic version of such products.

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 Atripla and Truvada. 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 infection, particularly Atripla and Truvada, to support our existing operations. Our HIV products contain tenofovir disoproxil fumarate and/or emtricitabine, which belong to the nucleoside class of antiviral therapeutics. Were the treatment paradigm for HIV to change, causing nucleoside-based therapeutics to fall out of favor, or if we were unable to continue increasing our HIV product sales, our results of operations would likely suffer and we would likely need to scale back our operations, including our spending on research and development (R&D) efforts. For the three months ended September 30, 2010, Atripla and Truvada product sales together were \$1.41 billion, or 73% of our total revenues. We may not be able to sustain the growth rate of sales of our HIV products, especially Atripla and Truvada, 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 \$34.5 million in royalty revenue for the quarter ended September 30, 2010 related to royalties received from

**Table of Contents**

sales of Tamiflu by Roche. Although such royalty revenue represented approximately 2% of our total revenues in the third quarter of 2010, it represented approximately 4% 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. Tamiflu royalties increased sharply in 2009 and the first quarter of 2010 primarily as a result of pandemic planning initiatives worldwide. Tamiflu royalties declined sharply in the second quarter of 2010 due to the fulfillment of many of the existing pandemic orders from governments and corporations. Based on Roche's reported sales of Tamiflu for the three months ended September 30, 2010, we expect Tamiflu royalties to further decrease to approximately \$21 million in the fourth quarter of 2010. We recognize royalties on Tamiflu sales by Roche in the quarter following the quarter in which Tamiflu is sold. As sales of Tamiflu 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 results of operations will be adversely affected by current and potential future healthcare reforms.**

Legislative and regulatory changes to government prescription drug procurement and reimbursement programs occur relatively frequently in the United States and foreign jurisdictions. In March 2010, healthcare reform legislation was adopted in the United States. As a result, we are required to further rebate or discount products reimbursed or paid for by various public payers, including Medicaid and other entities eligible to purchase discounted products through the 340B Drug Pricing Program under the Public Health Service Act, such as AIDS Drug Assistance Programs (ADAPs). The discounts, rebates and fees in the legislation that will impact us include:

effective January 1, 2010, our minimum base rebate amount owed to Medicaid on products reimbursed by Medicaid has been increased by 8%, and the discounts or rebates we owe to ADAPs and other Public Health Service entities which reimburse or purchase our products have also been increased by 8%;

effective March 23, 2010, we are required to extend rebates to patients receiving our products through Medicaid managed care organizations;

effective January 1, 2011, we will be required to provide a 50% discount on products sold to patients while they are in the Medicare Part D donut hole; and

effective 2011, we, along with other pharmaceutical manufacturers of branded drug products, will be required to pay a portion of a new industry fee (also known as the pharmaceutical excise tax), calculated based on select government sales during the 2010 calendar year as a percentage of total industry government sales.

We estimate that the full impact of healthcare reform for 2010 will be a reduction of approximately \$200 million in U.S. net product sales, and that the majority of this impact began in the third quarter and will continue throughout the fourth quarter of 2010 since some of the new discount and rebate requirements take two quarters to fully implement. For 2011, excluding the impact of the new pharmaceutical excise tax, we estimate that the impact of healthcare reform on product sales will be similar to 2010 as a percentage of our U.S. net product sales.

Many of the specific determinations necessary to implement the healthcare reform legislation have yet to be decided and communicated by the federal government. For example, we do not know how many or how quickly patients receiving our product under the Medicare Part D program will reach the donut hole or how the pharmaceutical excise tax will be calculated and reflected in our financial results. Based on the information that we have to date, we estimate the 2011 impact of the pharmaceutical excise tax to be less than \$50 million, which will be classified as selling, general and administrative (SG&A) expense. The excise tax is not tax deductible. In calculating the anticipated financial impacts of healthcare reform described above, we have made several estimates and assumptions with respect to our expected payer mix, how the reforms will be implemented and the timing for implementing the various discounts, rebates and fees contained in the legislation.



## **Table of Contents**

Further, even though not addressed in the healthcare reform legislation, discussions continue at the federal level on legislation that would either allow or require the federal government to directly negotiate price concessions from pharmaceutical manufacturers or set minimum requirements for Medicare Part D pricing.

In addition, state Medicaid programs could request additional supplemental rebates on our products as a result of the increase in the federal base Medicaid rebate. Private insurers could also use the enactment of these increased rebates to exert pricing pressure on our products, and 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.

### **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, state ADAPs, which purchase a significant portion of our HIV products, rely on federal, supplemental federal and state funding to help fund purchases of our products. If federal and state funds are not available in amounts sufficient to support the number of patients which rely on ADAPs, sales of our HIV products could be negatively impacted which would reduce our revenues. Further, 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 sales 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 healthcare 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 these efforts to continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the European Union. For example, in June 2010, Spain imposed an incremental discount on all branded drugs and in August 2010, Germany increased the rebate on prescription pharmaceuticals, which will decrease revenues on our products in Spain and Germany. Other countries have recently imposed or plan to impose similar discounts on our products. As generic drugs come to market, we may face price decreases for our products in some countries in the European Union.

## **Table of Contents**

**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. Drug development is inherently risky and many product candidates fail during the drug development process. For example, in April 2010, we announced our decision to terminate our Phase 2b clinical trial of GS 9450 for the treatment of chronic hepatitis C.

**Approximately 43% 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 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.

**Our inability to accurately estimate demand for our products, as well as sales fluctuations as a result of inventory levels held by wholesalers, pharmacies and non-retail customers make it difficult for us to accurately forecast sales and may cause our earnings to fluctuate, which could adversely affect our financial results and our stock price.**

During the three months ended September 30, 2010, approximately 81% 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 of 2009 were more 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.

---

**Table of Contents**

In addition, the non-retail sector in the United States, which includes government institutions, including state 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 patient demand. For example, in the first quarter of 2010, non-retail purchases, driven by certain state ADAPs, were lower as a percentage of their federal ADAP fiscal year purchases compared to the first quarters of 2008 and 2009. We believe this decrease was driven by higher purchasing patterns observed during the last three quarters of 2009 as compared to the same period in 2008. The annual grant cycles for federal and state ADAP funds may cause ADAP purchasing patterns to not reflect patient demand, and 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.

In light of the global economic downturn and budget crises faced by many Europe countries, we have observed variations in purchasing patterns induced by cost containment measures in Europe. We believe these measures have caused some purchasers to reduce inventory of our products in the distribution channels and in some cases even at the patient level which has decreased our revenues and caused fluctuations in our product sales and earnings. We may continue to see this trend in the future.

**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 the joint venture established by GlaxoSmithKline Inc. (GSK) and Pfizer Inc. (Pfizer) which markets fixed-dose combination products that compete with Atripla and Truvada.

For example, lamivudine, marketed by this joint venture, is competitive with emtricitabine, the active pharmaceutical ingredient of Emtriva and a component of both Atripla and Truvada. In May 2010, the compound patent covering Epivir (lamivudine) itself expired in the United States and we expect to see generic lamivudine in the United States in the near future. Generic lamivudine has been available in Spain since March 2010. This has exerted additional pricing pressure on our products in Spain. We expect that generic versions of lamivudine will be launched in the remainder of the European Union in the first quarter of 2011, which may result in similar pricing pressure.

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 at least two lipid formulations that claim similarity to AmBisome becoming available outside of the United States, including the possible entry of one such formulation in Greece. These formulations may reduce market demand for AmBisome. Furthermore, the manufacture of lipid formulations of amphotericin B is very complex and if any of these formulations are found to be unsafe, sales of AmBisome may be negatively impacted by association. Letairis competes directly with a product produced by Actelion Pharmaceuticals US, Inc. (Actelion) and indirectly with pulmonary arterial hypertension 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. Cayston competes with a product marketed by Novartis. Tamiflu competes with products sold by GSK and generic competitors.

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.

---

**Table of Contents**

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

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

Our product Letairis, which was approved by the U.S. Food and Drug Administration (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.

If serious safety, resistance or drug interaction issues arise with our marketed products, 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 Atripla, Truvada, Viread, Hepsera, Emtriva, AmBisome, Letairis, Ranexa and Cayston 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.

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. For example, on September 24, 2010, our San Dimas manufacturing facility received a Warning Letter from the FDA. See the Risk Factor entitled Manufacturing problems could delay product shipments and regulatory approvals, which may adversely affect our results of operations.

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.



---

**Table of Contents**

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. For example, in April 2010, we announced our decision to terminate our Phase 2b clinical trial of GS 9450 for the treatment of chronic hepatitis C. In addition, 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 for the treatment of HIV infection; the fixed-dose regimen of elvitegravir, cobicistat (formerly GS 9350) and Truvada for the treatment of HIV in treatment-naïve patients; 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.

**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 worldwide; and GSK for ambrisentan in territories outside of the United States. In some countries, we rely on international distributors for sales of Truvada, Viread,

## Table of Contents

Hepsera, Emtriva and AmBisome. Some of these relationships also involve the clinical development of these products by our partners. Reliance on collaborative relationships poses a number of risks, including the risk that:

we are unable to control the resources our corporate partners devote to our programs or products;

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

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

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

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

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

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

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. In November 2009, we entered into an agreement with GSK that provided GSK with exclusive commercialization rights and registration responsibilities for Viread for the treatment of chronic hepatitis B in China. In October 2010, we granted similar rights to GSK in Japan and Saudi Arabia. The success of Hepsera and Viread for the treatment of chronic hepatitis B 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 and Viread for the treatment of chronic hepatitis B 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 and Viread for the treatment of chronic hepatitis B 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 or Viread for the treatment of chronic hepatitis B in its territories, our potential revenues in these territories may be substantially reduced.

In addition, Cayston and Letairis are 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;

Edgar Filing: GILEAD SCIENCES INC - Form 10-Q

not effectively sell or support Cayston or Letairis;

not devote the resources necessary to sell Cayston or 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.



---

**Table of Contents**

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, Cayston may only be taken by patients using a specific inhalation device that delivers the drug to the lungs of patients. Our ongoing distribution of Cayston is entirely reliant upon the manufacturer of that device. For example, the manufacturer could encounter other issues with regulatory agencies related to the device or be unable to supply sufficient quantities of this device. In addition, the manufacturer may not be able to provide adequate warranty support for the device after it has been distributed to patients. With respect to distribution of the drug and device to patients, we are reliant on the capabilities of specialty pharmacies. For example, the distribution channel for drug and device is complicated and requires coordination. The reimbursement approval processes associated with both drug and device are similarly complex. If the device manufacturer is unable to obtain reimbursement approval or receives approval at a lower-than-expected price, sales of Cayston may be adversely affected. Any of the previously described issues may limit the sales of Cayston, which would adversely affect our financial results.

**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 and/or other regulatory agencies may require more clinical testing than we originally anticipated. Uneven and unexpected spending on these programs may cause our operating results to fluctuate from quarter to quarter, and our stock price may decline.

**Our success will depend to a significant degree on our ability to protect our patents and other intellectual property rights both domestically and internationally. We may not be able to obtain effective patents to protect our technologies from use by competitors and patents of other companies could require us to stop using or pay for the use of required technology.**

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

obtain patents and licenses to patent rights;

preserve trade secrets; and

operate without infringing on the proprietary rights of others.

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

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

## **Table of Contents**

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 products. 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 unpredictable and 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 have filed a civil action in Brazilian federal court to further appeal the action of the Brazilian patent authority. We cannot predict the outcome of this proceeding on our tenofovir disoproxil fumarate patent application. If we are unsuccessful in our appeal to the courts of the decision by the patent authority, the Brazilian government would likely purchase generic tenofovir disoproxil fumarate, which would significantly reduce our sales of HIV products in Brazil. In 2009, the Brazilian government purchased approximately \$50 million of our HIV products. For 2010, we anticipate that purchases of our HIV products by the Brazilian government will be at a similar level. We are aware of applications from two generic companies to sell a generic version of Viread in Brazil. The Brazilian government has historically entered into one year supply agreements towards the end of a calendar year to cover its needs for tenofovir disoproxil fumarate for the following year. If one or both of these generic applicants are able to compete for this contract for 2011, our sales in Brazil could be adversely affected.

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 have filed an appeal within the Indian Patent Office Intellectual Property Appellate Board on both of these applications. We cannot predict the outcome of these proceedings. If we are unsuccessful in our appeal of 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 unsuccessful in appealing 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 ranolazine, the active ingredient of Ranexa. Instead, when it was discovered that only a sustained release formulation of ranolazine would achieve therapeutic plasma levels, patents were obtained on those formulations and the characteristic plasma levels they achieve. 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, the indication for which Hepsera has been developed.

---

**Table of Contents**

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 in some countries.

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 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 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 challenged the same two emtricitabine patents. In May 2009, we filed another lawsuit against Teva for infringement of the two emtricitabine patents, and this lawsuit was consolidated with the lawsuit filed in December 2008. In January 2010, we received notice that Teva submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Viread. In the notice, Teva challenged four of the tenofovir disoproxil fumarate patents protecting Viread. In January 2010, we also received notices from Teva amending its ANDAs related to Truvada and Atripla. In the notice related to Truvada, Teva challenged four patents related to tenofovir disoproxil fumarate and two additional patents related to emtricitabine. In the notice related to Atripla, Teva challenged four patents related to tenofovir disoproxil fumarate, two additional patents related to emtricitabine and two patents related to efavirenz. In March 2010, we filed a lawsuit against Teva for infringement of the four Viread patents and two additional emtricitabine patents. In March 2010, BMS and Merck filed a lawsuit against Teva for infringement of the patents related to efavirenz.

In June 2010, we received notice that Lupin Limited (Lupin) submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Ranexa. In the notice, Lupin alleges that ten of the patents associated with Ranexa are invalid, unenforceable and/or will not be infringed by Lupin's manufacture, use or sale of a generic version of Ranexa. In July 2010, we filed a lawsuit against Lupin for infringement of our patents for Ranexa.

In August 2010, we received notice that Sigmapharm Labs (Sigmapharm) submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Hepsera. In the notice, Sigmapharm alleges that both of the patents associated with Hepsera are invalid, unenforceable and/or will not be infringed by Sigmapharm's manufacture, use or sale of a generic version of Hepsera. In September 2010, we filed a lawsuit against Sigmapharm for infringement of our patents for Hepsera.

One of the patents challenged by Sigmapharm is also being challenged by Ranbaxy, Inc. (Ranbaxy) pursuant to a notice received in October 2010. We are currently evaluating Ranbaxy's notice letter.

We cannot predict the ultimate outcome of these actions, and we may spend significant resources enforcing these patents. If we are unsuccessful in these lawsuits, some or all of our original claims in the patents may be narrowed or invalidated and the patent protection for Truvada, Atripla, Viread, Hepsera and Ranexa in the United

---

**Table of Contents**

States could be substantially shortened. Further, if all of the patents covering those products are invalidated, the FDA could approve the requests to manufacture a generic version of such products.

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

If we infringe the patents of others, we may be prevented from commercializing products or may be required to obtain licenses from these third parties. We may not be able to obtain alternative technologies or any required license on reasonable terms or at all. If we fail to obtain these licenses or alternative technologies, we may be unable to develop or commercialize some or all of our products. For example, we are aware of a body of patents that may relate to our operation of LEAP, our restricted distribution program designed to support Letairis. In addition, Actelion, which markets Tracleer, has applied for a patent that claims a method of use for 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 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 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 manufacturing operations are subject to routine inspections by regulatory agencies. For example, in January and February 2010, the FDA conducted a routine inspection of our San Dimas, California, manufacturing and distribution facility. At the conclusion of that inspection, the FDA issued Form 483 Inspectional Observations stating concerns over: the maintenance of aseptic processing conditions in the manufacturing suite for our AmBisome product; environmental maintenance issues in the San Dimas warehousing facility; batch sampling; and the timeliness of completion of annual product quality reports. In May 2010, we learned that FDA may be considering issuing a Warning Letter to us arising from this inspection and on September 24, 2010, our San Dimas manufacturing facility received the Warning Letter.

The Warning Letter details inadequacies identified by the FDA in the AmBisome manufacturing environment, including control systems and monitoring, procedures to prevent microbiological contamination and preventative cleaning and equipment maintenance. Referencing certain Viread lots, the letter also states concerns connected with quality procedures and controls and investigation procedures. Finally, the letter expresses a generalized concern over the effectiveness of the San Dimas quality unit in carrying out its responsibilities.

---

**Table of Contents**

We believe that we have addressed the FDA's concerns as stated in the Form 483 observations, and we are working diligently to resolve any outstanding FDA concerns listed in the Warning Letter.

Unless and until we are able to correct outstanding issues to the FDA's satisfaction, the FDA may withhold permission to export AmBisome to certain countries outside the United States and Europe. The FDA may also withhold approval of pending drug applications listing the San Dimas facility. Since, as required, we have notified appropriate international regulatory authorities of the letter's issuance, it is possible that the letter may impact our ability to supply our aseptic products manufactured at San Dimas (AmBisome, Cayston and Macugen) outside the United States. If as a result of a Warning Letter, we are unable to receive export or regulatory approvals for AmBisome or any other products at issue, we may be unable to sell sufficient quantities of these products to meet market demand, which would decrease our revenues and harm our business. As described further in the risk factor entitled "We may not be able to obtain materials or supplies necessary to conduct clinical trials or to manufacture and sell our products," below, we manufacture AmBisome and Cayston and fill and finish Macugen exclusively at our San Dimas facility.

We do not believe the Warning Letter will impact our ability to supply any of our solid dosage form products: Atripla, Emtriva, Hepsera, Letairis, Ranexa, Truvada or Viread. In the event our solid dosage form products were affected, we have alternate sites from which we could supply such products.

**Our ability to successfully manufacture and commercialize Cayston will depend upon our ability to manufacture in a multi-product facility.**

Aztreonam, the active pharmaceutical ingredient in Cayston, is a mono-bactam Gram-negative antibiotic that we manufacture by ourselves in San Dimas, California, 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 Cayston nor have we engaged a contract manufacturer with a single-product facility for Cayston. If the FDA prohibits the manufacture of mono-bactam antibiotics, like aztreonam, 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 Cayston and our anticipated financial results attributable to such product.

On September 24, 2010, our San Dimas manufacturing facility received a Warning Letter from the FDA. See the Risk Factor entitled "Manufacturing problems could delay product shipments and regulatory approvals, which may adversely affect our results of operations." It is possible that the Warning Letter may impact our ability to supply Cayston manufactured at San Dimas outside of the United States, which would decrease our revenues and harm our business.

**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 global 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

---

**Table of Contents**

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 Cayston and fill and finish Macugen exclusively at our facilities in San Dimas, California. In the event of a 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, Cayston and Macugen to meet market needs.

Cayston is dependent on two different third party 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. Disruptions or delays with any of these single suppliers could adversely affect our ability to produce Cayston in adequate quantities to support our commercial launch of Cayston, and we cannot be sure that alternative suppliers can be identified in a timely manner, or at all. See the Risk Factor entitled "Our ability to successfully manufacture and commercialize Cayston will depend upon our ability to manufacture in a multi-product facility."

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 Vistide, Ranexa and Cayston and for the tableting of Emtriva and Letairis. Astellas US LLC, which markets Lexiscan in the United States, is responsible for the commercial manufacture and supply of product in the 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.

A significant portion of the raw materials and intermediates used to manufacture our HIV products (Atripla, Truvada, Viread and Emtriva) are supplied by Chinese-based companies. As a result, an international trade dispute between China and the United States or any other actions by the Chinese government that would limit or prevent Chinese companies from supplying these materials would adversely affect our ability to manufacture and supply our HIV products to meet market needs and have a material and adverse effect on our operating results.

**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 \$970.4 million as of September 30, 2010, of which \$454.9 million was more than 120 days past due based on contractual payment terms. As a result of the fiscal and debt crises in these countries, the number of days our invoices are past due has continued to increase in line with that being experienced by other pharmaceutical companies that are also selling directly to hospitals. Historically, receivables balances with certain publicly-owned hospitals accumulate over a period of time and are 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. For example, at September 30, 2010, we

---

**Table of Contents**

had \$120.0 million due from publicly-owned hospitals in Greece. The Greek government has proposed to settle their outstanding receivables with zero-coupon bonds, which are expected to trade at a discount to face value. The proposal has been approved by Greek Parliament and at the end of September 2010 we submitted the required documentation to enable us to receive the bonds. At September 30, 2010, our allowance for doubtful accounts is adequate to cover exposure related to the expected discount on these bonds. In Spain, Italy and Portugal we are actively pursuing collection of the overdue receivables and taking action as necessary to enforce our legal right to payment.

**Our 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 130 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 thirteen 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.

**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 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 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 challenged the same two emtricitabine patents. In May 2009, we filed another lawsuit against Teva for infringement of the two emtricitabine patents, and this lawsuit was consolidated with the lawsuit filed in December 2008. In January 2010, we received notice that Teva submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Viread. In the notice, Teva challenged four of the tenofovir disoproxil fumarate patents protecting Viread. In January 2010, we also received notices from Teva amending its ANDAs related to Truvada and Atripla. In the notice related to Truvada, Teva challenged four patents related to tenofovir disoproxil fumarate and two additional patents related to emtricitabine. In the notice related to Atripla, Teva challenged four patents related to tenofovir disoproxil fumarate, two additional patents related to emtricitabine and two patents related to efavirenz. In March 2010, we filed a lawsuit against Teva for infringement of the four Viread patents

## **Table of Contents**

and two additional emtricitabine patents. In March 2010, BMS and Merck filed a lawsuit against Teva for infringement of the patents related to efavirenz.

In June 2010, we received notice that Lupin submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Ranexa. In the notice, Lupin alleges that ten of the patents associated with Ranexa are invalid, unenforceable and/or will not be infringed by Lupin's manufacture, use or sale of a generic version of Ranexa. In July 2010, we filed a lawsuit against Lupin for infringement of our patents for Ranexa.

In August 2010, we received notice that Sigmapharm submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Hepsera. In the notice, Sigmapharm alleges that both of the patents associated with Hepsera are invalid, unenforceable and/or will not be infringed by Sigmapharm's manufacture, use or sale of a generic version of Hepsera. In September 2010, we filed a lawsuit against Sigmapharm for infringement of our patents for Hepsera.

One of the patents challenged by Sigmapharm is also being challenged by Ranbaxy pursuant to a notice received in October 2010. We are currently evaluating Ranbaxy's notice letter.

We cannot predict the ultimate outcome of these actions, and we may spend significant resources enforcing these patents. If we are unsuccessful in these lawsuits, some or all of our original claims in the patents may be narrowed or invalidated and the patent protection for Truvada, Atripla, Viread, Hepsera and Ranexa in the United States could be substantially shortened. Further, if all of the patents covering those products are invalidated, the FDA could approve the requests to manufacture a generic version of such products.

In addition, 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. We have been cooperating and will continue to cooperate with any related governmental inquiry.

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.

### **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. This was the highest level of appeal available to us within the Brazilian patent authority. We have filed 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 2009, the Brazilian government purchased approximately \$50 million of our HIV products. For 2010, we anticipate that purchases of our HIV products by the Brazilian government will be at a similar level. We are aware of applications from two generic companies to sell a generic version of Viread in Brazil. The Brazilian government has historically entered into one year supply agreements towards the end of a calendar year to cover



---

**Table of Contents**

its needs for tenofovir disoproxil fumarate for the following year. If one or both of these generic applicants are able to compete for this contract for 2011, our sales in Brazil could be adversely affected.

In addition, concerns over the cost and availability of Tamiflu related to a potential avian flu pandemic and H1N1 influenza 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 cost-effective 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. As we do not carry earthquake insurance for direct quake-related losses and significant recovery time could be required to resume operations, our financial condition and operating results could be materially adversely affected in the event of a major earthquake.

**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, our portion of the non-tax deductible pharmaceutical excise tax that we will be required to pay starting in 2011 as a result of the enactment of U.S. healthcare reform legislation, 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 resolution 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.

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

**Table of Contents**

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.

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

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

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

Under our current three-year, \$5.0 billion stock repurchase program authorized by our Board in May 2010, we repurchased \$2.41 billion of our common stock through September 30, 2010. As of September 30, 2010, the remaining authorized amount of stock repurchases that may be made under our \$5.0 billion repurchase program was \$2.59 billion. During the nine months ended September 30, 2010, we utilized \$3.41 billion of cash to repurchase and retire 93.6 million shares of our common stock at an average purchase price of \$36.40 per share.

The table below summarizes our stock repurchase activity for the three months ended September 30, 2010 (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, 2010	21,605	\$ 33.74	21,598	\$ 3,418,224
August 1 August 31, 2010	19,175	\$ 33.85	19,171	\$ 2,769,327
September 1 September 30, 2010	5,025	\$ 34.80	5,023	\$ 2,594,546
Total	45,805(1)	\$ 33.90	45,792(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. REMOVED AND RESERVED****ITEM 5. OTHER INFORMATION**

Not applicable.

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

<b>Exhibit Footnote ±+(44)</b>	<b>Exhibit Number</b>	<b>Description of Document</b>
	2.1	Agreement and Plan of Merger among Registrant, Cougar Merger Sub, Inc. and CGI Pharmaceuticals, Inc., dated as of June 23, 2010
(1)	2.2	Agreement and Plan of Merger among Registrant, Apex Merger Sub, Inc. and CV Therapeutics, Inc., dated as of March 12, 2009
(1)	2.3	Stockholder Agreement by and between Registrant and Louis G. Lange, dated as of March 12, 2009
(2)	3.1	Restated Certificate of Incorporation of 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 Registrant
(5)	3.4	Amended and Restated Bylaws of 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 Registrant and ChaseMellon Shareholder Services, LLC, dated October 21, 1999
(7)	4.3	First Amendment to Amended and Restated Rights Agreement between Registrant and Mellon Investor Services, LLC (formerly known as ChaseMellon Shareholder Services, LLC), dated October 29, 2003
(8)	4.4	Second Amendment to Amended and Restated Rights Agreement between Registrant and Mellon Investor Services, LLC (formerly known as ChaseMellon Shareholder Services, LLC), dated May 11, 2006
(9)	4.5	Indenture related to the Convertible Senior Notes, due 2011, between Registrant and Wells Fargo Bank, National Association, as trustee (including form of 0.50% Convertible Senior Note due 2011), dated April 25, 2006
(9)	4.6	Indenture related to the Convertible Senior Notes, due 2013, between Registrant and Wells Fargo Bank, National Association, as trustee (including form of 0.625% Convertible Senior Note due 2013), dated April 25, 2006
(43)	4.7	Indenture related to the Convertible Senior Notes, due 2014, between Registrant and Wells Fargo Bank, National Association, as trustee (including form of 1.00% Convertible Senior Note due 2014), dated July 30, 2010
(43)	4.8	Indenture related to the Convertible Senior Notes, due 2016, between Registrant and Wells Fargo Bank, National Association, as trustee (including form of 1.625% Convertible Senior Note due 2016), dated July 30, 2010
(10)	10.1	Confirmation of OTC Convertible Note Hedge related to 2011 Notes, dated April 19, 2006, as amended and restated as of April 24, 2006, between Registrant and Bank of America, N.A.
(10)	10.2	Confirmation of OTC Convertible Note Hedge related to 2013 Notes, dated April 19, 2006, as amended and restated as of April 24, 2006, between Registrant and Bank of America, N.A.

**Table of Contents**

<b>Exhibit Footnote</b>	<b>Exhibit Number</b>	<b>Description of Document</b>
(10)	10.3	Confirmation of OTC Warrant Transaction, dated April 19, 2006, as amended and restated as of April 24, 2006, between Registrant and Bank of America, N.A. for warrants expiring in 2011
(10)	10.4	Confirmation of OTC Warrant Transaction, dated April 19, 2006, as amended and restated as of April 24, 2006, between Registrant and Bank of America, N.A. for warrants expiring in 2013
(11)	10.5	Amended and Restated Credit Agreement among Registrant, Gilead Biopharmaceutics Ireland Corporation, the lenders parties thereto and Bank of America, N.A., as Administrative Agent, Swing Line Lender and L/C Issuer, dated as of December 18, 2007
(11)	10.6	Parent Guaranty Agreement, dated as of December 18, 2007, by Registrant
(12)	10.7	Master Confirmation by and between Registrant and Citibank N.A., together with the Supplemental Confirmation, dated as of October 21, 2008
*(13)	10.8	Gilead Sciences, Inc. 1991 Stock Option Plan, as amended through January 29, 2003
*(14)	10.9	Form of option agreements used under the 1991 Stock Option Plan
*(13)	10.10	Gilead Sciences, Inc. 1995 Non-Employee Directors Stock Option Plan, as amended through January 30, 2002
*(15)	10.11	Form of option agreement used under the Gilead Sciences, Inc. 1995 Non-Employee Directors Stock Option Plan
*(16)	10.12	Gilead Sciences, Inc. 2004 Equity Incentive Plan, as amended through May 6, 2009
*(17)	10.13	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants prior to February 2008)
*(18)	10.14	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants made February 2008 through April 2009)
*(19)	10.15	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants commencing in May 2009)
*(20)	10.16	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants commencing in February 2010)
*(17)	10.17	Form of non-employee director stock option agreement used under 2004 Equity Incentive Plan (for grants prior to 2008)
*(18)	10.18	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for initial grants made in 2008)
*(18)	10.19	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for annual grants made in May 2008)
*(19)	10.20	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for annual grants commencing in May 2009)
*(19)	10.21	Form of restricted stock unit issuance agreement used under 2004 Equity Incentive Plan (for annual grants to non-employee directors commencing in May 2009)

**Table of Contents**

<b>Exhibit Footnote</b>	<b>Exhibit Number</b>	<b>Description of Document</b>
*(19)	10.22	Form of restricted stock award agreement used under 2004 Equity Incentive Plan (for annual grants to certain non-employee directors)
*(21)	10.23	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for grants made in 2007)
*(22)	10.24	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for grants made in 2008)
*(19)	10.25	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for grants made in 2009)
*(20)	10.26	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for grants made in 2010)
*(23)	10.27	Form of restricted stock unit issuance agreement used under the 2004 Equity Incentive Plan (for grants made prior to May 2009)
*(19)	10.28	Form of restricted stock unit issuance agreement used under the 2004 Equity Incentive Plan (for grants commencing in May 2009)
*(24)	10.29	Form of restricted stock unit issuance agreement used under the 2004 Equity Incentive Plan (service-based vesting for executive officers commencing in November 2009)
*(20)	10.30	Gilead Sciences, Inc. Employee Stock Purchase Plan, amended and restated on November 3, 2009
*(25)	10.31	Gilead Sciences, Inc. International Employee Stock Purchase Plan, adopted November 3, 2009
*(26)	10.32	Gilead Sciences, Inc. Deferred Compensation Plan Basic Plan Document
*(26)	10.33	Gilead Sciences, Inc. Deferred Compensation Plan Adoption Agreement
*(26)	10.34	Addendum to the Gilead Sciences, Inc. Deferred Compensation Plan
*(27)	10.35	Gilead Sciences, Inc. 2005 Deferred Compensation Plan, as amended and restated on October 23, 2008
*(20)	10.36	Gilead Sciences, Inc. Severance Plan, as amended on December 14, 2009
*(17)	10.37	Gilead Sciences, Inc. Corporate Bonus Plan
*(17)	10.38	Gilead Sciences, Inc. Code Section 162(m) Bonus Plan
*(28)	10.39	2010 Base Salaries for the Named Executive Officers
*(29)	10.40	Offer Letter dated April 16, 2008 between Registrant and Robin Washington
*(14)	10.41	Form of Indemnity Agreement entered into between Registrant and its directors and executive officers
*(14)	10.42	Form of Employee Proprietary Information and Invention Agreement entered into between Registrant and certain of its officers and key employees
*(20)	10.43	Form of Employee Proprietary Information and Invention Agreement entered into between Registrant and certain of its officers and key employees (revised in September 2006)

**Table of Contents**

<b>Exhibit Footnote</b>	<b>Exhibit Number</b>	<b>Description of Document</b>
+(30)	10.44	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)	10.45	Commercialization Agreement by and between Gilead Sciences Limited and Bristol-Myers Squibb Company, dated December 10, 2007
+(31)	10.46	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)
(32)	10.47	Amendment Agreement between Registrant and IOCB/REGA, dated December 27, 2000 amending the 1991 License Agreement and the December 1992 License Agreement
(30)	10.48	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
+(30)	10.49	Development and License Agreement among Registrant and F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc., dated September 27, 1996
+(33)	10.50	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
+(34)	10.51	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
+(35)	10.52	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
+(35)	10.53	Amended and Restated License Agreement between Registrant, Emory University and Investors Trust & Custodial Services (Ireland) Limited, solely in its capacity as Trustee of Royalty Pharma, dated July 21, 2005.
+(36)	10.54	License Agreement between Japan Tobacco Inc. and Registrant, dated March 22, 2005
+(37)	10.55	License Agreement between Registrant (as successor to Myogen, Inc.) and Abbott Deutschland Holding GmbH dated October 8, 2001
+(38)	10.56	License Agreement between Registrant (as successor to CV Therapeutics, Inc.) and Syntex (U.S.A.) Inc., dated March 27, 1996
+(38)	10.57	First Amendment to License Agreement between Registrant (as successor to CV Therapeutics, Inc.) and Syntex (U.S.A.) Inc., dated July 3, 1997
(38)	10.58	Amendment No. 2 to License Agreement between Registrant (as successor to CV Therapeutics, Inc.) and Syntex (U.S.A.) Inc., dated November 30, 1999

**Table of Contents**

<b>Exhibit Footnote</b>	<b>Exhibit Number</b>	<b>Description of Document</b>
+(39)	10.59	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
+(40)	10.60	License and Collaboration Agreement by and among Registrant, Gilead Sciences Limited and Tibotec Pharmaceuticals, dated July 16, 2009
+(41)	10.61	Master Clinical and Commercial Supply Agreement between Gilead World Markets, Limited, Registrant and Patheon Inc., dated January 1, 2003
+(35)	10.62	Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Gilead Sciences Limited and PharmaChem Technologies (Grand Bahama), Ltd., dated July 17, 2003
+(42)	10.63	Addendum to Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Gilead Sciences Limited and PharmaChem Technologies (Grand Bahama) Ltd., dated May 10, 2007
+(27)	10.64	Addendum to Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Gilead Sciences Limited and PharmaChem Technologies (Grand Bahama) Ltd., dated December 5, 2008
+(22)	10.65	Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Registrant and Ampac Fine Chemicals LLC, dated March 6, 2008
+(33)	10.66	Restated and Amended Toll Manufacturing Agreement between Gilead Sciences Limited, Registrant and ALTANA Pharma Oranienburg GmbH, dated November 7, 2005
+(11)	10.67	Emtricitabine Manufacturing Supply Agreement between Gilead Sciences Limited and Degussa AG, dated June 6, 2006
+(44)	10.68	Amendment No. 1 to Emtricitabine Manufacturing Supply Agreement between Gilead Sciences Limited and Evonik Degussa GmbH (formerly known as Degussa AG), dated April 30, 2010
(27)	10.69	Purchase and Sale Agreement and Escrow Instructions between Electronics for Imaging, Inc. and Registrant, dated October 23, 2008
(44)	10.70	Confirmation of OTC Convertible Note Hedge related to 2014 Notes, dated July 26, 2010, between Registrant and Goldman, Sachs & Co.
(44)	10.71	Confirmation of OTC Convertible Note Hedge related to 2014 Notes, dated July 26, 2010, between Registrant and JPMorgan Chase Bank, National Association
(44)	10.72	Confirmation of OTC Convertible Note Hedge related to 2016 Notes, dated July 26, 2010, between Registrant and Goldman, Sachs & Co.
(44)	10.73	Confirmation of OTC Convertible Note Hedge related to 2016 Notes, dated July 26, 2010, between Registrant and JPMorgan Chase Bank, National Association
(44)	10.74	Confirmation of OTC Warrant Transaction, dated July 26, 2010, between Registrant and Goldman, Sachs & Co. for warrants expiring in 2014
(44)	10.75	Confirmation of OTC Warrant Transaction, dated July 26, 2010, between Registrant and JPMorgan Chase Bank, National Association for warrants expiring in 2014
(44)	10.76	Confirmation of OTC Warrant Transaction, dated July 26, 2010, between Registrant and Goldman, Sachs & Co. for warrants expiring in 2016



**Table of Contents**

<b>Exhibit Footnote</b>	<b>Exhibit Number</b>	<b>Description of Document</b>
(44)	10.77	Confirmation of OTC Warrant Transaction, dated July 26, 2010, between Registrant and JPMorgan Chase Bank, National Association for warrants expiring in 2016
	10.78	Confirmation of OTC Additional Convertible Note Hedge related to 2014 Notes, dated August 5, 2010, between Registrant and Goldman, Sachs & Co.
	10.79	Confirmation of OTC Additional Convertible Note Hedge related to 2014 Notes, dated August 5, 2010, between Registrant and JPMorgan Chase Bank, National Association
	10.80	Confirmation of OTC Additional Convertible Note Hedge related to 2016 Notes, dated August 5, 2010, between Registrant and Goldman, Sachs & Co.
	10.81	Confirmation of OTC Additional Convertible Note Hedge related to 2016 Notes, dated August 5, 2010, between Registrant and JPMorgan Chase Bank, National Association
	10.82	Confirmation of OTC Additional Warrant Transaction, dated August 5, 2010, between Registrant and Goldman, Sachs & Co. for warrants expiring in 2014
	10.83	Confirmation of OTC Additional Warrant Transaction, dated August 5, 2010, between Registrant and JPMorgan Chase Bank, National Association for warrants expiring in 2014
	10.84	Confirmation of OTC Additional Warrant Transaction, dated August 5, 2010, between Registrant and Goldman, Sachs & Co. for warrants expiring in 2016
	10.85	Confirmation of OTC Additional Warrant Transaction, dated August 5, 2010, between Registrant and JPMorgan Chase Bank, National Association for warrants expiring in 2016
	10.86	Amendment to Confirmation of OTC Convertible Note Hedge related to 2014 Notes, dated August 30, 2010, between Registrant and Goldman, Sachs & Co.
	10.87	Amendment to Confirmation of OTC Convertible Note Hedge related to 2014 Notes, dated August 30, 2010, between Registrant and JPMorgan Chase Bank, National Association
	10.88	Amendment to Confirmation of OTC Convertible Note Hedge related to 2016 Notes, dated August 30, 2010, between Registrant and Goldman, Sachs & Co.
	10.89	Amendment to Confirmation of OTC Convertible Note Hedge related to 2016 Notes, dated August 30, 2010, between Registrant and JPMorgan Chase Bank, National Association
	10.90	Amendment to Confirmation of OTC Additional Convertible Note Hedge related to 2014 Notes, dated August 30, 2010, between Registrant and Goldman, Sachs & Co.
	10.91	Amendment to Confirmation of OTC Additional Convertible Note Hedge related to 2014 Notes, dated August 30, 2010, between Registrant and JPMorgan Chase Bank, National Association
	10.92	Amendment to Confirmation of OTC Additional Convertible Note Hedge related to 2016 Notes, dated August 30, 2010, between Registrant and Goldman, Sachs & Co.
	10.93	Amendment to Confirmation of OTC Additional Convertible Note Hedge related to 2016 Notes, dated August 30, 2010, between Registrant and JPMorgan Chase Bank, National Association
	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

**Table of Contents**

<b>Exhibit Footnote</b>	<b>Exhibit Number</b>	<b>Description of Document</b>
	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, 2010, formatted in Extensible Business Reporting Language (XBRL) includes: (i) Condensed Consolidated Balance Sheets at September 30, 2010 and December 31, 2009, (ii) Condensed Consolidated Statements of Income for the Three and Nine Months Ended September 30, 2010 and 2009, (iii) Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2010 and 2009, and (iv) Notes to Condensed Consolidated Financial Statements
(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 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 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.

**Table of Contents**

- (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, 2009, and incorporated herein by reference.
- (21) 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.
- (22) 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.
- (23) Filed as an exhibit to Registrant s Current Report on Form 8-K first filed on December 19, 2007, and incorporated herein by reference.
- (24) Filed as an exhibit to Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2010, and incorporated herein by reference.
- (25) Filed as an exhibit to Registrant s Registration Statement on Form S-8 (No. 333-163871) filed on December 21, 2009, and incorporated herein by reference.
- (26) Filed as an exhibit to Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2001, and incorporated herein by reference.
- (27) Filed as an exhibit to Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2008, and incorporated herein by reference.
- (28) Information is included in Registrant s Current Report on Form 8-K filed on February 1, 2010, and incorporated herein by reference.
- (29) 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.
- (30) 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.
- (31) 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.
- (32) 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.
- (33) 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.
- (34) 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.
- (35) 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.
- (36) 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.
- (37) 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.
- (38) 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.
- (39) 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.
- (40) Filed as an exhibit to Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2009, and incorporated herein by reference.
- (41) 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.
- (42) Filed as an exhibit to Registrant s Current Report on Form 8-K filed on August 7, 2007, and incorporated herein by reference.
- (43) Filed as an exhibit to Registrant s Current Report on Form 8-K filed on August 2, 2010, and incorporated herein by reference.
- (44) Filed as an exhibit to Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2010, and incorporated herein by reference.

**Table of Contents**

- ± The Agreement and Plan of Merger (the Merger Agreement) contains representations and warranties of Registrant, Cougar Merger Sub, Inc. and CGI Pharmaceuticals, Inc. made solely to each other as of specific dates. Those representations and warranties were made solely for purposes of the Merger Agreement and may be subject to important qualifications and limitations agreed to by Registrant, Cougar Merger Sub, Inc. and CGI Pharmaceuticals, Inc. Moreover, some of those representations and warranties may not be accurate or complete as of any specified date, may be subject to a standard of materiality provided for in the Merger Agreement and have been used for the purpose of allocating risk among Registrant, Cougar Merger Sub, Inc. and CGI Pharmaceuticals, Inc. rather than establishing matters as facts.
- \* 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.

**Table of Contents**

**SIGNATURES**

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

GILEAD SCIENCES, INC.

(Registrant)

Date: November 8, 2010

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

**Chairman and Chief Executive Officer**

**(Principal Executive Officer)**

Date: November 8, 2010

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

**Senior Vice President and Chief Financial Officer**

**(Principal Financial and Accounting Officer)**

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

<b>Exhibit Footnote ±+(44)</b>	<b>Exhibit Number</b>	<b>Description of Document</b>
	2.1	Agreement and Plan of Merger among Registrant, Cougar Merger Sub, Inc. and CGI Pharmaceuticals, Inc., dated as of June 23, 2010
(1)	2.2	Agreement and Plan of Merger among Registrant, Apex Merger Sub, Inc. and CV Therapeutics, Inc., dated as of March 12, 2009
(1)	2.3	Stockholder Agreement by and between Registrant and Louis G. Lange, dated as of March 12, 2009
(2)	3.1	Restated Certificate of Incorporation of 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 Registrant
(5)	3.4	Amended and Restated Bylaws of 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 Registrant and ChaseMellon Shareholder Services, LLC, dated October 21, 1999
(7)	4.3	First Amendment to Amended and Restated Rights Agreement between Registrant and Mellon Investor Services, LLC (formerly known as ChaseMellon Shareholder Services, LLC), dated October 29, 2003
(8)	4.4	Second Amendment to Amended and Restated Rights Agreement between Registrant and Mellon Investor Services, LLC (formerly known as ChaseMellon Shareholder Services, LLC), dated May 11, 2006
(9)	4.5	Indenture related to the Convertible Senior Notes, due 2011, between Registrant and Wells Fargo Bank, National Association, as trustee (including form of 0.50% Convertible Senior Note due 2011), dated April 25, 2006
(9)	4.6	Indenture related to the Convertible Senior Notes, due 2013, between Registrant and Wells Fargo Bank, National Association, as trustee (including form of 0.625% Convertible Senior Note due 2013), dated April 25, 2006
(43)	4.7	Indenture related to the Convertible Senior Notes, due 2014, between Registrant and Wells Fargo Bank, National Association, as trustee (including form of 1.00% Convertible Senior Note due 2014), dated July 30, 2010
(43)	4.8	Indenture related to the Convertible Senior Notes, due 2016, between Registrant and Wells Fargo Bank, National Association, as trustee (including form of 1.625% Convertible Senior Note due 2016), dated July 30, 2010
(10)	10.1	Confirmation of OTC Convertible Note Hedge related to 2011 Notes, dated April 19, 2006, as amended and restated as of April 24, 2006, between Registrant and Bank of America, N.A.
(10)	10.2	Confirmation of OTC Convertible Note Hedge related to 2013 Notes, dated April 19, 2006, as amended and restated as of April 24, 2006, between Registrant and Bank of America, N.A.

**Table of Contents**

<b>Exhibit Footnote</b>	<b>Exhibit Number</b>	<b>Description of Document</b>
(10)	10.3	Confirmation of OTC Warrant Transaction, dated April 19, 2006, as amended and restated as of April 24, 2006, between Registrant and Bank of America, N.A. for warrants expiring in 2011
(10)	10.4	Confirmation of OTC Warrant Transaction, dated April 19, 2006, as amended and restated as of April 24, 2006, between Registrant and Bank of America, N.A. for warrants expiring in 2013
(11)	10.5	Amended and Restated Credit Agreement among Registrant, Gilead Biopharmaceutics Ireland Corporation, the lenders parties thereto and Bank of America, N.A., as Administrative Agent, Swing Line Lender and L/C Issuer, dated as of December 18, 2007
(11)	10.6	Parent Guaranty Agreement, dated as of December 18, 2007, by Registrant
(12)	10.7	Master Confirmation by and between Registrant and Citibank N.A., together with the Supplemental Confirmation, dated as of October 21, 2008
*(13)	10.8	Gilead Sciences, Inc. 1991 Stock Option Plan, as amended through January 29, 2003
*(14)	10.9	Form of option agreements used under the 1991 Stock Option Plan
*(13)	10.10	Gilead Sciences, Inc. 1995 Non-Employee Directors Stock Option Plan, as amended through January 30, 2002
*(15)	10.11	Form of option agreement used under the Gilead Sciences, Inc. 1995 Non-Employee Directors Stock Option Plan
*(16)	10.12	Gilead Sciences, Inc. 2004 Equity Incentive Plan, as amended through May 6, 2009
*(17)	10.13	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants prior to February 2008)
*(18)	10.14	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants made February 2008 through April 2009)
*(19)	10.15	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants commencing in May 2009)
*(20)	10.16	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants commencing in February 2010)
*(17)	10.17	Form of non-employee director stock option agreement used under 2004 Equity Incentive Plan (for grants prior to 2008)
*(18)	10.18	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for initial grants made in 2008)
*(18)	10.19	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for annual grants made in May 2008)
*(19)	10.20	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for annual grants commencing in May 2009)
*(19)	10.21	Form of restricted stock unit issuance agreement used under 2004 Equity Incentive Plan (for annual grants to non-employee directors commencing in May 2009)

**Table of Contents**

<b>Exhibit Footnote</b>	<b>Exhibit Number</b>	<b>Description of Document</b>
*(19)	10.22	Form of restricted stock award agreement used under 2004 Equity Incentive Plan (for annual grants to certain non-employee directors)
*(21)	10.23	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for grants made in 2007)
*(22)	10.24	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for grants made in 2008)
*(19)	10.25	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for grants made in 2009)
*(20)	10.26	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for grants made in 2010)
*(23)	10.27	Form of restricted stock unit issuance agreement used under the 2004 Equity Incentive Plan (for grants made prior to May 2009)
*(19)	10.28	Form of restricted stock unit issuance agreement used under the 2004 Equity Incentive Plan (for grants commencing in May 2009)
*(24)	10.29	Form of restricted stock unit issuance agreement used under the 2004 Equity Incentive Plan (service-based vesting for executive officers commencing in November 2009)
*(20)	10.30	Gilead Sciences, Inc. Employee Stock Purchase Plan, amended and restated on November 3, 2009
*(25)	10.31	Gilead Sciences, Inc. International Employee Stock Purchase Plan, adopted November 3, 2009
*(26)	10.32	Gilead Sciences, Inc. Deferred Compensation Plan Basic Plan Document
*(26)	10.33	Gilead Sciences, Inc. Deferred Compensation Plan Adoption Agreement
*(26)	10.34	Addendum to the Gilead Sciences, Inc. Deferred Compensation Plan
*(27)	10.35	Gilead Sciences, Inc. 2005 Deferred Compensation Plan, as amended and restated on October 23, 2008
*(20)	10.36	Gilead Sciences, Inc. Severance Plan, as amended on December 14, 2009
*(17)	10.37	Gilead Sciences, Inc. Corporate Bonus Plan
*(17)	10.38	Gilead Sciences, Inc. Code Section 162(m) Bonus Plan
*(28)	10.39	2010 Base Salaries for the Named Executive Officers
*(29)	10.40	Offer Letter dated April 16, 2008 between Registrant and Robin Washington
*(14)	10.41	Form of Indemnity Agreement entered into between Registrant and its directors and executive officers
*(14)	10.42	Form of Employee Proprietary Information and Invention Agreement entered into between Registrant and certain of its officers and key employees
*(20)	10.43	Form of Employee Proprietary Information and Invention Agreement entered into between Registrant and certain of its officers and key employees (revised in September 2006)



**Table of Contents**

<b>Exhibit Footnote</b>	<b>Exhibit Number</b>	<b>Description of Document</b>
+(30)	10.44	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)	10.45	Commercialization Agreement by and between Gilead Sciences Limited and Bristol-Myers Squibb Company, dated December 10, 2007
+(31)	10.46	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)
(32)	10.47	Amendment Agreement between Registrant and IOCB/REGA, dated December 27, 2000 amending the 1991 License Agreement and the December 1992 License Agreement
(30)	10.48	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
+(30)	10.49	Development and License Agreement among Registrant and F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc., dated September 27, 1996
+(33)	10.50	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
+(34)	10.51	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
+(35)	10.52	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
+(35)	10.53	Amended and Restated License Agreement between Registrant, Emory University and Investors Trust & Custodial Services (Ireland) Limited, solely in its capacity as Trustee of Royalty Pharma, dated July 21, 2005
+(36)	10.54	License Agreement between Japan Tobacco Inc. and Registrant, dated March 22, 2005
+(37)	10.55	License Agreement between Registrant (as successor to Myogen, Inc.) and Abbott Deutschland Holding GmbH dated October 8, 2001
+(38)	10.56	License Agreement between Registrant (as successor to CV Therapeutics, Inc.) and Syntex (U.S.A.) Inc., dated March 27, 1996
+(38)	10.57	First Amendment to License Agreement between Registrant (as successor to CV Therapeutics, Inc.) and Syntex (U.S.A.) Inc., dated July 3, 1997
(38)	10.58	Amendment No. 2 to License Agreement between Registrant (as successor to CV Therapeutics, Inc.) and Syntex (U.S.A.) Inc., dated November 30, 1999

**Table of Contents**

<b>Exhibit Footnote</b>	<b>Exhibit Number</b>	<b>Description of Document</b>
+(39)	10.59	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
+(40)	10.60	License and Collaboration Agreement by and among Registrant, Gilead Sciences Limited and Tibotec Pharmaceuticals, dated July 16, 2009
+(41)	10.61	Master Clinical and Commercial Supply Agreement between Gilead World Markets, Limited, Registrant and Patheon Inc., dated January 1, 2003
+(35)	10.62	Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Gilead Sciences Limited and PharmaChem Technologies (Grand Bahama), Ltd., dated July 17, 2003
+(42)	10.63	Addendum to Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Gilead Sciences Limited and PharmaChem Technologies (Grand Bahama) Ltd., dated May 10, 2007
+(27)	10.64	Addendum to Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Gilead Sciences Limited and PharmaChem Technologies (Grand Bahama) Ltd., dated December 5, 2008
+(22)	10.65	Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Registrant and Ampac Fine Chemicals LLC, dated March 6, 2008
+(33)	10.66	Restated and Amended Toll Manufacturing Agreement between Gilead Sciences Limited, Registrant and ALTANA Pharma Oranienburg GmbH, dated November 7, 2005
+(11)	10.67	Emtricitabine Manufacturing Supply Agreement between Gilead Sciences Limited and Degussa AG, dated June 6, 2006
+(44)	10.68	Amendment No. 1 to Emtricitabine Manufacturing Supply Agreement between Gilead Sciences Limited and Evonik Degussa GmbH (formerly known as Degussa AG), dated April 30, 2010
(27)	10.69	Purchase and Sale Agreement and Escrow Instructions between Electronics for Imaging, Inc. and Registrant, dated October 23, 2008
(44)	10.70	Confirmation of OTC Convertible Note Hedge related to 2014 Notes, dated July 26, 2010, between Registrant and Goldman, Sachs & Co.
(44)	10.71	Confirmation of OTC Convertible Note Hedge related to 2014 Notes, dated July 26, 2010, between Registrant and JPMorgan Chase Bank, National Association
(44)	10.72	Confirmation of OTC Convertible Note Hedge related to 2016 Notes, dated July 26, 2010, between Registrant and Goldman, Sachs & Co.
(44)	10.73	Confirmation of OTC Convertible Note Hedge related to 2016 Notes, dated July 26, 2010, between Registrant and JPMorgan Chase Bank, National Association
(44)	10.74	Confirmation of OTC Warrant Transaction, dated July 26, 2010, between Registrant and Goldman, Sachs & Co. for warrants expiring in 2014
(44)	10.75	Confirmation of OTC Warrant Transaction, dated July 26, 2010, between Registrant and JPMorgan Chase Bank, National Association for warrants expiring in 2014

**Table of Contents**

<b>Exhibit Footnote</b>	<b>Exhibit Number</b>	<b>Description of Document</b>
(44)	10.76	Confirmation of OTC Warrant Transaction, dated July 26, 2010, between Registrant and Goldman, Sachs & Co. for warrants expiring in 2016
(44)	10.77	Confirmation of OTC Warrant Transaction, dated July 26, 2010, between Registrant and JPMorgan Chase Bank, National Association for warrants expiring in 2016
	10.78	Confirmation of OTC Additional Convertible Note Hedge related to 2014 Notes, dated August 5, 2010, between Registrant and Goldman, Sachs & Co.
	10.79	Confirmation of OTC Additional Convertible Note Hedge related to 2014 Notes, dated August 5, 2010, between Registrant and JPMorgan Chase Bank, National Association
	10.80	Confirmation of OTC Additional Convertible Note Hedge related to 2016 Notes, dated August 5, 2010, between Registrant and Goldman, Sachs & Co.
	10.81	Confirmation of OTC Additional Convertible Note Hedge related to 2016 Notes, dated August 5, 2010, between Registrant and JPMorgan Chase Bank, National Association
	10.82	Confirmation of OTC Additional Warrant Transaction, dated August 5, 2010, between Registrant and Goldman, Sachs & Co. for warrants expiring in 2014
	10.83	Confirmation of OTC Additional Warrant Transaction, dated August 5, 2010, between Registrant and JPMorgan Chase Bank, National Association for warrants expiring in 2014
	10.84	Confirmation of OTC Additional Warrant Transaction, dated August 5, 2010, between Registrant and Goldman, Sachs & Co. for warrants expiring in 2016
	10.85	Confirmation of OTC Additional Warrant Transaction, dated August 5, 2010, between Registrant and JPMorgan Chase Bank, National Association for warrants expiring in 2016
	10.86	Amendment to Confirmation of OTC Convertible Note Hedge related to 2014 Notes, dated August 30, 2010, between Registrant and Goldman, Sachs & Co.
	10.87	Amendment to Confirmation of OTC Convertible Note Hedge related to 2014 Notes, dated August 30, 2010, between Registrant and JPMorgan Chase Bank, National Association
	10.88	Amendment to Confirmation of OTC Convertible Note Hedge related to 2016 Notes, dated August 30, 2010, between Registrant and Goldman, Sachs & Co.
	10.89	Amendment to Confirmation of OTC Convertible Note Hedge related to 2016 Notes, dated August 30, 2010, between Registrant and JPMorgan Chase Bank, National Association
	10.90	Amendment to Confirmation of OTC Additional Convertible Note Hedge related to 2014 Notes, dated August 30, 2010, between Registrant and Goldman, Sachs & Co.
	10.91	Amendment to Confirmation of OTC Additional Convertible Note Hedge related to 2014 Notes, dated August 30, 2010, between Registrant and JPMorgan Chase Bank, National Association
	10.92	Amendment to Confirmation of OTC Additional Convertible Note Hedge related to 2016 Notes, dated August 30, 2010, between Registrant and Goldman, Sachs & Co.
	10.93	Amendment to Confirmation of OTC Additional Convertible Note Hedge related to 2016 Notes, dated August 30, 2010, between Registrant and JPMorgan Chase Bank, National Association

**Table of Contents**

<b>Exhibit Footnote</b>	<b>Exhibit Number</b>	<b>Description of Document</b>
	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, 2010, formatted in Extensible Business Reporting Language (XBRL) includes: (i) Condensed Consolidated Balance Sheets at September 30, 2010 and December 31, 2009, (ii) Condensed Consolidated Statements of Income for the Three and Nine Months Ended September 30, 2010 and 2009, (iii) Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2010 and 2009, and (iv) Notes to Condensed Consolidated Financial Statements
(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. 10.70 Confirmation of OTC Convertible Note Hedge related to 2014 Notes, dated July 26, 2010, between Registrant and Goldman, Sachs & Co.
(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 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 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.

**Table of Contents**

- (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, 2009, and incorporated herein by reference.
- (21) 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.
- (22) 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.
- (23) Filed as an exhibit to Registrant s Current Report on Form 8-K first filed on December 19, 2007, and incorporated herein by reference.
- (24) Filed as an exhibit to Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2010, and incorporated herein by reference.
- (25) Filed as an exhibit to Registrant s Registration Statement on Form S-8 (No. 333-163871) filed on December 21, 2009, and incorporated herein by reference.
- (26) Filed as an exhibit to Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2001, and incorporated herein by reference.
- (27) Filed as an exhibit to Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2008, and incorporated herein by reference.
- (28) Information is included in Registrant s Current Report on Form 8-K filed on February 1, 2010, and incorporated herein by reference.
- (29) 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.
- (30) 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.
- (31) 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.
- (32) 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.
- (33) 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.
- (34) 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.
- (35) 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.
- (36) 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.
- (37) 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.
- (38) 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.
- (39) 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.
- (40) Filed as an exhibit to Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2009, and incorporated herein by reference.
- (41) 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.
- (42) Filed as an exhibit to Registrant s Current Report on Form 8-K filed on August 7, 2007, and incorporated herein by reference.

**Table of Contents**

- (43) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on August 2, 2010, and incorporated herein by reference.
- (44) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2010, and incorporated herein by reference.
  
- ± The Agreement and Plan of Merger (the Merger Agreement) contains representations and warranties of Registrant, Cougar Merger Sub, Inc. and CGI Pharmaceuticals, Inc. made solely to each other as of specific dates. Those representations and warranties were made solely for purposes of the Merger Agreement and may be subject to important qualifications and limitations agreed to by Registrant, Cougar Merger Sub, Inc. and CGI Pharmaceuticals, Inc. Moreover, some of those representations and warranties may not be accurate or complete as of any specified date, may be subject to a standard of materiality provided for in the Merger Agreement and have been used for the purpose of allocating risk among Registrant, Cougar Merger Sub, Inc. and CGI Pharmaceuticals, Inc. rather than establishing matters as facts.
- \* 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.