

GILEAD SCIENCES INC  
Form 10-Q  
August 05, 2011  
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 **June 30, 2011**

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 July 29, 2011: 771,455,146

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

<b>PART I. <u>FINANCIAL INFORMATION</u></b>	<b>3</b>
Item 1. <u>Condensed Consolidated Financial Statements</u>	3
<u>Condensed Consolidated Balance Sheets at June 30, 2011 and December 31, 2010</u>	3
<u>Condensed Consolidated Statements of Income for the Three and Six Months Ended June 30, 2011 and 2010</u>	4
<u>Condensed Consolidated Statements of Cash Flows for the Three and Six Months Ended June 30, 2011 and 2010</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>	22
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	29
Item 4. <u>Controls and Procedures</u>	29
<b>PART II. <u>OTHER INFORMATION</u></b>	<b>30</b>
Item 1. <u>Legal Proceedings</u>	30
Item 1A. <u>Risk Factors</u>	31
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	44
Item 3. <u>Defaults Upon Senior Securities</u>	44
Item 4. <u>Removed and Reserved</u>	44
Item 5. <u>Other Information</u>	44
Item 6. <u>Exhibits</u>	45
<b><u>SIGNATURES</u></b>	<b>54</b>

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

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

(in thousands, except per share amounts)

	<b>June 30, 2011 (unaudited)</b>	<b>December 31, 2010</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 905,779	\$ 907,879
Short-term marketable securities	1,364,539	1,190,789
Accounts receivable, net	1,938,645	1,621,966
Inventories	1,321,615	1,203,809
Deferred tax assets	277,611	279,339
Prepaid taxes	241,698	320,424
Prepaid expenses	84,140	67,632
Other current assets	85,018	116,244
<b>Total current assets</b>	<b>6,219,045</b>	<b>5,708,082</b>
Property, plant and equipment, net	721,884	701,235
Noncurrent portion of prepaid royalties	189,271	203,790
Noncurrent deferred tax assets	87,168	153,379
Long-term marketable securities	3,228,994	3,219,403
Intangible assets	2,128,410	1,425,592
Other noncurrent assets	119,368	181,149
<b>Total assets</b>	<b>\$ 12,694,140</b>	<b>\$ 11,592,630</b>
<b>Liabilities and Stockholders Equity</b>		
Current liabilities:		
Accounts payable	\$ 1,102,319	\$ 803,025
Accrued government rebates	384,284	325,018
Accrued compensation and employee benefits	129,989	147,632
Income taxes payable	5,438	1,862
Other accrued liabilities	618,223	437,893
Deferred revenues	63,243	103,175
Current portion of long-term debt and other obligations, net	7,345	646,345
<b>Total current liabilities</b>	<b>2,310,841</b>	<b>2,464,950</b>
Long-term deferred revenues	27,706	32,844
Long-term debt, net	3,870,846	2,838,573
Long-term income taxes payable	117,025	107,025
Other long-term obligations	156,391	27,401
Commitments and contingencies (Note 10)		
Stockholders equity:		
Preferred stock, par value \$0.001 per share; 5,000 shares authorized; none outstanding		
Common stock, par value \$0.001 per share; 2,800,000 shares authorized; 776,405 and 801,998 shares issued and outstanding at June 30, 2011 and December 31, 2010, respectively	777	802

Edgar Filing: GILEAD SCIENCES INC - Form 10-Q

Additional paid-in capital	4,783,439	4,648,286
Accumulated other comprehensive income (loss)	(133,279)	30,911
Retained earnings	1,395,908	1,183,730
Total Gilead stockholders' equity	6,046,845	5,863,729
Noncontrolling interest	164,486	258,108
Total stockholders' equity	6,211,331	6,121,837
Total liabilities and stockholders' equity	\$ 12,694,140	\$ 11,592,630

See accompanying notes.

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

(unaudited)

(in thousands, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
<b>Revenues:</b>				
Product sales	\$ 2,039,588	\$ 1,806,061	\$ 3,903,166	\$ 3,594,124
Royalty revenues	94,321	117,790	152,986	411,471
Contract and other revenues	3,344	3,373	7,195	7,482
<b>Total revenues</b>	<b>2,137,253</b>	<b>1,927,224</b>	<b>4,063,347</b>	<b>4,013,077</b>
<b>Costs and expenses:</b>				
Cost of goods sold	533,863	455,525	1,007,974	895,955
Research and development	282,403	231,066	536,849	449,730
Selling, general and administrative	304,269	248,006	599,837	513,624
<b>Total costs and expenses</b>	<b>1,120,535</b>	<b>934,597</b>	<b>2,144,660</b>	<b>1,859,309</b>
<b>Income from operations</b>	<b>1,016,718</b>	<b>992,627</b>	<b>1,918,687</b>	<b>2,153,768</b>
Interest and other income, net	11,978	18,285	25,810	33,930
Interest expense	(46,107)	(17,764)	(87,323)	(34,719)
<b>Income before provision for income taxes</b>	<b>982,589</b>	<b>993,148</b>	<b>1,857,174</b>	<b>2,152,979</b>
Provision for income taxes	240,130	284,021	467,412	591,758
<b>Net income</b>	<b>742,459</b>	<b>709,127</b>	<b>1,389,762</b>	<b>1,561,221</b>
Net loss attributable to noncontrolling interest	3,768	2,934	7,606	5,741
<b>Net income attributable to Gilead</b>	<b>\$ 746,227</b>	<b>\$ 712,061</b>	<b>\$ 1,397,368</b>	<b>\$ 1,566,962</b>
<b>Net income per share attributable to Gilead common stockholders basic</b>	<b>\$ 0.95</b>	<b>\$ 0.81</b>	<b>\$ 1.77</b>	<b>\$ 1.76</b>
Shares used in per share calculation basic	784,807	881,802	790,430	891,649
<b>Net income per share attributable to Gilead common stockholders diluted</b>	<b>\$ 0.93</b>	<b>\$ 0.79</b>	<b>\$ 1.73</b>	<b>\$ 1.71</b>
Shares used in per share calculation diluted	800,800	898,753	806,462	913,819

See accompanying notes.

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

(unaudited)

(in thousands)

	<b>Six Months Ended June 30,</b>	
	<b>2011</b>	<b>2010</b>
<b>Operating Activities:</b>		
Net income	\$ 1,389,762	\$ 1,561,221
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation expense	36,030	33,386
Amortization expense	119,776	85,521
Stock-based compensation expenses	99,595	94,888
Excess tax benefits from stock-based compensation	(20,298)	(60,689)
Tax benefits from employee stock plans	17,796	62,722
Deferred income taxes	40,008	29,896
Other non-cash transactions	6,150	3,683
Changes in operating assets and liabilities:		
Accounts receivable, net	(221,966)	(242,381)
Inventories	(114,644)	(317,543)
Prepaid expenses and other assets	10,884	299
Accounts payable	295,648	262,262
Income taxes payable	51,585	(164,847)
Accrued liabilities	98,541	31,091
Deferred revenues	(45,070)	(9,861)
Net cash provided by operating activities	1,763,797	1,369,648
<b>Investing Activities:</b>		
Purchases of marketable securities	(2,714,090)	(2,016,151)
Proceeds from sales of marketable securities	2,225,064	1,601,656
Proceeds from maturities of marketable securities	348,968	306,406
Acquisitions, net of cash acquired	(588,608)	
Capital expenditures and other	(41,505)	(27,717)
Net cash used in investing activities	(770,171)	(135,806)
<b>Financing Activities:</b>		
Proceeds from issuances of senior notes, net of issuance costs	987,370	
Proceeds from issuances of common stock	115,912	144,291
Proceeds from credit facility		500,000
Repurchases of common stock	(1,272,862)	(1,854,081)
Repayment of convertible senior notes	(649,987)	
Repayments of other long-term obligations	(1,567)	(5,556)
Excess tax benefits from stock-based compensation	20,298	60,689
Distributions (to) from noncontrolling interest	(86,016)	5,153
Net cash used in financing activities	(886,852)	(1,149,504)
Effect of exchange rate changes on cash	(108,874)	125,343

Edgar Filing: GILEAD SCIENCES INC - Form 10-Q

Net change in cash and cash equivalents	(2,100)	209,681
Cash and cash equivalents at beginning of period	907,879	1,272,958
Cash and cash equivalents at end of period	\$ 905,779	\$ 1,482,639

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's interest in the joint ventures. All intercompany transactions have been eliminated. The Condensed Consolidated Financial Statements include the 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, 2010, included in our Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (SEC).

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

Basic net income per share attributable to Gilead common stockholders is calculated based on the weighted-average number of shares of our common stock outstanding during the period. Diluted net income per share attributable to Gilead common stockholders is calculated based on the weighted-average number of shares of our common stock outstanding and other dilutive securities outstanding during the period. The potential dilutive shares of our common stock resulting from the assumed exercise of outstanding stock options, restricted stock units, performance shares and warrants relating to the convertible senior notes due in 2011 (2011 Notes), 2013 (2013 Notes), 2014 (2014 Notes) and 2016 (2016 Notes) (collectively, the Convertible Notes) are determined under the treasury stock method.

Because the principal amount of the Convertible Notes is settled in cash, only the conversion spread relating to the Convertible 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 Convertible Notes has a dilutive effect when the average market price of our common stock during the period exceeds the conversion prices of approximately \$38.75, \$38.10, \$45.08 and \$45.41 for the 2011 Notes, 2013 Notes, 2014 Notes and 2016 Notes, respectively.

In May 2011, our 2011 Notes matured and as a result, we have only included their impact for the period they were outstanding on our net income per share calculations for the three and six months ended June 30, 2011. Warrants related to our 2011 Notes remained outstanding at June 30, 2011 and we have included their full impact on our net income per share calculations for the three and six months ended June 30, 2011. The warrants related to our 2011 Notes will expire in August 2011.

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

During the three and six months ended June 30, 2011 and 2010, 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. During the three and six months ended June 30, 2011, the average market prices of our common stock did not exceed the conversion prices of the 2014 Notes and 2016 Notes, which were issued in July 2010, and therefore did not have a dilutive effect on our net income per share for those periods.

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 six months ended June 30, 2011 and 2010 did not exceed the warrants' exercise prices relating to any of the Convertible Notes; therefore, these warrants did not have a dilutive effect on our net income per share for those periods.

**Table of Contents**

Stock options to purchase approximately 21.6 million and 21.8 million weighted-average shares of our common stock were outstanding during the three and six months ended June 30, 2011, respectively, but were not included in the computation of diluted net income per share attributable to Gilead common stockholders because their effect was antidilutive. Stock options to purchase approximately 23.4 million and 19.5 million weighted-average shares of our common stock were outstanding during the three and six months ended June 30, 2010, respectively, but were not included in the computation of diluted net income per share attributable to Gilead common stockholders because 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 June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
<b>Numerator:</b>				
Net income attributable to Gilead	\$ 746,227	\$ 712,061	\$ 1,397,368	\$ 1,566,962
<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	784,807	881,802	790,430	891,649
<b>Effect of dilutive securities:</b>				
Stock options and equivalents	14,461	16,503	14,817	18,746
Conversion spread related to the 2011 Notes	432	81	402	1,568
Conversion spread related to the 2013 Notes	1,100	367	813	1,856
Weighted-average shares of common stock outstanding used in the calculation of diluted net income per share attributable to Gilead common stockholders	800,800	898,753	806,462	913,819

**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 June 30, 2011.

**Recent Accounting Pronouncements**

In May 2011, the Financial Accounting Standards Board (FASB) issued amendments to its existing standard for fair value measurement to achieve common guidance between U.S. generally accepted accounting principles and International Financial Reporting Standards. In addition, the amended standard revises certain requirements for measuring fair value and for disclosure around fair value measurement. It does not require additional fair value measurements and was not intended to establish valuation standards or affect valuation practices outside of financial reporting. The updated standard is effective for us beginning in the first quarter of 2012. Early adoption is not permitted. The adoption of these amendments is not expected to have a material impact on our Condensed Consolidated Financial Statements.

In June 2011, the FASB issued an update to an existing standard for comprehensive income to make the presentation of items within other comprehensive income (OCI) more prominent. The updated standard prohibits the current presentation of OCI in the statement of stockholders equity and instead, provides public companies the option of presenting OCI in a continuous statement of comprehensive income or two separate consecutive statements. Additionally, the update requires that reclassification adjustments be displayed on the face of the financial statements where OCI is reported. The updated standard is effective for us beginning in the first quarter of 2012; however, early adoption is permitted and prior-year information would need to be presented in accordance with the requirements of the updated standard. Upon adoption, the updated standard will impact the presentation of our Condensed Consolidated Financial Statements; however, it will have no impact on our financial

position or results of operations.

## **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, and 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 Convertible Notes were \$2.88 billion and \$3.62 billion, respectively, as of June 30, 2011. The carrying value and fair value of the Convertible Notes were

**Table of Contents**

\$3.48 billion and \$3.97 billion, respectively, as of December 31, 2010. In March 2011, we issued senior unsecured notes due in 2021 (2021 Notes) in a registered offering for an aggregate principal amount of \$1.00 billion. The carrying value and fair value of the 2021 Notes were \$991.6 million and \$1.01 billion, respectively, as of June 30, 2011. The fair value of the Convertible Notes and 2021 Notes were 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.

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.

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):

	June 30, 2011				December 31, 2010			
	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	\$ 1,321,543	\$	\$	\$ 1,321,543	\$ 1,355,437	\$	\$	\$ 1,355,437
Money market funds	236,033			236,033	520,063			520,063
U.S. government agencies and FDIC guaranteed securities		1,018,855		1,018,855		1,296,110		1,296,110
Municipal debt securities		24,574		24,574		17,625		17,625
Non-U.S. government securities		218,626	45,756	264,382		278,610	9,594	288,204
Corporate debt securities		1,663,520		1,663,520		1,119,254		1,119,254
Residential mortgage and asset-backed securities		311,009		311,009		277,043		277,043
Student loan-backed securities			58,389	58,389			70,771	70,771
<b>Total debt securities</b>	<b>1,557,576</b>	<b>3,236,584</b>	<b>104,145</b>	<b>4,898,305</b>	<b>1,875,500</b>	<b>2,988,642</b>	<b>80,365</b>	<b>4,944,507</b>
Equity securities	8,302			8,302	4,631			4,631
Derivatives		2,214		2,214		64,461		64,461
	\$ 1,565,878	\$ 3,238,798	\$ 104,145	\$ 4,908,821	\$ 1,880,131	\$ 3,053,103	\$ 80,365	\$ 5,013,599
<b>Liabilities:</b>								
Contingent consideration	\$	\$	\$ 126,690	\$ 126,690	\$	\$	\$ 11,100	\$ 11,100
Derivatives		140,335		140,335		38,553		38,553
	\$	\$ 140,335	\$ 126,690	\$ 267,025	\$	\$ 38,553	\$ 11,100	\$ 49,653

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

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

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.

**Table of Contents**

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Balance, beginning of period	\$ 116,823	\$ 105,587	\$ 80,365	\$ 105,662
Total realized and unrealized gains (losses) included in:				
Interest and other income, net	1,624	115	2,871	115
Other comprehensive income, net	(7,853)	907	(5,694)	1,767
Sales of marketable securities	(6,450)	(12,547)	(27,280)	(13,482)
Transfers into Level 3	1		53,883	
Balance, end of period	\$ 104,145	\$ 94,062	\$ 104,145	\$ 94,062
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	\$	\$	\$	\$

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 comprised of auction rate securities and Greek government-issued bonds 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 three to seven 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 2.13%. Our auction rate securities reset every seven to 14 days with maturity dates ranging from 2025 through 2040 and have annual interest rates ranging from 0.16% to 1.09%. As of June 30, 2011, our auction rate securities continued to earn interest. Although there continued to be failed auctions as well as lack of market activity and liquidity, we believe we had no other-than-temporary impairments on these securities as of June 30, 2011 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.

In 2010, the Greek government agreed to settle the majority of its aged outstanding accounts receivable with zero-coupon bonds, which were expected to trade at a discount to face value. As of June 30, 2011, we received a total of \$63.5 million in bonds, of which \$53.9 million comprise the balance of transfers into Level 3 during the first six months of 2011. We have measured the fair value of the Greek zero-coupon bonds using Level 3 inputs due to the current lack of market activity and liquidity. The discount rates used in our fair value model for these bonds were based on credit default swap rates. We have the ability and intent to hold these bonds until maturity. Therefore, we believe we had no other-than-temporary impairments on these investments as of June 30, 2011.

As of June 30, 2011, our auction rate securities and Greek government-issued bonds were recorded in long-term marketable securities on our Condensed Consolidated Balance Sheet. As of December 31, 2010, our auction rate securities and substantially all of our Greek government-issued bonds were recorded in long-term marketable securities on our Consolidated Balance Sheet.

As of June 30, 2011, we had contingent consideration liabilities totaling \$126.7 million. These liabilities were incurred as a result of our acquisitions of CGI Pharmaceuticals, Inc. (CGI) in July 2010, Arresto Biosciences, Inc. (Arresto) in January 2011 and Calistoga Pharmaceuticals, Inc. (Calistoga) in April 2011. The fair value measurements of contingent consideration obligations are based on significant unobservable inputs, and accordingly, such amounts are considered Level 3 measurements. The majority of our contingent consideration liabilities is related to our acquisition of Calistoga. The estimated fair value of the contingent consideration liabilities for the Calistoga acquisition was based on the probability of technical and regulatory success to achieve each of the milestone events at the expected dates and the present value of the total earnout amount. We estimated the fair value using a discount rate of 8.00%. For the three and six months ended June 30, 2011, changes in the fair values of our contingent consideration liabilities were not significant. See Note 5 for a description of our

acquisitions.

**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>June 30, 2011</b>				
Debt securities:				
U.S. treasury securities	\$ 1,313,550	\$ 8,166	\$ (173)	\$ 1,321,543
Money market funds	236,033			236,033
U.S. government agencies and FDIC guaranteed securities	1,009,079	9,781	(5)	1,018,855
Municipal debt securities	24,422	161	(9)	24,574
Non-U.S. government securities	274,033	1,872	(11,523)	264,382
Corporate debt securities	1,653,769	10,509	(758)	1,663,520
Residential mortgage and asset-backed securities	311,504	980	(1,475)	311,009
Student loan-backed securities	62,650		(4,261)	58,389
<b>Total debt securities</b>	<b>4,885,040</b>	<b>31,469</b>	<b>(18,204)</b>	<b>4,898,305</b>
Equity securities	1,451	6,851		8,302
<b>Total</b>	<b>\$ 4,886,491</b>	<b>\$ 38,320</b>	<b>\$ (18,204)</b>	<b>\$ 4,906,607</b>
<b>December 31, 2010</b>				
Debt securities:				
U.S. treasury securities	\$ 1,349,348	\$ 7,109	\$ (1,020)	\$ 1,355,437
Money market funds	520,063			520,063
U.S. government agencies and FDIC guaranteed securities	1,284,654	11,919	(463)	1,296,110
Municipal debt securities	17,543	103	(21)	17,625
Non-U.S. government securities	286,410	1,880	(86)	288,204
Corporate debt securities	1,112,976	8,040	(1,762)	1,119,254
Residential mortgage and asset-backed securities	277,359	923	(1,239)	277,043
Student loan-backed securities	75,900		(5,129)	70,771
<b>Total debt securities</b>	<b>4,924,253</b>	<b>29,974</b>	<b>(9,720)</b>	<b>4,944,507</b>
Equity securities	1,451	3,180		4,631
<b>Total</b>	<b>\$ 4,925,704</b>	<b>\$ 33,154</b>	<b>\$ (9,720)</b>	<b>\$ 4,949,138</b>

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

	June 30, 2011	December 31, 2010
Cash and cash equivalents	\$ 313,074	\$ 538,946
Short-term marketable securities	1,364,539	1,190,789
Long-term marketable securities	3,228,994	3,219,403
<b>Total</b>	<b>\$ 4,906,607</b>	<b>\$ 4,949,138</b>



**Table of Contents**

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

	June 30, 2011		December 31, 2010	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
Less than one year	\$ 1,672,052	\$ 1,677,613	\$ 1,726,095	\$ 1,729,735
Greater than one year but less than five years	3,075,261	3,086,951	3,022,744	3,044,114
Greater than five years but less than ten years	27,315	27,979	33,076	33,580
Greater than ten years	110,412	105,762	142,338	137,078
<b>Total</b>	<b>\$ 4,885,040</b>	<b>\$ 4,898,305</b>	<b>\$ 4,924,253</b>	<b>\$ 4,944,507</b>

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Gross realized gains on sales	\$ 5,257	\$ 7,464	\$ 8,954	\$ 9,298
Gross realized losses on sales	\$ (415)	\$ (1,900)	\$ (1,777)	\$ (2,174)

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>June 30, 2011</b>						
Debt securities:						
U.S. treasury securities	\$ (173)	\$ 181,374	\$	\$	\$ (173)	\$ 181,374
U.S. government agencies and FDIC guaranteed securities	(5)	9,883			(5)	9,883
Municipal debt securities	(9)	11,943			(9)	11,943
Non-U.S. government securities	(11,523)	48,751			(11,523)	48,751
Corporate debt securities	(758)	278,102			(758)	278,102
Residential mortgage and asset-backed securities	(1,135)	152,088	(340)	14,433	(1,475)	166,521
Student loan-backed securities			(4,261)	58,389	(4,261)	58,389
<b>Total</b>	<b>\$ (13,603)</b>	<b>\$ 682,141</b>	<b>\$ (4,601)</b>	<b>\$ 72,822</b>	<b>\$ (18,204)</b>	<b>\$ 754,963</b>

**December 31, 2010**

Debt securities:

U.S. treasury securities	\$ (1,020)	\$ 531,184	\$	\$	\$ (1,020)	\$ 531,184
U.S. government agencies and FDIC guaranteed securities	(463)	226,176			(463)	226,176
Municipal debt securities	(21)	4,688			(21)	4,688
Non-U.S. government securities	(86)	44,317			(86)	44,317
Corporate debt securities	(1,762)	459,412			(1,762)	459,412
Residential mortgage and asset-backed securities	(1,239)	197,330			(1,239)	197,330
Student loan-backed securities			(5,129)	70,771	(5,129)	70,771

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

Total	\$ (4,591)	\$ 1,463,107	\$ (5,129)	\$ 70,771	\$ (9,720)	\$ 1,533,878
-------	------------	--------------	------------	-----------	------------	--------------

As of June 30, 2011 and December 31, 2010, approximately 19% and 34%, 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 June 30, 2011 and December 31, 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.

During the three and six months ended June 30, 2011, we recorded net unrealized gains on available-for-sale securities of \$2.4 million and \$0.7 million, respectively, in accumulated other comprehensive income (OCI) and reclassified gains of \$3.1 million and \$4.6 million, respectively, out of accumulated OCI into interest and other income, net. Comparatively, during the three and six months ended June 30, 2010, we recorded net unrealized gains on available-for-sale securities of \$6.9 million and \$8.7 million, respectively, in accumulated OCI and reclassified gains of \$3.1 million and \$4.0 million, respectively, out of accumulated OCI into interest and other income, net.

**Table of Contents**

**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 this risk, we hedge a portion of our foreign currency exposures related to outstanding monetary assets and liabilities as well as forecasted product sales using foreign currency exchange forward and option contracts. In general, the market risk related to these contracts is offset by corresponding gains and losses on the hedged transactions. The credit risk associated with these contracts is driven by changes in interest and currency exchange rates and, as a result, varies over time. By working only with major banks and closely monitoring current market conditions, we limit the risk that counterparties to these contracts may be unable to perform. We also limit our risk of loss by entering into contracts that permit 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 contracts for trading purposes, nor do we hedge our net investment in any of our foreign subsidiaries.

We hedge our exposure to foreign currency exchange rate fluctuations for certain monetary assets and liabilities of our foreign subsidiaries that are denominated in a non-functional currency. The derivative instruments we use to hedge this exposure are not designated as hedges, and as a result, changes in their fair value are recorded in interest and other income, net on our Condensed Consolidated Statements of Income.

We hedge our exposure to foreign currency exchange rate fluctuations for forecasted product sales that are denominated in a non-functional currency. The derivative instruments we use to hedge this exposure are designated as cash flow hedges and have maturity dates of 18 months or less. Upon executing a hedging contract and quarterly thereafter, we assess prospective hedge effectiveness using a regression analysis which calculates the change in cash flow as a result of the hedge instrument. On a monthly basis, we assess retrospective hedge effectiveness using a dollar offset approach. 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 our hedge is recorded as an unrealized gain or loss on the hedging instrument in accumulated OCI within stockholders' equity. When the hedged forecasted transaction occurs, the hedge is de-designated and the unrealized gains or losses are reclassified into product sales. The majority of gains and losses related to the hedged forecasted transactions reported in accumulated OCI at June 30, 2011 will be reclassified to product sales within 12 months.

We had notional amounts on foreign currency exchange contracts outstanding of \$3.89 billion and \$3.55 billion at June 30, 2011 and December 31, 2010, respectively.

**Table of Contents**

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

	June 30, 2011			
	Asset Derivatives		Liability Derivatives	
	Location	Fair Value	Location	Fair Value
Derivatives designated as hedges:				
Foreign currency exchange contracts	Other current assets	\$ 691	Other accrued liabilities	\$ 130,795
Foreign currency exchange contracts	Other noncurrent assets	1,521	Other long-term obligations	9,322
Total derivatives designated as hedges		2,212		140,117
Derivatives not designated as hedges:				
Foreign currency exchange contracts	Other current assets	2	Other accrued liabilities	218
Total derivatives not designated as hedges		2		218
Total derivatives		\$ 2,214		\$ 140,335

	December 31, 2010			
	Asset Derivatives		Liability Derivatives	
	Location	Fair Value	Location	Fair Value
Derivatives designated as hedges:				
Foreign currency exchange contracts	Other current assets	\$ 59,276	Other accrued liabilities	\$ 36,493
Foreign currency exchange contracts	Other noncurrent assets	5,089	Other long-term obligations	2,022
Total derivatives designated as hedges		64,365		38,515
Derivatives not designated as hedges:				
Foreign currency exchange contracts	Other current assets	96	Other accrued liabilities	38
Total derivatives not designated as hedges		96		38
Total derivatives		\$ 64,461		\$ 38,553

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

	Three Months Ended		Six Months Ended	
	June 30, 2011	2010	June 30, 2011	2010
Derivatives designated as hedges:				
Net gains (losses) recognized in OCI (effective portion)	\$ (46,608)	\$ 143,074	\$ (174,107)	\$ 250,344
Net gains (losses) reclassified from accumulated OCI into product sales (effective portion)	\$ (20,945)	\$ 32,029	\$ (11,016)	\$ 37,554
Net losses recognized in interest and other income, net (ineffective portion and amounts excluded from effectiveness testing)	\$ (4,061)	\$ (1,892)	\$ (3,066)	\$ (1,665)
Derivatives not designated as hedges:				
Net gains (losses) recognized in interest and other income, net	\$ (34,344)	\$ 83,943	\$ (120,190)	\$ 138,834

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

The net unrealized losses related to our cash flow hedges included in accumulated OCI, net of taxes, were \$141.6 million at June 30, 2011. Net unrealized gains related to our cash flow hedges included in accumulated OCI, net of taxes, were \$21.6 million at December 31, 2010.

There were no material amounts recorded in interest and other income, net, for the three or six months ended June 30, 2011 and 2010 as a result of the discontinuance of cash flow hedges because the forecasted transactions were no longer probable of occurring.

### 5. ACQUISITIONS

#### **Arresto Biosciences, Inc.**

In December 2010, we entered into an agreement to acquire Arresto for \$225.0 million plus potential future payments based on the achievement of certain sales targets. This transaction closed on January 14, 2011, at which time Arresto became a wholly-owned subsidiary. Arresto was a privately-held, development-stage biotechnology company based in Palo Alto, California, focused on developing antibodies for the potential treatment of fibrotic diseases and cancer. The lead product from the acquisition of Arresto is GS 6224 (formerly AB0024), a humanized monoclonal antibody (mAb) targeting the human lysyl oxidase-like-2 (LOXL2) protein. In addition to an ongoing Phase 1 study of GS 6224 in patients with advanced solid tumors, a Phase 1 study had also been initiated to evaluate GS 6224 in patients with idiopathic pulmonary fibrosis. We believe that Arresto's pipeline and research and development expertise are well aligned with our areas of focus.

**Table of Contents**

The acquisition was accounted for as a business combination. Arresto's results of operations since January 14, 2011 have been included in our Condensed Consolidated Statement of Income and were not significant.

The acquisition-date fair value of the total consideration transferred to acquire Arresto was \$227.1 million, and consisted of cash paid at or prior to closing of \$221.7 million and contingent consideration of \$5.4 million.

The following table summarizes the fair values of the assets acquired and liabilities assumed at January 14, 2011 (in thousands):

Intangible assets - IPR&D	\$ 117,000
Goodwill	134,482
Deferred tax assets	17,417
Deferred tax liabilities	(41,705)
Other net liabilities assumed	(125)
 Total consideration transferred	 \$ 227,069

*Intangible Assets*

Intangible assets associated with in-process research and development (IPR&D) projects relate to the GS 6224 product candidate. Management determined that the estimated acquisition-date fair value of intangible assets related to IPR&D was \$117.0 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 16%, which is based on the estimated weighted-average cost of capital for companies with profiles substantially similar to that of Arresto. This is comparable to the estimated internal rate of return for the acquisition and represents the rate that market participants would use to value the intangible assets. The projected cash flows from the IPR&D projects were based on key assumptions such as: estimates of revenues and operating profits related to each 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 product candidate 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.

*Goodwill*

The excess of the consideration transferred over the fair values assigned to the assets acquired and liabilities assumed is \$134.5 million, which represents the goodwill amount resulting from the Arresto acquisition. Management believes that the goodwill mainly represents the synergies expected from combining our research and development operations as well as acquiring Arresto'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.

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

**Calistoga Pharmaceuticals, Inc.**

In February 2011, we entered into an agreement to acquire Calistoga for \$375.0 million plus potential payments of up to \$225.0 million based on the achievement of certain milestones. This transaction closed on April 1, 2011, at which time Calistoga became a wholly-owned subsidiary. Calistoga was a privately-held, biotechnology company based in Seattle, Washington, focused on the development of medicines to treat cancer and inflammatory diseases. This acquisition has provided us with a portfolio of proprietary compounds that selectively target isoforms of phosphoinositide-3 kinase (P13K). The lead product candidate, CAL-101, is a first-in-class specific inhibitor of the P13K delta isoform. P13K

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

delta is preferentially expressed in leukocytes involved in a variety of inflammatory and autoimmune diseases and hematological cancers. We believe that the acquisition of Calistoga further broadens our pipeline and expertise in the areas of oncology and inflammation.

The acquisition was accounted for as a business combination. Calistoga's results of operations since April 1, 2011 have been included in our Condensed Consolidated Statement of Income and were not significant.

The acquisition-date fair value of the total consideration transferred to acquire Calistoga was \$484.3 million, and consisted of cash paid at or prior to closing of \$373.7 million and contingent consideration of \$110.6 million.

**Table of Contents**

The following table summarizes the fair values of the assets acquired and liabilities assumed at April 1, 2011 (in thousands):

Intangible assets - IPR&D	\$ 149,200
Goodwill	336,951
Other net liabilities assumed	(1,853)
 Total consideration transferred	 \$ 484,298

*Intangible Assets*

Intangible assets associated with IPR&D projects relate to the CAL-101 product candidate. Management determined that the estimated acquisition-date fair value of intangible assets related to IPR&D was \$149.2 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 11%, which considers both the estimated weighted-average cost of capital for companies with profiles substantially similar to that of Calistoga, as well as the acquirer's estimated weighted-average cost of capital. We believe this is appropriate given the unique characteristics of this acquisition which included a competitive bidding process. This rate is comparable to the estimated internal rate of return for the acquisition and represents the rate that market participants would use to value the intangible assets. The projected cash flows from the IPR&D projects were based on key assumptions such as: estimates of revenues and operating profits related to each 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 product candidate 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.

*Goodwill*

The excess of the consideration transferred over the fair values assigned to the assets acquired and liabilities assumed is \$337.0 million, which represents the goodwill amount resulting from the Calistoga acquisition. Management believes that the goodwill mainly represents the synergies expected from combining our research and development operations as well as acquiring Calistoga'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.

We do not consider the Calistoga 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. INVENTORIES**

Inventories are summarized as follows (in thousands):

	June 30, 2011	December 31, 2010
Raw materials	\$ 665,250	\$ 408,015
Work in process	271,644	454,652
Finished goods	384,721	341,142
 Total	 \$ 1,321,615	 \$ 1,203,809

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

As of June 30, 2011 and December 31, 2010, the joint ventures formed by Gilead and BMS, which are included in our Condensed Consolidated Financial Statements, held \$955.8 million and \$811.9 million in inventory, respectively, of efavirenz active pharmaceutical ingredient purchased from BMS at BMS's estimated net selling price of efavirenz.

**Table of Contents****7. INTANGIBLE ASSETS**

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

	June 30, 2011	December 31, 2010
Goodwill	\$ 1,004,102	\$ 532,669
Finite lived intangible assets	831,478	863,393
Indefinite lived intangible assets	292,830	29,530
Total	\$ 2,128,410	\$ 1,425,592

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

Balance at December 31, 2010	\$ 532,669
Goodwill resulting from the acquisition of Arresto	134,482
Goodwill resulting from the acquisition of Calistoga	336,951
Balance at June 30, 2011	\$ 1,004,102

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

	June 30, 2011		December 31, 2010	
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Intangible asset - Ranexa	\$ 688,400	\$ 75,948	\$ 688,400	\$ 54,795
Intangible asset - Lexiscan	262,800	56,851	262,800	43,979
Other	24,995	11,918	22,095	11,128
Total	\$ 976,195	\$ 144,717	\$ 973,295	\$ 109,902

Amortization expense related to intangible assets was \$17.4 million and \$34.8 million for the three and six months ended June 30, 2011, respectively, and was recorded in cost of goods sold in our Condensed Consolidated Statements of Income. Amortization expense related to intangible assets was \$15.0 million and \$30.0 million for the three and six months ended June 30, 2010, respectively, and was recorded in cost of goods sold in our Condensed Consolidated Statements of Income.

As of June 30, 2011, the estimated future amortization expense associated with our intangible assets for the remaining six months of 2011 and each of the five succeeding fiscal years are as follows (in thousands):

Fiscal Year	Amount
2011 (remaining six months)	\$ 34,815
2012	76,081
2013	82,391
2014	91,246
2015	100,952
2016	113,053

Total	\$ 498,538
-------	------------

As of December 31, 2010, we had indefinite-lived intangible assets of \$29.5 million, which consisted of \$26.6 million and \$2.9 million of purchased IPR&D from our acquisitions of CGI and CV Therapeutics, Inc. (CV Therapeutics), respectively. In the first quarter of 2011, the \$2.9 million purchased IPR&D project from CV Therapeutics was completed and reclassified as a finite-lived intangible asset, and is currently being amortized over its estimated useful life. As of June 30, 2011, we had indefinite-lived intangible assets of \$292.8 million related to purchased IPR&D from our acquisitions of CGI, Arresto and Calistoga.

## 8. COLLABORATIVE ARRANGEMENTS

From time to time, as a result of entering into strategic collaborations, we may hold investments in non-public companies. We review our interests in investee companies for consolidation and/or appropriate disclosure based on applicable guidance. Contractual terms which provide us control over an entity may require us to consolidate the entity. Entities consolidated because they are controlled by means other than a majority voting interest are referred to as variable interest entities (VIE). We assess whether we are the primary beneficiary of a VIE based on our power to direct the activities of the VIE that most significantly impact the VIE's economic performance and our obligation to absorb losses or the right to receive benefits from the VIE that could potentially be significant to the VIE. As of June 30, 2011, we determined that certain of our investee companies are VIEs; however, other than with respect to our joint ventures with BMS, we are not the primary beneficiary and therefore do not consolidate these investees.

---

**Table of Contents****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's Sustiva (efavirenz), which we sell as Atripla. The collaboration is structured as a joint venture and operates as a limited liability company named Bristol-Myers Squibb & Gilead Sciences, LLC, which we consolidate. The ownership interests of the joint venture and thus the sharing of product revenue and costs reflect the respective economic interests of BMS and Gilead and are based on the proportions of the net selling price of Atripla attributable to efavirenz and Truvada. Since the net selling price for Truvada may change over time relative to the net selling price of efavirenz, both BMS's and our respective economic interests in the joint venture may vary annually.

We share marketing and sales efforts with BMS and both parties are obligated to provide equivalent sales force efforts for a minimum number of years. Under the terms of the agreement, after the first quarter of 2011, the parties will only share in a limited number of activities in the United States that will be jointly managed. The parties will continue to collaborate on activities such as manufacturing, regulatory, compliance and pharmacovigilance. 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 June 30, 2011 and December 31, 2010, the joint venture held efavirenz active pharmaceutical ingredient which it purchased from BMS at BMS's estimated net selling price of efavirenz in the U.S. market. These amounts are included in inventories on our Condensed Consolidated Balance Sheets. As of June 30, 2011 and December 31, 2010, total assets held by the joint venture were \$1.47 billion and \$1.45 billion, respectively, and consisted primarily of cash and cash equivalents, accounts receivable (including intercompany receivables with Gilead) and inventories. As of June 30, 2011 and December 31, 2010, total liabilities held by the joint venture were \$1.03 billion and \$759.5 million, respectively, and consisted primarily of accounts payable (including intercompany payables with Gilead) and other accrued expenses. These asset and liability amounts do not reflect the impact of 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), a wholly-owned subsidiary 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's estimated net selling price of efavirenz in the European Territory. We are responsible for product distribution, inventory management and warehousing. Through our local subsidiaries, we have primary responsibility for order fulfillment, collection of receivables, customer relations and handling of sales returns in all the territories where we co-promote Atripla with BMS. We are also responsible for accounting, financial reporting and tax reporting for the collaboration. In December 2007, the European Commission approved Atripla for sale in the European Union. As of June 30, 2011 and December 31, 2010, efavirenz purchased from BMS at BMS's estimated net selling price of efavirenz in the European Territory is included in inventories on our Condensed Consolidated Balance Sheets.

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

**Yale School of Medicine**

In March 2011, we announced the formation of a multi-year research collaboration with the Yale School of Medicine (Yale), focused on the discovery of novel cancer therapies. The research effort will initially span four years with an option to renew for up to ten years. We will provide \$40.0 million in research support and basic science infrastructure development during the initial four-year period, and will provide a total of up to \$100.0 million over ten years should the collaboration be extended through that timeframe. We will have the first option to license any Yale inventions that result from the collaboration. Expenses related to this collaboration agreement commenced in April 2011 and will be recorded as part of research and development expenses on our Condensed Consolidated Statement of Income.



**Table of Contents****MicroDose Therapeutx, Inc.**

In April 2011, we announced an exclusive worldwide license and collaboration agreement with MicroDose Therapeutx, Inc. (MicroDose) for the development and commercialization of MDT-637, MicroDose's inhalable small molecule antiviral fusion inhibitor for the treatment of respiratory syncytial virus. Under the terms of the agreement, we paid MicroDose an upfront payment of \$8.0 million in the second quarter of 2011 which was recorded as part of research and development expenses on our Condensed Consolidated Statement of Income. We will also provide research funding to support MicroDose's continued development of MDT-637 through Phase 2a clinical trials. We can assume full responsibility for clinical development following Phase 2a. MicroDose could also receive additional payments based upon the achievement of certain development, regulatory and commercial milestones, as well as development fees and royalties on future potential net sales.

**9. LONG-TERM OBLIGATIONS****Financing Arrangements**

The following table summarizes the carrying amount of our borrowings under various financing arrangements (in thousands):

	June 30, 2011	December 31, 2010
2011 convertible senior notes	\$	\$ 638,991
2013 convertible senior notes	591,687	576,884
2014 convertible senior notes	1,167,549	1,153,805
2016 convertible senior notes	1,119,970	1,107,884
2021 senior unsecured notes	991,640	
Total debt, net	\$ 3,870,846	\$ 3,477,564
Less current portion (2011 convertible senior notes)		638,991
Total long-term debt, net	\$ 3,870,846	\$ 2,838,573

*2021 Senior Unsecured Notes*

In March 2011, we issued the 2021 Notes in a registered offering for an aggregate principal amount of \$1.00 billion. The 2021 Notes will mature on April 1, 2021 and pay interest at a fixed annual rate of 4.50%. Debt issuance costs incurred in connection with the issuance of this debt totaled approximately \$5.8 million and are being amortized to interest expense over the contractual term of the 2021 Notes.

The 2021 Notes may be redeemed at our option at any time or from time to time, at a redemption price equal to the greater of (i) 100% of the principal amount of the notes to be redeemed and (ii) the sum, as determined by an independent investment banker, of the present values of the remaining scheduled payments of principal and interest on the notes to be redeemed (exclusive of interest accrued to the date of redemption) discounted to the redemption date on a semiannual basis at the Treasury Rate plus 20 basis points, plus, in each case, accrued and unpaid interest on the notes to be redeemed to the date of redemption. At any time on or after January 1, 2021, we may redeem the notes, in whole or in part, at 100% of the principal amount of the notes to be redeemed, plus accrued and unpaid interest to the date of redemption. In addition, in the event of the occurrence of both a change in control and a downgrade in the rating of the 2021 Notes below an investment grade rating by Standard & Poor's Ratings Services and Moody's Investors Service, Inc., the holders may require us to purchase all or a portion of their notes at a price equal to 101% of their principal amount, plus accrued and unpaid interest.

We expect to use the net proceeds for general corporate purposes, which include the repayment of existing indebtedness and repurchases of our common stock.

*Maturity of 2011 Convertible Senior Notes*

In May 2011, our 2011 Notes matured and we repaid the aggregate principal balance of \$650.0 million. We also paid \$36.1 million in cash related to the conversion spread of the 2011 Notes, which represents the conversion value in excess of the principal amount, and received \$36.1 million in cash from our convertible note hedges related to the 2011 Notes. Warrants related to our 2011 Notes will expire in August 2011.

**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. As of June 30, 2011, we had \$2.4 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 June 30, 2011, we were in compliance with all such covenants.

**Table of Contents****10. COMMITMENTS AND CONTINGENCIES****Legal Proceedings**

In June 2011, we received a subpoena from the United States Attorney's Office for the Northern District of California requesting documents related to the manufacture, and related quality and distribution practices, of Atripla, Emtriva, Hepsara, Letairis, Truvada, Viread and our investigational fixed-dose combination of Truvada and Edurant. We have been cooperating and will continue to cooperate with this governmental inquiry. It is not possible to predict the outcome of this inquiry.

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

**11. 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 June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Cost of goods sold	\$ 2,887	\$ 2,967	\$ 5,531	\$ 5,820
Research and development expenses	19,420	21,521	36,140	41,590
Selling, general and administrative expenses	27,818	23,559	57,924	47,478
Stock-based compensation expenses included in total costs and expenses	50,125	48,047	99,595	94,888
Income tax effect	(12,210)	(13,652)	(25,066)	(26,080)
Stock-based compensation expenses included in net income	\$ 37,915	\$ 34,395	\$ 74,529	\$ 68,808

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

Under our current three-year, \$5.00 billion stock repurchase program authorized by our Board of Directors (Board) in May 2010, we repurchased \$4.29 billion of our common stock through June 30, 2011. As of June 30, 2011, the remaining authorized amount of stock repurchases that may be made under our current repurchase program was \$706.8 million. During the three and six months ended June 30, 2011, our total repurchase activities were \$723.9 million and \$1.27 billion, respectively, which resulted in the repurchase and retirement of 17.8 million and 31.8 million shares of our common stock, respectively, at average purchase prices of \$40.61 and \$39.95 per share, respectively.

In January 2011, our Board authorized an additional three-year, \$5.00 billion stock repurchase program which would be available for us to initiate upon the completion of our existing program authorized in May 2010.

We use the par value method of accounting for our stock repurchases. Under the par value method, common stock is first charged with the par value of the shares involved. The excess of the cost of shares acquired over the par value is allocated to additional paid-in capital (APIC) based on an estimated average sales price per issued share with the excess amounts charged to retained earnings. As a result of our stock repurchases during the six months ended June 30, 2011, we reduced common stock and APIC by an aggregate of \$97.3 million and charged \$1.19 billion to retained earnings.

**Table of Contents****Comprehensive Income**

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Net income	\$ 742,459	\$ 709,127	\$ 1,389,762	\$ 1,561,221
Other comprehensive income (loss):				
Net foreign currency translation gain (loss)	(4,358)	(2,345)	2,836	(11,754)
Net unrealized gain (loss) on available-for-sale securities, net of related tax effects	(723)	3,774	(3,842)	4,628
Net unrealized gain (loss) on cash flow hedges, net of related tax effects	(27,017)	104,722	(163,186)	202,508
Total other comprehensive income (loss)	(32,098)	106,151	(164,192)	195,382
Comprehensive income	710,361	815,278	1,225,570	1,756,603
Comprehensive loss attributable to noncontrolling interest	3,768	2,934	7,606	5,741
Comprehensive income attributable to Gilead	\$ 714,129	\$ 818,212	\$ 1,233,176	\$ 1,762,344

**13. 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 six months ended June 30, 2011 and 2010, 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 June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Antiviral products:				
Atripla	\$ 821,992	\$ 715,804	\$ 1,566,504	\$ 1,408,676
Truvada	711,301	641,682	1,384,412	1,299,481
Viread	185,717	176,172	354,112	356,858
Hepsera	38,656	51,334	76,752	109,458
Emtriva	6,732	6,745	13,308	13,901
Total antiviral products	1,764,398	1,591,737	3,395,088	3,188,374
AmBisome	88,625	78,174	167,131	155,223
Letairis	73,637	60,348	135,811	115,847
Ranexa	86,077	60,460	154,370	111,703
Other products	26,851	15,342	50,766	22,977
Total product sales	\$ 2,039,588	\$ 1,806,061	\$ 3,903,166	\$ 3,594,124

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

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.

**Table of Contents**

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
United States	\$ 1,144,621	\$ 1,039,883	\$ 2,180,415	\$ 2,052,367
Outside of the United States:				
Switzerland	76,055	99,838	108,621	361,083
France	149,021	125,362	282,918	250,079
Spain	129,676	112,965	249,307	237,285
United Kingdom	122,765	99,529	243,626	217,699
Italy	108,140	86,864	209,576	183,124
Germany	94,844	54,995	170,917	125,007
Other European countries	145,299	171,981	301,937	331,694
Other countries	166,832	135,807	316,030	254,739
<b>Total revenues outside of the United States</b>	<b>992,632</b>	<b>887,341</b>	<b>1,882,932</b>	<b>1,960,710</b>
<b>Total revenues</b>	<b>\$ 2,137,253</b>	<b>\$ 1,927,224</b>	<b>\$ 4,063,347</b>	<b>\$ 4,013,077</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 June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Cardinal Health, Inc.	17%	18%	17%	17%
McKesson Corp.	15%	14%	15%	13%
AmerisourceBergen Corp.	12%	13%	13%	12%

**14. INCOME TAXES**

Our income tax rate of 24.4% and 25.2% for the three and six months ended June 30, 2011, respectively, differed from the U.S. federal statutory rate of 35% due primarily to tax credits and certain operating earnings from non-U.S. subsidiaries that are considered indefinitely invested outside of the United States, partially offset by state taxes and the non-deductible pharmaceutical excise tax. 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 (IRS) for the 2008 and 2009 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. Each quarter we evaluate our exposures associated with our tax filing positions.

In June 2011, we reached agreement with the IRS on several issues related to the examinations of our federal income tax returns for the 2005, 2006 and 2007 tax years. As a result, we reduced our unrecognized tax benefits by \$5.8 million.

As of June 30, 2011, we believe it is reasonably possible that our unrecognized tax benefits will not decrease in the next 12 months as we do not expect to have clarification from the IRS and other tax authorities around any of our uncertain tax positions. With respect to the remaining unrecognized tax benefits, we are 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

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

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 of our uncertain tax positions 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, hope, 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 (SEC), 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, 2010 and our unaudited Condensed Consolidated Financial Statements for the three and six months ended June 30, 2011 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 Atripla<sup>®</sup> (efavirenz 600 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg), Truvada<sup>®</sup> (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; Cayston<sup>®</sup> (aztreonam for inhalation solution) as a treatment to improve respiratory symptoms in cystic fibrosis (CF) patients with *Pseudomonas aeruginosa*; and Vistide<sup>®</sup> (cidofovir injection) for the treatment of cytomegalovirus infection.

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 phosphate) for the treatment and prevention of influenza; GlaxoSmithKline Inc. (GSK) markets Hepsera and Viread for the treatment of chronic hepatitis B in certain territories outside of the United States; GSK also markets Volibris<sup>®</sup> (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<sup>®</sup> (regadenoson) injection in the United States for use as a pharmacologic stress agent in radionuclide myocardial perfusion imaging; Rapidscan Pharma Solutions, Inc. markets Rapiscan<sup>®</sup> (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*

During the second quarter of 2011, our operating results reflected an increase in product sales of 13% over the same quarter in 2010, driven by strong market demand growth across our therapeutic areas and geographies. While growing our business, we continue to invest considerably in research and development (R&D), internally and through acquisitions and strategic collaboration arrangements, positioning us for sustained growth.



## Table of Contents

In April 2011, we announced an exclusive worldwide license and collaboration agreement with MicroDose Therapeutx, Inc. (MicroDose) for the development and commercialization of MDT-637, MicroDose's inhalable small molecule antiviral fusion inhibitor for the treatment of respiratory syncytial virus. Under the terms of the agreement, we paid MicroDose an upfront payment of \$8.0 million in the current quarter. We will also provide research funding to support MicroDose's continued development of MDT-637 through Phase 2a clinical trials. We can assume full responsibility for clinical development following Phase 2a. MicroDose could also receive additional payments based upon the achievement of certain development, regulatory and commercial milestones, as well as development fees and royalties on future potential net sales.

Also in April 2011, we announced the appointment of Muzammil M. Mansuri, PhD. to Senior Vice President, Research and Development Strategy and Corporate Development. In this role, Dr. Mansuri will help define and implement our R&D strategy, explore new business opportunities, drive strategic and portfolio management activities and build and manage our alliances, partnerships and acquisitions. Dr. Mansuri joined us in July 2010 following our acquisition of CGI Pharmaceuticals, Inc., where he served as the Chairman and Chief Executive Officer.

In May 2011, we announced a five-year extension of funding to the Gilead Sciences Research Centre at the Institute of Organic Chemistry and Biochemistry (IOCB) of the Academy of Sciences of the Czech Republic. We will provide a \$1.15 million annual donation to IOCB in order to continue to fund the Research Centre's operations and ongoing research efforts. We first began providing these donations in 2006. We will have the first option to license any inventions that result from the Research Centre's scientific programs and drug discovery efforts.

In June 2011, we announced our agreement with Tibotec Pharmaceuticals (Tibotec) for the development and commercialization of a new fixed-dose antiretroviral combination product containing our cobicistat, an investigational pharmacoenhancing or boosting agent that increases blood levels of certain HIV medicines to allow for once-daily dosing and Tibotec's protease inhibitor Prezista<sup>®</sup> (darunavir), indicated in the United States for the treatment of HIV-infected individuals and is co-administered with ritonavir in combination with other antiretroviral agents. Subject to regulatory approval, Tibotec will be responsible for the formulation, manufacturing, registration, distribution and commercialization of the cobicistat and Prezista fixed-dose combination worldwide. We retain sole rights for the manufacture, development and commercialization of cobicistat as a stand-alone product and for use in combination with other agents. In connection with this agreement, the companies are also negotiating terms for the development and commercialization of a future single-tablet regimen (STR) combining Prezista with our Emtriva and our investigational agents GS 7340 and cobicistat. We would be responsible for the development and commercialization of the new STR on a worldwide basis. The agreement to develop the fixed-dose combination of cobicistat and Prezista is contingent upon the signing of the agreement to develop the Emtriva, GS 7340, cobicistat and Prezista STR.

### *Financial Highlights*

Total product sales were \$2.04 billion for the second quarter of 2011, an increase of 13% over total product sales of \$1.81 billion for the same period last year, driven primarily by the strong fundamentals of our business with antiviral market demand growth in Atripla and Truvada sales in Europe and the United States.

For the three months ended June 30, 2011, Atripla product sales increased 15% over the same period in 2010, primarily driven by sales volume growth in both the United States and Europe, and contributed \$822.0 million, or 47%, to our second quarter 2011 antiviral product sales. For the three months ended June 30, 2011, Truvada product sales increased 11% over the same period in 2010, primarily driven by sales volume growth in Europe and the United States, and contributed \$711.3 million, or 40% to our second quarter 2011 antiviral product sales. Sequentially, our product sales increased 9% from \$1.86 billion in the first quarter of 2011, driven by strong antiviral market demand growth and purchases in advance of the summer holidays in Europe. Foreign currency exchange had a favorable impact of \$27.3 million and \$9.7 million on our second quarter 2011 revenues and pre-tax earnings, respectively, compared to the second quarter of 2010.

In the second quarter of 2011, product sales in the United States increased 10% compared to the same quarter in 2010, primarily driven by the continued strong market demand growth in our antiviral franchise with major wholesaler inventory levels remaining consistent with levels at the end of the first quarter of 2011. The increase was partially offset by the impact of U.S. healthcare reform. In addition, increased demand contributed to the sales growth in our cardiovascular and respiratory franchises. Ranexa sales in the United States contributed \$85.9 million to our second quarter 2011 product sales, an increase of 43% over the same period in 2010. Letairis sales in the United States contributed \$73.6 million to our second quarter 2011 product sales, an increase of 22% over the same period in 2010. Also, Cayston sales in the United States contributed \$18.5 million to our second quarter 2011 product sales, an increase of 98% over the same period in 2010 as Cayston launched in the first quarter of 2010.

In the second quarter of 2011, product sales in Europe increased 16% compared to the same quarter in 2010, due to continued strong market demand growth in our antiviral franchise, partially offset by the impact of austerity measures in certain European countries. Antiviral product sales in Europe totaled \$697.6 million in the second quarter of 2011, an increase of 16% compared to \$600.8 million in the second quarter of 2010, driven primarily by sales of Atripla and Truvada. Foreign currency exchange also had a favorable impact on our European product sales in the second quarter of 2011 compared to the same quarter in 2010. Sequentially, antiviral product sales in Europe in the second quarter of 2011

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

increased 7% compared to the first quarter of 2011 driven primarily by underlying patient demand and purchases in advance of the summer holidays.

**Table of Contents**

Our R&D and selling, general and administrative (SG&A) expenses increased by \$107.6 million, or 22%, for the three months ended June 30, 2011 compared to the same period in 2010. The increase was due primarily to the impact of higher headcount and expenses associated with acquisitions, collaborations and the ongoing growth of our business, costs related to clinical studies performed by contract research organizations and the pharmaceutical excise tax resulting from U.S. healthcare reform.

Cash, cash equivalents and marketable securities increased by \$181.2 million during the six months ended June 30, 2011, driven primarily by our operating cash flows of \$1.76 billion and proceeds of \$987.4 million from the issuance of our 2021 senior unsecured notes (2021 Notes), net of related debt discount and issuance costs, partially offset by \$588.6 million used to acquire Arresto Biosciences, Inc. (Arresto) and Calistoga Pharmaceuticals, Inc. (Calistoga), \$650.0 million used to repay our convertible senior notes due in 2011 (2011 Notes) and repurchases of our common stock under our stock repurchase program. Under our current three-year, \$5.00 billion stock repurchase program, we repurchased \$4.29 billion of our common stock through June 30, 2011. During the six months ended June 30, 2011, our total repurchase activity was \$1.27 billion which resulted in the repurchase and retirement of 31.8 million shares of our common stock at an average purchase price of \$39.95 per share.

**Critical Accounting Policies, Estimates and Judgments**

There have been no material changes in our critical accounting policies, estimates and judgments during the six months ended June 30, 2011 compared to the disclosures in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2010.

**Results of Operations***Total Revenues*

Total revenues for the three months ended June 30, 2011 were \$2.14 billion, compared to \$1.93 billion for the same period in 2010. For the six months ended June 30, 2011, total revenues were \$4.06 billion, compared to \$4.01 billion for the same period in 2010. 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 a favorable impact of \$27.3 million on our second quarter 2011 revenues compared to the second quarter of 2010.

*Product Sales*

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

	Three Months Ended June 30,			Six Months Ended June 30,		
	2011	2010	Change	2011	2010	Change
Antiviral products:						
Atripla	\$ 821,992	\$ 715,804	15 %	\$ 1,566,504	\$ 1,408,676	11 %
Truvada	711,301	641,682	11 %	1,384,412	1,299,481	7 %
Viread	185,717	176,172	5 %	354,112	356,858	(1)%
Hepsera	38,656	51,334	(25)%	76,752	109,458	(30)%
Emtriva	6,732	6,745	(0)%	13,308	13,901	(4)%
Total antiviral products	1,764,398	1,591,737	11 %	3,395,088	3,188,374	6 %
AmBisome	88,625	78,174	13 %	167,131	155,223	8 %
Letairis	73,637	60,348	22 %	135,811	115,847	17 %
Ranexa	86,077	60,460	42 %	154,370	111,703	38 %
Other products	26,851	15,342	75 %	50,766	22,977	121 %
Total product sales	\$ 2,039,588	\$ 1,806,061	13 %	\$ 3,903,166	\$ 3,594,124	9%

Total product sales increased by 13% and 9% for the three and six months ended June 30, 2011, respectively, compared to the same periods in 2010. This increase was due primarily to the growth of Atripla and Truvada sales.

*Antiviral Products*

Antiviral product sales increased by 11% and 6% for the three and six months ended June 30, 2011, respectively, compared to the same periods in 2010.

*Atripla*

Atripla sales increased by 15% and 11% for the three and six months ended June 30, 2011, respectively, compared to the same periods in 2010, 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

**Table of Contents**

\$298.4 million and \$572.3 million for the three and six months ended June 30, 2011, respectively, and approximately \$262.5 million and \$518.3 million for the three and six months ended June 30, 2010, respectively. Atripla sales accounted for 47% and 46% of our total antiviral product sales for the three and six months ended June 30, 2011, respectively.

*Truvada*

Truvada sales increased by 11% and 7% for the three and six months ended June 30, 2011, respectively, compared to the same periods in 2010, driven primarily by sales volume growth in Europe and the United States. Truvada sales accounted for 40% and 41% of our total antiviral product sales for the three and six months ended June 30, 2011, respectively.

*Other Antiviral Products*

Other antiviral product sales, which include product sales of Viread, Hepsara and Emtriva, decreased by 1% for the three months ended June 30, 2011 compared to the same period in 2010, due primarily to decreased sales volume for Hepsara in Europe and the United States, partially offset by increased sales volume for Viread in Europe and the United States. Other antiviral product sales decreased by 8% for the six months ended June 30, 2011 compared to the same period in 2010, due primarily to decreased sales volume for Hepsara in Europe and the United States and for Viread in Europe and Latin America, partially offset by increased sales volume for Viread in the United States.

*AmBisome*

Sales of AmBisome increased by 13% and 8% for the three and six months ended June 30, 2011, respectively, compared to the same periods in 2010. The increases over both periods were driven primarily by sales volume growth in Europe and Latin America. 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 22% and 17% for the three and six months ended June 30, 2011, respectively, compared to the same periods in 2010, driven primarily by sales volume growth.

*Ranexa*

Sales of Ranexa increased by 42% and 38% for the three and six months ended June 30, 2011, respectively, compared to the same periods in 2010, driven primarily by sales volume growth.

*Royalty Revenues*

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

	Three Months Ended June 30,			Six Months Ended June 30,		
	2011	2010	Change	2011	2010	Change
Royalty revenues	\$ 94,321	\$ 117,790	(20)%	\$ 152,986	\$ 411,471	(63)%

Historically, our most significant source of royalty revenues has been from sales of Tamiflu by Roche. We recognize royalties on Tamiflu sales by Roche in the quarter following the quarter in which Tamiflu sales are recognized by Roche.

Royalty revenues for the three months ended June 30, 2011 were \$94.3 million, a decrease of 20% or \$23.5 million compared to the same period in 2010, due to lower Tamiflu royalties from Roche of \$50.6 million in the three months ended June 30, 2011, compared to Tamiflu royalties from Roche of \$83.8 million in the same period in 2010. Royalty revenues for the six months ended June 30, 2011 were \$153.0 million, a decrease of 63% or \$258.5 million compared to the same period in 2010, due to lower Tamiflu royalties from Roche of \$61.7 million in the six months ended June 30, 2011, compared to Tamiflu royalties from Roche of \$330.1 million in the same period in 2010. Tamiflu royalties declined sharply in the second quarter of 2010 and continued to decline through the first quarter of 2011 due to the fulfillment of many of the

existing pandemic orders from governments and corporations.

**Table of Contents***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 June 30,			Six Months Ended June 30,		
	2011	2010	Change	2011	2010	Change
Total product sales	\$ 2,039,588	\$ 1,806,061	13%	\$ 3,903,166	\$ 3,594,124	9%
Cost of goods sold	\$ 533,863	\$ 455,525	17%	\$ 1,007,974	\$ 895,955	13%
Product gross margin	74%	75%		74%	75%	

Our product gross margin for the three and six months ended June 30, 2011 was 74%, a decrease of 1% compared to the same periods in 2010, primarily due to the impact of U.S. healthcare reform and pricing pressures in Europe.

*Research and Development Expenses*

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

	Three Months Ended June 30,			Six Months Ended June 30,		
	2011	2010	Change	2011	2010	Change
Research and development	\$ 282,403	\$ 231,066	22%	\$ 536,849	\$ 449,730	19%

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, milestone payments under collaboration arrangements and overhead allocations consisting of various support and facilities-related costs.

R&D expenses for the three months ended June 30, 2011 increased by \$51.3 million, or 22%, compared to the same period in 2010, due primarily to a \$16.1 million increase in clinical studies costs, a \$10.9 million increase in compensation and benefits expenses related to higher headcount to support our increased R&D activities and a \$24.7 million increase in other contract and professional services associated with the ongoing growth of our business.

R&D expenses for the six months ended June 30, 2011 increased by \$87.1 million, or 19%, compared to the same period in 2010, due primarily to \$9.0 million of R&D expense reimbursements related to our collaboration with Tibotec, a \$17.8 million increase in compensation and benefits expenses related to higher headcount to support our increased R&D activities, a \$10.9 million increase in clinical studies costs and a \$40.7 million increase in other contract and professional services associated with the ongoing growth of our business.

*Selling, General and Administrative Expenses*

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

	Three Months Ended June 30,			Six Months Ended June 30,		
	2011	2010	Change	2011	2010	Change
Selling, general and administrative	\$ 304,269	\$ 248,006	23%	\$ 599,837	\$ 513,624	17%

SG&A expenses for the three months ended June 30, 2011 increased by \$56.3 million, or 23%, compared to the same period in 2010. This was due primarily to an \$18.0 million increase in compensation and benefits expenses related to higher headcount to support our expanding commercial activities, a \$20.9 million increase in contract and professional services expenses and a \$6.5 million increase in promotional costs. Additionally, we estimate that the impact of the pharmaceutical excise tax will result in approximately \$50 million in SG&A expenses for the full year of 2011 based on the information we have received to date.

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

SG&A expenses for the six months ended June 30, 2011 increased by \$86.2 million, or 17%, compared to the same period in 2010. This was due primarily to a \$30.2 million increase in compensation and benefits expenses related to higher headcount to support our expanding commercial activities, a \$31.5 million increase in contract and professional expenses and a \$9.4 million increase in bad debt expenses associated with slower collections in southern European countries. These increases were partially offset by a \$12.2 million decrease in expenses related to our 2010 restructuring activities which were comprised primarily of lease termination costs.

### *Interest and Other Income, Net*

Interest and other income, net, for the three months ended June 30, 2011 decreased by \$6.3 million compared to the same period in 2010, due primarily to increased costs related to our hedging activities. Interest and other income, net, for the six months ended June 30, 2011 decreased by \$8.1 million compared to the same period in 2010, due primarily to increased costs related to our hedging activities and an unfavorable net foreign currency exchange impact, partially offset by an increase in interest income.

**Table of Contents***Interest Expense*

Interest expense for the three and six months ended June 30, 2011 increased by \$28.3 million and \$52.6 million, respectively, compared to the same periods in 2010, due primarily to the issuance of our 2014 and 2016 convertible senior notes for \$2.46 billion, net of issuance costs, in July 2010 and the issuance of our 2021 Notes for \$987.4 million, net of related debt discount and issuance costs, in March 2011.

*Provision for Income Taxes*

Our provision for income taxes was \$240.1 million and \$467.4 million for the three and six months ended June 30, 2011, respectively, compared to \$284.0 million and \$591.8 million for the same periods in 2010, respectively. Our effective tax rate was 24.4% and 25.2% for the three and six months ended June 30, 2011, respectively, compared to our effective tax rate of 28.6% and 27.5% for the same periods in 2010, respectively. The effective tax rates for the three and six months ended June 30, 2011 were lower than the effective tax rates for the three and six months ended June 30, 2010 as a result of the federal research tax credit extension, resolution of certain tax positions with taxing authorities and lower state taxes, partially offset by the non-deductible pharmaceutical excise tax.

The effective tax rate for the three and six months ended June 30, 2011 differed from the U.S. federal statutory rate of 35% due primarily to tax credits and certain operating earnings from non-U.S. subsidiaries that are considered indefinitely invested outside of the United States, partially offset by state taxes and the non-deductible pharmaceutical excise tax. 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 June 30, 2011	As of December 31, 2010
Cash, cash equivalents and marketable securities	\$ 5,499,312	\$ 5,318,071
Working capital	\$ 3,908,204	\$ 3,243,132
	<b>Six Months Ended June 30,</b>	
	<b>2011</b>	<b>2010</b>
Cash provided by (used in):		
Operating activities	\$ 1,763,797	\$ 1,369,648
Investing activities	\$ (770,171)	\$ (135,806)
Financing activities	\$ (886,852)	\$ (1,149,504)

*Cash, Cash Equivalents and Marketable Securities*

Cash, cash equivalents and marketable securities totaled \$5.5 billion at June 30, 2011, an increase of \$181.2 million or 3% from December 31, 2010. This increase was primarily attributable to net cash provided by operations of \$1.76 billion and \$987.4 million of net proceeds from the issuance of our 2021 Notes, partially offset by \$588.6 million used in our recent acquisitions of Arresto and Calistoga, \$650.0 million used to repay our 2011 Notes and \$1.27 billion used to repurchase common stock under our current stock repurchase program, including commissions.

*Working Capital*

Working capital was \$3.91 billion at June 30, 2011, an increase of \$665.1 million or 21% from working capital as of December 31, 2010. This increase was primarily attributable to:

an increase of \$171.7 million in cash, cash equivalents and short-term marketable securities;

an increase of \$316.7 million in accounts receivable, net, primarily driven by slower collections in southern European countries; and

a decrease of \$639.0 million in the current portion of long-term debt and other obligations, net, due primarily to the repayment of the 2011 Notes upon maturity in May 2011.

---

**Table of Contents**

This increase was partially offset by:

an increase of \$299.3 million in accounts payable, due primarily to the purchases of efavirenz from Bristol-Myers Squibb Company; and

an increase of \$180.3 million in other accrued liabilities, due primarily to an increase in the fair value of our cash flow hedge liabilities related to our foreign currency exchange contracts and the pharmaceutical excise tax related to U.S. healthcare reform.

*Cash Provided by Operating Activities*

Cash provided by operating activities of \$1.76 billion for the six months ended June 30, 2011 primarily related to net income of \$1.39 billion, adjusted for non-cash items such as \$155.8 million of depreciation and amortization expenses, \$99.6 million of stock-based compensation expenses, \$40.0 million of deferred income taxes and \$75.0 million of net cash inflow related to changes in operating assets and liabilities. This was partially offset by \$20.3 million of excess tax benefits from stock option exercises which we reclassified to cash used in financing activities.

Cash provided by operating activities of \$1.37 billion for the six months ended June 30, 2010 primarily related to net income of \$1.56 billion, adjusted for non-cash items such as \$94.9 million of stock-based compensation expenses, \$118.9 million of depreciation and amortization expenses and \$62.7 million of tax benefits from employee stock plans, partially offset by \$441.0 million of net cash outflow related to changes in operating assets and liabilities and \$60.7 million of excess tax benefits from stock option exercises which we reclassified to cash used in financing activities.

*Cash Used in Investing Activities*

Cash used in investing activities for the six months ended June 30, 2011 was \$770.2 million, consisting of a net use of \$140.1 million in purchases of marketable securities, \$588.6 million used in our recent acquisitions of Arresto and Calistoga and \$41.5 million of capital expenditures.

Cash used in investing activities for the six months ended June 30, 2010 was \$135.8 million, consisting of a net use of \$108.1 million in purchases of marketable securities and \$27.7 million of capital expenditures for the period.

*Cash Used in Financing Activities*

Cash used in financing activities for the six months ended June 30, 2011 was \$886.9 million, driven primarily by \$1.27 billion used to repurchase our common stock under our stock repurchase program, including commissions, and \$650.0 million used to repay our 2011 Notes, partially offset by the \$987.4 million of net proceeds from the issuance of our 2021 Notes.

Cash used in financing activities for the six months ended June 30, 2010 was \$1.15 billion, driven primarily by \$1.85 billion used to repurchase our common stock under our stock repurchase programs, partially offset by \$500.0 million in proceeds from borrowings under our credit facility and \$144.3 million of proceeds from issuances of common stock under our employee stock plans.

*Other Information*

Under our current three-year, \$5.00 billion stock repurchase program authorized by our Board of Directors (Board) in May 2010, we repurchased \$4.29 billion of our common stock through June 30, 2011. As of June 30, 2011, the remaining authorized amount of stock repurchases that may be made under our \$5.00 billion repurchase program was \$706.8 million. During the three months ended June 30, 2011, our total repurchase activity was \$723.9 million which resulted in the repurchase and retirement of 17.8 million shares of our common stock at an average purchase price of \$40.61 per share.

In January 2011, our Board authorized an additional three-year, \$5.00 billion stock repurchase program which would be available for us to initiate upon the completion of our existing program authorized in May 2010. We intend to use the additional authorization to repurchase our shares from time to time to offset the dilution created by shares issued under employee stock plans and to repurchase shares opportunistically.

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

Under our amended and restated credit agreement, we, along with our wholly-owned subsidiary, Gilead Biopharmaceuticals 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 June 30, 2011, approximately \$1.25 billion was available to be drawn down under this credit agreement.

In March 2011, we issued the 2021 Notes in a registered offering for an aggregate principal amount of \$1.00 billion. The 2021 Notes will mature on April 1, 2021 and pay interest at a fixed annual rate of 4.50%.

In May 2011, our 2011 Notes matured. We repaid an aggregate principal balance of \$650.0 million. We also paid \$36.1 million in cash related to the conversion spread of the 2011 Notes, which represents the conversion value in excess of the principal amount, and received \$36.1 million in cash from our convertible note hedges related to the 2011 Notes. Warrants related to our 2011 Notes will expire in August 2011.

## **Table of Contents**

We believe that our existing funds, cash generated from operations and existing sources of and access to financing are adequate to satisfy our capital needs for the foreseeable future.

### **Off Balance Sheet Arrangements**

We do not have any off balance sheet arrangements.

### **Recent Accounting Pronouncements**

In May 2011, the Financial Accounting Standards Board (FASB) issued amendments to its existing standard for fair value measurement to achieve common guidance in U.S. generally accepted accounting principles and International Financial Reporting Standards. In addition, the amended standard revises certain requirements for measuring fair value and for disclosure around fair value measurement. It does not require additional fair value measurements and was not intended to establish valuation standards or affect valuation practices outside of financial reporting. The updated standard is effective for us beginning in the first quarter of 2012. Early adoption is not permitted. The adoption of these amendments is not expected to have a material impact on our Condensed Consolidated Financial Statements.

In June 2011, the FASB issued an update to an existing standard for comprehensive income to make the presentation of items within other comprehensive income (OCI) more prominent. The updated standard prohibits the current presentation of OCI in the statement of stockholders equity and instead, provides public companies the option of presenting OCI in a continuous statement of comprehensive income or two separate consecutive statements. Additionally, the update requires that reclassification adjustments be displayed on the face of the financial statements where OCI is reported. The updated standard is effective for us beginning in the first quarter of 2012; however, early adoption is permitted and prior-year information would need to be presented in accordance with the requirements of the updated standard. Upon adoption, the updated standard will impact the presentation of our Condensed Consolidated Financial Statements; however it will have no impact on our financial position or results of operations.

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

There have been no material changes in our market risk during the six months ended June 30, 2011 compared to the disclosures in Part II, Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2010.

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 2025 through 2040 and have annual interest rates ranging from 0.16% to 1.09%. As of June 30, 2011, our auction rate securities continued to earn interest.

If auctions continue to fail for securities in which we have invested, we may be unable to liquidate some or all of our auction rate securities at par should we need or desire to access the funds invested in those securities. However, based on our total cash and marketable securities position, our expected operating cash flows as well as access to funds through our credit facility, we believe that we will be able to hold these securities until there is a recovery in the auction market and the related securities, which may be at final maturity. As a result, we do not anticipate that the current illiquidity of these auction rate securities will have a material effect on our cash requirements or working capital.

In 2010, we agreed to settle a portion of our outstanding accounts receivable with the Greek government in zero-coupon bonds issued by the Greek government. As of June 30, 2011, we received a total of \$63.5 million in bonds. Currently, these bonds trade infrequently on the open market at a substantial discount to the face value. We believe we will be able to hold these securities until maturity. As a result, we do not anticipate that the illiquidity of these securities will have a material effect on our cash requirements or working capital.

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

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

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

An evaluation as of June 30, 2011 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 June 30, 2011.

**Table of Contents****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 June 30, 2011, and has concluded that there was no change during such quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Limitations on the Effectiveness of Controls**

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

**PART II. OTHER INFORMATION****ITEM 1. LEGAL PROCEEDINGS**

In November 2008, we received notice that Teva Pharmaceuticals (Teva) submitted an abbreviated new drug application (ANDA) to the U.S. Food and Drug Administration (FDA) requesting permission to manufacture and market a generic version of Truvada. In the notice, Teva alleges that two of the patents associated with emtricitabine, 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 Atripla and Truvada. 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 the notice related to Truvada, Teva challenged four patents related to tenofovir disoproxil fumarate and two additional patents related to emtricitabine. In March 2010, we filed a lawsuit against Teva for infringement of the four Viread patents and two additional emtricitabine patents. In March 2010, Bristol-Myers Squibb Company and Merck & Co., Inc. 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 in U.S. District Court in New Jersey 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. The patent challenged by Ranbaxy expires in July 2018. We are considering our options for enforcing our patent.

In February 2011, we received notice that Natco Pharma Ltd. (Natco) submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Tamiflu. In the notice, Natco alleges that one of the patents associated with Tamiflu is invalid, unenforceable and/or will not be infringed by Natco's manufacture, use or sale of a generic version of Tamiflu. In March 2011, we and F. Hoffmann-La Roche Ltd. filed a lawsuit in U.S. District Court in New Jersey and Delaware against Natco for infringement of the patent associated with Tamiflu.

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

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

Atripla, Truvada, Viread, Hepsera, Ranexa and Tamiflu 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 prior to the expiration date of those patents.

---

## **Table of Contents**

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 10. 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 maintain or 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 quarter ended June 30, 2011, Atripla and Truvada product sales together were \$1.53 billion, or 72% of our total revenues. We may not be able to maintain or 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.

**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 January 2011, we announced our decision to terminate our Phase 3 clinical trial of ambrisentan in patients with idiopathic pulmonary fibrosis (IPF). In April 2011, we announced our decision to terminate our Phase 3 clinical trial of aztreonam for inhalation solution for the treatment of cystic fibrosis (CF) in patients with *Burkholderia spp.* In addition, our new drug application (NDA) for the single-tablet regimen of Truvada and Tibotec Pharmaceuticals' investigational TMC278 for the treatment of HIV-1 infection in adults, which we re-filed in February 2011 in response to a refuse to file notification from the U.S. Food and Drug Administration (FDA) requesting additional information, may not be approved by the FDA. Further, even if marketing approval is granted, the product label negotiated with the FDA could limit the uptake of the product by patients.

**Our results of operations will be adversely affected by current and potential future healthcare reforms.**

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

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 impacted us include:

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%;

---

**Table of Contents**

we are required to extend rebates to patients receiving our products through Medicaid managed care organizations;

we are required to provide a 50% discount on products sold to patients while they are in the Medicare Part D donut hole; and

we, along with other pharmaceutical manufacturers of branded drug products, are 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 2009 calendar year as a percentage of total industry government sales.

Some 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. While we have received a preliminary estimate for the pharmaceutical excise tax, we are still awaiting the final invoice. Based on the information that we have received to date, we estimate the 2011 impact of the pharmaceutical excise tax to be approximately \$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 made several estimates and assumptions with respect to our expected payer mix and how the reforms will be implemented.

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.

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. Given the current economic downturn, we have experienced a shift in our payer mix as patients previously covered by private insurance move to public reimbursement programs that require rebates or discounts from us or as patients previously covered by one public reimbursement program move to another public reimbursement program that requires greater rebates or discounts from us. As a result of this shift, revenue growth may be lower than prescription growth. If federal and state funds are not available in amounts sufficient to support the number of patients that rely on ADAPs, sales of our HIV products could be negatively impacted which would reduce our revenues. For example, during the first quarter of 2011, the state budget crisis in Florida led to a temporary movement of patients who were previously covered by Florida's ADAP into industry-supported patient assistance programs. In recent quarters, due to the insufficiency of federal and state funds and as many states have reduced eligibility criteria, we have also seen and may continue to see an increase in the number of patients on ADAP wait lists. Until these patients are enrolled in ADAP, they generally receive product from industry-supported patient assistance programs or are unable to access treatment. 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,

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

governments control the prices of prescription pharmaceuticals, including through the implementation of reference pricing, price cuts, rebates, revenue-related taxes and profit control, and they 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 these efforts could 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. As generic drugs come to market, we may face price decreases for our products in some countries in the European Union.

---

## **Table of Contents**

### **Approximately 46% 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.**

In the quarter ended June 30, 2011, approximately 82% 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 fourth quarter of 2010, our wholesalers increased their inventory levels for our antiviral products. In the first quarter of 2011, our wholesalers drew down on their inventory such that inventory levels for our antiviral products moved to the lower end of the contractual boundaries set by our inventory management agreements. As inventory in the distribution channel fluctuates from quarter to quarter, we may continue to see fluctuations in our earnings and a mismatch between prescription demand for our products and our revenues.

In addition, the non-retail sector in the United States, which includes government institutions, including state ADAPs, 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 2011, 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 2009 and 2010. We believe this decrease was driven by uncertainty regarding the amount and availability of the federal ADAP budget for 2011-2012 and the lack of sufficient state funding. In the second quarter of 2011, only a portion of the full year federal budget was provided to the ADAPs, which resulted in measured purchasing by individual ADAPs during the quarter. Federal and state budget pressures, as well as the annual grant cycles for federal and state ADAP funds, may cause ADAP purchasing patterns to not reflect patient demand. As a result, 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 European 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.**

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

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.

**Table of Contents**

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 is available in Spain and Portugal, and recently received pricing approval in Italy. We expect that generic versions of lamivudine will be launched in other countries within the European Union.

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. 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. 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.

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

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

Our product Letairis, which was approved by the FDA in June 2007, is a member of a class of compounds called endothelin receptor antagonists (ERAs) which pose specific risks, including serious risks of 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, the European Medicines Agency 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, including those related to promotion and manufacturing, 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

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

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.

---

## **Table of Contents**

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 the distribution or use of a product.

Failure to comply with these or other requirements, if imposed on a sponsor by the FDA, could result in significant civil monetary penalties and our operating results may be adversely affected.

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

We are required to demonstrate the safety and efficacy of products that we develop for each intended use through extensive preclinical studies and clinical trials. The results from preclinical and early clinical studies do not always accurately predict results in later, large-scale clinical trials. Even successfully completed large-scale clinical trials may not result in marketable products. If any of our product candidates fails to achieve its primary endpoint in clinical trials, if safety issues arise or if the results from our clinical trials are otherwise inadequate to support regulatory approval of our product candidates, commercialization of that product candidate could be delayed or halted. For example, in January 2011, we announced our decision to terminate our Phase 3 clinical trial of ambrisentan in patients with IPF and, in April 2011, we announced our decision to terminate our Phase 3 clinical trial of aztreonam for inhalation solution for the treatment of CF in patients with *Burkholderia spp.* 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; and the fixed-dose regimen of elvitegravir, cobicistat and Truvada for the treatment of HIV in treatment-naïve patients; 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.**

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

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; F. Hoffmann-La Roche Ltd. (together with Hoffmann-La Roche Inc., 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, 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;

---

**Table of Contents**

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 and Viread for the treatment of chronic hepatitis B. 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;

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.

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.

---

## Table of Contents

**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 drafted 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 before a patent is issued. As a result, we may not know if our competitors filed patent applications for technology covered by our pending applications or if we were the first to invent the technology that is the subject of our patent applications. Competitors may have filed patent applications or received patents and may obtain additional patents and proprietary rights that block or compete with our 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 Atripla, Truvada 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 actions in the instance above, similar organizations may still challenge our patents in U.S. and 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 2010, the Brazilian government purchased approximately \$50.0 million of our HIV products. We are aware of applications from two generic companies to sell a generic version of Viread in Brazil, one of which has received approval from the Brazilian Health Ministry. If one or both of these generic applicants are able to compete for this contract for 2011, we would not expect the Brazilian government to purchase any of our HIV products in 2011.

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

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

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 the ranolazine compound, 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. Generic manufacturers have sought and may continue to seek FDA approval for a similar or identical drug through an abbreviated new drug application (ANDA), the application form typically used by manufacturers seeking approval of a generic drug.

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 Atripla and Truvada. 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. The patent challenged by Ranbaxy expires in July 2018. We have the option of filing a lawsuit at any time if we believe that Ranbaxy is infringing our patent.

In February 2011, we received notice that Natco Pharma Limited (Natco) submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Tamiflu. In the notice, Natco alleges that one of the patents associated with Tamiflu is invalid, unenforceable and/or will not be infringed by Natco's manufacture, use or sale of a generic version of Tamiflu. In March 2011, we and Roche filed a lawsuit against Natco for infringement of the patent associated with Tamiflu.

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

**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.

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

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.

**Table of Contents****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 current Good Manufacturing Practices (GMP), which are extensive regulations governing manufacturing processes, stability testing, record keeping and quality standards as defined by the FDA and the European Medicines Agency. 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, where we manufacture AmBisome and Cayston, fill and finish Macugen, and package solid dosage form products. 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. On September 24, 2010, our San Dimas manufacturing facility received a Warning Letter from the FDA further detailing the FDA's concerns over 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 stated concerns connected with quality procedures, controls and investigation procedures, and a generalized concern over the effectiveness of the San Dimas quality unit in carrying out its responsibilities.

In November and December 2010, the FDA re-inspected the San Dimas facility. The re-inspection closed with no additional Form 483 observations. Consequently, we believe that we have addressed the FDA's concerns as stated in the Form 483 observations and the Warning Letter, but we are awaiting confirmation of acceptance from the FDA.

Unless and until we receive confirmation from the FDA that it is satisfied we have corrected outstanding issues, the FDA may withhold permission to export AmBisome and Cayston manufactured at San Dimas 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, which would limit our ability to generate revenues" below, we manufacture AmBisome 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 the solid dosage form products that we package at the San Dimas facility, which include Atripla, Truvada, Viread, Emtriva, Hepsera, Letairis and Ranexa. 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. We manufacture Cayston 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.

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

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.

---

## **Table of Contents**

### **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 supplier is required. Even after a manufacturer is qualified by the FDA, the manufacturer must continue to expend time, money and effort in the area of production and quality control to ensure full compliance with GMP. Manufacturers are subject to regular, periodic inspections by the FDA following initial approval. If, as a result of these inspections, the FDA determines that the equipment, facilities, laboratories or processes do not comply with applicable FDA regulations and conditions of product approval, the FDA may suspend the manufacturing operations. If the manufacturing operations of any of the single suppliers for our products are suspended, we may be unable to generate sufficient quantities of commercial or clinical supplies of product to meet market demand, which would in turn decrease our revenues and harm our business. In addition, if delivery of material from our suppliers were interrupted for any reason, we may be unable to ship certain of our products for commercial supply or to supply our products in development for clinical trials. In addition, some of our products and the materials that we utilize in our operations are made at only one facility. For example, we manufacture AmBisome and fill and finish Macugen exclusively at our facilities in San Dimas, California. In the event of a disaster, including an earthquake, equipment failure or other difficulty, we may be unable to replace this manufacturing capacity in a timely manner and may be unable to manufacture AmBisome and Macugen to meet market needs.

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 supply 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 \$1.12 billion as of June 30, 2011, of which \$547.9 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, in 2011, the Greek government settled substantially all of its outstanding receivables subject to the bond settlement with zero-coupon bonds that trade at a discount to face value. As of June 30, 2011, we received a total of \$63.5 million in bonds. Our allowance for doubtful accounts was adequate to cover the exposure related to the 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.



**Table of Contents****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 have reduced and may continue to 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 Atripla and Truvada. 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 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. The patent challenged by Ranbaxy expires in July 2018. We are considering our options for enforcing our patent.

In February 2011, we received notice that Natco submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Tamiflu. In the notice, Natco alleges that one of the patents associated with Tamiflu is invalid, unenforceable and/or will not be infringed by Natco's manufacture, use or sale of a generic version of Tamiflu. In March 2011, we and Roche filed a lawsuit against Natco for infringement of the patent associated with Tamiflu.

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

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

covering those products are invalidated, the FDA could approve the requests to manufacture a generic version of such products prior to the expiration date of those patents.

In addition, in June 2011, we received a subpoena from the United States Attorney's Office for the Northern District of California requesting documents related to the manufacture, and related quality and distribution practices, of Atripla, Emtriva, Hepsera, Letairis, Truvada, Viread and our investigational fixed-dose combination of Truvada and Edurant.

The outcome of the lawsuits above, or any other lawsuits that may be brought against us, the investigation or any other investigations that may be initiated, 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.

**Table of Contents****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 2010, the Brazilian government purchased approximately \$50.0 million of our HIV products. Further, we are aware of applications from two generic companies to sell a generic version of Viread in Brazil, one of which has received approval from the Brazilian Health Ministry. If one or both of these generic applicants are able to compete for this contract for 2011, we would not expect the Brazilian government to purchase any of our HIV products in 2011.

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.

**Changes in royalty revenue disproportionately affect our pre-tax income, earnings per share and gross margins.**

A portion of our revenues is derived from royalty revenues recognized from collaboration agreements with third parties. Royalty revenues impact our pre-tax income, earnings per share and gross margins disproportionately more than their contributions to our revenues. Any increase or decrease to our royalty revenue could be material and could significantly impact our operating results. For example, we recognized \$386.5 million in royalty revenue for the year ended December 31, 2010 related to royalties received from sales of Tamiflu by F. Hoffmann-La Roche Ltd (together with Hoffmann-La Roche Inc., Roche). Although such royalty revenue represented approximately 5% of our total revenues in 2010, it represented approximately 10% 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 and continued to decline through the first quarter of 2011 due to the fulfillment of many of the existing pandemic orders from governments and corporations.

**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, so we may be unable to maintain sufficient coverage for product liabilities that may arise. 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 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.

**Business disruptions from natural or man-made disasters may harm our future revenues.**

Our worldwide operations will be subject to business interruptions stemming from natural or man-made disasters for which we may be self-insured. Our corporate headquarters and Palo Alto locations, which together house a majority of our research and development activities, and our San Dimas manufacturing facility are located in California, a seismically active region. As we do not carry earthquake insurance 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.

## **Table of Contents**

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

Various factors may have favorable or unfavorable effects on our income tax rate. These factors include, but are not limited to, interpretations of existing tax laws, changes in tax laws and rates, the non-deductible pharmaceutical excise tax that we will be required to pay in the third quarter of 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 2008 and 2009 tax years and by various state and foreign jurisdictions. There are differing interpretations of tax laws and regulations, and as a result, significant disputes may arise with these tax authorities involving issues of the timing and amount of deductions and allocations of income among various tax jurisdictions. Resolution of one or more of these exposures in any reporting period could have a material impact on the results of operations for that period.

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

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

### **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, \$5.00 billion stock repurchase program authorized by our Board of Directors (Board) in May 2010, we repurchased \$4.29 billion of our common stock through June 30, 2011. As of June 30, 2011, the remaining authorized amount of stock repurchases that may be made under our \$5.00 billion repurchase program was \$706.8 million. During the six months ended June 30, 2011, our total repurchase activity was \$1.27 billion which resulted in the repurchase and retirement of 31.8 million shares of our common stock at an average purchase price of \$39.95 per share.

In January 2011, our Board authorized an additional three-year, \$5.00 billion stock repurchase program which would be available for us to initiate upon the completion of our existing program authorized in May 2010.

The table below summarizes our stock repurchase activity for the three months ended June 30, 2011 (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
April 1 - April 30	4,765	\$ 40.60	4,760	\$ 1,237,445
May 1 - May 31	4,468	\$ 40.84	4,448	\$ 1,055,805
June 1 - June 30	8,619	\$ 40.50	8,618	\$ 706,805
Total	17,852 <sup>(1)</sup>	\$ 40.61	17,826 <sup>(1)</sup>	

<sup>(1)</sup> 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>Footnote</b>	<b>Exhibit Number</b>	<b>Description of Document</b>
(1)	1.1	Underwriting Agreement, dated March 23, 2011, among Registrant and J.P. Morgan Securities LLC, Merrill Lynch, Pierce, Fenner & Smith Incorporated and Morgan Stanley & Co. Incorporated, as representatives of the several underwriters name in Schedule 1 thereto.
(2)	2.1	Agreement and Plan of Merger among Registrant, Apex Merger Sub, Inc. and CV Therapeutics, Inc., dated as of March 12, 2009
±+(3)	2.2	Agreement and Plan of Merger among Registrant, Cougar Merger Sub, Inc. and CGI Pharmaceuticals, Inc., dated as of June 23, 2010
≠+(4)	2.3	Agreement and Plan of Merger among Registrant, Arroyo Merger Sub, Inc. and Arresto Biosciences, Inc., dated as of December 19, 2010
+(5)	2.4	Agreement and Plan of Merger among Registrant, Gilead Biopharmaceutics Ireland Corporation, Gilead Sciences Limited, Calistoga Pharmaceuticals, Inc. and Shareholder Representative Services LLC, as Stockholders Agent, dated as of February 21, 2011
+(5)	2.5	Amendment No. 1 to the Agreement and Plan of Merger, entered into as of March 24, 2011
(6)	3.1	Restated Certificate of Incorporation of Registrant, as amended through May 12, 2011
(7)	3.2	Certificate of Designation of the Series A Junior Participating Preferred Stock of Registrant
(8)	3.3	Certificate of Amendment to Certificate of Designation of Series A Junior Participating Preferred Stock of Registrant
(6)	3.4	Amended and Restated Bylaws of Registrant, as amended and restated on May 12, 2011
	4.1	Reference is made to Exhibit 3.1, Exhibit 3.2, Exhibit 3.3 and Exhibit 3.4
(9)	4.2	Amended and Restated Rights Agreement between Registrant and ChaseMellon Shareholder Services, LLC, dated October 21, 1999
(10)	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
(11)	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
(12)	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
(12)	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
(13)	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
(13)	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

**Table of Contents**

<b>Exhibit</b>	<b>Exhibit</b>	<b>Description of Document</b>
<b>Footnote</b>	<b>Number</b>	
(14)	4.9	Indenture, dated as of March 30, 2011, between Registrant and Wells Fargo, National Association, as Trustee
(14)	4.10	First Supplemental Indenture, dated as of March 30, 2011, between Registrant and Wells Fargo, National Association, as Trustee
(14)	4.11	Form of Note (included in Exhibit 4.10 above)
(15)	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.
(15)	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.
(15)	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
(15)	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
(16)	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
(15)	10.6	Parent Guaranty Agreement, dated as of December 18, 2007, by Registrant
(4)	10.7	Amendment No. 1 to Amended and Restated Credit Agreement and Limited Consent and Waiver dated as of June 3, 2009, among Registrant, Gilead Biopharmaceutics Ireland Corporation and Bank of America, N.A. in its capacity as administrative agent for the Lenders
(4)	10.8	Amendment No. 2 to Amended and Restated Credit Agreement among Registrant, Gilead Biopharmaceutics Ireland Corporation and Bank of America, N.A. in its capacity as administrative agent for the Lenders, dated December 22, 2010
(3)	10.9	Confirmation of OTC Convertible Note Hedge related to 2014 Notes, dated July 26, 2010, between Registrant and Goldman, Sachs & Co.
(3)	10.10	Confirmation of OTC Convertible Note Hedge related to 2014 Notes, dated July 26, 2010, between Registrant and JPMorgan Chase Bank, National Association
(3)	10.11	Confirmation of OTC Convertible Note Hedge related to 2016 Notes, dated July 26, 2010, between Registrant and Goldman, Sachs & Co.
(3)	10.12	Confirmation of OTC Convertible Note Hedge related to 2016 Notes, dated July 26, 2010, between Registrant and JPMorgan Chase Bank, National Association
(3)	10.13	Confirmation of OTC Warrant Transaction, dated July 26, 2010, between Registrant and Goldman, Sachs & Co. for warrants expiring in 2014
(3)	10.14	Confirmation of OTC Warrant Transaction, dated July 26, 2010, between Registrant and JPMorgan Chase Bank, National Association for warrants expiring in 2014
(3)	10.15	Confirmation of OTC Warrant Transaction, dated July 26, 2010, between Registrant and Goldman, Sachs & Co. for warrants expiring in 2016
(3)	10.16	Confirmation of OTC Warrant Transaction, dated July 26, 2010, between Registrant and JPMorgan Chase Bank, National Association for warrants expiring in 2016

**Table of Contents**

<b>Exhibit</b>		
<b>Footnote</b>	<b>Exhibit Number</b>	<b>Description of Document</b>
(17)	10.17	Confirmation of OTC Additional Convertible Note Hedge related to 2014 Notes, dated August 5, 2010, between Registrant and Goldman, Sachs & Co.
(17)	10.18	Confirmation of OTC Additional Convertible Note Hedge related to 2014 Notes, dated August 5, 2010, between Registrant and JPMorgan Chase Bank, National Association
(17)	10.19	Confirmation of OTC Additional Convertible Note Hedge related to 2016 Notes, dated August 5, 2010, between Registrant and Goldman, Sachs & Co.
(17)	10.20	Confirmation of OTC Additional Convertible Note Hedge related to 2016 Notes, dated August 5, 2010, between Registrant and JPMorgan Chase Bank, National Association
(17)	10.21	Confirmation of OTC Additional Warrant Transaction, dated August 5, 2010, between Registrant and Goldman, Sachs & Co. for warrants expiring in 2014
(17)	10.22	Confirmation of OTC Additional Warrant Transaction, dated August 5, 2010, between Registrant and JPMorgan Chase Bank, National Association for warrants expiring in 2014
(17)	10.23	Confirmation of OTC Additional Warrant Transaction, dated August 5, 2010, between Registrant and Goldman, Sachs & Co. for warrants expiring in 2016
(17)	10.24	Confirmation of OTC Additional Warrant Transaction, dated August 5, 2010, between Registrant and JPMorgan Chase Bank, National Association for warrants expiring in 2016
(17)	10.25	Amendment to Confirmation of OTC Convertible Note Hedge related to 2014 Notes, dated August 30, 2010, between Registrant and Goldman, Sachs & Co.
(17)	10.26	Amendment to Confirmation of OTC Convertible Note Hedge related to 2014 Notes, dated August 30, 2010, between Registrant and JPMorgan Chase Bank, National Association
(17)	10.27	Amendment to Confirmation of OTC Convertible Note Hedge related to 2016 Notes, dated August 30, 2010, between Registrant and Goldman, Sachs & Co.
(17)	10.28	Amendment to Confirmation of OTC Convertible Note Hedge related to 2016 Notes, dated August 30, 2010, between Registrant and JPMorgan Chase Bank, National Association
(17)	10.29	Amendment to Confirmation of OTC Additional Convertible Note Hedge related to 2014 Notes, dated August 30, 2010, between Registrant and Goldman, Sachs & Co.
(17)	10.30	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
(17)	10.31	Amendment to Confirmation of OTC Additional Convertible Note Hedge related to 2016 Notes, dated August 30, 2010, between Registrant and Goldman, Sachs & Co.
(17)	10.32	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
*(18)	10.33	Gilead Sciences, Inc. 1991 Stock Option Plan, as amended through January 29, 2003
*(19)	10.34	Form of option agreements used under the 1991 Stock Option Plan
*(18)	10.35	Gilead Sciences, Inc. 1995 Non-Employee Directors Stock Option Plan, as amended through January 30, 2002
*(20)	10.36	Form of option agreement used under the Gilead Sciences, Inc. 1995 Non-Employee Directors Stock Option Plan

**Table of Contents**

<b>Exhibit</b>	<b>Exhibit</b>	<b>Description of Document</b>
<b>Footnote</b>	<b>Number</b>	
*(21)	10.37	Gilead Sciences, Inc. 2004 Equity Incentive Plan, as amended through May 6, 2009
*(22)	10.38	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants prior to February 2008)
*(23)	10.39	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants made February 2008 through April 2009)
*(24)	10.40	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants commencing in May 2009)
*(25)	10.41	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants commencing in February 2010)
*(5)	10.42	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for 2011 and subsequent year grants)
*(22)	10.43	Form of non-employee director stock option agreement used under 2004 Equity Incentive Plan (for grants prior to 2008)
*(23)	10.44	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for initial grants made in 2008)
*(23)	10.45	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for annual grants made in May 2008)
*(24)	10.46	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for annual grants commencing in May 2009)
*(24)	10.47	Form of restricted stock unit issuance agreement used under 2004 Equity Incentive Plan (for annual grants to non-employee directors commencing in May 2009)
*(24)	10.48	Form of restricted stock award agreement used under 2004 Equity Incentive Plan (for annual grants to certain non-employee directors)
*(26)	10.49	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for grants made in 2007)
*(27)	10.50	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for grants made in 2008)
*(24)	10.51	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for grants made in 2009)
*(25)	10.52	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for grants made in 2010)
*(5)	10.53	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for 2011 and subsequent year grants)
*(28)	10.54	Form of restricted stock unit issuance agreement used under the 2004 Equity Incentive Plan (for grants made prior to May 2009)
*(24)	10.55	Form of restricted stock unit issuance agreement used under the 2004 Equity Incentive Plan (for grants commencing in May 2009)
*(29)	10.56	Form of restricted stock unit issuance agreement used under the 2004 Equity Incentive Plan (service-based vesting for executive officers commencing in November 2009)

**Table of Contents**

<b>Exhibit</b>		
<b>Footnote</b>	<b>Exhibit Number</b>	<b>Description of Document</b>
*(5)	10.57	Form of restricted stock unit issuance agreement used under the 2004 Equity Incentive Plan (for 2011 and subsequent year grants)
*(25)	10.58	Gilead Sciences, Inc. Employee Stock Purchase Plan, amended and restated on November 3, 2009
*(30)	10.59	Gilead Sciences, Inc. International Employee Stock Purchase Plan, adopted November 3, 2009
*(31)	10.60	Gilead Sciences, Inc. Deferred Compensation Plan Basic Plan Document
*(31)	10.61	Gilead Sciences, Inc. Deferred Compensation Plan Adoption Agreement
*(31)	10.62	Addendum to the Gilead Sciences, Inc. Deferred Compensation Plan
*(32)	10.63	Gilead Sciences, Inc. 2005 Deferred Compensation Plan, as amended and restated on October 23, 2008
*(25)	10.64	Gilead Sciences, Inc. Severance Plan, as amended on December 14, 2009
*(22)	10.65	Gilead Sciences, Inc. Corporate Bonus Plan
*(6)	10.66	Amended and Restated Gilead Sciences, Inc. Code Section 162(m) Bonus Plan
*(33)	10.67	2011 Base Salaries for the Named Executive Officers
*(34)	10.68	Offer Letter dated April 16, 2008 between Registrant and Robin Washington
*(19)	10.69	Form of Indemnity Agreement entered into between Registrant and its directors and executive officers
*(19)	10.70	Form of Employee Proprietary Information and Invention Agreement entered into between Registrant and certain of its officers and key employees
*(25)	10.71	Form of Employee Proprietary Information and Invention Agreement entered into between Registrant and certain of its officers and key employees (revised in September 2006)
+(35)	10.72	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
+(23)	10.73	Commercialization Agreement by and between Gilead Sciences Limited and Bristol-Myers Squibb Company, dated December 10, 2007
+(36)	10.74	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)
(37)	10.75	Amendment Agreement between Registrant and IOCB/REGA, dated December 27, 2000 amending the 1991 License Agreement and the December 1992 License Agreement
(35)	10.76	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
+(35)	10.77	Development and License Agreement among Registrant and F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc., dated September 27, 1996

**Table of Contents**

<b>Footnote</b>	<b>Exhibit Number</b>	<b>Description of Document</b>
+(38)	10.78	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
+(39)	10.79	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
+(40)	10.80	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
+(40)	10.81	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.
+(41)	10.82	License Agreement between Japan Tobacco Inc. and Registrant, dated March 22, 2005
+(42)	10.83	License Agreement between Registrant (as successor to Myogen, Inc.) and Abbott Deutschland Holding GmbH dated October 8, 2001
+(42)	10.84	License Agreement between Registrant (as successor to CV Therapeutics, Inc.) and Syntex (U.S.A.) Inc., dated March 27, 1996
+(43)	10.85	First Amendment to License Agreement between Registrant (as successor to CV Therapeutics, Inc.) and Syntex (U.S.A.) Inc., dated July 3, 1997
(43)	10.86	Amendment No. 2 to License Agreement between Registrant (as successor to CV Therapeutics, Inc.) and Syntex (U.S.A.) Inc., dated November 30, 1999
+(44)	10.87	Amendment No. 4 to Collaboration and License Agreement with Registrant (as successor to CV Therapeutics, Inc.) and Roche Palo Alto LLC (successor in interest by merger to Syntex (U.S.A.) Inc.), dated June 20, 2006
+(45)	10.88	License and Collaboration Agreement by and among Registrant, Gilead Sciences Limited and Tibotec Pharmaceuticals, dated July 16, 2009
+(46)	10.89	Master Clinical and Commercial Supply Agreement between Gilead World Markets, Limited, Registrant and Patheon Inc., dated January 1, 2003
+(40)	10.90	Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Gilead Sciences Limited and PharmaChem Technologies (Grand Bahama), Ltd., dated July 17, 2003
+(47)	10.91	Addendum to Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Gilead Sciences Limited and PharmaChem Technologies (Grand Bahama) Ltd., dated May 10, 2007
+(32)	10.92	Addendum to Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Gilead Sciences Limited and PharmaChem Technologies (Grand Bahama) Ltd., dated December 5, 2008
+(5)	10.93	Addendum to Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Gilead Sciences Limited and PharmaChem Technologies (Grand Bahama) Ltd., dated February 3, 2011
+(4)	10.94	Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Gilead Sciences Limited and Ampac Fine Chemicals LLC, dated November 3, 2010
+(38)	10.95	Restated and Amended Toll Manufacturing Agreement between Gilead Sciences Limited, Registrant and Nycomed GmbH (formerly ALTANA Pharma Oranienburg GmbH), dated November 7, 2005
+(15)	10.96	Emtricitabine Manufacturing Supply Agreement between Gilead Sciences Limited and Degussa AG, dated June 6, 2006

**Table of Contents**

<b>Exhibit</b>		
<b>Footnote</b>	<b>Exhibit Number</b>	<b>Description of Document</b>
+(3)	10.97	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
(32)	10.98	Purchase and Sale Agreement and Escrow Instructions between Electronics for Imaging, Inc. and Registrant, dated October 23, 2008
	31.1	Certification of Chief Executive Officer, as required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended
	31.2	Certification of Chief Financial Officer, as required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended
	32.1**	Certifications of Chief Executive Officer and Chief Financial Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350)
	101***	The following materials from Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2011, formatted in Extensible Business Reporting Language (XBRL) includes: (i) Condensed Consolidated Balance Sheets at June 30, 2011 and December 31, 2010, (ii) Condensed Consolidated Statements of Income for the Three and Six Months Ended June 30, 2011 and 2010, (iii) Condensed Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2011 and 2010, 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 28, 2011, and incorporated herein by reference.
(2)	Filed as an exhibit to Registrant's	Current Report on Form 8-K filed on March 12, 2009, and incorporated herein by reference.
(3)	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.
(4)	Filed as an exhibit to Registrant's	Annual Report on Form 10-K for the fiscal year ended December 31, 2010, and incorporated herein by reference.
(5)	Filed as an exhibit to Registrant's	Quarterly Report on Form 10-Q for the quarter ended March 31, 2011, and incorporated herein by reference.
(6)	Filed as an exhibit to Registrant's	Current Report on Form 8-K filed on May 17, 2011, and incorporated herein by reference.
(7)	Filed as an exhibit to Registrant's	Current Report on Form 8-K filed on November 22, 1994, and incorporated herein by reference.
(8)	Filed as an exhibit to Registrant's	Current Report on Form 8-K filed on May 11, 2006, and incorporated herein by reference.
(9)	Filed as an exhibit to Registrant's	Current Report on Form 8-K filed on October 22, 1999, and incorporated herein by reference.
(10)	Filed as an exhibit to Registrant's	Current Report on Form 8-K filed on October 31, 2003, and incorporated herein by reference.
(11)	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.
(12)	Filed as an exhibit to Registrant's	Current Report on Form 8-K filed on April 25, 2006, and incorporated herein by reference.
(13)	Filed as an exhibit to Registrant's	Current Report on Form 8-K filed on August 2, 2010, and incorporated herein by reference.
(14)	Filed as an exhibit to Registrant's	Current Report on Form 8-K filed on April 1, 2011, and incorporated herein by reference.
(15)	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.
(16)	Filed as an exhibit to Registrant's	Current Report on Form 8-K also filed on December 19, 2007, and incorporated herein by reference.

**Table of Contents**

- (17) Filed as an exhibit to Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2010, and incorporated herein by reference.
- (18) 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.
- (19) Filed as an exhibit to Registrant s Registration Statement on Form S-1 (No. 33-55680), as amended, and incorporated herein by reference.
- (20) 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.
- (21) Filed as an exhibit to Registrant s Current Report on Form 8-K filed on May 11, 2009, and incorporated herein by reference.
- (22) Filed as an exhibit to Registrant s Current Report on Form 8-K/A filed on February 22, 2006, and incorporated herein by reference.
- (23) 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.
- (24) 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.
- (25) 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.
- (26) 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.
- (27) 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.
- (28) Filed as an exhibit to Registrant s Current Report on Form 8-K first filed on December 19, 2007, and incorporated herein by reference.
- (29) 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.
- (30) 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.
- (31) 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.
- (32) 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.
- (33) Information is included in Registrant s Current Report on Form 8-K filed on January 25, 2011, and incorporated herein by reference.
- (34) 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.
- (35) 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.
- (36) 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.
- (37) 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.
- (38) 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.
- (39) 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.
- (40) 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.
- (41) 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.
- (42) 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.
- (43) 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.
- (44) 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.
- (45) 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.
- (46) 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.

**Table of Contents**

(47) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on August 7, 2007, 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.
- <sup>1</sup> The Agreement and Plan of Merger (the Merger Agreement) contains representations and warranties of Registrant, Arroyo Merger Sub, Inc. and Arresto Biosciences, 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, Arroyo Merger Sub, Inc. and Arresto Biosciences, 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, Arroyo Merger Sub, Inc. and Arresto Biosciences, Inc. rather than establishing matters as facts.  
 The Agreement and Plan of Merger (the Merger Agreement) contains representations and warranties of Registrant, Gilead Biopharmaceutics Ireland Corporation, Gilead Sciences Limited and Calistoga 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, Gilead Biopharmaceutics Ireland Corporation, Gilead Sciences Limited and Calistoga 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, Gilead Biopharmaceutics Ireland Corporation, Gilead Sciences Limited and Calistoga 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: August 5, 2011

/s/ JOHN C. MARTIN

**John C. Martin, Ph.D.**

**Chairman and Chief Executive Officer**

**(Principal Executive Officer)**

Date: August 5, 2011

/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</b>	<b>Exhibit Number</b>	<b>Description of Document</b>
(1)	1.1	Underwriting Agreement, dated March 23, 2011, among Registrant and J.P. Morgan Securities LLC, Merrill Lynch, Pierce, Fenner & Smith Incorporated and Morgan Stanley & Co. Incorporated, as representatives of the several underwriters name in Schedule 1 thereto.
(2)	2.1	Agreement and Plan of Merger among Registrant, Apex Merger Sub, Inc. and CV Therapeutics, Inc., dated as of March 12, 2009
±+(3)	2.2	Agreement and Plan of Merger among Registrant, Cougar Merger Sub, Inc. and CGI Pharmaceuticals, Inc., dated as of June 23, 2010
≠+(4)	2.3	Agreement and Plan of Merger among Registrant, Arroyo Merger Sub, Inc. and Arresto Biosciences, Inc., dated as of December 19, 2010
+	2.4	Agreement and Plan of Merger among Registrant, Gilead Biopharmaceutics Ireland Corporation, Gilead Sciences Limited, Calistoga Pharmaceuticals, Inc. and Shareholder Representative Services LLC, as Stockholders Agent, dated as of February 21, 2011
+	2.5	Amendment No. 1 to the Agreement and Plan of Merger, entered into as of March 24, 2011
(5)	3.1	Restated Certificate of Incorporation of Registrant, as amended through May 8, 2008
(6)	3.2	Certificate of Designation of the Series A Junior Participating Preferred Stock of Registrant
(7)	3.3	Certificate of Amendment to Certificate of Designation of Series A Junior Participating Preferred Stock of Registrant
(8)	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
(9)	4.2	Amended and Restated Rights Agreement between Registrant and ChaseMellon Shareholder Services, LLC, dated October 21, 1999
(10)	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
(11)	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
(12)	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
(12)	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
(13)	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

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

<b>Footnote</b>	<b>Exhibit Number</b>	<b>Description of Document</b>
(13)	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
(14)	4.9	Indenture, dated as of March 30, 2011, between Registrant and Wells Fargo, National Association, as Trustee
(14)	4.10	First Supplemental Indenture, dated as of March 30, 2011, between Registrant and Wells Fargo, National Association, as Trustee
(14)	4.11	Form of Note (included in Exhibit 4.10 above)
(15)	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.
(15)	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.
(15)	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
(15)	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
(16)	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
(15)	10.6	Parent Guaranty Agreement, dated as of December 18, 2007, by Registrant
(4)	10.7	Amendment No. 1 to Amended and Restated Credit Agreement and Limited Consent and Waiver dated as of June 3, 2009, among Registrant, Gilead Biopharmaceutics Ireland Corporation and Bank of America, N.A. in its capacity as administrative agent for the Lenders
(4)	10.8	Amendment No. 2 to Amended and Restated Credit Agreement among Registrant, Gilead Biopharmaceutics Ireland Corporation and Bank of America, N.A. in its capacity as administrative agent for the Lenders, dated December 22, 2010
(3)	10.9	Confirmation of OTC Convertible Note Hedge related to 2014 Notes, dated July 26, 2010, between Registrant and Goldman, Sachs & Co.
(3)	10.10	Confirmation of OTC Convertible Note Hedge related to 2014 Notes, dated July 26, 2010, between Registrant and JPMorgan Chase Bank, National Association
(3)	10.11	Confirmation of OTC Convertible Note Hedge related to 2016 Notes, dated July 26, 2010, between Registrant and Goldman, Sachs & Co.
(3)	10.12	Confirmation of OTC Convertible Note Hedge related to 2016 Notes, dated July 26, 2010, between Registrant and JPMorgan Chase Bank, National Association

**Table of Contents**

<b>Exhibit</b>		
<b>Footnote</b>	<b>Exhibit Number</b>	<b>Description of Document</b>
(3)	10.13	Confirmation of OTC Warrant Transaction, dated July 26, 2010, between Registrant and Goldman, Sachs & Co. for warrants expiring in 2014
(3)	10.14	Confirmation of OTC Warrant Transaction, dated July 26, 2010, between Registrant and JPMorgan Chase Bank, National Association for warrants expiring in 2014
(3)	10.15	Confirmation of OTC Warrant Transaction, dated July 26, 2010, between Registrant and Goldman, Sachs & Co. for warrants expiring in 2016
(3)	10.16	Confirmation of OTC Warrant Transaction, dated July 26, 2010, between Registrant and JPMorgan Chase Bank, National Association for warrants expiring in 2016
(17)	10.17	Confirmation of OTC Additional Convertible Note Hedge related to 2014 Notes, dated August 5, 2010, between Registrant and Goldman, Sachs & Co.
(17)	10.18	Confirmation of OTC Additional Convertible Note Hedge related to 2014 Notes, dated August 5, 2010, between Registrant and JPMorgan Chase Bank, National Association
(17)	10.19	Confirmation of OTC Additional Convertible Note Hedge related to 2016 Notes, dated August 5, 2010, between Registrant and Goldman, Sachs & Co.
(17)	10.20	Confirmation of OTC Additional Convertible Note Hedge related to 2016 Notes, dated August 5, 2010, between Registrant and JPMorgan Chase Bank, National Association
(17)	10.21	Confirmation of OTC Additional Warrant Transaction, dated August 5, 2010, between Registrant and Goldman, Sachs & Co. for warrants expiring in 2014
(17)	10.22	Confirmation of OTC Additional Warrant Transaction, dated August 5, 2010, between Registrant and JPMorgan Chase Bank, National Association for warrants expiring in 2014
(17)	10.23	Confirmation of OTC Additional Warrant Transaction, dated August 5, 2010, between Registrant and Goldman, Sachs & Co. for warrants expiring in 2016
(17)	10.24	Confirmation of OTC Additional Warrant Transaction, dated August 5, 2010, between Registrant and JPMorgan Chase Bank, National Association for warrants expiring in 2016
(17)	10.25	Amendment to Confirmation of OTC Convertible Note Hedge related to 2014 Notes, dated August 30, 2010, between Registrant and Goldman, Sachs & Co.
(17)	10.26	Amendment to Confirmation of OTC Convertible Note Hedge related to 2014 Notes, dated August 30, 2010, between Registrant and JPMorgan Chase Bank, National Association
(17)	10.27	Amendment to Confirmation of OTC Convertible Note Hedge related to 2016 Notes, dated August 30, 2010, between Registrant and Goldman, Sachs & Co.
(17)	10.28	Amendment to Confirmation of OTC Convertible Note Hedge related to 2016 Notes, dated August 30, 2010, between Registrant and JPMorgan Chase Bank, National Association
(17)	10.29	Amendment to Confirmation of OTC Additional Convertible Note Hedge related to 2014 Notes, dated August 30, 2010, between Registrant and Goldman, Sachs & Co.
(17)	10.30	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

**Table of Contents**

<b>Exhibit</b>	<b>Exhibit</b>	<b>Description of Document</b>
<b>Footnote</b>	<b>Number</b>	
(17)	10.31	Amendment to Confirmation of OTC Additional Convertible Note Hedge related to 2016 Notes, dated August 30, 2010, between Registrant and Goldman, Sachs & Co.
(17)	10.32	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
*(18)	10.33	Gilead Sciences, Inc. 1991 Stock Option Plan, as amended through January 29, 2003
*(19)	10.34	Form of option agreements used under the 1991 Stock Option Plan
*(18)	10.35	Gilead Sciences, Inc. 1995 Non-Employee Directors Stock Option Plan, as amended through January 30, 2002
*(20)	10.36	Form of option agreement used under the Gilead Sciences, Inc. 1995 Non-Employee Directors Stock Option Plan
*(21)	10.37	Gilead Sciences, Inc. 2004 Equity Incentive Plan, as amended through May 6, 2009
*(22)	10.38	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants prior to February 2008)
*(23)	10.39	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants made February 2008 through April 2009)
*(24)	10.40	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants commencing in May 2009)
*(25)	10.41	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants commencing in February 2010)
*	10.42	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for 2011 and subsequent year grants)
*(22)	10.43	Form of non-employee director stock option agreement used under 2004 Equity Incentive Plan (for grants prior to 2008)
*(23)	10.44	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for initial grants made in 2008)
*(23)	10.45	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for annual grants made in May 2008)
*(24)	10.46	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for annual grants commencing in May 2009)
*(24)	10.47	Form of restricted stock unit issuance agreement used under 2004 Equity Incentive Plan (for annual grants to non-employee directors commencing in May 2009)
*(24)	10.48	Form of restricted stock award agreement used under 2004 Equity Incentive Plan (for annual grants to certain non-employee directors)
*(26)	10.49	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for grants made in 2007)

**Table of Contents**

<b>Exhibit</b>		
<b>Footnote</b>	<b>Exhibit Number</b>	<b>Description of Document</b>
*(27)	10.50	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for grants made in 2008)
*(24)	10.51	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for grants made in 2009)
*(25)	10.52	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for grants made in 2010)
*	10.53	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for 2011 and subsequent year grants)
*(28)	10.54	Form of restricted stock unit issuance agreement used under the 2004 Equity Incentive Plan (for grants made prior to May 2009)
*(24)	10.55	Form of restricted stock unit issuance agreement used under the 2004 Equity Incentive Plan (for grants commencing in May 2009)
*(29)	10.56	Form of restricted stock unit issuance agreement used under the 2004 Equity Incentive Plan (service-based vesting for executive officers commencing in November 2009)
*	10.57	Form of restricted stock unit issuance agreement used under the 2004 Equity Incentive Plan (for 2011 and subsequent year grants)
*(25)	10.58	Gilead Sciences, Inc. Employee Stock Purchase Plan, amended and restated on November 3, 2009
*(30)	10.59	Gilead Sciences, Inc. International Employee Stock Purchase Plan, adopted November 3, 2009
*(31)	10.60	Gilead Sciences, Inc. Deferred Compensation Plan Basic Plan Document
*(31)	10.61	Gilead Sciences, Inc. Deferred Compensation Plan Adoption Agreement
*(31)	10.62	Addendum to the Gilead Sciences, Inc. Deferred Compensation Plan
*(32)	10.63	Gilead Sciences, Inc. 2005 Deferred Compensation Plan, as amended and restated on October 23, 2008
*(25)	10.64	Gilead Sciences, Inc. Severance Plan, as amended on December 14, 2009
*(22)	10.65	Gilead Sciences, Inc. Corporate Bonus Plan
*(22)	10.66	Gilead Sciences, Inc. Code Section 162(m) Bonus Plan
*(33)	10.67	2011 Base Salaries for the Named Executive Officers
*(34)	10.68	Offer Letter dated April 16, 2008 between Registrant and Robin Washington
*(19)	10.69	Form of Indemnity Agreement entered into between Registrant and its directors and executive officers
*(19)	10.70	Form of Employee Proprietary Information and Invention Agreement entered into between Registrant and certain of its officers and key employees

**Table of Contents**

<b>Exhibit</b>	<b>Exhibit</b>	<b>Description of Document</b>
<b>Footnote</b>	<b>Number</b>	
*(25)	10.71	Form of Employee Proprietary Information and Invention Agreement entered into between Registrant and certain of its officers and key employees (revised in September 2006)
+(35)	10.72	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
+(23)	10.73	Commercialization Agreement by and between Gilead Sciences Limited and Bristol-Myers Squibb Company, dated December 10, 2007
+(36)	10.74	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)
(37)	10.75	Amendment Agreement between Registrant and IOCB/REGA, dated December 27, 2000 amending the 1991 License Agreement and the December 1992 License Agreement
(35)	10.76	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
+(35)	10.77	Development and License Agreement among Registrant and F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc., dated September 27, 1996
+(38)	10.78	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
+(39)	10.79	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
+(40)	10.80	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
+(40)	10.81	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.
+(41)	10.82	License Agreement between Japan Tobacco Inc. and Registrant, dated March 22, 2005
+(42)	10.83	License Agreement between Registrant (as successor to Myogen, Inc.) and Abbott Deutschland Holding GmbH dated October 8, 2001
+(42)	10.84	License Agreement between Registrant (as successor to CV Therapeutics, Inc.) and Syntex (U.S.A.) Inc., dated March 27, 1996
+(43)	10.85	First Amendment to License Agreement between Registrant (as successor to CV Therapeutics, Inc.) and Syntex (U.S.A.) Inc., dated July 3, 1997

**Table of Contents**

<b>Exhibit</b>	<b>Exhibit</b>	<b>Description of Document</b>
<b>Footnote</b>	<b>Number</b>	
(43)	10.86	Amendment No. 2 to License Agreement between Registrant (as successor to CV Therapeutics, Inc.) and Syntex (U.S.A.) Inc., dated November 30, 1999
+(44)	10.87	Amendment No. 4 to Collaboration and License Agreement with Registrant (as successor to CV Therapeutics, Inc.) and Roche Palo Alto LLC (successor in interest by merger to Syntex (U.S.A.) Inc.), dated June 20, 2006
+(45)	10.88	License and Collaboration Agreement by and among Registrant, Gilead Sciences Limited and Tibotec Pharmaceuticals, dated July 16, 2009
+(46)	10.89	Master Clinical and Commercial Supply Agreement between Gilead World Markets, Limited, Registrant and Patheon Inc., dated January 1, 2003
+(40)	10.90	Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Gilead Sciences Limited and PharmaChem Technologies (Grand Bahama), Ltd., dated July 17, 2003
+(47)	10.91	Addendum to Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Gilead Sciences Limited and PharmaChem Technologies (Grand Bahama) Ltd., dated May 10, 2007
+(32)	10.92	Addendum to Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Gilead Sciences Limited and PharmaChem Technologies (Grand Bahama) Ltd., dated December 5, 2008
+	10.93	Addendum to Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Gilead Sciences Limited and PharmaChem Technologies (Grand Bahama) Ltd., dated February 3, 2011
+(4)	10.94	Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Gilead Sciences Limited and Ampac Fine Chemicals LLC, dated November 3, 2010
+(38)	10.95	Restated and Amended Toll Manufacturing Agreement between Gilead Sciences Limited, Registrant and Nycomed GmbH (formerly ALTANA Pharma Oranienburg GmbH), dated November 7, 2005
+(15)	10.96	Emtricitabine Manufacturing Supply Agreement between Gilead Sciences Limited and Degussa AG, dated June 6, 2006
+(3)	10.97	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
(32)	10.98	Purchase and Sale Agreement and Escrow Instructions between Electronics for Imaging, Inc. and Registrant, dated October 23, 2008
	31.1	Certification of Chief Executive Officer, as required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended
	31.2	Certification of Chief Financial Officer, as required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended
	32.1**	Certifications of Chief Executive Officer and Chief Financial Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350)

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

<b>Footnote</b>	<b>Exhibit Number</b>	<b>Description of Document</b>
	101***	The following materials from Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2011, formatted in Extensible Business Reporting Language (XBRL) includes: (i) Condensed Consolidated Balance Sheets at June 30, 2011 and December 31, 2010, (ii) Condensed Consolidated Statements of Income for the Three and Six Months Ended June 30, 2011 and 2010, (iii) Condensed Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2011 and 2010, 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 28, 2011, and incorporated herein by reference.
(2)		Filed as an exhibit to Registrant's Current Report on Form 8-K filed on March 12, 2009, and incorporated herein by reference.
(3)		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.
(4)		Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2010, and incorporated herein by reference.
(5)		Filed as an exhibit to Registrant's Current Report on Form 8-K filed on May 9, 2008, and incorporated herein by reference.
(6)		Filed as an exhibit to Registrant's Current Report on Form 8-K filed on November 22, 1994, and incorporated herein by reference.
(7)		Filed as an exhibit to Registrant's Current Report on Form 8-K filed on May 11, 2006, and incorporated herein by reference.
(8)		Filed as an exhibit to Registrant's Current Report on Form 8-K filed on October 28, 2008, and incorporated herein by reference.
(9)		Filed as an exhibit to Registrant's Current Report on Form 8-K filed on October 22, 1999, and incorporated herein by reference.
(10)		Filed as an exhibit to Registrant's Current Report on Form 8-K filed on October 31, 2003, and incorporated herein by reference.
(11)		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.
(12)		Filed as an exhibit to Registrant's Current Report on Form 8-K filed on April 25, 2006, and incorporated herein by reference.
(13)		Filed as an exhibit to Registrant's Current Report on Form 8-K filed on August 2, 2010, and incorporated herein by reference.
(14)		Filed as an exhibit to Registrant's Current Report on Form 8-K filed on April 1, 2011, and incorporated herein by reference.
(15)		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.
(16)		Filed as an exhibit to Registrant's Current Report on Form 8-K also filed on December 19, 2007, and incorporated herein by reference.
(17)		Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2010, and incorporated herein by reference.
(18)		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.
(19)		Filed as an exhibit to Registrant's Registration Statement on Form S-1 (No. 33-55680), as amended, and incorporated herein by reference.
(20)		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.
(21)		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**

- (22) Filed as an exhibit to Registrant s Current Report on Form 8-K/A filed on February 22, 2006, and incorporated herein by reference.
- (23) 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.
- (24) 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.
- (25) 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.
- (26) 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.
- (27) 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.
- (28) Filed as an exhibit to Registrant s Current Report on Form 8-K first filed on December 19, 2007, and incorporated herein by reference.
- (29) 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.
- (30) 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.
- (31) 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.
- (32) 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.
- (33) Information is included in Registrant s Current Report on Form 8-K filed on January 25, 2011, and incorporated herein by reference.
- (34) 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.
- (35) 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.
- (36) 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.
- (37) 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.
- (38) 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.
- (39) 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.
- (40) 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.
- (41) 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.
- (42) 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.
- (43) 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.
- (44) 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.
- (45) 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.
- (46) 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.

**Table of Contents**

(47) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on August 7, 2007, and incorporated herein by reference.

- ± The Agreement and Plan of Merger (the CGI 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 CGI 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 CGI 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.
- ≠ The Agreement and Plan of Merger (the Arresto Merger Agreement) contains representations and warranties of Registrant, Arroyo Merger Sub, Inc. and Arresto Biosciences, Inc. made solely to each other as of specific dates. Those representations and warranties were made solely for purposes of the Arresto Merger Agreement and may be subject to important qualifications and limitations agreed to by Registrant, Arroyo Merger Sub, Inc. and Arresto Biosciences, 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 Arresto Merger Agreement and have been used for the purpose of allocating risk among Registrant, Arroyo Merger Sub, Inc. and Arresto Biosciences, Inc. rather than establishing matters as facts.  
 The Agreement and Plan of Merger (the Calistoga Merger Agreement) contains representations and warranties of Registrant, Gilead Biopharmaceutics Ireland Corporation, Gilead Sciences Limited and Calistoga Pharmaceuticals, Inc. made solely to each other as of specific dates. Those representations and warranties were made solely for purposes of the Calistoga Merger Agreement and may be subject to important qualifications and limitations agreed to by Registrant, Gilead Biopharmaceutics Ireland Corporation, Gilead Sciences Limited and Calistoga 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 Calistoga Merger Agreement and have been used for the purpose of allocating risk among Registrant, Gilead Biopharmaceutics Ireland Corporation, Gilead Sciences Limited and Calistoga 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.