

GILEAD SCIENCES INC  
Form 10-Q  
October 31, 2008  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**WASHINGTON, D.C. 20549**

**FORM 10-Q**

**x      QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE  
         ACT OF 1934**

**For the quarterly period ended September 30, 2008**

**or**

**“      TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE  
         ACT OF 1934**

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_**

**Commission File Number: 0-19731**

**GILEAD SCIENCES, INC.**

**(Exact Name of Registrant as Specified in Its Charter)**

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**Delaware**  
(State or Other Jurisdiction of

**94-3047598**  
(IRS Employer

**Incorporation or Organization)**

**Identification No.)**

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

**94404**  
(Zip Code)

**650-574-3000**

(Registrant's Telephone Number, Including Area Code)

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

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

Large accelerated filer ☒ Accelerated filer ☐

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

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

Number of shares outstanding of the issuer's common stock, par value \$0.001 per share, as of October 27, 2008: 910,509,730

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

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

(in thousands, except per share amounts)

|                                                                                                                                                                                     | <b>September 30,<br/>2008<br/>(unaudited)</b> | <b>December 31,<br/>2007<br/>(1)</b> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|--------------------------------------|
| <b>Assets</b>                                                                                                                                                                       |                                               |                                      |
| Current assets:                                                                                                                                                                     |                                               |                                      |
| Cash and cash equivalents                                                                                                                                                           | \$ 1,209,424                                  | \$ 968,086                           |
| Short-term marketable securities                                                                                                                                                    | 709,870                                       | 203,892                              |
| Accounts receivable, net                                                                                                                                                            | 1,047,205                                     | 795,127                              |
| Inventories                                                                                                                                                                         | 897,623                                       | 599,966                              |
| Deferred tax assets                                                                                                                                                                 | 100,772                                       | 152,533                              |
| Prepaid taxes                                                                                                                                                                       | 220,998                                       | 216,909                              |
| Other current assets                                                                                                                                                                | 140,791                                       | 91,779                               |
| Total current assets                                                                                                                                                                | 4,326,683                                     | 3,028,292                            |
| Property, plant and equipment, net                                                                                                                                                  | 512,281                                       | 447,696                              |
| Noncurrent portion of prepaid royalties                                                                                                                                             | 267,994                                       | 290,742                              |
| Noncurrent deferred tax assets                                                                                                                                                      | 315,065                                       | 297,359                              |
| Long-term marketable securities                                                                                                                                                     | 1,336,968                                     | 1,550,444                            |
| Other noncurrent assets                                                                                                                                                             | 215,137                                       | 220,183                              |
| Total assets                                                                                                                                                                        | \$ 6,974,128                                  | \$ 5,834,716                         |
| <b>Liabilities and Stockholders' Equity</b>                                                                                                                                         |                                               |                                      |
| Current liabilities:                                                                                                                                                                |                                               |                                      |
| Accounts payable                                                                                                                                                                    | \$ 631,525                                    | \$ 290,333                           |
| Accrued government rebates                                                                                                                                                          | 152,258                                       | 115,495                              |
| Accrued compensation and employee benefits                                                                                                                                          | 102,974                                       | 90,553                               |
| Income taxes payable                                                                                                                                                                | 90,042                                        |                                      |
| Other accrued liabilities                                                                                                                                                           | 236,075                                       | 208,861                              |
| Deferred revenues                                                                                                                                                                   | 40,205                                        | 30,747                               |
| Current portion of other long-term obligations                                                                                                                                      | 6,055                                         | 286                                  |
| Total current liabilities                                                                                                                                                           | 1,259,134                                     | 736,275                              |
| Long-term deferred revenues                                                                                                                                                         | 56,153                                        | 61,316                               |
| Convertible senior notes                                                                                                                                                            | 1,299,854                                     | 1,300,000                            |
| Long-term income taxes payable                                                                                                                                                      | 44,074                                        | 125,232                              |
| Other long-term obligations                                                                                                                                                         | 21,367                                        | 11,604                               |
| Minority interest                                                                                                                                                                   | 127,636                                       | 140,299                              |
| Commitments and contingencies (Note 5)                                                                                                                                              |                                               |                                      |
| Stockholders' equity:                                                                                                                                                               |                                               |                                      |
| Preferred stock, par value \$0.001 per share; 5,000 shares authorized; none outstanding                                                                                             |                                               |                                      |
| Common stock, par value \$0.001 per share; 2,800,000 shares authorized; 920,744 and 932,484 shares issued and outstanding at September 30, 2008 and December 31, 2007, respectively | 921                                           | 932                                  |
| Additional paid-in capital                                                                                                                                                          | 3,616,798                                     | 3,214,341                            |

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|                                                |                  |                  |
|------------------------------------------------|------------------|------------------|
| Accumulated other comprehensive income (loss)  | 17,190           | (4,363)          |
| Retained earnings                              | 531,001          | 249,080          |
| <b>Total stockholders' equity</b>              | <b>4,165,910</b> | <b>3,459,990</b> |
| <br>Total liabilities and stockholders' equity | <br>\$ 6,974,128 | <br>\$ 5,834,716 |

- (1) The condensed consolidated balance sheet at December 31, 2007 has been derived from audited consolidated financial statements at that date, but does not include all of the information and footnotes required by U.S. generally accepted accounting principles for complete financial statements.

See accompanying notes.

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

(unaudited)

(in thousands, except per share amounts)

|                                               | <b>Three Months Ended<br/>September 30,</b> |                   | <b>Nine Months Ended<br/>September 30,</b> |                     |
|-----------------------------------------------|---------------------------------------------|-------------------|--------------------------------------------|---------------------|
|                                               | <b>2008</b>                                 | <b>2007</b>       | <b>2008</b>                                | <b>2007</b>         |
| Revenues:                                     |                                             |                   |                                            |                     |
| Product sales                                 | \$ 1,338,502                                | \$ 961,931        | \$ 3,697,024                               | \$ 2,707,214        |
| Royalty revenues                              | 25,161                                      | 91,003            | 185,221                                    | 407,212             |
| Contract and other revenues                   | 7,605                                       | 5,869             | 25,300                                     | 20,896              |
| <b>Total revenues</b>                         | <b>1,371,268</b>                            | <b>1,058,803</b>  | <b>3,907,545</b>                           | <b>3,135,322</b>    |
| Costs and expenses:                           |                                             |                   |                                            |                     |
| Cost of goods sold                            | 300,183                                     | 198,460           | 805,715                                    | 553,229             |
| Research and development                      | 188,062                                     | 140,357           | 519,905                                    | 406,378             |
| Selling, general and administrative           | 189,189                                     | 172,956           | 603,679                                    | 525,693             |
| Purchased in-process research and development |                                             |                   | 10,851                                     |                     |
| <b>Total costs and expenses</b>               | <b>677,434</b>                              | <b>511,773</b>    | <b>1,940,150</b>                           | <b>1,485,300</b>    |
| Income from operations                        | 693,834                                     | 547,030           | 1,967,395                                  | 1,650,022           |
| Interest and other income, net                | 3,637                                       | 29,502            | 40,363                                     | 80,295              |
| Interest expense                              | (2,951)                                     | (2,989)           | (9,230)                                    | (10,243)            |
| Minority interest                             | 2,160                                       | 2,478             | 6,195                                      | 7,032               |
| Income before provision for income taxes      | 696,680                                     | 576,021           | 2,004,723                                  | 1,727,106           |
| Provision for income taxes                    | 192,675                                     | 177,702           | 561,763                                    | 513,450             |
| <b>Net income</b>                             | <b>\$ 504,005</b>                           | <b>\$ 398,319</b> | <b>\$ 1,442,960</b>                        | <b>\$ 1,213,656</b> |
| <b>Net income per share basic</b>             | <b>\$ 0.55</b>                              | <b>\$ 0.43</b>    | <b>\$ 1.56</b>                             | <b>\$ 1.31</b>      |
| Shares used in per share calculation basic    | 920,807                                     | 926,963           | 923,894                                    | 928,519             |
| <b>Net income per share diluted</b>           | <b>\$ 0.52</b>                              | <b>\$ 0.42</b>    | <b>\$ 1.50</b>                             | <b>\$ 1.26</b>      |
| Shares used in per share calculation diluted  | 960,585                                     | 959,043           | 964,267                                    | 962,804             |

See accompanying notes.

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

(unaudited)

(in thousands)

|                                                                                   | <b>Nine Months Ended<br/>September 30,</b> |                    |
|-----------------------------------------------------------------------------------|--------------------------------------------|--------------------|
|                                                                                   | <b>2008</b>                                | <b>2007</b>        |
| <b>Operating Activities:</b>                                                      |                                            |                    |
| Net income                                                                        | \$ 1,442,960                               | \$ 1,213,656       |
| Adjustments to reconcile net income to net cash provided by operating activities: |                                            |                    |
| Depreciation                                                                      | 37,548                                     | 26,249             |
| Amortization                                                                      | 38,088                                     | 15,565             |
| Purchased in-process research and development expense                             | 10,851                                     |                    |
| Stock-based compensation expense                                                  | 114,605                                    | 151,162            |
| Excess tax benefits from stock-based compensation                                 | (155,723)                                  | (85,279)           |
| Tax benefits from employee stock plans                                            | 169,328                                    | 100,233            |
| Deferred income taxes                                                             | 34,055                                     | 93,589             |
| Other non-cash transactions                                                       | 3,717                                      | (27,958)           |
| Changes in operating assets and liabilities:                                      |                                            |                    |
| Accounts receivable, net                                                          | (259,086)                                  | (162,026)          |
| Inventories                                                                       | (298,382)                                  | 1,961              |
| Prepaid expenses and other assets                                                 | (22,275)                                   | (222,472)          |
| Accounts payable                                                                  | 341,462                                    | (104,043)          |
| Income taxes payable                                                              | 8,884                                      | 57,290             |
| Accrued liabilities                                                               | 94,770                                     | 62,613             |
| Deferred revenues                                                                 | 4,295                                      | 17,331             |
| Minority interest                                                                 | (6,468)                                    | 115,541            |
| <b>Net cash provided by operating activities</b>                                  | <b>1,558,629</b>                           | <b>1,253,412</b>   |
| <b>Investing Activities:</b>                                                      |                                            |                    |
| Purchases of marketable securities                                                | (2,251,247)                                | (2,500,619)        |
| Proceeds from sales of marketable securities                                      | 1,749,029                                  | 1,295,202          |
| Proceeds from maturities of marketable securities                                 | 169,020                                    | 143,695            |
| Acquisition of assets from Navitas                                                | (10,851)                                   |                    |
| Acquisition of assets from Nycomed                                                |                                            | (46,443)           |
| Capital expenditures and other                                                    | (73,345)                                   | (64,326)           |
| <b>Net cash used in investing activities</b>                                      | <b>(417,394)</b>                           | <b>(1,172,491)</b> |
| <b>Financing Activities:</b>                                                      |                                            |                    |
| Proceeds from issuances of common stock                                           | 176,416                                    | 186,350            |
| Repurchases of common stock                                                       | (1,216,068)                                | (454,888)          |
| Repayments of long-term debt and other obligations                                | (3,749)                                    | (99,377)           |
| Excess tax benefits from stock-based compensation                                 | 155,723                                    | 85,279             |
| <b>Net cash used in financing activities</b>                                      | <b>(887,678)</b>                           | <b>(282,636)</b>   |
| Effect of exchange rate changes on cash                                           | (12,219)                                   | (30,164)           |

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|                                                  |              |            |
|--------------------------------------------------|--------------|------------|
| Net change in cash and cash equivalents          | 241,338      | (231,879)  |
| Cash and cash equivalents at beginning of period | 968,086      | 816,007    |
| Cash and cash equivalents at end of period       | \$ 1,209,424 | \$ 584,128 |

See accompanying notes.

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**GILEAD SCIENCES, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

(unaudited)

**1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Basis of Presentation**

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared in accordance with U.S. generally accepted accounting principles for interim financial information. The financial statements include all adjustments (consisting only of normal recurring adjustments) that the management of Gilead Sciences, Inc. (Gilead, we or our) believes are necessary for a fair presentation of the periods presented. These interim financial results are not necessarily indicative of results expected for the full fiscal year or for any subsequent interim period.

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

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

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, 2007, included in our Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (SEC).

**Earnings Per Share**

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

The Notes are considered to be Instrument C securities as defined by Emerging Issues Task Force (EITF) Issue No. 90-19, *Convertible Bonds with Issuer Option to Settle for Cash upon Conversion* (EITF 90-19); therefore, only the conversion spread relating to the Notes is included in our diluted earnings per share calculation. The potential dilutive shares of our common stock resulting from the assumed settlement of the conversion spread of the Notes are determined under the method set forth in EITF 90-19. Under such method, the settlement of the conversion spread of the Notes has a dilutive effect when the average market price of our common stock during the period exceeds \$38.75 and \$38.10 for the 2011 Notes and 2013 Notes, respectively.

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The average market price of our common stock during the three and nine months ended September 30, 2007 did not exceed the conversion price of the 2011 Notes. The average market price of our common stock during the nine months ended September 30, 2007 did not exceed the conversion price of the 2013 Notes. For the periods where the average market price of our common stock did exceed the conversion price of either of our Notes, the dilutive effect is included in the table below.

Warrants relating to the 2011 Notes and 2013 Notes have a dilutive effect when the average market price of our common stock during the period exceeds the warrants' exercise prices of \$50.80 and \$53.90, respectively. The average market price of our common stock during the nine months ended September 30, 2008 and 2007 and three months ended September 30, 2007 did not exceed the warrants' exercise price relating to the 2011 Notes. The average market price of our common stock during the three and nine months ended September 30, 2008 and 2007 did not exceed the warrants' exercise price relating to the 2013 Notes. For the three months ended September 30, 2008, the dilutive effect of warrants related to the 2011 Notes is included in the table below.

Stock options to purchase approximately 10.0 million and 9.9 million weighted-average shares of our common stock were outstanding during the three and nine months ended September 30, 2008, respectively, but were not included in the computation of diluted earnings per share because the options' exercise prices were greater than the average market price of our common stock during these periods; therefore, their effect was antidilutive. Stock options to purchase approximately 18.7 million and 16.2 million weighted-average shares of our common stock were outstanding during the three and nine months ended September 30, 2007, respectively, but were not included in the computation of diluted earnings per share because the options' exercise prices were greater than the average market price of our common stock during these periods; therefore, their effect was antidilutive.

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

|                                                                                                       | <b>Three Months Ended<br/>September 30,</b> |             | <b>Nine Months Ended<br/>September 30,</b> |              |
|-------------------------------------------------------------------------------------------------------|---------------------------------------------|-------------|--------------------------------------------|--------------|
|                                                                                                       | <b>2008</b>                                 | <b>2007</b> | <b>2008</b>                                | <b>2007</b>  |
| <b>Numerator:</b>                                                                                     |                                             |             |                                            |              |
| Net income                                                                                            | \$ 504,005                                  | \$ 398,319  | \$ 1,442,960                               | \$ 1,213,656 |
| <b>Denominator:</b>                                                                                   |                                             |             |                                            |              |
| Weighted-average shares of common stock outstanding used in calculation of basic earnings per share   | 920,807                                     | 926,963     | 923,894                                    | 928,519      |
| <b>Effect of dilutive securities:</b>                                                                 |                                             |             |                                            |              |
| Stock options and equivalents                                                                         | 30,726                                      | 32,027      | 32,260                                     | 34,285       |
| Conversion spread related to 2011 convertible senior notes                                            | 4,223                                       |             | 3,914                                      |              |
| Conversion spread related to 2013 convertible senior notes                                            | 4,508                                       | 53          | 4,199                                      |              |
| Warrants related to convertible senior notes                                                          | 321                                         |             |                                            |              |
| Weighted-average shares of common stock outstanding used in calculation of diluted earnings per share | 960,585                                     | 959,043     | 964,267                                    | 962,804      |

**Fair Value**

In September 2006, the FASB issued Statement of Financial Accounting Standards (SFAS) No. 157, *Fair Value Measurements* (SFAS 157). SFAS 157 defines fair value, establishes a framework for measuring fair value and expands the disclosure requirements regarding fair value measurements. SFAS 157 is effective for fiscal years beginning after November 15, 2007 for financial assets and liabilities as well as for non-financial assets and

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liabilities that are recognized or disclosed at fair value on a recurring basis in the financial statements. In accordance with FASB Staff Position No. FAS 157-2, *Effective Date of FASB Statement No. 157*, for all other non-financial assets and liabilities, SFAS 157 will be effective for fiscal years beginning after November 15, 2008. In October 2008, the FASB issued FASB Staff Position (FSP) No. 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset is Not Active* (FSP 157-3), that clarifies the application of SFAS 157 in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. FSP 157-3 is applicable to the valuation of auction rate securities held by us for which there was no active market as of September 30, 2008. FSP 157-3 is effective upon issuance, including prior periods for which the financial statements have not been issued.

On January 1, 2008, we adopted the provisions of SFAS 157 on a prospective basis for our financial assets and liabilities. SFAS 157 requires that we determine the fair value of financial assets and liabilities using the fair value hierarchy established in SFAS 157 and describes three levels of inputs that may be used to measure fair value, as follows:

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

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

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

The adoption of SFAS 157 and FSP 157-3 had no effect on our consolidated net income for the three and nine months ended September 30, 2008.

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

|                       |               | Fair Value Measurement at September 30, 2008 Using |              |              |
|-----------------------|---------------|----------------------------------------------------|--------------|--------------|
|                       |               | Quoted Prices                                      |              |              |
|                       |               | in Active                                          | Significant  | Significant  |
|                       |               | Markets for                                        | Other        | Unobservable |
|                       |               | Identical                                          | Observable   | Unobservable |
|                       | September 30, | Assets                                             | Inputs       | Inputs       |
|                       | 2008          | (Level 1)                                          | (Level 2)    | (Level 3)    |
| Assets:               |               |                                                    |              |              |
| Cash equivalents      | \$ 482,746    | \$ 141,477                                         | \$ 341,269   | \$           |
| Marketable securities | 2,046,838     | 170,396                                            | 1,754,292    | 122,150      |
| Derivatives           | 51,338        |                                                    | 51,338       |              |
|                       | \$ 2,580,922  | \$ 311,873                                         | \$ 2,146,899 | \$ 122,150   |
| Liabilities:          |               |                                                    |              |              |
| Derivatives           | \$ 1,492      | \$                                                 | \$ 1,492     | \$           |

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

|                                                                                                                                                                                                                                          | Three Months Ended<br>September 30,<br>2008 | Nine Months Ended<br>September 30,<br>2008 |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|--------------------------------------------|
| Balance, beginning of period                                                                                                                                                                                                             | \$ 131,276                                  | \$ 7,258                                   |
| Total realized gains (losses) included in interest and other income, net                                                                                                                                                                 | 325                                         | (1,939)                                    |
| Total unrealized losses included in other comprehensive loss                                                                                                                                                                             | (6,244)                                     | (14,932)                                   |
| Purchases (sales), net                                                                                                                                                                                                                   | (3,207)                                     | (25,936)                                   |
| Transfers into Level 3                                                                                                                                                                                                                   |                                             | 157,699                                    |
| Balance, end of period                                                                                                                                                                                                                   | \$ 122,150                                  | \$ 122,150                                 |
| Total losses for the three and nine months ended September 30, 2008 included in earnings attributable to the change in unrealized losses relating to assets still held at the reporting date, reported in interest and other income, net | \$                                          | \$ (2,264)                                 |

Marketable securities measured at fair value using Level 3 inputs are comprised primarily of auction rate securities within our available-for-sale investment portfolio. The underlying assets of our auction rate securities are comprised of student loans. Although auction rate securities would typically be measured using Level 2 inputs, the failure of auctions and the lack of market activity and liquidity experienced since the beginning of 2008 required that these securities be measured using Level 3 inputs. The fair value of our auction rate securities was determined using a discounted cash flow model that considered projected cash flows for the issuing trusts, underlying collateral and expected yields. Projected cash flows were estimated based on the underlying loan principal, bonds outstanding and payout formulas. The weighted-average life over which the cash flows were projected considered the collateral composition of the securities and related historical and projected prepayments. The underlying student loans have a life of seven to ten years. The discount rates applied to the discounted cash flow model were based on market conditions for comparable or similar term asset-backed securities as well as other fixed income securities adjusted for an illiquidity discount. Our auction rate securities reset every seven to 35 days with maturity dates ranging from 2023 through 2041 and have interest rates ranging from 2.8% to 13.9%. As of September 30, 2008, our auction rate securities continued to earn interest.

Our auction rate securities were measured using Level 3 inputs and were recorded in long-term marketable securities on our Condensed Consolidated Balance Sheet at September 30, 2008. Although there have been failed auctions as well as lack of market activity and liquidity during the past nine months, based on our assessment of the underlying collateral, the creditworthiness of the issuers of the securities and our ability and intent to hold these securities until anticipated recovery, which could be at final maturity, we had no other-than-temporary impairments on these securities as of September 30, 2008.

**Recent Accounting Pronouncements**

In June 2008, the FASB ratified EITF Issue No. 07-5, *Determining Whether an Instrument (or Embedded Feature) is Indexed to an Entity's Own Stock* (EITF 07-5). EITF 07-5 provides guidance on how to determine if certain instruments (or embedded features) are considered indexed to our own stock, including instruments similar to our convertible senior notes, convertible note hedges, warrants to purchase our stock and the forward contract that we entered into as part of our accelerated share repurchase program in February 2008 and which was completed in June 2008 and the forward contract that we entered into as part of our accelerated share repurchase program in October 2008. EITF 07-5 requires companies to use a two-step approach to evaluate an instrument's contingent exercise provisions and settlement provisions in determining whether the instrument is considered to be indexed to its own stock and exempt from the application of SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*. Although EITF 07-5 is effective for fiscal years beginning after

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December 15, 2008, any outstanding instrument at the date of adoption will require a retrospective application of the accounting through a cumulative effect adjustment to retained earnings upon adoption. We do not expect the adoption of EITF 07-5 to have a material impact on our consolidated financial position or results of operations.

In May 2008, the FASB issued FSP APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)* (FSP APB 14-1). FSP APB 14-1 addresses instruments commonly referred to as Instrument C from EITF 90-19, which requires the issuer to settle the principal amount in cash and the conversion spread in cash or net shares at the issuer's option. FSP APB 14-1 requires that issuers of these instruments account for their liability and equity components separately by bifurcating the conversion option from the debt instrument, classifying the conversion option in equity and then accreting the resulting discount on the debt as additional interest expense over the expected life of the debt. FSP APB 14-1 is effective for fiscal years beginning after December 15, 2008 and interim periods within those fiscal years, and requires retrospective application to all periods presented. Early application is not permitted. We expect that the adoption of FSP APB 14-1 will have a material impact on our consolidated financial position and results of operations. Based on the requirements of FSP APB 14-1, we estimate that if FSP APB 14-1 was effective for the current and comparative periods, we would have reported additional interest expense related to our Notes of approximately \$13.5 million and \$39.5 million during the three and nine months ended September 30, 2008, respectively, and \$12.7 million and \$37.1 million during the three and nine months ended September 30, 2007, respectively.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements, an amendment of Accounting Research Bulletin No. 51, Consolidated Financial Statements* (SFAS 160). SFAS 160 establishes accounting and reporting standards for ownership interests in subsidiaries held by parties other than the parent, the amount of consolidated net income (loss) attributable to the parent and to the noncontrolling interests, changes in a parent's ownership interest and the valuation of retained noncontrolling equity investments when a subsidiary is deconsolidated. SFAS 160 also establishes additional reporting requirements that identify and distinguish between the ownership interest of the parent and the interest of the noncontrolling owners. SFAS 160 is effective for interim periods and fiscal years beginning after December 15, 2008. Upon adopting SFAS 160, we plan to reclassify the noncontrolling interest, or minority interest, on our consolidated balance sheet from liabilities to stockholders' equity and to present the noncontrolling interest, or minority interest, on our statement of income as net income attributable to the noncontrolling interest, which will be a component of total net income.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), *Business Combinations* (SFAS 141R). SFAS 141R establishes principles and requirements for recognizing and measuring assets acquired, liabilities assumed and any noncontrolling interests in the acquiree in a business combination. SFAS 141R also provides guidance for recognizing and measuring goodwill acquired in a business combination; requires purchased in-process research and development (IPR&D) to be capitalized at fair value as intangible assets at the time of acquisition; requires acquisition-related expenses and restructuring costs to be recognized separately from the business combination; and requires the acquirer to disclose information that users may need to evaluate and understand the financial effect of the business combination. SFAS 141R is effective on a prospective basis and will impact business combination transactions for which the acquisition date occurs in fiscal years beginning after December 15, 2008. Depending on the nature and magnitude of our future business combination transactions, SFAS 141R may have a material impact on our consolidated financial position and/or results of operations.

## **2. ASSET ACQUISITION**

In May 2008, we executed an asset purchase agreement with Navitas Assets, LLC (Navitas) to acquire all of the assets related to its cicletanine business. We acquired the exclusive rights to regulatory data and filings for development of cicletanine as a monotherapy for pulmonary arterial hypertension (PAH) and for other indications in the United States. We plan to evaluate cicletanine as a potential treatment of PAH.

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The aggregate purchase price for the acquisition was \$10.9 million, and consisted primarily of cash paid. In addition, Navitas is entitled to potential additional purchase consideration, including payments contingent on future achievement of certain development and regulatory milestones. These amounts will be recorded when and if the related contingencies are resolved. The purchase price was allocated to IPR&D which represents the in-process research and development program for cicletanine that had not yet reached technological feasibility and had no alternative future uses as of the acquisition date, and therefore, was expensed upon acquisition within our Condensed Consolidated Statement of Income.

**3. INVENTORIES**

Inventories are summarized as follows (in thousands):

|                   | September 30,<br>2008 | December 31,<br>2007 |
|-------------------|-----------------------|----------------------|
| Raw materials     | \$ 392,409            | \$ 244,725           |
| Work in process   | 188,702               | 136,651              |
| Finished goods    | 316,512               | 218,590              |
| Total inventories | \$ 897,623            | \$ 599,966           |

As of September 30, 2008 and December 31, 2007, the joint ventures formed by Gilead and BMS, which are included in our Condensed Consolidated Financial Statements, held a total of \$583.2 million and \$296.2 million, respectively, in inventory of efavirenz active pharmaceutical ingredient which the joint ventures purchased at the estimated average net selling price of Sustiva from BMS.

**4. CONVERTIBLE SENIOR NOTES**

During the three months ended September 30, 2008, the closing price of our common stock did not exceed the per share conversion prices of our Notes for at least 20 trading days during the last 30 consecutive trading day period; therefore, the Notes will not be eligible for conversion into shares of our common stock for the three months ending December 31, 2008. As a result, we classified the convertible senior notes as long-term liabilities at September 30, 2008. The conversion eligibility of the Notes in future quarters will depend on the closing prices of our common stock during the last 30 consecutive trading days of each quarter, which will determine whether the Notes will be classified as current or long-term liabilities within our Condensed Consolidated Balance Sheet at the end of each quarter.

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

On May 12, 2006, the United States District Court for the Northern District of California executed orders dismissing in its entirety and with prejudice the fourth consolidated amended complaint associated with a purported class action lawsuit against us and our Chief Executive Officer; Chief Operating Officer; former Executive Vice President of Operations; Executive Vice President of Research and Development and Chief Scientific Officer; Senior Vice President of Manufacturing; and Senior Vice President of Research, alleging that the defendants violated federal securities laws, specifically Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated by the SEC, by making certain alleged false and misleading statements. On August 11, 2008, the United States Court of Appeals for the Ninth Circuit reversed the district court's decision and will remand the case to the district court. It is not possible to predict the outcome of this case, and as such, no amounts have been accrued related to the outcome of this case.

On November 29, 2006, we received a subpoena from the United States Attorney's Office in San Francisco requesting documents regarding our marketing and medical education programs for Truvada, Viread and

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

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

## 6. STOCK-BASED COMPENSATION EXPENSE

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

|                                                                       | Three Months Ended<br>September 30, |           | Nine Months Ended<br>September 30, |            |
|-----------------------------------------------------------------------|-------------------------------------|-----------|------------------------------------|------------|
|                                                                       | 2008                                | 2007      | 2008                               | 2007       |
| Cost of goods sold                                                    | \$ 2,592                            | \$ 3,138  | \$ 7,134                           | \$ 8,350   |
| Research and development expenses                                     | 17,680                              | 18,360    | 49,945                             | 56,129     |
| Selling, general and administrative expenses                          | 21,322                              | 24,563    | 57,526                             | 86,683     |
| Stock-based compensation expense included in total costs and expenses | 41,594                              | 46,061    | 114,605                            | 151,162    |
| Income tax effect                                                     | (11,513)                            | (14,284)  | (32,114)                           | (44,939)   |
| Stock-based compensation expense included in net income               | \$ 30,081                           | \$ 31,777 | \$ 82,491                          | \$ 106,223 |

## 7. STOCKHOLDERS EQUITY

### Stock Option Plan

In May 2008, our stockholders approved an amendment to the Gilead Sciences, Inc. 2004 Equity Incentive Plan (2004 Plan) to increase the number of shares authorized for issuance under the 2004 Plan by 10,000,000 shares of our common stock. As of September 30, 2008, there were 41,521,112 shares authorized and available for future grant under the 2004 Plan.

### Stock Repurchase Program

In February 2008, we entered into an accelerated share repurchase agreement with Goldman, Sachs & Co. (Goldman Sachs) to repurchase \$500.0 million of our common stock on an accelerated basis. This accelerated share repurchase is part of the share repurchase program authorized by our board of directors in October 2007 for the repurchase of our common stock in an amount of up to \$3.00 billion through open market and private block transactions or privately negotiated purchases or other means. Under the terms of the accelerated share repurchase agreement, we paid \$500.0 million to Goldman Sachs to settle the initial purchase transaction and received 9,373,548 shares of our common stock at a price of \$53.34 per share. In June 2008, upon maturity of the agreement and in accordance with the share delivery provisions of the agreement, we received an additional 239,612 shares of our common stock based on the average of the daily volume weighted-average prices of our common stock during a specified period less a predetermined discount per share. As a result, the final purchase price of our common stock from the accelerated share repurchase was \$52.01 per share.

In accordance with EITF Issue No. 99-7, *Accounting for an Accelerated Share Repurchase Program*, we accounted for the accelerated share repurchase as two separate transactions: (a) as shares of common stock acquired in a treasury stock transaction recorded on the transaction date and (b) as a forward contract indexed to our own common stock. As such, we accounted for the 9,373,548 shares that we received as a repurchase of our common stock and retired those shares immediately for earnings per share purposes. The 239,612 additional

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shares that we received upon maturity of the contract in June 2008 were also recorded in stockholders' equity. We determined that the forward contract indexed to our own common stock met all of the applicable criteria for equity classification in accordance with EITF Issue No. 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*, and therefore, the contract was not accounted for as a derivative under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*.

During the three and nine months ended September 30, 2008, in addition to the repurchases made pursuant to the accelerated share repurchase agreement with Goldman Sachs, we also repurchased and retired 4,705,000 and 14,610,249 shares, respectively, of our common stock at an average purchase price of \$53.13 and \$48.99 per share, respectively, for an aggregate purchase price of \$250.0 million and \$715.8 million, respectively, through open market transactions. As of September 30, 2008, the remaining authorized amount of stock repurchases that may be made under this stock repurchase program which expires in December 2010 was \$1.75 billion.

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 three months ended September 30, 2008, we reduced common stock and APIC by an aggregate of \$11.6 million and charged \$238.4 million to retained earnings. During the nine months ended September 30, 2008, we reduced common stock and APIC by an aggregate of \$58.3 million and charged \$1.16 billion to retained earnings.

## Comprehensive Income

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

|                                                                                         | Three Months Ended<br>September 30, |            | Nine Months Ended<br>September 30, |              |
|-----------------------------------------------------------------------------------------|-------------------------------------|------------|------------------------------------|--------------|
|                                                                                         | 2008                                | 2007       | 2008                               | 2007         |
| Net income                                                                              | \$ 504,005                          | \$ 398,319 | \$ 1,442,960                       | \$ 1,213,656 |
| Net foreign currency translation gain (loss)                                            | (10,566)                            | 589        | (6,903)                            | 867          |
| Net unrealized gain (loss) on available-for-sale securities, net of related tax effects | (12,268)                            | 11,299     | (28,217)                           | (1,878)      |
| Net unrealized gain (loss) on cash flow hedges, net of related tax effects              | 40,035                              | (19,353)   | 56,673                             | (14,725)     |
| Comprehensive income                                                                    | \$ 521,206                          | \$ 390,854 | \$ 1,464,513                       | \$ 1,197,920 |

## 8. SEGMENT INFORMATION

We operate in one business segment which primarily focuses on the development and commercialization of human therapeutics for life threatening diseases. All of our products are included in one segment because our major products, Truvada, Atripla, Viread, Hepsera, Emtriva and AmBisome, which collectively accounted for substantially all of our total product sales for the three and nine months ended September 30, 2008 and 2007, have similar economic and other characteristics, including the nature of our products and production processes, type of customers, distribution methods and regulatory environment.

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Product sales consisted of the following (in thousands):

|                          | <b>Three Months Ended<br/>September 30,</b> |             | <b>Nine Months Ended<br/>September 30,</b> |              |
|--------------------------|---------------------------------------------|-------------|--------------------------------------------|--------------|
|                          | <b>2008</b>                                 | <b>2007</b> | <b>2008</b>                                | <b>2007</b>  |
| Antiviral products:      |                                             |             |                                            |              |
| Truvada                  | \$ 549,101                                  | \$ 409,084  | \$ 1,544,635                               | \$ 1,140,382 |
| Atripla                  | 427,623                                     | 241,101     | 1,106,941                                  | 643,668      |
| Viread                   | 155,958                                     | 149,108     | 459,306                                    | 464,683      |
| Hepsera                  | 91,217                                      | 79,273      | 264,604                                    | 225,790      |
| Emtriva                  | 7,634                                       | 6,461       | 24,111                                     | 24,388       |
| Total antiviral products | 1,231,533                                   | 885,027     | 3,399,597                                  | 2,498,911    |
| AmBisome                 | 72,884                                      | 68,508      | 213,680                                    | 194,764      |
| Other                    | 34,085                                      | 8,396       | 83,747                                     | 13,539       |
| Total product sales      | \$ 1,338,502                                | \$ 961,931  | \$ 3,697,024                               | \$ 2,707,214 |

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 partners. The following table summarizes total revenues from external customers and collaboration partners by geographic region (in thousands):

|                                             | <b>Three Months Ended<br/>September 30,</b> |              | <b>Nine Months Ended<br/>September 30,</b> |              |
|---------------------------------------------|---------------------------------------------|--------------|--------------------------------------------|--------------|
|                                             | <b>2008</b>                                 | <b>2007</b>  | <b>2008</b>                                | <b>2007</b>  |
| United States                               | \$ 750,288                                  | \$ 566,357   | \$ 2,101,134                               | \$ 1,573,110 |
| Outside of the United States:               |                                             |              |                                            |              |
| France                                      | 105,087                                     | 87,730       | 294,932                                    | 241,836      |
| Spain                                       | 91,348                                      | 59,185       | 259,778                                    | 174,663      |
| United Kingdom                              | 81,028                                      | 57,224       | 217,180                                    | 161,301      |
| Italy                                       | 64,946                                      | 50,586       | 209,171                                    | 152,232      |
| Germany                                     | 71,429                                      | 30,588       | 175,013                                    | 95,950       |
| Switzerland                                 | 18,151                                      | 84,123       | 167,071                                    | 387,067      |
| Other European countries                    | 98,139                                      | 59,275       | 214,397                                    | 162,327      |
| Other countries                             | 90,852                                      | 63,735       | 268,869                                    | 186,836      |
| Total revenues outside of the United States | 620,980                                     | 492,446      | 1,806,411                                  | 1,562,212    |
| Total revenues                              | \$ 1,371,268                                | \$ 1,058,803 | \$ 3,907,545                               | \$ 3,135,322 |

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

|                         | <b>Three Months Ended<br/>September 30,</b> |             | <b>Nine Months Ended<br/>September 30,</b> |             |
|-------------------------|---------------------------------------------|-------------|--------------------------------------------|-------------|
|                         | <b>2008</b>                                 | <b>2007</b> | <b>2008</b>                                | <b>2007</b> |
| Cardinal Health, Inc.   | 20%                                         | 19%         | 21%                                        | 20%         |
| McKesson Corp.          | 16%                                         | 17%         | 15%                                        | 15%         |
| AmerisourceBergen Corp. | 11%                                         | 10%         | 11%                                        | 10%         |

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|                          |   |   |   |     |
|--------------------------|---|---|---|-----|
| F. Hoffmann-La Roche Ltd | * | * | * | 12% |
|--------------------------|---|---|---|-----|

\* Amount less than 10%.

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### **9. INCOME TAXES**

Our income tax rate was 27.7% and 28.0% for the three and nine months ended September 30, 2008, respectively, compared to 30.8% and 29.7% for the three and nine months ended September 30, 2007, respectively. Our income tax rates differ from the U.S. federal statutory rate of 35% due primarily to certain earnings from operations in foreign tax jurisdictions for which no U.S. taxes have been provided because we plan to reinvest such earnings indefinitely outside the United States, partially offset by state taxes. We do not provide for U.S. income taxes on undistributed earnings of our foreign operations that are intended to be permanently reinvested.

We believe that it is reasonably possible that our unrecognized tax benefits will decrease by approximately \$80.0 million in the next 12 months as we expect to have clarification around certain of our uncertain tax positions. With respect to the remaining unrecognized tax benefits, we are currently unable to make a reasonably reliable estimate as to the period of cash settlement, if any, with the respective taxing authorities.

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

Our income tax returns are audited by federal, state and foreign tax authorities. We are currently under examination by the Internal Revenue Service for the 2003 and 2004 tax years and by various state and foreign jurisdictions. There are differing interpretations of tax laws and regulations, and as a result, significant disputes may arise with these tax authorities involving issues of the timing and amount of deductions and allocations of income among various tax jurisdictions. While we believe our positions comply with applicable laws, we periodically evaluate our exposures associated with our tax filing positions.

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

### **10. SUBSEQUENT EVENTS**

In October 2008, we entered into an accelerated share repurchase transaction with Citibank, N.A. (Citibank) to repurchase \$750.0 million of our common stock on an accelerated basis. This accelerated share repurchase is part of the \$3.00 billion share repurchase program authorized by our board of directors in October 2007. Under the terms of the accelerated share repurchase agreement, we paid \$750.0 million to Citibank to settle the initial purchase transaction and received 14,874,519 shares of our common stock at a price of \$50.42 per share. On or before April 2009, subject to extension under certain circumstances as well as the maximum and minimum share delivery provisions of the agreement, we may receive additional shares from Citibank depending on the average of the daily volume weighted-average prices of our common stock during a specified period less a predetermined discount per share. After making the initial payment of \$750.0 million, we will not be obligated to deliver any cash or shares to Citibank except in certain limited circumstances in which case the method of delivery (cash or shares of our common stock) would be at our discretion. As the terms of this accelerated share repurchase agreement are substantially similar to the accelerated share repurchase agreement we entered into in February 2008 and completed in June 2008 (see Note 7), the related accounting impact on our consolidated financial statements would be similar under this new agreement. As of October 31, 2008, the remaining authorized amount of stock repurchases that may be made under the \$3.00 billion stock repurchase program which expires in December 2010 was \$1.00 billion.

In October 2008, we signed a purchase and sale agreement with Electronics For Imaging, Inc., under which we plan to purchase an office building and approximately 30 acres of land located in Foster City, California, for

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an aggregate purchase price of approximately \$137.5 million. We made an initial refundable deposit of \$5.0 million and will make an additional payment of \$5.0 million on or around December 12, 2008 if we elect to proceed with the acquisition prior to such time. Until December 12, 2008, we may terminate the purchase and sale agreement in our sole discretion, for any reason. If we elect to proceed with the acquisition, the closing of the transaction will remain subject to satisfaction of certain closing conditions. Upon completion or waiver of these conditions, the parties will close the transaction and the remaining balance of the purchase price will become payable. The transaction is currently expected to close in January 2009.

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

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

You should read the following management's discussion and analysis of our financial condition and results of operations in conjunction with our audited Consolidated Financial Statements and related notes thereto included as part of our Annual Report on Form 10-K for the year ended December 31, 2007, and our unaudited Condensed Consolidated Financial Statements for the three and nine months ended September 30, 2008 and other disclosures (including the disclosures under Part II, Item 1A, Risk Factors) included in this Quarterly Report on Form 10-Q. Our Condensed Consolidated Financial Statements have been prepared in accordance with U.S. generally accepted accounting principles and are presented in U.S. dollars.

**Management Overview**

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

**Business Highlights**

In September 2008, Viread for the treatment of chronic hepatitis B was approved in Canada. We received similar approval from the U.S. Food and Drug Administration (FDA) in August, in Australia in July, and in the European Union, Turkey, and New Zealand in April 2008.

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In September 2008, we received a complete response letter from the FDA informing us that the FDA cannot approve our New Drug Application (NDA) for aztreonam for inhalation for treatment of cystic fibrosis (CF) in its current form and requesting we conduct an additional Phase 3 clinical study. We are working with the FDA to determine whether further analyses of the existing data could lead to approval or whether we will need to conduct an additional study.

During the third quarter of 2008, we began dosing patients in our Phase 3 clinical study of elvitegravir (GS 9137), our novel integrase inhibitor for HIV, which we licensed from Japan Tobacco Inc. (Japan Tobacco) in 2005. In the hepatitis C area, we completed our Phase 1 study for GS 9190, a non-nucleoside polymerase inhibitor, and we are targeting initiation of the Phase 2 study in patients infected with the hepatitis C virus before the end of this year. We are continuing our Phase 2a study in patients with hepatitis C of GS 9450, the caspase inhibitor licensed from LG Life Sciences in 2007, and we expect data from this trial by the end of the year. Pending positive results from this study, we anticipate initiating a Phase 2b study in the first half of next year. We are also completing a Phase 1 study of GS 9450 to evaluate its safety and effect on liver enzymes in patients with non-alcoholic steatohepatitis (NASH). In the cardiovascular area, we completed enrollment in one of the two Phase 3 studies for darusentan for treatment of resistant hypertension and we anticipate having data from this study in the second quarter of 2009. We continued to enroll patients in our second Phase 3 study for darusentan, and we anticipate completing the enrollment and having data from this study before the end of 2009. We have completed a Phase 1 study to evaluate GS 9350 for safety and its ability to boost blood levels of midazolam, a common substrate used to investigate pharmacokinetic boosters. Based on the results obtained, we are now investigating the pharmacokinetics and bioequivalence of a GS 9350, elvitegravir and Truvada co-formulation into a single pill.

### *Financial Highlights*

Our operating results for the third quarter of 2008 were led by product sales of \$1.34 billion. Antiviral product sales (Truvada, Atripla, Viread, Hepsera and Emtriva) increased 39% to \$1.23 billion in the third quarter of 2008 from the third quarter of 2007 and were the key drivers for total product sales growth of 39% in the third quarter of 2008 as compared to the third quarter of 2007. Atripla contributed \$427.6 million, or 35%, to our third quarter antiviral product sales resulting from the continued uptake of Atripla in the United States and product launches in Europe. The growth of Atripla product sales and its increased proportion to overall product sales, caused total product gross margin to decrease as expected, due to the efavirenz component of Atripla sales at zero gross margin. Truvada product sales for the third quarter of 2008 were \$549.1 million, or 45% of our third quarter antiviral product sales. Truvada product sales for the third quarter of 2008 increased 34% from the third quarter of 2007 due primarily to sales volume growth as well as a favorable foreign currency exchange impact. There was a favorable foreign currency impact of approximately \$58.8 million on total revenues and \$36.7 million on pre-tax income in the third quarter of 2008 when compared to the third quarter of 2007.

Under our collaborations with corporate partners, we recognized \$25.2 million in royalty revenues in the third quarter of 2008, a decrease of 72% from royalty revenues of \$91.0 million in the third quarter of 2007. The decrease in royalty revenues was primarily due to decreased Tamiflu sales by Roche related to pandemic planning initiatives worldwide.

The increased research and clinical activity related to the compounds in our pipeline, along with higher headcount required to support our expanding programs, contributed to higher research and development (R&D) expenses of \$188.1 million for the third quarter of 2008 as compared to \$140.4 million in the third quarter of 2007, an increase of 34%.

Selling, general and administrative (SG&A) expenses for the third quarter of 2008 increased by 9% from the third quarter of 2007 driven primarily by higher headcount and higher operating costs to support the continued growth of our business. Although the expansion of our business activities has required an increase in operating expenses, we continued our focus on cost control.

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Our cash, cash equivalents and marketable securities increased by \$533.8 million during the nine months ended September 30, 2008, driven primarily by our operating cash flows of \$1.56 billion, partially offset by common stock repurchases of \$1.22 billion under our stock repurchase program. In October 2008, we entered into an accelerated share repurchase transaction with Citibank, N.A. (Citibank) to repurchase \$750.0 million of our common stock on an accelerated basis. Under the terms of the accelerated share repurchase agreement, we paid \$750.0 million to Citibank to settle the initial purchase transaction and received 14,874,519 shares of our common stock at a price of \$50.42 per share. On or before April 2009, subject to extension under certain circumstances as well as the maximum and minimum share delivery provisions of the agreement, we may receive additional shares from Citibank depending on the average of the daily volume weighted-average prices of our common stock during a specified period less a predetermined discount per share. As of October 31, 2008, the remaining authorized amount of stock repurchases that may be made under the \$3.00 billion stock repurchase program which expires in December 2010 was \$1.00 billion.

In light of the volatility and developments that we have seen in the financial markets, we continued to review our cash equivalents and marketable securities carefully as well as invest prudently. We believe that maintaining the primary goals of our investment policy, safety and preservation of principal and diversification of risk, as well as liquidity, has protected us from much of the risks in the credit markets while allowing us to continue to meet our operating cash flow requirements as well as execute on other opportunities such as our \$750.0 million accelerated share repurchase.

## Critical Accounting Policies, Estimates and Judgments

There have been no material changes in our critical accounting policies, estimates and judgments during the quarter ended September 30, 2008 compared to the disclosures in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2007.

## Results of Operations

### Total Revenues

Total revenues were \$1.37 billion for the third quarter of 2008 and \$1.06 billion for the third quarter of 2007. Total revenues were \$3.91 billion for the nine months ended September 30, 2008 and \$3.14 billion for the same period in 2007. Included in total revenues were product sales, royalty revenues and contract and other revenues.

### Product Sales

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

|                          | Three Months Ended<br>September 30, |            |        | Nine Months Ended<br>September 30, |              |        |
|--------------------------|-------------------------------------|------------|--------|------------------------------------|--------------|--------|
|                          | 2008                                | 2007       | Change | 2008                               | 2007         | Change |
| Antiviral products:      |                                     |            |        |                                    |              |        |
| Truvada                  | \$ 549,101                          | \$ 409,084 | 34%    | \$ 1,544,635                       | \$ 1,140,382 | 35%    |
| Atripla                  | 427,623                             | 241,101    | 77%    | 1,106,941                          | 643,668      | 72%    |
| Viread                   | 155,958                             | 149,108    | 5%     | 459,306                            | 464,683      | (1)%   |
| Hepsera                  | 91,217                              | 79,273     | 15%    | 264,604                            | 225,790      | 17%    |
| Emtriva                  | 7,634                               | 6,461      | 18%    | 24,111                             | 24,388       | (1)%   |
| Total antiviral products | 1,231,533                           | 885,027    | 39%    | 3,399,597                          | 2,498,911    | 36%    |
| AmBisome                 | 72,884                              | 68,508     | 6%     | 213,680                            | 194,764      | 10%    |
| Other                    | 34,085                              | 8,396      | 306%   | 83,747                             | 13,539       | 519%   |
| Total product sales      | \$ 1,338,502                        | \$ 961,931 | 39%    | \$ 3,697,024                       | \$ 2,707,214 | 37%    |

Total product sales increased by 39% and 37% for the three and nine months ended September 30, 2008, respectively, compared to the same periods in 2007, due primarily to an overall increase in our antiviral product



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sales including the strong growth of Atripla sales, as well as the continued growth of Truvada sales. Foreign currency denominated product sales experienced a net benefit from the depreciation of the U.S. dollar of approximately \$58.8 million and \$143.6 million for the three and nine months ended September 30, 2008, respectively, compared to the same periods in 2007.

### *Antiviral Products*

Antiviral product sales increased by 39% and 36% for the three and nine months ended September 30, 2008, respectively, compared to the same periods in 2007, driven primarily by sales volume growth of Atripla and Truvada, as well as a favorable foreign currency exchange impact.

#### *Truvada*

Truvada sales increased by 34% and 35% for the three and nine months ended September 30, 2008, respectively, compared to the same periods in 2007, driven primarily by sales volume growth in the United States and Europe, and a favorable foreign currency exchange impact. Truvada sales accounted for 45% of our total antiviral product sales for the three and nine months ended September 30, 2008.

#### *Atripla*

Atripla sales increased by 77% and 72% for the three and nine months ended September 30, 2008, respectively, compared to the same periods in 2007, driven primarily by strong sales volume growth in the United States and Europe. We consolidate 100% of Atripla product sales because we are the primary beneficiary of our joint venture with Bristol-Myers Squibb Company (BMS) in the United States. The efavirenz portion of these Atripla sales which is purchased from BMS at BMS's estimated net selling price of efavirenz, was approximately \$155.9 million and \$406.0 million for the three and nine months ended September 30, 2008, respectively, and approximately \$89.1 million and \$237.9 million for the three and nine months ended September 30, 2007, respectively. Atripla was approved for sale in the United States and in the European Union in July 2006 and December 2007, respectively. Atripla sales accounted for 35% and 33% of our total antiviral product sales in the three and nine months ended September 30, 2008, respectively.

#### *Hepsera*

Hepsera sales increased by 15% and 17% for the three and nine months ended September 30, 2008, respectively, compared to the same periods in 2007, driven primarily by a favorable foreign currency exchange impact and sales volume growth in North America and certain European markets.

#### *AmBisome*

AmBisome sales increased by 6% and 10% for the three and nine months ended September 30, 2008, respectively, compared to the same periods in 2007, driven primarily by a favorable foreign currency exchange impact.

For the full year of 2008, we expect total product sales to continue to grow as we continue to expand our sales and marketing efforts in North America and Europe, driven by the uptake of Atripla in North America and in the European Union, where the product is earlier in its launch, and driven by the launch of Viread for chronic hepatitis B.

### *Royalty Revenues*

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

|                  | Three Months Ended<br>September 30, |           |        | Nine Months Ended<br>September 30, |            |        |
|------------------|-------------------------------------|-----------|--------|------------------------------------|------------|--------|
|                  | 2008                                | 2007      | Change | 2008                               | 2007       | Change |
| Royalty revenues | \$ 25,161                           | \$ 91,003 | (72)%  | \$ 185,221                         | \$ 407,212 | (55)%  |



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Royalty revenues decreased by 72% and 55% for the three and nine months ended September 30, 2008, respectively, compared to the same periods in 2007, driven primarily by the recognition of Tamiflu royalties from Roche of \$8.6 million and \$139.5 million in the three and nine months ended September 30, 2008, respectively, compared to Tamiflu royalties from Roche of \$77.4 million and \$368.4 million recognized in the three and nine months ended September 30, 2007, respectively. The decrease in Tamiflu royalties is primarily due to decreased sales related to pandemic planning initiatives worldwide. We recognize royalties on Tamiflu sales by Roche one quarter in arrears of the quarter in which the product is sold.

Roche reported in October 2008 that it expects a significant decrease in Tamiflu sales in 2008 compared to 2007 due to significantly lower pandemic sales; therefore, we expect our royalty revenues for 2008 to be significantly lower compared to 2007.

### Cost of Goods Sold and Product Gross Margin

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

|                      | Three Months Ended<br>September 30, |            |        | Nine Months Ended<br>September 30, |              |        |
|----------------------|-------------------------------------|------------|--------|------------------------------------|--------------|--------|
|                      | 2008                                | 2007       | Change | 2008                               | 2007         | Change |
| Total product sales  | \$ 1,338,502                        | \$ 961,931 | 39%    | \$ 3,697,024                       | \$ 2,707,214 | 37%    |
| Cost of goods sold   | \$ 300,183                          | \$ 198,460 | 51%    | \$ 805,715                         | \$ 553,229   | 46%    |
| Product gross margin | 77.6%                               | 79.4%      |        | 78.2%                              | 79.6%        |        |

Product gross margin for the third quarter of 2008 was 77.6%, compared to 79.4% for the third quarter of 2007. Product gross margin for the nine months ended September 30, 2008 was 78.2%, compared to 79.6% for the same period in 2007. The lower product gross margins for the three and nine months ended September 30, 2008 compared to the same periods in 2007 were due primarily to the higher proportion of Atripla sales, which include the efavirenz portion at zero product gross margin and the impact of higher royalty expense attributable to changes in the product and geographic mix of product sales.

We expect product gross margin for the full year of 2008 to be slightly lower than that of 2007, due primarily to a higher mix of Atripla product sales.

### Research and Development Expenses

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

|                                | Three Months Ended<br>September 30, |            |        | Nine Months Ended<br>September 30, |            |        |
|--------------------------------|-------------------------------------|------------|--------|------------------------------------|------------|--------|
|                                | 2008                                | 2007       | Change | 2008                               | 2007       | Change |
| Research                       | \$ 44,344                           | \$ 36,762  | 21%    | \$ 119,610                         | \$ 96,718  | 24%    |
| Clinical development           | 116,377                             | 85,719     | 36%    | 321,132                            | 250,000    | 28%    |
| Pharmaceutical development     | 27,341                              | 17,876     | 53%    | 79,163                             | 59,660     | 33%    |
| Total research and development | \$ 188,062                          | \$ 140,357 | 34%    | \$ 519,905                         | \$ 406,378 | 28%    |

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



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R&D expenses for the third quarter of 2008 increased by \$47.7 million compared to the same quarter of 2007, due primarily to increased clinical study expenses of \$19.4 million primarily in the antiviral and cardiovascular areas, as well as increased compensation and benefit expenses of \$14.5 million due primarily to higher headcount to support the growth of our business. Third quarter 2008 R&D expenses also included a \$7.0 million milestone payment made to Japan Tobacco related to the dosing of patients with elvitegravir in Phase 3 studies.

R&D expenses for the nine months ended September 30, 2008 increased by \$113.5 million compared to the same period in 2007, due primarily to increased clinical study expenses of \$55.3 million primarily in the antiviral and cardiovascular areas, as well as increased compensation and benefit expenses of \$36.4 million due primarily to higher headcount.

We expect R&D expenses for the full year of 2008 to be higher than that of 2007, reflecting increased spending on our internal and collaborative R&D efforts relating to the progress of our product candidates into more advanced clinical studies, as well as the continuation of our existing clinical trials.

### *Selling, General and Administrative Expenses*

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

|                                     | Three Months Ended<br>September 30, |            |        | Nine Months Ended<br>September 30, |            |        |
|-------------------------------------|-------------------------------------|------------|--------|------------------------------------|------------|--------|
|                                     | 2008                                | 2007       | Change | 2008                               | 2007       | Change |
| Selling, general and administrative | \$ 189,189                          | \$ 172,956 | 9%     | \$ 603,679                         | \$ 525,693 | 15%    |

SG&A expenses for the third quarter of 2008 increased by \$16.2 million compared to the same quarter of 2007, due primarily to increased compensation and benefit expenses of \$11.1 million, as well as increased infrastructure and technology-related expenses of \$3.7 million to support the continued growth in our business. The increase in compensation and benefit expenses from headcount growth was partially offset by the decrease in stock-based compensation expense of \$3.2 million due primarily to the accelerated stock-based compensation expense recorded during the three months ended September 30, 2007 related to certain employee terminations from our acquisition of Myogen, Inc. (Myogen) in 2006.

SG&A expenses for the nine months ended September 30, 2008 increased by \$78.0 million compared to the same period in 2007, due primarily to increased marketing and promotional expenses of \$19.2 million, other consulting and support services expenses of \$12.8 million related to the growth in our business, as well as costs of \$12.4 million associated with certain termination-related disputes in our international operations. Headcount growth also resulted in increased compensation and benefit expenses of \$38.7 million for the nine months ended September 30, 2008 compared to the same period in 2007, net of a decrease in stock-based compensation expense of \$29.2 million due primarily to the higher expense associated with unvested stock options that we had assumed from Myogen, including accelerated stock-based compensation expenses related to certain Myogen employee terminations during the nine months ended September 30, 2007.

We expect SG&A expenses for the full year of 2008 to be higher than that of 2007 due primarily to headcount related expenses to support the continued growth of our business, including the continued expansion of our international operations, and increased sales and marketing efforts to support the growth of our product franchises.

### *Purchased In-process Research and Development Expenses*

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

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

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

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

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

| Program                  | Description                                                                                                                    | Status of Development                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Estimated<br>Acquisition Date<br>Fair Value<br>(in millions) |
|--------------------------|--------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------|
| Inhaled aztreonam for CF | Aztreonam formulation for inhalation to be used against Gram-negative bacteria that cause lung infections in patients with CF. | In Phase 3 clinical trials as of the acquisition date. We filed an NDA with the FDA in November 2007. In September 2008, we received a complete response letter from the FDA informing us that the FDA cannot approve our NDA for aztreonam for inhalation for treatment of CF in its current form and requesting we conduct an additional Phase 3 clinical study. We are working with the FDA to determine whether further analyses of the existing data could lead to approval or whether we will need to conduct an additional study. | \$ 335.6                                                     |

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

In connection with our acquisition of the cicletanine assets from Navitas Assets, LLC, we recorded IPR&D expense of \$10.9 million during the nine months ended September 30, 2008. As we do not consider the acquisition to be a material transaction, we have not made further disclosures regarding the related purchased IPR&D.

*Interest and Other Income, net*

Interest and other income, net, was \$3.6 million and \$40.4 million for the three and nine months ended September 30, 2008, respectively, a decrease of \$25.9 million and \$39.9 million from the same periods in 2007, respectively. The decrease of \$25.9 million for the third quarter of 2008 as compared to the same quarter of 2007, was driven primarily by increased expenses related to our hedging activities of \$8.9 million, net foreign currency losses of \$8.0 million, as well as a \$4.5 million decrease in interest income and a \$4.1 million other-than-temporary write-down in a marketable equity investment. Interest and other income, net, for the nine months ended September 30, 2008 decreased by \$39.9 million compared to the same period in 2007, due primarily to increased expenses related to our hedging activities of \$26.8 million, net foreign currency losses of \$18.0 million, partially offset by increased interest income of \$9.2 million.

**Table of Contents***Provision for Income Taxes*

Our income tax rate was 27.7% and 28.0% for the three and nine months ended September 30, 2008, respectively, compared to 30.8% and 29.7% for the three and nine months ended September 30, 2007, respectively. Our provision for income taxes for the three and nine months ended September 30, 2008 was \$192.7 million and \$561.8 million, respectively, compared to \$177.7 million and \$513.5 million for the three and nine months ended September 30, 2007, respectively. The tax rates for the three and nine months ended September 30, 2008 differed from the U.S. federal statutory rate of 35% due primarily to earnings from operations in certain foreign tax jurisdictions for which no U.S. taxes have been provided because we plan to reinvest such earnings indefinitely outside the United States, which is partially offset by state income taxes. In October 2008 the President signed into law the Emergency Economic Stabilization Act of 2008 which included the extension of the federal research and development tax credit for two years through December 31, 2009. The impact of the extension for 2008 will be included in our fourth quarter provision for income taxes.

**Liquidity and Capital Resources**

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

|                                                         | As of<br>September 30,<br>2008     | As of<br>December 31,<br>2007 |
|---------------------------------------------------------|------------------------------------|-------------------------------|
| Cash, cash equivalents and marketable securities        | \$ 3,256,262                       | \$ 2,722,422                  |
| Working capital                                         | \$ 3,067,549                       | \$ 2,292,017                  |
|                                                         | Nine Months Ended<br>September 30, |                               |
|                                                         | 2008                               | 2007                          |
| Cash provided by (used in):                             |                                    |                               |
| Operating activities                                    | \$ 1,558,629                       | \$ 1,253,412                  |
| Investing activities                                    | \$ (417,394)                       | \$ (1,172,491)                |
| Financing activities                                    | \$ (887,678)                       | \$ (282,636)                  |
| <i>Cash, Cash Equivalents and Marketable Securities</i> |                                    |                               |

Cash, cash equivalents and marketable securities totaled \$3.26 billion at September 30, 2008, an increase of \$533.8 million or 20% from December 31, 2007. This increase was primarily attributable to:

net cash provided by operations of \$1.56 billion; and

proceeds from issuances of common stock under our employee stock plans of \$176.4 million.

These increases were partially offset by our repurchases of \$1.22 billion of our common stock under our stock repurchase program during the first nine months of 2008.

*Working Capital*

Working capital was \$3.07 billion at September 30, 2008, an increase of \$775.5 million from December 31, 2007. This increase was primarily attributable to:

an increase of \$297.7 million in inventories due primarily to the purchases of efavirenz at the approximate market value of Sustiva from BMS;

an increase of \$252.1 million in accounts receivable, net, driven primarily by increased product sales; and

a \$747.3 million increase in cash, cash equivalents and short-term marketable securities.

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These increases were partially offset by:

a \$341.2 million increase in accounts payable due primarily to the purchases of efavirenz at the approximate market value of Sustiva from BMS.

### *Cash Provided by Operating Activities*

Cash provided by operating activities of \$1.56 billion for the nine months ended September 30, 2008 primarily related to net income of \$1.44 billion adjusted for non-cash items, such as \$169.3 million of tax benefits from employee stock plans and \$114.6 million of stock-based compensation expense, and \$136.8 million of cash outflow related to changes in operating assets and liabilities. This was partially offset by \$155.7 million of excess tax benefits from stock option exercises which we reclassified to cash provided by financing activities in accordance with Statement of Financial Accounting Standards (SFAS) No. 123 (revised 2004), *Share-Based Payment*.

Cash provided by operating activities of \$1.25 billion for the nine months ended September 30, 2007 was comprised primarily of \$1.21 billion in net income which was adjusted for non-cash items such as \$151.2 million of stock-based compensation expense and \$100.2 million of tax benefits from employee stock plans, partially offset by a \$233.8 million net cash outflow related to changes in operating assets and liabilities.

### *Cash Used in Investing Activities*

Cash used in investing activities for the nine months ended September 30, 2008 primarily related to purchases, sales and maturities of marketable securities, as well as capital expenditures. Cash used in investing activities for the nine months ended September 30, 2007 primarily related to purchases, sales and maturities of marketable securities, capital expenditures and our acquisition of Nycomed Limited, a wholly-owned Irish subsidiary of Germany-based, Nycomed GmbH.

We used \$417.4 million of cash in investing activities during the nine months ended September 30, 2008, compared to \$1.17 billion during the nine months ended September 30, 2007. The decrease was due primarily to more cash being used in financing activities during the nine months ended September 30, 2008 compared to the same period in 2007 to fund our stock repurchases.

Capital expenditures of \$73.3 million made in the nine months ended September 30, 2008 related primarily to the expansion and upgrading of our facilities and information systems to accommodate our growth.

In October 2008, we signed a purchase and sale agreement with Electronics For Imaging, Inc., under which we plan to purchase an office building and approximately 30 acres of land located in Foster City, California, for an aggregate purchase price of approximately \$137.5 million. We made an initial refundable deposit of \$5.0 million and will make an additional payment of \$5.0 million on or around December 12, 2008 if we elect to proceed with the acquisition prior to such time. Until December 12, 2008, we may terminate the purchase and sale agreement in our sole discretion, for any reason. If we elect to proceed with the acquisition, the closing of the transaction will remain subject to satisfaction of certain closing conditions. Upon completion or waiver of these conditions, the parties will close the transaction and the remaining balance of the purchase price will become payable. The transaction is currently expected to close in January 2009.

### *Cash Used in Financing Activities*

Cash used in financing activities for the nine months ended September 30, 2008 was \$887.7 million, driven primarily by the \$1.22 billion used to repurchase our common stock under our stock repurchase program. The cash outflows were partially offset by \$155.7 million of excess tax benefits from stock option exercises, as well as proceeds of \$176.4 million that we received from issuances of common stock under our employee stock plans.

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Cash used in financing activities for the nine months ended September 30, 2007 was \$282.6 million, driven primarily by the \$454.9 million used to repurchase our common stock under our stock repurchase program and \$99.0 million used to pay off the remaining amount due on our term loan. These cash outflows were partially offset by proceeds of \$186.4 million that we received from issuances of common stock under our employee stock plans, as well as \$85.3 million of excess tax benefits from stock option exercises.

As of September 30, 2008, we had \$1.75 billion remaining under our stock repurchase program which expires in December 2010.

In October 2008, we entered into an accelerated share repurchase transaction with Citibank to repurchase \$750.0 million of our common stock on an accelerated basis. This accelerated share repurchase is part of the \$3.00 billion share repurchase program authorized by our board of directors in October 2007. Under the terms of the accelerated share repurchase agreement, we paid \$750.0 million to Citibank to settle the initial purchase transaction and received 14,874,519 shares of our common stock at a price of \$50.42 per share. The number of shares of our common stock we will repurchase is based generally on the average of the daily volume weighted average share prices of our common stock during a specified period of time, subject to certain provisions that establish a minimum and maximum number of shares that may be repurchased based on the average of the daily volume weighted-average share prices over an initial hedge period. On or before April 2009, subject to extension under certain circumstances as well as the maximum and minimum share delivery provisions of the agreement, we may receive additional shares from Citibank depending on the average of the daily volume weighted-average prices of our common stock during a specified period less a predetermined discount per share. After making the initial payment of \$750.0 million, we will not be obligated to deliver any cash or shares to Citibank except in certain limited circumstances in which case the method of delivery (cash or shares of our common stock) would be at our discretion. Shares repurchased under the accelerated share repurchase agreement will be retired. As of October 31, 2008, the remaining authorized amount of stock repurchases that may be made under the \$3.00 billion stock repurchase program which expires in December 2010 was \$1.00 billion.

### *Other Information*

As of September 30, 2008, we had an uncollateralized revolving credit facility of \$1.25 billion, of which there were no amounts outstanding.

On January 1, 2008, we adopted the provisions of SFAS No. 157, *Fair Value Measurements* (SFAS 157) on a prospective basis for our financial assets and liabilities. SFAS 157 requires that we determine the fair value of financial assets and liabilities using the fair value hierarchy established in SFAS 157 and describes three levels of inputs that may be used to measure fair value, as follows:

Level 1 inputs include quoted prices in active markets for identical assets or liabilities and were used to measure the fair value of our U.S. treasury securities which are highly liquid and are actively traded in over-the-counter markets.

Level 2 inputs 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. Level 2 inputs were used to measure the fair value of our municipal securities, agency securities, corporate debt securities, variable rate demand notes, asset-backed securities and derivatives relating to our foreign currency forward and option contracts.

Level 3 inputs 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. Auction rate securities were

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measured using Level 3 inputs. Although auction rate securities would typically be measured using Level 2 inputs as described above, 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 discount rates applied to the discounted cash flow model were based on market conditions for comparable or similar term asset-backed securities as well as other fixed income securities adjusted for an illiquidity discount.

As of September 30, 2008, we had a total of \$2.53 billion of cash equivalents and marketable securities. Of that total, approximately 95%, or \$2.41 billion, of our total portfolio was measured using Level 1 or 2 inputs, while the remainder of our portfolio, or \$122.2 million, was measured using Level 3 inputs. See Part I, Item 3. Quantitative and Qualitative Disclosures about Market Risk for a further discussion of our auction rate securities measured using Level 3 inputs.

### **Recent Accounting Pronouncements**

In June 2008, the Financial Accounting Standards Board (FASB) ratified Emerging Issues Task Force (EITF) Issue No. 07-5, *Determining Whether an Instrument (or Embedded Feature) is Indexed to an Entity's Own Stock* (EITF 07-5). EITF 07-5 provides guidance on how to determine if certain instruments (or embedded features) are considered indexed to our own stock, including instruments similar to our convertible senior notes, convertible note hedges, warrants to purchase our stock and the forward contract that we entered into as part of our accelerated share repurchase program in February 2008 and which was completed in June 2008 and the forward contract that we entered into as part of our accelerated share repurchase program in October 2008. EITF 07-5 requires companies to use a two-step approach to evaluate an instrument's contingent exercise provisions and settlement provisions in determining whether the instrument is considered to be indexed to its own stock and exempt from the application of SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*. Although EITF 07-5 is effective for fiscal years beginning after December 15, 2008, any outstanding instrument at the date of adoption will require a retrospective application of the accounting through a cumulative effect adjustment to retained earnings upon adoption. We do not expect the adoption of EITF 07-5 to have a material impact on our consolidated financial position or results of operations.

In May 2008, the FASB issued FASB Staff Position No. APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)* (FSP APB 14-1). FSP APB 14-1 addresses instruments commonly referred to as Instrument C from EITF Issue No. 90-19, *Convertible Bonds with Issuer Option to Settle for Cash upon Conversion*, which requires the issuer to settle the principal amount in cash and the conversion spread in cash or net shares at the issuer's option. FSP APB 14-1 requires that issuers of these instruments account for their liability and equity components separately by bifurcating the conversion option from the debt instrument, classifying the conversion option in equity and then accreting the resulting discount on the debt as additional interest expense over the expected life of the debt. FSP APB 14-1 is effective for fiscal years beginning after December 15, 2008 and interim periods within those fiscal years, and requires retrospective application to all periods presented. Early application is not permitted. We expect that the adoption of FSP APB 14-1 will have a material impact on our consolidated financial position and results of operations. Based on the requirements of FSP APB 14-1, we estimate that if FSP APB 14-1 was effective for the current and comparative periods, we would have reported additional interest expense related to our Notes of approximately \$13.5 million and \$39.5 million during the three and nine months ended September 30, 2008, respectively, and \$12.7 million and \$37.1 million during the three and nine months ended September 30, 2007, respectively.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements, an amendment of Accounting Research Bulletin No. 51, Consolidated Financial Statements* (SFAS

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160). SFAS 160 establishes accounting and reporting standards for ownership interests in subsidiaries held by parties other than the parent, the amount of consolidated net income (loss) attributable to the parent and to the noncontrolling interests, changes in a parent's ownership interest and the valuation of retained noncontrolling equity investments when a subsidiary is deconsolidated. SFAS 160 also establishes additional reporting requirements that identify and distinguish between the ownership interest of the parent and the interest of the noncontrolling owners. SFAS 160 is effective for interim periods and fiscal years beginning after December 15, 2008. Upon adopting SFAS 160, we plan to reclassify the noncontrolling interest, or minority interest, on our consolidated balance sheet from liabilities to stockholders' equity and to present the noncontrolling interest, or minority interest, on our statement of income as net income attributable to the noncontrolling interest, which will be a component of total net income.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), *Business Combinations* (SFAS 141R). SFAS 141R establishes principles and requirements for recognizing and measuring assets acquired, liabilities assumed and any noncontrolling interests in the acquiree in a business combination. SFAS 141R also provides guidance for recognizing and measuring goodwill acquired in a business combination; requires purchased IPR&D to be capitalized at fair value as intangible assets at the time of acquisition; requires acquisition-related expenses and restructuring costs to be recognized separately from the business combination; and requires the acquirer to disclose information that users may need to evaluate and understand the financial effect of the business combination. SFAS 141R is effective on a prospective basis and will impact business combination transactions for which the acquisition date occurs in fiscal years beginning after December 15, 2008. Depending on the nature and magnitude of our future business combination transactions, SFAS 141R may have a material impact on our consolidated financial position and/or results of operations.

### **Off-Balance Sheet Arrangements**

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

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

There have been no material changes in our market risk during the nine months ended September 30, 2008 compared to the disclosures in Part II, Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2007.

A portion of our marketable securities are held in auction rate securities. During the quarter ended March 31, 2008, we began observing the failed auctions for our auction rate securities for which the underlying assets are comprised of student loans. Most of our auction rate securities, including those subject to the failed auctions, are currently rated AAA, consistent with the high quality rating required by our investment policy, are supported by the federal government as part of the Federal Family Education Loan Program, and are over-collateralized. Our auction rate securities reset every seven to 35 days with maturity dates ranging from 2023 through 2041 and have interest rates ranging from 2.8% to 13.9%. As of September 30, 2008, 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, we believe that, 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 are able to hold these securities until there is a recovery in the auction market and the related securities, which may be at final maturity. As a result, we do not anticipate that the current illiquidity of these auction rate securities will have a material effect on our cash requirements or working capital.

In light of the volatility and developments that we have seen in the financial markets, we continued to review our cash equivalents and marketable securities carefully as well as invest prudently. We believe that

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maintaining the primary goals of our investment policy, safety and preservation of principal and diversification of risk, as well as liquidity, has protected us from much of the risks in the credit markets while allowing us to continue to meet our operating cash flow requirements as well as execute on other opportunities such as our \$750.0 million accelerated share repurchase.

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

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

An evaluation as of September 30, 2008 was carried out under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures, which are defined under Securities and Exchange Commission (SEC) rules as controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Securities Exchange Act of 1934, as amended, (Exchange Act) is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at September 30, 2008.

#### **Changes in Internal Control over Financial Reporting**

Our management, including our Chief Executive Officer and Chief Financial Officer, has evaluated any changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2008, and has concluded that there was no change during such quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

#### **Limitations on the Effectiveness of Controls**

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

## **PART II. OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

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

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### **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. 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 risk 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 a limited number of products. If we are unable to maintain or continue increasing sales of our HIV products, our results of operations may be adversely affected.**

We are currently dependent on sales of our products for the treatment of HIV, especially Truvada and Atripla, to support our existing operations. Our HIV products contain tenofovir disoproxil fumarate and/or emtricitabine, which belong to the nucleoside class of antiviral therapeutics. Were the treatment paradigm for HIV to change, causing nucleoside-based therapeutics to fall out of favor, or if we were unable to continue increasing our HIV product sales, our results of operations would likely suffer and we would likely need to scale back our operations, including our spending on research and development (R&D) efforts. HIV product sales for the third quarter of 2008 were \$1.14 billion, or 83% of our total revenues, and sales of Truvada and Atripla accounted for 48% and 38%, respectively, of our total HIV product sales during the third quarter of 2008. We may not be able to sustain the growth rate of sales of our HIV products for the reasons stated in this risk factor section and, in particular, for the following reasons:

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 may be affected.

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

During the nine months ended September 30, 2008, approximately 89% of our product sales in the United States were to three wholesalers, Cardinal Health, Inc., McKesson Corp. and AmerisourceBergen Corp. Inventory levels held by those wholesalers can cause our operating results to fluctuate unexpectedly if our sales to wholesalers do not match end user demand. The U.S. wholesalers with whom we have entered into inventory management agreements may not be completely effective in matching inventory levels to end user demand, as they make estimates to determine end user demand. The non-retail sector in the United States, which includes government institutions, including state AIDS Drug Assistance Programs (ADAP), correctional facilities and large health maintenance organizations, tends to be less consistent in terms of buying patterns, and often causes quarter over quarter fluctuations that do not necessarily mirror the purchasing patterns that can be seen of the retail sector. For example, in the first quarter of 2008, we observed large non-retail purchases by a small number

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of state ADAPs that purchase centrally and have significant warehousing capacity. We believe such purchases were driven by the grant cycle for federal ADAP funds rather than current patient demand, which tempered orders and our associated product sales, revenues and earnings in the second quarter of 2008 as these organizations depleted their increased inventory levels established during the first quarter of 2008. We expect to continue to experience fluctuations in the purchasing patterns of our non-retail customers which may result in similar fluctuations in our product sales, revenues and earnings in the future.

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

### **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 or increase revenues from our existing products, we will not be able to increase or maintain our total revenues. Each new product commercialization effort, including Letairis for the treatment of pulmonary arterial hypertension (PAH), which we launched in the United States in June 2007, and Viread for the treatment of chronic hepatitis B, which we launched in Europe in April 2008 and in the United States in August 2008, will face the risks outlined in this section. If we fail to increase sales of our products or bring new products to market, we may not be able to increase revenues and expand our R&D efforts. The marketing authorization application submitted by us for aztreonam for inhalation for the treatment of cystic fibrosis (CF) in the United States was recently delayed when we received a complete response letter from the FDA informing us that the FDA cannot approve the application in its current form and requesting we conduct an additional Phase 3 clinical study. We are working with the FDA to determine whether further analyses of the existing data could lead to approval or whether we will need to conduct an additional study. Existing data from any ongoing or from any further clinical trials that we may commence to satisfy FDA concerns may not support FDA approval of aztreonam for inhalation, which may cause us considerable expense and may lead to further delays or cause us to abandon further development of the product. There are also risks that health authorities in other countries where new drug applications are pending will undertake similar additional reviews which would compound the risks described above.

Further, in December 2007, the Committee for Medicinal Product for Human Use of the European Medicines Agency (EMA) granted marketing authorization for Atripla in the European Union for the treatment of HIV-1 infection in adults with virologic suppression to HIV-1 RNA levels of less than 50 copies/mL on their current combination antiretroviral therapy for more than three months. Patients must not have experienced virological failure on any prior antiretroviral therapy and must be known not to have harbored virus strains with mutations conferring significant resistance to any of the three components contained in Atripla. This restriction of Atripla's use in the European Union will prevent us from promoting Atripla for use in patients who are not currently achieving this reduction in viral load through the use of antiretroviral therapy, including newly diagnosed patients. If we seek to expand the indication for Atripla in the European Union, the EMA may require us to perform additional clinical trials, which we may be unable to complete. If we are unable to expand the indication for Atripla to include a broader population of patients, the impact to future sales of Atripla in the European Union is unknown but could be more limited than in other markets, including the United States, where we have no such restrictions. In addition, sales of Atripla may increase at the expense of product sales of its component products and our overall total revenues and gross margin may not increase as Atripla sales increase.

We face numerous risks and uncertainties with our product candidates, including elvitegravir, our novel HIV integrase inhibitor and darusentan for the treatment of resistant hypertension, both currently in Phase 3 clinical trials, which 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.

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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.

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

A significant percentage of our product sales are denominated in foreign currencies, primarily the Euro. We use foreign currency forward and option contracts to hedge a percentage of our forecasted international sales, primarily those denominated in the Euro. We also hedge a portion of our accounts receivable balances denominated in foreign currencies, which reduces but does not eliminate our exposure to currency fluctuations between the date a sale is recorded and the date that cash is collected. 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 increase. 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. Recently the U.S. dollar has appreciated against major European currencies, and the amount of the favorable impact on our product sales which resulted from the previously relatively weak U.S. dollar has decreased. The net foreign currency exchange impact on our third quarter 2008 revenues and pre-tax earnings, which includes revenues and expenses generated from outside the United States, was a favorable \$58.8 million and \$36.7 million, respectively, compared to the third quarter of 2007. Though we cannot predict future fluctuations in the foreign exchange rate of the U.S. dollar, if the U.S. dollar continues to appreciate against certain currencies and our hedging program does not sufficiently offset the effects of such appreciation, our results of operation will be adversely affected.

### **We face significant competition.**

We face significant competition from large pharmaceutical and biotechnology companies, most of whom have substantially greater resources than we do. In addition, our competitors have more products and have operated in the fields in which we compete for longer than we have. Our HIV products compete primarily with products from GlaxoSmithKline Inc. (GSK), which markets fixed-dose combination products that compete with Truvada and Atripla. For Hepsera and Viread for treatment of chronic hepatitis B, we compete primarily with products produced by GSK, Bristol-Myers Squibb Company (BMS) and Novartis Pharmaceuticals Corporation (Novartis) in the United States, the European Union and China. For AmBisome, we compete primarily with products produced by Merck & Co., Inc. (Merck) and Pfizer Inc. (Pfizer). In addition, we are aware of at least three lipid formulations that claim similarity to AmBisome becoming available outside of the United States, including the possible entry of two such formulations in Greece. These formulations may reduce market demand for AmBisome. Furthermore, the manufacture of lipid formulations of amphotericin B is very complex and if any of these formulations are found to be unsafe, sales of AmBisome may be negatively impacted by association. Letairis competes directly with Actelion Pharmaceuticals US, Inc. (Actelion) and indirectly with PAH products from United Therapeutics Corporation and Pfizer. Tamiflu competes with products sold by GSK and generic competitors. In addition, BioCryst Pharmaceuticals, Inc. is developing injectable formulations of peramivir, an influenza neuraminidase inhibitor, which is currently in Phase 2 clinical trials, and, if approved, would compete with Tamiflu. Aztreonam for inhalation for the treatment of CF, if approved for marketing, will compete with a product marketed by Novartis.

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

The data supporting the marketing approvals for our products and forming the basis for the safety warnings in our product labels were obtained in controlled clinical trials of limited duration and, in some cases, from post-approval use. As our products are used over longer periods of time by many patients with underlying health

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problems, taking numerous other medicines, we expect to continue to find new issues such as safety, resistance or drug interaction issues, which may require us to provide additional warnings or contraindications on our labels or narrow our approved indications, each of which could reduce the market acceptance of these products.

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

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

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

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

In September 2008, we received a complete response letter from the FDA informing us that the FDA cannot approve our NDA for aztreonam for inhalation for treatment of CF in its current form and requesting we conduct an additional Phase 3 clinical study. We are working with the FDA to determine whether further analyses of the existing data could lead to approval or whether we will need to conduct an additional study. Existing data from any ongoing or from any further clinical trials that we may commence to satisfy FDA concerns may not support FDA approval of aztreonam for inhalation, which may cause us considerable expense and may lead to further delays or cause us to abandon further development of the product. There are also risks that health authorities in other countries where new drug applications are pending will undertake similar additional reviews which would compound the risks described above.

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

On September 27, 2007, President Bush signed into law the Food and Drug Administration Amendments Act of 2007 (FDAAA), 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

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

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

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

We are required to demonstrate the safety and efficacy of products that we develop for each intended use through extensive preclinical studies and clinical trials. The results from preclinical and early clinical studies do not always accurately predict results in later, large-scale clinical trials. Even successfully completed large-scale clinical trials may not result in marketable products. If any of our product candidates fails to achieve its primary endpoint in clinical trials, if safety issues arise or if the results of our clinical trials are otherwise inadequate to support regulatory approval of our product candidates, commercialization of that product candidate could be delayed or halted. We may also face challenges in clinical trial protocol design. If the clinical trials for any of the product candidates in our pipeline are delayed or terminated, our prospects for future revenue growth would be adversely impacted. In addition, clinical trials involving our commercial products could raise new safety issues for our existing products, which could in turn decrease our revenues and harm our business.

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

We extensively outsource our clinical trial activities and usually perform only a small portion of the start-up activities in-house. We rely on independent third-party contract research organizations (CROs), over which we do not have control, to perform most of our clinical studies, including document preparation, site identification, screening and preparation, pre-study visits, training, program management and bioanalytical analysis. If there is any dispute or disruption in our relationship with our CROs, our clinical trials may be delayed. Moreover, in our regulatory submissions, we rely on the quality and validity of the clinical work performed by third-party CROs. If any of our CROs' processes, methodologies or results were determined to be invalid or inadequate, our own clinical data and results and related regulatory approvals could be adversely impacted. In February 2007, we were advised by the FDA that it discovered certain irregularities during its inspection of bioanalytical analyses conducted for various organizations by one of our third-party CROs. During the period under review, the CRO performed bioanalytical analyses in studies for certain of our products. In February 2008, we received correspondence from the FDA requesting that we verify results obtained by the CRO for certain studies through the conduct of an audit and that we make changes to the presentation of certain clinical pharmacology data in product labeling. If the results of an audit prove unsatisfactory, possible outcomes include a requirement to repeat the affected clinical pharmacology studies and/or to further modify the clinical pharmacology data contained in the product label.

### **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 Truvada, Atripla, Viread, Hepsera, Emtriva, Letairis and Vistide. 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 and third-party manufacturers are subject to the FDA's current Good Manufacturing Practices (GMP), which are extensive regulations governing manufacturing processes, stability testing, record-keeping and quality standards. Similar regulations are in effect in other countries. Our manufacturing operations are also subject to routine inspections by regulatory agencies. Additionally, these third-party manufacturers are

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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 fail to perform as required, this could impair our ability to deliver our products on a timely basis or receive royalties or cause delays in our clinical trials and applications for regulatory approval. To the extent these risks materialize and affect their performance obligations to us, our financial results may be adversely affected.

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

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

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

We need access to certain supplies and products to conduct our clinical trials and to manufacture our products. Our inability to obtain any of these materials in a timely manner may delay our development efforts for our product candidates or limit our ability to manufacture our products, which would limit our ability to generate revenues.

Suppliers of key components and materials must be named in an NDA filed with the FDA for any product candidate for which we are seeking FDA approval, and significant delays can occur if the qualification of a new supplier is required. Even after a manufacturer is qualified by the FDA, the manufacturer must continue to expend time, money and effort in the area of production and quality control to ensure full compliance with GMP. Manufacturers are subject to regular, periodic inspections by the FDA following initial approval. If, as a result of these inspections, the FDA determines that the equipment, facilities, laboratories or processes do not comply with applicable FDA regulations and conditions of product approval, the FDA may suspend the manufacturing operations. If the manufacturing operations of any of the single suppliers for our products are suspended, we may be unable to generate sufficient quantities of commercial or clinical supplies of product to meet market demand, which would in turn decrease our revenues and harm our business.

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

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

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

**We 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 other companies could negatively impact our business.**

We rely on a number of significant collaborative relationships with major pharmaceutical companies for our sales and marketing performance in certain territories. These include collaborations with BMS for Atripla in the United States, Europe and Canada; Roche for Tamiflu; and GSK for ambrisentan in territories outside of the United States. In many 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:

inability to control the resources our corporate partners devote to our programs or products;

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

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

corporate partners having 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;

corporate partners with marketing rights that 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

distributors and corporate partners that may be unable to pay us.

Given these risks, there is a great deal of uncertainty regarding the success of our current and future collaborative efforts. If these efforts fail, our product development or commercialization of new products could be delayed or revenues from products could decline.

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

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

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

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not effectively sell or support Letairis;

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

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

cease operations.

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

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

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

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

obtain patents and licenses to patent rights;

preserve trade secrets; and

operate without infringing on the proprietary rights of others.

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



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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 at least some period of time until a patent is issued. As a result, we may not know if our competitors filed patent applications for technology covered by our pending applications or if we were the first to invent the technology that is the subject of our patent applications. Competitors may have filed patent applications or received patents and may obtain additional patents and proprietary rights that block or compete with our patents. In addition, if competitors file patent applications covering our technology, we may have to participate in interference proceedings or litigation to determine the right to a patent. Litigation and interference proceedings are expensive even if we are ultimately successful.

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

Although we were successful in responding to the PTO office actions, similar organizations may still challenge our patents in foreign jurisdictions. For example, in April 2008, the Brazilian Health Ministry, citing the pending 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 DF 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 DF we have filed in Brazil. The next step in the process is for us to respond to this final rejection by filing an appeal within the patent authority responding to the questions raised in the rejection. We cannot predict the outcome of these proceedings on our tenofovir DF patent application. If we are unsuccessful in these proceedings, and thereafter unable to successfully appeal the decision by the patent authority in the courts, the Brazilian patent authority will reject the tenofovir DF patent application. If the tenofovir DF patent application is rejected by the Brazilian patent authority, the Brazilian government would likely purchase generic tenofovir DF, which would significantly reduce our sales of HIV products in Brazil.

Patents do not cover the active ingredients in AmBisome. In addition, we do not have patent filings in China or certain other Asian countries covering all forms of adefovir dipivoxil, the active ingredient in Hepsera. Asia is a major market for therapies for hepatitis B infection, the indication for which Hepsera has been developed. Flolan's patent and market exclusivity protection has expired. As a result, one or more generic pharmaceutical companies may launch a generic version of Flolan in the United States.

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

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

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In August 2007, the PTO adopted new rules which were scheduled to become effective on November 1, 2007. In October 2007, GSK successfully obtained a preliminary injunction against implementation of these rules, and in April 2008, the court ruled in support of GSK's challenge to the rules and obtained a permanent injunction against their implementation. The rules would have restricted the number of claims permitted in a patent application and the number of continuing patent applications that can be filed. Following the court's ruling, the PTO filed a notice of appeal to the Federal Court of Appeals. If the PTO successfully appeals the court's decision and the rules are implemented, we may be limited in our ability to obtain broad patent coverage for our products and product candidates and this may allow competitors to market products very similar to ours or to obtain patent coverage for closely related products.

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

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

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

### **We 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. Our accounts receivable from government-owned or supported customers in these countries totaled approximately \$556.2 million as of September 30, 2008. Historically, receivables accumulated over a period of time and were settled as large lump sum payments as government funding became available. If significant changes were to occur in the reimbursement practices of these European governments or if government funding becomes unavailable, we may not be able to collect on amounts due to us from these customers and our results of operations would be adversely affected.

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

Prices for our products are based on local market economics and competition and sometimes differ from country to country. Our sales in countries with relatively higher prices may be reduced if products can be imported into those or other countries from lower price markets. There have been cases in which other pharmaceutical products were sold at steeply discounted prices in the developing world and then re-exported to European countries where they could be re-sold at much higher prices. If this happens with our products, particularly Truvada and Viread, which we have agreed to make available at substantially reduced prices to more than 125 countries participating in our Gilead Access Program, or Atripla, which Merck distributes at substantially reduced prices to HIV-infected patients in developing countries under our August 2006 agreement, our revenues would be adversely affected. In addition, we have established partnerships with ten Indian generic manufacturers to distribute high-quality, low-cost generic versions of tenofovir disoproxil fumarate to 95 developing world countries, including India. If generic versions of our medications under these licenses are then re-exported to the United States, Europe or other markets outside of these 95 countries, our revenues would be adversely affected.

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

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

In a number of developing countries, government officials and other interested groups have suggested that pharmaceutical companies should make drugs for HIV infection available at low cost. Alternatively, governments in those developing countries could require that we grant compulsory licenses to allow competitors to manufacture and sell their own versions of our products, thereby reducing our product sales. For example, in the past, certain offices of the government of Brazil have expressed concern over the affordability of our HIV products and declared that they were considering issuing compulsory licenses to permit the manufacture of otherwise patented products for HIV infection, including Viread. As a result of discussions with the Brazilian government, we reached agreement with the Brazilian Health Ministry in May 2006 to reduce the price of Viread in Brazil by approximately 50%. In addition, concerns over the cost and availability of Tamiflu related to a potential avian flu pandemic have generated international discussions over compulsory licensing of our Tamiflu patents. For example, the Canadian government may allow Canadian manufacturers to manufacture and export the active ingredient in Tamiflu to eligible developing and least-developed countries under Canada's Access to Medicines Regime. Furthermore, Roche has issued voluntary licenses to permit third-party manufacturing of Tamiflu. For example, Roche has granted a sublicense to Shanghai Pharmaceutical (Group) Co., Ltd. for China and a sublicense to India's Hetero Drugs Limited for India and certain developing countries. Should one or more compulsory licenses be issued permitting generic manufacturing to override our Tamiflu patents, or should Roche issue additional voluntary licenses to permit third-party manufacturing of Tamiflu, those developments could reduce royalties we receive from Roche's sales of Tamiflu. Certain countries do not permit enforcement of our patents, and 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.

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

Successful commercialization of our products depends, in part, on the availability of governmental and third-party payor reimbursement for the cost of such products and related treatments. Government health administration authorities, private health insurers and other organizations generally provide reimbursement. Government authorities and third-party payors increasingly are challenging the price of medical products and

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services, particularly for innovative new products and therapies. This has resulted in lower average sales prices. For example, a majority of our sales of Truvada, Atripla, Viread, Hepsera, AmBisome, Vistide and Letairis are subject to reimbursement by government agencies, resulting in significant discounts from list price and rebate obligations. Our business may be adversely affected by an increase in pricing pressures in the United States and internationally. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and health care reform, pharmaceutical reimbursement policies and pricing in general.

In Europe, the success of Truvada, Atripla, Viread, Hepsera, Emtriva, AmBisome, Tamiflu and Volibris also depends 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. We also expect that the success of our product candidates, particularly in Europe, will depend on our ability to obtain reimbursement for these product candidates if approved and commercialized. Even if reimbursement is available, reimbursement policies may adversely affect our ability to sell our products on a profitable basis. For example, in Europe as in many international markets, governments control the prices of prescription pharmaceuticals and expect prices of prescription pharmaceuticals to decline over the life of the product or as volumes increase. As new drugs come to market, we may face significant price decreases for our products across most of the European countries. We believe that this will continue into the foreseeable future as governments struggle with escalating health care spending. As a result of these pricing practices, it may become difficult to maintain our historic levels of profitability or to achieve expected rates of growth.

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

Legislative and regulatory changes to government prescription drug procurement and reimbursement programs occur relatively frequently in the United States and foreign jurisdictions. There have been significant changes to the federal Medicare system in recent years in the United States that could impact the pricing of our products. Under the Medicare Prescription Drug Improvement and Modernization Act of 2003, Medicare beneficiaries are now able to elect coverage for prescription drugs under Medicare Part D. The prescription drug program began on January 1, 2006 and although we have benefited initially from patients transitioning from Medicaid to Medicare Part D in 2006, the longer term impact of this new law on our business will depend on several factors. Specifically, some of the entities providing Medicare Part D coverage have attempted to negotiate price concessions from pharmaceutical manufacturers. Discussions are also taking place at the federal level to pass legislation that would either allow or require the federal government to directly negotiate price concessions from pharmaceutical manufacturers. In addition, specific decisions regarding the level of coverage provided for the therapeutic categories in which our products are included, the terms on which such coverage is provided, and the extent to which preference is given to selected products in a category will also determine in part the future impact of Medicare Part D. Finally, Medicare patients have to pay co-insurance, which may influence which products are recommended by physicians and selected by patients. Our results of operations could be materially adversely affected by these and other reimbursement changes emerging from the Medicare prescription drug coverage and possible legislative changes. In addition to federal Medicare proposals, state Medicaid drug payment changes could also lower payment for our products. Specifically, some states have joined together to form Medicaid drug purchasing pools to negotiate additional price concessions from pharmaceutical manufacturers in exchange for inclusion of drugs on state preferred drug lists or formularies. 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. Additionally, health care reform at both the federal and state levels could adversely affect payment for our drugs. At this time, a few states have already enacted health care reform legislation.

### **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

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consumers, healthcare providers, pharmaceutical companies or others. In recent years, coverage and availability of product liability insurance has decreased. In addition, the cost to defend lawsuits or pay damages for product liability claims may exceed our coverage. If we are unable to maintain adequate coverage or if claims exceed our coverage, our financial condition and our ability to clinically test our product candidates and to market our products will be adversely impacted. In addition, negative publicity associated with any claims, regardless of their merit, may impair our financial condition and future demand for our products.

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

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

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

We, along with certain of our officers and a former officer, were named as defendants in a class action lawsuit alleging violations of federal securities laws. The lawsuit was dismissed by the United States District Court for the Northern District of California, but in August 2008 the United States Court of Appeals for the Ninth Circuit reversed the dismissal and will remand the case to the district court.

In addition, in November 2006, we received a subpoena from the U.S. Attorney's Office in San Francisco requesting documents regarding our marketing and medical education programs for Truvada, Viread and Emtriva. We have been cooperating and will continue to cooperate with any related governmental inquiry. The outcome of the class action lawsuit, any other lawsuits brought against us, the investigation or any other such investigations brought against us, are inherently uncertain, and adverse developments or outcomes can result in significant expenses, monetary damages, penalties or injunctive relief against us that could significantly reduce our earnings and cash flows and harm our business.

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

Various factors may have favorable or unfavorable effects on our income tax rate. These factors include, but are not limited to, interpretations of existing tax laws, changes in tax laws and rates, the accounting for stock options and other share-based payments, mergers and acquisitions, changes in accounting standards, changes in our valuation allowance, changes in the mix of earnings in the various tax jurisdictions in which we operate, changes in overall levels of pre-tax earnings and finalization of federal, state and foreign income tax audits. The impact on our income tax provision resulting from the above-mentioned factors may be significant and could have a negative impact on our net income.

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

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

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

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For example, in May 2008, the Financial Accounting Standards Board (FASB) issued FASB Staff Position No. APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)* (FSP APB 14-1). FSP APB 14-1 addresses instruments commonly referred to as Instrument C from Emerging Issues Task Force Issue No. 90-19, *Convertible Bonds with Issuer Option to Settle for Cash upon Conversion*, which requires the issuer to settle the principal amount in cash and the conversion spread in cash or net shares at the issuer's option. FSP APB 14-1 requires that issuers of these instruments account for their liability and equity components separately by bifurcating the conversion option from the debt instrument, classifying the conversion option in equity and then accreting the resulting discount on the debt as additional interest expense over the expected life of the debt. FSP APB 14-1 is effective for fiscal years beginning after December 15, 2008 and interim periods within those fiscal years, and requires retrospective application to all periods presented. Early application is not permitted. We expect that the adoption of FSP APB 14-1 will have a material impact on our consolidated financial position and results of operations. Based on the requirements of FSP APB 14-1, we estimate that if FSP APB 14-1 was effective for the current and comparative periods, we would have reported additional interest expense related to our convertible senior notes of approximately \$13.5 million and \$39.5 million during the three and nine months ended September 30, 2008, respectively, and \$12.7 million and \$37.1 million during the three and nine months ended September 30, 2007, respectively.

In addition, in December 2007, the FASB issued Statement of Financial Accounting Standards (SFAS) No. 141 (revised 2007), *Business Combinations* (SFAS 141R). SFAS 141R establishes principles and requirements for recognizing and measuring assets acquired, liabilities assumed and any noncontrolling interests in the acquiree in a business combination. SFAS 141R also provides guidance for recognizing and measuring goodwill acquired in a business combination; requires purchased in-process research and development to be capitalized at fair value as intangible assets at the time of acquisition; requires acquisition-related expenses and restructuring costs to be recognized separately from the business combination; and requires the acquirer to disclose information that users may need to evaluate and understand the financial effect of the business combination. SFAS 141R is effective on a prospective basis and will impact business combination transactions for which the acquisition date occurs in fiscal years beginning after December 15, 2008. Depending on the nature and magnitude of our future business combination transactions, SFAS 141R may have a material impact on our consolidated financial position and/or 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**

The table below summarizes our stock repurchase activity for the three months ended September 30, 2008 (in thousands, except per share amounts):

|             |                    | Total Number of<br>Shares Purchased | Average Price Paid<br>per Share | Total Number of<br>Shares Purchased<br>as Part of Publicly<br>Announced<br>Programs | Maximum Fair<br>Value of Shares<br>that May Yet<br>Be<br>Purchased Under<br>the Program |
|-------------|--------------------|-------------------------------------|---------------------------------|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| July 1      | July 31, 2008      | 4,000                               | \$ 52.85                        | 4,000                                                                               | \$ 1,790,140                                                                            |
| August 1    | August 31, 2008    | 705                                 | \$ 54.71                        | 705                                                                                 | \$ 1,751,569                                                                            |
| September 1 | September 30, 2008 |                                     | \$                              |                                                                                     | \$ 1,751,569                                                                            |
| Total       |                    | 4,705(1)                            | \$ 53.13                        | 4,705(1)                                                                            |                                                                                         |

- (1) These repurchases are part of the share repurchase program authorized by our board of directors in October 2007 for the repurchase of our common stock in an amount of up to \$3.00 billion through open market and private block transactions, privately negotiated purchases or other means. This stock repurchase program expires in December 2010. During the three months ended September 30, 2008, we repurchased and retired 4,705,000 shares of our common stock at an average purchase price of \$53.13 per share for an aggregate purchase price of \$250.0 million through open market transactions. As of September 30, 2008, the remaining authorized amount of stock repurchases that may be made under our stock repurchase program was \$1.75 billion.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

Not applicable.

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

None.

**ITEM 5. OTHER INFORMATION**

Not applicable.

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**ITEM 6. EXHIBITS**

| <b>Exhibit<br/>Footnote</b> | <b>Exhibit<br/>Number</b> | <b>Description of Document</b>                                                                                                                                                                                                             |
|-----------------------------|---------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| (1)                         | 3.1                       | Restated Certificate of Incorporation of the Registrant                                                                                                                                                                                    |
| (2)                         | 3.2                       | Certificate of Designation of the Series A Junior Participating Preferred Stock of Registrant                                                                                                                                              |
| (3)                         | 3.3                       | Amendment to Certificate of Designation of the Series A Junior Participating Preferred Stock of Registrant                                                                                                                                 |
| (4)                         | 3.4                       | Amended and Restated Bylaws of the Registrant, as amended and restated on October 24, 2008                                                                                                                                                 |
|                             | 4.1                       | Reference is made to Exhibit 3.1, Exhibit 3.2, Exhibit 3.3 and Exhibit 3.4                                                                                                                                                                 |
| (5)                         | 4.2                       | Amended and Restated Rights Agreement between the Registrant and ChaseMellon Shareholder Services, LLC, dated October 21, 1999                                                                                                             |
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| *(9)                        | 10.4                      | Form of option agreements used under the 1991 Stock Option Plan                                                                                                                                                                            |
| +(9)                        | 10.5                      | Letter Agreement between Registrant and IOCB/REGA, dated September 23, 1991                                                                                                                                                                |
| *(11)                       | 10.6                      | Registrant's Employee Stock Purchase Plan, as amended through May 9, 2007                                                                                                                                                                  |
| *(12)                       | 10.7                      | Registrant's 1991 Stock Option Plan and related agreements, as amended and restated April 5, 2000, as amended January 18, 2001 and as amended January 30, 2002                                                                             |

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| *(12), (13)                 | 10.8                      | Registrant's 1995 Non-Employee Directors' Stock Option Plan, including the form of option agreement thereunder, as amended January 26, 1999, and as amended January 30, 2002                                                                                   |
| +(14)                       | 10.9                      | Amendment Agreement between Registrant and IOCB/REGA, dated October 25, 1993                                                                                                                                                                                   |
| (15)                        | 10.10                     | Amendment Agreement between Registrant and IOCB/REGA, dated December 27, 2000                                                                                                                                                                                  |
| +(16)                       | 10.11                     | Development and License Agreement among Registrant and F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc., dated September 27, 1996                                                                                                                           |
| +(17)                       | 10.12                     | Settlement Agreement between Registrant (as successor to NeXstar Pharmaceuticals, Inc.), Astellas Pharma Inc. (as successor to Fujisawa U.S.A., Inc.) and The Liposome Company, Inc., dated August 11, 1997                                                    |
| *(18)                       | 10.13                     | Gilead Sciences, Inc. Deferred Compensation Plan Basic Plan Document                                                                                                                                                                                           |
| *(18)                       | 10.14                     | Gilead Sciences, Inc. Deferred Compensation Plan Adoption Agreement                                                                                                                                                                                            |
| *(18)                       | 10.15                     | Addendum to the Gilead Sciences, Inc. Deferred Compensation Plan                                                                                                                                                                                               |
| +(19)                       | 10.16                     | Licensing Agreement between Gilead Sciences Limited and Glaxo Group Limited, dated April 26, 2002                                                                                                                                                              |
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| +(22)                       | 10.20                     | Master Clinical and Commercial Supply Agreement between Gilead Sciences Limited, Ltd., Registrant and Patheon Inc., dated January 1, 2003                                                                                                                      |
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| +(23)                       | 10.22                     | License Agreement between Japan Tobacco Inc. and Registrant, dated March 22, 2005                                                                                                                                                                              |
| +(24)                       | 10.23                     | Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Gilead Sciences Limited and PharmaChem Technologies (Grand Bahama), Ltd., dated July 17, 2003                                                                                      |
| +(24)                       | 10.24                     | 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                                                          |
| +(24)                       | 10.25                     | 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                                               |

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| Exhibit<br>Footnote | Exhibit<br>Number | Description of Document                                                                                                                                                                                                                               |
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| *(25)               | 10.26             | Form of employee stock option agreement used under 2004 Equity Incentive Plan                                                                                                                                                                         |
| *(25)               | 10.27             | Form of non-employee stock option agreement used under 2004 Equity Incentive Plan                                                                                                                                                                     |
| *(25)               | 10.28             | Gilead Sciences, Inc. Corporate Bonus Plan                                                                                                                                                                                                            |
| +(26)               | 10.29             | 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                                                    |
| +(26)               | 10.30             | Restated and Amended Toll Manufacturing Agreement between Gilead Sciences Limited, Registrant and ALTANA Pharma Oranienburg GmbH, dated November 7, 2005                                                                                              |
| +(27)               | 10.31             | Amended and Restated Agreement between Registrant (as successor to Vestar, Inc.) and Astellas Pharma Inc. (as successor to Fujisawa USA, Inc.), dated June 10, 2004                                                                                   |
| *(3)                | 10.32             | Gilead Sciences, Inc. Code Section 162(m) Bonus Plan                                                                                                                                                                                                  |
| (28)                | 10.33             | 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.                                                                    |
| (28)                | 10.34             | 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.                                                                    |
| (28)                | 10.35             | 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                                                               |
| (28)                | 10.36             | 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                                                               |
| +(28)               | 10.37             | Emtricitabine Manufacturing Supply Agreement between Gilead Sciences Limited and Degussa AG, dated June 6, 2006                                                                                                                                       |
| *(16)               | 10.38             | Form of Restricted Award Agreement used under 2004 Equity Incentive Plan                                                                                                                                                                              |
| (16)                | 10.39             | Sixth Amendment Agreement to the License Agreement, between the Institute of Organic Chemistry and Biochemistry of the Academy of Sciences of the Czech Republic, and the K. U. Leuven Research and Development and Registrant, dated August 18, 2006 |
| +(16)               | 10.40             | Amended and Restated Collaboration Agreement by and among Registrant, Gilead Holdings, LLC, Bristol-Myers Squibb Company, E.R. Squibb & Sons, L.L.C., and Bristol-Myers Squibb & Gilead Sciences, LLC, dated September 28, 2006                       |
| *(10)               | 10.41             | Form of Performance Share Award Agreement used under the 2004 Equity Incentive Plan                                                                                                                                                                   |
| +(29)               | 10.42             | License Agreement between Registrant (as successor to Myogen, Inc.) and Abbott Laboratories, dated June 30, 2003                                                                                                                                      |
| +(29)               | 10.43             | License Agreement between Registrant (as successor to Myogen, Inc.) and Abbott Deutschland Holding GmbH dated October 8, 2001                                                                                                                         |
| +(30)               | 10.44             | License Agreement between Registrant (as successor to Myogen, Inc.) and Glaxo Group Limited, dated March 3, 2006                                                                                                                                      |

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| Exhibit<br>Footnote | Exhibit<br>Number | Description of Document                                                                                                                                                                                                          |
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| +(31)               | 10.45             | 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)               | 10.46             | Form of Restricted Stock Unit Issuance Agreement of the Company                                                                                                                                                                  |
| (33)                | 10.47             | Credit Agreement, dated as of December 18, 2007, 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 |
| (33)                | 10.48             | Parent Guaranty Agreement, dated as of December 18, 2007, by Registrant                                                                                                                                                          |
| *(34)               | 10.49             | 2008 Base Salaries for the Named Executive Officers                                                                                                                                                                              |
| *(35)               | 10.50             | Offer Letter dated October 4, 2007 between Registrant and Caroline Dorsa                                                                                                                                                         |
| *(35)               | 10.51             | Gilead Sciences, Inc. 2005 Deferred Compensation Plan, as amended and restated effective January 1, 2008                                                                                                                         |
| +(35)               | 10.52             | Commercialization Agreement dated December 10, 2007, by and between Gilead Sciences Limited and Bristol-Myers Squibb Company                                                                                                     |
| *(35)               | 10.53             | Form of employee stock option agreement used under 2004 Equity Incentive Plan (revised in January 2008)                                                                                                                          |
| *(35)               | 10.54             | Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for initial grants; revised in January 2008)                                                                                               |
| *(35)               | 10.55             | Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for annual grants; revised in January 2008)                                                                                                |
| *(36)               | 10.56             | Form of Performance Share Award Agreement used under 2004 Equity Incentive Plan (for award grants in January 2008)                                                                                                               |
| (37)                | 10.57             | Master Confirmation, dated as of October 21, 2008 by and between Registrant and Citibank N.A., together with the Supplemental Confirmation                                                                                       |
| +(36)               | 10.58             | Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement dated March 6, 2008 by and between Registrant and Ampac Fine Chemicals LLC                                                                                          |
| *(38)               | 10.59             | Gilead Sciences, Inc. 2004 Equity Incentive Plan, as amended through May 8, 2008                                                                                                                                                 |
| *(38)               | 10.60             | Gilead Sciences, Inc. Severance Plan, as amended and restated effective May 7, 2008                                                                                                                                              |
| *(38)               | 10.61             | Offer Letter dated April 16, 2008 between Registrant and Robin Washington                                                                                                                                                        |
|                     | 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**              | 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)                    |

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- (1) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on May 9, 2008, and incorporated herein by reference.
- (2) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on November 22, 1994, and incorporated herein by reference.
- (3) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on May 11, 2006, and incorporated herein by reference.
- (4) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on October 28, 2008, and incorporated herein by reference.
- (5) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on October 22, 1999, and incorporated herein by reference.
- (6) Filed as an exhibit to the Registrant's Current Report on Form 8-K filed on October 31, 2003, and incorporated herein by reference.
- (7) 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.
- (8) Filed as an exhibit to the Registrant's Current Report on Form 8-K filed on April 25, 2006, and incorporated herein by reference.
- (9) Filed as an exhibit to Registrant's Registration Statement on Form S-1 (No. 33-55680), as amended, and incorporated herein by reference.
- (10) 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.
- (11) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on May 11, 2007, and incorporated herein by reference.
- (12) 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.
- (13) 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.
- (14) 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.
- (15) 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.
- (16) 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.
- (17) Filed as an exhibit to NeXstar Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 1997, and incorporated herein by reference.
- (18) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2001, and incorporated herein by reference.
- (19) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, and incorporated herein by reference.
- (20) Filed as an exhibit to Triangle Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 1999, and incorporated herein by reference.
- (21) Filed as an exhibit to Triangle Pharmaceuticals, Inc.'s Current Report on Form 8-K filed on September 19, 2002, and incorporated herein by reference.
- (22) 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.
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- (24) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2005, and incorporated herein by reference.
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- (26) 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.
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- (29) 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.
- (30) Filed as an exhibit to Myogen, Inc.'s Quarterly Report on Form 10-Q filed on May 9, 2006, and incorporated herein by reference.
- (31) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on August 7, 2007, and incorporated herein by reference.
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\* Management contract or compensatory plan or arrangement.

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

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

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**SIGNATURES**

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

GILEAD SCIENCES, INC.  
(Registrant)

Date: October 31, 2008

/s/ JOHN C. MARTIN  
**John C. Martin, Ph.D.**  
**Chairman and Chief Executive Officer**

**(Principal Executive Officer)**

Date: October 31, 2008

/s/ ROBIN L. WASHINGTON  
**Robin L. Washington**  
**Senior Vice President and Chief Financial Officer**

**(Principal Financial and Accounting Officer)**

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**Exhibit Index**

**(a) Exhibits**

| <b>Exhibit<br/>Footnote</b> | <b>Exhibit<br/>Number</b> | <b>Description of Document</b>                                                                                                                                                                                                             |
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| (1)                         | 3.1                       | Restated Certificate of Incorporation of the Registrant                                                                                                                                                                                    |
| (2)                         | 3.2                       | Certificate of Designation of the Series A Junior Participating Preferred Stock of Registrant                                                                                                                                              |
| (3)                         | 3.3                       | Amendment to Certificate of Designation of the Series A Junior Participating Preferred Stock of Registrant                                                                                                                                 |
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| (28)                        | 10.34                     | 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.                                                                    |
| (28)                        | 10.35                     | 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                                                               |
| (28)                        | 10.36                     | 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                                                               |
| +(28)                       | 10.37                     | Emtricitabine Manufacturing Supply Agreement between Gilead Sciences Limited and Degussa AG, dated June 6, 2006                                                                                                                                       |
| *(16)                       | 10.38                     | Form of Restricted Award Agreement used under 2004 Equity Incentive Plan                                                                                                                                                                              |
| (16)                        | 10.39                     | Sixth Amendment Agreement to the License Agreement, between the Institute of Organic Chemistry and Biochemistry of the Academy of Sciences of the Czech Republic, and the K. U. Leuven Research and Development and Registrant, dated August 18, 2006 |
| +(16)                       | 10.40                     | Amended and Restated Collaboration Agreement by and among Registrant, Gilead Holdings, LLC, Bristol-Myers Squibb Company, E.R. Squibb & Sons, L.L.C., and Bristol-Myers Squibb & Gilead Sciences, LLC, dated September 28, 2006                       |
| *(10)                       | 10.41                     | Form of Performance Share Award Agreement used under the 2004 Equity Incentive Plan                                                                                                                                                                   |
| +(29)                       | 10.42                     | License Agreement between Registrant (as successor to Myogen, Inc.) and Abbott Laboratories, dated June 30, 2003                                                                                                                                      |

**Table of Contents**

| <b>Exhibit<br/>Footnote</b> | <b>Exhibit<br/>Number</b> | <b>Description of Document</b>                                                                                                                                                                                                   |
|-----------------------------|---------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| +(29)                       | 10.43                     | License Agreement between Registrant (as successor to Myogen, Inc.) and Abbott Deutschland Holding GmbH dated October 8, 2001                                                                                                    |
| +(30)                       | 10.44                     | License Agreement between Registrant (as successor to Myogen, Inc.) and Glaxo Group Limited, dated March 3, 2006                                                                                                                 |
| +(31)                       | 10.45                     | 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)                       | 10.46                     | Form of Restricted Stock Unit Issuance Agreement of the Company                                                                                                                                                                  |
| (33)                        | 10.47                     | Credit Agreement, dated as of December 18, 2007, 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 |
| (33)                        | 10.48                     | Parent Guaranty Agreement, dated as of December 18, 2007, by Registrant                                                                                                                                                          |
| *(34)                       | 10.49                     | 2008 Base Salaries for the Named Executive Officers                                                                                                                                                                              |
| *(35)                       | 10.50                     | Offer Letter dated October 4, 2007 between Registrant and Caroline Dorsa                                                                                                                                                         |
| *(35)                       | 10.51                     | Gilead Sciences, Inc. 2005 Deferred Compensation Plan, as amended and restated effective January 1, 2008                                                                                                                         |
| +(35)                       | 10.52                     | Commercialization Agreement dated December 10, 2007, by and between Gilead Sciences Limited and Bristol-Myers Squibb Company                                                                                                     |
| *(35)                       | 10.53                     | Form of employee stock option agreement used under 2004 Equity Incentive Plan (revised in January 2008)                                                                                                                          |
| *(35)                       | 10.54                     | Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for initial grants; revised in January 2008)                                                                                               |
| *(35)                       | 10.55                     | Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for annual grants; revised in January 2008)                                                                                                |
| *(36)                       | 10.56                     | Form of Performance Share Award Agreement used under 2004 Equity Incentive Plan (for award grants in January 2008)                                                                                                               |
| (37)                        | 10.57                     | Master Confirmation, dated as of October 21, 2008 by and between Registrant and Citibank N.A., together with the Supplemental Confirmation                                                                                       |
| +(36)                       | 10.58                     | Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement dated March 6, 2008 by and between Registrant and Ampac Fine Chemicals LLC                                                                                          |
| *(38)                       | 10.59                     | Gilead Sciences, Inc. 2004 Equity Incentive Plan, as amended through May 8, 2008                                                                                                                                                 |
| *(38)                       | 10.60                     | Gilead Sciences, Inc. Severance Plan, as amended and restated effective May 7, 2008                                                                                                                                              |
| *(38)                       | 10.61                     | Offer Letter dated April 16, 2008 between Registrant and Robin Washington                                                                                                                                                        |

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| <b>Exhibit<br/>Footnote</b> | <b>Exhibit<br/>Number</b>                             | <b>Description of Document</b>                                                                                                                                                                                |
|-----------------------------|-------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                             | 31.1                                                  | Certification of Chief Executive Officer, as required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended                                                                  |
|                             | 31.2                                                  | Certification of Chief Financial Officer, as required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended                                                                  |
|                             | 32**                                                  | Certifications of Chief Executive Officer and Chief Financial Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350) |
| (1)                         | Filed as an exhibit to Registrant                     | s Current Report on Form 8-K filed on May 9, 2008, and incorporated herein by reference.                                                                                                                      |
| (2)                         | Filed as an exhibit to Registrant                     | s Current Report on Form 8-K filed on November 22, 1994, and incorporated herein by reference.                                                                                                                |
| (3)                         | Filed as an exhibit to Registrant                     | s Current Report on Form 8-K filed on May 11, 2006, and incorporated herein by reference.                                                                                                                     |
| (4)                         | Filed as an exhibit to Registrant                     | s Current Report on Form 8-K filed on October 28, 2008, and incorporated herein by reference.                                                                                                                 |
| (5)                         | Filed as an exhibit to Registrant                     | s Current Report on Form 8-K filed on October 22, 1999, and incorporated herein by reference.                                                                                                                 |
| (6)                         | Filed as an exhibit to the Registrant                 | s Current Report on Form 8-K filed on October 31, 2003, and incorporated herein by reference.                                                                                                                 |
| (7)                         | 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.                                                                                           |
| (8)                         | Filed as an exhibit to the Registrant                 | s Current Report on Form 8-K filed on April 25, 2006, and incorporated herein by reference.                                                                                                                   |
| (9)                         | Filed as an exhibit to Registrant                     | s Registration Statement on Form S-1 (No. 33-55680), as amended, and incorporated herein by reference.                                                                                                        |
| (10)                        | 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.                                                                                               |
| (11)                        | Filed as an exhibit to Registrant                     | s Current Report on Form 8-K filed on May 11, 2007, and incorporated herein by reference.                                                                                                                     |
| (12)                        | 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.                                                                                        |
| (13)                        | 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.                                                                                             |
| (14)                        | 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.                                                                                                  |
| (15)                        | 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.                                                                                               |
| (16)                        | 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.                                                                                               |
| (17)                        | Filed as an exhibit to NeXstar Pharmaceuticals, Inc.  | s Quarterly Report on Form 10-Q for the quarter ended September 30, 1997, and incorporated herein by reference.                                                                                               |
| (18)                        | Filed as an exhibit to Registrant                     | s Annual Report on Form 10-K for the fiscal year ended December 31, 2001, and incorporated herein by reference.                                                                                               |
| (19)                        | Filed as an exhibit to Registrant                     | s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, and incorporated herein by reference.                                                                                                    |
| (20)                        | Filed as an exhibit to Triangle Pharmaceuticals, Inc. | s Quarterly Report on Form 10-Q for the quarter ended September 30, 1999, and incorporated herein by reference.                                                                                               |

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- (21) Filed as an exhibit to Triangle Pharmaceuticals, Inc. s Current Report on Form 8-K filed on September 19, 2002, and incorporated herein by reference.
- (22) 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.
- (23) 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.
- (24) 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.
- (25) Filed as an exhibit to Registrant s Current Report on Form 8-K filed on February 22, 2006, 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, 2005, 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, 2006, and incorporated herein by reference.
- (28) 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.
- (29) 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.
- (30) Filed as an exhibit to Myogen, Inc. s Quarterly Report on Form 10-Q filed on May 9, 2006, and incorporated herein by reference.
- (31) Filed as an exhibit to Registrant s Current Report on Form 8-K filed on August 7, 2007, and incorporated herein by reference.
- (32) Filed as an exhibit to Registrant s Current Report on Form 8-K first filed on December 19, 2007, and incorporated herein by reference.
- (33) Filed as an exhibit to Registrant s Current Report on Form 8-K also filed on December 19, 2007, and incorporated herein by reference.
- (34) Filed as an exhibit to Registrant s Current Report on Form 8-K filed on February 5, 2008, and incorporated herein by reference.
- (35) Filed as an exhibit to Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2007, and incorporated herein by reference.
- (36) Filed as an exhibit to Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2008, and incorporated herein by reference.
- (37) Filed as an exhibit to Registrant s Current Report on Form 8-K filed on October 21, 2008, and incorporated herein by reference.
- (38) 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.

\* Management contract or compensatory plan or arrangement.

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

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