

GILEAD SCIENCES INC  
Form 10-Q  
May 04, 2007  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**WASHINGTON, D.C. 20549**

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**FORM 10-Q**

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**x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the quarterly period ended March 31, 2007

or

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

Commission File No. 0-19731

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**GILEAD SCIENCES, INC.**

(Exact Name of Registrant as Specified in Its Charter)

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Delaware  
(State or Other Jurisdiction of

Incorporation or Organization)

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

94-3047598  
(IRS Employer

Identification No.)

94404  
(Zip Code)

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650-574-3000

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

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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, or a non-accelerated filer. (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer

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

Number of shares outstanding of the issuer's common stock, par value \$0.001 per share, as of April 30, 2007: 416,916,711

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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®, HEPSERA®, VIREAD®, VISTIDE®, AMBISOME®, EMTRIVA® and TRUVADA®. ATRIPLA® is a 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>March 31,<br/>2007<br/>(unaudited)</b> | <b>December 31,<br/>2006<br/>(1)</b> |
|---|---|--------------------------------------|
| <b>Assets</b>   |   |                                      |
| Current assets:   |   |                                      |
| Cash and cash equivalents   | \$ 729,142                                | \$ 816,007                           |
| Short-term marketable securities  | 196,594                                   | 120,844                              |
| Accounts receivable, net  | 692,066                                   | 609,320                              |
| Inventories   | 522,410                                   | 564,145                              |
| Deferred tax assets   | 219,700                                   | 245,916                              |
| Prepaid expenses  | 48,526                                    | 50,111                               |
| Other current assets  | 32,121                                    | 22,863                               |
| Total current assets  | 2,440,559                                 | 2,429,206                            |
| Property, plant and equipment, net  | 377,067                                   | 361,299                              |
| Noncurrent portion of prepaid royalties   | 313,512                                   | 317,743                              |
| Noncurrent deferred tax assets  | 356,047                                   | 302,539                              |
| Long-term marketable securities   | 934,722                                   | 452,715                              |
| Goodwill  | 131,409                                   | 162,974                              |
| Other noncurrent assets   | 62,063                                    | 59,505                               |
| Total assets  | \$ 4,615,379                              | \$ 4,085,981                         |
| <b>Liabilities and Stockholders' Equity</b>   |   |                                      |
| Current liabilities:  |   |                                      |
| Accounts payable  | \$ 297,267                                | \$ 367,029                           |
| Accrued clinical and preclinical expenses   | 16,477                                    | 15,693                               |
| Accrued compensation and employee benefits  | 70,501                                    | 75,659                               |
| Income taxes payable  | 19,395                                    | 26,654                               |
| Other accrued liabilities   | 278,911                                   | 242,717                              |
| Deferred revenue  | 27,628                                    | 17,777                               |
| Current portion of other long-term obligations  | 307                                       | 18,747                               |
| Total current liabilities   | 710,486                                   | 764,276                              |
| Long-term deferred revenue  | 68,359                                    | 61,049                               |
| Convertible senior notes  | 1,300,000                                 | 1,300,000                            |
| Other long-term obligations   | 95,966                                    | 91,847                               |
| Minority interest in joint venture  | 57,889                                    | 53,091                               |
| Commitments and contingencies   |   |                                      |
| Stockholders' equity:   |   |                                      |
| Preferred stock, par value \$0.001 per share; 5,000 shares authorized; none outstanding   |   |                                      |
| Common stock, par value \$0.001 per share; 1,400,000 shares authorized; 465,545 and 461,123 shares issued and outstanding at March 31, 2007 and December 31, 2006, respectively | 466                                       | 461                                  |
| Additional paid-in capital  | 2,885,295                                 | 2,704,399                            |
| Accumulated other comprehensive income (loss)   | (5,051)                                   | 2,221                                |
| Accumulated deficit   | (498,031)                                 | (891,363)                            |

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|  |              |              |
|--|--------------|--------------|
| Total stockholders' equity                 | 2,382,679    | 1,815,718    |
| Total liabilities and stockholders' equity | \$ 4,615,379 | \$ 4,085,981 |

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- (1) The condensed consolidated balance sheet at December 31, 2006 has been derived from audited consolidated financial statements at that date but does not include all of the information and footnotes required by United States 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/>March 31,</b> |                   |
|---|---|-------------------|
|   | <b>2007</b>                             | <b>2006</b>       |
| <b>Revenues:</b>                                |   |                   |
| Product sales                                   | \$ 840,225                              | \$ 559,353        |
| Royalty revenue                                 | 180,462                                 | 129,429           |
| Contract and other revenues                     | 7,743                                   | 4,096             |
| <b>Total revenues</b>                           | <b>1,028,430</b>                        | <b>692,878</b>    |
| <b>Costs and expenses:</b>                      |   |                   |
| Cost of goods sold                              | 171,638                                 | 90,357            |
| Research and development                        | 130,090                                 | 88,400            |
| Selling, general and administrative             | 166,558                                 | 142,469           |
| <b>Total costs and expenses</b>                 | <b>468,286</b>                          | <b>321,226</b>    |
| <b>Income from operations</b>                   | <b>560,144</b>                          | <b>371,652</b>    |
| Interest and other income, net                  | 23,104                                  | 28,525            |
| Interest expense                                | (4,547)                                 | (3,724)           |
| Minority interest in joint venture              | 2,153                                   | 994               |
| <b>Income before provision for income taxes</b> | <b>580,854</b>                          | <b>397,447</b>    |
| Provision for income taxes                      | 173,447                                 | 134,743           |
| <b>Net income</b>                               | <b>\$ 407,407</b>                       | <b>\$ 262,704</b> |
| Net income per share basic                      | \$ 0.88                                 | \$ 0.57           |
| Shares used in per share calculation basic      | 463,470                                 | 461,425           |
| Net income per share diluted                    | \$ 0.85                                 | \$ 0.55           |
| Shares used in per share calculation diluted    | 481,358                                 | 481,802           |

See accompanying notes.

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

(unaudited)

(in thousands)

|   | <b>Three Months Ended<br/>March 31,</b> |                  |
|---|---|------------------|
|   | <b>2007</b>                             | <b>2006</b>      |
| <b>OPERATING ACTIVITIES:</b>  |   |                  |
| Net income  | \$ 407,407                              | \$ 262,704       |
| Adjustments to reconcile net income to net cash provided by operating activities: |   |                  |
| Depreciation  | 7,427                                   | 6,948            |
| Amortization  | 4,244                                   | 4,295            |
| Stock-based compensation expense  | 57,294                                  | 29,632           |
| Excess tax benefits from stock-based compensation                                 | (33,770)                                | (37,380)         |
| Tax benefits from employee stock plans  | 39,934                                  |                  |
| Deferred income taxes   | 7,848                                   | (626)            |
| Asset impairment  |   | 7,883            |
| Write-down of inventory   |   | 6,820            |
| Minority interest in joint venture  | (2,153)                                 | (994)            |
| Other non-cash transactions   | 3,103                                   | 4,881            |
| Changes in operating assets and liabilities:                                      |   |                  |
| Accounts receivable, net  | (74,836)                                | (41,329)         |
| Inventories   | 41,923                                  | (13,104)         |
| Prepaid expenses and other assets   | (796)                                   | (5,832)          |
| Accounts payable  | (71,150)                                | (874)            |
| Income taxes payable  | 58,695                                  | 9,642            |
| Accrued liabilities   | 21,211                                  | (7,245)          |
| Deferred revenue  | 17,161                                  | (6,410)          |
| Minority interest in joint venture  | 6,951                                   | 2,883            |
| <b>Net cash provided by operating activities</b>                                  | <b>490,493</b>                          | <b>221,894</b>   |
| <b>INVESTING ACTIVITIES:</b>  |   |                  |
| Purchases of marketable securities  | (825,041)                               | (1,044,377)      |
| Proceeds from sales of marketable securities                                      | 214,251                                 | 278,201          |
| Proceeds from maturities of marketable securities                                 | 45,400                                  | 90,440           |
| Capital expenditures and other  | (25,041)                                | (14,258)         |
| <b>Net cash used in investing activities</b>                                      | <b>(590,431)</b>                        | <b>(689,994)</b> |
| <b>FINANCING ACTIVITIES:</b>  |   |                  |
| Proceeds from issuances of common stock   | 83,586                                  | 43,529           |
| Repayments of long-term debt and other obligations                                | (99,137)                                | (56,132)         |
| Excess tax benefits from stock-based compensation                                 | 33,770                                  | 37,380           |
| <b>Net cash provided by financing activities</b>                                  | <b>18,219</b>                           | <b>24,777</b>    |
| Effect of exchange rate changes on cash   | (5,146)                                 | 4,087            |
| <b>Net decrease in cash and cash equivalents</b>                                  | <b>(86,865)</b>                         | <b>(439,236)</b> |
| Cash and cash equivalents at beginning of period                                  | 816,007                                 | 707,913          |

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Cash and cash equivalents at end of period

\$ 729,142

\$ 268,677

See accompanying notes.



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**GILEAD SCIENCES, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**March 31, 2007**

(unaudited)

**1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Basis of Presentation**

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared in accordance with United States 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.

Preparing financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures. Management evaluates its estimates on an on-going basis, including those related to revenue recognition, allowance for doubtful accounts, inventories, prepaid royalties, clinical trial accruals, income tax provision and stock-based compensation. We base our estimates on historical experience and on various other market-specific and other relevant assumptions that we believe are 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, its wholly owned subsidiaries and its joint venture with Bristol-Myers Squibb Company (BMS), of which we are the primary beneficiary as determined under Financial Accounting Standards Board (FASB) Interpretation No. 46, *Consolidation of Variable Interest Entities* (FIN 46R). We record a minority interest in our Condensed Consolidated Financial Statements to reflect BMS's interest in the joint venture. Significant intercompany transactions have been eliminated.

The accompanying financial information should be read in conjunction with the audited consolidated financial statements for the year ended December 31, 2006, included in our Annual Report on Form 10-K as filed with the Securities and Exchange Commission (SEC).

**Earnings Per Share**

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

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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/>March 31,</b> |             |
|---|---|-------------|
|   | <b>2007</b>                             | <b>2006</b> |
| <b>Numerator:</b>   |   |             |
| Net income  | \$ 407,407                              | \$ 262,704  |
| <b>Denominator:</b>   |   |             |
| Weighted-average shares of common stock outstanding used in calculation of basic earnings per share   | 463,470                                 | 461,425     |
| <b>Effect of dilutive securities:</b>   |   |             |
| Stock options and equivalents   | 17,888                                  | 20,377      |
| Weighted-average shares of common stock outstanding used in calculation of diluted earnings per share | 481,358                                 | 481,802     |

Stock options to purchase approximately 12.2 million and 4.9 million weighted-average shares of common stock were also outstanding during the three months ended March 31, 2007 and 2006, 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. In addition, our diluted earnings per share computation will not give effect to the dilution from the conversion of the Notes until the average share price of our common stock exceeds \$77.50 and \$76.20 for the 2011 Notes and 2013 Notes, respectively.

**2. INVENTORIES**

Inventories are summarized as follows (in thousands):

|                   | <b>March 31,<br/>2007</b> | <b>December 31,<br/>2006</b> |
|-------------------|---------------------------|------------------------------|
| Raw materials     | \$ 215,917                | \$ 361,584                   |
| Work in process   | 112,317                   | 46,163                       |
| Finished goods    | 194,176                   | 156,398                      |
| Total inventories | \$ 522,410                | \$ 564,145                   |

As of March 31, 2007 and December 31, 2006, the joint venture formed by Gilead and BMS, which is included in our Condensed Consolidated Financial Statements, held \$87.5 million and \$209.2 million, respectively, of efavirenz, the active pharmaceutical ingredient in Sustiva, which it purchased from BMS at BMS's estimated net selling price of Sustiva in the U.S. market.

**3. ACQUISITION OF MYOGEN, INC.**

In November 2006, we completed the acquisition of all of the outstanding shares of common stock of Myogen, Inc. (Myogen) via a cash tender offer. Myogen was a publicly-held biopharmaceutical company based in Westminster, Colorado that focused on the discovery, development and commercialization of small molecule therapeutics for the treatment of cardiovascular disorders. The Myogen acquisition was accounted for as a business combination in accordance with Statement of Financial Accounting Standards (SFAS) No. 141, *Business Combinations* (SFAS 141).

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During the three months ended March 31, 2007, we finalized our review of the acquired federal net operating loss carryforwards available to us, which resulted in an increase to net deferred tax assets. We also recognized a reduction to income taxes payable related to the exercise during the quarter of stock options assumed from Myogen that were vested as of the acquisition date, which resulted in a decrease in the purchase price. As a result, our updated allocation of purchase price is as follows (in thousands):

|   |                     |
|---|---------------------|
| Purchased in-process research and development | \$ 2,058,500        |
| Net deferred tax assets                       | 182,614             |
| Net tangible assets                           | 109,994             |
| Goodwill                                      | 74,173              |
| <b>Total purchase price</b>                   | <b>\$ 2,425,281</b> |

This updated purchase price allocation is still preliminary and has not been finalized in that we are continuing to assess the tax deductibility of certain acquisition-related transaction costs in accordance with SFAS 141 and Emerging Issues Task Force (EITF) Issue No. 93-7, *Uncertainties Related to Income Taxes in a Purchase Business Combination*. We also anticipate further adjustments to the purchase price due to the exercise in future periods of stock options assumed from Myogen that were vested as of the acquisition date. Material changes, if any, to the purchase price allocation summarized above will be reported as the related uncertainties are resolved.

**4. GLAXOSMITHKLINE INC.**

As a result of our acquisition of Myogen, we assumed all rights to the March 2006 license agreement and distribution and supply agreement between Myogen and GlaxoSmithKline Inc. (GSK). Under the terms of the license agreement, GSK received an exclusive sublicense to our rights to ambrisentan for certain hypertensive conditions in territories outside of the United States. We received an up-front payment and, subject to the achievement of specific milestones, we will be eligible to receive additional milestone payments. In addition, we will be entitled to receive stepped royalties based on net commercial sales of ambrisentan in the GSK territory. GSK has an option to negotiate for an exclusive sublicense to additional therapeutic uses for ambrisentan in the GSK territory during the term of the license agreement. We will continue to conduct, and bear the expenses of, all clinical development activities that we believe are required to obtain and maintain regulatory approvals for ambrisentan in the United States, Canada and the European Economic Area and each party may conduct additional development activities in its territory at its own expense. The parties may agree to jointly develop ambrisentan for new indications in the licensed field and each party will pay its share of external costs associated with such joint development. In March 2007, we received a milestone payment of \$11.0 million from GSK for validation by the European Medicines Agency of the Marketing Authorisation Application for ambrisentan for the treatment of pulmonary arterial hypertension. This milestone and the up-front license payment have been recorded as deferred revenue and will be amortized to contract revenue over the period for which we have performance obligations under the agreement, which is approximately eight years.

**5. CREDIT FACILITIES**

In December 2005, we entered into an agreement with a syndicate of banks for a five-year \$500.0 million senior credit facility. The \$500.0 million facility consisted of an uncollateralized \$300.0 million term loan, which was entered into by Gilead Biopharmaceuticals Ireland Corporation (GBIC), one of our wholly-owned Irish subsidiaries, and an uncollateralized \$200.0 million revolving credit facility, which was entered into by the U.S. parent company, Gilead Sciences, Inc. The proceeds from the term loan were used by GBIC in December 2005 to

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facilitate a cash dividend distribution of \$280.0 million to the parent company as part of the repatriation of our qualified foreign earnings under the provisions of the American Jobs Creation Act.

Under the terms of our term loan, the minimum amount of the principal payment that is required to be repaid at the end of each calendar quarter, beginning on March 31, 2006, is five percent of the outstanding balance. Interest is accrued at a rate of LIBOR plus a tiered contractual rate of up to 62.5 basis points and is payable quarterly in arrears. GBIC can prepay the term loan, together with accrued interest on the prepaid principal, at any time in whole or in part without penalty or premium. The U.S. parent company and another wholly-owned subsidiary, Gilead Vintage Park, LLC, are guarantors. During the three months ended March 31, 2007, we repaid all remaining amounts due under the term loan of \$99.0 million.

Under the terms of the revolving credit facility, interest is accrued and payable at a rate of LIBOR plus a tiered contractual rate of up to 50 basis points, and is payable quarterly in arrears. The parent company can prepay any outstanding borrowings, together with accrued interest on the prepaid principal, at any time in whole or in part without penalty or premium. Any outstanding interest or principal at December 2010 is payable on demand. We have the ability to irrevocably cancel any unutilized portion of the revolving credit facility, in whole or in part. Any proceeds obtained under the revolving credit facility are expected to be used for working capital, capital expenditures and other general corporate purposes, including the issuance of letters of credit up to \$25.0 million. Gilead Vintage Park, LLC is the guarantor. In March 2007, the revolving credit facility was increased to \$500.0 million as a result of our repayment of all remaining amounts due on our term loan. As of March 31, 2007, there were no borrowings outstanding under this revolving credit facility.

**6. CONTINGENCIES**

**Legal Proceedings**

A number of states, counties and municipalities have filed complaints alleging that a large number of pharmaceutical company defendants, including Gilead in some instances, reported inaccurate prices for their products, causing the governmental entity named as the plaintiff to overpay for pharmaceutical products furnished to participants in the Medicaid program. Separate actions filed by New York City and numerous New York counties were consolidated into a multi-district litigation proceeding before the United States District Court for the District of Massachusetts. On August 23, 2005, these cases were voluntarily dismissed with respect to Gilead. On August 3, 2006, Gilead was voluntarily dismissed from a similar action titled State of Alabama v. Abbott Laboratories, Inc. et al., currently pending in the Circuit Court of Montgomery County, Alabama. Gilead was originally named in another similar case, State of Mississippi v. Abbott Laboratories, Inc., et al., currently pending in the Chancery Court of the First Judicial District of Hinds County, Mississippi, but no allegations were made against Gilead in the amended complaint filed on October 5, 2006. On March 20, 2007, three similar actions were voluntarily dismissed with respect to Gilead: County of Erie v. Abbott Laboratories et al., County of Oswego v. Abbott Laboratories et al., and County of Schenectady v. Abbott Laboratories et al. which are all currently pending in the United States District Court for the District of Massachusetts. To our knowledge, we have been named in one additional case, County of Orange v. Abbott Laboratories, Inc. et al., filed on April 5, 2007 in the United States District Court for the Southern District of New York. The complaint asserts claims under state and federal law and seeks damages (and, in some cases, treble damages) and attorneys' fees. We intend to defend this case vigorously. This case is at a preliminary stage and it is not possible to predict the outcome. As such, no amounts have been accrued related to the outcome of this case.

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

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purported class action lawsuit against Gilead and our Chief Executive Officer, Chief Operating Officer and Chief Financial Officer; former Executive Vice President of Operations; Executive Vice President of Research and Development and Chief Scientific Officer; Senior Vice President of Manufacturing; and Senior Vice President of Research, alleging that the defendants violated federal securities laws, specifically Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated by the SEC, by making certain alleged false and misleading statements. The plaintiffs have appealed the dismissal.

On September 29, 2006, we received service of an amended complaint adding us as a defendant in Colahan v. Ward, et al., a case filed in the Superior Court of the District of Columbia. In 1987, the plaintiff in this action was diagnosed with HIV although he was not infected with HIV, and from 1998 to 2000, he participated in our emtricitabine clinical trial. He alleges we were negligent in our conduct of this clinical trial and seeks damages against all defendants, jointly and severally. We deny any liability and intend to defend the action vigorously. The case is at a preliminary stage and it is not possible to predict the outcome. As such, no amounts have been accrued related to the outcome of this case.

On November 29, 2006, we received a subpoena from the United States Attorney's Office in San Francisco requesting documents regarding our marketing and medical education programs for Truvada, Viread and Emtriva. We intend to continue to comply with the U.S. Attorney's subpoena and to cooperate in any related government investigation.

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

**7. STOCK-BASED COMPENSATION****Stock-based Compensation Expense**

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

|   | <b>Three Months Ended<br/>March 31,</b> |             |
|---|---|-------------|
|   | <b>2007</b>                             | <b>2006</b> |
| Cost of goods sold  | \$ 2,530                                | \$ 3,187    |
| Research and development expenses                                     | 21,108                                  | 11,949      |
| Selling, general and administrative expenses                          | 33,656                                  | 14,496      |
| Stock-based compensation expense included in total costs and expenses | 57,294                                  | 29,632      |
| Income tax effect   | (17,108)                                | (6,129)     |
| Stock-based compensation expense included in net income               | \$ 40,186                               | \$ 23,503   |

**Performance Shares**

In January 2007, we granted 184,840 performance-based share awards (allotted performance shares) under our 2004 Equity Incentive Plan. Subject to our achievement of specified market and performance goals relative to a pre-determined peer group, these awards will vest over a three-year period. The actual number of

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performance shares that we will ultimately issue will be calculated by multiplying the number of allotted performance shares by a payout percentage ranging from 0% to 200%. Performance shares will vest only when a committee (or subcommittee) of our Board of Directors has determined that we have achieved our specified market and performance goals. The fair value of the market-related component of the performance shares is estimated at grant date using a Monte Carlo valuation methodology, and the fair value of the performance-related component of the performance shares is equivalent to the grant-date fair value of our common stock. Stock-based compensation for these performance shares is recognized as expense over the requisite performance periods using a straight-line expense attribution approach reduced for estimated forfeitures. The weighted-average grant-date fair value of the performance shares was \$69.59, and there were no vested or forfeited performance shares as of March 31, 2007.

**8. COMPREHENSIVE INCOME**

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

|  | <b>Three Months Ended<br/>March 31,</b> |                   |
|--|---|-------------------|
|  | <b>2007</b>                             | <b>2006</b>       |
| Net income   | \$ 407,407                              | \$ 262,704        |
| Net foreign currency translation gain (loss)                                     | 5                                       | (109)             |
| Net unrealized gain (loss) on cash flow hedges, net of related tax effects       | 811                                     | (6,263)           |
| Net unrealized loss on available-for-sale securities, net of related tax effects | (8,088)                                 | (7,679)           |
| <b>Comprehensive income</b>  | <b>\$ 400,135</b>                       | <b>\$ 248,653</b> |

**9. SEGMENT INFORMATION**

We operate in one business segment, which primarily focuses on the development and commercialization of human therapeutics for life threatening diseases. All products are included in one segment, because our major products, Truvada, Atripla, Viread, Emtriva, Hepsera and AmBisome, which together accounted for substantially all of our total product sales for each of the three months ended March 31, 2007 and 2006, have similar economic and other characteristics, including the nature of the products and production processes, type of customers, distribution methods, and regulatory environment.

Product sales consisted of the following (in thousands):

|                                | <b>Three Months Ended<br/>March 31,</b> |                   |
|--------------------------------|---|-------------------|
|                                | <b>2007</b>                             | <b>2006</b>       |
| <b>HIV products:</b>           |   |                   |
| Truvada                        | \$ 345,938                              | \$ 248,946        |
| Atripla                        | 190,183                                 |                   |
| Viread                         | 160,678                                 | 191,775           |
| Emtriva                        | 8,323                                   | 9,962             |
| <b>Total HIV product sales</b> | <b>705,122</b>                          | <b>450,683</b>    |
| Hepsera                        | 71,344                                  | 52,655            |
| AmBisome                       | 61,502                                  | 53,800            |
| Other                          | 2,257                                   | 2,215             |
| <b>Total product sales</b>     | <b>\$ 840,225</b>                       | <b>\$ 559,353</b> |

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

|  | Three Months Ended<br>March 31, |                   |
|--|---------------------------------|-------------------|
|  | 2007                            | 2006              |
| United States                                      | \$ 494,203                      | \$ 300,594        |
| Outside of the United States:                      |                                 |                   |
| Switzerland  | 173,907                         | 118,945           |
| France   | 69,456                          | 48,315            |
| Spain  | 55,347                          | 35,145            |
| United Kingdom                                     | 49,541                          | 35,043            |
| Italy  | 49,488                          | 35,215            |
| Germany  | 33,166                          | 28,914            |
| Other European countries                           | 52,979                          | 48,055            |
| Other countries                                    | 50,343                          | 42,652            |
| <b>Total revenues outside of the United States</b> | <b>534,227</b>                  | <b>392,284</b>    |
| <b>Total revenues</b>                              | <b>\$ 1,028,430</b>             | <b>\$ 692,878</b> |

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

|                          | Three Months Ended<br>March 31, |      |
|--------------------------|---------------------------------|------|
|                          | 2007                            | 2006 |
| Cardinal Health, Inc.    | 20%                             | 16%  |
| F. Hoffmann-La Roche Ltd | 16%                             | 17%  |
| McKesson Corp.           | 14%                             | 11%  |
| AmerisourceBergen Corp.  | 10%                             | 10%  |

**10. INCOME TAXES**

Our income tax rate of 29.9% for the three months ended March 31, 2007 differs from the U.S. federal statutory rate of 35% primarily due to state taxes, offset by tax credits and certain earnings from operations in lower tax jurisdictions for which no U.S. taxes have been provided because such earnings are planned to be reinvested indefinitely outside the United States. We do not provide for U.S. income taxes on undistributed earnings of our foreign operations that are intended to be permanently reinvested.

In June 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* (FIN 48), an interpretation of SFAS No. 109, *Accounting for Income Taxes* (SFAS 109). FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS 109 by prescribing a minimum recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006.

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On January 1, 2007, we adopted FIN 48 and adjusted our liability for unrecognized tax benefits by \$14.1 million with a corresponding charge to the opening balance of accumulated deficit, as permitted under FIN 48. As of the date of adoption, we had total federal, state, and foreign unrecognized tax benefits of \$86.2 million recorded in other long-term obligations on our Condensed Consolidated Balance Sheet, including accrued liabilities related to interest and penalties of \$4.0 million. Of the total unrecognized tax benefits, \$78.0 million, if recognized, would reduce our effective tax rate in the period of recognition. As permitted under the provisions of FIN 48, we will continue to classify interest and penalties related to unrecognized tax benefits as part of our income tax provision in our Condensed Consolidated Statements of Income. During the three months ended March 31, 2007, we recognized \$1.4 million in interest and penalties.

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 the Franchise Tax Board of California for the 2004 and 2005 tax years. 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. Prior to the adoption of FIN 48, we recorded liabilities related to uncertain tax positions based upon SFAS No. 5, *Accounting for Contingencies*.



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

*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 following risks could materially and adversely affect our business, results of operations and financial condition. In particular, 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, plan, could, should, might, believe, seek, estimate, continue, may, variations of such words, and similar expressions are intended to identify 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. Given these risks and uncertainties, you are cautioned not to place undue reliance on forward-looking statements. The forward-looking statements included in this report are made only as of the date hereof. Except as required under federal securities laws and the rules and regulations of the Securities and Exchange Commission (SEC), we do not undertake 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.*

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, 2006, and our unaudited Condensed Consolidated Financial Statements for the three months ended March 31, 2007 and other disclosures (including the disclosures under "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.

**Executive Summary**

We are a biopharmaceutical company that discovers, develops and commercializes innovative therapeutics in areas of unmet medical need. Our mission is to advance the care of patients suffering from life-threatening diseases worldwide. Headquartered in Foster City, California, we have operations in North America, Europe and Australia. Currently, we market Truvada<sup>®</sup> (emtricitabine and tenofovir disoproxil fumarate), Atripla (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) for the treatment of chronic hepatitis B infection; AmBisome<sup>®</sup> (amphotericin B) liposome for injection for the treatment of fungal infection; Vistide<sup>®</sup> (cidofovir injection) for the treatment of cytomegalovirus (CMV) infection; and Flolan<sup>®</sup> (epoprostenol sodium) for the treatment of pulmonary hypertension. F. Hoffmann-La Roche Ltd (together with F. Hoffman-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. (OSI) 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.

Our operating results for the first quarter of 2007 were led by strong net product sales of \$840.2 million including HIV product sales (Truvada, Atripla, Viread and Emtriva) of \$705.1 million. HIV product sales, which

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grew by 56% in the first quarter of 2007 over the comparable period in 2006, were the key driver for total product sales growth of 50% in the first quarter of 2007 over the same comparable period in 2006. HIV product sales were up 10% sequentially from the fourth quarter of 2006, mainly due to the strong sales of Atripla following its launch in July 2006 in the United States as well as continued growth of Truvada in Europe. AmBisome product sales in the first quarter of 2007 increased by 14% compared to the first quarter of 2006 primarily driven by sales volume growth across major European countries, as well as a favorable foreign currency exchange impact. Hepsera product sales for the first quarter of 2007 increased 35% from the first quarter of 2006 driven primarily by sales volume growth in both the United States and Europe. On the collaborative front, we recognized \$180.5 million in royalty revenue in the first quarter of 2007, of which \$167.9 million related to royalties received from fourth quarter 2006 sales of Tamiflu by Roche. Tamiflu royalties increased by 46% from the same period in 2006 due to increased sales of Tamiflu by Roche.

During the first quarter of 2007, we continued to make progress on the development of compounds and drug candidates in-licensed from our collaboration partners. In HIV, we announced in February 2007 that a Phase 2 clinical trial of our novel integrase inhibitor for HIV, GS 9137, had met its primary endpoint of non-inferiority in viral load reduction in HIV-positive patients. We licensed GS 9137 from Japan Tobacco Inc. (Japan Tobacco) in 2005. Pending the outcome of our discussions with the U.S. Food and Drug Administration (FDA), we currently anticipate initiating a Phase 3 clinical study in the second half of 2007. In the hepatitis area, we and our collaboration partner, Achillion Pharmaceutical, Inc. (Achillion), announced results from a Phase 1b/2 trial evaluating GS 9132 (also known as ACH-806), a novel NS4A antagonist, in patients infected with hepatitis C virus (HCV). Preliminary data demonstrated positive antiviral activity of GS 9132, but an unsuitable safety profile led to the discontinuation of the clinical program. We and Achillion will continue to explore other NS4A antagonists discovered by Achillion with us taking the lead on future preclinical and clinical development work once an appropriate candidate is identified. Our two pivotal Phase 3 clinical studies of tenofovir disoproxil fumarate for chronic hepatitis B are ongoing, and we expect 48-week data from these studies around the second half of 2007. Contingent on positive outcomes from these studies, if any, we intend to file a new drug application (NDA) with the FDA, as well as a Marketing Authorisation Application (MAA) with the European Medicines Agency (EMA) in the second half of 2007. Our Phase 1 clinical study for GS 9190, a non-nucleoside HCV polymerase inhibitor for the potential treatment of hepatitis C, is underway and we anticipate data in the third quarter of 2007. In the cardiopulmonary area, we announced in February 2007 that the FDA granted us priority review status for the NDA of ambrisentan for the treatment of pulmonary arterial hypertension (PAH), a program obtained from our acquisition of Myogen, Inc. (Myogen) and established a target review date of June 18, 2007. In addition, during the first quarter of 2007, we received an \$11.0 million milestone payment from GlaxoSmithKline Inc. (GSK) for the validation by the EMA of the MAA for ambrisentan for the treatment of PAH. This amount has been recorded as deferred revenue to be amortized into contract revenue over the period for which we have performance obligations under our license agreement with GSK. We continue to enroll patients in our Phase 3 clinical study for darusentan, another program obtained from the Myogen acquisition, for the treatment of resistant hypertension. We have plans to commence a second Phase 3 clinical study for the same indication in the second quarter of this year. In the respiratory area, in January 2007, we completed enrollment in a second Phase 3 clinical study of aztreonam lysine for inhalation, an inhaled antibiotic for the treatment of patients with cystic fibrosis who have pulmonary infection with *Pseudomonas aeruginosa*. We expect preliminary data from this second Phase 3 clinical study in the second quarter of 2007. Contingent on positive outcomes from this study, if any, we intend to file a NDA with the FDA in the second half of this year. In the area of hematologic cancer, we announced in March 2007 that GS 9219, a novel nucleotide analog, had shown evidence of anti-cancer activity in preclinical studies, and we have filed an Investigational New Drug application to begin a Phase 1 clinical study of patients with non-Hodgkin's lymphoma and chronic lymphocytic leukemia sometime in 2007.

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Our cash, cash equivalents and marketable securities grew by \$470.9 million in the first quarter of 2007 primarily driven by our operating cash flows for the quarter. In March 2007, we paid off the remaining amounts due under our term loan of \$99.0 million. Our existing cash, cash equivalents and marketable securities will allow us to further our corporate development initiatives, as well as to meet our ongoing working capital and infrastructure needs.

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

There have been no material changes in our critical accounting policies, estimates and judgments during the three months ended March 31, 2007 compared to the disclosures in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2006, other than as disclosed herein.

#### *Income Taxes*

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 the Franchise Tax Board of California for the 2004 and 2005 tax years. 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 exposures associated with our tax filing positions.

In June 2006, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* (FIN 48), an interpretation of Statement of Financial Accounting Standards (SFAS) No. 109, *Accounting for Income Taxes* (SFAS 109). FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS 109 by prescribing a minimum recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006.

On January 1, 2007, we adopted FIN 48 and adjusted our liability for unrecognized tax benefits by \$14.1 million with a corresponding charge to the opening balance of accumulated deficit, as permitted under FIN 48. As of the date of adoption, we had total unrecognized tax benefits of \$86.2 million recorded in other long-term obligations on our Condensed Consolidated Balance Sheet, including accrued liabilities related to interest and penalties of \$4.0 million. Of the total unrecognized tax benefits, \$78.0 million, if recognized, would reduce our effective tax rate in the period of recognition. As permitted under the provisions of FIN 48, we will continue to classify interest and penalties related to unrecognized tax benefits as part of our income tax provision in our Condensed Consolidated Statements of Income. With respect to the 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.

Prior to the adoption of FIN 48, we recorded liabilities related to uncertain tax positions based upon SFAS No. 5, *Accounting for Contingencies*.

**Table of Contents****Results of Operations***Total Revenues*

We had total revenues of \$1.03 billion for the first quarter of 2007 compared with \$692.9 million for the first quarter of 2006. Included in total revenues are product sales, royalty revenue, and contract and other revenues.

*Product Sales*

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

|                         | <b>Three Months Ended<br/>March 31,</b> |             | <b>Change</b> |
|-------------------------|---|-------------|---------------|
|                         | <b>2007</b>                             | <b>2006</b> |               |
| HIV products:           |   |             |               |
| Truvada                 | \$ 345,938                              | \$ 248,946  | 39%           |
| Atripla                 | 190,183                                 |             |               |
| Viread                  | 160,678                                 | 191,775     | (16)%         |
| Emtriva                 | 8,323                                   | 9,962       | (16)%         |
| <br>                    |   |             |               |
| Total HIV product sales | 705,122                                 | 450,683     | 56%           |
| Hepsera                 | 71,344                                  | 52,655      | 35%           |
| AmBisome                | 61,502                                  | 53,800      | 14%           |
| Other                   | 2,257                                   | 2,215       | 2%            |
| <br>                    |   |             |               |
| Total product sales     | \$ 840,225                              | \$ 559,353  | 50%           |

Total product sales increased 50% in the first quarter of 2007 compared to the first quarter of 2006, primarily due to an overall increase in our HIV product sales volume.

*HIV Products*

HIV product sales for the first quarter of 2007 were \$705.1 million, an increase of 56% compared to the first quarter of 2006 primarily driven by product volume growth. We continued to experience overall steady prescription gains for our HIV product portfolio in the first quarter of 2007.

*Truvada*

Truvada sales were \$345.9 million in the first quarter of 2007, an increase of 39% compared to the first quarter of 2006, primarily driven by strong sales volume growth in Europe and a favorable foreign currency exchange impact. Truvada sales accounted for 49% and 55% of our total HIV product sales for the first quarter of 2007 and 2006, respectively.

*Atripla*

Atripla was approved for sale in the United States in July 2006 and Atripla sales accounted for 27% of our first quarter 2007 HIV product sales. Atripla sales were \$190.2 million in the first quarter of 2007. We consolidate 100% of Atripla product sales because we are the primary beneficiary of our joint venture with Bristol-Myers Squibb Company (BMS). As a result, approximately \$70.4 million of these revenues relate to Sustiva (efavirenz). We are currently seeking approval of Atripla for sale in the European Union.



**Table of Contents***Viread*

Viread sales were \$160.7 million in the first quarter of 2007, a 16% decrease from \$191.8 million in the first quarter of 2006 primarily due to lower sales volume in the United States and Europe.

*Emtriva*

Emtriva sales were \$8.3 million for the first quarter of 2007, a decrease of 16% from the first quarter of 2006. The decrease was primarily driven by lower sales volume in the United States and Europe, partially offset by increased sales volume in Latin America.

*Hepsera*

Hepsera sales increased by 35% in the first quarter of 2007 compared to the first quarter of 2006, primarily driven by increased sales volume in the United States and Europe.

*AmBisome*

Sales of AmBisome increased by 14% in the first quarter of 2007 compared to the first quarter of 2006, primarily driven by sales volume growth in various European territories as well as a favorable foreign currency exchange impact.

For the full year 2007, we expect total product sales of our currently marketed products to grow from 2006 levels as we continue to expand our sales and marketing efforts.

*Royalty Revenue*

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

|                 | Three Months Ended<br>March 31, |            | Change |
|-----------------|---------------------------------|------------|--------|
|                 | 2007                            | 2006       |        |
| Royalty revenue | \$ 180,462                      | \$ 129,429 | 39%    |

Royalty revenue for the first quarter of 2007 was \$180.5 million, an increase of 39% compared to the first quarter of 2006. The increase was primarily driven by Tamiflu royalties from Roche of \$167.9 million recognized in the first quarter of 2007 compared to Tamiflu royalties from Roche of \$115.3 million recognized in the first quarter of 2006. The increase in Tamiflu royalties is due to the higher Tamiflu sales recorded by Roche in the fourth quarter of 2006 as compared to the same period in 2005, including sales related to pandemic planning initiatives worldwide. We recognize royalties on Tamiflu sales by Roche in the quarter following the quarter in which the product is sold.

*Contract and Other Revenues*

The following table summarizes the period over period changes in our contract and other revenues (in thousands):

|                             | Three Months Ended<br>March 31, |          | Change |
|-----------------------------|---------------------------------|----------|--------|
|                             | 2007                            | 2006     |        |
| Contract and other revenues | \$ 7,743                        | \$ 4,096 | 89%    |

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Contract and other revenues totaled \$7.7 million in the first quarter of 2007, an increase of 89% compared to the first quarter of 2006. In the first quarter of 2007, contract and other revenues consisted primarily of net product distribution service revenue of \$2.1 million that we received from GSK from our sales of Flolan, revenue earned from various contract manufacturing projects as well as the amortization of previously deferred milestone and other revenues.

*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 (each, in thousands) and our product gross margin:

|                      | Three Months Ended<br>March 31, |            | Change |
|----------------------|---------------------------------|------------|--------|
|                      | 2007                            | 2006       |        |
| Total product sales  | \$ 840,225                      | \$ 559,353 | 50%    |
| Cost of goods sold   | \$ 171,638                      | \$ 90,357  | 90%    |
| Product gross margin | 80%                             | 84%        |        |

Our product gross margin for the first quarter of 2007 was 80%, compared to 84% for the same quarter of 2006. The lower gross margin was primarily due to the launch of Atripla in the United States in July 2006 as well as product mix changes, partially offset by the lower effective royalty rate resulting from our July 2005 emtricitabine royalty buyout and lower active pharmaceutical ingredient (API) costs. In addition, our gross margin for the first quarter of 2006 included a \$6.8 million write-down of inventory for our Gilead Access Program to its estimated net realizable value.

Atripla product sales decreased our product gross margin, without a corresponding impact to our product gross profit. As the primary beneficiary of our joint venture with BMS, we consolidate 100% of Atripla product sales but only benefit from the product gross margin on the Truvada portion of Atripla. The Sustiva portion of Atripla product sales carries a zero product gross profit since the joint venture purchases Sustiva API from BMS at BMS's estimated net selling price of Sustiva in the U.S. market.

We expect our product gross margin for the full year of 2007 to be lower than that of 2006, driven by the higher mix of Atripla product sales, which include the Sustiva portion at zero product gross profit, partially offset by gross margin improvements driven by lower API costs and the continued benefit associated with our prepaid emtricitabine royalties.

*Research and Development Expenses*

The following table summarizes the period over period changes in our research and development (R&D) expenses into these major components (in thousands):

|   | Three Months Ended<br>March 31, |           | Change |
|---|---------------------------------|-----------|--------|
|   | 2007                            | 2006      |        |
| Research                                | \$ 30,193                       | \$ 18,365 | 64%    |
| Clinical development                    | 78,311                          | 55,519    | 41%    |
| Pharmaceutical development              | 21,586                          | 14,516    | 49%    |
| Total research and development expenses | \$ 130,090                      | \$ 88,400 | 47%    |

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

R&D expenses for the first quarter of 2007 increased by \$41.7 million compared to the same quarter of 2006, primarily due to higher headcount which increased compensation and benefits by \$19.2 million, as well as increased contract service and clinical study expenses of \$19.8 million relating to clinical, product development and research activities in our HIV and hepatitis programs and our newly-acquired programs in the respiratory and cardiopulmonary areas. Additionally, significant collaboration payments during a quarter can cause our R&D expenses to fluctuate. During the first quarter of 2006, we incurred a milestone payment of \$5.0 million related to the dosing of the first patient in a Phase 2 study for our lead integrase inhibitor, GS 9137, under our HIV integrase license agreement with Japan Tobacco.

We expect R&D expenses for the full year of 2007 to be higher than that of 2006, reflecting increased spending on our internal and collaborative R&D efforts, as well as product licensing activity relating to our expectation that our product candidates will progress into more advanced clinical trials, especially in the respiratory and cardiopulmonary areas.

*Selling, General and Administrative Expenses*

The following summarizes the period over period changes in our selling, general and administrative (SG&A) expenses (in thousands):

|  | <b>Three Months Ended</b> |             | <b>Change</b> |
|--|---------------------------|-------------|---------------|
|  | <b>March 31,</b>          |             |               |
|  | <b>2007</b>               | <b>2006</b> |               |
| Selling, general and administrative expenses | \$ 166,558                | \$ 142,469  | 17%           |

SG&A expenses for the first quarter of 2007 increased by \$24.1 million compared to the same quarter in 2006. Higher expenses were primarily driven by increased compensation and benefits of \$29.1 million, due primarily to higher headcount and the expensing of accelerated stock options for certain terminated employees from our acquisition of Myogen. SG&A expenses in the first quarter of 2006 included the write-off of certain capital assets of \$7.9 million related to renovations at our corporate headquarters.

We expect SG&A expenses for the full year of 2007 to be higher than that of 2006, primarily due to increased administrative activities and sales and marketing efforts to support our business growth, sales force expansion in anticipation of the launch of ambrisentan in the United States, ongoing investment in our global commercial organization through additional hiring and promotional programs and incremental operating expenses associated with our acquisitions of Myogen and Corus Pharma, Inc. (Corus) in 2006.

*Purchased In-process Research and Development Expense*

In connection with our acquisitions of Myogen and Corus in 2006, we recorded purchased in-process research and development (IPR&D) expense of \$2.06 billion and \$335.6 million, respectively, for 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 research and development 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. In February 2007, the FDA granted us priority review status for the NDA for marketing approval of ambrisentan for the treatment of PAH, and established a target review date of June 18, 2007. Additionally, in March 2007, the EMEA validated the MAA for ambrisentan for the treatment of PAH, filed by our collaboration partner, 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 estimated fair value of the purchased IPR&D was determined using the income approach, which discounts expected future cash flows to present value. We estimated the related future net cash flows using a present value risk-adjusted discount rate of 14%, which is a significant assumption and is based on the estimated internal rate of return for Myogen's operations and is comparable to the estimated weighted average cost of capital for companies with Myogen's profile. The projected cash flows from the ambrisentan and darusentan programs were based on key assumptions such as estimates of revenues and operating profits related to the programs considering their stages of development; the time and resources needed to complete the development and approval of the related products; the life of the potential commercialized products and associated risks, including the inherent difficulties and uncertainties in developing a drug compound such as obtaining FDA and other regulatory approvals; and risks related to the viability of and potential alternative treatments in any future target markets.

The remaining efforts for completing Myogen's IPR&D programs primarily consist 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 ability to enroll patients in clinical trials, 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 either ambrisentan or darusentan, purchased from Myogen, 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. The acquired product candidates

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under development may never be successfully commercialized. As a result, we may make a strategic decision to discontinue development of these product candidates if, for example, we believe commercialization will be difficult relative to other opportunities in our pipeline. If these programs 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 projects will materialize as estimated. For these reasons, among others, actual results may vary significantly from estimated results.

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

| <b>Program</b>                               | <b>Description</b>  | <b>Status of Development</b>   | <b>Estimated Acquisition Date Fair Value (in millions)</b> |
|--|---|--|--|
| Inhaled aztreonam lysine for cystic fibrosis | Aztreonam formulation for inhalation to be used against Gram-negative bacteria that cause lung infections in patients with cystic fibrosis. | In Phase 3 clinical trials as of the acquisition date and the date of this filing. | \$335.6  |

The estimated fair value of the purchased IPR&D was determined using the income approach, which discounts expected future cash flows to present value. We estimated the related future net cash flows using a present value risk-adjusted discount rate of 16%, which is a significant assumption and is based on the estimated internal rate of return for Corus's operations and is comparable to the estimated weighted-average cost of capital for companies with Corus's profile. The projected cash flows from the aztreonam lysine for inhalation program were based on key assumptions such as estimates of revenues and operating profits related to the program considering its stage of development; the time and resources needed to complete the development and approval of the related product; the life of the potential commercialized product and associated risks, including the inherent difficulties and uncertainties in developing a drug compound such as obtaining FDA and other regulatory approvals; and risks related to the viability of and potential alternative treatments in any future target markets. Corus's two other early-stage candidates were not included in the valuation of purchased IPR&D because they were early-stage programs that did not have identifiable revenues and expenses associated with them.

The remaining efforts for completing Corus's IPR&D program primarily consist 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 ability to enroll patients in clinical trials, 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 aztreonam lysine for cystic fibrosis, purchased from Corus, will be approved in the United States or 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. The acquired product candidate under development may never be successfully commercialized. As a result, we may make a strategic decision to

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discontinue development of this product candidate 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.

*Interest and Other Income, net*

Interest and other income, net, was \$23.1 million for the first quarter of 2007, a decrease of \$5.4 million from the first quarter of 2006. The decrease in the first quarter of 2007 was primarily attributable to the lower average cash and investment balances over the prior year.

*Interest Expense*

Interest expense for the first quarter of 2007 was \$4.5 million, an increase of \$0.8 million from the first quarter of 2006. The increase in the first quarter of 2007 was primarily due to interest on our convertible senior notes which we issued in the second quarter of 2006, partially offset by lower interest expense resulting from a decreased average balance on our term loan.

*Minority Interest in Joint Venture*

The minority interest in joint venture on our Condensed Consolidated Financial Statements reflects BMS' s interest in the operating results of our joint venture with BMS in the United States. As the primary beneficiary of the joint venture as determined under FASB Interpretation No. 46, *Consolidation of Variable Interest Entities*, we consolidate the operations of the joint venture in our Condensed Consolidated Financial Statements. The operations of the joint venture commenced in 2005 with activities primarily focusing on the co-formulation of the once-daily single tablet regimen of Truvada and Sustiva. In July 2006, we received approval from the FDA for the single tablet regimen in the United States, which has been given the trade name Atripla. In September 2006, we and BMS amended the joint venture' s collaboration agreement to allow the joint venture to sell Atripla in Canada.

*Provision for Income Taxes*

Our income tax rate was 29.9% for the first quarter of 2007 compared to 33.9% for the first quarter of 2006. Our provision for income taxes for the first quarter of 2007 was \$173.4 million compared to \$134.7 million for the first quarter of 2006. The tax rate for the first quarter of 2007 differs from the U.S. federal statutory rate of 35% primarily due to state taxes, offset by tax credits and certain earnings from operations in lower tax jurisdictions for which no U.S. taxes have been provided because such earnings are planned to be reinvested indefinitely outside the United States. We do not provide for U.S. income taxes on undistributed earnings of our foreign operations that are intended to be permanently reinvested.

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, our adoption of FIN 48, mergers and acquisitions, future levels of R&D spending, changes in accounting standards, future levels of capital expenditures, 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 and state 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.

**Table of Contents****Liquidity and Capital Resources**

The following table summarizes our cash, cash equivalents and marketable securities, our working capital, and our statements of cash flows (in thousands):

|  | As of<br>March 31,<br>2007              | As of<br>December 31,<br>2006 |
|--|---|-------------------------------|
| Cash, cash equivalents and marketable securities | \$ 1,860,458                            | \$ 1,389,566                  |
| Working capital                                  | 1,730,073                               | 1,664,930                     |
|  | <b>Three Months Ended<br/>March 31,</b> |                               |
|  | <b>2007</b>                             | <b>2006</b>                   |
| Cash provided by (used in):                      |   |                               |
| Operating activities                             | \$ 490,493                              | \$ 221,894                    |
| Investing activities                             | (590,431)                               | (689,994)                     |
| Financing activities                             | 18,219                                  | 24,777                        |

*Cash, Cash Equivalents and Marketable Securities*

Cash, cash equivalents and marketable securities totaled \$1.86 billion at March 31, 2007, an increase of 34% from December 31, 2006. The increase of \$470.9 million was primarily attributable to \$490.5 million of operating cash flows generated during the first quarter of 2007 and \$83.6 million of proceeds that we received from the issuance of stock under employee stock plans, partially offset by our repayment of all remaining amounts due under our term loan of \$99.0 million.

*Working Capital*

Working capital at March 31, 2007 was \$1.73 billion compared to \$1.66 billion at December 31, 2006. Significant factors that resulted in the increase in working capital as of March 31, 2007 were:

\$82.7 million increase in accounts receivable, net, primarily due to increased product sales; and

\$69.8 million decrease in accounts payable primarily related to the settlement of Sustiva API purchases from BMS by our joint venture.

These working capital increases were partially offset by:

\$41.7 million decrease in inventory due primarily to strong Atripla product sales since its launch in the United States; and

\$36.2 million increase in other accrued liabilities primarily attributed to increased Medicaid rebate obligations associated with higher product sales for the first quarter of 2007.

*Cash Provided by Operating Activities*

Cash provided by operating activities of \$490.5 million for the first quarter of 2007 was comprised primarily of \$407.4 million in net income which was adjusted for non-cash items such as stock-based compensation expense of \$57.3 million and \$39.9 million of tax benefits related to employee stock plans, partially offset by \$33.8 million of excess tax benefits from stock option exercises.



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Cash provided by operating activities of \$221.9 million for the first quarter of 2006 was comprised primarily of \$262.7 million in net income which was adjusted for non-cash items such as stock-based compensation expense of \$29.6 million and depreciation and amortization of \$11.2 million, partially offset by a \$62.3 million net cash outflow related to changes in operating assets and liabilities and \$37.4 million of excess tax benefits from stock option exercises.

### *Cash Used in Investing Activities*

Cash used in investing activities primarily related to purchases, sales and maturities of our available-for-sale securities, as well as capital expenditures. We used \$590.4 million of net cash for investing activities during the first quarter of 2007, compared to \$690.0 million during the first quarter of 2006. The decrease was primarily due to lower activity in purchases, sales and maturities of marketable securities during the first quarter of 2007, compared to the first quarter of 2006.

Capital expenditures made in the first quarter of 2007 related primarily to the expansion and upgrading of our facilities to accommodate our growth. Capital expenditures made in the first quarter of 2006 related to expanding certain aspects of our manufacturing capabilities, upgrading our facilities as well as additional spending on computer and laboratory equipment to accommodate our growth.

### *Cash Provided by Financing Activities*

Cash provided by financing activities in the first quarter of 2007 was \$18.2 million, primarily related to proceeds that we received from employee stock option exercises of \$83.6 million, as well as \$33.8 million of excess tax benefits from stock option exercises. These cash inflows were partially offset by \$99.0 million used to pay off all remaining amounts due on our term loan.

Cash provided by financing activities in the first quarter of 2006 was \$24.8 million, primarily related to proceeds that we received from employee stock option exercises of \$43.5 million, as well as \$37.4 million of excess tax benefits from stock option exercises. These cash inflows were partially offset by \$56.0 million used to pay down principal on our term loan.

### *Other Information*

As of March 31, 2007, we had an uncollateralized revolving credit facility of \$500.0 million of which there were no outstanding amounts.

## **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 financial position or results of operations.

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

There have been no material changes in our market risk during the three months ended March 31, 2007 compared to the disclosures in Part II, Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2006.

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

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

An evaluation as of March 31, 2007 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 the design and operation of our disclosure controls and procedures, which are defined under 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 under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within required time periods. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that subject to the limitations described below, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in this quarterly report on Form 10-Q was recorded, processed, summarized and reported within the time periods specified in the SEC's rules on Form 10-Q.

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

Our management, including our Chief Executive Officer and Chief Financial Officer, has evaluated any changes in our internal control over financial reporting that occurred during the quarter ended March 31, 2007, 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 Item 1. Condensed Consolidated Financial Statements Note 6. Contingencies Legal Proceedings to the interim Condensed Consolidated Financial Statements, and is incorporated by reference herein.

### **ITEM 1A. RISK FACTORS**

In evaluating our business, you should carefully consider the following risks in addition to the other information in this Quarterly Report on Form 10-Q. Any of the following risks could materially and adversely affect our business, results of operations and financial condition. We note these factors for investors as permitted by the Private Securities Litigation Reform Act of 1995. It is not possible to predict or identify all such factors and, therefore, you should not consider any of the below risks to be a complete statement of all the potential risks or uncertainties that we face.

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**Substantially all of our revenues are 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 HIV products, 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 efforts. HIV product sales for the first quarter of 2007 were \$705.1 million, or approximately 69% of our total revenues, and sales of Truvada and Atripla accounted for 49% and 27%, respectively, of our total HIV product sales during the first quarter of 2007. We may not be able to continue 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 on our labels, narrow our approved indications or halt sales of a product, each of which could reduce our revenues.

As a product matures, 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.

**If we fail to commercialize new products or expand the indications for existing products, our prospects for future revenues and our stock price 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 will face the risks outlined in this section. If we fail to increase our sales of our products or bring new products to market, we may not be able to increase revenues and expand our research and development efforts. Although our joint venture with Bristol-Myers Squibb Company (BMS) launched the single tablet regimen of Truvada and Sustiva, trade-named Atripla, in July 2006 in the United States, physicians may be reluctant to prescribe Atripla if they fail to see advantages of the single tablet regimen over other antiretrovirals and as a result, we may not be able to increase revenues from our HIV products. In addition, product sales of Atripla may increase at the expense of product sales of its component products and our overall total revenues may not increase from the launch of Atripla. Furthermore, the marketing authorization application submitted by BMS, Merck & Co, Inc. (Merck) and us in October 2006 seeking approval of Atripla in the European Union may not be granted on a timely basis, or at all. We cannot be certain that aztreonam lysine for inhalation for the treatment of cystic fibrosis (CF), purchased from Corus Pharma, Inc. (Corus), darusentan for resistant hypertension, or ambrisentan for the treatment of pulmonary arterial hypertension (PAH), which is pending U.S. Food and Drug Administration (FDA) review, both of which were purchased from Myogen, Inc. (Myogen), 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



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regulatory agencies will determine the amount of data needed and timelines for review, which may differ materially from current projections. The acquired product candidates under development may never be successfully commercialized. As a result, we may make a strategic decision to discontinue development of these product candidates if, for example, we believe commercialization will be difficult relative to other opportunities in our pipeline. If either of these programs cannot be completed on a timely basis or at all, then our prospects for future revenue growth may be adversely impacted.

**We face significant competition.**

We face significant competition from businesses that 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 AmBisome, we are encountering significant competition from new products produced by Merck and Pfizer. In addition, we are aware of reports of at least three lipid formulations that claim similarity to AmBisome becoming available outside of the United States, including the possible entry of one such formulation in Greece. These formulations may reduce market demand for AmBisome. Furthermore, the manufacture of lipid formulations of amphotericin B is very complex and if any of these formulations are found to be unsafe, sales of AmBisome may be negatively impacted by association. For Hepsera, we have encountered increased competition with the launch of BMS's Baraclude (entecavir) and the launch of Novartis/Idenix's Tyzeka/Sebivo (telbivudine) in the United States, the European Union and China. In addition, we are developing ambrisentan for the treatment of PAH and aztreonam lysine for inhalation for the treatment of bacterial infections in patients with CF. If approved, ambrisentan would compete directly with Actelion Ltd.'s Tracleer (bosentan), Encysive Pharmaceuticals Inc.'s Thelin (sitaxentan sodium), which is pending FDA approval, and indirectly with PAH products from United Therapeutics Corporation and Pfizer. Aztreonam lysine for inhalation, if and when approved for marketing, would compete with TOBI (tobramycin for inhalation), 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 that support the marketing approvals for our products and that form the basis for the safety warnings in our product labels were obtained in controlled clinical trials of limited duration and, in some cases, from limited post-approval use. As our products, including Truvada, Atripla, Viread, Emtriva, AmBisome and Hepsera, are used over longer periods of time by many patients taking numerous other medicines, many of whom have underlying health problems, 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. Safety and efficacy studies of Viread and Emtriva, dosed as separate products, are ongoing and have been underway for a longer period of time than the safety and efficacy studies of Truvada (Viread and Emtriva together), which are also underway. We are also conducting similar studies of Atripla (Truvada and Sustiva together). If serious safety, resistance or interaction issues arise with our marketed products, sales of these products could be limited or halted by us or by regulatory authorities.

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### **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 that 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, Emtriva, AmBisome and Hepsera 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 marketing approval on a timely basis, or at all.

In addition, our marketed products and how we manufacture and sell these products are subject to extensive continued 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.

### **The results 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 effectiveness 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. In addition, even successfully completed large-scale clinical trials may not result in marketable products. If any of our products under development 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 drug candidate could be delayed or halted. 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.

In addition, following our acquisition of Myogen, we are developing new product candidates (darusentan and ambrisentan) that have different safety profiles than our currently marketed products. As these new product candidates are developed, they may prove to be more susceptible to safety or drug interaction issues than we have experienced in the past. If safety issues arise with either of these product candidates, our clinical development programs may be limited or halted by us or by regulatory authorities and the product candidates may never become marketable products.

### **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

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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. We do not know whether the investigation involves or will impact any of our clinical data results or related regulatory approvals.

### **We may not be able to successfully integrate our existing business with the businesses of Corus, Raylo Chemicals Inc. and Myogen.**

Integrating these businesses with our existing business will be a complex and time-consuming process. Until recently, Corus, Raylo and Myogen operated independently of us, each with its own business, corporate culture, locations, employees and systems. As a result of these acquisitions, we have to operate our existing business, along with the businesses of Corus, Raylo and Myogen, as one combined organization utilizing common information and communication systems, operating procedures, financial controls and human resources practices, including benefits, training and professional development programs. There may be substantial difficulties, costs and delays involved in the integration of these companies with us and the integration with us of any other company or assets that we may from time to time acquire. The failure to successfully integrate these companies with us, or any other assets or companies we may acquire, may have a material adverse effect on our business, financial condition and results of operations.

The remaining efforts for completion of Corus' and Myogen's research and development programs primarily consist of clinical trials, the cost, length and success of which are extremely difficult to predict, and obtaining necessary regulatory approvals. We may face numerous risks and uncertainties in our integration that could prevent completion of development, including the ability to enroll patients in clinical trials, 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 or delays in later stage clinical trials or additional trials to be performed.

### **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, Emtriva, Hepsera and Vistide. 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 our manufacturers are subject to the FDA's current Good Manufacturing Practices, which are extensive regulations governing manufacturing processes, stability testing, record-keeping and quality standards and similar regulations are in effect in other countries. Our manufacturing operations are also subject to routine inspections by regulatory agencies. Additionally, our third-party manufacturers are independent entities who are subject to their own unique operational and financial risks which are out of our control. To the extent that these risks materialize and affect their performance obligations to us, it may adversely affect our financial results.

In addition, F. Hoffmann-La Roche Ltd. (together with Hoffmann-La Roche Inc., Roche), either by itself or through third parties, is responsible for manufacturing Tamiflu. If 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. These events could harm our competitive position and financial results.

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**We may not be able to manufacture AmBisome and Macugen to meet market needs in the event of business interruptions at our San Dimas facility.**

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

Aztreonam lysine is a mono-bactam Gram-negative antibiotic that we currently plan to manufacture, by ourselves or through third parties, in a multi-product manufacturing facility. Historically, the FDA has permitted the manufacture of mono-bactams in multi-product manufacturing facilities; however, there can be no assurances 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 lysine for inhalation nor have we engaged a contract manufacturer with a single-product facility for aztreonam lysine for inhalation. If the FDA prohibits the manufacture of mono-bactam antibiotics, like aztreonam lysine 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 lysine 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 manufacture or sell our products, which could limit our ability to generate revenues.**

Some of the materials that we utilize in our operations are made at only one facility. For example, we depend on a single supplier for high quality cholesterol, which is used in the manufacture of AmBisome. Because the suppliers of key components and materials must be named in the new drug application (NDA) filed with the FDA for a product, significant delays can occur if the qualification of a new supplier is required. If delivery of material from our suppliers were interrupted for any reason, we may be unable to ship Truvada, Atripla, Viread, Emtriva, Hepsera, AmBisome or Vistide, or to supply any of our products in development for clinical trials. In addition, we will depend on single suppliers for the ambrisentan API and tableting, which is pending FDA approval. Problems with these suppliers could adversely impact our commercial launch of ambrisentan, if and when regulatory approval is obtained. Further, the aztreonam lysine for inhalation that we are developing is administered to the lungs of patients through a device that is made by a single supplier.

**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 Astellas Pharma, Inc. and Dainippon Sumitomo Pharma Co., Ltd. for AmBisome, GSK for Hepsera, Roche for Tamiflu, Pfizer for Vistide, OSI and Pfizer Inc. for Macugen, Japan Tobacco Inc. for Viread, Truvada and Emtriva and our joint venture with BMS for Atripla. In many countries, we rely on international distributors for sales of Truvada, Viread, Emtriva, AmBisome and Hepsera. Some of these relationships also involve the clinical development of these products by our partners. Reliance on collaborative relationships poses a number of risks, including:

the risk that we are not able to control the resources our corporate partners devote to our programs or products;

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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

the risk that our distributors and corporate partners 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 revenue from existing 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 The Republic of Korea. The success of Hepsera in these territories will depend 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, ambrisentan, if approved by the FDA, will be distributed through third-party specialty pharmacies, which are pharmacies specializing in the dispensing of medications for complex or chronic conditions that often require a high level of patient education and ongoing counseling to monitor compliance. The use of specialty pharmacies will require significant coordination with our sales and marketing, medical affairs, regulatory affairs, legal and finance organizations and involve risks, including but not limited to risks that these specialty pharmacies:

will not provide us with accurate or timely information regarding their inventories, the number of patients who are using ambrisentan or safety complaints;

will not effectively sell or support ambrisentan;

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

be unable to satisfy financial obligations to us or others; or

will cease operations.



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Pending approval of ambrisentan, any such failure may result in decreased product sales and lower product sales to us, which would harm our business. Further, the aztreonam lysine for inhalation that we are developing is administered to the lungs of patients through a device that is made by a single supplier.

Further, we will rely on the supplier of the inhalation device that delivers aztreonam lysine for inhalation, if and when regulatory approval is obtained, to distribute the device through specialty pharmacies or other distribution channels. If sufficient quantities of this device are not available at the time of a commercial launch or following such a launch, the commercial launch of aztreonam lysine for inhalation could be delayed, and the anticipated contribution of aztreonam lysine for inhalation to our financial results could be adversely effected.

### **Expenses associated with clinical trials and sales fluctuations as a result of inventory levels held by wholesalers 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.

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. For example, as a result of our review of inventory realizability, during the first and fourth quarters of 2006, we recorded write-downs of a portion of our Gilead Access Program inventory. Additional write-downs of inventory for our Gilead Access Program may be necessary if demand for our HIV products in the Access Program countries is not sufficient to consume existing inventories.

During the first quarter of 2007, approximately 94% of our product sales in the United States were to three wholesalers, AmerisourceBergen Corp., Cardinal Health, Inc. and McKesson 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, correctional facilities and large health maintenance organizations, which currently contributes to approximately 30% of our HIV business, tends to be less consistent in terms of buying patterns, and often causes quarter over quarter fluctuations that do not necessarily mirror the growth patterns that can be seen in the retail prescription data. The unpredictable variability of Roche's Tamiflu sales and the strong relationship between this revenue and global pandemic planning also cause our royalty revenues 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. 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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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.

We have a number of U.S. and foreign patents, patent applications and rights to patents related to the 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. Competitors may have filed patent applications or received patents and may obtain additional patents and proprietary rights that block or compete with our 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. 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. In addition, from time to time, certain individuals or entities may challenge our patents. For example, in March 2007, the Public Patent Foundation filed Requests for Reexamination with the United States Patent and Trademark Office challenging four of our patents related to tenofovir disoproxil fumarate, which is an API in Truvada, Atripla and Viread.

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 HBV, 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, or attempt to launch, a generic version of Flolan in the United States in 2007 or thereafter.

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.

Our competitors may file patent applications covering our technology. If so, 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.

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.

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



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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 such licenses or alternative technologies, we may be unable to develop or commercialize some or all of our products.

In addition, 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.

### **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 such licenses or alternative technologies, we may be unable to develop or commercialize some or all of our products.

In addition, 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.

### **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. Increases in the value of the U.S. dollar against foreign currencies in the past have reduced, and in the future may reduce, our U.S. dollar equivalent sales and negatively impact our financial condition and results of operations. We use foreign currency forward contracts to hedge a percentage of our forecasted international sales, primarily those denominated in the Euro currency. 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. Our hedging program only hedges a portion of our total exposure and significant foreign exchange rate fluctuations within a short period of time could adversely affect our results of operations.

### **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 \$354.2 million as of March 31, 2007. 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 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

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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 no-profit prices to 97 countries participating in our Gilead Access Program, or Atripla, which Merck will distribute at low cost to HIV-infected patients in developing countries under our August 2006 agreement, our revenues would be adversely affected. In addition, we have granted non-exclusive, voluntary licenses for the manufacture of tenofovir disoproxil fumarate to eleven generic manufacturers in India for the local Indian market and for manufacturers to export product to 95 of the developing world countries included in our Gilead Access Program. If generic versions of Viread under these licenses are then re-exported to the United States, Europe or other markets outside of India or the 97 developing world countries participating in our Gilead Access Program, our revenues would be adversely affected.

In addition, in the European Union, we are required to permit cross-border sales. This allows buyers in countries where government-approved prices for our products are relatively high to purchase our products legally from countries where they are sold at lower prices. 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 gross margin and may cause our sales to fluctuate from quarter to quarter. During the first quarter of 2007, we have seen increased instances of such cross-border sales in Europe. Additionally, some U.S. consumers have been able to purchase products, including HIV products, from internet pharmacies in other countries at substantial discounts. Such cross-border sales could adversely affect our revenues.

**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 groups have suggested that pharmaceutical companies should make drugs for HIV infection available at low cost. Alternatively, governments in those 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 as fear grows about a potential avian flu pandemic have generated international discussions over potential compulsory licensing of our Tamiflu patents. For example, the Canadian government has allowed Canadian manufacturers to manufacture and sell the active ingredient in Tamiflu in Canada and certain other countries. 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.

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

Successful commercialization of our products depends, in part, on the availability of governmental and third-party payor reimbursement for the cost of such products and related treatments. Government health administration authorities, private health insurers and other organizations generally provide reimbursement. Government authorities and third-party payors increasingly are challenging the price of medical products and services, particularly for innovative new products and therapies. This has resulted in lower average sales prices. For example, a majority of our sales of AmBisome and Vistide, and a majority of our sales of Truvada, Atripla, Viread and Hepsera, 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 U.S. or international pricing pressures. 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, Viread, Emtriva, Hepsera, AmBisome and Tamiflu, as well as Atripla, if and when approved in the European Union, will also depend largely on obtaining and maintaining government reimbursement because in many European countries, patients are unlikely to use prescription drugs that are not reimbursed by their governments. In addition, negotiating prices with governmental authorities can delay commercialization by twelve months or more. We also expect that the success of our products in development, particularly in Europe, will depend on the ability to obtain reimbursement. 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 much of Europe. 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. Recently, there have been significant changes to the federal Medicare system 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. Some of the entities providing Medicare Part D coverage have attempted to negotiate price concessions from pharmaceutical manufacturers. In addition, discussions are taking place at the federal level to pass a non-interference bill that would either allow or require the federal government to directly negotiate price concessions from pharmaceutical manufacturers. The increasing pressure to lower prescription drug prices may limit drug access for Medicare Part D enrollees. 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 is not yet clear to us, and the impact will depend in part on specific decisions regarding the level of coverage provided for the therapeutic categories in which our products are included, the terms on which such coverage is provided, and the extent to which preference is given to selected products in a category. Further, Medicare patients will have to pay co-insurance, which may influence which products are recommended by physicians and selected by patients. These changes in Medicare reimbursement could have a negative effect on revenues. Federal Medicare proposals, along with State Medicaid drug payment changes and healthcare reforms could also lower payment for our products. Our results of operations could be materially adversely

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affected by the reimbursement changes emerging from the Medicare prescription drug coverage legislation. In addition, to the extent that private insurers such as Blue Cross and Blue Shield or managed care programs follow Medicaid coverage and payment developments, the adverse effects of lower Medicare payment may be magnified by private insurers adopting lower payment schedules. Additionally, some states have enacted health care reform legislation. Further federal and state developments are possible.

### **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 products in development, involve substantial risk of product liability claims. These claims may be made directly by consumers, healthcare providers, pharmaceutical companies or others. Our product liability insurance may not cover a successful product liability claim against us and we could be required to pay amounts beyond that provided by our insurance, either of which could impair our financial condition and our ability to clinically test and to market 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 are named as a defendant in a lawsuit regarding average wholesale pricing practices under Medicaid. In addition, we, along with certain of our officers, were named as defendants in a class action lawsuit alleging violations of federal securities laws, which lawsuit has been dismissed by the court. However, the plaintiffs have appealed the dismissal. In September 2006, we were named as a defendant in a lawsuit alleging we were negligent in our conduct of our emtricitabine clinical trial. In November 2006, we received a subpoena from the United States Attorney's Office in San Francisco requesting documents regarding our marketing and medical education programs for Truvada, Viread and Emtriva. We are complying with the U.S. Attorney's subpoena and intend to cooperate with any related government investigation. The outcome of these lawsuits, 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 monetary damages, penalties or injunctive relief against us that could significantly reduce our earnings and cash flows.

### **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, our adoption of Financial Accounting Standards Board Interpretation No. 48, *Accounting for Uncertainty in Income Taxes*, an interpretation of Statement of Financial Accounting Standards No. 109, *Accounting for Income Taxes*, mergers and acquisitions, future levels of research and development (R&D) spending, changes in accounting standards, future levels of capital expenditures, 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 and state 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.

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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 the Franchise Tax Board of California for the 2004 and 2005 tax years. 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 interim reporting period could have a material impact on the results of operations for that period.

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

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

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

Not applicable.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

Not applicable.

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

Not applicable.

**ITEM 5. OTHER INFORMATION**

Not applicable.

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

| <b>Exhibit Footnote</b> | <b>Exhibit Number</b> | <b>Description of Document</b>   |
|-------------------------|-----------------------|--|
| (1)                     | 2.1                   | Asset Purchase Agreement between Registrant and OSI Pharmaceuticals, Inc., dated November 26, 2001   |
| (2)                     | 2.2                   | Agreement and Plan of Merger, among Registrant, Simbolo Acquisition Sub, Inc., a wholly-owned subsidiary of Registrant, and Triangle Pharmaceuticals, Inc., dated December 3, 2002   |
| (3)                     | 2.3                   | Agreement and Plan of Merger, among Registrant, Gryphon Acquisition Sub, Inc., Corus Pharma, Inc. and Rodney A. Ferguson, Ph.D., as Chairman of and on behalf of the Stockholder Representative Committee, dated April 12, 2006            |
| *(4)                    | 2.4                   | Stock Purchase Agreement, among Registrant, Degussa AG, Laporte Nederland BV and Raylo Chemicals Inc., dated June 6, 2006  |
| (5)                     | 2.5                   | Agreement and Plan of Merger, among Registrant, Mustang Merger Sub, Inc. and Myogen, Inc., dated October 1, 2006   |
| (6)                     | 3.1                   | Restated Certificate of Incorporation of the Registrant, as amended  |
| (7)                     | 3.2                   | Certificate of Amendment to the Restated Certificate of Incorporation of Registrant  |
| (8)                     | 3.3                   | Certificate of Designation of the Series A Junior Participating Preferred Stock of Registrant  |
| (7)                     | 3.4                   | Amendment to Certificate of Designation of the Series A Junior Participating Preferred Stock of Registrant   |
| (9)                     | 3.5                   | Amended and Restated Bylaws of the Registrant, as amended and restated on December 19, 2006  |
|                         | 4.1                   | Reference is made to Exhibit 3.1, Exhibit 3.2, Exhibit 3.3, Exhibit 3.4 and Exhibit 3.5  |
| (10)                    | 4.2                   | Amended and Restated Rights Agreement between the Registrant and ChaseMellon Shareholder Services, LLC, dated October 21, 1999   |
| (11)                    | 4.3                   | First Amendment to Amended and Restated Rights Agreement between the Registrant and Mellon Investor Services, LLC (formerly known as ChaseMellon Shareholder Services, LLC), dated October 29, 2003  |
| (12)                    | 4.4                   | Second Amendment to Amended and Restated Rights Agreement between the Registrant and Mellon Investor Services, LLC (formerly known as ChaseMellon Shareholder Services, LLC), dated May 11, 2006   |
| (13)                    | 4.5                   | Indenture related to the Convertible Senior Notes, due 2011, between Registrant and Wells Fargo Bank, National Association, as trustee (including form of 0.50% Convertible Senior Note due 2011), dated April 25, 2006                    |
| (13)                    | 4.6                   | Indenture related to the Convertible Senior Notes, due 2013, between Registrant and Wells Fargo Bank, National Association, as trustee (including form of 0.625% Convertible Senior Note due 2013), dated April 25, 2006                   |
| (13)                    | 4.7                   | Registration Rights Agreement, by and among Registrant and Merrill Lynch, Pierce, Fenner & Smith Incorporated, Morgan Stanley & Co. Incorporated, Banc of America Securities LLC and Goldman, Sachs & Co. Inc., dated as of April 25, 2006 |

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| <b>Exhibit Footnote</b> | <b>Exhibit Number</b> | <b>Description of Document</b>  |
|-------------------------|-----------------------|---|
| *(14)                   | 10.1                  | Form of Indemnity Agreement entered into between the Registrant and its directors and executive officers  |
| *(14)                   | 10.2                  | Form of Employee Proprietary Information and Invention Agreement entered into between Registrant and certain of its officers and key employees  |
| *(9)                    | 10.3                  | Form of Employee Proprietary Information and Invention Agreement entered into between Registrant and certain of its officers and key employees, revised in September 2006   |
| *(14)                   | 10.4                  | Form of option agreements used under the 1991 Stock Option Plan   |
| +(14)                   | 10.5                  | Letter Agreement between Registrant and IOCB/REGA, dated September 23, 1991   |
| *(15)                   | 10.6                  | Registrant's Employee Stock Purchase Plan, as amended through July 27, 2005   |
| *(16)                   | 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  |
| *(16),(17)              | 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  |
| +(18)                   | 10.9                  | Amendment Agreement between Registrant and IOCB/REGA, dated October 25, 1993  |
| (19)                    | 10.10                 | Amendment Agreement between Registrant and IOCB/REGA, dated December 27, 2000   |
| +(3)                    | 10.11                 | Development and License Agreement among Registrant and F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc., dated September 27, 1996  |
| (20)                    | 10.12                 | NeXstar Pharmaceuticals, Inc.'s 1993 Incentive Stock Plan, adopted February 8, 1993, as amended   |
| (21)                    | 10.13                 | NeXstar Pharmaceuticals, Inc.'s 1995 Director Option Plan, adopted July 25, 1995  |
| +(22)                   | 10.17                 | License and Distribution Agreement between Dainippon Sumitomo Pharma Co., Ltd. (as successor to Sumitomo Pharmaceuticals Co., Ltd.) and Registrant (as successor to NeXstar Pharmaceuticals, Inc.), dated September 26, 1996  |
| +(23)                   | 10.18                 | 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   |
| (24)                    | 10.19                 | Amendment, dated April 30, 1998, between Sumitomo Pharmaceuticals Co., Ltd. and Registrant (as successor to NeXstar Pharmaceuticals, Inc.) to the License and Distribution Agreement, dated September 26, 1996, between Sumitomo and Registrant (as successor to NeXstar Pharmaceuticals, Inc.) |
| *(25)                   | 10.20                 | Gilead Sciences, Inc. Deferred Compensation Plan - Basic Plan Document  |
| *(25)                   | 10.21                 | Gilead Sciences, Inc. Deferred Compensation Plan - Adoption Agreement   |
| *(25)                   | 10.22                 | Addendum to the Gilead Sciences, Inc. Deferred Compensation Plan  |
| +(26)                   | 10.23                 | Licensing Agreement between Gilead World Markets, Limited and Glaxo Group Limited, dated April 26, 2002   |

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| <b>Exhibit<br/>Footnote</b> | <b>Exhibit<br/>Number</b> | <b>Description of Document</b>   |
|-----------------------------|---------------------------|--|
| (27)                        | 10.24                     | Triangle Pharmaceuticals, Inc. 1996 Stock Incentive Plan   |
| +(28)                       | 10.25                     | Exclusive License Agreement between Registrant (as successor to Triangle Pharmaceuticals, Inc.), Glaxo Group Limited, The Wellcome Foundation Limited, Glaxo Wellcome Inc. and Emory University, dated May 6, 1999   |
| +(28)                       | 10.26                     | Settlement Agreement between Registrant (as successor to Triangle Pharmaceuticals, Inc.), Emory University, Dr. David W. Barry, Glaxo Wellcome plc, Glaxo Wellcome Inc., Glaxo Group Limited and The Wellcome Foundation Limited, dated May 6, 1999            |
| +(29)                       | 10.27                     | Settlement and Exclusive License Agreement between Registrant (as successor to Triangle Pharmaceuticals, Inc.), Shire Biochem Inc., Shire Pharmaceuticals Group plc, Emory University and the University of Georgia Research Foundation, dated August 30, 2002 |
| +(30)                       | 10.29                     | Master Clinical and Commercial Supply Agreement between Gilead World Markets, Ltd., Registrant and Patheon Inc., dated January 1, 2003   |
| +(30)                       | 10.30                     | Licensing Agreement between Registrant and OSI Pharmaceuticals, Inc. (as successor to Eyetech Pharmaceuticals, Inc.), dated March 31, 2000 and amended on May 9, 2000, December 4, 2001 and April 12, 2002   |
| (30)                        | 10.31                     | Amendment No. 1 to Licensing Agreement between Eyetech Pharmaceuticals, Inc. and Registrant, dated May 9, 2000   |
| (30)                        | 10.32                     | Amendment No. 2 to Licensing Agreement between OSI Pharmaceuticals, Inc. (as successor to Eyetech Pharmaceuticals, Inc.) and Registrant, dated December 4, 2001  |
| +(30)                       | 10.33                     | Amendment No. 3 to Licensing Agreement between OSI Pharmaceuticals, Inc. (as successor to Eyetech Pharmaceuticals, Inc.) and Registrant, dated August 30, 2002   |
| +(30)                       | 10.34                     | Amendment No. 1 dated May 19, 2003 to Licensing Agreement dated 26 April 2002 between Glaxo Group Limited and Gilead World Markets Limited   |
| +(31)                       | 10.35                     | License Agreement between Japan Tobacco Inc. and Registrant, dated March 22, 2005  |
| +(32)                       | 10.36                     | Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Gilead World Markets, Ltd. and Pharmachem Technologies (Grand Bahama), Ltd., dated July 17, 2003   |
| +(32)                       | 10.37                     | 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  |
| +(32)                       | 10.38                     | 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   |
| (33)                        | 10.39                     | Term Loan Agreement between Gilead Biopharmaceutics Ireland Corporation, the lenders party thereto and Bank of America, N.A., as Administrative Agent, dated December 21, 2005   |
| (33)                        | 10.40                     | Parent Guaranty Agreement by Registrant dated December 21, 2005 in favor of Bank Of America, N.A (in connection with the Term Loan Agreement)  |



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| <b>Exhibit<br/>Footnote</b> | <b>Exhibit<br/>Number</b> | <b>Description of Document</b>  |
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| (33)                        | 10.41                     | Subsidiary Guaranty Agreement by Gilead Vintage Park, LLC (in connection with the Term Loan Agreement), dated December 21, 2005   |
| (33)                        | 10.42                     | Credit Agreement between Registrant, the lenders party thereto and Bank of America, N.A., as Administrative Agent, Swing Line Lender and L/C Issuer, dated as of December 21, 2005                |
| (33)                        | 10.43                     | Subsidiary Guaranty Agreement by Gilead Vintage Park, LLC, dated December 21, 2005 (in connection with the Credit Agreement)  |
| *(34)                       | 10.44                     | Form of employee stock option agreement used under 2004 Equity Incentive Plan   |
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| *(34)                       | 10.46                     | Gilead Sciences, Inc. Corporate Bonus Plan  |
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| *(7)                        | 10.53                     | Gilead Sciences, Inc. 2005 Deferred Compensation Plan   |
| (4)                         | 10.54                     | 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.                |
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| *(36)                       | 10.59                     | Corus Pharma, Inc. 2001 Stock Plan  |

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| *(36)                   | 10.60                 | Form of Corus Pharma, Inc. 2001 Stock Plan Stock Option Agreement   |
| *(3)                    | 10.61                 | Form of Restricted Award Agreement used under 2004 Equity Incentive Plan  |
| (3)                     | 10.62                 | 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 |
| +(3)                    | 10.63                 | 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                       |
| *(37)                   | 10.64                 | 2007 Base Salaries for the Named Executive Officers   |
| *(9)                    | 10.65                 | Form of Performance Share Award Agreement used under the 2004 Equity Incentive Plan   |
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| +(38)                   | 10.67                 | License Agreement between Abbott Deutschland Holding GmbH and the Company, dated October 8, 2001.   |
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|                         | 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**                  | Certification 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 January 4, 2002, and incorporated herein by reference.
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- (3) 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.
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- (11) Filed as an exhibit to the Registrant's Current Report on Form 8-K filed on October 31, 2003, and incorporated herein by reference.
- (12) 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.
- (13) Filed as an exhibit to the Registrant's Current Report on Form 8-K filed on April 25, 2006, and incorporated herein by reference.
- (14) Filed as an exhibit to Registrant's Registration Statement on Form S-1 (No. 33-55680), as amended, and incorporated herein by reference.
- (15) Filed as an exhibit to Registrant's Form 10-K for the fiscal year ended December 31, 2005, and incorporated herein by reference.
- (16) 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.
- (17) 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.
- (18) 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.
- (19) Filed as an exhibit to Registrant's Form 10-K for the fiscal year ended December 31, 2000, and incorporated herein by reference.
- (20) Filed as an exhibit to NeXstar Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q for the quarter ended June 30, 1997, and incorporated herein by reference.
- (21) Filed as an exhibit to NeXstar Pharmaceuticals, Inc.'s Form 10-Q for the quarter ended September 30, 1995, and incorporated herein by reference.
- (22) Filed as an exhibit to NeXstar Pharmaceuticals, Inc.'s Form 10-K for the fiscal year ended December 31, 1996, and incorporated herein by reference.
- (23) Filed as an exhibit to NeXstar Pharmaceuticals, Inc.'s Form 10-Q for the quarter ended September 30, 1997, and incorporated herein by reference.
- (24) Filed as an exhibit to NeXstar Pharmaceuticals, Inc.'s Form 10-Q for the quarter ended June 30, 1998, and incorporated herein by reference.
- (25) Filed as an exhibit to Registrant's Form 10-K for the fiscal year ended December 31, 2001, and incorporated herein by reference.
- (26) 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.
- (27) Filed as an exhibit to Registrant's Registration Statement on Form S-8 (No. 333-102911) filed on January 31, 2003, and incorporated herein by reference.
- (28) 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.
- (29) 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.
- (30) Filed as an exhibit to Registrant's Form 10-K for the fiscal year ended December 31, 2003, and incorporated herein by reference.
- (31) Filed as an exhibit to Registrant's Form 10-Q for the quarter ended March 31, 2005, and incorporated herein by reference.
- (32) Filed as an exhibit to Registrant's Form 10-Q for the quarter ended September 30, 2005, and incorporated herein by reference.
- (33) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on December 27, 2005, and incorporated herein by reference.
- (34) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on February 22, 2006, and incorporated herein by reference.

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- (35) Filed as an exhibit to Registrant's Form 10-Q for the quarter ended March 31, 2006, and incorporated herein by reference.
- (36) Filed as an exhibit to Registrant's Registration Statement on Form S-8 (No. 333-136814) filed on August 22, 2006, and incorporated herein by reference.
- (37) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on January 23, 2007, and incorporated herein by reference.
- (38) 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.
- (39) Filed as an exhibit to Myogen, Inc.'s Quarterly Report on Form 10-Q filed on May 9, 2006, and incorporated herein by reference.

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- \* Management contract or compensatory plan or arrangement required to be filed pursuant to Item 15(b) of Form 10-K.
  - + 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.
  - \*\* 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.

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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: May 4, 2007

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

**President and Chief Executive Officer**

**(Principal Executive Officer)**

Date: May 4, 2007

/s/ JOHN F. MILLIGAN  
**John F. Milligan, Ph.D.**

**Chief Operating Officer and Chief Financial Officer**

**(Principal Financial and Accounting Officer)**

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(a) Exhibits

| <b>Exhibit Footnote</b> | <b>Exhibit Number</b> | <b>Description of Document</b>  |
|-------------------------|-----------------------|---|
| (1)                     | 2.1                   | Asset Purchase Agreement between Registrant and OSI Pharmaceuticals, Inc., dated November 26, 2001  |
| (2)                     | 2.2                   | Agreement and Plan of Merger, among Registrant, Simbolo Acquisition Sub, Inc., a wholly-owned subsidiary of Registrant, and Triangle Pharmaceuticals, Inc., dated December 3, 2002  |
| (3)                     | 2.3                   | Agreement and Plan of Merger, among Registrant, Gryphon Acquisition Sub, Inc., Corus Pharma, Inc. and Rodney A. Ferguson, Ph.D., as Chairman of and on behalf of the Stockholder Representative Committee, dated April 12, 2006 |
| *(4)                    | 2.4                   | Stock Purchase Agreement, among Registrant, Degussa AG, Laporte Nederland BV and Raylo Chemicals Inc., dated June 6, 2006   |
| (5)                     | 2.5                   | Agreement and Plan of Merger, among Registrant, Mustang Merger Sub, Inc. and Myogen, Inc., dated October 1, 2006  |
| (6)                     | 3.1                   | Restated Certificate of Incorporation of the Registrant, as amended   |
| (7)                     | 3.2                   | Certificate of Amendment to the Restated Certificate of Incorporation of Registrant   |
| (8)                     | 3.3                   | Certificate of Designation of the Series A Junior Participating Preferred Stock of Registrant   |
| (7)                     | 3.4                   | Amendment to Certificate of Designation of the Series A Junior Participating Preferred Stock of Registrant  |
| (9)                     | 3.5                   | Amended and Restated Bylaws of the Registrant, as amended and restated on December 19, 2006   |
|                         | 4.1                   | Reference is made to Exhibit 3.1, Exhibit 3.2, Exhibit 3.3, Exhibit 3.4 and Exhibit 3.5   |
| (10)                    | 4.2                   | Amended and Restated Rights Agreement between the Registrant and ChaseMellon Shareholder Services, LLC, dated October 21, 1999  |
| (11)                    | 4.3                   | First Amendment to Amended and Restated Rights Agreement between the Registrant and Mellon Investor Services, LLC (formerly known as ChaseMellon Shareholder Services, LLC), dated October 29, 2003                             |
| (12)                    | 4.4                   | Second Amendment to Amended and Restated Rights Agreement between the Registrant and Mellon Investor Services, LLC (formerly known as ChaseMellon Shareholder Services, LLC), dated May 11, 2006                                |
| (13)                    | 4.5                   | Indenture related to the Convertible Senior Notes, due 2011, between Registrant and Wells Fargo Bank, National Association, as trustee (including form of 0.50% Convertible Senior Note due 2011), dated April 25, 2006         |
| (13)                    | 4.6                   | Indenture related to the Convertible Senior Notes, due 2013, between Registrant and Wells Fargo Bank, National Association, as trustee (including form of 0.625% Convertible Senior Note due 2013), dated April 25, 2006        |

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| <b>Exhibit Footnote</b> | <b>Exhibit Number</b> | <b>Description of Document</b>  |
|-------------------------|-----------------------|---|
| (13)                    | 4.7                   | Registration Rights Agreement, by and among Registrant and Merrill Lynch, Pierce, Fenner & Smith Incorporated, Morgan Stanley & Co. Incorporated, Banc of America Securities LLC and Goldman, Sachs & Co. Inc., dated as of April 25, 2006  |
| *(14)                   | 10.1                  | Form of Indemnity Agreement entered into between the Registrant and its directors and executive officers  |
| *(14)                   | 10.2                  | Form of Employee Proprietary Information and Invention Agreement entered into between Registrant and certain of its officers and key employees  |
| *(9)                    | 10.3                  | Form of Employee Proprietary Information and Invention Agreement entered into between Registrant and certain of its officers and key employees, revised in September 2006   |
| *(14)                   | 10.4                  | Form of option agreements used under the 1991 Stock Option Plan   |
| +(14)                   | 10.5                  | Letter Agreement between Registrant and IOCB/REGA, dated September 23, 1991   |
| *(15)                   | 10.6                  | Registrant's Employee Stock Purchase Plan, as amended through July 27, 2005   |
| *(16)                   | 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  |
| *(16),(17)              | 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  |
| +(18)                   | 10.9                  | Amendment Agreement between Registrant and IOCB/REGA, dated October 25, 1993  |
| (19)                    | 10.10                 | Amendment Agreement between Registrant and IOCB/REGA, dated December 27, 2000   |
| +(3)                    | 10.11                 | Development and License Agreement among Registrant and F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc., dated September 27, 1996  |
| (20)                    | 10.12                 | NeXstar Pharmaceuticals, Inc.'s 1993 Incentive Stock Plan, adopted February 8, 1993, as amended   |
| (21)                    | 10.13                 | NeXstar Pharmaceuticals, Inc.'s 1995 Director Option Plan, adopted July 25, 1995  |
| +(22)                   | 10.17                 | License and Distribution Agreement between Dainippon Sumitomo Pharma Co., Ltd. (as successor to Sumitomo Pharmaceuticals Co., Ltd.) and Registrant (as successor to NeXstar Pharmaceuticals, Inc.), dated September 26, 1996  |
| +(23)                   | 10.18                 | 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   |
| (24)                    | 10.19                 | Amendment, dated April 30, 1998, between Sumitomo Pharmaceuticals Co., Ltd. and Registrant (as successor to NeXstar Pharmaceuticals, Inc.) to the License and Distribution Agreement, dated September 26, 1996, between Sumitomo and Registrant (as successor to NeXstar Pharmaceuticals, Inc.) |
| *(25)                   | 10.20                 | Gilead Sciences, Inc. Deferred Compensation Plan Basic Plan Document  |
| *(25)                   | 10.21                 | Gilead Sciences, Inc. Deferred Compensation Plan Adoption Agreement   |
| *(25)                   | 10.22                 | Addendum to the Gilead Sciences, Inc. Deferred Compensation Plan  |

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| +(26)                   | 10.23                 | Licensing Agreement between Gilead World Markets, Limited and Glaxo Group Limited, dated April 26, 2002  |
| (27)                    | 10.24                 | Triangle Pharmaceuticals, Inc. 1996 Stock Incentive Plan   |
| +(28)                   | 10.25                 | Exclusive License Agreement between Registrant (as successor to Triangle Pharmaceuticals, Inc.), Glaxo Group Limited, The Wellcome Foundation Limited, Glaxo Wellcome Inc. and Emory University, dated May 6, 1999   |
| +(28)                   | 10.26                 | Settlement Agreement between Registrant (as successor to Triangle Pharmaceuticals, Inc.), Emory University, Dr. David W. Barry, Glaxo Wellcome plc, Glaxo Wellcome Inc., Glaxo Group Limited and The Wellcome Foundation Limited, dated May 6, 1999            |
| +(29)                   | 10.27                 | Settlement and Exclusive License Agreement between Registrant (as successor to Triangle Pharmaceuticals, Inc.), Shire Biochem Inc., Shire Pharmaceuticals Group plc, Emory University and the University of Georgia Research Foundation, dated August 30, 2002 |
| +(30)                   | 10.29                 | Master Clinical and Commercial Supply Agreement between Gilead World Markets, Ltd., Registrant and Patheon Inc., dated January 1, 2003   |
| +(30)                   | 10.30                 | Licensing Agreement between Registrant and OSI Pharmaceuticals, Inc. (as successor to Eyetech Pharmaceuticals, Inc.), dated March 31, 2000 and amended on May 9, 2000, December 4, 2001 and April 12, 2002   |
| (30)                    | 10.31                 | Amendment No. 1 to Licensing Agreement between Eyetech Pharmaceuticals, Inc. and Registrant, dated May 9, 2000   |
| (30)                    | 10.32                 | Amendment No. 2 to Licensing Agreement between OSI Pharmaceuticals, Inc. (as successor to Eyetech Pharmaceuticals, Inc.) and Registrant, dated December 4, 2001  |
| +(30)                   | 10.33                 | Amendment No. 3 to Licensing Agreement between OSI Pharmaceuticals, Inc. (as successor to Eyetech Pharmaceuticals, Inc.) and Registrant, dated August 30, 2002   |
| +(30)                   | 10.34                 | Amendment No. 1 dated May 19, 2003 to Licensing Agreement dated 26 April 2002 between Glaxo Group Limited and Gilead World Markets Limited   |
| +(31)                   | 10.35                 | License Agreement between Japan Tobacco Inc. and Registrant, dated March 22, 2005  |
| +(32)                   | 10.36                 | Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Gilead World Markets, Ltd. and Pharmachem Technologies (Grand Bahama), Ltd., dated July 17, 2003   |
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- (11) Filed as an exhibit to the Registrant's Current Report on Form 8-K filed on October 31, 2003, and incorporated herein by reference.
- (12) 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.
- (13) Filed as an exhibit to the Registrant's Current Report on Form 8-K filed on April 25, 2006, and incorporated herein by reference.
- (14) Filed as an exhibit to Registrant's Registration Statement on Form S-1 (No. 33-55680), as amended, and incorporated herein by reference.
- (15) Filed as an exhibit to Registrant's Form 10-K for the fiscal year ended December 31, 2005, and incorporated herein by reference.
- (16) 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.
- (17) 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.
- (18) 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.
- (19) Filed as an exhibit to Registrant's Form 10-K for the fiscal year ended December 31, 2000, and incorporated herein by reference.
- (20) Filed as an exhibit to NeXstar Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q for the quarter ended June 30, 1997, and incorporated herein by reference.
- (21) Filed as an exhibit to NeXstar Pharmaceuticals, Inc.'s Form 10-Q for the quarter ended September 30, 1995, and incorporated herein by reference.
- (22) Filed as an exhibit to NeXstar Pharmaceuticals, Inc.'s Form 10-K for the fiscal year ended December 31, 1996, and incorporated herein by reference.
- (23) Filed as an exhibit to NeXstar Pharmaceuticals, Inc.'s Form 10-Q for the quarter ended September 30, 1997, and incorporated herein by reference.
- (24) Filed as an exhibit to NeXstar Pharmaceuticals, Inc.'s Form 10-Q for the quarter ended June 30, 1998, and incorporated herein by reference.
- (25) Filed as an exhibit to Registrant's Form 10-K for the fiscal year ended December 31, 2001, and incorporated herein by reference.
- (26) 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.
- (27) Filed as an exhibit to Registrant's Registration Statement on Form S-8 (No. 333-102911) filed on January 31, 2003, and incorporated herein by reference.
- (28) 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.
- (29) 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.
- (30) Filed as an exhibit to Registrant's Form 10-K for the fiscal year ended December 31, 2003, and incorporated herein by reference.
- (31) Filed as an exhibit to Registrant's Form 10-Q for the quarter ended March 31, 2005, and incorporated herein by reference.
- (32) Filed as an exhibit to Registrant's Form 10-Q for the quarter ended September 30, 2005, and incorporated herein by reference.
- (33) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on December 27, 2005, and incorporated herein by reference.
- (34) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on February 22, 2006, and incorporated herein by reference.

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- (35) Filed as an exhibit to Registrant's Form 10-Q for the quarter ended March 31, 2006, and incorporated herein by reference.
- (36) Filed as an exhibit to Registrant's Registration Statement on Form S-8 (No. 333-136814) filed on August 22, 2006, and incorporated herein by reference.
- (37) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on January 23, 2007, and incorporated herein by reference.
- (38) 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.
- (39) Filed as an exhibit to Myogen, Inc.'s Quarterly Report on Form 10-Q filed on May 9, 2006, and incorporated herein by reference.

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- \* Management contract or compensatory plan or arrangement required to be filed pursuant to Item 15(b) of Form 10-K.
  - + 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.
  - \*\* 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.