

GILEAD SCIENCES INC  
Form 10-K  
February 27, 2009  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-K**

(Mark One)

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

For the fiscal year ended December 31, 2008

or

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

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

Commission File No. 0-19731

**GILEAD SCIENCES, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of incorporation or organization)  
**333 Lakeside Drive, Foster City, California**  
(Address of principal executive offices)  
**Registrant's telephone number, including area code: 650-574-3000**

**94-3047598**  
(I.R.S. Employer Identification No.)  
**94404**  
(Zip Code)

**SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT:**

<b>Title of each class</b>	<b>Name of each exchange on which registered</b>
Common Stock, \$0.001 par value per share	The Nasdaq Global Select Market

**SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE ACT: NONE**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer  Accelerated filer  Non-Accelerated filer  Smaller reporting company   
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant based upon the closing price of its Common Stock on the Nasdaq Global Select Market on June 30, 2008 was \$45,855,192,117.\*

The number of shares outstanding of the registrant's Common Stock on February 20, 2009 was 910,954,602.

**DOCUMENTS INCORPORATED BY REFERENCE**

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

Specified portions of the registrant's proxy statement, which will be filed with the Commission pursuant to Regulation 14A in connection with the registrant's 2009 Annual Meeting of Stockholders, to be held on May 6, 2009, are incorporated by reference into Part III of this Report.

\* Based on a closing price of \$52.95 per share on June 30, 2008. Excludes 56,609,605 shares of the registrant's Common Stock held by executive officers, directors and any stockholders whose ownership exceeds 5% of registrant's common stock outstanding at June 30, 2008. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant or that such person is controlled by or under common control with the registrant.

**Table of Contents****GILEAD SCIENCES, INC.****2008 Form 10-K Annual Report****Table of Contents****PART I**

Item 1	<u>Business</u>	2
Item 1A	<u>Risk Factors</u>	22
Item 1B	<u>Unresolved Staff Comments</u>	37
Item 2	<u>Properties</u>	37
Item 3	<u>Legal Proceedings</u>	38
Item 4	<u>Submission of Matters to a Vote of Security Holders</u>	38

**PART II**

Item 5	<u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	39
Item 6	<u>Selected Financial Data</u>	42
Item 7	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	44
Item 7A	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	66
Item 8	<u>Financial Statements and Supplementary Data</u>	69
Item 9	<u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	69
Item 9A	<u>Controls and Procedures</u>	69
Item 9B	<u>Other Information</u>	71

**PART III**

Item 10	<u>Directors, Executive Officers and Corporate Governance</u>	71
Item 11	<u>Executive Compensation</u>	71
Item 12	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	71
Item 13	<u>Certain Relationships and Related Transactions, and Director Independence</u>	71
Item 14	<u>Principal Accountant Fees and Services</u>	71

**PART IV**

Item 15	<u>Exhibits and Financial Statement Schedules</u>	72
---------	---	----

**SIGNATURES**

129

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

**Table of Contents**

*This Annual Report on Form 10-K, including the section entitled Management's Discussion and Analysis of Financial Condition and Results of Operations, contains forward-looking statements regarding future events and our future results that are subject to the safe harbors created under the Securities Act of 1933, as amended (the Securities Act), and the Securities Exchange Act of 1934, as amended (the Exchange Act). Words such as expect, anticipate, target, goal, project, hope, intend, plan, believe, seek, estimate, continue, may, could, should, might, variations of such words and similar expressions are intended to identify such forward-looking statements. In addition, any statements other than statements of historical fact are forward-looking statements, including statements regarding overall trends, operating cost trends, liquidity and capital needs and other statements of expectations, beliefs, future plans and strategies, anticipated events or trends and similar expressions. We have based these forward-looking statements on our current expectations about future events. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Our actual results may differ materially from those suggested by these forward-looking statements for various reasons, including those identified below under Risk Factors, beginning at page 22. Given these risks and uncertainties, you are cautioned not to place undue reliance on forward-looking statements. The forward-looking statements included in this report are made only as of the date hereof. Except as required under federal securities laws and the rules and regulations of the Securities and Exchange Commission (SEC), we do not undertake and specifically decline any obligation to update any of these statements or to publicly announce the results of any revisions to any forward-looking statements after the distribution of this report, whether as a result of new information, future events, changes in assumptions or otherwise.*

---

**Table of Contents**

**PART I**

**ITEM 1. BUSINESS**

**Overview**

Gilead Sciences, Inc. (Gilead, we, us or our), incorporated in Delaware on June 22, 1987, is 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. To date, we have focused our efforts on bringing novel therapeutics for the treatment of life threatening diseases to market. We continue to seek to add to our existing portfolio of products through our internal discovery and clinical development programs and through an active product acquisition and in-licensing strategy.

**Our Products**

*Truvada* (emtricitabine and tenofovir disoproxil fumarate) is an oral formulation dosed once a day as part of combination therapy to treat human immunodeficiency virus (HIV) infection in adults. It is a fixed dose combination of our anti-HIV medications, Viread (tenofovir disoproxil fumarate) and Emtriva (emtricitabine).

*Atripla* (efavirenz 600 mg/ emtricitabine 200 mg/ tenofovir disoproxil fumarate 300 mg) is an oral formulation dosed once a day for the treatment of HIV infection in adults. Atripla is the first once daily single tablet regimen for HIV intended as a stand alone therapy or in combination with other antiretrovirals. It is a fixed dose combination of our anti-HIV medications, Viread and Emtriva, and Bristol Myers-Squibb Company's non-nucleoside reverse transcriptase inhibitor, Sustiva (efavirenz).

*Viread* is an oral formulation of a nucleotide analogue reverse transcriptase inhibitor, dosed once a day as part of combination therapy to treat HIV infection in adults. In 2008, we received marketing approval of Viread for the treatment of chronic hepatitis B in the United States, the European Union and other countries, including Canada and Turkey.

*Emtriva* is an oral formulation of a nucleoside analogue reverse transcriptase inhibitor, dosed once a day as part of combination therapy to treat HIV infection in adults. In the United States and Europe, Emtriva is also approved as part of combination therapy to treat HIV infection in children.

*Hepsera* (adefovir dipivoxil) is an oral formulation of a nucleotide analogue polymerase inhibitor, dosed once a day to treat chronic hepatitis B. We have licensed the rights to commercialize Hepsera for the treatment of hepatitis B in Asia, Latin America and certain other territories to GlaxoSmithKline Inc. (GSK).

*AmBisome* (amphotericin B liposome for injection) is a proprietary liposomal formulation of amphotericin B, an antifungal agent to treat serious invasive fungal infections caused by various fungal species. Our corporate partner, Astellas Pharma, Inc. (Astellas), promotes and sells AmBisome in the United States and Canada, and we promote and sell AmBisome in Europe, Australia and New Zealand.

*Letairis* (ambrisentan) is an endothelin receptor antagonist (ERA) indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) in patients with WHO Class II or III symptoms to improve exercise capacity and delay clinical worsening. Letairis is available only through a special restricted distribution program called the Letairis Education and Access Program (LEAP). Only prescribers and pharmacies registered with LEAP may prescribe, sell and

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

distribute Letairis. We sublicensed to GSK the rights to ambrisentan, marketed by GSK as Volibris, for certain hypertensive conditions in territories outside of the United States.

**Vistide** (cidofovir injection) is an antiviral medication for the treatment of cytomegalovirus retinitis in patients with AIDS. We sell Vistide in the United States through our wholesale channel and in 25 countries outside the United States.

**Table of Contents**

**Flolan** (epoprostenol sodium) is an injected medication for the long-term intravenous treatment of primary pulmonary hypertension and pulmonary hypertension associated with the scleroderma spectrum of disease in New York Heart Association Class III and Class IV patients who do not respond adequately to conventional therapy. We have exclusive rights to market, promote and distribute Flolan and the sterile diluent for Flolan in the United States until April 2009. Flolan is distributed in the United States through a specialty pharmacy.

The following table lists aggregate product sales for our major products (in thousands):

	2008	% of Total Product Sales	2007	% of Total Product Sales	2006	% of Total Product Sales
<b>Antiviral products:</b>						
Truvada	\$ 2,106,687	41%	\$ 1,589,229	43%	\$ 1,194,292	46%
Atripla	1,572,455	31%	903,381	24%	205,729	8%
Viread	621,187	12%	613,169	16%	689,356	27%
Hepsera	341,023	7%	302,722	8%	230,531	9%
Emtriva	31,080	1%	31,493	1%	36,393	1%
<b>Total antiviral products</b>	<b>4,672,432</b>	<b>92%</b>	<b>3,439,994</b>	<b>92%</b>	<b>2,356,301</b>	<b>91%</b>
AmBisome	289,651	6%	262,571	7%	223,031	9%
Letairis	112,855	2%	21,020	1%		
Other	9,858		9,524		8,865	
<b>Total product sales</b>	<b>\$ 5,084,796</b>	<b>100%</b>	<b>\$ 3,733,109</b>	<b>100%</b>	<b>\$ 2,588,197</b>	<b>100%</b>

See Item 8, Note 15 to our Consolidated Financial Statements on page 122 included in this Annual Report on Form 10-K, for our total revenues by geographic area.

**Royalties from Other Products**

**Tamiflu** (oseltamivir phosphate) is an oral antiviral available in capsule form for the treatment and prevention of influenza A and B. Tamiflu is approved for the treatment of influenza in children and adults in more than 60 countries, including the United States, Japan and the European Union and is also approved for the prevention of influenza in children and adults in the United States, Japan and the European Union. We developed Tamiflu with F. Hoffmann-La Roche Ltd (together with Hoffmann-La Roche Inc., Roche). Roche has the exclusive right to manufacture and sell Tamiflu worldwide, subject to its obligation to pay us royalties based on a percentage of the net sales of Tamiflu worldwide.

**Macugen** (pegaptanib sodium injection) is an intravitreal injection of an anti-angiogenic oligonucleotide for the treatment of neovascular age-related macular degeneration. Macugen was developed by OSI Pharmaceuticals, Inc. (OSI) using technology licensed from us and is now promoted in the United States by OSI. OSI holds the exclusive rights to manufacture and sell Macugen in the United States, and Pfizer Inc. (Pfizer) holds the exclusive right to manufacture and sell Macugen in the rest of the world. We receive royalties from OSI based on sales of Macugen worldwide.

**Commercialization and Distribution**

We have U.S. and international commercial sales operations, with marketing subsidiaries in Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Ireland, Italy, the Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States.

Our products are marketed through our commercial teams and/or in conjunction with third party distributors and corporate partners. Our commercial teams promote our products through direct field contact with physicians,





## **Table of Contents**

hospitals, clinics and other healthcare providers. We generally grant our third party distributors the exclusive right to promote our product in a territory for a specified period of time. Most of our agreements with these distributors provide for collaborative efforts between the distributor and Gilead in obtaining and maintaining regulatory approval for the product in the specified territory.

In the United States, our commercial team promotes Truvada, Viread, Emtriva, Hepsera, Letairis and Flolan. We promote Atripla in the United States with our joint venture partner, Bristol Myers-Squibb Company (BMS). We currently distribute Truvada, Atripla, Viread, Emtriva, Hepsera and Vistide in the United States exclusively through the wholesale channel. Our product sales to three large wholesalers, Cardinal Health, Inc., McKesson Corp. and AmerisourceBergen Corp., each accounted for more than 10% of total revenues for each of the years ended December 31, 2008, 2007 and 2006. On a combined basis, these wholesalers accounted for approximately 90% of our product sales in the United States and approximately 48% of our total revenues. Our corporate partner, Astellas, promotes, sells and distributes AmBisome for us in the United States. Two of our products, Letairis and Flolan, are distributed exclusively by specialty pharmacies. These specialty pharmacies specialize in the dispensing of medications for complex or chronic conditions that may require a high level of patient education and ongoing counseling.

In territories outside the United States, we sell and distribute Truvada, Viread, Emtriva, Hepsera and AmBisome in Asia, Australia, Europe, Latin America, the Middle East and New Zealand either through our commercial teams or third party distributors. We promote Atripla jointly with BMS in the majority of countries in Europe and are responsible for selling and distributing the product in these countries. In a limited number of Central and Eastern European countries, either we, BMS or a third party distributor are the sole promoting, selling and distributing company. In a smaller group of non-European Union Eastern and Central European countries, Atripla is promoted by BMS either directly or through third party distributors. Under an agreement with Merck & Co., Inc. (Merck), we plan to promote and distribute Atripla in twelve countries in Latin America and Asia-Pacific either through Merck or our existing third party distributor partners. We rely on our corporate partner, Japan Tobacco Inc., to promote and sell Truvada, Viread and Emtriva in Japan. Our corporate partner, Astellas, also promotes, sells and distributes AmBisome in Canada. Dainippon Sumitomo Pharma Co., Ltd is responsible for promotion and distribution of AmBisome in Japan.

### **Access in the Developing World**

Through the Gilead Access Program, established in 2003, certain of Gilead's HIV products are available at substantially reduced prices in more than 125 countries in the developing world. We have developed a system of tiered pricing that reflects the economic status (using gross national income GNI per capita) and HIV prevalence. This approach allows us to price our therapies based on a country's ability to pay. For example, if a higher prevalence exists in a certain country, but the country also has a relatively high GNI, the country would be moved to a lower price tier to accommodate higher burden of disease.

We also support many clinical studies through the donation of our products to help define the best treatment strategies in developing world countries. For example, in November 2002, we entered into a collaborative agreement with the Medical Research Council (MRC) of the United Kingdom, Boehringer Ingelheim GmbH and GSK in connection with a clinical study conducted by the MRC on antiretroviral HIV therapy in Africa. The trial is called the DART (Development of AntiRetroviral Therapy) study and is aimed at studying clinical versus laboratory monitoring practices and structured treatment interruptions on continuous antiretroviral therapy in adults with HIV infection in sub-Saharan Africa. We provide Viread at no cost for the DART study.

We also work closely with the World Health Organization and with non-governmental organizations to provide AmBisome for the treatment of leishmaniasis, a parasitic disease, at a preferential price in resource limited settings. We support numerous clinical studies investigating the role of AmBisome to treat visceral and cutaneous leishmaniasis in developing countries through collaborations with organizations such as the Drugs for Neglected Diseases initiative and Médecins Sans Frontières.

---

## **Table of Contents**

We have also entered into a number of collaborations related to access of our products in the developing world, which include:

**PharmaChem Technologies (Grand Bahama), Ltd.** In 2005, PharmaChem Technologies established a facility in The Bahamas to manufacture tenofovir disoproxil fumarate, the active pharmaceutical ingredient in Viread and one of the active pharmaceutical ingredients in Truvada and Atripla, for resource limited countries through a cooperative effort with PharmaChem Technologies and the Grand Bahama Port Authority.

**Aspen Pharmacare Holdings Ltd (Aspen).** In October 2005, we entered into a non-exclusive manufacturing and distribution agreement with Aspen, providing for the manufacture and distribution of Viread and Truvada for the treatment of HIV infection to certain developing world countries included in our Gilead Access Program. In November 2007, we amended our agreement with Aspen. Under the amended agreement, Aspen retained the right to manufacture and distribute Viread and Truvada for the treatment of HIV infection in certain developing world countries in our Gilead Access Program. Aspen has the right to purchase Viread and Truvada in brite-stock form from us for distribution in such countries, and also has the right to manufacture Viread and Truvada using active pharmaceutical ingredient that has been purchased by Aspen from suppliers approved by us. Aspen was also granted the right to manufacture and distribute generic versions of emtricitabine and tenofovir disoproxil fumarate, including versions of tenofovir disoproxil fumarate in combination with emtricitabine for the treatment of HIV infection. Aspen is required to pay us royalties on net sales of Viread and Truvada, as well as royalties on net sales of generic versions of tenofovir disoproxil fumarate, including versions of tenofovir disoproxil fumarate in combination with emtricitabine that are manufactured and distributed by Aspen.

**Generic Licenses.** During 2006, we entered into non-exclusive license agreements with ten Indian generic manufacturers, granting them the rights to produce and distribute generic versions of tenofovir disoproxil fumarate for the treatment of HIV infection to 95 low income countries around the world, which included India and many of the low income countries in our Gilead Access Program. The agreements require that the generic manufacturers meet certain national and international regulatory standards and include technology transfer to enable expeditious production of large volumes of high quality generic versions of tenofovir disoproxil fumarate. In addition, these agreements allow for the manufacture of commercial quantities of both active pharmaceutical ingredient and finished product.

**Merck.** In August 2006, we entered into an agreement with an affiliate of Merck pursuant to which we provide Atripla at substantially reduced prices to HIV infected patients in developing countries in Africa, the Caribbean, Latin America and Southeast Asia. Under the agreement, we manufacture Atripla using efavirenz supplied by Merck, and Merck handles distribution of the product in the countries covered by the agreement.

**International Partnership for Microbicides (IPM) and CONRAD.** In December 2006, we entered into an agreement under which we granted rights to IPM and CONRAD, a cooperating agency of the U.S. Agency for International Development (USAID) committed to improving reproductive health by expanding the contraceptive choices of women and men, to develop, manufacture and, if proven efficacious, arrange for distribution in resource limited countries of tenofovir as a microbicide to prevent HIV infection.

## **Competition**

Our products and development programs target a number of areas, including viral, fungal, respiratory and cardiovascular diseases. There are many commercially available products for the treatment of these diseases. Many companies and institutions are making substantial investments in developing additional products to treat these diseases. Our products compete with other available products based primarily on:

efficacy;

safety;

**Table of Contents**

tolerability;

acceptance by doctors;

ease of patient compliance;

patent protection;

ease of use;

price;

insurance and other reimbursement coverage;

distribution; and

marketing.

***Our HIV Products.*** The HIV landscape is becoming more competitive and complex as treatment trends continue to evolve. A growing number of anti-HIV drugs are currently sold or are in advanced stages of clinical development. Of the approximately 28 branded HIV drugs available in the United States, our products primarily compete with the fixed dose combination products in the nucleotide/nucleoside reverse transcriptase inhibitors (NRTI) class, including Combivir (lamivudine/zidovudine); Epzicom/Kivexa (abacavir/lamivudine) and Trizivir (abacavir/lamivudine/zidovudine), each sold by GSK. Other HIV products compete directly with products in the same NRTI class sold by BMS, although our HIV products also compete broadly with HIV products from Abbott Laboratories, Inc., Boehringer Ingelheim GmbH, Merck, Pfizer, Roche and Tibotec Therapeutics, a division of Ortho Biotech Products, L.P., a subsidiary of Johnson & Johnson.

BMS's Videx EC (didanosine, dDI) became the first generic HIV product in the United States in 2004. GSK's Retrovir (zidovudine) also faces generic competition in the United States as a result of the launch of generic zidovudine in 2005. GSK's Zerit (stavudine) also faces generic competition in the United States as a result of the launch of generic stavudine in 2008. To date, there has been little impact from generic didanosine, zidovudine or stavudine on the price of our HIV products; however, price decreases for all HIV products may result in the longer term.

***AmBisome.*** AmBisome faces strong competition from several current and expected competitors. Competition from these current and expected competitors may erode the revenues we receive from sales of AmBisome. AmBisome faces competition from Vfend (voriconazole) developed by Pfizer and caspofungin, a product developed by Merck that is marketed as Cancidas in the United States and as Caspofungin elsewhere. AmBisome also competes with other lipid-based amphotericin B products, including Abelcet (amphotericin B lipid complex injection), sold by Enzon Pharmaceuticals, Inc. in the United States, Canada and Japan and by Zeneus Pharma Ltd. in Europe; Amphotec (amphotericin B cholesteryl sulfate complex for injection), sold by Three Rivers Pharmaceuticals, LLC worldwide; and Anfogen (amphotericin B liposomal), sold by Genpharma, S.A. in Argentina. BMS and numerous generic manufacturers sell conventional amphotericin B, which also competes with AmBisome.

We are aware of at least two lipid formulations that claim similarity to AmBisome becoming available outside of the United States, including the possible entry of one such formulation in Greece. These formulations may reduce market demand for AmBisome. Furthermore, the manufacture of lipid formulations of amphotericin B is very complex and if any of these formulations are found to be unsafe, sales of AmBisome may be negatively impacted by association.

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

***Our HBV Products.*** Our hepatitis B virus (HBV) products, Hepsera and Viread, face significant competition from existing and expected therapies for treating patients with chronic hepatitis B. Our HBV products face competition from Baraclude (entecavir), an oral nucleoside analogue developed by BMS and launched in the United States in 2005, and Tyzeka/Sebivo (telbivudine), an oral nucleoside analogue developed by Novartis Pharmaceuticals Corporation (Novartis) for sale in the United States, the European Union and China.

## **Table of Contents**

Our HBV products also compete with Epivir-HBV/Zeffix (lamivudine), developed by GSK in collaboration with Shire Pharmaceuticals Group PLC and sold in the major countries throughout North and South America, Europe and Asia.

Hepsera and Viread for the treatment of hepatitis B also compete with established immunomodulatory therapies, including Intron-A (interferon alfa-2b), which is sold by Schering Plough Corporation in major countries throughout North and South America, Europe and Asia, and Pegasys (pegylated interferon alfa-2a), an injectable drug similar to Intron-A sold by Roche for the treatment of chronic hepatitis B.

**Letairis.** Letairis competes directly with Tracleer (bosentan) sold by Actelion Pharmaceuticals US, Inc. and indirectly with PAH products from United Therapeutics Corporation and Pfizer.

**Vistide.** Vistide competes with a number of drugs that also treat cytomegalovirus retinitis, including Cytovene IV and Cytovene (ganciclovir), sold in intravenous and oral formulations by Roche and as an ocular implant by Bausch & Lomb Incorporated; Valcyte (valganciclovir), also marketed by Roche; Foscavir (foscarnet), an intravenous drug sold by AstraZeneca PLC; and Vitravene (fomivirsen), a drug injected directly into the eye, sold by CibaVision.

**Flolan.** Flolan competes primarily with Remodulin (treprostinil), a form of prostacyclin that is administered via continuous subcutaneous infusion or continuous intravenous infusion, which is sold by United Therapeutics Corporation in the United States. Flolan also competes with Ventavis (iloprost), an inhaled form of prostacyclin sold by affiliates of Actelion Ltd. in the United States. In addition, because the patent covering Flolan has expired, one or more generic pharmaceutical companies may launch a generic version of Flolan in the United States.

**Tamiflu.** Tamiflu competes with Relenza (zanamivir), an anti-influenza drug that is sold by GSK. Relenza is a neuraminidase inhibitor that is delivered as an orally-inhaled dry powder. Generic competitors include amantadine and rimantadine, both oral tablets that only inhibit the replication of the influenza A virus. BioCryst Pharmaceuticals, Inc. is developing injectable formulations of peramivir, an influenza neuraminidase inhibitor, for the treatment of influenza, which are currently in Phase 2 clinical trials.

**Macugen.** Macugen competes primarily with Visudyne (verteporfin for injection), which is sold by Novartis and used in connection with photodynamic therapy, and Lucentis (ranibizumab), which is sold by Genentech, Inc.

A number of companies are pursuing the development of technologies which are competitive with our research programs. These competing companies include specialized pharmaceutical firms and large pharmaceutical companies acting either independently or together with other pharmaceutical companies. Furthermore, academic institutions, government agencies and other public and private organizations conducting research may seek patent protection and may establish collaborative arrangements for competitive products and programs.

## **Collaborative Relationships**

As part of our business strategy, we establish collaborations with other companies, universities and medical research institutions to assist in the clinical development and/or commercialization of certain of our products and product candidates and to provide support for our research programs. We also evaluate opportunities for acquiring products or rights to products and technologies that are complementary to our business from other companies, universities and medical research institutions. More information regarding certain of these relationships, including their ongoing financial and accounting impact on our business can be found in Item 8, Note 9 to our Consolidated Financial Statements on pages 107 through 111 included in this Annual Report on Form 10-K.

---

**Table of Contents*****Commercial Collaborations***

Although we currently have a number of collaborations with corporate partners that govern the manufacture, sale, distribution and/or marketing of our products in various territories worldwide, the following commercial collaborations are those that are most significant to us from a financial statement perspective and where significant ongoing collaboration activity exists.

**Bristol-Myers Squibb Company (BMS).** In December 2004, we entered into a collaboration with BMS to develop and commercialize the single tablet regimen of our Truvada and BMS's Sustiva in the United States. This combination was approved for use in the United States in July 2006 and is sold under the name Atripla. We and BMS structured this collaboration as a joint venture by forming a limited liability company called Bristol-Myers Squibb & Gilead Sciences, LLC. Under the terms of the collaboration, we and BMS granted royalty free sublicenses to the joint venture for the use of our respective company owned technologies and, in return, were granted a license by the joint venture to use any intellectual property that results from the collaboration. The economic interests of the joint venture held by us and BMS (including share of revenues and out-of-pocket expenses) are based on the portion of the net selling price of Atripla attributable to Truvada (emtricitabine and tenofovir disoproxil fumarate) and Sustiva (efavirenz), respectively. Since the net selling price for Truvada may change over time relative to the net selling price of Sustiva, both our and BMS's respective economic interests in the joint venture may vary annually. We and BMS share marketing and sales efforts, with both parties providing equivalent sales force efforts at levels agreed to annually by BMS and us. The daily operations of the joint venture are governed by four primary joint committees formed by both BMS and us. We are responsible for accounting, financial reporting, tax reporting and product distribution for the joint venture. In September 2006, we and BMS amended the joint venture's collaboration agreement to allow the joint venture to sell Atripla into Canada. The agreement will continue until terminated by the mutual agreement of the parties. In addition, either party may terminate the other party's participation in the collaboration within 30 days after the launch of at least one generic version of such other party's single agent products (or the double agent products). The non-terminated party then has the right to continue to sell Atripla and a short-term obligation to pay royalties to the terminated party.

In December 2007, we entered into a collaboration with BMS which sets forth the terms and conditions under which we and BMS commercialize Atripla in the European Union, Norway, Iceland, Switzerland and Liechtenstein. Either we, BMS or a third party distributor act as the selling party in these countries and are responsible for, among other things, receiving and processing customer orders, warehousing product, collecting sales and handling returns. Manufacturing of Atripla is coordinated by us, and we are primarily responsible for distribution logistics. In general, the parties share revenues and out-of-pocket expenses in proportion to the net selling prices of Truvada, with respect to us, and efavirenz, with respect to BMS. The agreement will terminate upon the expiration of the last to expire patent which affords market exclusivity to Atripla or one of its components in the European countries covered by the agreement. Prior to such time, either party may terminate the agreement for any reason, with such termination to be effective in December 2013. The non-terminating party has the right to continue to sell Atripla, but will be obligated to pay the terminating party certain royalties for a three year period following the effective date of the termination. In the event the non-terminating party decides not to sell Atripla, the effective date of the termination will be the date Atripla is withdrawn in each country or the date on which a third party assumes distribution of Atripla, whichever is earlier.

**F. Hoffmann-La Roche Ltd (together with Hoffmann-La Roche Inc., Roche).** In September 1996, we entered into a development and license agreement with Roche to develop and commercialize therapies to treat and prevent viral influenza. Tamiflu, an antiviral oral formulation for the treatment and prevention of influenza, was co-developed by us and Roche. Under the original agreement, Roche had the exclusive right and obligation to manufacture and sell Tamiflu worldwide, subject to its obligation to pay us a percentage of the net sales that Roche generated from Tamiflu sales. Under the agreement, we received an up-front payment in the amount of \$5.0 million and were entitled to receive additional milestone payments of up to \$40.0 million upon the achievement of certain development and



---

**Table of Contents**

regulatory objectives. We have received all such milestone payments. In October 1996, Roche also made a cash payment to us in the amount of \$5.3 million related to reimbursement for certain research and preclinical development expenses and our obligation to prosecute and maintain certain patents under the agreement. In November 2005, we entered into a first amendment and supplement to the original agreement with Roche. The amendment eliminated cost of goods adjustments from the royalty calculation, retroactive to calendar year 2004 and for all future calculations. The amendment also provided for the formation of a joint manufacturing committee to review Roche's manufacturing capacity for Tamiflu and global plans for manufacturing Tamiflu, a U.S. commercial committee to evaluate commercial plans and strategies for Tamiflu in the United States and a joint supervisory committee to evaluate Roche's overall commercial plans for Tamiflu on a global basis. Each of the committees consists of representatives from both Roche and us. Under the amendment, we have the option to provide a specialized sales force to supplement Roche's U.S. marketing efforts for Tamiflu, which we have not exercised to date. The agreement and Roche's obligation to pay royalties to us will terminate on a country-by-country basis as patents providing exclusivity for Tamiflu in such countries expire. Roche may terminate the agreement for any reason in which case all rights to Tamiflu would revert to us. Either party may terminate the agreement in response to a material breach by the other party.

**GlaxoSmithKline Inc. (GSK).** In March 2006, we exclusively sublicensed to GSK rights to ambrisentan (the active pharmaceutical ingredient in Letairis, which is marketed under the name Volibris in territories outside the United States) for certain hypertensive conditions in territories outside of the United States. Under the license agreement, we received an up-front payment of \$20.0 million and, subject to the achievement of specific milestones, we are eligible to receive total additional milestone payments of \$80.0 million. Through December 31, 2008, we have received \$37.5 million of such potential milestone payments. In addition, we will receive royalties based on net sales of Volibris in the GSK territories. GSK has an option to negotiate from us an exclusive sublicense for additional therapeutic uses for Volibris in the GSK territories during the term of the license agreement. Under the agreement, we will continue to conduct and bear the expense of all clinical development activities that we believe are required to obtain and maintain regulatory approvals for Letairis and Volibris in the United States, Canada and the European Economic Area, and each party may conduct additional development activities in its territories 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. The agreement and GSK's obligation to pay royalties to us will terminate on a country-by-country basis on the earlier of the date on which generic equivalents sold in a country achieve a certain percentage of total prescriptions for the product plus its generic equivalents or the fifteenth anniversary of commercial launch in such country. GSK may terminate the agreement for any reason. Upon such termination events, all rights to the product would revert to us. Either party may terminate the agreement in response to a material breach by the other party.

***Research Collaborations***

We currently have a number of collaborations with corporate partners that govern our research and development of certain compounds and drug candidates. The following research collaborations are those that are most significant to us from a financial statement perspective and where significant ongoing collaboration activity exists.

**Abbott Laboratories, Inc. (Abbott).** In June 2003, we entered into an exclusive worldwide license agreement with Abbott to develop and commercialize darusentan for all conditions except oncology and made initial license payments totaling \$5.0 million. Under the terms of the agreement, Abbott has the right of first negotiation to participate with us in the co-promotion of the product and has a right of first negotiation to become our exclusive development and commercialization partner in Japan. In addition, we are obligated to make future milestone payments of up to \$45.0 million upon the achievement of certain regulatory approvals, as well as pay royalties based on net sales if we

## **Table of Contents**

successfully commercialize the drug for any indication. We are obligated to use commercially reasonable efforts to develop and commercialize the product in certain countries. If we do not commercialize darusentan in certain countries, Abbott may market the product on its own in the affected markets and pay us a royalty on its sales. Darusentan is currently being studied in Phase 3 clinical trials for the treatment of patients with resistant hypertension. Through December 31, 2008, we have made \$2.0 million in milestone payments. Our obligation to pay royalties will terminate on a country-by-country basis as patents providing exclusivity for the product in such countries expire. We may terminate the agreement in certain circumstances, including if we determine the product would not have a reasonable likelihood of commercial success, in which case all rights and responsibilities for the product would revert to Abbott. Either party may terminate the agreement in response to a material breach by the other party.

**Japan Tobacco Inc. (Japan Tobacco).** In March 2005, we entered into a licensing agreement with Japan Tobacco, under which Japan Tobacco granted us exclusive rights to develop and commercialize elvitegravir, a novel HIV integrase inhibitor, in all countries of the world, excluding Japan, where Japan Tobacco would retain such rights. Under the agreement, we are responsible for seeking regulatory approval in our territories and are required to use diligent efforts to commercialize a product for the treatment of HIV. We will bear all costs and expenses associated with such commercialization efforts. Under the terms of the agreement, we paid an up-front license fee of \$15.0 million and are obligated to make total potential milestone payments of up to \$90.0 million upon the achievement of certain clinical, regulatory and commercial objectives. Additionally, we are obligated to pay royalties based on any net sales in the territories where we market the product. Through December 31, 2008, we have made total milestone payments of \$12.0 million. The agreement and our obligation to pay royalties to Japan Tobacco will terminate on a product-by-product basis as patents providing exclusivity for the product expire or, if later, on the tenth anniversary of commercial launch for such product. We may terminate the agreement for any reason in which case the license granted by Japan Tobacco to us would terminate. Either party may terminate the agreement in response to a material breach by the other party.

## **Research and Development**

In addition to entering into collaborations with other companies, universities and medical research institutions, we seek to add to our existing portfolio of products through our internal discovery and clinical development programs and through an active in-licensing and product acquisition strategy, such as with our acquisitions of Myogen, Inc. and Corus Pharma, Inc. in 2006. In 2008, we acquired all of Navitas Assets, LLC's assets related to its cicletanine business, which we are evaluating as a potential treatment of PAH. We have research scientists in Foster City and San Dimas, California; Durham, North Carolina; Seattle, Washington; and Boulder and Westminster, Colorado, engaged in the discovery and development of new molecules and technologies that we hope will lead to new medicines and novel formulations of existing drugs.

Our product development efforts cover a wide range of medical conditions, including HIV/AIDS, liver disease, cardiovascular disease and respiratory disease. Below is a summary of our key products and their corresponding current stages of development. For additional information on our development pipeline, visit our website at [www.gilead.com](http://www.gilead.com).

**Table of Contents**

<b>Product Candidate</b>	<b>Description</b>
<b>Marketing Applications Pending</b>	
Aztreonam for inhalation solution for the treatment of cystic fibrosis (CF)	A new drug application (NDA) for aztreonam for inhalation solution for the treatment cystic fibrosis was submitted to the U.S. Food and Drug Administration (FDA) in November 2007. In September 2008, we received a complete response letter from the FDA informing us that the FDA will not approve our NDA for aztreonam for inhalation solution for the treatment of CF in its current form and requesting we conduct an additional Phase 3 clinical study. In November 2008, we filed a request for a formal dispute resolution with the FDA. In February 2009, in response to our appeal, the FDA notified us that it is reiterating its position that we will need to conduct another clinical study of aztreonam for inhalation solution before we can resubmit our NDA. We have also submitted a marketing authorization application in the European Union and received notice of acceptance and priority review by Health Canada for approval in Canada. We are still awaiting responses from the respective regulatory bodies.
<b>Phase 3</b>	
Ambrisentan	Ambrisentan is an oral ERA being evaluated for the treatment of idiopathic pulmonary fibrosis (IPF).
Darusentan	Darusentan is an oral ERA being investigated as an add-on therapy for patients with resistant hypertension.
Elvitegravir	Elvitegravir is an oral integrase inhibitor that is being evaluated as part of combination therapy for HIV in treatment experienced patients.
<b>Preparing for Phase 3</b>	
Ambrisentan	Ambrisentan is also going to be evaluated for the treatment of chronic allograft injury in kidney transplant recipients and pulmonary hypertension in patients with IPF.
<b>Phase 2</b>	
GS 9190	GS 9190 is an oral non-nucleoside polymerase inhibitor being evaluated as part of combination therapy with peg-interferon alfa 2A and ribavirin in treatment-naïve hepatitis C virus (HCV) infected patients (genotype 1).
GS 9310/11	GS 9310/11 is an inhaled co-formulation of fosfomycin and tobramycin under evaluation for bacterial infections associated with CF.
GS 9450	GS 9450 is an oral caspase inhibitor under evaluation for the treatment of inflammatory and fibrotic conditions, including HCV and nonalcoholic steatohepatitis.
Aztreonam for inhalation solution	Aztreonam for inhalation solution is also being evaluated for bronchiectasis.
Cicletanine	Cicletanine is an oral agent in development for PAH.
<b>Preparing for Phase 2</b>	
GS 9350	GS 9350 is a pharmacoenhancer that is in development as a boosting agent for certain HIV medicines.
Elvitegravir / GS 9350 / Truvada	This is a four-in-one fixed dose regimen that combines elvitegravir, GS 9350, tenofovir disoproxil fumarate and emtricitabine under evaluation for the treatment of HIV/AIDS in treatment-naïve patients.

**Table of Contents****Product Candidate****Description****Phase 1**

GS 9191	GS 9191 is a nucleotide analogue under evaluation as a topical ointment in patients with external genital and perianal warts caused by human papilloma virus infection.
GS 9219	GS 9219 is a nucleotide analogue under evaluation in patients with non-Hodgkin's lymphoma and chronic lymphocytic leukemia.
GS 9411	GS 9411 is an oral epithelial sodium channel blocker designed to increase airway hydration in patients with pulmonary disease.

In total, our research and development expenses for 2008 were \$721.8 million, compared with \$591.0 million for 2007 and \$383.9 million for 2006.

**Patents and Proprietary Rights**

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. We also rely on trade secrets, internal know-how, technological innovations and agreements with third parties to develop, maintain and protect our competitive position. Our ability to be competitive will depend on the success of this strategy.

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

The following table shows the actual or estimated expiration dates in the United States and Europe for the primary patents and for patents that may issue under pending applications that cover the compounds in our marketed products:

	<b>U.S. Patent</b>	<b>European Patent</b>
<b>Products</b>	<b>Expiration</b>	<b>Expiration</b>
Vistide	2010	2012
Hepsera	2014	2011*
Letairis	2015	2015
AmBisome	2016	2008
Tamiflu	2016	2016
Macugen	2017	2017
Viread	2017	2018
Emtriva	2021	2016
Truvada	2021	2018**
Atripla	2021	2018**

\* Supplementary Protection Certificate protection has been obtained in certain European countries that confers an auxiliary form of patent exclusivity until 2016.

\*\* Based on the European patent expiration date of Viread, one of the components of Truvada.

Patents covering the active pharmaceutical ingredients of Truvada, Atripla, Viread, Emtriva, Hepsera, Letairis and Vistide are held by third parties. We acquired exclusive rights to these patents in the agreements we

## **Table of Contents**

have with these parties. Patents do not cover the active ingredients in AmBisome. Instead, we hold patents to the liposomal formulations of this compound and also protect formulations through trade secrets. In addition, we do not have patent filings in China and certain other Asian countries covering all forms of adefovir dipivoxil, the active ingredient in Hepsera. We do have applications pending in various countries in Asia, including China, that relate to specific forms and formulations of Hepsera. Asia is a major market for therapies for hepatitis B infection, the indication for which Hepsera has been developed. Further, the patent covering Flolan and market exclusivity protection have expired. As a result, one or more generic pharmaceutical companies may launch a generic version of Flolan in the United States.

We may obtain patents for certain products many years before we obtain marketing approval 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. For example, extensions for the patents on many of our products have been granted in the United States and in a number of European countries, compensating in part for delays in obtaining marketing approval. Similar patent term extensions may be available for other products that we are developing, but we cannot be certain we will obtain them.

It is also very important that we do not infringe patents or proprietary rights of others and that we do not violate the agreements that grant proprietary rights to us. If we do infringe patents or violate these agreements, we could be prevented from developing or selling products or from using the processes covered by those patents or agreements, or we could be required to obtain a license from third parties to allow us to use their technology. We cannot be certain that, if required, we could obtain a license to any third party technology or that we could obtain one at a reasonable cost. If we were not able to obtain a required license or alternative technologies, we may be unable to develop or commercialize some or all of our products, and our business could be adversely affected. For example, we are aware of a body of patents that may relate to our operation of LEAP, our restricted distribution program designed to support Letairis. In addition, Actelion, which markets Tracleer, has applied for a patent that claims a method of use for ERAs for the treatment of IPF. If issued, this patent may interfere with our efforts to commercialize our own ERA, ambrisentan, for IPF.

Because patent applications are confidential for a period of time until a patent is issued, we may not know if our competitors have filed patent applications for technology covered by our pending applications or if we were the first to invent the technology that is the subject of our patent applications. Competitors may have filed patent applications or received patents and may obtain additional patents and proprietary rights that block or compete with our patents. If competitors file patent applications covering our technology, we may have to participate in interference proceedings or litigation to determine the right to a patent. Litigation and interference proceedings are expensive, such that, even if we are ultimately successful, our results of operations may be adversely affected by such events.

Patents relating to pharmaceutical, biopharmaceutical and biotechnology products, compounds and processes such as those that cover our existing compounds, products and processes and those that we will likely file in the future, do not always provide complete or adequate protection. Future litigation or re-examination proceedings regarding the enforcement or validity of our existing patents or any future patents could invalidate our patents or substantially reduce their protection. For example, in 2007, the Public Patent Foundation filed requests for re-examination with the United States Patent and Trademark Office (PTO) challenging four of our patents related to tenofovir disoproxil fumarate, which is an active ingredient in Truvada, Atripla and Viread. The PTO granted these requests and issued non-final rejections for the four patents, which is a step common in a proceeding to initiate the re-examination process. In 2008, the PTO confirmed the patentability of all four patents.

Although we were successful in responding to the PTO office actions in the instance above, similar organizations may still challenge our patents in foreign jurisdictions. For example, in April 2008, the Brazilian Health Ministry, citing the pending U.S. patent re-examination proceedings as grounds for rejection, requested

---

**Table of Contents**

that the Brazilian patent authority issue a decision that is not supportive of our patent application for tenofovir disoproxil fumarate in Brazil. In August 2008, an examiner in the Brazilian patent authority issued a final rejection of our fumarate salt patent application, the only patent application for tenofovir disoproxil fumarate we have filed in Brazil. We have filed an appeal with the patent authority responding to the questions raised in the rejection. We cannot predict the outcome of this proceeding on our tenofovir disoproxil fumarate patent application. If we are unable to successfully appeal the decision by the patent authority in the courts, the Brazilian patent authority will reject the tenofovir disoproxil fumarate patent application. If the tenofovir disoproxil fumarate patent application is rejected by the Brazilian patent authority, the Brazilian government would likely purchase generic tenofovir disoproxil fumarate, which would significantly reduce our sales of HIV products in Brazil.

Our pending patent applications and the patent applications filed by our collaborative partners may not result in the issuance of any patents or may result in patents that do not provide adequate protection. As a result, we may not be able to prevent third parties from developing compounds or products that are closely related to those which we have developed or are developing. In addition, certain countries in Africa and Asia, including China, do not permit enforcement of our patents, and third party manufacturers are able to sell generic versions of our products in those countries.

As part of the approval process of some of our products, the FDA granted an exclusivity period during which other manufacturers' applications for approval of generic versions of our product will not be granted. Generic manufacturers often wait to challenge the patents protecting products that have been granted exclusivity until one year prior to the end of the exclusivity period. From time to time, we have received notices from manufacturers indicating that they intend to import chemical intermediates possibly for use in making our products. It is, therefore, possible that generic manufacturers are considering attempts to seek FDA approval for a similar or identical drug through an abbreviated new drug application (ANDA), which is the application form typically used by manufacturers seeking approval of a generic drug. If our patents are subject to challenges, we may need to spend significant resources to defend such challenges and we may not be able to defend our patents successfully. For example, in November 2008, we received notice that Teva Pharmaceuticals submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Truvada. In the notice, Teva alleges that two of the patents associated with emtricitabine, owned by Emory University and licensed exclusively to us, are invalid, unenforceable and/or will not be infringed by Teva's manufacture, use or sale of a generic version of Truvada. In December 2008, we filed a lawsuit in U.S. District Court in New York against Teva for infringement of the two emtricitabine patents. We cannot predict the ultimate outcome of the action, and we may spend significant resources defending these patents. If we are unsuccessful in the lawsuit, some or all of our original claims in the patents may be narrowed or invalidated, and the patent protection for Truvada in the United States would be shortened to expire in 2017 instead of 2021.

We also rely on unpatented trade secrets and improvements, unpatented internal know-how and technological innovation. In particular, a great deal of our liposomal manufacturing expertise, which is a key component of our liposomal technology, is not covered by patents but is instead protected as a trade secret. We protect these rights mainly through confidentiality agreements with our corporate partners, employees, consultants and vendors. These agreements provide that all confidential information developed or made known to an individual during the course of their relationship with us will be kept confidential and will not be used or disclosed to third parties except in specified circumstances. In the case of employees, the agreements provide that all inventions made by an individual while employed by us will be our exclusive property. We cannot be certain that these parties will comply with these confidentiality agreements, that we have adequate remedies for any breach or that our trade secrets will not otherwise become known or be independently discovered by our competitors. Under some of our research and development agreements, inventions become jointly owned by us and our corporate partner and in other cases become the exclusive property of one party. In certain circumstances, it can be difficult to determine who owns a particular invention and disputes could arise regarding those inventions.

---

## **Table of Contents**

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

### **Manufacturing and Raw Materials**

Our manufacturing strategy is to contract with third parties to manufacture the majority of our solid dose products. We also rely on our corporate partners to manufacture certain of our products. Additionally, we own manufacturing facilities in San Dimas, California; Edmonton, Alberta, Canada; and Dublin and Cork, Ireland where we manufacture certain products for clinical and commercial uses.

We contract with third parties to manufacture certain products for clinical and commercial purposes, including Truvada, Atripla, Viread, Emtriva, Hepsera and Vistide. We use multiple third party contract manufacturers to manufacture tenofovir disoproxil fumarate, the active pharmaceutical ingredient in Viread and one of the active pharmaceutical ingredients in Truvada and Atripla; emtricitabine, the active pharmaceutical ingredient in Emtriva and one of the active pharmaceutical ingredients in Truvada and Atripla; and adefovir dipivoxil, the active pharmaceutical ingredient in Hepsera. We also rely on third party contract manufacturers to tablet or capsule products. For example, we use multiple third party contract manufacturers to tablet Truvada, Atripla, Viread, Emtriva and Hepsera. Emtriva capsulation is also completed by third party contract manufacturers. We rely on a single third party supplier to tablet Letairis.

We also have manufacturing agreements with our corporate partners. Roche, by itself and through third parties, is responsible for the manufacturing of Tamiflu. Under our agreement with Roche, through a joint manufacturing committee composed of representatives from Roche and us, we have the opportunity to review Roche's existing manufacturing capacity for Tamiflu and global plans for manufacturing Tamiflu. GSK and its affiliates, by themselves or through third parties, manufacture Flolan for distribution by us in the United States under the terms of our distribution and supply agreement with GSK.

At our San Dimas facility, we manufacture, fill and package products. We manufacture AmBisome exclusively at this facility. We depend on a single supplier for high quality cholesterol, which is used in the manufacture of AmBisome. We fill and finish Macugen exclusively at our facilities in San Dimas under our manufacturing agreements with OSI and Pfizer. OSI currently provides pegaptanib sodium, the active pharmaceutical ingredient in Macugen. We also fill and package drug product for Truvada, Atripla, Viread, Emtriva and Hepsera in their finished forms at our facilities in San Dimas. The FDA recently approved our facilities in San Dimas to manufacture aztreonam for inhalation solution, subject to FDA approval of the product and delivery device.

At our Edmonton, Alberta facility, we carry out process research and scale-up of our clinical development candidates, manufacture our active pharmaceutical ingredients for investigational products and conduct chemical development activities to improve existing commercial manufacturing processes. In addition, we utilize this site for the manufacture of emtricitabine. We also manufacture the active pharmaceutical ingredient in Letairis exclusively at our Edmonton site, although another supplier is qualified to make the active pharmaceutical ingredient in Letairis.

We fill and package drug product for Truvada, Atripla, Viread, Emtriva and Hepsera in their finished forms at our facilities near Dublin, Ireland. We also perform quality control testing, final labeling and packaging of

## **Table of Contents**

AmBisome and distribution of many of our products for the European Union and elsewhere at this facility. We utilize our Cork, Ireland facility primarily for solid dose tablet manufacturing of certain of our antiviral products, as well as product packaging activities.

The manufacturing process for pharmaceutical products is highly regulated and regulators may shut down manufacturing facilities that they believe do not comply with regulations. We, our third party manufacturers and our corporate partners are subject to the FDA's current Good Manufacturing Practices, which are extensive regulations governing manufacturing processes, stability testing, record keeping and quality standards. Similar regulations are in effect in other countries. Our manufacturing operations are also subject to routine inspections by regulatory agencies. Additionally, our third party manufacturers and our corporate partners are independent entities who are subject to their own unique operational and financial risks which are out of our control. If we or any of our third party manufacturers or our corporate partners fail to perform as required, this could impair our ability to deliver our products on a timely basis or receive royalties or cause delays in our clinical trials and applications for regulatory approval. To the extent these risks materialize and affect their performance obligations to us, our financial results may be adversely affected.

We believe the technology we use to manufacture our products is proprietary. For products manufactured by our third party contract manufacturers, we have disclosed all necessary aspects of this technology to enable them to manufacture the products for us. We have agreements with these third party manufacturers that are intended to restrict these manufacturers from using or revealing this technology, but we cannot be certain that these third party manufacturers will comply with these restrictions. In addition, these third party manufacturers could develop their own technology related to the work they perform for us that we may need to manufacture our products. We could be required to enter into additional agreements with these third party manufacturers if we want to use that technology ourselves or allow another manufacturer to use that technology. The third party manufacturer could refuse to allow us to use their technology or could demand terms to use their technology that are not acceptable to us.

We need access to certain supplies and products to manufacture our products. If delivery of material from our suppliers were interrupted for any reason or if we are unable to purchase sufficient quantities of raw materials used to manufacture our products, we may be unable to ship certain of our products for commercial supply or to supply our product candidates in development for clinical trials. In addition, some of our products and the materials that we utilize in our operations are made at only one facility. For example, because we manufacture AmBisome and fill and finish Macugen exclusively at our facilities in San Dimas, California, in the event of a natural disaster, including an earthquake, equipment failure or other difficulty, we may be unable to replace this manufacturing capacity in a timely manner and may be unable to manufacture AmBisome and Macugen to meet market needs. Our product candidate, aztreonam for inhalation solution, which is pending FDA approval, is dependent on four different single-source suppliers. First, aztreonam, the active pharmaceutical ingredient in aztreonam for inhalation solution, is manufactured by a single supplier at a single site. Second, it is administered to the lungs of patients through a device that is made by a single supplier at a single site. Third, the FDA recently approved our facilities in San Dimas to manufacture aztreonam for inhalation solution, subject to FDA approval of the product and delivery device. The San Dimas facility is the only manufacturing site authorized to manufacture aztreonam for inhalation solution, although we are pursuing FDA approval of a third party manufacturer. Fourth, the diluent for aztreonam for inhalation solution will be manufactured by a single manufacturer at a single site. Problems with any of the single suppliers we depend on may negatively impact our development and commercialization efforts.

For our future products, we will continue to consider developing additional manufacturing capabilities and establishing additional third party suppliers to manufacture sufficient quantities of our product candidates to undertake clinical trials and to manufacture sufficient quantities of any product that is approved for commercial sale. If we are unable to develop manufacturing capabilities internally or contract for large scale manufacturing with third parties on acceptable terms for our future products, our ability to conduct large scale clinical trials and meet customer demand for commercial products will be adversely affected.



## **Table of Contents**

### **Seasonal Operations and Backlog**

Our worldwide product sales do not reflect any significant degree of seasonality. However, our royalty revenues, which represented about 4% of our total revenues in 2008 and of which Tamiflu royalties comprised a significant portion, are affected by seasonality. Royalty revenue that we recognize from Roche's sales of Tamiflu can be impacted by the severity associated with flu seasons and product delivery in response to the avian influenza pandemic threat.

For the most part, we operate in markets characterized by short lead times and the absence of significant backlogs. We do not believe that backlog information is material to our business as a whole.

### **Government Regulation**

Our operations and activities are subject to extensive regulation by numerous government authorities in the United States and other countries. In the United States, drugs are subject to rigorous FDA regulation. The Federal Food, Drug and Cosmetic Act and other federal and state statutes and regulations govern the testing, manufacture, safety, efficacy, labeling, storage, record keeping, approval, advertising and promotion of our products. As a result of these regulations, product development and product approval processes are very expensive and time consuming.

The FDA must approve a drug before it can be sold in the United States. The general process for this approval is as follows:

#### ***Preclinical Testing***

Before we can test a drug candidate in humans, we must study the drug in laboratory experiments and in animals to generate data to support the drug candidate's potential benefits and safety. We submit this data to the FDA in an investigational new drug (IND) application seeking their approval to test the compound in humans.

#### ***Clinical Trials***

If the FDA accepts the IND application, we study the drug candidate in human clinical trials to determine if the drug candidate is safe and effective. These clinical trials involve three separate phases that often overlap, can take many years and are very expensive. These three phases, which are subject to considerable regulation, are as follows:

Phase 1. The drug candidate is given to a small number of healthy human control subjects or patients suffering from the indicated disease, to test for safety, dose tolerance, pharmacokinetics, metabolism, distribution and excretion.

Phase 2. The drug candidate is given to a limited patient population to determine the effect of the drug candidate in treating the disease, the best dose of the drug candidate, and the possible side effects and safety risks of the drug candidate. It is not uncommon for a drug candidate that appears promising in Phase 1 clinical trials to fail in the more rigorous Phase 2 clinical trials.

Phase 3. If a drug candidate appears to be effective and safe in Phase 2 clinical trials, Phase 3 clinical trials are commenced to confirm those results. Phase 3 clinical trials are conducted over a longer term, involve a significantly larger population, are conducted at numerous sites in different geographic regions and are carefully designed to provide reliable and conclusive data regarding the safety and benefits of a drug candidate. It is not uncommon for a drug candidate that appears promising in Phase 2 clinical trials to fail in the more rigorous and extensive Phase 3 clinical trials.

## **Table of Contents**

### ***FDA Approval Process***

When we believe that the data from the Phase 3 clinical trials show an adequate level of safety and efficacy, we submit the appropriate filing, usually in the form of an NDA or supplemental NDA, with the FDA seeking approval to sell the drug candidate for a particular use. The FDA may hold a public hearing where an independent advisory committee of expert advisors asks additional questions and makes recommendations regarding the drug candidate. This committee makes a recommendation to the FDA that is not binding but is generally followed by the FDA. If the FDA agrees that the compound has met the required level of safety and efficacy for a particular use, it will allow us to sell the drug candidate in the United States for that use. It is not unusual, however, for the FDA to reject an application because it believes that the drug candidate is not safe enough or efficacious enough or because it does not believe that the data submitted is reliable or conclusive.

At any point in this process, the development of a drug candidate can be stopped for a number of reasons including safety concerns and lack of treatment benefit. We cannot be certain that any clinical trials that we are currently conducting or any that we conduct in the future will be completed successfully or within any specified time period. We may choose, or the FDA may require us, to delay or suspend our clinical trials at any time if it appears that the patients are being exposed to an unacceptable health risk or if the drug candidate does not appear to have sufficient treatment benefit.

The FDA may also require Phase 4 non-registrational studies to explore scientific questions to further characterize safety and efficacy during commercial use of our drug. The FDA may also require us to provide additional data or information, improve our manufacturing processes, procedures or facilities or may require extensive surveillance to monitor the safety or benefits of our product candidates if it determines that our filing does not contain adequate evidence of the safety and benefits of the drug. In addition, even if the FDA approves a drug, it could limit the uses of the drug. The FDA can withdraw approvals if it does not believe that we are complying with regulatory standards or if problems are uncovered or occur after approval.

In addition to obtaining FDA approval for each drug, we obtain FDA approval of the manufacturing facilities for any drug we sell, including those of companies who manufacture our drugs for us. All of these facilities are subject to periodic inspections by the FDA. The FDA must also approve foreign establishments that manufacture products to be sold in the United States and these facilities are subject to periodic regulatory inspection. Our manufacturing facilities located in California, including our San Dimas facilities, also must be licensed by the State of California in compliance with local regulatory requirements. Our manufacturing facilities located in Canada, including our Edmonton, Alberta facility and our facilities located near Dublin and in Cork, Ireland, also must obtain local licenses and permits in compliance with local regulatory requirements.

Drugs that treat serious or life threatening diseases and conditions that are not adequately addressed by existing drugs and for which the development program is designed to address the unmet medical need may be designated as fast track candidates by the FDA and may be eligible for accelerated and priority review. Drugs for the treatment of HIV that are designated for use under the U.S. President's Emergency Plan for AIDS Relief may also qualify for an expedited or priority review. Viread, Truvada and Atripla received accelerated approval and priority reviews. Drugs receiving accelerated approval must be monitored in post-marketing clinical trials in order to confirm the safety and benefits of the drug.

We are also subject to other federal, state and local regulations regarding workplace safety and protection of the environment. We use hazardous materials, chemicals, viruses and various radioactive compounds in our research and development activities and cannot eliminate the risk of accidental contamination or injury from these materials. Any misuse or accidents involving these materials could lead to significant litigation, fines and penalties.

Drugs are also subject to extensive regulation outside of the United States. In the European Union, there is a centralized approval procedure that authorizes marketing of a product in all countries of the European Union

---

**Table of Contents**

(which includes most major countries in Europe). If this centralized approval procedure is not used, approval in one country of the European Union can be used to obtain approval in another country of the European Union under one of two simplified application processes: the mutual recognition procedure or the decentralized procedure, both of which rely on the principle of mutual recognition. After receiving regulatory approval through any of the European registration procedures, separate pricing and reimbursement approvals are also required in most countries.

***Pricing and Reimbursement***

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. In the United States, the European Union and other significant or potentially significant markets for our products and product candidates, government authorities and third party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. For example, a significant portion of our sales of the majority of our products are subject to significant discounts from list price and rebate obligations. In addition, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the European Union will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our product revenues and profitability. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and health care reform, pharmaceutical reimbursement policies and pricing in general.

Legislative and regulatory changes to government prescription drug procurement and reimbursement programs occur relatively frequently in the United States and foreign jurisdictions. There have been significant changes to the federal Medicare system in recent years in the United States that could impact the pricing of our products. Under the Medicare Prescription Drug Improvement and Modernization Act of 2003, Medicare beneficiaries are able to elect coverage for prescription drugs under Medicare Part D. The prescription drug program began on January 1, 2006 and although we have benefited from patients transitioning from Medicaid to Medicare Part D since 2006, the longer term impact of Medicare Part D on our business is not yet clear to us, and the impact will depend in part on specific decisions regarding the level of coverage provided for the therapeutic categories in which our products are included, the terms on which such coverage is provided, and the extent to which preference is given to selected products in a category. Third party payors providing Medicare Part D coverage have attempted to negotiate price concessions from pharmaceutical manufacturers. In addition, discussions are taking place at the federal level to pass legislation that would either allow or require the federal government to directly negotiate price concessions from pharmaceutical manufacturers or set minimum requirements for Medicare pricing. The increasing pressure to lower prescription drug prices may limit drug access for Medicare Part D enrollees. Further, Medicare patients have to pay co-insurance, which may influence which products are recommended by physicians and selected by patients. Our results of operations could be materially adversely affected by the reimbursement changes emerging from Medicare prescription drug coverage legislation. In addition to federal Medicare proposals, state Medicaid drug payment changes could also lower payment for our products. To the extent that private insurers or managed care programs follow Medicaid coverage and payment developments, the adverse effects may be magnified by private insurers adopting lower payment schedules. Additionally, any additional statutory or regulatory changes, including potential changes to Medicare Part D, and health care reform at both the federal and state levels could adversely affect payment for our drugs and demand for our product. At this time, a few states have already enacted health care reform legislation, and the federal government and individual state governments continue to consider health care reform policies and legislation. The pricing and reimbursement environment for our products may change in the future and become more challenging due to, among other reasons, new policies of the new presidential administration or new health care legislation passed by Congress.

The Ryan White Program, the largest federal program designed to provide care and support services for people living with HIV in the United States, provides funding for our HIV products through state AIDS Drug

## **Table of Contents**

Assistance Programs (ADAP) to many patients who are uninsured or underinsured. Federal funding is appropriated by Congress each year and is provided to cities, states, providers and other organizations. In addition to federal funding, some states and localities provide additional funding for Ryan White services. The program is due to be reauthorized again by September 2009 unless otherwise extended by Congress, and there may be changes to the program which would change or decrease the funding available for our HIV products. For example, if appropriations for Ryan White are held at the same amount as in previous years and more people access our drugs through ADAP, then it is likely that we will face pressures to provide even greater discounts for drugs purchased through the program. In addition, falling state revenues and budget cuts may result in reduction of state or local funding for Ryan White, which could lead to increased demand on our patient assistance programs, under which we offer our HIV products free of charge to eligible patients.

In Europe, the success of our commercialized products, and any other product candidates we may develop, will depend largely on obtaining and maintaining government reimbursement, because in many European countries patients are unlikely to use prescription drugs that are not reimbursed by their governments. In addition, negotiating prices with governmental authorities can delay commercialization by 12 months or more. For example, we have not launched Atripla in France as we remain in reimbursement discussions with French government authorities. Reimbursement policies may adversely affect our ability to sell our products on a profitable basis. In many international markets, governments control the prices of prescription pharmaceuticals, including through the implementation of reference pricing, price cuts, rebates, retrospective taxes and profit control, and expect prices of prescription pharmaceuticals to decline over the life of the product or as volumes increase. In recent years, many countries in the European Union have increased the amount of required discounts on our products, and we expect this to continue as countries attempt to manage health care expenditures, especially in light of the global economic downturn. As new drugs come to market, we may face significant price decreases for our products across most of the European countries. We believe that this will continue into the foreseeable future as governments struggle with escalating health care spending. As a result of these pricing practices, it may become difficult to maintain our historic levels of profitability or to achieve expected rates of growth.

Government agencies also issue regulations and guidelines directly applicable to us and to our products. In addition, from time to time, professional societies, practice management groups, private health/science foundations and organizations publish guidelines or recommendations directed to certain health care and patient communities. Such recommendations and guidelines may relate to such matters as product usage, dosage, route of administration, and use of related or competing therapies and can consequently result in increased or decreased usage of our products.

### ***Health Care Fraud and Abuse Laws***

We are subject to various federal and state laws pertaining to health care fraud and abuse, including anti-kickback laws and false claims laws. Anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug. Due to the breadth of the statutory provisions and the increasing attention being given to them by law enforcement authorities, it is possible that certain of our practices may be challenged under anti-kickback or similar laws. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment to third party payors (including Medicare and Medicaid), claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed or claims for medically unnecessary items or services. Our sales and marketing activities may be subject to scrutiny under these laws. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from federal health care programs (including Medicare and Medicaid). If the government were to allege against or convict us of violating these laws, there could be a material adverse effect on our results of operations.

## **Table of Contents**

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 will continue to cooperate with any related governmental inquiry.

### ***Compulsory Licenses***

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

### **Employees**

As of January 31, 2009, we had approximately 3,441 full-time employees. We believe that we have good relations with our employees.

### **Environment**

We seek to comply with all applicable statutory and administrative requirements concerning environmental quality. We have made, and will continue to make, expenditures for environmental compliance and protection. Expenditures for compliance with environmental laws have not had, and are not expected to have, a material effect on our capital expenditures, results of operations or competitive position.

### **Other Information**

We are subject to the information requirements of the Exchange Act. Therefore, we file periodic reports, proxy statements and other information with the SEC. Such reports, proxy statements and other information may be obtained by visiting the Public Reference Room of the SEC at 100 F Street, NE, Washington, D.C. 20549 or by calling the SEC at 1-800-SEC-0330, by sending an electronic message to the SEC at [publicinfo@sec.gov](mailto:publicinfo@sec.gov) or by sending a fax to the SEC at 1-202-777-1027. In addition, the SEC maintains a website ([www.sec.gov](http://www.sec.gov)) that contains reports, proxy and information statements, and other information regarding issuers that file electronically.

---

## **Table of Contents**

The mailing address of our headquarters is 333 Lakeside Drive, Foster City, California 94404, and our telephone number at that location is 650-574-3000. Our website is [www.gilead.com](http://www.gilead.com). Through a link on the Investors section of our website (under SEC Filings in the Financial Information section), we make available the following filings as soon as reasonably practicable after they are electronically filed with or furnished to the SEC: our Annual Reports on Form 10-K; Quarterly Reports on Form 10-Q; Current Reports on Form 8-K; and any amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act. All such filings are available free of charge upon request.

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

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

#### **A substantial portion of our revenues is derived from sales of our HIV products. If we are unable to maintain or continue increasing sales of our HIV products, our results of operations may be adversely affected.**

We are currently dependent on sales of our products for the treatment of HIV, especially Truvada and Atripla, to support our existing operations. Our HIV products contain tenofovir disoproxil fumarate and/or emtricitabine, which belong to the nucleoside class of antiviral therapeutics. Were the treatment paradigm for HIV to change, causing nucleoside-based therapeutics to fall out of favor, or if we were unable to continue increasing our HIV product sales, our results of operations would likely suffer and we would likely need to scale back our operations, including our spending on research and development (R&D) efforts. HIV product sales for the year ended December 31, 2008 were \$4.33 billion, or 81% of our total revenues, and sales of Truvada and Atripla accounted for 49% and 36%, respectively, of our total HIV product sales during 2008. We may not be able to sustain the growth rate of sales of our HIV products for the reasons stated in this risk factor section and, in particular, for the following reasons:

As our HIV products are used over a longer period of time in many patients and in combination with other products, and additional studies are conducted, new issues with respect to safety, resistance and interactions with other drugs may arise, which could cause us to provide additional warnings or contraindications on our labels, narrow our approved indications or halt sales of a product, each of which could reduce our revenues.

As our HIV products mature, private insurers and government reimbursers often reduce the amount they will reimburse patients for these products, which increases pressure on us to reduce prices.

A large part of the market for our HIV products consists of patients who are already taking other HIV drugs. If we are not successful in encouraging physicians to change patients' regimens to include our HIV products, the sales of our HIV products will be limited.

As generic HIV products are introduced into major markets, our ability to maintain pricing and market share may be affected.

---

**Table of Contents**

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

During the year ended December 31, 2008, approximately 90% of our product sales in the United States were to three wholesalers, Cardinal Health, Inc., McKesson Corp. and AmerisourceBergen Corp. The U.S. wholesalers with whom we have entered into inventory management agreements make estimates to determine end user demand and may not be completely effective in matching their inventory levels to actual end user demand. As a result, changes in inventory levels held by those wholesalers can cause our operating results to fluctuate unexpectedly if our sales to these wholesalers do not match end user demand. In addition, inventory is held at retail pharmacies and other non-wholesale locations with whom we have no inventory management agreements and no control over buying patterns. Adverse changes in economic conditions or other factors may cause retail pharmacies to reduce their inventories of our products, which would reduce their orders from wholesalers and, consequently, the wholesalers' orders from us, even though end user demand has not changed. For example, in the fourth quarter of 2008, strong prescription demand for Truvada and Atripla was not fully reflected in our revenues for the fourth quarter. We believe this is because during the quarter, inventories were drawn down within the retail distribution channel. As inventory in the distribution channel fluctuates from quarter to quarter, we may continue to see the mismatch between prescription demand for our products and our revenues. In addition, the non-retail sector in the United States, which includes government institutions, including state AIDS Drug Assistance Programs (ADAP), correctional facilities and large health maintenance organizations, tends to be even less consistent in terms of buying patterns, and often causes quarter over quarter fluctuations that do not necessarily mirror the purchasing patterns that can be seen within the retail sector. For example, in the first quarter of 2008, we observed large non-retail purchases by a small number of state ADAPs that purchase centrally and have significant warehousing capacity. We believe such purchases were driven by the grant cycle for federal ADAP funds rather than current patient demand, which tempered orders and our associated product sales, revenues and earnings in the second quarter of 2008 as these organizations depleted their increased inventory levels established during the first quarter of 2008. We expect to continue to experience fluctuations in the purchasing patterns of our non-retail customers which may result in fluctuations in our product sales, revenues and earnings in the future.

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

**If we fail to commercialize new products or expand the indications for existing products, our prospects for future revenues may be adversely affected.**

If we do not introduce new products to market or increase sales of our existing products, we will not be able to increase or maintain our total revenues and continue to expand our R&D efforts.

For example, in December 2007, the Committee for Medicinal Product for Human Use of the European Medicines Agency (EMA) granted marketing authorization for Atripla in the European Union for the treatment of HIV-1 infection in adults with virologic suppression to HIV-1 RNA levels of less than 50 copies/mL on their current combination antiretroviral therapy for more than three months. Patients must not have experienced virological failure on any prior antiretroviral therapy and must be known not to have harbored virus strains with mutations conferring significant resistance to any of the three components contained in Atripla. This restriction of Atripla's use in the European Union will prevent us from promoting Atripla for use in patients who are not currently achieving this reduction in viral load through the use of antiretroviral therapy, including newly diagnosed patients. If we seek to expand the indication for Atripla in the European Union, the EMA may require us to perform additional clinical trials, which we may be unable to complete. If we are unable to expand the indication for Atripla to include a broader population of patients, the impact to future sales of Atripla in the

---

**Table of Contents**

European Union is unknown but could be more limited than in other markets, including the United States, where we have no such restrictions. In addition, sales of Atripla may increase at the expense of product sales of its component products and our overall total revenues and gross margin may not increase as Atripla sales increase.

Further, the marketing authorization application submitted by us for aztreonam for inhalation solution for the treatment of cystic fibrosis (CF) in the United States was delayed when we received a complete response letter from the FDA informing us that the FDA will not approve the application in its current form and requesting we conduct an additional Phase 3 clinical study. In November 2008, we filed a request for dispute resolution with the FDA to determine whether further analyses of the existing data could lead to approval or whether we will need to conduct an additional study. In February 2009, in response to our appeal, the FDA notified us that it is reiterating its position that we will need to conduct another clinical study of aztreonam for inhalation solution before we can resubmit our new drug application (NDA). Existing data from any ongoing or from any additional clinical trial that we may commence to satisfy FDA concerns may not support FDA approval of aztreonam for inhalation solution, which may cause us considerable expense and may lead to further delays or cause us to abandon further development of the product. There are also risks that health authorities in other countries where marketing authorization applications are pending will undertake similar additional reviews which would compound the risks described above.

**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.**

Because a significant percentage of our product sales are denominated in foreign currencies, primarily the Euro, we face exposure to adverse movements in foreign currency exchange rates. When the U.S. dollar strengthens against these foreign currencies, the relative value of sales made in the respective foreign currency decreases. Conversely, when the U.S. dollar weakens against these currencies, the relative value of such sales increase. Overall, we are a net receiver of foreign currencies and, therefore, benefit from a weaker U.S. dollar and are adversely affected by a stronger U.S. dollar relative to those foreign currencies in which we transact significant amounts of business. The net foreign currency exchange impact on our 2008 revenues and pre-tax earnings, which includes revenues and expenses generated from outside the United States, was a favorable \$148.2 million and \$92.6 million, respectively, compared to 2007. Recently, the U.S. dollar has appreciated against major European currencies, and the amount of the favorable impact on our product sales which resulted from the previously relatively weak U.S. dollar has decreased.

We use foreign currency forward and option contracts to hedge a percentage of our forecasted international sales, primarily those denominated in the Euro. We also hedge certain monetary assets and liabilities denominated in foreign currencies, which reduces but does not eliminate our exposure to currency fluctuations between the date a transaction is recorded and the date that cash is collected or paid. We cannot predict future fluctuations in the foreign currency exchange rate of the U.S. dollar. If the U.S. dollar continues to appreciate against certain currencies and our hedging program does not sufficiently offset the effects of such appreciation, our results of operation will be adversely affected and our stock price may decline.

**We face significant competition.**

We face significant competition from large pharmaceutical and biotechnology companies, most of whom have substantially greater resources than we do. In addition, our competitors have more products and have operated in the fields in which we compete for longer than we have. Our HIV products compete primarily with products from GlaxoSmithKline Inc. (GSK), which markets fixed dose combination products that compete with Truvada and Atripla. For Hepsera and Viread for treatment of chronic hepatitis B, we compete primarily with products produced by GSK, Bristol-Myers Squibb Company (BMS) and Novartis Pharmaceuticals Corporation (Novartis) in the United States, the European Union and China. For AmBisome, we compete primarily with products produced by Merck & Co., Inc. (Merck) and Pfizer Inc. (Pfizer). In addition, we are aware of at least two lipid formulations that claim similarity to AmBisome becoming available outside of the United States, including the possible entry of one such formulation in Greece. These formulations may reduce market demand



---

## **Table of Contents**

for AmBisome. Furthermore, the manufacture of lipid formulations of amphotericin B is very complex and if any of these formulations are found to be unsafe, sales of AmBisome may be negatively impacted by association. Letairis competes directly with Actelion Pharmaceuticals US, Inc. (Actelion) and indirectly with PAH products from United Therapeutics Corporation and Pfizer. Tamiflu competes with products sold by GSK and generic competitors. Aztreonam for inhalation solution for the treatment of CF, if approved for marketing, will compete with a product marketed by Novartis.

In addition, a number of companies are pursuing the development of technologies which are competitive with our research programs. These competing companies include specialized pharmaceutical firms and large pharmaceutical companies acting either independently or together with other pharmaceutical companies. Furthermore, academic institutions, government agencies and other public and private organizations conducting research may seek patent protection and may establish collaborative arrangements for competitive products and programs.

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

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

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

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

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

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

In September 2008, we received a complete response letter from the FDA informing us that the FDA will not approve our NDA for aztreonam for inhalation solution for treatment of CF in its current form and requesting we conduct an additional Phase 3 clinical study. In November 2008, we filed a request for dispute resolution with

---

**Table of Contents**

the FDA to determine whether further analyses of the existing data could lead to approval or whether we will need to conduct an additional study. In February 2009, in response to our appeal, the FDA notified us that it is reiterating its position that we will need to conduct another clinical study of aztreonam for inhalation solution before we can resubmit our NDA. Existing data from any ongoing clinical trials or any additional clinical trial that we may commence to satisfy FDA concerns may not support FDA approval of aztreonam for inhalation solution, which may cause us considerable expense and may lead to further delays or cause us to abandon further development of the product. There are also risks that health authorities in other countries where marketing authorization applications are pending will undertake similar additional reviews which would compound the risks described above.

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

On September 27, 2007, President Bush signed into law the Food and Drug Administration Amendments Act of 2007, which significantly expanded the FDA's authority, including, among other things, to:

require sponsors of marketed products to conduct post-approval clinical studies to assess a known serious risk, signals of serious risk or to identify an unexpected serious risk;

mandate labeling changes to products, at any point in a product's lifecycle, based on new safety information; and

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

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

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

We are required to demonstrate the safety and efficacy of products that we develop for each intended use through extensive preclinical studies and clinical trials. The results from preclinical and early clinical studies do not always accurately predict results in later, large-scale clinical trials. Even successfully completed large-scale clinical trials may not result in marketable products. If any of our product candidates fails to achieve its primary endpoint in clinical trials, if safety issues arise or if the results from our clinical trials are otherwise inadequate to support regulatory approval of our product candidates, commercialization of that product candidate could be delayed or halted. We may also face challenges in clinical trial protocol design. If the clinical trials for any of the product candidates in our pipeline are delayed or terminated, our prospects for future revenue growth would be adversely impacted. For example, we face numerous risks and uncertainties with our product candidates, including elvitegravir, our novel HIV integrase inhibitor; darusentan for the treatment of resistant hypertension; and ambrisentan for the treatment of idiopathic pulmonary fibrosis (IPF), each currently in Phase 3 clinical trials that could prevent completion of development of these product candidates. These risks include our ability to enroll patients in clinical trials, the possibility of unfavorable results of our clinical trials, the need to modify or delay our clinical trials or to perform additional trials and the risk of failing to obtain FDA and other regulatory body approvals. As a result, our product candidates may never be successfully commercialized. Further, we may make a strategic decision to discontinue development of our product candidates if, for example, we believe commercialization will be difficult relative to other opportunities in our pipeline. If these programs and others in

---

**Table of Contents**

our pipeline cannot be completed on a timely basis or at all, then our prospects for future revenue growth may be adversely impacted. In addition, clinical trials involving our commercial products could raise new safety issues for our existing products, which could in turn decrease our revenues and harm our business.

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

We extensively outsource our clinical trial activities and usually perform only a small portion of the start-up activities in-house. We rely on independent third party contract research organizations (CROs), 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.

**We depend on relationships with other companies for sales and marketing performance and revenues. Failure to maintain these relationships, poor performance by these companies or disputes with these companies could negatively impact our business.**

We rely on a number of significant collaborative relationships with major pharmaceutical companies for our sales and marketing performance in certain territories. These include collaborations with BMS for Atripla in the United States, Europe and Canada; Roche for Tamiflu; and GSK for ambrisentan in territories outside of the United States. In some countries, we rely on international distributors for sales of Truvada, Viread, Hepsera, Emtriva and AmBisome. Some of these relationships also involve the clinical development of these products by our partners. Reliance on collaborative relationships poses a number of risks, including:

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

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

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

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

our corporate partners 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;

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

our distributors and our corporate partners may be unable to pay us, particularly in light of current economic conditions. Given these risks, there is a great deal of uncertainty regarding the success of our current and future collaborative efforts. If these efforts fail, our product development or commercialization of new products could be delayed or revenues from products could decline.

Under our April 2002 licensing agreement with GSK, we gave GSK the right to control clinical and regulatory development and commercialization of Hepsera in territories in Asia, Africa and Latin America. These include major markets for Hepsera, such as China, Japan,

Taiwan and South Korea. The success of Hepsera in

---

## Table of Contents

these territories depends almost entirely on the efforts of GSK. In this regard, GSK promotes Epivir-HBV/Zeffix, a product that competes with Hepsera. Consequently, GSK's marketing strategy for Hepsera may be influenced by its promotion of Epivir-HBV/Zeffix. We receive royalties from GSK equal to a percentage of GSK's net sales of Hepsera as well as net sales of GSK's Epivir-HBV/Zeffix. If GSK fails to devote sufficient resources to, or does not succeed in developing or commercializing Hepsera in its territories, our potential revenues from sales of Hepsera from these territories may be substantially reduced.

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

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

not effectively sell or support Letairis;

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

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

cease operations.

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

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

### **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. In the United States, the European Union and other significant or potentially significant markets for our products and product candidates, government authorities and third party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. For example, a significant portion of our sales of the majority of our products are subject to significant discounts from list price and rebate obligations. In addition, the



---

**Table of Contents**

increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the European Union will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our product revenues and profitability. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and health care reform, pharmaceutical reimbursement policies and pricing in general.

In Europe, the success of our commercialized products, and any other product candidates we may develop, will depend largely on obtaining and maintaining government reimbursement, because in many European countries patients are unlikely to use prescription drugs that are not reimbursed by their governments. In addition, negotiating prices with governmental authorities can delay commercialization by 12 months or more. For example, we have not launched Atripla in France as we remain in reimbursement discussions with French government authorities. Reimbursement policies may adversely affect our ability to sell our products on a profitable basis. In many international markets, governments control the prices of prescription pharmaceuticals, including through the implementation of reference pricing, price cuts, rebates, retrospective taxes and profit control, and expect prices of prescription pharmaceuticals to decline over the life of the product or as volumes increase. In recent years, many countries in the European Union have increased the amount of discounts required on our products, and we expect this to continue as countries attempt to manage health care expenditures, especially in light of the global economic downturn. As new drugs come to market, we may face significant price decreases for our products across most of the European countries. We believe that this will continue into the foreseeable future as governments struggle with escalating health care spending. As a result of these pricing practices, it may become difficult to maintain our historic levels of profitability or to achieve expected rates of growth.

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

Legislative and regulatory changes to government prescription drug procurement and reimbursement programs occur relatively frequently in the United States and foreign jurisdictions. There have been significant changes to the federal Medicare system in recent years in the United States that could impact the pricing of our products. Under the Medicare Prescription Drug Improvement and Modernization Act of 2003, Medicare beneficiaries are able to elect coverage for prescription drugs under Medicare Part D. The prescription drug program began on January 1, 2006 and although we have benefited from patients transitioning from Medicaid to Medicare Part D since 2006, the longer term impact of Medicare Part D on our business is not yet clear to us, and the impact will depend in part on specific decisions regarding the level of coverage provided for the therapeutic categories in which our products are included, the terms on which such coverage is provided, and the extent to which preference is given to selected products in a category. Third party payors providing Medicare Part D coverage have attempted to negotiate price concessions from pharmaceutical manufacturers. In addition, discussions are taking place at the federal level to pass legislation that would either allow or require the federal government to directly negotiate price concessions from pharmaceutical manufacturers or set minimum requirements for Medicare pricing. The increasing pressure to lower prescription drug prices may limit drug access for Medicare Part D enrollees. Further, Medicare patients have to pay co-insurance, which may influence which products are recommended by physicians and selected by patients. Our results of operations could be materially adversely affected by the reimbursement changes emerging from Medicare prescription drug coverage legislation. In addition to federal Medicare proposals, state Medicaid drug payment changes could also lower payment for our products. To the extent that private insurers or managed care programs follow Medicaid coverage and payment developments, the adverse effects may be magnified by private insurers adopting lower payment schedules. Additionally, any additional statutory or regulatory changes, including potential changes to Medicare Part D, and health care reform at both the federal and state levels could adversely affect payment for our drugs and demand for our product. At this time, a few states have already enacted health care reform legislation, and the federal government and individual state governments continue to consider health care reform policies and legislation. The pricing and reimbursement environment for our products may change in the future and become more challenging due to, among other reasons, new policies of the new presidential administration or new health care legislation passed by Congress.

---

## **Table of Contents**

The Ryan White Program, the largest federal program designed to provide care and support services for people living with HIV in the United States, provides funding for our HIV products through state AIDS Drug Assistance Programs (ADAP) to many patients who are uninsured or underinsured. Federal funding is appropriated by Congress each year and is provided to cities, states, providers and other organizations. In addition to federal funding, some states and localities provide additional funding for Ryan White services. The program is due to be reauthorized again by September 2009 unless otherwise extended by Congress, and there may be changes to the program which would change or decrease the funding available for our HIV products. For example, if appropriations for Ryan White are held at the same amount as in previous years and more people access our drugs through ADAP, then it is likely that we will face pressures to provide even greater discounts for drugs purchased through the program. In addition, falling state revenues and budget cuts may result in reduction of state or local funding for Ryan White, which could lead to increased demand on our patient assistance programs, under which we offer our HIV products free of charge to eligible patients.

### **Expenses associated with clinical trials may cause our earnings to fluctuate, which could adversely affect our stock price.**

The clinical trials required for regulatory approval of our products, as well as clinical trials we are required to conduct after approval, are very expensive. It is difficult to accurately predict or control the amount or timing of these expenses from quarter to quarter. Uneven and unexpected spending on these programs may cause our operating results to fluctuate from quarter to quarter, and our stock price may decline.

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

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

obtain patents and licenses to patent rights;

preserve trade secrets; and

operate without infringing on the proprietary rights of others.

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

We have a number of U.S. and foreign patents, patent applications and rights to patents related to our compounds, products and technology, but we cannot be certain that issued patents will be enforceable or provide adequate protection or that pending patent applications will result in issued patents. Patent applications are confidential for a period of time until a patent is issued. As a result, we may not know if our competitors filed patent applications for technology covered by our pending applications or if we were the first to invent the technology that is the subject of our patent applications. Competitors may have filed patent applications or received patents and may obtain additional patents and proprietary rights that block or compete with our patents. In addition, if competitors file patent applications covering our technology, we may have to participate in interference proceedings or litigation to determine the right to a patent. Litigation and interference proceedings are expensive, such that, even if we are ultimately successful, our results of operations may be adversely affected by such events.



## **Table of Contents**

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

Although we were successful in responding to the PTO office actions in the instance above, similar organizations may still challenge our patents in foreign jurisdictions. For example, in April 2008, the Brazilian Health Ministry, citing the pending U.S. patent re-examination proceedings as grounds for rejection, requested that the Brazilian patent authority issue a decision that is not supportive of our patent application for tenofovir disoproxil fumarate in Brazil. In August 2008, an examiner in the Brazilian patent authority issued a final rejection of our fumarate salt patent application, the only patent application for tenofovir disoproxil fumarate we have filed in Brazil. We have filed an appeal within the patent authority responding to the questions raised in the rejection. We cannot predict the outcome of this proceeding on our tenofovir disoproxil fumarate patent application. If we are unable to successfully appeal the decision by the patent authority in the courts, the Brazilian patent authority will reject the tenofovir DF patent application. If the tenofovir disoproxil fumarate patent application is rejected by the Brazilian patent authority, the Brazilian government would likely purchase generic tenofovir disoproxil fumarate, which would significantly reduce our sales of HIV products in Brazil.

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

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

As part of the approval process of some of our products, the FDA granted an exclusivity period during which other manufacturers' applications for approval of generic versions of our product will not be granted. Generic manufacturers often wait to challenge the patents protecting products that have been granted exclusivity until one year prior to the end of the exclusivity period. From time to time, we have received notices from manufacturers indicating that they intend to import chemical intermediates possibly for use in making our products. It is, therefore, possible that generic manufacturers are considering attempts to seek FDA approval for a similar or identical drug through an abbreviated new drug application (ANDA), which is the application form typically used by manufacturers seeking approval of a generic drug. If our patents are subject to challenges, we may need to spend significant resources to defend such challenges and we may not be able to defend our patents successfully. For example, in November 2008, we received notice that Teva Pharmaceuticals submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Truvada. In the notice, Teva alleges that two of the patents associated with emtricitabine, owned by Emory University and licensed exclusively to us, are invalid, unenforceable and/or will not be infringed by Teva's manufacture, use or sale of a generic version of Truvada. In December 2008, we filed a lawsuit in U.S. District Court in New York against Teva for infringement of the two emtricitabine patents. We cannot predict the ultimate outcome of the action and we may spend significant resources defending these patents. If we are unsuccessful in the lawsuit, some or all of our original claims in the patents may be narrowed or invalidated and the patent protection for Truvada in the United States would be shortened to expire in 2017 instead of 2021.

In August 2007, the PTO adopted new rules which were scheduled to become effective on November 1, 2007. In October 2007, GSK successfully obtained a preliminary injunction against implementation of these rules, and in April 2008, the court ruled in support of GSK's challenge to the rules and obtained a permanent

---

## **Table of Contents**

injunction against their implementation. The rules would have restricted the number of claims permitted in a patent application and the number of continuing patent applications that can be filed. Following the court's ruling, the PTO filed a notice of appeal to the Federal Court of Appeals. If the PTO successfully appeals the court's decision and the rules are implemented, we may be limited in our ability to obtain broad patent coverage for our products and product candidates, which may allow competitors to market products very similar to ours or to obtain patent coverage for closely related products.

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

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

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

### **Manufacturing problems could delay product shipments and regulatory approvals, which may adversely affect our results of operations.**

We depend on third parties to perform manufacturing activities effectively and on a timely basis for the majority of our solid dose products. In addition, Roche, either by itself or through third parties, is responsible for manufacturing Tamiflu. The manufacturing process for pharmaceutical products is highly regulated and regulators may shut down manufacturing facilities that they believe do not comply with regulations. We, our third party manufacturers and our corporate partners are subject to the FDA's current Good Manufacturing Practices (GMP), which are extensive regulations governing manufacturing processes, stability testing, record keeping and quality standards. Similar regulations are in effect in other countries. Our manufacturing operations are also subject to routine inspections by regulatory agencies. Additionally, these third party manufacturers and corporate partners are independent entities who are subject to their own unique operational and financial risks which are out of our control. If we or any of these third party manufacturers or corporate partners fail to perform as required, this could impair our ability to deliver our products on a timely basis or receive royalties or cause delays in our clinical trials and applications for regulatory approval. To the extent these risks materialize and affect their performance obligations to us, our financial results may be adversely affected.

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

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

---

## **Table of Contents**

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

We need access to certain supplies and products to conduct our clinical trials and to manufacture our products. In light of the economic downturn, we have had increased difficulty in purchasing certain of the raw materials used in our manufacturing process. If we are unable to purchase sufficient quantities of these materials or find suitable alternate materials in a timely manner, our development efforts for our product candidates may be delayed or our ability to manufacture our products would be limited, which would limit our ability to generate revenues.

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

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

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

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

### **We face credit risks from our European customers that may adversely affect our results of operations.**

Our European product sales to government-owned or supported customers in Greece, Italy, Portugal and Spain are subject to significant payment delays due to government funding and reimbursement practices. This has resulted and may continue to result in an increase in days sales outstanding due to the average length of time that we have accounts receivable outstanding. Our accounts receivable in these countries totaled approximately \$543.8 million as of December 31, 2008, of which \$191.0 million was more than 120 days past due. 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.

---

**Table of Contents**

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

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

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

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

In a number of developing countries, government officials and other interested groups have suggested that pharmaceutical companies should make drugs for HIV infection available at low cost. Alternatively, governments in those developing countries could require that we grant compulsory licenses to allow competitors to manufacture and sell their own versions of our products, thereby reducing our product sales. For example, in the past, certain offices of the government of Brazil have expressed concern over the affordability of our HIV products and declared that they were considering issuing compulsory licenses to permit the manufacture of otherwise patented products for HIV infection, including Viread. As a result of discussions with the Brazilian government, we reached agreement with the Brazilian Health Ministry in May 2006 to reduce the price of Viread in Brazil by approximately 50%. In addition, concerns over the cost and availability of Tamiflu related to a potential avian flu pandemic have generated international discussions over compulsory licensing of our Tamiflu patents. For example, the Canadian government may allow Canadian manufacturers to manufacture and export the active ingredient in Tamiflu to eligible developing and least developed countries under Canada's Access to Medicines Regime. Furthermore, Roche has issued voluntary licenses to permit third party

---

**Table of Contents**

manufacturing of Tamiflu. For example, Roche has granted a sublicense to Shanghai Pharmaceutical (Group) Co., Ltd. for China and a sublicense to India's Hetero Drugs Limited for India and certain developing countries. Should one or more compulsory licenses be issued permitting generic manufacturing to override our Tamiflu patents, or should Roche issue additional voluntary licenses to permit third party manufacturing of Tamiflu, those developments could reduce royalties we receive from Roche's sales of Tamiflu. Certain countries do not permit enforcement of our patents, and third party manufacturers are able to sell generic versions of our products in those countries. Compulsory licenses or sales of generic versions of our products could significantly reduce our sales and adversely affect our results of operations, particularly if generic versions of our products are imported into territories where we have existing commercial sales.

**We may face significant liability resulting from our products that may not be covered by insurance and successful claims could materially reduce our earnings.**

The testing, manufacturing, marketing and use of our commercial products, as well as product candidates in development, involve substantial risk of product liability claims. These claims may be made directly by consumers, healthcare providers, pharmaceutical companies or others. In recent years, coverage and availability of product liability insurance has decreased. In addition, the cost to defend lawsuits or pay damages for product liability claims may exceed our coverage. If we are unable to maintain adequate coverage or if claims exceed our coverage, our financial condition and our ability to clinically test our product candidates and to market our products will be adversely impacted. In addition, negative publicity associated with any claims, regardless of their merit, may decrease the future demand for our products and impair our financial condition.

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

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

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

In November 2008, we received notice that Teva Pharmaceuticals submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Truvada. In the notice, Teva alleges that two of the patents associated with emtricitabine, owned by Emory University and licensed exclusively to us, are invalid, unenforceable and/or will not be infringed by Teva's manufacture, use or sale of a generic version of Truvada. In December 2008, we filed a lawsuit in U.S. District Court in New York against Teva for infringement of the two emtricitabine patents. We cannot predict the ultimate outcome of the action, and we may spend significant resources defending these patents. If we are unsuccessful in the lawsuit, some or all of our original claims in the patents may be narrowed or invalidated, and the patent protection for Truvada in the United States would be shortened to expire in 2017 instead of 2021.

In addition, we, along with certain of our officers and a former officer, were named as defendants in a class action lawsuit alleging violations of federal securities laws. The lawsuit was dismissed by the United States District Court for the Northern District of California, but in August 2008 the United States Court of Appeals for the Ninth Circuit reversed the dismissal and remanded the case to the district court. In February 2009, we filed a petition for a writ of certiorari with the Supreme Court of the United States, requesting that the Court review the judgment of the court of appeals. While the Supreme Court reviews our petition, the case continues before the district court.

Further, in November 2006, we received a subpoena from the U.S. Attorney's Office in San Francisco requesting documents regarding our marketing and medical education programs for Truvada, Viread and

---

## **Table of Contents**

Emtriva. We have been cooperating and will continue to cooperate with any related governmental inquiry. The outcome of the class action lawsuit, any other lawsuits brought against us, the investigation or any other such investigations brought against us, are inherently uncertain, and adverse developments or outcomes can result in significant expenses, monetary damages, penalties or injunctive relief against us that could significantly reduce our earnings and cash flows and harm our business.

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

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

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

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

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

For example, in May 2008, the Financial Accounting Standards Board (FASB) issued FASB Staff Position No. APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)* (FSP APB 14-1). FSP APB 14-1 addresses instruments commonly referred to as Instrument C from Emerging Issues Task Force Issue No. 90-19, *Convertible Bonds with Issuer Option to Settle for Cash upon Conversion*, which requires the issuer to settle the principal amount in cash and the conversion spread in cash or net shares at the issuer's option. FSP APB 14-1 requires that issuers of these instruments account for their liability and equity components separately by bifurcating the conversion option from the debt instrument, classifying the conversion option in equity and then accreting the resulting discount on the debt as additional interest expense over the expected life of the debt. FSP APB 14-1 is effective for fiscal years beginning after December 15, 2008 and interim periods within those fiscal years, and requires retrospective application to all periods presented. Early application is not permitted. We expect that the adoption of FSP APB 14-1 will have a material impact on our consolidated financial position and results of operations. Based on the requirements of FSP APB 14-1, we estimate that if FSP APB 14-1 was effective for the current and comparative periods, we would have reported additional interest expense related to our convertible senior notes of approximately \$53.2 million, \$50.0 million and \$32.7 million during 2008, 2007 and 2006, respectively.

In addition, in December 2007, the FASB issued Statement of Financial Accounting Standards (SFAS) No. 141 (revised 2007), *Business Combinations* (SFAS 141R). SFAS 141R establishes principles and requirements for recognizing and measuring assets acquired, liabilities assumed and any noncontrolling interests in the acquiree in a business combination. SFAS 141R also provides guidance for recognizing and measuring goodwill acquired in a business combination; requires purchased in-process research and development to be

## **Table of Contents**

capitalized at fair value as intangible assets at the time of acquisition; requires acquisition-related expenses and restructuring costs to be recognized separately from the business combination; expands the definition of what constitutes a business; and requires the acquirer to disclose information that users may need to evaluate and understand the financial effect of the business combination. SFAS 141R is effective on a prospective basis and will impact business combination transactions for which the acquisition date occurs in fiscal years beginning after December 15, 2008. Depending on the nature and magnitude of our future business combination transactions, SFAS 141R may have a material impact on our consolidated financial position and/or results of operations.

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

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

### **ITEM 1B. UNRESOLVED STAFF COMMENTS**

Not applicable.

### **ITEM 2. PROPERTIES**

Our corporate headquarters, including our principal offices and some of our commercial, administrative, research and development (R&D) facilities, are located in Foster City, California. In January 2009, we purchased approximately 30 acres of land and the office building located at 301 Velocity Way in Foster City. With this purchase, we now own 18 buildings in Foster City.

We lease facilities in Foster City and San Dimas, California, to house some of our manufacturing, warehousing and R&D activities. In addition, we also lease facilities in Durham, North Carolina; Boulder and Westminster, Colorado; and Seattle, Washington to house some of our administrative and R&D activities.

Our international headquarters, which include some of our commercial, medical and administrative facilities, are located and leased in the London area in the United Kingdom.

We also lease and own facilities in the Dublin area of Ireland to house our manufacturing and distribution activities. We acquired a manufacturing facility in Cork, Ireland in September 2007 in connection with the acquisition of Nycomed Limited. We have transferred certain of our operations from our Dublin area site to this facility and utilize the site primarily for solid dose tablet manufacturing of our antiviral products, as well as product packaging activities.

We also own a manufacturing facility in Edmonton, Alberta, Canada, that we primarily use to conduct process research and scale-up of our clinical development candidates, the manufacturing of our active pharmaceutical ingredients for both investigational and commercial products and our chemical development activities to improve existing commercial manufacturing processes.

We have leased additional facilities to house our commercial, medical and administrative activities in Australia, Austria, Belgium, Canada, France, Germany, Greece, Italy, Netherlands, Portugal, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

**Table of Contents**

We believe that our existing properties, including both owned and leased sites, are in good condition and suitable for the conduct of our business. We believe our capital resources are sufficient to purchase, lease or construct any additional facilities required to meet our expected long-term growth needs.

**ITEM 3. LEGAL PROCEEDINGS**

In November 2008, we received notice that Teva Pharmaceuticals submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Truvada. In the notice, Teva alleges that two of the patents associated with emtricitabine, U.S. Patent Numbers 6,642,245 and 6,703,396, owned by Emory University and licensed exclusively to us, are invalid, unenforceable and/or will not be infringed by Teva's manufacture, use or sale of a generic version of Truvada. In December 2008, we filed a lawsuit in U.S. District Court in New York against Teva for infringement of the two emtricitabine patents. We cannot predict the ultimate outcome of the action, and we may spend significant resources defending these patents. If we are unsuccessful in the lawsuit, some or all of our original claims in the patents may be narrowed or invalidated, and the patent protection for Truvada in the United States would be shortened to expire in 2017 instead of 2021.

Information pertaining to certain of our other legal proceedings can be found under the heading "Legal Proceedings" in Item 8, Note 11

"Commitments and Contingencies" to our Consolidated Financial Statements on page 114 of this Annual Report on Form 10-K and is incorporated by reference herein.

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

No matters were submitted to a vote of our security holders during the quarter ended December 31, 2008.



**Table of Contents****PART II****ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES**

Our common stock is traded on The Nasdaq Global Select Market under the symbol GILD. The following table sets forth for the periods indicated the high and low intra-day sale prices per share of our common stock on The Nasdaq Global Select Market. These prices represent quotations among dealers without adjustments for retail mark-ups, markdowns or commissions and may not represent prices of actual transactions.

	High	Low
<b>2008</b>		
First Quarter	\$ 51.65	\$ 42.16
Second Quarter	\$ 56.95	\$ 49.58
Third Quarter	\$ 57.63	\$ 39.80
Fourth Quarter	\$ 52.26	\$ 35.60
<b>2007</b>		
First Quarter	\$ 38.54	\$ 30.96
Second Quarter	\$ 42.24	\$ 37.87
Third Quarter	\$ 41.37	\$ 35.22
Fourth Quarter	\$ 47.90	\$ 40.80

As of February 20, 2009, we had 910,954,602 shares of common stock outstanding held by approximately 486 stockholders of record.

We have not paid cash dividends on our common stock since our inception. We currently expect to retain earnings primarily for use in the operation and expansion of our business, and therefore, do not anticipate paying any cash dividends in the near future. In an effort to return value to our stockholders and minimize dilution from stock issuances, our Board of Directors (Board) authorized a program for the repurchase of our common stock in an aggregate amount of up to \$3.00 billion through open market and private block transactions pursuant to Rule 10b5-1 plans, privately negotiated purchases or other means. See Note 12 Stockholders' Equity to our Consolidated Financial Statements on pages 115 through 116 of this Annual Report on Form 10-K for more information regarding our repurchase program.

**Table of Contents**

*Performance Graph<sup>(1)</sup>*

The following graph compares our total stockholder returns for the past five years to two indices: the Standard & Poor's 500 Stock Index, labeled S&P500 Index; and the Nasdaq Biotechnology Index, labeled NBI Index. The total return for each index assumes the reinvestment of all dividends, if any, paid by companies included in these indices and are calculated as of December 31 of each year.

We are a composite member of each of the S&P500 Index and the NBI Index and we intend to use these indices as comparators for our stock performance for the purposes of the following graph going forward. As a composite member of the S&P500 Index, we are required under applicable regulations to use this index as a comparator, and we believe the NBI Index is a relevant comparator since it is composed of peer companies in lines-of-business similar to ours.

The stockholder return shown on the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns.

**Comparison of Cumulative Total Return on Investment for the Past Five Years<sup>(2)</sup>**

- (1) This section is not soliciting material, is not deemed filed with the SEC and is not to be incorporated by reference in any of our filings under the Securities Act or the Exchange Act whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.
- (2) Shows the cumulative return on investment assuming an investment of \$100 in our common stock, the NBI Index and the S&P500 Index on December 31, 2003.

**Table of Contents***Issuer Purchases of Equity Securities*

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

The table below summarizes our stock repurchase activity for the three months ended December 31, 2008 (in thousands, except per share amounts):

		<b>Total Number of Shares Purchased</b>	<b>Average Price Paid per Share</b>	<b>Total Number of Shares Purchased as Part of Publicly Announced Programs</b>	<b>Maximum Fair Value of Shares that May Yet Be Purchased Under the Program</b>
October 1	October 31, 2008	14,875 <sup>(1)</sup>	\$ 50.42	14,875 <sup>(1)</sup>	\$ 1,001,569
November 1	November 30, 2008	86	\$ 40.74	86	\$ 998,057
December 1	December 31, 2008	6	\$ 48.28		\$ 998,057
<b>Total</b>		<b>14,967 <sup>(2)</sup></b>	<b>\$ 50.37</b>	<b>14,961 <sup>(2)</sup></b>	

- (1) In October 2008, we entered into an accelerated share repurchase transaction with a financial institution to repurchase \$750.0 million of our common stock on an accelerated basis. This accelerated share repurchase is part of the \$3.00 billion share repurchase program authorized by our Board in October 2007. Under the terms of the accelerated share repurchase agreement, we paid \$750.0 million to the financial institution to settle the initial purchase transaction and received 14,874,519 shares of our common stock at a price of \$50.42 per share. On or before April 2009, subject to extension under certain circumstances as well as the maximum and minimum share delivery provisions of the agreement, we may receive additional shares from the financial institution depending on the average of the daily volume weighted-average prices of our common stock during a specified period less a predetermined discount per share. After making the initial payment of \$750.0 million, we are not obligated to deliver any cash or shares to the financial institution except in certain limited circumstances, in which case the method of delivery (cash or shares of our common stock) would be at our discretion.
- (2) The difference between the total number of shares purchased and the total number of shares purchased as part of publicly announced programs is due to shares of common stock withheld by us from employee restricted stock awards in order to satisfy our applicable tax withholding obligations.

**Table of Contents****ITEM 6. SELECTED FINANCIAL DATA****GILEAD SCIENCES, INC.****SELECTED CONSOLIDATED FINANCIAL DATA****(in thousands, except per share data)**

	Year ended December 31,				
	2008	2007	2006	2005	2004
<b>CONSOLIDATED STATEMENT OF OPERATIONS DATA:</b>					
Total revenues <sup>(1)</sup>	\$ 5,335,750	\$ 4,230,045	\$ 3,026,139	\$ 2,028,400	\$ 1,324,621
Purchased in-process research and development <sup>(1)</sup>	\$ 10,851	\$	\$ 2,394,051	\$	\$
Total costs and expenses <sup>(2)</sup>	\$ 2,657,209	\$ 2,065,538	\$ 3,784,892	\$ 919,333	\$ 697,234
Income (loss) from operations	\$ 2,678,541	\$ 2,164,507	\$ (758,753)	\$ 1,109,067	\$ 627,387
Gain on warrant <sup>(1)</sup>	\$	\$	\$	\$	\$ 20,576
Provision for income taxes <sup>(1)(2)</sup>	\$ 723,251	\$ 655,040	\$ 551,750	\$ 347,878	\$ 207,051
Net income (loss)	\$ 2,011,154	\$ 1,615,298	\$ (1,189,957)	\$ 813,914	\$ 449,371
Net income (loss) per share basic	\$ 2.18	\$ 1.74	\$ (1.30)	\$ 0.90	\$ 0.52
Shares used in per share calculation basic	920,693	929,133	918,212	908,677	864,001
Net income (loss) per share diluted	\$ 2.10	\$ 1.68	\$ (1.30)	\$ 0.86	\$ 0.49
Shares used in per share calculation diluted	958,825	964,356	918,212	948,569	928,492
	As of December 31,				
	2008	2007	2006	2005	2004
<b>CONSOLIDATED BALANCE SHEET DATA:</b>					
Cash, cash equivalents and marketable securities	\$ 3,239,639	\$ 2,722,422	\$ 1,389,566	\$ 2,311,033	\$ 1,250,624
Working capital	\$ 3,079,289	\$ 2,292,017	\$ 1,664,930	\$ 2,627,045	\$ 1,596,241
Total assets	\$ 7,018,574	\$ 5,834,716	\$ 4,085,981	\$ 3,766,316	\$ 2,155,963
Other long-term obligations <sup>(3)</sup>	\$ 21,462	\$ 11,604	\$ 91,847	\$ 240,650	\$ 234
Convertible senior notes <sup>(3)</sup>	\$ 1,299,854	\$ 1,300,000	\$ 1,300,000	\$	\$
Retained earnings (accumulated deficit)	\$ 382,874	\$ 249,080	\$ (891,363)	\$ 809,642	\$ (4,272)
Total stockholders' equity	\$ 4,152,487	\$ 3,459,990	\$ 1,815,718	\$ 3,027,778	\$ 1,870,872

(1)

During 2008, we completed the acquisition of all of the assets of Navitas Assets, LLC related to its cicletanine business for an aggregate purchase price of \$10.9 million which was allocated to purchased in-process research and development (IPR&D).

During 2006, we completed the acquisition of Myogen, Inc. for an aggregate purchase price of \$2.42 billion, of which \$2.06 billion was allocated to purchased IPR&D, \$180.8 million was allocated to deferred tax assets primarily related to federal net operating loss and tax credit carryforwards and certain state amortizations, \$70.9 million was allocated to goodwill and \$110.0 million was allocated to net tangible assets. In 2006, we also acquired the net assets of Corus Pharma, Inc. for \$415.5 million, of which \$335.6 million was allocated to purchased IPR&D, \$71.2 million was allocated to net



**Table of Contents**

**GILEAD SCIENCES, INC.**

**SELECTED CONSOLIDATED FINANCIAL DATA (Continued)**

deferred tax assets primarily related to federal net operating loss and tax credit carryforwards and certain state amortizations, \$7.2 million was allocated to net tangible assets and \$1.6 million was allocated to assembled workforce.

During 2005, we recognized \$80.7 million in royalty revenue relating to the resolution of our dispute with F. Hoffmann-La Roche Ltd (together with Hoffmann-La Roche Inc.). We also recorded a tax provision benefit of \$25.1 million related to our repatriation of qualified foreign earnings under the American Jobs Creation Act (AJCA).

During 2004, we recorded a gain of \$20.6 million related to our warrant to purchase capital stock of Eyetech Pharmaceuticals, Inc., as predecessor to OSI Pharmaceuticals, Inc., which completed its initial public offering.

- (2) We adopted Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment* on a modified prospective basis, beginning on January 1, 2006. See Notes 1 and 13 to our Consolidated Financial Statements on pages 88 and 119 of this Annual Report on Form 10-K.
- (3)

During 2006, we issued \$1.30 billion principal amount of convertible senior notes in a private placement.

During 2005, we entered into an uncollateralized \$300.0 million term loan agreement to facilitate a cash dividend distribution as part of the repatriation of our qualified foreign earnings under the provisions of the AJCA.

**Table of Contents****ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

The following Management's Discussion and Analysis (MD&A) is intended to help the reader understand our results of operations and financial condition. MD&A is provided as a supplement to, and should be read in conjunction with, our audited Consolidated Financial Statements and the accompanying notes to the Consolidated Financial Statements and other disclosures included in this Annual Report on Form 10-K (including the disclosures under Item 1A. Risk Factors). Our Consolidated Financial Statements have been prepared in accordance with U.S. generally accepted accounting principles and are presented in U.S. dollars.

**Management Overview**

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

*Business Highlights*

During 2008, we made significant progress in various areas of our business. We grew our product sales significantly, executed on product approvals and product launches in multiple territories, made progress on moving our product candidates forward and continued to strengthen our worldwide organization and infrastructure to support our expanded international footprint and business activities.

Our commercial achievements for the year included the continued rollout of Atripla in the European Union (EU), driving growth of Atripla and Truvada in the United States and Canada, launching Viread for hepatitis B in the EU and the United States, making gains in the PAH market with Letairis, as well as continuing the expansion of our sales and marketing infrastructure, including the establishment of new international marketing subsidiaries.

During the year, we received marketing authorization for Viread for the treatment of chronic hepatitis B in adults in all 27 member states of the European Union, Turkey, New Zealand, Australia, the United States and Canada.

Along with the marketing approvals we received in 2008, we made significant advances on the compounds and product candidates in our research and development (R&D) pipeline, including:

In the HIV area, we received positive feedback from the U.S. Food and Drug Administration (FDA) during the latter part of the year, regarding our development plans for elvitegravir, our novel integrase inhibitor for HIV which we licensed from Japan Tobacco Inc. in 2005; GS 9350, our pharmacoenhancer that is in development as a boosting agent for certain HIV medicines; and our single

**Table of Contents**

tablet fixed dose regimen of elvitegravir, GS 9350 and Truvada. The FDA agreed with our proposal to simultaneously develop these three product candidates, allowing us to eventually support three separate new drug application (NDA) filings with four Phase 3 clinical studies: one study for elvitegravir, two studies for the single tablet fixed dose regimen mentioned above, and one study for GS 9350. As a result of this proposal, we will be combining the second of our two previously planned Phase 3 studies for elvitegravir with the first Phase 3 elvitegravir study which we began dosing in the third quarter of 2008.

In hepatitis C, we completed dosing of patients in the continuation of the Phase 1b study of GS 9190, a non-nucleoside polymerase inhibitor, and began enrolling the Phase 2 study in patients infected with the hepatitis C virus. During the year, we completed our Phase 2a study of GS 9450, the caspase inhibitor we licensed from LG Life Sciences in 2007, and expect to initiate the Phase 2b study in the second quarter of 2009 to evaluate the longer term safety and efficacy of GS 9450. We are enrolling patients with nonalcoholic steatohepatitis in a Phase 2a study of GS 9450 to evaluate its safety and effect on liver enzymes and anticipate having data from this study before the end of 2009.

In the cardiovascular area, we completed enrollment of one of our two Phase 3 studies for darusentan for the treatment of resistant hypertension and we anticipate having data from this study in the second quarter of 2009. We continued to enroll patients in our second Phase 3 study for darusentan, and we anticipate completing the enrollment before the end of 2009 with data available in early 2010. We are developing cicletanine for PAH and expect to initiate a Phase 2 clinical trial examining both once daily and twice daily dosing in early 2009. We are also preparing to initiate a Phase 3 study of ambrisentan in patients with pulmonary hypertension in idiopathic pulmonary fibrosis in the second quarter of 2009.

In the respiratory area, we submitted an NDA for aztreonam for inhalation solution for the treatment of cystic fibrosis (CF) to the FDA in November 2007. In September 2008, we received a complete response letter from the FDA informing us that the FDA will not approve our NDA for aztreonam for inhalation for the treatment of CF and requesting an additional Phase 3 clinical study. In November 2008, we filed a request for a formal dispute resolution with the FDA. In February 2009, in response to our appeal, the FDA notified us that it is reiterating its position that we will need to conduct another clinical study of aztreonam for inhalation solution before we can resubmit our NDA. We have also submitted a marketing authorization application (MAA) in the EU and received notice of acceptance and priority review by Health Canada for approval in Canada. We are still awaiting responses from the respective regulatory bodies. Also in the respiratory area, we began enrolling patients with non-CF bronchiectasis in a Phase 2 study evaluating aztreonam for inhalation solution for this indication; we initiated a Phase 1 study in the fourth quarter of 2008 to evaluate the safety and tolerability of GS 9411, a novel epithelial sodium channel blocker designed to increase airway hydration for the treatment of pulmonary disease; and in the fourth quarter of 2008, we also initiated a Phase 2 study evaluating the safety and efficacy of GS 9310/11, an inhaled co-formulation of fosfomycin and tobramycin, for bacterial infections associated with CF.

*Financial Highlights*

Our operating results for the year were led by total product sales of \$5.08 billion. Antiviral product sales (Truvada, Atripla, Viread, Hepsara and Emtriva) increased 36% to \$4.67 billion in 2008 from \$3.44 billion in 2007, and were the key drivers for total product sales growth of 36% for 2008 as compared to 2007. With the continued uptake of Atripla in the United States and product launches in Europe, Atripla contributed \$1.57 billion, or 34%, to our total 2008 antiviral product sales. The growth of Atripla product sales and its increased proportion to overall product sales caused total product gross margin to decrease as expected to 78% in 2008 from 79% in 2007, due primarily to the efavirenz component of Atripla sales at zero gross margin. Truvada product sales for 2008 comprised \$2.11 billion, or 45% of our total 2008 antiviral product sales. Truvada product sales for 2008 increased 33% from 2007 primarily due to continued sales volume growth as well as a favorable foreign currency exchange impact. Foreign currency fluctuations in 2008 had a favorable impact of approximately \$148.2 million on total revenues and \$92.6 million on pre-tax income when compared to 2007.



---

**Table of Contents**

Royalty revenues that we recognized from our collaborations with corporate partners were \$218.2 million in 2008, a decrease of 53% from royalty revenues of \$468.2 million in 2007. The decrease in royalty revenues was due primarily to decreased Tamiflu sales by Roche related to pandemic planning initiatives worldwide.

Operating expenses which include R&D, selling, general and administrative (SG&A) and purchased in-process research and development (IPR&D) expenses increased \$233.2 million in 2008, or 18%, compared to 2007, reflecting the increased research and clinical study activity in our development pipeline, our expanded commercial activities worldwide, as well as the higher headcount, infrastructure and technology-related costs required to support the continued growth of our business. In 2008, we continued to be very focused on cost control and operating margins and will continue to do so in 2009. Our operating margin is impacted by the efavirenz component of a growing Atripla revenue stream and a declining trend for Tamiflu royalties.

Cash, cash equivalents and marketable securities increased by \$517.2 million during the year, driven primarily by our operating cash flows of \$2.20 billion. Our strong cash position allowed us to complete two accelerated share repurchase transactions as well as make significant common stock repurchases from the open market under the \$3.00 billion stock repurchase program authorized by our Board of Directors (Board) in October 2007, which expires in December 2010. During 2008, we repurchased a total of \$1.97 billion under our stock repurchase program, or approximately 39.2 million shares. As of December 31, 2008, the remaining authorized amount of stock repurchases that may be made under the Board authorized stock repurchase program was \$998.1 million.

In light of the volatility and developments in the financial markets, we continued to review our cash equivalents and marketable securities carefully as well as invest prudently in 2008. Safety and preservation of principal and diversification of risk, as well as liquidity of investments sufficient to meet cash flow requirements, continued to be of primary importance to our investment goals. This approach helped protect us from the significant risks in the credit markets in 2008 while allowing us to meet our operating cash flow requirements and execute on other opportunities such as our share repurchases.

*2009 Outlook*

We anticipate that the high level of productivity and financial performance experienced in 2008 will continue in 2009. Our operating objectives include the expansion of our commercial markets, both from a franchise perspective as well as leveraging the new international marketing subsidiaries that we have established in the last two years, reaching our significant R&D development timelines, continuing to strengthen our pipeline with internally developed and/or externally in-licensed or purchased opportunities and strengthening our key alliances.

From a commercial standpoint, a number of internal and external initiatives may help promote the continued growth of our franchises. In the HIV area, we should be favorably impacted by the presentation of important data sets at upcoming medical conferences, continued testing and screening initiatives, and recent changes in HIV treatment guidelines. In the area of hepatitis B, a broad platform of educational activities concentrated in Asian American communities, highlighting the need to screen, diagnose and link patients to care, will help support Viread for HBV. In the United States, since the launch of Viread for HBV in August 2008, our hepatitis sales and medical affairs teams have concentrated their efforts solely on promotion of Viread. In the cardiovascular area, we will continue to build our presence within the PAH community and to support the growth of Letairis in 2009.

We are mindful that conditions in our current macroeconomic environment could affect our ability to achieve our goals. Some of the factors that could affect our business include: the volatility in foreign currency exchange rates, government pricing pressures in both the United States and internationally, as well as changes in the financial health and/or practices of our significant business partners and customers. Although we have not yet seen significant changes, we will continue to monitor the credit and foreign currency exchange markets,

## **Table of Contents**

developments in health care reform and legislation as well as the practices of our suppliers, manufacturers, corporate partners and customers, and will adjust our business processes as needed to mitigate these risks to our business.

The successes we experienced in 2008 have helped us maintain and build a financially sound business model that we believe will allow us to continue to expand our commercial, collaborative and R&D activities, and maintain the infrastructure to ensure quality and compliance in all areas of our business. As we continue to grow our business and achieve greater operational leverage, we remain focused on profitable revenue growth and prudent expense management that we believe will enable solid execution of our operating objectives for 2009.

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

The discussion and analysis of our financial condition and results of operations is based on our Consolidated Financial Statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosures. On an ongoing basis, we evaluate our estimates, including those related to revenue recognition, allowance for doubtful accounts, prepaid royalties, clinical trial accruals, our tax provision and stock-based compensation. We base our estimates on historical experience and on various other market specific assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results, however, may differ significantly from these estimates.

We believe the following critical accounting policies reflect the more significant judgments and estimates used in the preparation of our Consolidated Financial Statements.

#### *Revenue Recognition*

##### *Product Sales*

We recognize revenues from product sales when there is persuasive evidence that an arrangement exists, delivery to the customer has occurred, the price is fixed or determinable and collectibility is reasonably assured. We record estimated reductions to revenues for government rebates such as Medicaid reimbursements, customer incentives such as cash discounts for prompt payment, distributor fees and expected returns of expired products. These estimates are deducted from gross product sales at the time such revenues are recognized. Of these reductions from gross product sales, government rebates significantly impact our reported net product sales and are based upon certain estimates that require complex and significant judgment by management.

##### *Government Rebates*

We estimate amounts payable by us to government managed Medicaid programs as well as to certain other qualifying federal, state and foreign government programs for the reimbursement of portions of the retail price of prescriptions filled that are covered by these programs. Government rebates that are invoiced directly to us are recorded in other accrued liabilities on our Consolidated Balance Sheets. For qualified programs that can purchase our products through wholesalers at a lower contractual government price, the wholesalers charge back to us the difference between their acquisition cost and the lower price, which we record as allowances against accounts receivable. Although we may pay rebates in countries outside of the United States, to date, payments made to foreign governments have not represented a significant portion of our total government rebates. For government programs in the United States, we estimate these sales allowances based on contractual terms, historical utilization rates, new information regarding changes in these programs regulations and guidelines that would impact the amount of the actual rebates, our expectations regarding future utilization rates for these programs and, for U.S. product sales, channel inventory data obtained from our major U.S. wholesalers in accordance with our inventory management agreements. During 2008, 2007 and 2006, U.S government rebates

**Table of Contents**

of \$625.0 million, \$423.3 million and \$232.5 million, respectively, representing 10%, 10% and 8% of total gross product sales, respectively, were deducted from gross product sales. Based on the current information available to us, actual government rebates claimed for these periods have varied by less than 3% from our estimates recorded in those periods. As of December 31, 2008 and 2007, we had accrued U.S. government rebates of \$173.4 million and \$114.1 million, respectively, in other accrued liabilities and an allowance of \$32.8 million and \$25.3 million, respectively, recorded against accounts receivable.

The following table summarizes the aggregate activity in our U.S. government rebates allowance and accrued liabilities accounts:

	Balance at Beginning of Year	Charged to Expense	Deducted from Accruals	Balance at End of Year
<b>Year ended December 31, 2008:</b>				
Government rebates allowances and accrued liabilities				
Activity related to 2008 sales	\$	\$ 627,935	\$ 424,298	\$ 203,637
Activity related to sales prior to 2008	139,370	(2,965)	133,769	2,636
<b>Total</b>	<b>\$ 139,370</b>	<b>\$ 624,970</b>	<b>\$ 558,067</b>	<b>\$ 206,273</b>
<b>Year ended December 31, 2007:</b>				
Government rebates allowances and accrued liabilities				
Activity related to 2007 sales	\$	\$ 426,084	\$ 298,189	\$ 127,895
Activity related to sales prior to 2007	75,663	(2,753)	61,435	11,475
<b>Total</b>	<b>\$ 75,663</b>	<b>\$ 423,331</b>	<b>\$ 359,624</b>	<b>\$ 139,370</b>

*Allowance for Doubtful Accounts*

We also maintain an allowance for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. This allowance is based on our analysis of several factors including, but not limited to, contractual payment terms, historical payment patterns of our customers and individual customer circumstances, an analysis of days sales outstanding by customer and geographic region and a review of the local economic environment and its potential impact on government funding and reimbursement practices. If the financial condition of our customers or the economic environment in which they operate were to deteriorate, resulting in an inability to make payments, additional allowances may be required. Our allowance for doubtful accounts balance as a percentage of total accounts receivable did not materially change from December 31, 2007 to December 31, 2008. We believe that the allowance for doubtful accounts is adequate to cover anticipated losses under current conditions; however, significant deterioration in any of the above factors, especially with respect to the government funding and reimbursement practices in the European market could materially change these expectations and may result in an increase to our allowance for doubtful accounts.

*Prepaid Royalties*

We capitalize royalties that we have prepaid at cost, specifically those related to the emtricitabine royalties we paid to Emory University (Emory) for the HIV indication, based on the present value of the future royalty obligation that we would expect to pay to Emory assuming certain expected future levels of our product sales incorporating emtricitabine. The present value of our future royalty obligation was derived using our weighted-average cost of capital. We review quarterly the expected future sales levels of our products and any indicators that might require a write-down in the net recoverable value of our asset or a change in the estimated life of the prepaid royalty. Some potential indicators of impairment include the launch of a significant product by a competitor, significant deviations in recognized product sales compared to forecast and product safety issues and recalls.

---

**Table of Contents**

We amortize our prepaid royalties based on an effective royalty rate that we derive from forecasted HIV product sales incorporating emtricitabine. Our product sales forecasts are prepared annually and determined using our best estimates of future activity upon considering such factors as historical and expected future patient usage or uptake of our products, the introduction of complimentary or combination therapies or products and future product launch plans. If a previously unanticipated and significant change occurs to our sales forecasts, including the introduction of a competing product by us or one of our competitors in the same HIV market as emtricitabine, we will prospectively update the royalty rate used to amortize our prepaid royalties which may increase future royalty expense. As of December 31, 2008, we had a prepaid royalty asset relating to the emtricitabine royalties we paid to Emory of \$275.0 million. Amortization expense relating to this prepaid royalty asset was \$31.8 million, \$14.3 million and \$15.1 million, for the years ended December 31, 2008, 2007 and 2006, respectively.

*Clinical Trial Accruals*

We record accruals for estimated clinical study costs. Most of our clinical studies are performed by third party contract research organizations (CROs). These costs are a significant component of R&D expenses. During 2008, 2007 and 2006, we incurred CRO costs of \$111.8 million, \$65.6 million and \$30.2 million, respectively. We accrue costs for clinical studies performed by CROs on a straight-line basis over the service periods specified in the contracts and adjust our estimates, if required, based upon our ongoing review of the level of effort and costs actually incurred by the CROs. We validate our accruals quarterly with our vendors and perform detailed reviews of the activities related to our significant contracts. Based upon the results of these validation processes, we assess the appropriateness of our accruals and make any adjustments we deem necessary to ensure that our expenses reflect the actual effort incurred by the CROs.

Generally, a significant portion of the total clinical trial costs is associated with start up activities for the trial and patient enrollment. We extensively outsource our clinical trial activities and usually perform only a small portion of the start-up activities in-house. As a result, CROs typically perform most of the total start-up activities for our trials, including document preparation, site identification, screening and preparation, pre-study visits, training and program management. Start-up costs usually occur within a few months after the contract has been executed and are milestone or event driven in nature.

The remaining clinical activities and related costs, such as patient monitoring and administration, generally occur ratably throughout the life of the individual contract or study. Most contracts are negotiated as fixed per unit prices and can vary in length between three months for a single dose Phase 1 clinical study and up to two years or more for a more complex Phase 3 clinical study. The average length of contracts in 2008, 2007 and 2006 has been at the upper end of this range in order to provide long-term safety and efficacy data to support the commercial launches of Truvada, Atripla, Viread, Hepsera, Emtriva and Letairis. All of our material CRO contracts are terminable by us upon written notice and we are generally only liable for actual effort expended by the CRO and certain non-cancelable expenses incurred at any point of termination. Amounts paid in advance relating to uncompleted services will be refunded to us if a contract is terminated. Some contracts may include additional termination payments that become due and payable if we terminate the contract. Such additional termination payments are only recorded if it becomes probable that a contract will be terminated. Through December 31, 2008, differences between actual and estimated activity levels for any particular study have not been material. However, if management does not receive complete and accurate information from our vendors or underestimates activity levels associated with a study at a given point in time, we may have to record additional and potentially significant R&D expenses in future periods.

*Tax Provision*

We estimate our income tax provision, including deferred tax assets and liabilities, based on significant management judgment. We evaluate the realization of all or a portion of our deferred tax assets on a quarterly basis. We record a valuation allowance to reduce our deferred tax assets to the amounts that are more likely than not to be realized. We consider future taxable income, ongoing tax planning strategies and our historical financial performance in assessing the need for a valuation allowance.

---

**Table of Contents**

If we expect to realize deferred tax assets for which we have previously recorded a valuation allowance, we will reduce the valuation allowance in the period in which such determination is first made. Such an adjustment was made in 2008 and 2007 when we determined that it was more likely than not that certain of our deferred tax assets would be realized, and therefore, we released the related valuation allowance. This resulted in a credit to goodwill of approximately \$8.0 million for 2008 and an income tax benefit of approximately \$15.5 million and \$1.5 million for 2008 and 2007, respectively.

Our future effective income tax rate may be affected by such factors as changes in tax laws, regulations or rates, changing interpretation of existing laws or regulations, the impact of accounting for stock-based compensation, changes in our international organization and changes in overall levels of income before tax.

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 increased 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. In addition, we reclassified \$68.4 million of unrecognized tax benefits from short-term income taxes payable and noncurrent deferred tax assets to long-term income taxes payable. As of the date of adoption, we had total federal, state and foreign unrecognized tax benefits of \$86.2 million recorded primarily in long-term income taxes payable on our Consolidated Balance Sheet, including accrued liabilities related to interest of \$4.0 million. Of the total unrecognized tax benefits, \$78.0 million, if recognized, would have reduced our effective tax rate in the period of recognition. As permitted under the provisions of FIN 48, we have continued to classify interest and penalties related to unrecognized tax benefits as part of our income tax provision in our Consolidated Statements of Operations.

At December 31, 2008 and 2007, we had total federal, state and foreign unrecognized tax benefits of \$119.3 million and \$111.7 million, respectively, including interest of \$10.1 million and \$8.3 million, respectively. Of the total unrecognized tax benefits at December 31, 2008 and 2007, \$111.1 million and \$103.5 million, respectively, if recognized, would reduce our effective tax rate in the period of recognition.

During 2008, we reached agreement with the Internal Revenue Service (IRS) on several issues related to the examinations of our federal income tax returns for 2003 and 2004. As a result, we reduced our unrecognized tax benefits by \$30.0 million.

As of December 31, 2008, we believe it is reasonably possible that our unrecognized tax benefits will decrease by approximately \$56.0 million in the next 12 months as we expect to have clarification from the IRS around certain of our uncertain tax positions. With respect to the remaining unrecognized tax benefits, we are currently unable to make a reasonable estimate as to the period of cash settlement, if any, with the respective taxing authorities.

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

Our income tax returns are audited by federal, state and foreign tax authorities. We are currently under examination by the IRS for the 2003 and 2004 tax years and by various state and foreign jurisdictions. There are

**Table of Contents**

differing interpretations of tax laws and regulations, and as a result, significant disputes may arise with these tax authorities involving issues of the timing and amount of deductions and allocations of income among various tax jurisdictions. We periodically evaluate our exposures associated with our tax filing positions.

We record liabilities related to uncertain tax positions based upon FIN 48. We do not believe any of the currently pending items will have a material adverse effect on our Consolidated Financial Statements, although an adverse resolution of several or more of these items in any period could have a material impact on the results of operations for that period. Prior to the adoption of FIN 48, we recorded liabilities related to uncertain tax positions based upon SFAS No. 5, *Accounting for Contingencies*.

*Stock-based Compensation*

In December 2004, the FASB issued SFAS No. 123 (revised 2004), *Share-Based Payment* (SFAS 123R), which requires that all share-based payments to employees and directors, including grants of stock options, be recognized in the statement of operations based on their fair values. SFAS 123R supersedes Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25) and amends SFAS No. 95, *Statement of Cash Flows*. On January 1, 2006, we adopted SFAS 123R using the modified prospective method of adoption as permitted under SFAS 123R, which requires that compensation expense be recorded for all nonvested stock options and other stock-based awards as of the beginning of the first quarter of adoption.

In connection with our adoption of SFAS 123R, we refined our valuation assumptions and the methodologies used to derive those assumptions; however, we elected to continue using the Black-Scholes option valuation model. The fair value of stock options granted prior to the adoption of SFAS 123R was calculated using the multiple option approach while the fair value of stock options granted beginning January 1, 2006 was calculated using the single option approach. Concurrent with our adoption of SFAS 123R, we determined that a blend of historical volatility along with implied volatility for traded options on our stock would be a better measure of market conditions and expected volatility. Previously, we used historical stock price volatility as it was the most reliable source of volatility data. We estimate the weighted-average expected term of our stock options based on historical cancellation and exercise data related to our stock options as well as the contractual term and vesting terms of the awards. We record stock-based compensation expense using a graded vesting expense attribution approach for nonvested stock options granted prior to the adoption of SFAS 123R consistent with the expense attribution approach used for our historical SFAS 123 disclosures and use a straight-line expense attribution approach for stock options granted after the adoption of SFAS 123R. We currently believe that the straight-line expense attribution approach better reflects the level of service to be provided by our employees over the vesting period of our awards. Stock-based compensation expense related to stock options is recognized net of estimated forfeitures. We estimate forfeitures based on our historical experience. As a result of the adoption of SFAS 123R, we will only recognize a tax benefit from stock-based compensation in additional paid-in-capital (APIC) if an incremental tax benefit is realized after all other tax attributes currently available to us have been utilized. In addition, we have elected to account for the indirect benefits of stock-based compensation on the research tax credit and the extraterritorial income deduction through the Consolidated Statements of Operations rather than through APIC.

During the years ended December 31, 2008, 2007 and 2006, we recognized stock-based compensation expense of \$153.4 million, \$184.6 million and \$133.8 million, respectively, in operating expenses, and we capitalized \$9.9 million, \$9.8 million and \$10.2 million, respectively, to inventory. As of December 31, 2008, we had unrecognized stock-based compensation of \$405.3 million related to nonvested stock options, which we expect to expense over an estimated weighted-average period of 2.9 years.

Our management has discussed the development, selection and disclosure of these critical accounting policies with the Audit Committee of our Board of Directors, and the Audit Committee has reviewed the disclosure presented above relating to these critical accounting policies.

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

We had total revenues of \$5.34 billion in 2008, \$4.23 billion in 2007 and \$3.03 billion in 2006. Included in total revenues were product sales, royalty revenues and contract and other revenues.

*Product Sales*

Product sales for the last three years consisted of the following (in thousands):

	2008	Change	2007	Change	2006
<b>Antiviral products:</b>					
Truvada	\$ 2,106,687	33%	\$ 1,589,229	33%	\$ 1,194,292
Atripla	1,572,455	74%	903,381	339%	205,729
Viread	621,187	1%	613,169	(11)%	689,356
Hepsera	341,023	13%	302,722	31%	230,531
Emtriva	31,080	(1)%	31,493	(13)%	36,393
<b>Total antiviral products</b>	<b>4,672,432</b>	<b>36%</b>	<b>3,439,994</b>	<b>46%</b>	<b>2,356,301</b>
AmBisome	289,651	10%	262,571	18%	223,031
Letairis	112,855	437%	21,020		
Other	9,858	4%	9,524	7%	8,865
<b>Total product sales</b>	<b>\$ 5,084,796</b>	<b>36%</b>	<b>\$ 3,733,109</b>	<b>44%</b>	<b>\$ 2,588,197</b>

Total product sales increased by 36% in 2008 compared to 2007, due primarily to an overall increase in our antiviral product sales including the strong growth of Atripla sales as well as the continued growth of Truvada sales. Foreign currency denominated product sales experienced a net benefit from the depreciation of the U.S. dollar of approximately \$148.2 million for 2008 compared to 2007. Total product sales increased by 44% in 2007 compared to 2006, due primarily to an increase in our total product sales volume of \$1.04 billion and a favorable foreign currency exchange impact of \$97.9 million. A significant percentage of our product sales continued to be denominated in foreign currencies. We used foreign currency forward and option contracts to hedge a percentage of our forecasted international sales, primarily those denominated in Euro. This reduced, but did not eliminate, fluctuations in sales due to changes in foreign currency exchange rates, as seen by the net benefit mentioned above.

*Antiviral Products*

Antiviral product sales in 2008 increased by 36% compared to 2007 and by 46% in 2007 compared to 2006, driven primarily by sales volume growth of Atripla and Truvada, as well as a favorable foreign currency exchange impact.

*Truvada*

Truvada sales increased by 33% in 2008 compared to 2007 driven primarily by sales volume growth in the United States and Europe, and a favorable foreign currency exchange impact. Truvada sales increased by 33% in 2007 compared to 2006 driven primarily by strong sales volume growth in Europe as well as a favorable foreign currency exchange environment in 2007. Truvada sales accounted for 45%, 46% and 51% of our total antiviral product sales for 2008, 2007 and 2006, respectively.

*Atripla*

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

Atripla sales increased by 74% in 2008 compared to 2007, driven primarily by the continued uptake of Atripla in the United States, as well as launches of the product in most European countries. Atripla sales increased 339% in 2007 compared to 2006, due primarily to the first full year of Atripla sales in



**Table of Contents**

2007 as Atripla was launched in the United States in July 2006 as well as the continued strong uptake of Atripla in the United States. We consolidate 100% of Atripla product sales because we are the primary beneficiary of our joint venture with Bristol Myers-Squibb Company (BMS) in the United States. Outside of the United States, we also recognize 100% of Atripla product sales. The efavirenz portion of our Atripla sales was approximately \$576.0 million, \$334.3 million and \$76.0 million in 2008, 2007 and 2006, respectively. Atripla sales accounted for 34%, 26% and 9% of our total antiviral product sales for 2008, 2007 and 2006, respectively. Sales of Atripla in the European Union were not significant in 2007 as Atripla was approved for sale in the European Union in December 2007.

*Other Antiviral Products*

Other antiviral product sales, which include product sales of Viread, Hepsara and Emtriva, increased by 5% in 2008 compared to 2007 driven primarily by a 13% increase in Hepsara sales which benefited from a favorable foreign currency impact as well as sales volume growth in certain European countries. Other antiviral product sales decreased by 1% in 2007 compared to 2006 driven primarily by an 11% and 13% decrease in the sales of Viread and Emtriva, respectively, due to the impact of patients switching from Viread and Emtriva containing regimens to regimens containing Truvada and/or Atripla in countries where these combination products were available, partially offset by a 31% increase in Hepsara sales due primarily to sales volume growth across all major geographical regions and a favorable foreign currency exchange environment.

*AmBisome*

Sales of AmBisome increased 10% in 2008 compared to 2007, due primarily to a favorable foreign currency exchange impact and sales volume growth in certain European markets. Sales of AmBisome increased 18% in 2007 compared to 2006, due primarily to sales volume growth in Europe as well as a favorable foreign currency exchange impact. AmBisome product sales in the United States relate solely to our sales of AmBisome to Astellas Pharma Inc. which are recorded at our manufacturing cost.

*Letairis*

Sales of Letairis for the treatment of PAH increased 437% in 2008 compared to 2007, driven primarily by sales volume growth in the United States as Letairis was launched in June 2007.

We expect total product sales to continue to grow in 2009 as we continue to expand our sales and marketing efforts.

*Royalty Revenues*

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

	2008	Change	2007	Change	2006
Royalty revenues	\$ 218,180	(53)%	\$ 468,155	12%	\$ 416,526

Our most significant source of royalty revenues for 2008, 2007 and 2006 was from sales of Tamiflu by F. Hoffmann-La Roche Ltd (together with Hoffmann-La Roche Inc., Roche).

Royalty revenues for 2008 were \$218.2 million, a decrease of 53% compared to 2007, driven primarily by the recognition of Tamiflu royalties from Roche of \$155.5 million in 2008 compared to Tamiflu royalties from Roche of \$414.5 million in 2007. The lower Tamiflu royalties for 2008 was due primarily to decreased Roche sales related to pandemic planning initiatives worldwide. Royalty revenues for 2007 were \$468.2 million, an increase of 12% compared to 2006, driven primarily by the recognition of higher Tamiflu royalties from Roche in 2007, compared to \$364.6 million recorded in 2006. The higher Tamiflu royalties for 2007 were due to the

**Table of Contents**

higher Tamiflu sales recorded by Roche, including sales related to pandemic planning initiatives worldwide during 2007. We recognize royalties on Tamiflu sales by Roche in the quarter following the quarter in which Tamiflu is sold.

*Cost of Goods Sold and Product Gross Margin*

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

	2008	Change	2007	Change	2006
Total product sales	\$ 5,084,796	36%	\$ 3,733,109	44%	\$ 2,588,197
Cost of goods sold	\$ 1,127,246	47%	\$ 768,771	77%	\$ 433,320
Product gross margin	78%		79%		83%

Our product gross margin for 2008 was 78% compared to 79% for 2007 and 83% for 2006. The decreases in product gross margin are due primarily to the growing proportion of Atripla sales, which include the efavirenz portion at zero product gross margin and the impact of changes in the product and geographic mix of our product sales.

A higher mix of Atripla product sales decreases our overall product gross margin. Although we record 100% of Atripla product sales, we only benefit from the product gross margin on the Truvada portion of Atripla sales. The efavirenz portion of Atripla sales carries a zero product gross profit and gross margin since we purchase efavirenz from BMS at BMS's net selling price of efavirenz.

We expect our product gross margin in 2009 to be lower compared to 2008, due primarily to higher expected Atripla sales.

*Research and Development Expenses*

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

	2008	Change	2007	Change	2006
Research	\$ 159,148	21%	\$ 131,019	54%	\$ 85,202
Clinical development	449,598	25%	361,091	52%	238,270
Pharmaceutical development	113,022	14%	98,916	64%	60,389
Total research and development	\$ 721,768	22%	\$ 591,026	54%	\$ 383,861

R&D expenses consist primarily of personnel costs, including salaries, benefits and stock-based compensation, clinical studies performed by CROs, materials and supplies, license 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 in 2008 increased by \$130.7 million or 22%, compared to 2007, due primarily to increased clinical study expenses of \$75.2 million primarily in the antiviral and cardiovascular areas, as well as increased compensation and benefit expenses of \$50.7 million due primarily to higher headcount.

R&D expenses in 2007 increased by \$207.2 million or 54%, compared to 2006, due primarily to increased compensation and benefit expenses of \$65.2 million due largely to higher headcount, increased clinical study

**Table of Contents**

expenses of \$58.6 million and increased contract service expenses of \$19.6 million relating to clinical, product development and research activities in our cardiovascular programs. In addition, we paid a \$20.0 million up-front license fee to LG Life Sciences, Ltd. (LGLS) and a \$13.5 million license related fee to PARI GmbH (PARI) in 2007, both of which we expensed as there were no future alternative uses for these technologies.

In general, significant collaboration payments, like those made to LGLS and PARI, will cause our R&D expenses to fluctuate period over period.

In 2009, we expect R&D expenses to increase over 2008 levels due to increased spending on our internal and collaborative R&D efforts as we anticipate progressing our product candidates into more advanced clinical studies as well as adding more clinical development programs to our pipeline.

*Selling, General and Administrative Expenses*

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

	2008	Change	2007	Change	2006
Selling, general and administrative	\$ 797,344	13%	\$ 705,741	23%	\$ 573,660

SG&A expenses for 2008 increased by \$91.6 million or 13%, compared to 2007, due primarily to increased compensation and benefit expenses of \$41.6 million due largely to higher headcount, increased marketing and promotional expenses of \$19.9 million to support our expanded commercial operations, increased consulting and support services expenses of \$13.0 million related to the growth in our business, costs of \$12.4 million associated with certain employee termination related disputes in our international operations as well as increased infrastructure and technology expenses of \$11.7 million. The increase in 2008 compared to 2007 was partially offset by a decrease in stock-based compensation expense of \$24.8 million due primarily to the higher expense associated with unvested stock options that we had assumed from Myogen, including accelerated stock-based compensation expenses related to certain Myogen employee terminations during 2007.

SG&A expenses for 2007 increased by \$132.1 million or 23%, compared to 2006. The increase was due primarily to an increase in compensation and benefits expenses of \$79.6 million due largely to higher headcount, as well as an increase in marketing and promotional expenses of \$20.0 million in the antiviral and cardiovascular areas, including those related to our launch of Letairis for the treatment of PAH.

In 2009, we expect SG&A expenses to remain essentially consistent with 2008 SG&A expenses. We believe that our 2008 organizational and geographic expansion activities will provide the appropriate infrastructure to support our business in 2009.

*Purchased In-process Research and Development Expenses*

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

**Table of Contents**

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

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

The 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 fair value of the purchased IPR&D using a present value discount rate of 14%, which is based on the estimated internal rate of return for Myogen's operations, is comparable to the estimated weighted-average cost of capital for companies with Myogen's profile, and represents the rate that market participants would use to value the purchased IPR&D. We compensated for the differing phases of development of ambrisentan and darusentan by probability-adjusting our estimation of the expected future cash flows associated with each program. We then determined at that time the present value of the expected future cash flows using the discount rate of 14%. 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 product candidates; the life of the potential commercialized products and associated risks, including the inherent difficulties and uncertainties in developing a drug compound such as obtaining FDA and other regulatory approvals; and risks related to the viability of and potential alternative treatments in any future target markets.

For the purpose of estimating the fair value of the ambrisentan program, we estimated that the program was approximately 78% complete as of the acquisition date, based on estimated time and cost to complete, as Phase 3 clinical trials had been completed. As of the acquisition date, we estimated that we would incur future R&D costs of approximately \$35 million to \$45 million from the date of acquisition through and including the year when commercialization was expected to occur. Material net cash inflows were estimated to begin in 2009 for ambrisentan, assuming the necessary regulatory approvals would be received and the product would be successfully commercialized by that date.

**Table of Contents**

For the purpose of estimating the fair value of the darusentan program, we estimated that the program was approximately 35% complete as of the acquisition date, based on estimated time and cost to complete, and remaining efforts would include the completion of Phase 3 clinical development as well as preparing for and filing an NDA with the FDA. As of the acquisition date, we estimated that we would incur future R&D costs of approximately \$130 million to \$140 million from the date of acquisition through and including the year when commercialization was expected to occur. Material net cash inflows were estimated to begin in 2012 for darusentan, assuming the necessary regulatory approvals would be received and the product would be successfully commercialized by that date.

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

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

<b>Program</b>	<b>Description</b>	<b>Status of Development</b>	<b>Estimated Acquisition Date Fair Value (in millions)</b>
Aztreonam for inhalation solution for the treatment of CF	Aztreonam formulation for inhalation to be used against Gram-negative bacteria that cause lung infections in patients with CF.	In Phase 3 clinical trials as of the acquisition date. We filed an NDA with the FDA in November 2007. In September 2008, we received a complete response letter from the FDA informing us that the FDA will not approve our NDA for aztreonam for inhalation solution for the treatment of CF in its current form and requesting we conduct an additional Phase 3 clinical study. In November 2008, we filed a request for a formal dispute resolution with the FDA. In February 2009, in response to our appeal, the FDA notified us that it is reiterating its position that we will need to conduct another clinical study of aztreonam for inhalation solution before we can resubmit our NDA. We have also submitted a marketing authorization application in the European Union and received notice of acceptance and priority review by Health Canada for approval in Canada. We are still awaiting responses from the respective regulatory bodies.	\$ 335.6

**Table of Contents**

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 fair value of the purchased IPR&D using a present value discount rate of 16%, which is based on the estimated internal rate of return for Corus's operations, is comparable to the estimated weighted-average cost of capital for companies with Corus's profile, and represents the rate that market participants would use to value the purchased IPR&D. The projected cash flows from the aztreonam for inhalation solution 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 candidate; the life of the potential commercialized product and associated risks, including the inherent difficulties and uncertainties in developing a drug compound such as obtaining 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 projects that did not have identifiable revenues and expenses associated with them.

For the purpose of estimating the fair value of the aztreonam for inhalation solution program, we estimated that the program was approximately 71% complete as of the acquisition date, based on estimated time and cost to complete, and remaining efforts would include the completion of Phase 3 clinical development as well as preparing for and filing an NDA with the FDA. As of the acquisition date, we estimated that we would incur future R&D costs of approximately \$30 million to \$35 million from the date of acquisition through and including the year when commercialization was expected to occur. Material net cash inflows were estimated to begin in 2009 for the aztreonam for inhalation solution program, assuming the necessary regulatory approvals would be received and the product would be successfully commercialized by that date.

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

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

*Interest and Other Income, Net*

We recorded interest and other income, net, of \$59.4 million, \$109.8 million and \$134.6 million in 2008, 2007 and 2006, respectively. The decrease in 2008 compared to 2007 was due primarily to increased costs related to our hedging activities of \$32.3 million, net foreign currency losses of \$15.7 million and decreased interest income of \$7.5 million due primarily to lower interest rates, partially offset by the write-downs of certain securities recorded in 2007 and which are mentioned below. The decrease in 2007 compared to 2006 was primarily attributable to the lower average cash and investment balances over 2006, as well as the write-down of \$7.0 million and \$1.8 million relating to the other-than-temporary impairment of our investments in Achillion Pharmaceuticals, Inc. and the asset-backed commercial paper of a structured investment vehicle, respectively.

---

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

Our provision for income taxes was \$723.3 million, \$655.0 million and \$551.8 million in 2008, 2007 and 2006, respectively. The 2008 effective tax rate of 26.5% differs from the U.S. federal statutory rate of 35% due primarily to tax credits, the resolution of certain tax positions with taxing authorities and certain operating earnings from non-U.S. subsidiaries that are considered indefinitely invested outside the United States, offset by state taxes.

The 2007 effective tax rate of 28.9% differs from the U.S. federal statutory rate of 35% due primarily to tax credits and certain operating earnings from non-U.S. subsidiaries that are considered indefinitely invested outside the United States, offset by state taxes.

Included in our operating income in 2006 were pre-tax charges of \$335.6 million and \$2.06 billion for the purchased IPR&D expenses associated with our Corus and Myogen acquisitions, respectively. We did not record any income tax benefit related to the purchased IPR&D expenses as such amounts are non-deductible. The 2006 effective tax rate of (86.5)% differs from the U.S. federal statutory rate of 35% due primarily to tax credits and certain operating earnings from non-U.S. subsidiaries that are considered indefinitely invested outside the United States, offset by our federal tax non-deductible purchased IPR&D expenses and state taxes.

In June 2006, the FASB issued FIN 48, which 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 increased 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. In addition, we reclassified \$68.4 million of unrecognized tax benefits from short-term income taxes payable and noncurrent deferred tax assets to long-term income taxes payable. As of the date of adoption, we had total federal, state and foreign unrecognized tax benefits of \$86.2 million recorded primarily in long-term income taxes payable on our Consolidated Balance Sheet, including accrued liabilities related to interest of \$4.0 million. Of the total unrecognized tax benefits, \$78.0 million, if recognized, would have reduced our effective tax rate in the period of recognition. As permitted under the provisions of FIN 48, we have continued to classify interest and penalties related to unrecognized tax benefits as part of our income tax provision in our Consolidated Statements of Operations.

As of December 31, 2008 and 2007, we had total federal, state and foreign unrecognized tax benefits of \$119.3 million and \$111.7 million, respectively, including interest of \$10.1 million and \$8.3 million, respectively. Of the total unrecognized tax benefits at December 31, 2008 and 2007, \$111.1 million and \$103.5 million, respectively, if recognized, would reduce our effective tax rate in the period of recognition.

During 2008, we reached agreement with the IRS on several issues related to the examinations of our federal income tax returns for 2003 and 2004. As a result, we reduced our unrecognized tax benefits by \$30.0 million.

As of December 31, 2008, we believe it is reasonably possible that our unrecognized tax benefits will decrease by approximately \$56.0 million in the next 12 months as we expect to have clarification from the IRS around certain of our uncertain tax positions. With respect to the remaining unrecognized tax benefits, we are currently unable to make a reasonable estimate as to the period of cash settlement, if any, with the respective taxing authorities.

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

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

	2008	2007	2006
<b>As of December 31:</b>			
Cash, cash equivalents and marketable securities	\$ 3,239,639	\$ 2,722,422	\$ 1,389,566
Working capital	\$ 3,079,289	\$ 2,292,017	\$ 1,664,930
<b>Year Ended December 31:</b>			
Cash provided by (used in):			
Operating activities	\$ 2,204,659	\$ 1,765,398	\$ 1,218,059
Investing activities	\$ (178,819)	\$ (1,302,467)	\$ (1,739,334)
Financing activities	\$ (1,535,844)	\$ (267,299)	\$ 649,261
<i>Cash, Cash Equivalents and Marketable Securities</i>			

Cash, cash equivalents and marketable securities totaled \$3.24 billion at December 31, 2008, an increase of \$517.2 million or 19% from December 31, 2007. This increase was primarily attributable to:

net cash provided by operations of \$2.20 billion in 2008; and

proceeds from issuances of common stock under our employee stock plans of \$246.1 million in 2008.

These increases were partially offset by our repurchases of \$1.97 billion of our common stock under our stock repurchase program during 2008.

Cash, cash equivalents and marketable securities totaled \$2.72 billion at December 31, 2007, an increase of \$1.33 billion or 96% from December 31, 2006. The increase of \$1.33 billion was primarily attributable to:

net cash provided by operations of \$1.77 billion in 2007; and

proceeds from issuances of stock under our employee stock plans of \$243.4 million in 2007.

These increases were partially offset by:

our repurchases of \$487.5 million of our common stock under our stock repurchase programs in 2007;

our repayment of all remaining amounts due under our term loan of \$99.0 million in 2007; and

capital expenditures of \$76.5 million relating to the expansion of our facilities to accommodate our growth in 2007.

*Working Capital*

Working capital at December 31, 2008 was \$3.08 billion, an increase of \$787.3 million from December 31, 2007. This increase was primarily attributable to:



an increase of \$327.9 million in inventories due primarily to the purchases of efavirenz at the estimated market value of efavirenz from BMS;

an increase of \$228.3 million in accounts receivable, net, driven primarily by increased product sales; and

a \$618.1 million increase in cash, cash equivalents and short-term marketable securities.

These increases were partially offset by a \$310.9 million increase in accounts payable due primarily to the purchases of efavirenz at the estimated market value of Sustiva from BMS.

---

**Table of Contents**

Working capital at December 31, 2007 was \$2.29 billion compared to \$1.66 billion at December 31, 2006. Significant factors that resulted in an increase in working capital in 2007 were:

\$235.1 million increase in cash, cash equivalents and short-term marketable securities due primarily to cash provided by operating activities and proceeds from issuances of our common stock under our employee stock plans, which were partially offset by our repurchases of our common stock under our stock repurchase program, the repayment of our term loan and capital spending;

\$215.1 million increase in prepaid taxes related to intercompany profits between our U.S. parent company and our joint venture; and

\$185.8 million increase in accounts receivable, net, due primarily to increased sales in 2007.

*Cash Provided by Operating Activities*

Cash provided by operating activities of \$2.20 billion in 2008 primarily related to net income of \$2.01 billion which was adjusted for non-cash items such as \$209.5 million of tax benefits from employee stock plans and \$153.4 million of stock-based compensation expense. This was partially offset by \$191.9 million of excess tax benefits from stock option exercises which we reclassified to cash provided by financing activities in accordance with SFAS 123R and \$66.9 million of cash outflow related to changes in operating assets and liabilities.

Cash provided by operating activities of \$1.77 billion in 2007 was comprised primarily of \$1.62 billion in net income which was adjusted for non-cash items such as \$184.6 million of stock-based compensation expense, \$133.1 million of deferred income taxes and \$110.7 million of tax benefits related to employee stock plans and \$76.3 million of excess tax benefits from stock option exercises. This was partially offset by a \$236.0 million net cash outflow related to changes in operating assets and liabilities.

Cash provided by operating activities of \$1.22 billion in 2006 was comprised primarily of \$1.19 billion in net loss which was adjusted for non-cash items such as our \$2.39 billion purchased IPR&D expense, stock-based compensation expense of \$133.8 million and \$127.6 million of tax benefits related to employee stock plans and \$95.3 million of excess tax benefits from stock option exercises. This was partially offset by a \$225.1 million net cash outflow related to changes in operating assets and liabilities.

*Cash Used in Investing Activities*

Cash used in investing activities in 2008 primarily related to purchases, sales and maturities of available-for-sale securities as well as capital expenditures. Cash used in investing activities in 2007 primarily related to purchases, sales and maturities of available-for-sale securities, capital expenditures and our acquisition of Nycomed Limited. Cash used in investing activities in 2006 primarily related to purchases, sales and maturities of available-for-sale securities, our acquisitions of Myogen, Raylo Chemicals Inc. (Raylo) and Corus, as well as capital expenditures.

We used \$178.8 million of cash in investing activities in 2008 compared to \$1.30 billion in 2007. The decrease was due primarily to more cash being used in financing activities during 2008 compared to 2007 to fund our stock repurchases.

We used \$1.30 billion of cash for investing activities in 2007 compared to \$1.74 billion in 2006, a decrease of \$436.9 million. The decrease was due primarily to our acquisitions of Myogen, Raylo and Corus for a total of \$2.74 billion in 2006, as well as more cash used in the purchases, sales and maturities of marketable securities activities during 2007 compared to 2006.

Capital expenditures made in 2008, 2007 and 2006 related primarily to the expansion of our manufacturing capabilities, upgrades to our facilities and spending on computer and laboratory equipment, as well as enterprise

**Table of Contents**

software, to accommodate our continued business growth. In 2007, capital expenditures also included the construction of a new building at our Foster City, California headquarters. In 2006, capital expenditures also included the purchase of two buildings that we previously leased as well as construction costs of the new building at our Foster City, California headquarters. As of December 31, 2008, we had capital expenditure commitments of \$292.7 million, which included the purchase of an office building and land, as well as three aircraft to be constructed for delivery in 2010 and 2013, both of which are discussed below. We expect to fulfill such commitments from funds generated from our operating cash flows.

In October 2008, we signed a purchase and sale agreement to purchase an office building and approximately 30 acres of land located in Foster City, California, for an aggregate purchase price of approximately \$137.5 million. We made an initial refundable deposit of \$5.0 million into escrow in October, and in January 2009, the remaining balance of \$132.5 million was paid into escrow upon closing the transaction. As part of closing, the purchase and sale agreement was amended to allow for a holdback in escrow of up to \$15.5 million of the purchase price, to be released depending on the outcome of certain requirements mutually agreed to at closing.

In August 2007, as a result of a review of the terms under our existing corporate aircraft leases and upon consideration of the various alternatives available to us upon their expiration, we entered into agreements to purchase three aircraft to be constructed for delivery in 2010 and 2013. The aggregate purchase price under the purchase agreements was \$98.6 million. As of December 31, 2008, we had made deposits totaling \$7.4 million which has been recorded in other noncurrent assets on our Consolidated Balance Sheet. Future deposits due under the terms of the purchase agreements are as follows: \$23.0 million in 2009, \$31.1 million in 2010, \$4.1 million in 2011, \$20.7 million in 2012 and \$12.4 million in 2013. We have the option to terminate the purchase agreements, subject to a maximum payment of 7.5% of the fully equipped price of the aircraft.

*Cash Provided by (Used in) Financing Activities*

Cash used in financing activities in 2008 was \$1.54 billion, driven primarily by the \$1.97 billion used to repurchase our common stock under our stock repurchase program. The cash outflows were partially offset by proceeds of \$246.1 million that we received from issuances of common stock under our employee stock plans, as well as \$191.9 million of excess tax benefits from stock option exercises. In October 2007, our Board authorized a program for the repurchase of our common stock in an aggregate amount of up to \$3.00 billion through open market and private block transactions pursuant to Rule 10b5-1 plans, privately negotiated purchases or other means. This stock repurchase program expires in December 2010. Under this stock repurchase program, in 2008 we repurchased shares in the open market and also entered into two structured accelerated share repurchase transactions with third parties which are described below.

In February 2008, we entered into an accelerated share repurchase agreement with a financial institution to repurchase \$500.0 million of our common stock on an accelerated basis. Under the terms of this accelerated share repurchase agreement with the financial institution, we paid \$500.0 million to the financial institution to settle the initial purchase transaction and received 9,373,548 shares of our common stock at a price of \$53.34 per share. In June 2008, upon maturity of the agreement and in accordance with the share delivery provisions of the agreement, we received an additional 239,612 shares of our common stock based on the average of the daily volume weighted-average prices of our common stock during a specified period less a predetermined discount per share. As a result, the final purchase price of our common stock from this accelerated share repurchase was \$52.01 per share.

In October 2008, we entered into an accelerated share repurchase transaction with a financial institution to repurchase \$750.0 million of our common stock on an accelerated basis. Under the terms of this accelerated share repurchase agreement with the financial institution, we paid \$750.0 million to the financial institution to settle the initial purchase transaction and received 14,874,519 shares of our common stock at a price of \$50.42 per share. On or before April 2009, subject to extension under certain circumstances as well as the maximum and minimum share delivery provisions of the agreement, we may receive additional shares from the financial institution depending on the average of the daily volume weighted-average prices of our common stock during a

---

## **Table of Contents**

specified period less a predetermined discount per share. After making the initial payment of \$750.0 million, we are not obligated to deliver any cash or shares to the financial institution except in certain limited circumstances in which case the method of delivery (cash or shares of our common stock) would be at our discretion.

As of December 31, 2008, the remaining authorized amount of stock repurchases that may be made under the stock repurchase program which expires in December 2010 was \$998.1 million.

Cash used in financing activities in 2007 was \$267.4 million, driven primarily by the \$487.5 million used to repurchase our common stock under our 2006 stock repurchase program, \$99.0 million used to pay off all remaining amounts due on our term loan, partially offset by the proceeds from issuance of stock under employee stock plans of \$243.3 million as well as \$76.3 million of excess tax benefits from stock option exercises.

Cash provided by financing activities in 2006 was \$649.3 million, driven primarily by the \$587.6 million of net proceeds generated from the issuance of our convertible senior notes due in 2011 (2011 Notes) and the convertible senior notes due in 2013 (2013 Notes) (collectively, the Notes) and related transactions. In addition, we received proceeds from the issuance of stock under employee stock plans of \$167.9 million, as well as \$95.3 million of excess tax benefits from employee stock option exercises. These cash inflows were partially offset by \$201.0 million in principal repayments on our term loan during 2006.

### *Other Information*

In December 2007, we, along with our wholly-owned subsidiary, Gilead Biopharmaceuticals Ireland Corporation (GBIC), entered into an amended and restated credit agreement, which superseded the existing revolving credit agreement, with a syndicate of banks to increase the credit facility to \$1.25 billion. The amended and restated credit agreement also includes a sub-facility for swing-line loans and letters of credit. Under the terms of the amended and restated credit agreement, we may borrow initially up to an aggregate of \$1.25 billion in revolving credit loans. Loans under the amended and restated credit agreement bear interest at either (i) LIBOR plus a margin ranging from 20 basis points to 32 basis points or (ii) the base rate, as defined in the amended and restated credit agreement. We can prepay any outstanding borrowings at any time in whole or in part without penalty or premium, and any outstanding interest or principal would be due and payable in December 2012. In connection with the amended and restated credit agreement, we entered into a parent guaranty agreement under which we guaranteed the obligations of GBIC under the amended and restated credit agreement. We expect to use the proceeds of any loans under the amended and restated credit agreement for working capital requirements and general corporate purposes. As of December 31, 2008, we had a \$3.7 million letter of credit outstanding under the amended and restated credit agreement.

We believe that our existing capital resources, supplemented by cash generated from our operations, will be adequate to satisfy our capital needs for the foreseeable future. Our future capital requirements will depend on many factors, including but not limited to the following:

the commercial performance of our current and future products;

the progress and scope of our R&D efforts, including preclinical studies and clinical trials;

the cost, timing and outcome of regulatory reviews;

the expansion of our sales and marketing capabilities;

administrative expenses;

the possibility of acquiring additional manufacturing capabilities or office facilities;

the possibility of acquiring other companies or new products;

the establishment of additional collaborative relationships with other companies; and

costs associated with the defense, settlement and adverse results of litigation and government investigations.

**Table of Contents**

We may in the future require additional funding, which could be in the form of proceeds from equity or debt financings. If such funding is required, we cannot assure that it will be available to us on favorable terms, if at all.

**Off Balance Sheet Arrangements**

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

**Contractual Obligations**

Our contractual obligations consist of debt obligations, operating leases as well as purchase obligations primarily in the form of capital commitments, purchase obligations for active pharmaceutical ingredients and inventory related items and clinical trials contracts. The following table summarizes our significant enforceable and legally binding obligations, future commitments and obligations related to all contracts that we are likely to continue regardless of the fact that certain of these obligations may be cancelable as of December 31, 2008 (in thousands):

Contractual Obligations	Total	Payments due by Period			
		Less than one year	1-3 years	3-5 years	More than 5 years
Convertible senior notes <sup>(1)</sup>	\$ 1,299,854	\$ 29,946	\$ 649,987	\$ 649,867	\$ 79,602
Operating lease obligations	212,938	29,946	58,308	45,082	79,602
Capital commitments <sup>(2)</sup>	292,749	203,034	56,675	33,040	
Purchase obligations <sup>(3)(4)</sup>	1,085,104	635,578	279,337	170,189	
Clinical trials <sup>(5)</sup>	326,938	157,385	130,935	31,072	7,546
Total	\$ 3,217,583	\$ 1,025,943	\$ 1,175,242	\$ 929,250	\$ 87,148

(1) At December 31, 2008, we had outstanding principal of \$1.30 billion on the Notes that we issued in April 2006.

(2) At December 31, 2008, we had firm capital project commitments of approximately \$292.7 million primarily relating to the expansion of our facilities and infrastructure as well as purchase commitments of three corporate aircraft to be constructed for delivery in 2010 and 2013.

(3) At December 31, 2008, we had firm purchase commitments related to active pharmaceutical ingredients and certain inventory related items. The amounts related to active pharmaceutical ingredients only represent minimum purchase requirements. Actual purchases are expected to significantly exceed these amounts.

(4) In addition to the above, we have committed to make potential future milestone payments to third parties as part of licensing and development programs. Payments under these agreements generally become due and payable only upon achievement of certain developmental, regulatory and/or commercial milestones. Because the achievement of these milestones is neither probable nor reasonably estimable, such contingencies have not been recorded on our Consolidated Balance Sheet and have not been included in the table above.

(5) At December 31, 2008, we had several clinical studies in various clinical trial phases. Our most significant clinical trial expenditures are to CROs. Although most of our contracts with CROs are cancelable, we generally have not cancelled such contracts. These amounts reflect commitments based on existing contracts and do not reflect any future modifications to, or termination of, existing contracts and anticipated or potential new contracts.

We had total gross unrecognized tax benefit liabilities of \$138.4 million as of December 31, 2008. We believe that it is reasonably possible that our unrecognized tax benefits will decrease by approximately \$66.0 million in the next 12 months as we expect to have clarification from the IRS around certain of our uncertain tax

## **Table of Contents**

positions. With respect to the remaining unrecognized tax benefits, we are currently unable to make a reasonable estimate as to the period of cash settlement, if any, with the respective taxing authorities. Such amounts were included in long-term income taxes payable and long-term deferred tax assets on our Consolidated Balance Sheet, and have not been included in the table above.

### **Recent Accounting Pronouncements**

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

In May 2008, the FASB issued FSP APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)* (FSP APB 14-1). FSP APB 14-1 addresses instruments commonly referred to as Instrument C from EITF 90-19, which requires the issuer to settle the principal amount in cash and the conversion spread in cash or net shares at the issuer's option. FSP APB 14-1 requires that issuers of these instruments account for their liability and equity components separately by bifurcating the conversion option from the debt instrument, classifying the conversion option in equity and then accreting the resulting discount on the debt as additional interest expense over the expected life of the debt. FSP APB 14-1 is effective for fiscal years beginning after December 15, 2008 and interim periods within those fiscal years, and requires retrospective application to all periods presented. Early application is not permitted. We expect that the adoption of FSP APB 14-1 will have a material impact on our consolidated financial position and results of operations. Based on the requirements of FSP APB 14-1, we estimate that if FSP APB 14-1 was effective for the current and comparative periods, we would have reported additional interest expense related to our Notes of approximately \$53.2 million, \$50.0 million and \$32.7 million during 2008, 2007 and 2006, respectively.

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

In December 2007, the FASB issued SFAS No. 141 (revised 2007), *Business Combinations* (SFAS 141R). SFAS 141R establishes principles and requirements for recognizing and measuring assets acquired, liabilities assumed and any noncontrolling interests in the acquiree in a business combination. SFAS 141R also provides

**Table of Contents**

guidance for recognizing and measuring goodwill acquired in a business combination; requires purchased IPR&D to be capitalized at fair value as intangible assets at the time of acquisition; requires acquisition-related expenses and restructuring costs to be recognized separately from the business combination; expands the definition of what constitutes a business; and requires the acquirer to disclose information that users may need to evaluate and understand the financial effect of the business combination. SFAS 141R is effective on a prospective basis and will impact business combination transactions for which the acquisition date occurs after December 15, 2008. Depending on the nature and magnitude of our future business combination transactions, SFAS 141R may have a material impact on our consolidated financial position and/or results of operations.

**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

*Foreign Currency Exchange Risk*

Our operations include manufacturing and sales activities in the United States, Canada and Ireland as well as sales activities in countries outside the United States, including Europe and Australia. As a result, our financial results could be significantly affected by factors such as changes in foreign currency exchange rates or weak economic conditions in the foreign markets in which we distribute our products. Our operating results are exposed to changes in foreign currency exchange rates between the U.S. dollar and various foreign currencies, the most significant of which is the Euro. When the U.S. dollar strengthens against these currencies, the relative value of sales made in the respective foreign currency decreases. Conversely, when the U.S. dollar weakens against these currencies, the relative amounts of such sales increase. Overall, we are a net receiver of foreign currencies and, therefore, benefit from a weaker U.S. dollar and are adversely affected by a stronger U.S. dollar relative to those foreign currencies in which we transact significant amounts of business.

A significant percentage of our product sales are denominated in foreign currencies. We enter into foreign currency exchange forward contracts and foreign currency exchange option contracts to partially mitigate the impact of changes in currency exchange rates on net cash flows from our foreign currency denominated sales. We also hedge certain monetary assets and liabilities denominated in foreign currencies, which reduces but does not eliminate our exposure to currency fluctuations between the date a transaction is recorded and the date that cash is collected or paid. In general, the market risks of these contracts are offset by corresponding gains and losses on the transactions being hedged.

In recent years, foreign currency exchange fluctuations have primarily had a positive impact to product sales and gross margin; however, the full impact of the foreign currency fluctuations have been moderated by our hedging program.



**Table of Contents**

The following table summarizes the notional amounts, weighted-average currency exchange rates and fair values of our open foreign currency exchange forward and option contracts at December 31, 2008. All contracts have maturities of 18 months or less. Weighted-average rates are stated in terms of the amount of U.S. dollars per foreign currency. Fair values represent estimated settlement amounts at December 31, 2008 (notional amounts and fair values in U.S. dollars in thousands):

**Foreign Currency Exchange Forward Contracts**

<b>Currency</b>	<b>Notional Amount</b>	<b>Weighted-Average Settlement Price</b>	<b>Fair Value</b>
Euro	\$ 1,867,814	1.45	\$ 42,919
British Pound	154,339	1.69	21,575
Australian Dollar	49,241	0.73	2,767
Danish Krone	23,046	5.33	152
Norwegian Krone	10,409	7.15	(9)
Swiss Franc	46,785	1.05	(82)
<b>Total</b>	<b>\$ 2,151,634</b>		<b>\$ 67,322</b>

**Foreign Currency Exchange Option Contracts**

<b>Currency</b>	<b>Notional Amount</b>	<b>Weighted-Average Strike Price</b>	<b>Fair Value</b>
British Pound	\$ 42,234	2.00	\$ 11,547
Euro	183,979	1.44	9,571
Australian Dollar	10,573	0.88	2,279
<b>Total</b>	<b>\$ 236,786</b>		<b>\$ 23,397</b>
<b>Total Foreign Exchange Forward and Option Contracts</b>	<b>\$ 2,388,420</b>		<b>\$ 90,719</b>

The total notional amount of \$2.39 billion and total fair value relating to our net asset of \$90.7 million on our open foreign currency exchange forward and option contracts at December 31, 2008 compares with a total notional amount of \$1.61 billion and a total fair value relating to our net liability of \$11.5 million on our open foreign currency exchange forward contracts at December 31, 2007.

*Interest Rate Risk*

Our portfolio of available-for-sale marketable securities and our fixed and variable rate liabilities create an exposure to interest rate risk. With respect to our investment portfolio, we adhere to an investment policy that requires us to limit amounts invested in securities based on duration, industry group and investment type and issuer, except for securities issued by the U.S. government. The goals of our investment policy, in order of priority, are as follows:

safety and preservation of principal and diversification of risk;

liquidity of investments sufficient to meet cash flow requirements; and

competitive after-tax rate of return.

**Table of Contents**

The following table summarizes the expected maturities and average interest rates of our interest generating assets and interest-bearing liabilities at December 31, 2008 (dollars in thousands):

	Years ending December 31,						Total Fair Value at December 31, 2008
	2009	2010	2011	2012	2013	Thereafter	
<b>Assets</b>							
Available-for-sale debt securities	\$ 1,265,660	\$ 479,908	\$ 584,164	\$ 68,108	\$ 50,399	\$ 101,796	\$ 2,550,035
Average interest rate	1.9%	2.1%	2.2%	3.8%	3.8%	2.3%	
<b>Liabilities</b>							
Convertible senior notes <sup>(1)</sup>	\$	\$	\$ 649,987	\$	\$ 649,867	\$	\$ 1,299,854
Average interest rate			0.5%		0.6%		

- (1) In April 2006, we issued \$650.0 million principal amount of convertible senior notes due 2011 (2011 Notes) and \$650.0 million principal amount of convertible senior notes due 2013 (2013 Notes) in a private placement pursuant to Rule 144A of the Securities Act of 1933, as amended. The 2011 Notes and 2013 Notes were issued at par and bear interest rates of 0.50% and 0.625%, respectively, and may be converted subject to certain circumstances.

*Credit Risk*

A portion of our marketable securities are held in auction rate securities. In 2008, we began observing the failed auctions for auction rate securities whose underlying assets are comprised of student loans. As of December 31, 2008, we held approximately \$122.4 million of auction rate securities within our available-for-sale long-term marketable securities whose underlying assets were comprised of student loans. Our auction rate securities comprised approximately 4% of our total cash, cash equivalents and marketable securities as of December 31, 2008. Most of our auction rate securities, including those subject to the failed auctions, are currently rated AAA, consistent with the high quality rating required by our investment policy. If auctions continue to fail for securities in which we have invested, we may be unable to liquidate some or all of our auction rate securities at par, should we need or desire to access the funds invested in those securities. However, we believe that, based on our total cash and marketable securities position, our expected operating cash flows as well as access to funds through our credit facility, we are able to hold these securities until there is a recovery in the auction market, which may be at final maturity. As a result, we do not anticipate that the current illiquidity of these auction rate securities will have a material effect on our cash requirements or working capital.

In light of the volatility and developments that we have seen in the financial markets, we continued to review our cash equivalents and marketable securities carefully as well as invest prudently in 2008. We believe that maintaining the primary goals of our investment policy, safety and preservation of principal and diversification of risk, as well as liquidity of investments sufficient to meet cash flow requirements, has protected us from much of the risks in the credit markets while allowing us to continue to meet our operating cash flow requirements as well as execute on other opportunities such as our \$500.0 million and \$750.0 million accelerated share repurchases.

Our accounts receivable balance at December 31, 2008 was \$1.02 billion, compared to \$795.1 million at December 31, 2007. The growth in our accounts receivable balances was due primarily to higher product sales of our antiviral products in the United States and Europe. Our European product sales to government-owned or supported customers in Greece, Italy, Portugal and Spain are subject to significant payment delays due to government funding and reimbursement practices. This has resulted and may continue to result in an increase in days sales outstanding due to the average length of time that we have accounts receivable outstanding. This, in turn, may increase the credit risk related to certain of our customers. Sales to customers in these countries in Europe that tend to pay relatively slowly have increased, and may continue to further increase, the average length of time that we have accounts receivable outstanding. At December 31, 2008, our accounts receivable for Greece, Italy, Portugal and Spain totaled \$543.8 million, of which \$191.0 million was more than 120 days past due. To

**Table of Contents**

date, we have not experienced significant losses with respect to the collection of our accounts receivable, and we believe that substantially all of our accounts receivable balances are collectible. We perform credit evaluations of our customers' financial condition and generally have not required collateral.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

The financial statements required by this item are set forth beginning at page 78 of this report and are incorporated herein by reference.

**ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

Not applicable.

**ITEM 9A. CONTROLS AND PROCEDURES**

(a) Evaluation of Disclosure Controls and Procedures

An evaluation as of December 31, 2008 was carried out under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, which are defined under Securities and Exchange (SEC) rules as controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Securities Exchange Act of 1934, as amended, (Exchange Act) is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective.

(b) Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Our internal control system is designed to provide reasonable assurance regarding the preparation and fair presentation of financial statements for external purposes in accordance with generally accepted accounting principles. All internal control systems, no matter how well designed, have inherent limitations and can provide only reasonable assurance that the objectives of the internal control system are met.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on our evaluation, we concluded that our internal control over financial reporting was effective as of December 31, 2008.

Our independent registered public accounting firm, Ernst & Young LLP, has audited our Consolidated Financial Statements included in this Annual Report on Form 10-K and have issued a report on the effectiveness of our internal control over financial reporting as of December 31, 2008. Their report on the audit of internal control over financial reporting appears below.

**Table of Contents**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Stockholders of Gilead Sciences, Inc.

We have audited Gilead Sciences, Inc.'s internal control over financial reporting as of December 31, 2008, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Gilead Sciences, Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Gilead Sciences, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the 2008 consolidated financial statements of Gilead Sciences, Inc. and our report dated February 25, 2009 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Palo Alto, California

February 25, 2009

**Table of Contents**

(c) 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 December 31, 2008, and has concluded that there was no change during such quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION**

Not applicable.

**PART III**

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

The information required by this Item concerning our directors and executive officers is incorporated by reference to the sections of our Definitive Proxy Statement to be filed with the SEC pursuant to Regulation 14A in connection with our 2009 Annual Meeting of Stockholders (the Proxy Statement) under the headings Nominees, Board Committees and Meetings, Executive Officers, and Section 16(a) Beneficial Ownership Reporting Compliance.

Our written Code of Ethics applies to all of our directors and employees, including our executive officers, including without limitation our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions. The Code of Ethics is available on our website at <http://www.gilead.com> in the Investors section under Corporate Governance. Changes to or waivers of the Code of Ethics will be disclosed on the same website. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding any amendment to, or waiver of, any provision of the Code of Ethics by disclosing such information on the same website.

**ITEM 11. EXECUTIVE COMPENSATION**

The information required by this Item is incorporated by reference to the sections of the Proxy Statement under the headings Executive Compensation, Compensation Committee Interlocks and Insider Participation, Compensation Committee Report, and Compensation of Non-Employee Board Members.

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

The information required by this Item is incorporated by reference to the section of the Proxy Statement under the headings Security Ownership of Certain Beneficial Owners and Management and Securities Authorized for Issuance under Equity Compensation Plans.

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

The information required by this Item is incorporated by reference to the section of the Proxy Statement under the headings Nominees and Certain Relationships and Related Party Transactions.

**ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

The information required by this Item is incorporated by reference to the section of the Proxy Statement under the heading Principal Accountant Fees and Services.



**Table of Contents****PART IV****ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

(a) The following documents are filed as part of this Annual Report on Form 10-K:

(1) Index list to Consolidated Financial Statements:

<u>Report of Independent Registered Public Accounting Firm</u>	79
Audited Consolidated Financial Statements:	
<u>Consolidated Balance Sheets</u>	80
<u>Consolidated Statements of Operations</u>	81
<u>Consolidated Statement of Stockholders' Equity</u>	82
<u>Consolidated Statements of Cash Flows</u>	83
<u>Notes to Consolidated Financial Statements</u>	84

(2) Schedule II is included on page 128 of this report. All other schedules are omitted because they are not required or the required information is included in the financial statements or notes thereto.

(3) Exhibits.

The following exhibits are filed herewith or incorporated by reference:

Exhibit Footnote	Exhibit Number	Description of Document
(1)	3.1	Restated Certificate of Incorporation of the Registrant
(2)	3.2	Certificate of Designation of the Series A Junior Participating Preferred Stock of Registrant
(3)	3.3	Certificate of Amendment to Certificate of Designation of the Series A Junior Participating Preferred Stock of Registrant
(4)	3.4	Amended and Restated Bylaws of the Registrant, as amended and restated on October 24, 2008
	4.1	Reference is made to Exhibit 3.1, Exhibit 3.2, Exhibit 3.3 and Exhibit 3.4
(5)	4.2	Amended and Restated Rights Agreement between the Registrant and ChaseMellon Shareholder Services, LLC, dated October 21, 1999
(6)	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
(7)	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
(8)	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
(8)	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

**Table of Contents**

<b>Exhibit Footnote</b>	<b>Exhibit Number</b>	<b>Description of Document</b>
(9)	10.1	Confirmation of OTC Convertible Note Hedge related to 2011 Notes, dated April 19, 2006, as amended and restated as of April 24, 2006, between Registrant and Bank of America, N.A.
(9)	10.2	Confirmation of OTC Convertible Note Hedge related to 2013 Notes, dated April 19, 2006, as amended and restated as of April 24, 2006, between Registrant and Bank of America, N.A.
(9)	10.3	Confirmation of OTC Warrant Transaction, dated April 19, 2006, as amended and restated as of April 24, 2006, between Registrant and Bank of America, N.A. for warrants expiring in 2011
(9)	10.4	Confirmation of OTC Warrant Transaction, dated April 19, 2006, as amended and restated as of April 24, 2006, between Registrant and Bank of America, N.A. for warrants expiring in 2013
(10)	10.5	Amended and Restated Credit Agreement among Registrant, Gilead Biopharmaceutics Ireland Corporation, the lenders parties thereto and Bank of America, N.A., as Administrative Agent, Swing Line Lender and L/C Issuer, dated as of December 18, 2007
(10)	10.6	Parent Guaranty Agreement, dated as of December 18, 2007, by Registrant
(11)	10.7	Master Confirmation by and between Registrant and Citibank N.A., together with the Supplemental Confirmation, dated as of October 21, 2008
*(12)	10.8	Gilead Sciences, Inc. 1991 Stock Option Plan, as amended through January 29, 2003
*(13)	10.9	Form of option agreements used under the 1991 Stock Option Plan
*(12)	10.10	Gilead Sciences, Inc. 1995 Non-Employee Directors Stock Option Plan, as amended through January 30, 2002
*(14)	10.11	Form of option agreement used under the Gilead Sciences, Inc. 1995 Non-Employee Directors Stock Option Plan
*(15)	10.12	Gilead Sciences, Inc. 2004 Equity Incentive Plan, as amended through May 8, 2008
*(16)	10.13	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants prior to February 2008)
*(17)	10.14	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants commencing in February 2008)
*(16)	10.15	Form of non-employee director stock option agreement used under 2004 Equity Incentive Plan (for grants prior to 2008)
*(17)	10.16	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for initial grants commencing in 2008)
*(17)	10.17	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for annual grants commencing in May 2008)
*(18)	10.18	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for grants in 2007)
*(19)	10.19	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for grants commencing in 2008)
*(20)	10.20	Form of restricted award agreement used under 2004 Equity Incentive Plan (for grants prior to 2008)
*(21)	10.21	Form of restricted stock unit issuance agreement used under the 2004 Equity Incentive Plan (for grants commencing in 2008)



**Table of Contents**

<b>Exhibit Footnote</b>	<b>Exhibit Number</b>	<b>Description of Document</b>
*(22)	10.22	Gilead Sciences, Inc. Employee Stock Purchase Plan, as amended through May 9, 2007
*(23)	10.23	Gilead Sciences, Inc. Deferred Compensation Plan Basic Plan Document
*(23)	10.24	Gilead Sciences, Inc. Deferred Compensation Plan Adoption Agreement
*(23)	10.25	Addendum to the Gilead Sciences, Inc. Deferred Compensation Plan
*	10.26	Gilead Sciences, Inc. 2005 Deferred Compensation Plan, as amended and restated on October 23, 2008
*	10.27	Gilead Sciences, Inc. Severance Plan, as amended on December 15, 2008
*(16)	10.28	Gilead Sciences, Inc. Corporate Bonus Plan
*(16)	10.29	Gilead Sciences, Inc. Code Section 162(m) Bonus Plan
*(24)	10.30	2009 Base Salaries for the Named Executive Officers
*(17)	10.31	Offer Letter dated October 4, 2007 between Registrant and Caroline Dorsa
*(15)	10.32	Offer Letter dated April 16, 2008 between Registrant and Robin Washington
*(13)	10.33	Form of Indemnity Agreement entered into between the Registrant and its directors and executive officers
*(13)	10.34	Form of Employee Proprietary Information and Invention Agreement entered into between Registrant and certain of its officers and key employees
*(18)	10.35	Form of Employee Proprietary Information and Invention Agreement entered into between Registrant and certain of its officers and key employees (revised in September 2006)
+(20)	10.36	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
+(17)	10.37	Commercialization Agreement by and between Gilead Sciences Limited and Bristol-Myers Squibb Company, dated December 10, 2007
+(13)	10.38	Letter Agreement between Registrant and Institute of Organic Chemistry and Biochemistry of the Academy of Sciences of the Czech Republic (IOCB) and REGA Stichting v.z.w. (REGA, and together with IOCB, IOCB/REGA), dated September 23, 1991
+(25)	10.39	Amendment Agreement between Registrant and IOCB/REGA, dated October 25, 1993
(26)	10.40	Amendment Agreement between Registrant and IOCB/REGA, dated December 27, 2000
(20)	10.41	Sixth Amendment Agreement to the License Agreement, between the IOCB and the K. U. Leuven Research and Development and Registrant, dated August 18, 2006
+(20)	10.42	Development and License Agreement among Registrant and F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc., dated September 27, 1996
+(27)	10.43	First Amendment and Supplement dated November 15, 2005 to the Development and Licensing Agreement between Registrant, F. Hoffmann-La Roche Ltd and Hoffman-La Roche Inc. dated September 27, 1996
+(28)	10.44	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
+(29)	10.45	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

**Table of Contents**

<b>Exhibit Footnote</b>	<b>Exhibit Number</b>	<b>Description of Document</b>
+(29)	10.46	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.
+(30)	10.47	License Agreement between Japan Tobacco Inc. and Registrant, dated March 22, 2005
+(31)	10.48	License Agreement between Registrant (as successor to Myogen, Inc.) and Abbott Deutschland Holding GmbH dated October 8, 2001
+(31)	10.49	License Agreement between Registrant (as successor to Myogen, Inc.) and Abbott Laboratories, dated June 30, 2003
+(32)	10.50	Master Clinical and Commercial Supply Agreement between Gilead World Markets, Limited, Registrant and Patheon Inc., dated January 1, 2003
+(29)	10.51	Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Gilead Sciences Limited and PharmaChem Technologies (Grand Bahama), Ltd., dated July 17, 2003
+(33)	10.52	Addendum to Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Gilead Sciences Limited and PharmaChem Technologies (Grand Bahama) Ltd., dated May 10, 2007
+	10.53	Addendum to Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Gilead Sciences Limited and PharmaChem Technologies (Grand Bahama) Ltd., dated December 5, 2008
+(19)	10.54	Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Registrant and Ampac Fine Chemicals LLC, dated March 6, 2008
+(27)	10.55	Restated and Amended Toll Manufacturing Agreement between Gilead Sciences Limited, Registrant and ALTANA Pharma Oranienburg GmbH, dated November 7, 2005
+(10)	10.56	Emtricitabine Manufacturing Supply Agreement between Gilead Sciences Limited and Degussa AG, dated June 6, 2006
	10.57	Purchase and Sale Agreement and Escrow Instructions between Electronics for Imaging, Inc. and Registrant, dated October 23, 2008, as amended
	21.1	Subsidiaries of Registrant
	23.1	Consent of Independent Registered Public Accounting Firm
	24.1	Power of Attorney, reference is made to the signature page
	31.1	Certification of Chief Executive Officer, as required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended
	31.2	Certification of Chief Financial Officer, as required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended
	32.1**	Certifications of Chief Executive Officer and Chief Financial Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350)

- (1) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on May 9, 2008, and incorporated herein by reference.
- (2) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on November 22, 1994, and incorporated herein by reference.
- (3) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on May 11, 2006, and incorporated herein by reference.
- (4) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on October 28, 2008, and incorporated herein by reference.
- (5) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on October 22, 1999, and incorporated herein by reference.

**Table of Contents**

- (6) Filed as an exhibit to the Registrant's Current Report on Form 8-K filed on October 31, 2003, and incorporated herein by reference.
- (7) Filed as an exhibit to Registrant's Registration Statement on Form S-8 (No. 333-135412) filed on June 28, 2006, and incorporated herein by reference.
- (8) Filed as an exhibit to the Registrant's Current Report on Form 8-K filed on April 25, 2006, and incorporated herein by reference.
- (9) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2006, and incorporated herein by reference.
- (10) Filed as an exhibit to Registrant's Current Report on Form 8-K also filed on December 19, 2007, and incorporated herein by reference.
- (11) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on October 21, 2008, and incorporated herein by reference.
- (12) Filed as an exhibit to Registrant's Registration Statement on Form S-8 (No. 333-102912) filed on January 31, 2003, and incorporated herein by reference.
- (13) Filed as an exhibit to Registrant's Registration Statement on Form S-1 (No. 33-55680), as amended, and incorporated herein by reference.
- (14) 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.
- (15) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008, and incorporated herein by reference.
- (16) Filed as an exhibit to Registrant's Current Report on Form 8-K/A filed on February 22, 2006, and incorporated herein by reference.
- (17) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2007, and incorporated herein by reference.
- (18) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2006, and incorporated herein by reference.
- (19) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2008, and incorporated herein by reference.
- (20) 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.
- (21) Filed as an exhibit to Registrant's Current Report on Form 8-K first filed on December 19, 2007, and incorporated herein by reference.
- (22) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on May 11, 2007, and incorporated herein by reference.
- (23) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2001, and incorporated herein by reference.
- (24) Information is included in Registrant's Current Report on Form 8-K filed on January 21, 2009, and incorporated herein by reference.
- (25) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended March 31, 1994, and incorporated herein by reference.
- (26) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2000, and incorporated herein by reference.
- (27) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2005, and incorporated herein by reference.
- (28) Filed as an exhibit to Triangle Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q/A filed on November 3, 1999, and incorporated herein by reference.
- (29) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2005, and incorporated herein by reference.
- (30) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2005, and incorporated herein by reference.
- (31) 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.

**Table of Contents**

- (32) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2003, and incorporated herein by reference.
- (33) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on August 7, 2007, and incorporated herein by reference.

\* Management contract or compensatory plan or arrangement.

\*\* This certification accompanies the Form 10-K 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-K), irrespective of any general incorporation language contained in such filing.

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

**Table of Contents**

**GILEAD SCIENCES, INC.**

**CONSOLIDATED FINANCIAL STATEMENTS**

**Years ended December 31, 2008, 2007, and 2006**

**CONTENTS**

<u>Report of Independent Registered Public Accounting Firm</u>	79
Audited Consolidated Financial Statements:	
<u>Consolidated Balance Sheets</u>	80
<u>Consolidated Statements of Operations</u>	81
<u>Consolidated Statement of Stockholders' Equity</u>	82
<u>Consolidated Statements of Cash Flows</u>	83
<u>Notes to Consolidated Financial Statements</u>	84

**Table of Contents**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Stockholders of Gilead Sciences, Inc.

We have audited the accompanying consolidated balance sheets of Gilead Sciences, Inc. as of December 31, 2008 and 2007, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2008. Our audits also included the financial statement schedule listed in the Index at Item 15(a). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Gilead Sciences, Inc. at December 31, 2008 and 2007, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2008, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Gilead Sciences, Inc.'s internal control over financial reporting as of December 31, 2008, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 25, 2009 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

Palo Alto, California

February 25, 2009

**Table of Contents****GILEAD SCIENCES, INC.****Consolidated Balance Sheets****(in thousands, except per share amounts)**

	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 1,459,302	\$ 968,086
Short-term marketable securities	330,760	203,892
Accounts receivable, net of allowances of \$90,694 at December 31, 2008 and \$72,217 at December 31, 2007	1,023,397	795,127
Inventories	927,868	599,966
Deferred tax assets	162,755	152,533
Prepaid taxes	198,318	216,909
Prepaid expenses	71,815	56,537
Other current assets	126,066	35,242
<b>Total current assets</b>	<b>4,300,281</b>	<b>3,028,292</b>
Property, plant and equipment, net	528,799	447,696
Noncurrent portion of prepaid royalties	257,208	290,742
Noncurrent deferred tax assets	283,214	297,359
Long-term marketable securities	1,449,577	1,550,444
Other noncurrent assets	199,495	220,183
<b>Total assets</b>	<b>\$ 7,018,574</b>	<b>\$ 5,834,716</b>
<b>Liabilities and Stockholders Equity</b>		
Current liabilities:		
Accounts payable	\$ 601,200	\$ 290,333
Accrued government rebates	176,939	115,495
Accrued compensation and employee benefits	103,840	90,553
Accrued royalties	58,855	45,640
Income taxes payable	44,757	
Other accrued liabilities	186,807	163,221
Deferred revenues	42,963	30,747
Current portion of other long-term obligations	5,631	286
<b>Total current liabilities</b>	<b>1,220,992</b>	<b>736,275</b>
Long-term deferred revenues	74,181	61,316
Convertible senior notes	1,299,854	1,300,000
Long-term income taxes payable	56,588	125,232
Other long-term obligations	21,462	11,604
Minority interest	193,010	140,299
Commitments and contingencies (Note 11)		
Stockholders equity:		
Preferred stock, par value \$0.001 per share; 5,000 shares authorized; none outstanding		
Common stock, par value \$0.001 per share; 2,800,000 shares authorized; 909,819 and 932,484 shares issued and outstanding at December 31, 2008 and 2007, respectively	910	932
Additional paid-in capital	3,727,463	3,214,341
Accumulated other comprehensive income (loss)	41,240	(4,363)
Retained earnings	382,874	249,080

Edgar Filing: GILEAD SCIENCES INC - Form 10-K

Total stockholders' equity	4,152,487	3,459,990
Total liabilities and stockholders' equity	\$ 7,018,574	\$ 5,834,716

See accompanying notes.



**Table of Contents****GILEAD SCIENCES, INC.****Consolidated Statements of Operations****(in thousands, except per share amounts)**

	Year ended December 31,		
	2008	2007	2006
<b>Revenues:</b>			
Product sales	\$ 5,084,796	\$ 3,733,109	\$ 2,588,197
Royalty revenues	218,180	468,155	416,526
Contract and other revenues	32,774	28,781	21,416
<b>Total revenues</b>	<b>5,335,750</b>	<b>4,230,045</b>	<b>3,026,139</b>
<b>Costs and expenses:</b>			
Cost of goods sold	1,127,246	768,771	433,320
Research and development	721,768	591,026	383,861
Selling, general and administrative	797,344	705,741	573,660
Purchased in-process research and development	10,851		2,394,051
<b>Total costs and expenses</b>	<b>2,657,209</b>	<b>2,065,538</b>	<b>3,784,892</b>
Income (loss) from operations	2,678,541	2,164,507	(758,753)
Interest and other income, net	59,401	109,823	134,642
Interest expense	(12,101)	(13,100)	(20,362)
Minority interest	8,564	9,108	6,266
Income (loss) before provision for income taxes	2,734,405	2,270,338	(638,207)
Provision for income taxes	723,251	655,040	551,750
<b>Net income (loss)</b>	<b>\$ 2,011,154</b>	<b>\$ 1,615,298</b>	<b>\$ (1,189,957)</b>
<b>Net income (loss) per share basic</b>	<b>\$ 2.18</b>	<b>\$ 1.74</b>	<b>\$ (1.30)</b>
Shares used in per share calculation basic	920,693	929,133	918,212
<b>Net income (loss) per share diluted</b>	<b>\$ 2.10</b>	<b>\$ 1.68</b>	<b>\$ (1.30)</b>
Shares used in per share calculation diluted	958,825	964,356	918,212

See accompanying notes.

**Table of Contents****GILEAD SCIENCES, INC.****Consolidated Statement of Stockholders Equity**

(in thousands)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Deferred Stock Compensation	Retained Earnings (Accumulated Deficit)	Total Stockholders Equity
	Shares	Amount					
Balance at December 31, 2005	919,453	\$ 920	\$ 2,205,768	\$ 11,578	\$ (130)	\$ 809,642	\$ 3,027,778
Net loss						(1,189,957)	(1,189,957)
Unrealized gain on available-for-sale securities, net of tax				8,141			8,141
Foreign currency translation adjustment				3,621			3,621
Unrealized loss on cash flow hedges, net of tax				(21,119)			(21,119)
Comprehensive loss							(1,199,314)
Issuances under employee stock purchase plan	968	1	17,503				17,504
Stock option exercises, net	18,496	18	150,369				150,387
Tax benefits from employee stock plans			127,580				127,580
Reversal of deferred stock compensation			(130)		130		
Compensatory stock transactions	62		136,199				136,199
Assumption of stock options in connection with acquisitions			95,282				95,282
Purchase of convertible note hedges			(379,145)				(379,145)
Sale of warrants			235,495				235,495
Deferred tax assets on convertible note hedges			148,894				148,894
Repurchases of common stock	(16,734)	(17)	(33,877)			(511,048)	(544,942)
Balance at December 31, 2006	922,245	922	2,703,938	2,221		(891,363)	1,815,718
Adoption of FIN 48, Accounting for Uncertainty in Income Taxes						(14,075)	(14,075)
Net income						1,615,298	1,615,298
Unrealized gain on available-for-sale securities, net of tax				3,636			3,636
Foreign currency translation adjustment				1,572			1,572
Unrealized loss on cash flow hedges, net of tax				(11,792)			(11,792)
Comprehensive income							1,608,714
Issuances under employee stock purchase plan	913	1	23,651				23,652
Stock option exercises, net	21,229	21	219,754				219,775
Tax benefits from employee stock plans			110,678				110,678
Compensatory stock transactions	31		183,162				183,162
Repurchases of common stock	(11,934)	(12)	(26,842)			(460,780)	(487,634)
Balance at December 31, 2007	932,484	932	3,214,341	(4,363)		249,080	3,459,990
Net income						2,011,154	2,011,154
Unrealized loss on available-for-sale securities, net of tax				(15,316)			(15,316)
Foreign currency translation adjustment				(21,149)			(21,149)
Unrealized gain on cash flow hedges, net of tax				82,068			82,068
Comprehensive income							2,056,757

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

Issuances under employee stock purchase plan	960	1	30,385	30,386
Stock option exercises, net	15,443	15	215,724	215,739
Tax benefits from employee stock plans			209,519	209,519
Compensatory stock transactions	191		153,269	153,269
Repurchases of common stock	(39,259)	(38)	(95,775)	(1,877,360) (1,973,173)
Balance at December 31, 2008	909,819	\$ 910	\$ 3,727,463	\$ 41,240 \$ 382,874 \$ 4,152,487

See accompanying notes.

**Table of Contents****GILEAD SCIENCES, INC.****Consolidated Statements of Cash Flows**

(in thousands)

	Year ended December 31,		
	2008	2007	2006
<b>Operating activities:</b>			
Net income (loss)	\$ 2,011,154	\$ 1,615,298	\$ (1,189,957)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Depreciation	51,722	36,888	27,620
Amortization	50,745	14,391	19,664
Purchased in-process research and development	10,851		2,394,051
Stock-based compensation expense	153,364	184,605	133,826
Excess tax benefits from stock-based compensation	(191,939)	(76,276)	(95,259)
Tax benefits from employee stock plans	209,519	110,678	127,580
Deferred income taxes	(4,081)	133,069	(9,220)
Other non-cash transactions	(19,821)	(17,190)	34,901
Changes in operating assets and liabilities:			
Accounts receivable, net	(257,161)	(138,034)	(184,370)
Inventories	(330,726)	(34,619)	(358,184)
Prepaid expenses and other assets	9,719	(252,489)	19,028
Accounts payable	312,568	(77,549)	263,965
Income taxes payable	(23,887)	76,986	(69,085)
Accrued liabilities	136,276	80,087	38,698
Deferred revenues	25,081	13,237	3,779
Minority interest	61,275	96,316	61,022
<b>Net cash provided by operating activities</b>	<b>2,204,659</b>	<b>1,765,398</b>	<b>1,218,059</b>
<b>Investing activities:</b>			
Purchases of marketable securities	(3,273,112)	(3,502,119)	(2,600,831)
Proceeds from sales of marketable securities	3,026,459	2,134,348	3,254,059
Proceeds from maturities of marketable securities	193,690	195,395	457,470
Acquisitions, net of cash acquired	(10,851)	(46,443)	(2,736,172)
Purchases of non-marketable equity securities		(5,000)	(8,652)
Capital expenditures and other	(115,005)	(78,648)	(105,208)
<b>Net cash used in investing activities</b>	<b>(178,819)</b>	<b>(1,302,467)</b>	<b>(1,739,334)</b>
<b>Financing activities:</b>			
Proceeds from issuances of common stock	246,125	243,427	167,891
Proceeds from issuance of convertible senior notes, net of issuance costs			1,276,242
Proceeds from sale of warrants			235,495
Purchases of convertible note hedges			(379,145)
Repurchases of common stock	(1,969,582)	(487,543)	(544,942)
Repayments of long-term debt and other obligations	(4,326)	(99,459)	(201,539)
Excess tax benefits from stock-based compensation	191,939	76,276	95,259
<b>Net cash provided by (used in) financing activities</b>	<b>(1,535,844)</b>	<b>(267,299)</b>	<b>649,261</b>
Effect of exchange rate changes on cash	1,220	(43,553)	(19,892)

Edgar Filing: GILEAD SCIENCES INC - Form 10-K

Net change in cash and cash equivalents	491,216	152,079	108,094
Cash and cash equivalents at beginning of period	968,086	816,007	707,913
Cash and cash equivalents at end of period	\$ 1,459,302	\$ 968,086	\$ 816,007

**Supplemental disclosure of cash flow information:**

Interest paid	\$ 7,388	\$ 7,480	\$ 15,710
Income taxes paid	\$ 495,544	\$ 565,156	\$ 489,660

**Non-cash investing and financing activities:**

Reclassification of Achillion equity investment from other noncurrent assets to marketable securities upon Achillion's initial public offering	\$	\$	\$ 12,617
--	----	----	-----------

See accompanying notes.

---

**Table of Contents**

**GILEAD SCIENCES, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Overview**

Gilead Sciences, Inc. (Gilead, we, us or our), incorporated in Delaware on June 22, 1987, is 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. To date, we have focused our efforts on bringing novel therapeutics for the treatment of life threatening diseases to market. Currently, we market Truvada (emtricitabine and tenofovir disoproxil fumarate), Atripla (efavirenz 600 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg), Viread (tenofovir disoproxil fumarate) and Emtriva (emtricitabine) for the treatment of human immunodeficiency virus (HIV) infection; Hepsera (adefovir dipivoxil) and Viread for the treatment of chronic hepatitis B infection; AmBisome (amphotericin B, liposome for injection) for the treatment of severe fungal infection; Letairis (ambrisentan) for the treatment of pulmonary arterial hypertension (PAH); Vistide (cidofovir injection) for the treatment of cytomegalovirus infection; and Flolan (epoprostenol sodium) for the treatment of pulmonary hypertension. F. Hoffman-La Roche Ltd (together with Hoffman-La Roche Inc., Roche) markets Tamiflu (oseltamivir phosphate) for the treatment of influenza, under a royalty paying collaborative agreement with us. We perform manufacturing activities for Macugen (pegaptamib sodium for injection) under our manufacturing agreement with OSI Pharmaceuticals, Inc. (OSI), who sells Macugen for the treatment of neovascular age-related macular degeneration, under a royalty paying collaborative agreement with us.

**Basis of Presentation**

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

**Significant Accounting Policies, Estimates and Judgments**

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

**Revenue Recognition**

*Product Sales*

We recognize revenue from product sales when there is persuasive evidence an arrangement exists, delivery to the customer has occurred, the price is fixed or determinable and collectibility is reasonably assured. Upon

**Table of Contents**

**GILEAD SCIENCES, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

recognition of revenue from product sales, provisions are made for government rebates, customer incentives such as cash discounts for prompt payment, certain distributor fees and estimated future returns of products that may expire, as appropriate.

*Items Deducted from Gross Product Sales*

*Government Rebates*

We estimate amounts payable by us to government managed Medicaid programs as well as to certain other qualifying federal, state and foreign government programs based on contractual terms, historical utilization rates, new information regarding changes in these programs regulations and guidelines that would impact the amount of the actual rebates, our expectations regarding future utilization rates for these programs and, for our U.S. product sales, the channel inventory data as obtained from our major U.S. wholesalers in accordance with our inventory management agreements. Government rebates that are invoiced directly to us are recorded in other accrued liabilities in our Consolidated Balance Sheets. For qualified programs that can purchase our products through wholesalers at a lower contractual government price, the wholesalers charge back to us the difference between their acquisition cost and the lower contractual government price, which we record as allowances against accounts receivable.

*Cash Discounts*

We estimate cash discounts based on contractual terms, historical utilization rates and our expectations regarding future utilization rates.

*Distributor Fees*

Under our inventory management agreements with our significant U.S. wholesalers, we pay the wholesalers a fee primarily for the compliance of certain contractually determined covenants such as the maintenance of agreed upon inventory levels. These distributor fees are based on a contractually determined fixed percentage of sales.

*Product Returns*

We do not provide our customers with a general right of product return, but permit returns if the product is damaged or defective when received by the customer, or in the case of product sold in the United States, if the product has expired. We will accept product returns in the United States that have expired for one year after their expiration dates. Our estimates for expected returns of expired products are based primarily on an ongoing analysis of historical return patterns.

*Royalty Revenues*

Royalty revenue from distributor sales of AmBisome is recognized in the month following the month in which the corresponding sales occur. Royalty revenue from sales of our other products is generally recognized when received, which is generally in the quarter following the quarter in which the corresponding sales occur.

*Contract and Other Revenues*

Revenue from non-refundable up-front license fees and milestone payments where we continue to have obligations, such as through a development collaboration or an obligation to supply product, is recognized as performance occurs and our obligations are completed. In accordance with the specific terms of Gilead's

**Table of Contents**

**GILEAD SCIENCES, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

obligations under these types of arrangements, revenue is recognized as the obligation is fulfilled or ratably over the development or manufacturing period. Revenue associated with substantive at-risk milestones is recognized based upon the achievement of the milestones as defined in the respective agreements. Advance payments received in excess of amounts earned are classified as deferred revenue on our Consolidated Balance Sheets.

Contract and other revenues include net revenue from product distribution services, which is recognized when there is persuasive evidence an arrangement exists, delivery to the customer has occurred, the price is fixed or determinable, and collectibility is reasonably assured. In accordance with Emerging Issues Task Force (EITF) Issue No. 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent*, we record product distribution services revenue, net of the supply price paid to the manufacturer/licensor, distribution fees paid to specialty pharmacies and allowances for product returns, cash discounts and government rebates, in contract and other revenues in our Consolidated Statements of Operations.

**Shipping and Handling Costs**

Shipping and handling costs incurred for inventory purchases and product shipments are recorded in cost of goods sold in our Consolidated Statements of Operations.

**Research and Development Expenses**

Major components of research and development (R&D) expenses consist of personnel costs, including salaries, benefits and stock-based compensation, clinical studies performed by contract research organizations (CROs), materials and supplies, licenses and fees and overhead allocations consisting of various support and facilities related costs. Our R&D activities are also 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 costs consist of expenses incurred in connection with product formulation and chemical analysis.

We charge R&D costs, including clinical study costs, to expense when incurred, consistent with Statement of Financial Accounting Standards (SFAS) No. 2, *Accounting for Research and Development Costs*. Clinical study costs are a significant component of R&D expenses. Most of our clinical studies are performed by third party CROs. We monitor levels of performance under each significant contract including the extent of patient enrollment and other activities through communications with our CROs, and we accrue costs for clinical studies to reflect the level of effort expended by each CRO.

All of our material CRO contracts are terminable by us upon written notice and we are generally only liable for actual effort expended by the CRO and certain non-cancelable expenses incurred at any point of termination. Amounts paid in advance related to incomplete services will be refunded if a contract is terminated. Some contracts include additional termination payments that become due and payable if we terminate the contract. Such additional termination payments are only recorded if a contract is terminated.

**Advertising Expenses**

We expense the costs of advertising, including promotional expenses, as incurred. Advertising expenses were \$96.2 million in 2008, \$81.1 million in 2007 and \$67.3 million in 2006.

**Net Income (Loss) Per Share**

Basic net income (loss) per share is calculated based on the weighted-average number of shares of our common stock outstanding during the period. Diluted net income (loss) per share is calculated based on the





**Table of Contents****GILEAD SCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

The Notes are considered to be Instrument C securities as defined by EITF Issue No. 90-19, *Convertible Bonds with Issuer Option to Settle for Cash upon Conversion* (EITF 90-19); therefore, only the conversion spread relating to the Notes is included in our diluted net income (loss) per share calculation. The potential dilutive shares of our common stock resulting from the assumed settlement of the conversion spread of the Notes are determined under the method set forth in EITF 90-19. Under such method, the settlement of the conversion spread of the Notes has a dilutive effect when the average market price of our common stock during the period exceeds \$38.75 and \$38.10 for the 2011 Notes and 2013 Notes, respectively. The average market price of our common stock during the year ended December 31, 2006 did not exceed the conversion prices of the Notes. For the years ended 2008 and 2007, where the average market price of our common stock exceeded the conversion price of either of our Notes, the dilutive effect is included in the table below.

Warrants relating to the 2011 Notes and 2013 Notes have a dilutive effect when the average market price of our common stock during the period exceeds the warrants' exercise prices of \$50.80 and \$53.90, respectively. The average market price of our common stock during the years ended December 31, 2008, 2007 and 2006 did not exceed the warrants' exercise prices relating to the Notes.

Stock options to purchase approximately 11.4 million and 15.5 million weighted-average shares of our common stock were outstanding during the years ended December 31, 2008 and 2007, respectively, but were not included in the computation of diluted net income 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. Due to our net loss for 2006, approximately 38.4 million weighted-average number of outstanding stock options and other common stock equivalents were not included in the computation of diluted net loss per share because their inclusion would have been antidilutive.

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

	Year ended December 31,		
	2008	2007	2006
<b>Numerator:</b>			
Net income (loss)	\$ 2,011,154	\$ 1,615,298	\$ (1,189,957)
<b>Denominator:</b>			
Weighted-average shares of common stock outstanding used in calculation of basic net income (loss) per share	920,693	929,133	918,212
<b>Effect of dilutive securities:</b>			
Stock options and equivalents	30,727	34,235	
Conversion spread related to 2011 convertible senior notes	3,559	351	
Conversion spread related to 2013 convertible senior notes	3,846	637	
Weighted-average shares of common stock outstanding used in calculation of diluted net income (loss) per share	958,825	964,356	918,212

---

**Table of Contents**

**GILEAD SCIENCES, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Stock-Based Compensation**

On January 1, 2006, we adopted the provisions of SFAS No. 123 (revised 2004), *Share-Based Payment* (SFAS 123R), which requires that all share-based payments to employees and directors, including grants of stock options, be recognized in the Consolidated Statements of Operations based on their fair values. SFAS 123R also requires the benefit of tax deductions in excess of recognized compensation cost to be reported in the Consolidated Statements of Cash Flows as a financing activity, rather than as an operating activity. We applied the modified prospective method, which requires that compensation expense be recorded for the vesting of all nonvested stock options and other stock-based awards at the beginning of the first quarter of adoption of SFAS 123R. In addition, we calculated our pool of excess tax benefits available within additional paid-in capital (APIC) in accordance with the provisions of SFAS 123R.

**Cash and Cash Equivalents**

We consider highly liquid investments with insignificant interest rate risk and an original maturity of three months or less on the purchase date to be cash equivalents. We may enter into overnight repurchase agreements (repos) under which we purchase securities with an obligation to resell them the following day. Securities purchased under agreements to resell are recorded at face value and reported as cash and cash equivalents. Under our investment policy, we may enter into repos with major banks and authorized dealers provided that such repos are collateralized by U.S. government securities with a fair value of at least 102% of the fair value of securities sold to us. Other eligible instruments under our investment policy that are included in cash equivalents include commercial paper, money market funds and other bank obligations.

**Marketable and Nonmarketable Securities**

We determine the appropriate classification of our marketable securities, which consist primarily of debt securities and which include auction rate securities and variable rate demand obligations, at the time of purchase and reevaluate such designation at each balance sheet date. All of our marketable securities are considered as available-for-sale and carried at estimated fair values and reported in either cash equivalents, short-term marketable securities or long-term marketable securities. Unrealized gains and losses on available-for-sale securities are excluded from net income (loss) and are reported in accumulated other comprehensive income (loss) as a separate component of stockholders' equity. Interest and other income, net, includes interest, dividends, amortization of purchase premiums and discounts, realized gains and losses on sales of securities and other-than-temporary declines in the fair value of securities, if any. The cost of securities sold is based on the specific identification method. We regularly review all of our investments for other-than-temporary declines in fair value. Our review includes the consideration of the cause of the impairment, including the creditworthiness of the security issuers, the number of securities in an unrealized loss position, as well as the severity and duration of the unrealized losses. When we determine that the decline in fair value of an investment is below our accounting basis and this decline is other-than-temporary, we reduce the carrying value of the security we hold and record a loss for the amount of such decline.

As a result of entering into collaborations, from time to time, we may hold investments in non-public companies. We record these nonmarketable securities at cost in other noncurrent assets, less any amounts for other-than-temporary impairment. We regularly review our investments for indicators of impairment. Investments in nonmarketable securities are not material for the periods presented.

**Concentrations of Risk**

We are subject to credit risk from our portfolio of cash equivalents and marketable securities. Under our investment policy, we limit amounts invested in such securities by duration, industry group, investment type and

---

**Table of Contents**

**GILEAD SCIENCES, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

issuer, except for securities issued by the U.S. government. We are not exposed to any significant concentrations of credit risk from these financial instruments. The goals of our investment policy, in order of priority, are as follows: safety and preservation of principal and diversification of risk; liquidity of investments sufficient to meet cash flow requirements; and a competitive after-tax rate of return.

We are also subject to credit risk from our accounts receivable related to our product sales. The majority of our trade accounts receivable arises from product sales in the United States and Europe. In certain countries where payments are typically slow, primarily Greece, Italy, Portugal and Spain, our aggregated accounts receivable balances are significant. In most cases, slow payment practices in these countries reflect the pace at which governmental entities reimburse our customers. This, in turn, may increase the financial risk related to certain of our customers. Sales to customers in these countries in Europe that tend to pay relatively slowly have increased, and may continue to further increase, the average length of time that we have accounts receivable outstanding. At December 31, 2008, our accounts receivable for Greece, Italy, Portugal and Spain totaled \$543.8 million, of which \$191.0 million was more than 120 days past due. At December 31, 2007, our accounts receivable for the same countries totaled \$436.4 million, of which \$147.6 million was more than 120 days past due. To date, we have not experienced significant losses with respect to the collection of our accounts receivable and believe that all of our past due accounts receivable, net of allowances, as reflected in our Consolidated Balance Sheets, are collectible. We perform credit evaluations of our customers' financial conditions and generally have not required collateral.

Certain of the raw materials that we utilize in our operations are obtained through single suppliers. Many of the raw materials that we utilize in our operations are made at only one facility. Since the suppliers of key components and raw materials must be named in a new drug application (NDA) filed with the U.S. Food and Drug Administration (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 our products or to supply any of our drug candidates for clinical trials.

**Accounts Receivable**

Trade accounts receivable are recorded net of allowances for wholesaler chargebacks for government rebates, cash discounts for prompt payment, doubtful accounts and sales returns. Estimates for wholesaler chargebacks for government rebates, cash discounts and sales returns are based on contractual terms, historical trends and our expectations regarding the utilization rates for these programs. Estimates for our allowance for doubtful accounts is determined based on existing contractual obligations, historical payment patterns of our customers and individual customer circumstances, an analysis of days sales outstanding by customer and geographic region and a review of the local economic environment and its potential impact on government funding and reimbursement practices. Historically, the amounts of uncollectible accounts receivable that have been written off have been insignificant and consistent with management's expectations.

**Inventories**

Inventories are recorded at the lower of cost or market, with cost determined on a first-in, first-out basis. We periodically review the composition of our inventories in order to identify obsolete, slow-moving or otherwise unsaleable items. If unsaleable items are observed and there are no alternate uses for the inventory, we will record a write-down to net realizable value in the period that the impairment is first recognized.

**Prepaid Royalties**

Prepaid royalties are capitalized at cost which initially is equivalent to the present value of the future royalty obligation that we would expect to pay to the licensor on expected levels of product sales incorporating the

**Table of Contents****GILEAD SCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

related technology. We review quarterly our expected future sales levels of our products and any indicators that might require a write-down of the net recoverable value or a change in the estimated life of the prepaid royalty. We amortize our prepaid royalties to cost of goods sold over the remaining life of the underlying patent based on an effective royalty rate derived from forecasted future product sales incorporating the related technology. We review our effective royalty rate at least annually and prospectively adjust the effective rate based on significant new facts or circumstances that may arise from our review.

Our prepaid royalties are primarily comprised of emtricitabine royalties we paid to Emory University (Emory) for the HIV indication when we and Royalty Pharma purchased the royalty interest owned by Emory in 2005. Under the terms of the transaction, we and Royalty Pharma paid 65% and 35%, respectively, of the total purchase price of \$525.0 million to Emory in exchange for the elimination of the emtricitabine royalties due to Emory on worldwide net sales of products containing emtricitabine. As a result of this transaction, we capitalized as prepaid royalties our 65% share of the \$525.0 million purchase price, or \$341.3 million. As of December 31, 2008, we had an unamortized prepaid royalty asset of \$275.0 million. In 2008, 2007 and 2006, \$31.8 million, \$14.3 million and \$15.1 million were amortized to cost of goods sold, respectively.

**Property, Plant and Equipment**

Property, plant and equipment is stated at cost less accumulated depreciation and amortization. Depreciation and amortization are recognized using the straight-line method. Repairs and maintenance costs are expensed as incurred. Estimated useful lives in years are as follows:

<b>Description</b>	<b>Estimated Useful Life</b>
Buildings and improvements	20-35
Laboratory and manufacturing equipment	4-10
Office and computer equipment	3-7
Leasehold improvements	Shorter of useful life or lease term

Office and computer equipment includes capitalized software. All of our capitalized software is purchased; we have no internally developed software. We had unamortized capitalized software costs of \$17.9 million and \$12.7 million on our Consolidated Balance Sheet as of December 31, 2008 and 2007, respectively. Leasehold improvements and capitalized leased equipment are amortized over the shorter of the lease term or the asset's useful life. Amortization of capitalized leased equipment is included in depreciation expense. Capitalized interest on construction in-progress is included in property, plant and equipment. Interest capitalized in 2008, 2007 and 2006 was not significant.

**Goodwill and Intangible Assets**

Goodwill represents the excess of the purchase price over the estimated fair value of net assets acquired in a business combination. In accordance with SFAS No. 142, *Goodwill and Other Intangible Assets* (SFAS 142), goodwill is not amortized, but is required to be tested annually for impairment. In accordance with SFAS 142, we test goodwill for impairment on an annual basis and in between annual tests if we become aware of any events occurring or changes in circumstances that would indicate a reduction in the fair value of the goodwill below its carrying amount.

Intangible assets with definite lives are amortized over their estimated useful lives and are reviewed for impairment when facts or circumstances suggest that the carrying value of these assets may not be recoverable.

---

**Table of Contents**

**GILEAD SCIENCES, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Impairment of Long-Lived Assets**

The carrying value of long-lived assets is reviewed on a regular basis for the existence of facts or circumstances both internally and externally that may suggest impairment. Specific potential indicators of impairment include a significant decrease in the fair value of an asset, a significant change in the extent or manner in which an asset is used or a significant physical change in an asset, a significant adverse change in legal factors or in the business climate that affects the value of an asset, an adverse action or assessment by the FDA or another regulator, an accumulation of costs significantly in excess of the amount originally expected to acquire or construct an asset and operating or cash flow losses combined with a history of operating or cash flow losses or a projection or forecast that demonstrates continuing losses associated with an income producing asset.

Should there be an indication of impairment, we will test for recoverability by comparing the estimated undiscounted future cash flows expected to result from the use of the asset or asset group and its eventual disposition to the carrying amount of the asset or asset group. In estimating these future cash flows, assets and liabilities are grouped at the lowest level for which there are identifiable cash flows that are largely independent of the cash flows generated by other such groups. If the undiscounted future cash flows are less than the carrying amount of the asset or asset group, an impairment loss, measured as the excess of the carrying value of the asset or asset group over its estimated fair value, will be recognized. The cash flow estimates used in such calculations are based on management's best estimates, using appropriate and customary assumptions and projections at the time.

**Foreign Currency Translation, Transactions and Contracts**

Adjustments resulting from translating the financial statements of our foreign subsidiaries into U.S. dollars are excluded from the determination of net income (loss) and are recorded in accumulated other comprehensive income (loss) as a separate component of stockholders' equity. Net foreign currency exchange transaction gains or losses are included in interest and other income, net, in our Consolidated Statements of Operations. Net transaction gains (losses) totaled \$(36.5) million, \$11.4 million and \$17.3 million in 2008, 2007 and 2006, respectively.

We hedge certain of our foreign currency exposures related to outstanding monetary assets and liabilities and forecasted product sales with foreign currency exchange forward contracts and foreign currency exchange option contracts. In general, the market risks of these contracts are offset by corresponding gains and losses on the transactions being hedged. Our exposure to credit risk from these contracts is a function of changes in interest and currency exchange rates and, therefore, varies over time. We limit the risk that counterparties to these contracts may be unable to perform by transacting only with major banks, all of which we monitor closely in the context of current market conditions. We also limit risk of loss by entering into contracts that provide for net settlement at maturity. Therefore, our overall risk of loss in the event of a counterparty default is limited to the amount of any unrecognized gains on outstanding contracts (i.e., those contracts that have a positive fair value) at the date of default. We do not enter into speculative foreign currency transactions. We do not hedge our net investment in any of our foreign subsidiaries.

**Fair Value of Financial Instruments**

Our financial instruments consist principally of cash and cash equivalents, marketable securities, accounts receivable, certain other noncurrent assets, foreign currency exchange forward and option contracts, accounts payable, long-term debt and other long-term obligations. Cash and cash equivalents, marketable securities (see Note 6), and foreign currency exchange contracts that hedge accounts receivable (see above and Note 2) are reported at their respective fair values on our balance sheets. Foreign currency exchange contracts that hedge forecasted sales are recorded at fair value, net of the related deferred gain or loss, resulting in a reported net balance of zero. The remaining financial instruments are reported on our Consolidated Balance Sheets at amounts that approximate current fair values.

**Table of Contents****GILEAD SCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* (SFAS 157). SFAS 157 defines fair value, establishes a framework for measuring fair value and expands the disclosure requirements regarding fair value measurements. SFAS 157 is effective for fiscal years beginning after November 15, 2007 for financial assets and liabilities as well as for non-financial assets and liabilities that are recognized or disclosed at fair value on a recurring basis in the financial statements. In accordance with FASB Staff Position (FSP) No. FAS 157-2, *Effective Date of FASB Statement No. 157*, for all other non-financial assets and liabilities, SFAS 157 will be effective for fiscal years beginning after November 15, 2008. In October 2008, the FASB issued FSP No. 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset is Not Active* (FSP 157-3), that clarifies the application of SFAS 157 in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. FSP 157-3 is applicable to the valuation of auction rate securities held by us for which there was no active market as of December 31, 2008. FSP 157-3 is effective upon issuance, including prior periods for which the financial statements have not been issued.

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

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

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

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

The adoption of SFAS 157 and FSP 157-3 had no effect on our consolidated net income for the year ended December 31, 2008.

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

	December 31, 2008	Fair Value Measurement at December 31, 2008 Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
Cash equivalents	\$ 182,347	\$ 2,500	\$ 179,847	\$
Marketable securities	1,780,337	200,502	1,477,202	102,633
Derivatives	90,870		90,870	
	\$ 2,053,554	\$ 203,002	\$ 1,747,919	\$ 102,633
<b>Liabilities:</b>				
Derivatives	\$ 150	\$	\$ 150	\$





**Table of Contents****GILEAD SCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

	<b>Year ended</b>
	<b>December 31, 2008</b>
Balance, beginning of period	\$ 7,258
Total realized losses included in interest and other income, net	(2,406)
Total unrealized losses included in other comprehensive income	(20,601)
Sales of marketable securities, net of purchases	(39,317)
Transfers into Level 3	157,699
Balance, end of period	\$ 102,633
Total losses for the year ended December 31, 2008 included in earnings attributable to the change in unrealized losses relating to assets still held at the reporting date, reported in interest and other income, net	\$ (2,731)

Marketable securities, measured at fair value using Level 3 inputs, are substantially comprised of auction rate securities within our available-for-sale investment portfolio. The underlying assets of our auction rate securities are comprised of student loans. Although auction rate securities would typically be measured using Level 2 inputs, the failure of auctions and the lack of market activity and liquidity experienced since the beginning of 2008 required that these securities be measured using Level 3 inputs. The fair value of our auction rate securities was determined using a discounted cash flow model that considered projected cash flows for the issuing trusts, underlying collateral and expected yields. Projected cash flows were estimated based on the underlying loan principal, bonds outstanding and payout formulas. The weighted-average life over which the cash flows were projected considered the collateral composition of the securities and related historical and projected prepayments. The underlying student loans have a weighted-average useful life of three to nine years. The discount rates used in our discounted cash flow model were based on market conditions for comparable or similar term asset-backed securities as well as other fixed income securities adjusted for an illiquidity discount resulting in a discount rate of 7.6%. Our auction rate securities reset every seven to 35 days with maturity dates ranging from 2023 through 2041 and have interest rates ranging from 1.3% to 2.6%. As of December 31, 2008, our auction rate securities continued to earn interest.

Our auction rate securities were measured using Level 3 inputs and were recorded in long-term marketable securities on our Consolidated Balance Sheet at December 31, 2008. Although there have been failed auctions as well as lack of market activity and liquidity during 2008, based on our assessment of the underlying collateral, the creditworthiness of the issuers of the securities and our ability and intent to hold these securities until anticipated recovery, which could be at final maturity, we had no other-than-temporary impairments on these securities as of December 31, 2008.

**Income Taxes**

Our income tax provision is computed under the liability method. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Significant estimates are required in determining our provision for income taxes. Some of these estimates are based on interpretations of existing tax laws or regulations. Various factors may have favorable or unfavorable effects on our income tax rate. These factors include, but are not limited to, interpretations of existing tax laws, changes in tax laws and rates, the accounting for stock options and other share-based payments, mergers and acquisitions, future levels of

**Table of Contents****GILEAD SCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

R&D spending, changes in accounting standards, changes in the mix of earnings in the various tax jurisdictions in which we operate, changes in overall levels of pre-tax earnings and finalization of federal, state and foreign income tax audits. The impact on our income tax provision resulting from the above mentioned factors may be significant and could have a negative impact on our consolidated net income.

On January 1, 2007, we adopted 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. As a result of our adoption of FIN 48, we increased 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. In addition, we reclassified \$68.4 million of unrecognized tax benefits from short-term income taxes payable and noncurrent deferred tax assets to long-term income taxes payable. As of the date of adoption, we had total federal, state and foreign unrecognized tax benefits of \$86.2 million recorded primarily in long-term income taxes payable on our Consolidated Balance Sheet, including accrued liabilities related to interest of \$4.0 million. Of the total unrecognized tax benefits, \$78.0 million, if recognized, would have reduced our effective tax rate in the period of recognition. As permitted under the provisions of FIN 48, we have continued to classify interest and penalties related to unrecognized tax benefits as part of our income tax provision in our Consolidated Statements of Operations.

**Recent Accounting Pronouncements**

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

In May 2008, the FASB issued FSP APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)* (FSP APB 14-1). FSP APB 14-1 addresses instruments commonly referred to as Instrument C from EITF 90-19, which requires the issuer to settle the principal amount in cash and the conversion spread in cash or net shares at the issuer's option. FSP APB 14-1 requires that issuers of these instruments account for their liability and equity components separately by bifurcating the conversion option from the debt instrument, classifying the conversion option in equity and then accreting the resulting discount on the debt as additional interest expense over the expected life of the debt. FSP APB 14-1 is effective for fiscal years beginning after December 15, 2008 and interim periods within those fiscal years, and requires retrospective application to all periods presented. Early application is not permitted. We expect that the adoption of FSP APB 14-1 will have a material impact on our consolidated financial position and

**Table of Contents****GILEAD SCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

results of operations. Based on the requirements of FSP APB 14-1, we estimate that if FSP APB 14-1 was effective for the current and comparative periods, we would have reported additional interest expense related to our convertible senior notes of approximately \$53.2 million, \$50.0 million and \$32.7 million during 2008, 2007 and 2006, respectively.

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

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

**2. DERIVATIVE FINANCIAL INSTRUMENTS**

All derivatives are recognized as either assets or liabilities measured at fair value, based on quoted market prices. We enter into foreign currency forward contracts to hedge against changes in the fair value of certain monetary assets and liabilities denominated in a non-functional currency. We record changes in the fair value of such instruments in interest and other income, net, as these derivative instruments are not designated as hedges under SFAS Nos. 133 and 138, *Accounting for Derivative Instruments and Hedging Activities*, (collectively referred to as SFAS 133).

We enter into foreign currency forward and option contracts, all with maturities of 18 months or less, to hedge a percentage of our future cash flows related to forecasted product sales in certain foreign currencies. These derivative instruments are employed to eliminate or minimize certain foreign currency exposures that can be confidently identified and quantified. Hedges related to forecasted foreign currency denominated product sales designated and documented at the inception of the respective hedge are designated as cash flow hedges under SFAS 133 and evaluated for effectiveness quarterly. At the inception of a hedging relationship and on a quarterly basis, we perform a regression analysis taking the change in cash flow of the underlying contract and regressing it against the change in cash flow of the hedge instrument (excluding time value) to assess effectiveness of the hedging relationship. We assess hedge effectiveness on a retrospective basis using a dollar offset approach

**Table of Contents****GILEAD SCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

monthly. We exclude time value from our effectiveness testing and recognize changes in the time value of the hedge in interest and other income, net. For 2008, 2007 and 2006, we excluded gains (losses) of \$(14.9) million, \$4.0 million and \$8.6 million from our assessment of hedge effectiveness, respectively. The effective component of the hedge is recorded in accumulated other comprehensive income (loss) as an unrealized gain or loss on the hedging instrument (see Note 14). When the hedged forecasted transactions occur, the hedges are de-designated and the unrealized gains and losses are reclassified into product sales at that time. Substantially all values reported in accumulated other comprehensive income at December 31, 2008 will be reclassified to product sales within 12 months. At December 31, 2008 and 2007, we had net unrealized gains (losses) of \$54.9 million and \$(27.2) million, respectively, on our open foreign currency exchange contracts. Net losses on cash flow hedges, which are recorded in product sales, decreased product sales by \$17.0 million, \$44.0 million and \$15.6 million in 2008, 2007 and 2006, respectively.

Any residual changes in fair value of the hedging instruments (including those resulting from the cancellation or de-designation of hedge contracts) or other ineffectiveness are recognized immediately in interest and other income, net. The impact of hedge ineffectiveness during 2008, 2007 and 2006 was not significant to our Consolidated Statements of Operations.

We had notional amounts on foreign currency exchange forward and option contracts outstanding of \$2.39 billion at December 31, 2008 and \$1.61 billion at December 31, 2007. We had a hedge asset (liability) fair value of \$90.7 million and \$(11.5) million at December 31, 2008 and 2007, respectively.

**3. ACQUISITIONS****Navitas Assets, LLC**

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

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

**Nycomed Limited**

On September 6, 2007, we completed the acquisition of Nycomed Limited (Nycomed), a wholly-owned Irish subsidiary of Germany-based pharmaceutical company, Nycomed GmbH. The Nycomed facility, located in Cork, Ireland, conducted manufacturing and tableting operations for Nycomed GmbH. We transferred certain of our manufacturing operations from our Dublin, Ireland area site to this facility and utilize the site primarily for solid dose tablet manufacturing of existing and future products, as well as product packaging. The Nycomed acquisition has been accounted for as a business combination in accordance with SFAS No. 141, *Business Combinations* (SFAS 141). The results of operations of Nycomed since the completion of the acquisition on September 6, 2007 have been included in our Consolidated Statements of Operations.

**Table of Contents****GILEAD SCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The aggregate purchase price for all of Nycomed's common stock was \$48.3 million, which consisted of cash paid at closing of \$46.6 million, estimated direct transaction costs of \$1.0 million and employee-related severance costs of \$0.7 million. Employee-related severance costs were capitalized as part of the purchase price, as we established a workforce reduction plan as part of the acquisition transaction in accordance with EITF Issue No. 95-3, *Recognition of Liabilities in Connection with a Purchase Business Combination* (EITF 95-3). These costs have been fully paid. The purchase price was allocated primarily to property, plant and equipment of \$48.5 million with the remaining balance allocated to net working capital at September 6, 2007.

In connection with the transfer of certain manufacturing operations from our Dublin, Ireland area site to the Cork facility, we finalized our personnel plan with respect to our Dublin employees and met the criteria for recognizing and expensing one-time termination benefits under SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*, in the fourth quarter of 2007. Estimated termination benefits totaled approximately \$3.2 million.

**Myogen, Inc.**

On November 17, 2006, we completed the acquisition of all of the outstanding shares of common stock of Myogen through a cash tender offer, under the terms of an agreement and plan of merger entered into on October 1, 2006. 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. Myogen had two product candidates in late stage clinical development: ambrisentan for the treatment of patients with PAH and darusentan for the treatment of patients with resistant hypertension. The acquisition provided us with an opportunity to expand into the cardiovascular therapeutic area.

The Myogen acquisition was accounted for as a business combination in accordance with SFAS 141. The results of operations of Myogen since November 17, 2006 have been included in our Consolidated Statement of Operations.

The aggregate purchase price for all of Myogen's common stock was \$2.42 billion, and consisted of cash paid at or prior to closing of \$2.34 billion; the fair value of vested stock options assumed of \$85.5 million; direct transaction costs of \$13.1 million, which consisted primarily of investment banking fees; employee-related severance costs of \$4.0 million; and a reduction to income taxes payable of \$23.6 million which resulted primarily from the exercise in 2007 of stock options assumed from Myogen that were vested as of the acquisition date. This reduction to income taxes payable resulted in a decrease to the aggregate purchase price. Employee-related severance costs were capitalized as part of the purchase price, as we established a workforce reduction plan as part of the acquisition transaction in accordance with EITF 95-3. These costs have been fully paid.

In accordance with the merger agreement that we entered into with Myogen, the conversion value of each stock option assumed was determined based on the exercise price of each option to purchase shares of common stock of Myogen and the average closing price of our common stock for the five consecutive trading days immediately preceding (but not including) the tender offer acceptance date of November 14, 2006, which was \$34.02 per share. The estimated fair value of stock options assumed was determined using an average price of \$34.02 per share, which approximated the price that would have resulted from averaging the closing price of our common stock from two trading days before to two trading days after the acceptance date in accordance with EITF Issue No. 99-12, *Determination of the Measurement Date for the Market Price of Acquirer Securities Issued in a Purchase Business Combination*. The fair value of stock options assumed was calculated using a Black-Scholes valuation model with the following assumptions: expected term ranging from 1.2 to 3.7 years, risk-free interest rate ranging from 4.7% to 5.0%, expected volatility ranging from 30.4% to 35.5% and no dividend yield. The fair value of the as converted Gilead stock options did not exceed the fair value of the Myogen stock options immediately prior to the exchange.

**Table of Contents****GILEAD SCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Approximately 2.8 million of the 5.8 million as converted shares subject to outstanding Myogen stock options were fully vested as of the acquisition date. The estimated fair value of vested options of \$85.5 million was included in the purchase price. The estimated fair value of the unvested options of \$59.5 million was not included in the purchase price and is being recognized as stock-based compensation expense over the remaining future vesting period of the options.

The following table summarizes the purchase price allocation at November 17, 2006 (in thousands):

Cash and cash equivalents	\$ 84,385
Short-term marketable securities	63,268
Accounts receivable, net	8,876
Prepaid expenses	7,114
Other assets	5,941
Accounts payable	(30,177)
Deferred revenue	(23,970)
Other liabilities	(5,443)
<b>Net tangible assets</b>	<b>109,994</b>
Deferred tax assets	180,827
Purchased in-process research and development	2,058,500
Goodwill	70,939
<b>Total purchase price</b>	<b>\$ 2,420,260</b>

The \$24.0 million of deferred revenue reflected the fair value of deferred revenue for which we have legal performance obligations, in accordance with EITF Issue No. 01-3, *Accounting in a Business Combination for Deferred Revenue of an Acquiree*. The \$180.8 million of deferred tax assets was primarily related to federal net operating loss and tax credit carryforwards and certain state amortizations. We concluded that, based on the standard set forth in SFAS 109, it is more likely than not that we will realize the benefits from these deferred tax assets. Because we elected to treat the Myogen acquisition as an asset acquisition for California state tax purposes, purchased IPR&D and goodwill resulting from the acquisition are deductible for California state income tax purposes, although such amounts are not deductible for federal income tax purposes.

The estimated fair value of purchased IPR&D of \$2.06 billion was determined by our management. The purchased IPR&D represents Myogen's incomplete R&D programs that had not yet reached technological feasibility and had no alternative future uses as of the acquisition date and, therefore, was expensed upon acquisition within our Consolidated Statement of Operations. A summary of these programs at the acquisition date, updated for subsequent changes in status of development, is as follows:

**Table of Contents****GILEAD SCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

The 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 fair value of the purchased IPR&D using a present value discount rate of 14%, which is based on the estimated internal rate of return for Myogen's operations, is comparable to the estimated weighted-average cost of capital for companies with Myogen's profile, and represents the rate that market participants would use to value the purchased IPR&D. We compensated for the differing phases of development of ambrisentan and darusentan by probability-adjusting our estimation of the expected future cash flows associated with each program. We then determined at that time the present value of the expected future cash flows using the discount rate of 14%. 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 product candidates; the life of the potential commercialized products and associated risks, including the inherent difficulties and uncertainties in developing a drug compound such as obtaining 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 the darusentan IPR&D program consist primarily of clinical trials, the cost, length and success of which are extremely difficult to predict, and obtaining necessary regulatory approvals. Numerous risks and uncertainties exist that could prevent completion of development, including the possibility of unfavorable results of our clinical trials and the risk of failing to obtain FDA and other regulatory body approvals. Feedback from regulatory authorities or results from clinical trials might require modifications to or delays in later stage clinical trials or additional trials to be performed. We cannot be certain that darusentan for the treatment of resistant hypertension will be approved in the United States or in countries outside of the United States or whether marketing approvals will have significant limitations on its use. Future discussions with regulatory agencies will determine the amount of data needed and timelines for review, which may differ materially from current projections. Darusentan may never be successfully commercialized. As a result, we may make a strategic decision to discontinue development of darusentan if, for example, we believe commercialization will be difficult relative to other opportunities in our pipeline. If this program cannot be completed on a timely basis or at all, then our prospects for future revenue growth may be adversely impacted. No assurance can be given that the underlying assumptions used to forecast the above cash flows or the timely

**Table of Contents****GILEAD SCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

and successful completion of this project will materialize as estimated. For these reasons, among others, actual results may vary significantly from estimated results.

The excess of the purchase price over the fair value amounts assigned to the assets acquired and liabilities assumed was \$70.9 million, which represented the goodwill amount resulting from the Myogen acquisition. We recorded the goodwill as a noncurrent asset in our Consolidated Balance Sheet as of the acquisition date. In accordance with SFAS 142, goodwill is tested for impairment on an annual basis and between annual tests if we become aware of any events occurring or changes in circumstances that would indicate a reduction in the fair value of the goodwill below its carrying amount.

**Raylo Chemicals Inc.**

On November 3, 2006, we completed the acquisition of all of the outstanding shares of common stock of Raylo Chemicals Inc. (Raylo), a wholly-owned subsidiary of Germany-based specialty chemicals company Degussa AG. Located in Edmonton, Canada, Raylo's operations encompassed custom manufacturing of active pharmaceutical ingredients and advanced intermediates for the pharmaceutical and biopharmaceutical industries. We utilize the Raylo site for process research and scale-up of our clinical development candidates, the manufacture of our active pharmaceutical ingredients for both investigational and commercial products and for our chemical development activities to improve existing commercial manufacturing processes.

The Raylo acquisition was accounted for as a business combination in accordance with SFAS 141. The results of operations of Raylo since November 3, 2006 have been included in our Consolidated Statements of Operations.

The aggregate purchase price for all of Raylo's common stock was \$133.4 million, and consisted of cash paid at or prior to closing of \$132.4 million, direct transaction costs of \$0.8 million and employee-related severance costs of \$0.1 million. Employee-related severance costs were capitalized as part of the purchase price, as we established a workforce reduction plan as part of the acquisition transaction in accordance with EITF 95-3. These costs have been fully paid.

The following table summarizes the purchase price allocation at November 3, 2006 (in thousands):

Net tangible assets	\$ 67,164
GMP qualification intangible asset	8,500
Goodwill	57,713
 Total purchase price	 \$ 133,377

The \$67.2 million of net tangible assets included \$8.2 million of cash, \$47.7 million of property, plant and equipment and \$14.0 million of other tangible assets, less assumed liabilities of \$2.7 million. The estimated fair value of \$8.5 million associated with the good manufacturing practices (GMP) qualification of Raylo's facilities was determined by our management. This value was recorded as an intangible asset to be amortized on a straight-line basis over three years, which is the estimated useful life of the asset determined by management based on the amount of time over which we would derive benefit before having to make substantial upgrades or revisions to the acquired manufacturing practices. As of December 31, 2008 and 2007, the accumulated amortization on this asset was \$6.1 million and \$3.3 million, respectively. The amortization expense recognized in 2008, 2007 and 2006 was \$2.8 million, \$2.8 million and \$0.5 million, respectively. The estimated amortization expense to be recognized in 2009 is approximately \$2.4 million. The asset is expected to be fully amortized by November 2009.

The excess of the purchase price over the fair value amounts assigned to the assets acquired and liabilities assumed was \$57.7 million, which represented the goodwill resulting from the Raylo acquisition. We recorded





**Table of Contents**

**GILEAD SCIENCES, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

the goodwill as a noncurrent asset in our Consolidated Balance Sheet as of the acquisition date. Because we elected to treat the Raylo acquisition as an asset acquisition for federal and California state tax purposes, the goodwill resulting from the acquisition was deductible for both federal and California state income tax purposes.

Prior to the acquisition, Raylo was one of our long-standing contract manufacturers. We determined, in accordance with EITF Issue No. 04-1, *Accounting for Preexisting Relationships between the Parties to a Business Combination*, that there was no settlement of the pre-existing relationship as part of the business combination and that no value needed to be assigned to the pre-existing relationship in the purchase price allocation summarized above. Raylo's assets as of the acquisition date included \$2.0 million of trade receivables from us, which were eliminated in our Consolidated Balance Sheet upon completion of the acquisition.

**Corus Pharma, Inc.**

On August 11, 2006, we completed the acquisition of Corus, a privately-held biopharmaceutical company based in Seattle, Washington. Corus was a development stage company that focused on the development and commercialization of novel drugs for respiratory and infectious diseases. Corus had one lead product candidate in late stage clinical trials and two early stage product candidates. This acquisition provided us with an opportunity to expand into the respiratory therapeutic area as well as augment our pipeline.

The Corus acquisition was accounted for as an acquisition of assets rather than as a business combination in accordance with the criteria outlined in EITF Issue No. 98-3, *Determining Whether a Nonmonetary Transaction Involves Receipt of Productive Assets or of a Business* and SFAS 141. Corus was considered a development stage company because it had not commenced its planned principal operations. Additionally, it lacked all the necessary elements of a business, including not having a completed product and, therefore, no ability to access customers. The results of operations of Corus since August 11, 2006 have been included in our Consolidated Statements of Operations.

In April 2006, we purchased \$25.0 million of Corus's Series C preferred stock, which represented approximately 15% of Corus's voting equity interests at the time. In conjunction with the purchase of Series C preferred stock, we also entered into the agreement and plan of merger under which we had an option to acquire by merger the remaining outstanding shares of Corus. In July 2006, we announced that we had agreed to exercise this option and concurrently entered into an agreement with Novartis Vaccines and Diagnostics, Inc. (Novartis) whereby Novartis agreed to dismiss its litigation against Corus for a payment to be made by us to Novartis. Since the claims made by Novartis directly implicated Corus's right to develop and commercialize its products, settling with Novartis was deemed appropriate to allow completion of the acquisition and to ensure claims by Novartis could not impede our ability to further develop and commercialize Corus's product candidates. Without a settlement, the results of the ongoing trial at the time of settlement would have been uncertain for a sustained period following the closing due to legal appeals and other potential proceedings. Upon completion of the acquisition, we included our investment in Corus's Series C preferred stock and the payment to Novartis as part of the acquisition purchase price.

The aggregate purchase price for all of the acquired shares was \$415.5 million and consisted of cash paid at or prior to closing of \$363.6 million, the fair value of vested stock options assumed of \$7.4 million, direct transaction costs of \$4.0 million and employee-related severance costs of \$4.0 million. In addition, a holdback amount of \$36.5 million was payable to Corus stockholders by us one year after the closing of the merger, except to the extent utilized to pay claims made by us within that one year. Because we had assessed that it was probable that we would pay out this holdback amount, we recorded the amount in other accrued liabilities on our Consolidated Balance Sheet as of the acquisition date. We paid the holdback amount of \$36.5 million in August 2007. Employee-related severance costs were capitalized as part of the purchase price, as we established a workforce reduction plan as part of the acquisition transaction. These costs have been fully paid.

**Table of Contents****GILEAD SCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The following table summarizes the purchase price allocation at August 11, 2006 (in thousands):

Net tangible assets	\$ 7,191
Assembled workforce	1,597
Net deferred tax assets	71,170
Purchased in-process research and development	335,551
<b>Total purchase price</b>	<b>\$ 415,509</b>

The \$7.2 million of net tangible assets included \$8.5 million of cash, \$4.3 million of marketable securities and \$4.9 million of other tangible assets, less assumed liabilities of \$10.5 million. The \$1.6 million value assigned to the assembled workforce is being amortized over three years, which is the estimated useful life of the asset. The \$71.2 million of net deferred tax assets was primarily related to federal net operating loss and tax credit carryforwards and certain state amortizations. We concluded that, based on the standard set forth in SFAS 109, it is more likely than not that we will realize the benefits from these deferred tax assets. Because we elected to treat the Corus acquisition as an asset acquisition for California state tax purposes, the purchased IPR&D resulting from the acquisition is deductible for California state income tax purposes, although such amount is not deductible for federal income tax purposes.

The estimated fair value of purchased IPR&D and assembled workforce was determined by our management. The estimated fair value of purchased IPR&D was greater than the purchase price paid; therefore, the amount that was allocated to purchased IPR&D consisted of the net amount remaining after allocating the purchase price to the net tangible assets, assembled workforce and net deferred tax assets. The purchased IPR&D represented Corus' incomplete R&D program that had not yet reached technological feasibility and had no alternative future use as of the acquisition date and, therefore, was expensed upon acquisition within our Consolidated Statement of Operations. A summary 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>
Aztreonam for inhalation solution for the treatment of cystic fibrosis (CF)	Aztreonam formulation for inhalation to be used against Gram-negative bacteria that cause lung infections in patients with CF.	In Phase 3 clinical trials as of the acquisition date. We filed an NDA with the FDA in November 2007. In September 2008, we received a complete response letter from the FDA informing us that the FDA will not approve our NDA for aztreonam for inhalation solution for the treatment of CF in its current form and requesting we conduct an additional Phase 3 clinical study. In November 2008, we filed a request for a formal dispute resolution with the FDA. In February 2009, in response to our appeal, the FDA notified us that it is reiterating its position that we will need to conduct another clinical study of aztreonam for inhalation solution before we can resubmit our NDA. We have also submitted a marketing authorization application in the European Union and received notice of acceptance and priority review by Health Canada for approval in Canada. We are still awaiting responses from the respective regulatory bodies.	\$ 335.6



**Table of Contents****GILEAD SCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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 fair value of the purchased IPR&D using a present value discount rate of 16%, which is based on the estimated internal rate of return for Corus' operations, is comparable to the estimated weighted-average cost of capital for companies with Corus' profile, and represents the rate that market participants would use to value the purchased IPR&D. The projected cash flows from the aztreonam for inhalation solution 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 candidate; the life of the potential commercialized product and associated risks, including the inherent difficulties and uncertainties in developing a drug compound such as obtaining FDA and other regulatory approvals; and risks related to the viability of and potential alternative treatments in any future target markets. Corus' two other early stage candidates were not included in the valuation of purchased IPR&D because they were early stage projects that did not have identifiable revenues and expenses associated with them.

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

**4. ACQUISITION OF REAL ESTATE**

In October 2008, we signed a purchase and sale agreement to purchase an office building and approximately 30 acres of land located in Foster City, California, for an aggregate purchase price of approximately \$137.5 million. We made an initial refundable deposit of \$5.0 million into escrow in October which was included in other current assets as of December 31, 2008, and in January 2009, the remaining balance of \$132.5 million was paid into escrow upon closing the transaction. As part of closing, the purchase and sale agreement was amended to allow for a holdback in escrow of \$15.5 million of the purchase price, to be released depending on the outcome of certain requirements mutually agreed to at closing.

**5. ASSET DISPOSAL**

In March 2006, we received local city approval to proceed with the demolition of two of our buildings in Foster City, California, and to begin construction of a new facility. We included the charge associated with the write-off of these buildings, equal to their aggregate net book value of \$7.9 million, in SG&A expenses.

**Table of Contents****GILEAD SCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****6. AVAILABLE-FOR-SALE SECURITIES**

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

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
<b>December 31, 2008</b>				
Debt securities:				
U.S. treasury securities	\$ 199,962	\$ 2,281	\$	\$ 202,243
U.S. government sponsored entity debt securities	669,721	12,105	(52)	681,774
Corporate debt securities	450,567	2,146	(1,983)	450,730
Asset-backed securities	156,306	926	(1,795)	155,437
Municipal debt securities	291,956	3,987	(126)	295,817
Other debt securities	783,901	735	(20,602)	764,034
Total debt securities	2,552,413	22,180	(24,558)	2,550,035
Equity securities	1,451		(692)	759
Total	\$ 2,553,864	\$ 22,180	\$ (25,250)	\$ 2,550,794
<b>December 31, 2007</b>				
Debt securities:				
U.S. treasury securities	\$ 104,695	\$ 1,859	\$ (48)	\$ 106,506
U.S. government sponsored entity debt securities	454,069	4,944	(4)	459,009
Corporate debt securities	297,953	1,866	(883)	298,936
Asset-backed securities	116,556	186	(701)	116,041
Municipal debt securities	539,550	5,812	(19)	545,343
Other debt securities	458,012	1		458,013
Total debt securities	1,970,835	14,668	(1,655)	1,983,848
Equity securities	5,568			5,568
Total	\$ 1,976,403	\$ 14,668	\$ (1,655)	\$ 1,989,416

As of December 31, 2008 and 2007, other debt securities consisted primarily of money market funds and auction rate securities.

The following table presents the classification of the available-for-sale securities on our Consolidated Balance Sheets (in thousands):

	December 31,	
	2008	2007
Cash and cash equivalents	\$ 770,457	\$ 235,080
Short-term marketable securities	330,760	203,892
Long-term marketable securities	1,449,577	1,550,444

Edgar Filing: GILEAD SCIENCES INC - Form 10-K

Total	\$ 2,550,794	\$ 1,989,416
-------	--------------	--------------

At December 31, 2008, our portfolio of available-for-sale debt securities comprised \$1.10 billion of securities with a contractual maturity of less than one year and \$1.14 billion of securities with a contractual

**Table of Contents****GILEAD SCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

maturity greater than one year but less than five years, \$44.0 million of securities with a contractual maturity of greater than five years but less than ten years, and \$266.9 million of securities with a contractual maturity of greater than ten years. Securities with a contractual maturity of greater than ten years comprised asset-backed securities (which included mortgage-backed securities) and auction rate securities.

The following table presents certain information related to sales of marketable securities (in thousands):

	Year ended December 31,		
	2008	2007	2006
Gross realized gains on sales	\$ 28,368	\$ 10,394	\$ 4,040
Gross realized losses on sales	\$ (18,732)	\$ (1,617)	\$ (7,618)

At December 31, 2008 and 2007, we had the following available-for-sale debt securities that were in a continuous unrealized loss position, but were not deemed to be other-than-temporarily impaired (in thousands):

	Less Than 12 Months		12 Months or Greater	
	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value
<b>December 31, 2008</b>				
U.S. government sponsored entity debt securities	\$ (51)	\$ 46,944	\$	\$
Corporate debt securities	(1,599)	138,726	(384)	9,887
Asset-backed securities	(355)	44,651	(1,441)	14,237
Municipal debt securities	(126)	24,871		
Other debt securities	(20,602)	101,798		
<b>Total</b>	<b>\$ (22,733)</b>	<b>\$ 356,990</b>	<b>\$ (1,825)</b>	<b>\$ 24,124</b>
<b>December 31, 2007</b>				
U.S. treasury securities	\$ (48)	\$ 7,960	\$	\$
U.S. government sponsored entity debt securities	(4)	26,391		
Corporate debt securities	(883)	99,184		
Asset-backed securities	(607)	44,512	(94)	4,350
Municipal debt securities	(19)	20,799		
<b>Total</b>	<b>\$ (1,561)</b>	<b>\$ 198,846</b>	<b>\$ (94)</b>	<b>\$ 4,350</b>

As of December 31, 2008, the gross unrealized losses were primarily caused by an increase in the yield-to-maturity of the underlying securities, and approximately 29% of the total number of our investments was in unrealized loss positions. In the case of auction rate securities, gross unrealized losses were caused by a higher discount rate used in the valuation of these securities as compared to the coupon rates of these securities. No significant facts or circumstances have arisen to indicate that there has been any deterioration in the creditworthiness of the issuers of these securities. Based on our review of these securities, including the assessment of the duration and severity of the related unrealized losses and our ability and intent to hold the investments until maturity, we had no other-than-temporary impairments on these securities as of December 31, 2008.

As a result of our review of investments for other-than-temporary impairment, in 2008 we recorded a total charge of \$4.4 million in interest and other income, net, to write-down the cost basis of our investments in the common stock of Achillion Pharmaceuticals, Inc. (Achillion) (See Note 9) and the asset-backed commercial paper (ABCP) of a structured investment vehicle to \$4.1 million and \$0.3 million, respectively. In



December

**Table of Contents****GILEAD SCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

2007, we recorded a total charge of \$8.8 million in interest and other income, net, to write-down the cost basis of our investments in the common stock of Achillion and the asset-backed commercial paper ABCP of a structured investment vehicle to \$7.0 million and \$1.8 million, respectively. The other-than-temporary impairments for Achillion were based on the quoted market price of Achillion common stock on September 30, 2008 and December 31, 2007, compared to our cost basis. Our assessment was based primarily on the observation that the quoted market value of the investment had been less than its carrying value over three consecutive quarters. The other-than-temporary impairment for the ABCP in 2007 was based on various market factors, including the estimated fair value of the underlying collateral of the ABCP. As of December 31, 2008, our investment in the common stock of Achillion and the ABCP were \$0.8 million and \$0.8 million, respectively, which were recorded in long-term marketable securities and short-term marketable securities, respectively, on our Consolidated Balance Sheet.

**7. INVENTORIES**

Inventories are summarized as follows (in thousands):

	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
Raw materials	\$ 505,106	\$ 244,725
Work in process	140,333	136,651
Finished goods	282,429	218,590
Total inventories	\$ 927,868	\$ 599,966

As of December 31, 2008 and 2007, the joint ventures formed by Gilead and BMS (See Note 9), which are included in our Consolidated Financial Statements, held \$607.7 million and \$296.2 million in inventory, respectively, of efavirenz active pharmaceutical ingredient, purchased from BMS at BMS's estimated net selling price of Sustiva.

We established the Gilead Access Program in 2003, pursuant to which we make Truvada and Viread available at substantially reduced prices in more than 125 countries in the developing world. Based on our regular evaluation of forecasted sales, pricing and inventory shelf life in 2006, we concluded that we would not fully recover the full carrying value associated with the inventory of Truvada and Viread for our Gilead Access Program. As a result, we recorded a charge of \$15.8 million in 2006 in cost of goods sold to write down this inventory to its estimated net realizable value.

**Table of Contents****GILEAD SCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****8. PROPERTY, PLANT AND EQUIPMENT**

Property, plant and equipment are summarized as follows (in thousands):

	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
<b>Property, plant and equipment, net:</b>		
Buildings and improvements (including leasehold improvements)	\$ 348,033	\$ 333,818
Laboratory and manufacturing equipment	158,515	129,245
Office and computer equipment	106,510	91,712
Capitalized leased equipment	15,420	15,764
Construction in progress	81,192	12,514
<b>Subtotal</b>	<b>709,670</b>	<b>583,053</b>
Less accumulated depreciation and amortization (including \$15,078 and \$15,149 relating to capitalized leased equipment for 2008 and 2007, respectively)	(247,191)	(201,340)
<b>Subtotal</b>	<b>462,479</b>	<b>381,713</b>
Land	66,320	65,983
<b>Total</b>	<b>\$ 528,799</b>	<b>\$ 447,696</b>

**9. COLLABORATIVE ARRANGEMENTS**

As a result of entering into strategic collaborations from time to time, we may hold investments in non-public companies. We review our interests in our investee companies for consolidation and/or appropriate disclosure under the provisions of FIN 46R. As of December 31, 2008, we determined that certain of our investee companies are variable interest entities; however, other than with respect to our joint ventures with BMS, we are not the primary beneficiary and therefore do not consolidate these investees.

**Bristol-Myers Squibb Company***North America*

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

We share marketing and sales efforts with BMS and both parties are obligated to provide equivalent sales force efforts for a minimum number of years. We are responsible for accounting, financial reporting, tax reporting and product distribution for the joint venture. Both parties provide their respective bulk active pharmaceutical ingredients to the joint venture at their approximate market values. In July 2006, the joint venture received approval from the FDA to sell Atripla in the United States. In September 2006, we and BMS amended the joint venture's collaboration agreement to allow the joint venture to sell Atripla into Canada. In October 2007, the joint venture received approval from Health Canada to sell Atripla in Canada. As of December 31, 2008 and 2007, the joint venture held efavirenz active pharmaceutical ingredient which it purchased from BMS.



**Table of Contents****GILEAD SCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

at BMS's estimated net selling price of Sustiva in the U.S. market. These amounts are included in inventories on our Consolidated Balance Sheets. As of December 31, 2008 and 2007, total assets held by the joint venture were \$1.07 billion and \$832.6 million, respectively, and consisted of cash and cash equivalents, accounts receivable (including intercompany receivables with Gilead), inventories and prepaid and other assets. As of December 31, 2008 and 2007, total liabilities held by the joint venture were \$548.0 million and \$454.9 million, respectively, and consisted of accounts payable (including intercompany payables with Gilead) and other accrued expenses. Although we are the primary beneficiary of the joint venture, the legal structure of the joint venture limits the recourse that its creditors will have over our general credit or assets.

*Europe*

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

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

**PARI GmbH**

As a result of the acquisition of Corus in August 2006, we assumed all rights to the February 2002 development agreement between Corus and PARI GmbH (PARI) for the development of aztreonam for inhalation solution and development of an inhalation delivery device for this drug candidate. Under the terms of the agreement, we are obligated to pay PARI for services rendered, and subject to the achievement of specific milestones, we are obligated to pay certain milestone payments to PARI. In addition, we will make royalty payments based on net sales of aztreonam for inhalation solution, if approved for commercialization. The agreement also provided us the right to reduce the royalty rate payable to PARI. In November 2007, we paid PARI \$13.5 million to reduce the royalty rate under the agreement. As aztreonam for inhalation solution has not yet been approved for commercialization, we recorded this payment in R&D expenses in our Consolidated Statement of Operations. In April 2008, pursuant to the February 2002 development agreement, we entered into a commercialization agreement with PARI which provides for the supply and manufacture of an inhalation delivery device and accessories for use with aztreonam for inhalation solution. Under the terms of this agreement, we are obligated to pay royalties on future net sales of these products pursuant to the 2002 development agreement.

**Table of Contents****GILEAD SCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****LG Life Sciences, Ltd.**

In November 2007, we entered into a license agreement with LG Life Sciences, Ltd. (LGLS) to develop and commercialize certain caspase inhibitors for the treatment of fibrotic diseases. The agreement granted us commercialization rights to LGLS's caspase inhibitors, including LB84451 (GS 9450). Under the terms of the agreement, our license is worldwide, with the exception of Korea, China and India where LGLS has retained rights. LGLS also retains the right to develop and commercialize caspase inhibitors for ophthalmic and topical uses worldwide. In accordance with the terms of the agreement, we paid a \$20.0 million up-front license fee that was recorded in R&D expenses in our Consolidated Statement of Operations as there was no future alternative use for this technology. The agreement also obligated us to fund a collaborative research program for two years to identify other potential caspase inhibitor drug candidates. In addition, we are obligated to make additional milestone payments of up to \$182.0 million upon the achievement of certain development, regulatory and commercial objectives. We are also obligated to pay royalties on future net sales of products that are developed and approved in relation to this collaboration.

**Parion Sciences, Inc.**

In August 2007, we entered into a research collaboration and license agreement with Parion Sciences, Inc. (Parion) to research, develop and commercialize certain epithelial sodium channel inhibitors for the treatment of pulmonary diseases. The agreement granted us worldwide commercialization rights to P-680 (GS 9411), an epithelial sodium channel (ENaC) inhibitor discovered by Parion, for the treatment of pulmonary diseases, including CF, chronic obstructive pulmonary disease and non-CF bronchiectasis. In accordance with the terms of the agreement, we paid a \$5.0 million up-front license fee that was recorded in R&D expenses in our Consolidated Statement of Operations as there was no future alternative use for this technology, and made a \$5.0 million investment in Parion in the form of convertible debt, which was recorded as other noncurrent assets in our Consolidated Balance Sheet. Under the collaboration agreement, we will lead all development and commercialization activities and provide funding of full time equivalent employees for certain research activities. In addition, we are obligated to make additional payments upon the achievement of certain milestones and pay royalties on future net sales of products that are developed and approved in relation to this collaboration.

**Roche**

In September 1996, we entered into a development and license agreement (the 1996 Agreement) Roche, to develop and commercialize therapies to treat and prevent viral influenza. Tamiflu, an antiviral oral formulation for the treatment and prevention of influenza, was co-developed by us and Roche. Under the 1996 Agreement, Roche has the exclusive right to manufacture and sell Tamiflu worldwide, subject to its obligation to pay us a percentage of the net revenues that Roche generates from Tamiflu sales, which, in turn, has been subject to reduction for certain defined manufacturing costs.

In November 2005, we entered into a first amendment and supplement to the 1996 Agreement with Roche. The amended agreement provided for the formation of a joint manufacturing committee to review Roche's manufacturing capacity for Tamiflu and its global plans for manufacturing Tamiflu, a U.S. commercial committee to evaluate commercial plans and strategies for Tamiflu in the United States and a joint supervisory committee to evaluate Roche's overall commercial plans for Tamiflu on a global basis in each case, consisting of representatives of Roche and us. Under the amended agreement, we also have the option to provide a specialized sales force to supplement Roche's marketing efforts in the United States for Tamiflu.

The royalties payable to us on net sales of Tamiflu sold by Roche remain the same under the amended agreement, which are as follows: (a) 14% of the first \$200.0 million in worldwide net sales in a given calendar year; (b) 18% of the next \$200.0 million in worldwide net sales during the same calendar year; and (c) 22% of

**Table of Contents****GILEAD SCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

worldwide net sales in excess of \$400.0 million during the same calendar year. The amended agreement revised the provision in the 1996 Agreement relating to the calculation of royalty payments such that in any given calendar quarter Roche will pay royalties based on the actual royalty rates applicable to such quarter. In addition, under the amended agreement, royalties payable by Roche to us will no longer be subject to a cost of goods sold adjustment that was provided in the 1996 Agreement. We recorded a total of \$155.5 million, \$414.5 million and \$364.6 million of Tamiflu royalties in 2008, 2007 and 2006, respectively.

**Japan Tobacco Inc.**

In March 2005, Japan Tobacco granted us exclusive rights to develop and commercialize elvitegravir, a novel HIV integrase inhibitor known as GS 9137, in all countries of the world, excluding Japan, where Japan Tobacco retained such rights. Under the terms of the agreement, we incurred an up-front license fee of \$15.0 million which was included in R&D expenses in 2005 as there was no future alternative use for this technology. In March 2006, we recorded \$5.0 million in R&D expenses related to a milestone we incurred as a result of dosing the first patient in a Phase 2 clinical study and in July 2008, we recorded \$7.0 million in R&D expenses related to a milestone we paid related to the dosing of the first patient in a Phase 3 clinical study. We are obligated to make additional payments upon the achievement of other milestones as well as pay royalties on any future product sales arising from this collaboration.

**Achillion Pharmaceuticals, Inc.**

In November 2004, Achillion granted us worldwide rights for the research, development and commercialization of certain small molecule hepatitis C virus (HCV) replication inhibitors involving HCV protease, for the treatment of hepatitis C. Under this collaboration, Achillion is obligated to continue the development of the inhibitor compounds according to a mutually agreed upon development plan, through completion of a proof of concept clinical study in HCV infected patients. The costs incurred to achieve proof of concept would be shared equally between Achillion and us. Following the proof of concept study, we are obligated to assume full responsibilities and incur all costs associated with development and commercialization of compounds warranting further development. Achillion has the option to participate in U.S. commercialization efforts for future products arising from this collaboration. In conjunction with the signing of the collaboration, we paid a \$5.0 million up-front license fee, which was recorded in R&D expenses as there was no future alternative use for the licensed technology. Additionally, we invested in \$17.1 million Achillion's convertible preferred stock and agreed to make payments to Achillion upon achievement of certain milestones outlined in our agreement as well as pay royalties on future net sales of products arising from this collaboration.

In October 2006, Achillion completed an initial public offering and our convertible preferred stock was converted into shares of Achillion common stock. In 2008 and 2007, we recorded a write-down of \$4.1 million and \$7.0 million, respectively, as part of our review for other-than-temporary impairment since the quoted market price of Achillion's common stock had been less than our cost basis for more than three consecutive quarters.

**GlaxoSmithKline Inc.**

In April 2002, we granted GSK the right to commercialize Hepsersa, our oral antiviral for the treatment of chronic hepatitis B, in Asia, Latin America and certain other territories. Under the agreement, we retained rights to Hepsersa in the United States, Canada, Europe, Australia, New Zealand and Turkey. GSK received exclusive rights to develop Hepsersa solely for the treatment of chronic hepatitis B in all of its territories, the most significant of which include China, Japan, South Korea and Taiwan. GSK has full responsibility for the development and commercialization of Hepsersa in its territories. Under the terms of the agreement, we received

**Table of Contents****GILEAD SCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

an up-front license payment of \$10.0 million and from 2002 to 2004, we received an aggregate of \$17.0 million in milestone payments related to the commercial approvals of Hepsera in various countries. In 2006, we received an aggregate of \$10.0 million in milestone payments from GSK for the achievement by GSK of four consecutive quarters of Hepsera gross sales exceeding \$75.0 million and the achievement of a certain drug status in China. The up-front license fee and milestone payments have been recorded as deferred revenue with a total of \$3.4 million, \$3.6 million and \$3.0 million being amortized into contract revenue in 2008, 2007 and 2006, respectively. The \$24.5 million balance of deferred revenue at December 31, 2008 is expected to be amortized into contract revenue over the period of our supply of Hepsera to GSK. Under the terms of the agreement, GSK is also required to pay us royalties on net sales that GSK generates from sales of Hepsera and Epivir-HBV/Zeffix (GSK's hepatitis product) in the GSK territories. We recorded \$27.5 million, \$22.8 million and \$16.1 million of royalty revenues in 2008, 2007 and 2006, respectively.

As a result of the acquisition of Myogen in November 2006, we assumed all rights to the March 2006 license and distribution and supply agreements between Myogen and 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 of \$20.0 million and, subject to the achievement of specific milestones, we are eligible to receive total additional milestone payments of \$80.0 million. In addition, we will receive stepped royalties based on net sales of ambrisentan in the GSK territories. GSK has an option to negotiate from us an exclusive sublicense for additional therapeutic uses for ambrisentan in the GSK territories during the term of the license agreement. We will continue to conduct and bear the expense 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 territories 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 2007, we received a milestone payment of \$11.0 million from GSK for validation by the EMEA of the marketing authorization application for ambrisentan for the treatment of PAH, and in 2008, we received a \$20.0 million milestone payment related to the European Commission marketing authorization approval for ambrisentan for the treatment of PAH, marketed under the name Volibris by GSK. The milestone and up-front license payments have been recorded as deferred revenue and are being amortized into contract revenue over the remaining period for which we have performance obligations under the agreement, which is approximately seven years. We amortized \$5.0 million, \$3.9 million and \$2.5 million to contract revenue in 2008, 2007 and 2006, respectively.

**10. LONG-TERM OBLIGATIONS***Convertible Senior Notes*

In April 2006, we issued \$650.0 million principal amount of convertible senior notes due 2011 (2011 Notes) and \$650.0 million principal amount of convertible senior notes due 2013 (2013 Notes) (collectively, the Notes) in a private placement pursuant to Rule 144A of the Securities Act of 1933, as amended. The 2011 Notes and the 2013 Notes were issued at par and bear interest rates of 0.50% and 0.625%, respectively. Debt issuance costs of \$23.8 million in connection with the issuance of the Notes were recorded in other noncurrent assets and are being amortized to interest expense on a straight-line basis over the contractual terms of the Notes. The aggregate principal amount of the Notes sold reflects the full exercise by the initial purchasers of their option to purchase additional Notes to cover over-allotments. The 2011 Notes may be convertible into our common stock based on an initial conversion rate of 25.8048 shares per \$1,000 principal amount of 2011 Notes (which represents an initial conversion price of approximately \$38.75 per share). The 2013 Notes may be convertible into our common stock based on an initial conversion rate of 26.2460 shares per \$1,000 principal amount of 2013 Notes (which represents an initial conversion price of approximately \$38.10 per share). The Notes may be converted, subject to adjustment, only under the following circumstances: 1) during any calendar quarter beginning after



**Table of Contents****GILEAD SCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

September 30, 2006 if the closing price of our common stock for at least 20 trading days during the last 30 consecutive trading day period of the previous quarter is more than 130% of the applicable conversion price per share, 2) if we make specified distributions to holders of our common stock or if specified corporate transactions occur, or 3) during the last month prior to maturity of the applicable Notes. Upon conversion, a holder would receive an amount in cash equal to the lesser of (i) the principal amount of the note or (ii) the conversion value for such note. If the conversion value exceeds \$1,000, we may also deliver, at our option, cash or common stock or a combination of cash and common stock for the conversion value in excess of \$1,000. If the Notes are converted in connection with a change in control, we may be required to provide a make whole premium in the form of an increase in the conversion rate, subject to a stated maximum amount. In addition, in the event of a change in control, the holders may require us to purchase all or a portion of their notes at a purchase price equal to 100% of the principal amount of the Notes, plus accrued and unpaid interest thereon, if any. At December 31, 2008, the fair values of the 2011 Notes and 2013 Notes were approximately \$886.4 million and \$877.3 million, respectively, based on their quoted market values.

Concurrent with the issuance of the Notes, we purchased convertible note hedges in private transactions at a cost of \$379.1 million to cover, subject to customary anti-dilution adjustments, 33.8 million shares of our common stock at strike prices that correspond to the initial conversion prices of the Notes. If the market value per share of our common stock at the time of conversion of the Notes is above the strike price of the applicable convertible note hedges, we are entitled to receive from the counterparties in the transactions cash or shares of our common stock or a combination of cash and common stock, at our option, for the excess of the then market price of the common stock over the strike price of the convertible note hedges. The convertible note hedges will terminate upon the maturity of the related Notes or when none of the related Notes remain outstanding due to conversion or otherwise. We also sold warrants to acquire 33.8 million shares of our common stock, subject to customary anti-dilution adjustments, in private transactions and received net proceeds of \$235.5 million. If the market value of our common stock at the time of the exercise of the applicable warrants exceeds their respective strike prices, we will be required to net settle in cash or shares of our common stock, at our option, with the respective counterparties for the value of the warrants in excess of the warrant strike prices. The maximum number of shares of common stock that could be issued by us should we choose to net share settle the warrants is 35.5 million shares, or 105% of the underlying share amount, which we have reserved for potential future issuance. The warrants have strike prices of \$50.80 per share (for the warrants expiring in 2011) and \$53.90 per share (for the warrants expiring in 2013) and are exercisable only on the respective expiration dates. Taken together, the convertible note hedges and warrants are intended to reduce the potential dilution upon future conversions of the Notes by effectively increasing the initial conversion price to \$50.80 per share for the 2011 Notes and \$53.90 per share for the 2013 Notes. The net cost of \$143.7 million of the convertible note hedges and warrant transactions was recorded in stockholders' equity.

Because we have the choice of settling the convertible note hedges and warrants in cash or shares of our stock, and these contracts meet all of the applicable criteria for equity classification as outlined in EITF Issue No. 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock* (EITF 00-19), the cost of the convertible note hedges and net proceeds from the sale of the warrants are classified in stockholders' equity. In addition, because both of these contracts are classified in stockholders' equity and are indexed to our own common stock, they are not accounted for as derivatives under SFAS 133. We also recorded a deferred tax asset of \$148.9 million in APIC for the effect of the future tax benefits related to the convertible note hedges in accordance with SFAS 109 and EITF Issue No. 05-08, *Income Tax Consequences of Issuing Convertible Debt with a Beneficial Conversion Feature*.

Contemporaneously with the closing of the sale of the Notes, a portion of the net proceeds from the Notes' issuance and the proceeds of the warrant transactions were used to repurchase 16.7 million shares of our common stock for \$544.9 million under our 2006 stock repurchase program.

---

**Table of Contents****GILEAD SCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The terms of the Notes agreements require us to comply with certain covenants. As of December 31, 2008, we were in compliance with all such covenants.

*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 facilitate a cash dividend distribution of \$280.0 million to the U.S. parent company as part of the repatriation of our qualified foreign earnings under the provisions of the American Jobs Creation Act (AJCA). During the year ended December 31, 2007, we repaid \$99.0 million, which represented the remaining amounts due under the term loan at which time, the term loan was terminated.

Under the terms of the revolving credit facility entered into in December 2005, interest accrued and was payable at a rate of LIBOR plus a tiered contractual rate of up to 50 basis points, and was payable quarterly in arrears. The U.S. parent company could 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 would be payable on demand. The capacity of the revolving credit facility would increase to a maximum of \$500.0 million as the term loan was repaid. We had 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 were 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. One of our wholly-owned subsidiaries was the guarantor.

In December 2007, we entered into an amended and restated credit agreement, which superseded the existing revolving credit agreement above, with a syndicate of banks to increase the credit facility to \$1.25 billion. The amended and restated credit agreement also includes a sub-facility for swing-line loans and letters of credit, and was entered into by GBIC and the U.S. parent company. Under the terms of the amended and restated credit agreement, we may borrow initially up to an aggregate of \$1.25 billion in revolving credit loans. Loans under the amended and restated credit agreement bear interest at either (i) LIBOR plus a margin ranging from 20 basis points to 32 basis points or (ii) the base rate, as defined in the amended and restated credit agreement. We can prepay any outstanding borrowings at any time in whole or in part without penalty or premium, and any outstanding interest or principal would be due and payable in December 2012. In connection with the amended and restated credit agreement, the U.S. parent company entered into an agreement guaranteeing the obligations of GBIC under the amended and restated credit agreement. We expect to use the proceeds of any loans under the amended and restated credit agreement for working capital requirements and general corporate purposes. As of December 31, 2008, we had \$3.7 million letters of credit outstanding under the amended and restated credit agreement. We are required to comply with certain covenants under the amended and restated credit agreement and as of December 31, 2008, we were in compliance with all such covenants.

**11. COMMITMENTS AND CONTINGENCIES****Lease Arrangements**

We have entered into various long-term non-cancelable operating leases for equipment and facilities. We lease facilities in Foster City and San Dimas, California; Durham, North Carolina; Boulder and Westminster, Colorado; Seattle, Washington; the Dublin area of Ireland and the London area of the United Kingdom. We also

**Table of Contents****GILEAD SCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

have operating leases for sales, marketing and administrative facilities in Europe, Canada and Australia. Our leases expire on various dates between 2009 and 2029. Our leases in Ireland and the United Kingdom are for 25 and 10 years, respectively, with rent subject to increase on the fifth anniversary of the respective commencement dates. Many of our facility leases have options to renew. Our equipment leases include three corporate aircraft, with varying terms, with renewal options upon expiration of the lease terms.

Lease expense under our operating leases totaled approximately \$29.3 million in 2008, \$28.8 million in 2007 and \$24.4 million in 2006. Aggregate non-cancelable future minimum rental payments under operating leases for each of the years ending December 31 are as follows (in thousands):

2009	\$ 29,946
2010	30,159
2011	28,149
2012	24,053
2013	21,029
Thereafter	79,602
	<b>\$ 212,938</b>

**Legal Proceedings**

On May 12, 2006, the United States District Court for the Northern District of California executed orders dismissing in its entirety and with prejudice the fourth consolidated amended complaint associated with a purported class action lawsuit against us and our Chief Executive Officer; Chief Operating Officer; former Executive Vice President of Operations; Executive Vice President of Research and Development and Chief Scientific Officer; Senior Vice President of Manufacturing; and Senior Vice President of Research, alleging that the defendants violated federal securities laws, specifically Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated by the SEC, by making certain alleged false and misleading statements. On August 11, 2008, the United States Court of Appeals for the Ninth Circuit reversed the district court's decision and remanded the case to the district court. On February 6, 2009, we filed a petition for a writ of certiorari with the Supreme Court of the United States, requesting that the court review the judgment of the court of appeals. While the Supreme Court reviews our petition, the case continues before the district court, and on February 13, 2009 we filed a further motion to dismiss the fourth consolidated amended complaint. It is not possible to predict the outcome of this case, and as such, no amounts have been accrued related to the outcome of this case.

On November 29, 2006, we received a subpoena from the United States Attorney's Office in San Francisco requesting documents regarding our marketing and medical education programs for Truvada, Viread and Emtriva. We have been cooperating and will continue to cooperate with any related governmental inquiry. It is not possible to predict the outcome of this inquiry, and as such, no amounts have been accrued related to the outcome of this inquiry.

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

**Other Commitments**

In August 2007, as a result of a review of the terms under our existing corporate aircraft leases and upon consideration of the various alternatives available to us upon their expiration, we entered into agreements to



---

**Table of Contents****GILEAD SCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

purchase three aircraft to be constructed for delivery in 2010 and 2013. The aggregate purchase price under the purchase agreements is \$98.6 million. As of December 31, 2008, we have made deposits totaling \$7.4 million which have been recorded as other noncurrent assets in our Consolidated Balance Sheet. Future deposits due under the terms of the purchase agreements are as follows: \$23.0 million in 2009, \$31.1 million in 2010, \$4.1 million in 2011, \$20.7 million in 2012 and \$12.4 million in 2013. We have the option to terminate the purchase agreements, subject to a maximum payment of 7.5% of the fully equipped price of the aircraft.

In the normal course of business, we enter into various firm purchase commitments related to active pharmaceutical ingredients and certain inventory related items. As of December 31, 2008, commitments for the next five years were \$635.6 million in 2009, \$152.1 million in 2010, \$127.2 million in 2011, \$121.5 million in 2012 and \$48.7 million in 2013. The amounts related to active pharmaceutical ingredients only represent minimum purchase requirements. Actual payments for the purchases related to these active pharmaceutical ingredients were \$1.04 billion, \$548.3 million and \$200.6 million during the years ended December 31, 2008, 2007 and 2006, respectively.

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

In March 2006, our Board of Directors (Board) authorized a program for the repurchase of our common stock in an amount of up to \$1.00 billion over a two year period through open market and private block transactions pursuant to Rule 10b5-1 plans or privately negotiated purchases or other means, including accelerated stock repurchase transactions or similar arrangements. In April 2006, we repurchased and retired 16,734,000 shares of our common stock at \$32.57 per share for an aggregate purchase price of \$544.9 million. In May and June 2007, we repurchased and retired an aggregate of 11,228,656 shares of our common stock at an average purchase price of \$40.51 per share for an aggregate purchase price of \$454.9 million. The 2006 stock repurchase program expired in March 2008.

In October 2007, our Board authorized a new program for the repurchase of our common stock in an amount of up to \$3.00 billion through open market and private block transactions pursuant to Rule 10b5-1 plans or privately negotiated purchases or other means, including accelerated stock repurchase transactions or similar arrangements. This repurchase plan expires in December 2010. In 2007, we repurchased and retired 705,600 shares of our common stock at \$46.28 per share for an aggregate of \$32.7 million under the \$3.00 billion stock repurchase program.

In February 2008, we entered into an accelerated share repurchase agreement with a financial institution to repurchase \$500.0 million of our common stock on an accelerated basis. Under the terms of this accelerated share repurchase agreement, we paid \$500.0 million to the financial institution to settle the initial purchase transaction and received 9,373,548 shares of our common stock at a price of \$53.34 per share. In June 2008, upon maturity of the agreement and in accordance with the share delivery provisions of the agreement, we received an additional 239,612 shares of our common stock based on the average of the daily volume weighted-average prices of our common stock during a specified period less a predetermined discount per share. As a result, the final purchase price of our common stock from the accelerated share repurchase was \$52.01 per share.

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

---

**Table of Contents**

**GILEAD SCIENCES, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

shares that we received upon maturity of the contract in June 2008 were also recorded in stockholders' equity. We determined that the forward contract indexed to our own common stock met all of the applicable criteria for equity classification in accordance with EITF 00-19, and therefore, the contract was not accounted for as a derivative under SFAS 133.

In October 2008, we entered into an accelerated share repurchase agreement with a financial institution to repurchase \$750.0 million of our common stock on an accelerated basis. Under the terms of the accelerated share repurchase agreement, we paid \$750.0 million to the financial institution to settle the initial purchase transaction and received 14,874,519 shares of our common stock at a price of \$50.42 per share. On or before April 2009, subject to extension under certain circumstances as well as the maximum and minimum share delivery provisions of the agreement, we may receive additional shares from the financial institution depending on the average of the daily volume weighted-average prices of our common stock during a specified period less a predetermined discount per share. After making the initial payment of \$750.0 million, we are not obligated to deliver any cash or shares to the financial institution except in certain limited circumstances in which case the method of delivery (cash or shares of our common stock) would be at our discretion. The accounting for this accelerated share repurchase was consistent with that of our previous accelerated share repurchase.

In 2008, in addition to the common stock repurchased under the two accelerated share repurchase transactions, we repurchased and retired 14,696,449 shares of our common stock at an average purchase price of \$48.94 per share, for an aggregate purchase price of \$719.3 million through open market transactions. As of December 31, 2008, the remaining authorized amount of stock repurchases that may be made under the \$3.00 billion stock repurchase program which expires in December 2010 was \$998.1 million.

We use the par value method of accounting for our stock repurchases. Under the par value method, common stock is first charged with the par value of the shares involved. The excess of the cost of shares acquired over the par value is allocated to APIC based on an estimated average sales price per issued share with the excess amounts charged to retained earnings. As a result of our stock repurchases in 2007, we reduced common stock and APIC by an aggregate of \$26.9 million and charged \$460.8 million to retained earnings. As a result of our stock repurchases in 2008, we reduced common stock and APIC by an aggregate of \$95.8 million and charged \$1.88 billion to retained earnings.

**Preferred Stock**

We have 5,000,000 shares of authorized preferred stock issuable in series. Our Board is authorized to determine the designation, powers, preferences and rights of any such series. We have designated 800,000 shares of Series A Junior Participating Preferred Stock for potential issuance under our November 1994 rights agreement with BNY Mellon Investor Services, LLC (formerly known as ChaseMellon Shareholder Services, LLC), as amended (the Rights Plan). There was no preferred stock outstanding as of December 31, 2008 and 2007.

**Rights Plan**

The Rights Plan provides for the distribution of a preferred stock purchase right as a dividend for each share of our common stock. The purchase rights are not currently exercisable. Under certain conditions involving an acquisition or proposed acquisition by any person or group of 15% or more of our common stock, the purchase rights permit the holders (other than the 15% holder) to purchase our common stock at a 50% discount from the market price at that time, upon payment of a specified exercise price per purchase right. In addition, in the event of certain business combinations, the purchase rights permit the purchase of the common stock of an acquirer at a 50% discount from the market price at that time. Under certain conditions, the purchase rights may be redeemed.

**Table of Contents****GILEAD SCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

by the Board in whole, but not in part, at a price of \$0.0025 per purchase right. The purchase rights have no voting privileges and are attached to and automatically trade with our common stock.

In October 1999, October 2003 and May 2006, the Board approved amendments to the Rights Plan. The first amendment provided, among other things, for an increase in the exercise price of a right under the plan from \$15 to \$100 and an extension of the term of the plan from November 2004 to October 2009. The second amendment provides, among other things, for an increase in the exercise price of a right under the plan from \$100 to \$400 and an extension of the term of the Rights Plan to October 2013. The third amendment was a clarifying amendment entered into in connection with an increase in the designated number of shares of Series A Junior Participating Preferred Stock for potential issuance under the Rights Plan in May 2006.

**Stock Option Plans**

In May 2004, our stockholders approved and we adopted our 2004 Equity Incentive Plan (the 2004 Plan). Stock options under the NeXstar Pharmaceuticals, Inc. (NeXstar), Triangle Pharmaceuticals, Inc. (Triangle), Corus and Myogen stock option plans, which we assumed as a result of the acquisitions of NeXstar, Triangle, Corus, and Myogen have been converted into our options to purchase our common stock effective with the closing of the respective acquisitions. The 2004 Plan is a broad based incentive plan that allows for the awards to be granted to our employees, directors and consultants. The 2004 Plan provides for option grants designated as either non-qualified or incentive stock options. Prior to January 1, 2006, we granted both non-qualified and incentive stock options, but all stock options granted after January 1, 2006 have been nonqualified stock options. Under the 2004 Plan, employee stock options generally vest over five years, are exercisable over a period not to exceed the contractual term of ten years from the date the stock options are issued and are granted at prices not less than the fair value of our common stock on the grant date. Stock option exercises are settled with newly issued common stock from the 2004 Plan's previously authorized and available pool of shares. In May 2008, our stockholders approved an increase of an additional 10,000,000 shares of common stock available for issuance under the 2004 Plan. As of December 31, 2008, a total of 101,591,941 shares of common stock have been authorized for grant and 40,895,202 shares remain available for future grant under the 2004 Plan.

The following table summarizes activity under our stock option plans. All option grants presented in the table had exercise prices not less than the fair value of the underlying common stock on the grant date (shares in thousands):

	2008		Year ended December 31, 2007		2006	
	Shares	Weighted-Average Exercise Price	Shares	Weighted-Average Exercise Price	Shares	Weighted-Average Exercise Price
Outstanding, beginning of year	84,977	\$ 20.33	93,757	\$ 15.23	91,839	\$ 11.30
Granted and assumed	9,807	\$ 47.11	16,437	\$ 37.11	24,662	\$ 24.83
Forfeited	(2,530)	\$ 30.17	(3,988)	\$ 22.73	(4,251)	\$ 16.85
Exercised	(15,443)	\$ 13.97	(21,229)	\$ 10.35	(18,493)	\$ 8.13
Outstanding, end of year	76,811	\$ 24.70	84,977	\$ 20.33	93,757	\$ 15.23
Exercisable, end of year	45,235	\$ 17.29	44,971	\$ 13.46	47,350	\$ 9.61
Weighted-average grant date fair value of options granted during the year		\$ 16.95		\$ 14.03		\$ 12.55

**Table of Contents****GILEAD SCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The total intrinsic value of options exercised during the years ended December 31, 2008, 2007 and 2006 was \$551.7 million, \$606.0 million and \$427.5 million, respectively. The total fair value of stock options that vested during the years ended December 31, 2008, 2007 and 2006 was \$169.2 million, \$193.2 million and \$130.9 million, respectively.

As of December 31, 2008, the number of options outstanding that are expected to vest, net of estimated future option forfeitures in accordance with the provisions of SFAS 123R, was 23,647,802 with a weighted-average exercise price of \$35.47, an aggregate intrinsic value of \$377.0 million and a weighted-average remaining contractual life of 8.0 years. The aggregate intrinsic value of stock options outstanding and stock options exercisable as of December 31, 2008 were \$2.04 billion and \$1.53 billion, respectively. As of December 31, 2008, the weighted-average remaining contractual life for options outstanding and stock options exercisable were 6.3 and 5.2 years, respectively.

The following is a summary of our stock options outstanding and stock options exercisable at December 31, 2008 (options in thousands):

Range of Exercise Prices	Options Outstanding		Options Exercisable	
	Options Outstanding	Weighted-Average Exercise Price	Options Exercisable	Weighted-Average Exercise Price
\$ 0.82 - \$ 8.22	7,744	\$ 5.33	7,740	\$ 5.33
\$ 8.23 - \$12.42	7,104	\$ 8.95	7,102	\$ 8.95
\$12.60 - \$15.27	9,647	\$ 14.74	8,860	\$ 14.75
\$15.40 - \$21.99	13,189	\$ 17.10	9,597	\$ 17.01
\$22.14 - \$30.38	12,384	\$ 28.37	6,313	\$ 28.34
\$30.39 - \$40.04	13,572	\$ 34.65	4,249	\$ 34.29
\$41.41 - \$56.77	13,171	\$ 45.81	1,374	\$ 42.88
Total	76,811	\$ 24.70	45,235	\$ 17.29

As of December 31, 2008, there was \$405.3 million of unrecognized compensation cost related to stock options, which is expected to be recognized over an estimated weighted-average period of 2.9 years.

**Performance Shares and Restricted Stock Awards**

In January 2007, we granted 369,680 performance based share awards under the 2004 Plan. These awards were divided into three tranches for both vesting and performance measurement purposes. 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 shares of our common stock that we will ultimately issue will be calculated by multiplying the number of performance shares by a payout percentage ranging from 0% to 200%. Performance shares will vest only when a committee (or subcommittee) of our Board has determined that we have achieved our specified market and performance goals. The fair value of the performance shares is estimated at grant date using a Monte Carlo valuation methodology. Stock-based compensation for these performance shares is recognized as expense over the requisite service periods using a straight-line expense attribution approach reduced for estimated forfeitures. The weighted-average grant date fair value of the performance shares was \$34.80 per share. We recognized \$3.9 million and \$7.8 million of stock-based compensation expense in 2008 and 2007, respectively, relating to these performance shares.

In January 2008, we granted 219,690 performance based share awards with terms substantially similar to the awards granted in 2007 except that there was a single three year performance measurement and vesting period.



**Table of Contents****GILEAD SCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The weighted-average grant date fair value of the performance shares was \$56.61 per share. We recognized \$3.6 million of stock-based compensation expense in 2008 relating to these performance shares.

We also granted restricted stock awards to certain of our employees under the 2004 Plan. The vesting of certain of these awards is subject to the achievement of specified performance goals. The number of restricted stock awards issued to date has not been significant. As of December 31, 2008 and 2007 there were 46,001 and 58,000 nonvested outstanding awards, respectively.

**Employee Stock Purchase Plan**

Under our Employee Stock Purchase Plan, as amended (ESPP), employees can purchase shares of our common stock based on a percentage of their compensation subject to certain limits. The purchase price per share is equal to the lower of 85% of the fair value of our common stock on the offering date or the purchase date. A two year look-back feature in our ESPP causes the offering period to reset if the fair value of our common stock on the purchase date is less than that on the original offering date. ESPP purchases by employees are settled with newly issued common stock from the ESPP's previously authorized and available pool of shares. In May 2007, our stockholders approved amendments to our ESPP to increase the number of shares authorized and reserved for issuance under the ESPP by an additional 8,000,000 shares of our common stock and to extend the term of the ESPP for an additional ten years until January 2017. During 2008, 960,242 shares were issued under the ESPP for \$30.4 million. A total of 33,280,000 shares of common stock have been reserved for issuance under the ESPP, and there were 8,610,343 shares available for issuance under the ESPP as of December 31, 2008.

As of December 31, 2008, there was \$5.2 million of unrecognized compensation cost related to ESPP, which is expected to be recognized over an estimated weighted-average period of 0.7 years.

**13. STOCK-BASED COMPENSATION**

On January 1, 2006, we adopted the provisions of SFAS 123R, which requires that all share-based payments to employees and directors, including grants of stock options, be recognized in the Consolidated Statements of Operations based on their fair values.

The table below summarizes stock-based compensation expense under SFAS 123R (in thousands, except per share amounts):

	<b>Year ended December 31,</b>		
	<b>2008</b>	<b>2007</b>	<b>2006</b>
Cost of goods sold	\$ 10,312	\$ 11,224	\$ 10,870
Research and development expenses	66,523	72,082	52,163
Selling, general and administrative expenses	76,529	101,299	70,793
Stock-based compensation expense included in total costs and expenses	153,364	184,605	133,826
Income tax effect	(40,565)	(53,261)	(32,118)
Stock-based compensation expense included in net income (loss)	\$ 112,799	\$ 131,344	\$ 101,708
Stock-based compensation expense included in net income (loss) per share:			
Basic	\$ 0.12	\$ 0.14	\$ 0.11
Diluted	\$ 0.12	\$ 0.14	\$ 0.11



**Table of Contents****GILEAD SCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

During the years ended December 31, 2008, 2007 and 2006, we capitalized \$9.9 million, \$9.8 million and \$10.2 million of stock-based compensation costs to inventory, respectively.

Stock-based compensation is recognized as expense over the requisite service periods in our Consolidated Statements of Operations using a graded vesting expense attribution approach for nonvested stock options granted prior to the adoption of SFAS 123R and using the straight-line expense attribution approach for stock options granted after the adoption of SFAS 123R. As stock-based compensation expense related to stock options recognized on adoption of SFAS 123R is based on awards ultimately expected to vest, gross expense has been reduced for estimated forfeitures. SFAS 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. We estimated forfeitures based on our historical experience. Prior to the adoption of SFAS 123R, pro forma information required under SFAS 123 included forfeitures as they occurred. As a result of the adoption of SFAS 123R, we will only recognize a tax benefit from stock-based compensation in APIC if an incremental tax benefit is realized after all other tax attributes currently available to us have been utilized. In addition, we have elected to account for the indirect benefits of stock-based compensation on the research tax credit and the extraterritorial income deduction through the Consolidated Statements of Operations rather than through APIC.

**Valuation Assumptions**

Fair values of awards granted under our stock option plans and ESPP were estimated at grant or purchase dates using a Black-Scholes option valuation model. The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options, which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions, including expected stock price volatility and expected award life. In connection with our adoption of SFAS 123R, we refined the methodologies used to derive our valuation model assumptions. We used the following assumptions to calculate the estimated fair value of the awards:

	<b>Year ended December 31,</b>		
	<b>2008</b>	<b>2007</b>	<b>2006</b>
Expected volatility:			
Stock options	34%	34%	39%
ESPP	31%	30%	33%
Expected term in years:			
Stock options	5.3	5.0	5.2
ESPP	1.2	1.2	1.2
Risk-free interest rate:			
Stock options	2.8%	4.6%	4.7%
ESPP	2.1%	4.7%	4.9%
Expected dividend yield	0%	0%	0%

The fair value of stock options granted prior to the adoption of SFAS 123R was calculated using the multiple option approach while the fair value of stock options granted beginning January 1, 2006 was calculated using the single option approach.

Prior to the adoption of SFAS 123R, we used historical stock price volatility in connection with the Black-Scholes option valuation model. In connection with our adoption of SFAS 123R, we determined that a blend of historical volatility along with implied volatility for traded options on our common stock is a better reflection of our expected volatility.

**Table of Contents****GILEAD SCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The expected term of stock-based awards represents the weighted-average period the awards are expected to remain outstanding. We estimate the weighted-average expected term based on historical cancellation and historical exercise data related to our stock options as well as the contractual term and vesting terms of the awards.

The risk-free interest rate is based upon observed interest rates appropriate for the term of the stock-based awards. The dividend yield is based on our history and expectation of dividend payouts.

**14. COMPREHENSIVE INCOME (LOSS)**

Comprehensive income (loss) comprises net income (loss) and certain changes in stockholders' equity that are excluded from net income (loss), such as changes in the fair value of our outstanding effective cash flow hedges, changes in unrealized gains and losses on our available-for-sale securities and changes in our cumulative foreign currency translation account. Comprehensive income (loss) for the years ended December 31, 2008, 2007 and 2006 is included in our Consolidated Statement of Stockholders' Equity. The components of comprehensive income (loss) are shown net of related taxes where the underlying assets or liabilities are held in jurisdictions that are expected to generate a future tax benefit or liability.

The following reclassifications were recorded in connection with net realized gains (losses) on sales of securities and cash flow hedges that were previously included in comprehensive income (loss) (in thousands):

	Year ended December 31,		
	2008	2007	2006
Net unrealized gain (loss) related to available-for-sale securities, net of tax benefit (provision) of \$11,487, \$1,102, and \$(3,809) for 2008, 2007 and 2006, respectively	\$ (21,607)	\$ (1,750)	\$ 5,958
Net unrealized gain (loss) related to cash flow hedges, net of tax benefit (provision) of \$(40,681), \$0 and \$0 for 2008, 2007 and 2006, respectively	93,962	(55,818)	(36,679)
Reclassification adjustments, net of tax benefit of \$1,805, \$3,391, and \$1,395, for 2008, 2007 and 2006, respectively	(5,603)	49,412	17,743
Other comprehensive income (loss)	\$ 66,752	\$ (8,156)	\$ (12,978)

The balance of accumulated other comprehensive income (loss), net of taxes, as reported on our Consolidated Balance Sheets consists of the following components (in thousands):

	As of December 31,	
	2008	2007
Net unrealized gain (loss) on available-for-sale securities	\$ (6,359)	\$ 8,957
Net unrealized gain (loss) on cash flow hedges	54,875	(27,193)
Cumulative foreign currency translation adjustment	(7,276)	13,873
Accumulated other comprehensive income (loss)	\$ 41,240	\$ (4,363)

**15. DISCLOSURES ABOUT SEGMENTS OF AN ENTERPRISE AND RELATED 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

**Table of Contents****GILEAD SCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

products, Truvada, Atripla, Viread, Hepsara, Emtriva and AmBisome, which together accounted for substantially all of our total product sales for each of the years ended December 31, 2008, 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 consist of the following (in thousands):

	Year ended December 31,		
	2008	2007	2006
Antiviral products:			
Truvada	\$ 2,106,687	\$ 1,589,229	\$ 1,194,292
Atripla	1,572,455	903,381	205,729
Viread	621,187	613,169	689,356
Hepsara	341,023	302,722	230,531
Emtriva	31,080	31,493	36,393
<b>Total antiviral products</b>	<b>4,672,432</b>	<b>3,439,994</b>	<b>2,356,301</b>
AmBisome	289,651	262,571	223,031
Letairis	112,855	21,020	
Other	9,858	9,524	8,865
<b>Total product sales</b>	<b>\$ 5,084,796</b>	<b>\$ 3,733,109</b>	<b>\$ 2,588,197</b>

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

	Year ended December 31,		
	2008	2007	2006
United States	\$ 2,857,472	\$ 2,166,066	\$ 1,467,322
Outside of the United States:			
France	395,672	349,277	228,791
Spain	356,607	246,252	169,832
United Kingdom	297,276	223,066	157,387
Italy	277,441	206,890	149,399
Germany	242,193	120,467	126,428
Switzerland	193,314	442,455	382,361
Other European countries	346,722	213,510	172,951
Other countries	369,053	262,062	171,668
<b>Total revenues outside of the United States</b>	<b>2,478,278</b>	<b>2,063,979</b>	<b>1,558,817</b>
<b>Total revenues</b>	<b>\$ 5,335,750</b>	<b>\$ 4,230,045</b>	<b>\$ 3,026,139</b>

At December 31, 2008, the net book value of our property, plant and equipment in the United States, Ireland and Canada was \$353.4 million, \$102.6 million and \$57.5 million, respectively, which comprised approximately 97% of the total net book value of our property, plant and

equipment.

**Table of Contents****GILEAD SCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

	Year ended December 31,		
	2008	2007	2006
Cardinal Health, Inc.	21%	20%	18%
McKesson Corp.	16%	15%	12%
AmerisourceBergen Corp.	11%	11%	11%
F. Hoffmann-La Roche Ltd	*	*	12%

\* Amount less than 10%

**16. INCOME TAXES**

The provision for income taxes consists of the following (in thousands):

		Year ended December 31,		
		2008	2007	2006
Federal:	Current	\$ 585,075	\$ 408,508	\$ 430,611
	Deferred	23,470	90,915	2,551
		608,545	499,423	433,162
State:	Current	56,223	108,850	99,721
	Deferred	27,850	2,246	(4,412)
		84,073	111,096	95,309
Foreign:	Current	38,738	44,067	23,364
	Deferred	(8,105)	454	(85)
		30,633	44,521	23,279
Provision for income taxes		\$ 723,251	\$ 655,040	\$ 551,750

Foreign pre-tax income was \$903.0 million, \$740.9 million and \$461.6 million in 2008, 2007 and 2006, respectively. The cumulative unremitted foreign earnings that are considered to be permanently invested outside the United States and for which no U.S. taxes have been provided, were approximately \$1.94 billion and \$1.10 billion as of December 31, 2008 and 2007, respectively. The residual U.S. tax liability, if such amounts were remitted, would be approximately \$678.3 million and \$386.1 million as of December 31, 2008 and 2007, respectively.





**Table of Contents****GILEAD SCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The difference between the provision for income taxes and the amount computed by applying the U.S. federal statutory income tax rate to income (loss) before provision for income taxes is as follows (in thousands):

	Year ended December 31,		
	2008	2007	2006
Income (loss) before provision for income taxes	\$ 2,734,405	\$ 2,270,338	\$ (638,207)
Tax at federal statutory rate	\$ 957,042	\$ 794,618	\$ (223,374)
State taxes, net of federal benefit	60,452	78,444	59,773
Foreign earnings at different rates	(257,835)	(195,416)	(116,843)
Purchased in-process R&D expenses			837,918
Research and other credits	(32,270)	(15,251)	(21,600)
Net unbenefited stock compensation	5,224	12,227	14,721
Other	(9,362)	(19,582)	1,155
Provision for income taxes	\$ 723,251	\$ 655,040	\$ 551,750

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of our deferred tax assets and liabilities are as follows (in thousands):

	December 31,	
	2008	2007
Deferred tax assets:		
Convertible note hedges	\$ 89,871	\$ 111,479
Stock-based compensation	85,362	61,833
Capitalized intangibles	70,110	61,690
Reserves and accruals not currently deductible	42,202	30,137
Depreciation related	39,467	33,731
Research and other tax credit carryforwards	33,728	50,152
Net operating loss carryforwards	30,208	65,368
Other, net	74,984	74,927
Total deferred tax assets before valuation allowance	465,932	489,317
Valuation allowance		(23,498)
Total deferred tax assets	465,932	465,819
Deferred tax liabilities:		
Unremitted foreign earnings	(15,928)	(15,928)
Other	(48,828)	(10,270)
Total deferred tax liabilities	(64,756)	(26,198)
Net deferred tax assets	\$ 401,176	\$ 439,621

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

The valuation allowance increased (decreased) by \$(23.5) million, \$0.3 million and \$7.1 million for the years ended December 31, 2008, 2007 and 2006, respectively. We have concluded, based on the standard set forth in SFAS 109, that it is more likely than not that we will realize the benefit from the deferred tax assets related to certain state net operating loss and tax credit carryforwards as of December 31, 2008, and therefore, we released the related valuation allowance resulting in a credit to goodwill of approximately \$8.0 million and an income tax benefit of approximately \$15.5 million.

**Table of Contents**

**GILEAD SCIENCES, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

At December 31, 2008, we had U.S. federal net operating loss carryforwards of approximately \$67.0 million. The federal net operating loss carryforwards will start to expire in 2011, if not utilized. We also had federal tax credit carryforwards of approximately \$33.2 million which will start to expire in 2011 if not utilized. In addition, we had state net operating loss and tax credit carryforwards of approximately \$519.8 million and \$0.8 million, respectively. The state net operating loss and tax credit carryforwards will start to expire in 2013 and 2017, respectively, if not utilized.

Utilization of net operating losses and tax credits may be subject to an annual limitation due to ownership change limitations provided in the Internal Revenue Code of 1986, as amended, and similar state provisions. This annual limitation may result in the expiration of the net operating losses and credits before utilization.

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 (IRS) for the 2003 and 2004 tax years and by various state and foreign jurisdictions. There are differing interpretations of tax laws and regulations, and as a result, significant disputes may arise with these tax authorities involving issues of the timing and amount of deductions and allocations of income among various tax jurisdictions. We periodically evaluate our exposures associated with our tax filing positions.

As of December 31, 2008 and 2007, we had total federal, state and foreign unrecognized tax benefits of \$119.3 million and \$111.7 million, respectively, including interest of \$10.1 million and \$8.3 million, respectively. Of the total unrecognized tax benefits at December 31, 2008 and 2007, \$111.1 million and \$103.5 million, respectively, if recognized, would reduce our effective tax rate in the period of recognition. As permitted under the provisions of FIN 48, we have continued to classify interest and penalties related to unrecognized tax benefits as part of our income tax provision in our Consolidated Statements of Operations.

During 2008, we reached agreement with the IRS on several issues related to the examinations of our federal income tax returns for 2003 and 2004. As a result, we reduced our unrecognized tax benefits by \$30.0 million.

As of December 31, 2008, we believe it is reasonably possible that our unrecognized tax benefits will decrease by approximately \$56.0 million in the next 12 months as we expect to have clarification from the IRS around certain of our uncertain tax positions. With respect to the remaining unrecognized tax benefits, we are currently unable to make a reasonable estimate as to the period of cash settlement, if any, with the respective taxing authorities.

**Table of Contents****GILEAD SCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The following is a rollforward of our total gross unrecognized tax benefit liabilities for the years ended December 31, 2008 and 2007 (in thousands):

	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
Balance, beginning of period	\$ 115,087	\$ 91,086
Tax positions related to current year:		
Additions	37,495	25,882
Reductions		
Tax positions related to prior years:		
Additions	4,298	
Reductions	(23,307)	(1,881)
Settlements	(10,252)	
Lapse of statute of limitations	(1,897)	
Balance, end of period	\$ 121,424	\$ 115,087

**17. DEFERRED COMPENSATION PLANS**

We maintain a retirement savings plan under which eligible employees may defer compensation for income tax purposes under Section 401(k) of the Internal Revenue Code (Gilead Plan). Under the Gilead Plan, employees may contribute up to 60% of their eligible annual compensation, subject to IRS plan limits. We make matching contributions under the Gilead Plan. In 2008, we contributed up to 50% of an employee's contributions up to an annual maximum match of \$5,000. In 2007 and 2006, we contributed up to 50% of an employee's first 6% of contributions up to an annual maximum match of \$3,500 and \$2,500, respectively. Our total matching contribution expense under the Gilead Plan was \$7.8 million in 2008, \$4.5 million in 2007, and \$2.9 million in 2006.

We maintain a deferred compensation plan under which our directors and key employees may defer compensation for income tax purposes. The deferred compensation plan is a non-qualified deferred compensation plan which is not subject to the qualification requirements under Section 401(a) of the Internal Revenue Code. Compensation deferred after December 31, 2004 is subject to the requirements of Section 409A of the Internal Revenue Code. Under the plan, officers and other senior grade level employees may contribute up to 70% of their annual salaries and up to 100% of their annual bonus while directors may contribute up to 100% of their annual retainer fee. Amounts deferred by participants are deposited with a rabbi trust and are recorded in other noncurrent assets in our Consolidated Balance Sheets. Beginning in 2004, directors may also elect to receive all or a portion of their annual cash retainer in phantom shares, which gives the participant the right to receive an amount equal to the value of a specified number of shares over a specified period of time and which will be payable in shares of our common stock (with fractional shares paid out in cash) as established by the plan administrator. As of December 31, 2008, we had 20,289 phantom shares outstanding. Participants can elect one of several distribution dates available under the plan at which they will receive their deferred compensation payment.

**Table of Contents****GILEAD SCIENCES, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****18. QUARTERLY RESULTS OF OPERATIONS (UNAUDITED)**

The following amounts are in thousands, except per share amounts:

	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
<b>2008<sup>(1)</sup></b>				
Total revenues	\$ 1,258,152	\$ 1,278,125	\$ 1,371,268	\$ 1,428,205
Gross profit on product sales	\$ 901,458	\$ 951,532	\$ 1,038,319	\$ 1,066,241
Total costs and expenses	\$ 590,106	\$ 672,610	\$ 677,434	\$ 717,059
Net income	\$ 496,127	\$ 442,828	\$ 504,005	\$ 568,194
Net income per share basic	\$ 0.53	\$ 0.48	\$ 0.55	\$ 0.62
Net income per share diluted	\$ 0.51	\$ 0.46	\$ 0.52	\$ 0.60
<b>2007</b>				
Total revenues	\$ 1,028,430	\$ 1,048,089	\$ 1,058,803	\$ 1,094,723
Gross profit on product sales	\$ 668,587	\$ 721,927	\$ 763,471	\$ 810,353
Total costs and expenses	\$ 468,286	\$ 505,241	\$ 511,773	\$ 580,238
Net income	\$ 407,407	\$ 407,930	\$ 398,319	\$ 401,642
Net income per share basic	\$ 0.44	\$ 0.44	\$ 0.43	\$ 0.43
Net income per share diluted	\$ 0.42	\$ 0.42	\$ 0.42	\$ 0.41

- (1) In the second quarter of 2008, we recognized a \$10.9 million charge for purchased IPR&D associated with our acquisition of all of the assets of Navitas related to its cicletanine business.

**Table of Contents****GILEAD SCIENCES, INC.****Schedule II: Valuation and Qualifying Accounts**

	Balance at Beginning of Period	Additions/ Charged to Expense	Deductions	Balance at End of Period
Year ended December 31, 2008:				
Accounts receivable allowances <sup>(1)</sup>	\$ 72,217	\$ 500,037	\$ 481,560	\$ 90,694
Valuation allowance for deferred tax assets	\$ 23,498	\$ 965	\$ 24,463	\$
Year ended December 31, 2007:				
Accounts receivable allowances <sup>(1)</sup>	\$ 51,000	\$ 329,029	\$ 307,812	\$ 72,217
Valuation allowance for deferred tax assets <sup>(2)</sup>	\$ 23,188	\$ 1,767	\$ 1,457	\$ 23,498
Year ended December 31, 2006:				
Accounts receivable allowances <sup>(1)</sup>	\$ 33,234	\$ 178,391	\$ 160,625	\$ 51,000
Valuation allowance for deferred tax assets <sup>(2)</sup>	\$ 16,131	\$ 7,057	\$	\$ 23,188

(1) Allowances are for doubtful accounts, sales returns, cash discounts and chargebacks.

(2) Valuation allowance for deferred tax assets includes \$7.4 million and \$7.1 million as of December 31, 2007 and 2006, respectively, related to our acquisitions.

**Table of Contents****SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) 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.

By: */s/* JOHN C. MARTIN  
**John C. Martin**

*Chairman and Chief Executive Officer*

**POWER OF ATTORNEY**

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints John C. Martin and Gregg H. Alton, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place, and stead, in any and all capacities, to sign any and all amendments to this Report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming that all said attorneys-in-fact and agents, or any of them or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof. Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
<i>/s/</i> JOHN C. MARTIN <b>John C. Martin</b>	Chairman and Chief Executive Officer ( <i>Principal Executive Officer</i> )	February 27, 2009
<i>/s/</i> ROBIN L. WASHINGTON <b>Robin L. Washington</b>	Senior Vice President and Chief Financial Officer ( <i>Principal Financial and Accounting Officer</i> )	February 27, 2009
<i>/s/</i> JAMES M. DENNY <b>James M. Denny</b>	Director	February 27, 2009
<i>/s/</i> PAUL BERG <b>Paul Berg</b>	Director	February 27, 2009
<i>/s/</i> JOHN F. COGAN <b>John F. Cogan</b>	Director	February 27, 2009
<i>/s/</i> ETIENNE F. DAVIGNON <b>Etienne F. Davignon</b>	Director	February 27, 2009





**Table of Contents**

<b>Signature</b>	<b>Title</b>	<b>Date</b>
<i>/s/</i> CARLA A. HILLS <b>Carla A. Hills</b>	Director	February 27, 2009
<i>/s/</i> JOHN W. MADIGAN <b>John W. Madigan</b>	Director	February 27, 2009
<i>/s/</i> GORDON E. MOORE <b>Gordon E. Moore</b>	Director	February 27, 2009
<i>/s/</i> NICHOLAS G. MOORE <b>Nicholas G. Moore</b>	Director	February 27, 2009
<i>/s/</i> RICHARD J. WHITLEY <b>Richard J. Whitley</b>	Director	February 27, 2009
<i>/s/</i> GAYLE E. WILSON <b>Gayle E. Wilson</b>	Director	February 27, 2009