GILEAD SCIENCES INC
Form 10-K
March 01, 2010
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2009

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	94-3047598
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
333 Lakeside Drive, Foster City, California	94404
(Address of principal executive offices)	(Zip Code)

Registrant s telephone number, including area code: 650-574-3000

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

Title of each class	Name of each exchange on which registered
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 x 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 x

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 x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x 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 x	Accelerated filer ¨	Non-Accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

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, 2009 was $39,885,530,020.*

The number of shares outstanding of the registrant s Common Stock on February 19, 2010 was 903,378,986.

DOCUMENTS INCORPORATED BY REFERENCE

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 2010 Annual Meeting of Stockholders, to be held on May 11, 2010, are incorporated by reference into Part III of this Report.

* Based on a closing price of $46.84 per share on June 30, 2009. Excludes 53,682,316 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, 2009. 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.

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GILEAD SCIENCES, INC.

2009 Form 10-K Annual Report

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

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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 and revenue trends, liquidity and capital needs and other statements of expectations, beliefs, future plans and strategies, anticipated events or trends and similar expressions. We have based these forward-looking statements on our current expectations about future events. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Our actual results may differ materially from those suggested by these forward-looking statements for various reasons, including those identified below under Risk Factors, beginning at page 18. 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.

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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.

In 2009, we acquired CV Therapeutics, Inc. (CV Therapeutics), a publicly-held biopharmaceutical company based in Palo Alto, California, primarily focused on the discovery, development and commercialization of small molecule drugs for the treatment of cardiovascular diseases. CV Therapeutics had two marketed products, Ranexa (ranolazine) and Lexiscan (regadenoson), as well as several product candidates in clinical development for the treatment of cardiovascular, metabolic and pulmonary diseases.

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. We have licensed to GlaxoSmithKline Inc. (GSK) the rights to commercialize Viread for the treatment of chronic hepatitis B in China.

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 to GSK the rights to commercialize Hepsera for the treatment of chronic hepatitis B in Asia, Latin America and certain other territories.

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 US, Inc., 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. We sublicensed to GSK the rights to ambrisentan, marketed by GSK as Volibris (ambrisentan), for PAH in territories outside of the United States.

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Ranexa is indicated for the treatment of chronic angina. We have licensed to Menarini International Operations Luxembourg SA the rights to Ranexa in territories outside of the United States.

Vistide (cidofovir injection) is an antiviral medication for the treatment of cytomegalovirus retinitis in patients with AIDS.

Cayston (aztreonam for inhalation solution) is an inhaled antibiotic as a treatment to improve respiratory systems in cystic fibrosis (CF) patients with *Pseudomonas aeruginosa (P. aeruginosa)*. In September 2009, we received conditional marketing approval of Cayston in Europe and Canada. In February 2010, we received marketing approval of Cayston in the United States.

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

	2009	% of Total Product Sales	2008	% of Total Product Sales	2007	% of Total Product Sales
Antiviral products:						
Truvada	$ 2,489,682	38%	$ 2,106,687	41%	$ 1,589,229	43%
Atripla	2,382,113	37%	1,572,455	31%	903,381	24%
Viread	667,510	10%	621,187	12%	613,169	16%
Hepsera	271,595	4%	341,023	7%	302,722	8%
Emtriva	27,974	0%	31,080	1%	31,493	1%
Total antiviral products	5,838,874	90%	4,672,432	92%	3,439,994	92%
AmBisome	298,597	5%	289,651	6%	262,571	7%
Letairis	183,949	3%	112,855	2%	21,020	1%
Ranexa	131,062	2%				
Other	16,829	0%	9,858	0%	9,524	0%
Total product sales	$ 6,469,311	100%	$ 5,084,796	100%	$ 3,733,109	100%

See Item 8, Note 15 to our Consolidated Financial Statements 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. Tamiflu 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.

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 Eyetech Inc. (Eyetech) using technology licensed from us and is now promoted in the United States by Eyetech. Eyetech 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 Eyetech based on sales of Macugen worldwide.

Lexiscan injection is indicated for use as a pharmacologic stress agent in radionuclide myocardial perfusion imaging (MPI), a test that detects and characterizes coronary artery disease, in patients unable to undergo adequate exercise stress. Astellas US LLC has exclusive rights to manufacture and

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sell Lexiscan in the United States, subject to its obligations to pay us royalties based on sales of Lexiscan in the United States. In May 2009, our marketing authorization application for regadenoson for MPI in the European Union was validated by the European Medicines Agency.

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, 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 Ranexa. We promote Atripla in the United States with our joint venture partner, Bristol Myers-Squibb Company (BMS). We distribute Truvada, Atripla, Viread, Emtriva, Hepsera, Vistide and Ranexa 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, 2009, 2008 and 2007. On a combined basis, these wholesalers accounted for approximately 85% of our product sales in the United States and approximately 43% of our total revenues. Our corporate partner, Astellas, promotes, sells and distributes AmBisome and Lexiscan for us in the United States. Cayston and Letairis 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.

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, third party distributors or corporate partners. 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 Gilead, BMS or a third party distributor is the sole promoting, selling and distributing company. Under an agreement with Merck & Co., Inc. (Merck), we promote and distribute Atripla in 12 countries in Latin America and Asia-Pacific either through Merck or our existing third party distributors. GSK promotes, sells and distributes Hepsera in Asia, Latin America and certain other territories and plans to promote, sell and distribute Viread for the treatment of chronic hepatitis B in China. We rely on our corporate partner, Japan Tobacco Inc., to promote and sell Truvada, Viread and Emtriva in Japan. Our corporate partner, Astellas, 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 our HIV products are available at substantially reduced prices in 130 countries in the developing world. We have developed a system of tiered pricing that reflects 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 HIV 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.

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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.

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 (PharmaChem). In 2005, PharmaChem, one of our manufacturing partners, 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 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 these developing world countries. Aspen has the right to purchase Viread and Truvada in unlabeled bottles 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 generic versions of emtricitabine that are manufactured and distributed by Aspen.

Generic Licenses. We have entered into non-exclusive license agreements with thirteen 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 includes 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 transfers 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 & Co., Inc. (Merck). In August 2006, we entered into an agreement with an affiliate of Merck pursuant to which Gilead and Merck 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.

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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 committed to improving reproductive health by expanding the contraceptive choices of women and men, to develop, manufacture and, if proven efficacious, arrange for the distribution in resource limited countries certain formulations of tenofovir for use as a topical 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;
- 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 32 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 a joint venture established in November 2009 by GSK and Pfizer focused on HIV therapies. 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.

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. BMS 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.

In May 2010, the compound patent covering Epivir (lamivudine) itself will expire. Lamivudine is marketed by the joint venture established by GSK and Pfizer and is competitive with emtricitabine, the active pharmaceutical ingredient of Emtriva and a component of both Truvada and Atripla. Certain third party payors or plans may use the entry of generic lamivudine as a reason to exert pricing pressure on our HIV products.

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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. 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.

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.

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 chronic 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. (Actelion) and indirectly with PAH products from United Therapeutics Corporation and Pfizer.

Ranexa. Ranexa competes predominantly with generic compounds from three distinct classes of drugs for the treatment of chronic angina in the United States, including generic and/or branded beta-blockers, calcium channel blockers and long-acting nitrates. In addition, surgical treatments and interventions such as coronary artery bypass grafting and percutaneous coronary intervention can be another option for angina patients, and may be perceived by healthcare practitioners as preferred methods to treat the cardiovascular disease that underlies and causes angina.

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.

Cayston. Cayston competes primarily with Tobi (tobramycin inhalation solution, USP), an inhaled medication sold by Novartis for the treatment of CF patients whose lungs contain *P. aeruginosa*.

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

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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 3 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.

Lexiscan. In the United States, there are numerous marketed generic and/or branded pharmacologic stress agents that compete with Lexiscan. Clinical Data, Inc. is developing apadenoson as a pharmacologic stress agent for MPI which is currently in Phase 2 clinical trials. King Pharmaceuticals, Inc. is developing binodenoson, a pharmacologic stress agent currently in Phase 3 clinical trials. These product candidates could also compete with Lexiscan.

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 included in this Annual Report on Form 10-K.

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 brand 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 and Sustiva, 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

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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, Iceland, Liechtenstein, Norway and Switzerland. 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 receivables 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 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 sublicensed to GSK exclusive rights to market ambrisentan (the active pharmaceutical ingredient in Letairis, which is marketed under the name

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Volibris in territories outside the United States) for PAH 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, 2009, we have received $42.5 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, 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 (R&D) 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.

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 infection. 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, 2009, 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.

Tibotec Pharmaceuticals (Tibotec). In July 2009, we entered into a license and collaboration agreement with Tibotec, a wholly-owned subsidiary of Johnson & Johnson, under which we will develop and commercialize a fixed-dose combination of our Truvada and Tibotec s non-nucleoside reverse transcriptase inhibitor, TMC278 (25 mg rilpivirine hydrochloride), which is currently in Phase 3 clinical trials. Under the agreement, Tibotec granted us an exclusive license to the combination product for administration to adults in a once daily, oral dosage form, worldwide excluding developing world countries and Japan. Neither party is restricted from combining its drugs with any other drugs. We will pay Tibotec up to 71.5 million of Tibotec s development costs for TMC278 and are required to use commercially reasonable efforts to develop and formulate the combination product, including

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completion of bioequivalence studies. For the year ended December 31, 2009, we recorded $52.4 million in reimbursable R&D expenses incurred by Tibotec in the development of TMC278. Tibotec is required to use commercially reasonable efforts to develop TMC278 and obtain its approval in the United States and Europe. We will manufacture the combination product and assume the lead role in registration, distribution and, subject to regulatory approval, commercialization of the combination product in the licensed countries. Tibotec will have the right to detail the combination product in the licensed countries, and, at its option, can request that it be the distributor of the combination product in a limited number of such countries. The price of the combination product is expected to be the sum of the price of Truvada and the price of TMC278 purchased separately. The cost of TMC278 purchased by us from Tibotec for the combination product will approximate the market price of TMC278, less a specified percentage of up to thirty percent.

Either party may terminate the agreement if the combination product is withdrawn from the market, if the other party materially breaches the agreement or if certain clinical or regulatory conditions are not met. We may terminate the agreement in the United States and Canada on or after the expiration of the last-to-expire patent for tenofovir disoproxil fumarate in the United States, and may terminate the agreement in any other country on or after the expiration of the last-to-expire patent for tenofovir disoproxil fumarate in a country of the European Union. Tibotec may terminate the agreement in the United States and Canada on or after the expiration of the last to-expire patent for TMC278 in the United States, and may terminate the agreement in any other country on or after the expiration of the last-to-expire patent for TMC278 in a country of the European Union.

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. In 2009, we acquired CV Therapeutics to further expand into the cardiovascular therapeutic area.

We have research scientists in Foster City, Palo Alto and San Dimas, California; Durham, North Carolina; and Seattle, Washington, 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 product candidates and their corresponding current stages of development. For additional information on our development pipeline, visit our website at www.gilead.com.

Product Candidate	Description
Marketing Application Pending	
Regadenoson	In May 2009, our marketing authorization application for regadenoson for use as a pharmacologic stress agent in radionuclide MPI in the European Union was validated by the European Medicines Agency.
Phase 3	
Ambrisentan	Ambrisentan is an oral endothelin receptor antagonist also being evaluated for the treatment of idiopathic pulmonary fibrosis (IPF) and pulmonary hypertension secondary to IPF.

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Product Candidate	Description
Elvitegravir	Elvitegravir is an oral integrase inhibitor that is being evaluated as part of combination therapy for HIV in treatment experienced patients.
Combination of Truvada and TMC278	The combination of tenofovir disoproxil fumarate, emtricitabine and TMC278 is under evaluation for the treatment of HIV/AIDS in treatment-naive patients, and formulation work is underway to develop a once-daily, fixed-dose regimen of these three compounds.
Phase 2	
Aztreonam for inhalation solution	Aztreonam for inhalation solution is also being evaluated for the treatment of bronchiectasis.
Cicletanine	Cicletanine is an oral agent under evaluation for the treatment of PAH.
Cobicistat (formerly GS 9350)	Cobicistat is a pharmacoenhancer that is under evaluation as a boosting agent for certain HIV medicines and other antiretrovirals.
Fixed-dose combination of elvitegravir, cobicistat and Truvada	The once-daily, fixed-dose Quad regimen of elvitegravir, cobicistat, tenofovir disoproxil fumarate and emtricitabine is under evaluation for the treatment of HIV/AIDS in treatment-naïve patients.
GS 9190	GS 9190 is an oral non-nucleoside polymerase inhibitor being evaluated for the treatment of hepatitis C.
GS 9310/11	GS 9310/11 is an inhaled co-formulation of fosfomycin and tobramycin under evaluation for the treatment of bacterial infections associated with CF.
GS 9450	GS 9450 is an oral caspase inhibitor under evaluation for the treatment of hepatitis C and nonalcoholic steatohepatitis.
Preparing for Phase 2	
Ranolazine	Ranolazine is a late sodium current inhibitor and is also going to be evaluated for the treatment of diastolic heart failure in patients with preserved ejection fraction.
Phase 1	
GS 6201	GS 6201 is an A_{2B} adenosine antagonist under evaluation for the treatment of pulmonary diseases.
GS 9256	GS 9256 is a novel protease inhibitor being evaluated for the treatment of hepatitis C.
GS 9411	GS 9411 is an oral epithelial sodium channel blocker designed to increase airway hydration in patients with pulmonary disease.
GS 9667	GS 9667 is a partial A_1 adenosine antagonist under evaluation for the treatment of diabetes and hypertriglyceridemia.

In total, our R&D expenses for 2009 were $939.9 million compared with $721.8 million for 2008 and $591.0 million for 2007.

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

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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:

	U.S. Patent	European Patent
Products	**Expiration**	**Expiration**
Vistide	2010	2012
Hepsera	2014	2011[(1)]
Letairis	2015	2015
AmBisome	2016	2008
Tamiflu	2016	2016
Macugen	2017	2017
Viread	2017	2018
Ranexa	2019	2019[(2)]
Lexiscan	2019[(3)]	2020[(4)]
Emtriva	2021	2016
Truvada	2021	2018[(5)]
Atripla	2021	2018[(6)]
Cayston	2021	2021[(7)]

(1) Supplementary Protection Certificate (SPC) protection has been obtained in certain European countries that confers an auxiliary form of patent exclusivity until 2016.

(2) SPC protection has been obtained in certain European countries that confers an auxiliary form of patent exclusivity until 2023.

(3) Patent term extension applied for.

(4) An SPC can be applied for upon marketing approval in the European Union.

(5) Based on the European patent expiration date of Viread, one of the components of Truvada

(6) Based on the European patent expiration date of Viread, one of the components of Atripla.

(7) Application pending.

Patents covering the active pharmaceutical ingredients of Truvada, Atripla, Viread, Emtriva, Hepsera, Letairis, Vistide and Lexiscan are held by third parties. We acquired exclusive rights to these patents in the agreements we have with these parties. Patents do not cover ranolazine, the active ingredient of Ranexa. Instead, when it was discovered that only a sustained release formulation of ranolazine would achieve therapeutic plasma levels, patents were obtained on those formulations and the characteristic plasma levels they achieve. Patents do not cover the active ingredients in AmBisome. 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

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formulations of Hepsera. Asia is a major market for therapies for hepatitis B, the indication for which Hepsera has been developed.

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 Letairis Education and Access Program (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 participation in 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 and tenofovir disoproxil fumarate, which is an active pharmaceutical ingredient in Truvada, Atripla and Viread. The PTO granted these requests and issued non-final rejections for the four patents, which is a step common in a proceeding to initiate the re-examination process. In 2008, the PTO confirmed the patentability of all four patents.

Although we were successful in responding to the PTO office actions in the instance above, similar organizations may still challenge our patents in foreign jurisdictions. For example, in April 2008, the Brazilian Health Ministry, citing the U.S. patent re-examination proceedings as grounds for rejection, requested that the Brazilian patent authority issue a decision that is not supportive of our patent application for tenofovir disoproxil fumarate in Brazil. In August 2008, an examiner in the Brazilian patent authority issued a final rejection of our fumarate salt patent application, the only patent application for tenofovir disoproxil fumarate we have filed in Brazil. We then filed an appeal within the patent authority responding to the questions raised in the rejection. In July 2009, the Brazilian patent authority again rejected the application. This was the highest level of appeal available to us within the Brazilian patent authority. We have filed a civil action in Brazilian federal court to

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further appeal the action of the Brazilian patent authority. We cannot predict the outcome of this proceeding on our tenofovir disoproxil fumarate patent application. If we are unable to successfully appeal the decision by the patent authority in the courts, the Brazilian government would likely purchase generic tenofovir disoproxil fumarate, which would significantly reduce our sales of HIV products in Brazil. In 2009, the Brazilian government purchased approximately $50 million of our HIV products. For 2010, we anticipate that purchases of our HIV products by the Brazilian government will be at a similar level.

As another example, the Patent Office of India initially allowed our claims covering tenofovir disoproxil and tenofovir disoproxil fumarate. However, under Indian civil procedure, prior to the official grant of allowed applications, several parties filed legal actions to protest the decision to grant the patents. In August 2009, the Indian Patent Office announced that it had decided these actions against us and would not therefore allow the patents to be granted. We have filed an appeal within the Indian Patent Office on both of these applications. We cannot predict the outcome of these proceedings. If we are unable to successfully appeal these decisions, any further appeals will have to be pursued in the Indian court system, and may ultimately prove unsuccessful. In the meantime, any competitor is able to sell generic tenofovir disoproxil fumarate in India. In addition, if we are unable to successfully appeal any further negative decisions by the Indian Patent Office in the Indian courts, these competitors would be able to continue to sell generic tenofovir disoproxil fumarate, which could reduce the amount of royalties we receive from our Indian generic licenses.

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

For example, in November 2008, we received notice that Teva Pharmaceuticals (Teva) submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Truvada. In the notice, Teva alleges that two of the patents associated with emtricitabine, owned by Emory University and licensed exclusively to us, are invalid, unenforceable and/or will not be infringed by Teva s manufacture, use or sale of a generic version of Truvada. In December 2008, we filed a lawsuit in U.S. District Court in New York against Teva for infringement of the two emtricitabine patents. In March 2009, we received notice that Teva submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Atripla. In the notice, Teva challenged the same two emtricitabine patents. In May 2009, we filed another lawsuit against Teva in U.S. District Court in New York for infringement of the two emtricitabine patents, and this lawsuit was consolidated with the lawsuit filed in December 2008. In January 2010, we received notice that Teva submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Viread. In the notice, Teva challenged four of the tenofovir patents protecting Viread. In January 2010, we also received notices from Teva amending its ANDAs related to Truvada and Atripla. In the notice related to Truvada, Teva challenged four patents related to tenofovir and two additional patents related to emtricitabine. In the notice related to Atripla, Teva challenged four patents related to tenofovir, two additional patents related to

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emtricitabine and two patents related to efavirenz. We expect to file a lawsuit against Teva for infringement of the four Viread patents and two additional emtricitabine patents. BMS and Merck have the rights to enforce and defend the patents related to efavirenz. We cannot predict the ultimate outcome of these actions, and we may spend significant resources enforcing these patents. If we are unsuccessful in these lawsuits, some or all of our original claims in the patents may be narrowed or invalidated and the patent protection for Truvada, Atripla and Viread in the United States could be substantially shortened. Further, if all of the patents covering those products are invalidated, the FDA could approve Teva s request to manufacture a generic version of such products.

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 R&D 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.

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 Cork, Ireland, where we manufacture certain products and active pharmaceutical ingredients 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, Ranexa, Vistide and Cayston. 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; and emtricitabine, the active pharmaceutical ingredient in Emtriva and one of the active pharmaceutical ingredients in Truvada and Atripla. We rely on a single third party manufacturer to manufacture the active pharmaceutical ingredients of Vistide, Ranexa and Cayston. The diluent for Cayston is also manufactured by a single manufacturer at a single site.

We also rely on third party contract manufacturers to tablet or capsulate products. For example, we use multiple third party contract manufacturers to tablet Truvada, Atripla, Viread, Hepsera and Ranexa. Emtriva capsulation is also completed by third party contract manufacturers. We rely on a single third party supplier to tablet Emtriva and Letairis.

We also have manufacturing agreements with many of 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. Astellas, our corporate partner for Lexiscan in America, is responsible for the commercial manufacture and supply of product in United States and is dependent on a single supplier for the active pharmaceutical ingredient of Lexiscan. PARI Pharma GmbH is responsible for the manufacturing of the device required to administer Cayston to the lungs of patients. This device is made by a single supplier at a single site.

At our San Dimas facility, we manufacture, fill and package products. We manufacture AmBisome and Cayston exclusively at this facility. We depend on a single supplier for high quality cholesterol, which is used in

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the manufacture of AmBisome. We fill and finish Macugen exclusively at our facilities in San Dimas under our manufacturing agreements with Eyetech and Pfizer. Eyetech currently provides us with pegaptanib sodium, the active pharmaceutical ingredient in Macugen. We also fill and package drug product for Truvada, Atripla, Viread, Emtriva Hepsera and Ranexa in their finished forms at our facilities in San Dimas.

At our Edmonton, Alberta facility, we carry out process research and scale-up of our clinical development candidates, manufacture active pharmaceutical ingredients for both investigational and commercial 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 ingredients in Letairis and Hepsera 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, Cayston and Hepsera in their finished forms at our facilities in Cork, Ireland. We also perform quality control testing, final labeling and packaging of 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 Cayston and fill and finish Macugen exclusively at our facilities in San Dimas, California, in the event of a disaster, including an earthquake, equipment failure or other difficulty, we may be unable to replace this manufacturing capacity in a timely manner and may be unable to manufacture AmBisome, Cayston and Macugen to meet market needs. Problems with any of the single suppliers we depend on may negatively impact our development and commercialization efforts.

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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.

Seasonal Operations and Backlog

Our worldwide product sales do not reflect any significant degree of seasonality. However, our royalty revenues, which represented about 7% of our total revenues in 2009 and consisted primarily of Tamiflu royalties, are affected by seasonality. Royalty revenue that we recognize from Roche s sales of Tamiflu can be impacted by the severity of flu seasons and product delivery in response to the H1N1 influenza pandemic.

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, the drug candidate can then be studied 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,

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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.

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 infection 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.

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 (which includes most major countries in Europe). If this centralized approval procedure is not used, approval in

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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 payer reimbursement for the cost of such products and related treatments. Government health administration authorities, private health insurers and other organizations generally provide reimbursement. In the United States, the European Union and other significant or potentially significant markets for our products and product candidates, government authorities and third party payers are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. For example, a significant portion of our sales of the majority of our products are subject to significant discounts from list price and rebate obligations. In addition, 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 clear, 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 payers 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. 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.

Both President Obama s Administration and the United States Congress have made healthcare reform a top priority and have proposed reforms to extend coverage to millions of uninsured Americans and to reduce the rate of growth in the costs of government-sponsored healthcare programs. Impending reform legislation in Congress may include reducing the coverage and reimbursement of our products and additional healthcare reform costs being borne by pharmaceutical and biotechnology companies, including us, which could have an adverse impact on our business.

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.

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Reimbursement policies may adversely affect our ability to sell our products on a profitable basis. In many international markets, governments control the prices of prescription pharmaceuticals, including through the implementation of reference pricing, price cuts, rebates, revenue-related taxes and profit control, and expect prices of prescription pharmaceuticals to decline over the life of the product or as volumes increase. Recently, many countries in the European Union have increased the amount of discounts required on our products, and we expect 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 payers (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.

On August 12, 2009, we received a subpoena from the Office of the Inspector General of the U.S. Department of Health and Human Services requesting documents regarding the development, marketing and sales of Ranexa. We have been cooperating and will continue to cooperate with any related governmental inquiry.

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. In July 2009, the Brazilian patent authority rejected our patent application for tenofovir disoproxil fumarate, the active pharmaceutical ingredient in Viread. This was the highest level of appeal available to us within the Brazilian patent authority. We have filed a civil action in Brazilian federal court to further appeal the action of the Brazilian patent authority. If we are unable to successfully appeal the decision by the patent authority in the courts, the Brazilian government would likely purchase generic tenofovir disoproxil fumarate, which would significantly reduce our sales of HIV products in Brazil.

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In 2009, the Brazilian government purchased approximately $50 million of our HIV products. For 2010, we anticipate that purchases of our HIV products by the Brazilian government will be at a similar level.

In addition, concerns over the cost and availability of Tamiflu related to a potential avian flu and H1N1 influenza 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 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.

Employees

As of January 31, 2010, we had approximately 3,852 full-time employees. We believe we have good relations with our employees.

Environment, Health and Safety

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

We are voluntarily assessing our greenhouse gas emissions, and have begun to take action to reduce such emissions, for example through establishing employee commuter programs and evaluating the energy efficiency of our buildings. Various laws and regulations have been implemented or are under consideration to mitigate the effects of climate change caused by greenhouse gas emissions. For example, the California Air Resources Board is in the process of drafting regulations to meet state emissions targets. Based on current information and subject to the finalization of the proposed regulations, we believe that our primary risk related to climate change is the risk of increased energy costs. However, because we are not an energy intensive business, we do not anticipate being subject to a cap and trade system or any other mitigation measures that would likely to be material to our capital expenditures, results of operations or competitive position.

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 R&D activities and cannot eliminate the risk of accidental contamination or injury from these materials. Certain misuse or accidents involving these materials could lead to significant litigation, fines and penalties.

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 or by sending a fax to the SEC at 1-202-777-1027. In addition, the SEC maintains a website (www.sec.gov) that contains reports, proxy and information statements, and other information regarding issuers that file electronically.

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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. 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, particularly Truvada and Atripla. If we are unable to maintain or continue increasing sales of these products, our results of operations may be adversely affected.

We are currently dependent on sales of our products for the treatment of HIV infection, particularly 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. For the year ended December 31, 2009, Truvada and Atripla product sales together were $4.87 billion, or 69% of our total revenues. We may not be able to sustain the growth rate of sales of our HIV products, especially Truvada and Atripla, for any number of reasons including, but not limited to, the following:

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

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

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

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

A portion of our pre-tax income is derived from royalty revenue recognized from sales of Tamiflu by Roche. If sales of Tamiflu were to decrease, our pre-tax income will be disproportionately and adversely affected.

F. Hoffmann-La Roche Ltd (together with Hoffmann-La Roche Inc., Roche) markets Tamiflu worldwide for the treatment and prevention of influenza under a royalty-paying collaborative agreement with us. We recognized $392.7 million in royalty revenue for the year ended December 31, 2009 related to royalties received from sales

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of Tamiflu by Roche. Although such royalty revenue represented approximately 6% of our total revenues in 2009, it represented 11% of our pre-tax income during the period. Roche s Tamiflu sales have unpredictable variability due to their strong relationship with global pandemic planning efforts. Sales of Tamiflu increased sharply in 2009 primarily as a result of pandemic planning initiatives worldwide. If sales of Tamiflu were to decrease, our royalty revenues will decrease and our pre-tax income will decrease disproportionately. Any such decrease could be material and could adversely impact our operating results.

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

In 2009, approximately 85% of our product sales in the United States were to three wholesalers, Cardinal Health, Inc., McKesson Corp. and AmerisourceBergen Corp. The U.S. wholesalers with whom we have entered into inventory management agreements make estimates to determine end user demand and may not be completely effective in matching their inventory levels to actual end user demand. As a result, changes in inventory levels held by those wholesalers can cause our operating results to fluctuate unexpectedly if our sales to these wholesalers do not match end user demand. In addition, inventory is held at retail pharmacies and other non-wholesale locations with whom we have no inventory management agreements and no control over buying patterns. Adverse changes in economic conditions or other factors may cause retail pharmacies to reduce their inventories of our products, which would reduce their orders from wholesalers and, consequently, the wholesalers orders from us, even if end user demand has not changed. For example, during the second quarter of 2009, the wholesalers increased their inventory levels for Atripla and Truvada, while inventory levels for Viread decreased. In the third quarter of 2009, the wholesalers drew down on their inventory such that inventory levels for Atripla and Truvada at the end of the third quarter were more consistent with the levels held during the first quarter of 2009. As inventory in the distribution channel fluctuates from quarter to quarter, we may continue to see fluctuations in our earnings and a mismatch between prescription demand for our products and our revenues.

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 2009, we announced our Phase 3 clinical trial evaluating darusentan for the treatment of resistant hypertension did not achieve its co-primary efficacy endpoints and as a result of this outcome, we decided to discontinue the development of darusentan for the treatment of resistant hypertension.

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Approximately 45% of our product sales occur outside the United States, and currency fluctuations and hedging expenses may cause our earnings to fluctuate, which could adversely affect our stock price.

Because a significant percentage of our product sales are denominated in foreign currencies, primarily the Euro, we face exposure to adverse movements in foreign currency exchange rates. When the U.S. dollar strengthens against these foreign currencies, the relative value of sales made in the respective foreign currency decreases. Conversely, when the U.S. dollar weakens against these currencies, the relative value of such sales increases. Overall, we are a net receiver of foreign currencies and, therefore, benefit from a weaker U.S. dollar and are adversely affected by a stronger U.S. dollar relative to those foreign currencies in which we transact significant amounts of business.

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

Additionally, the expenses that we recognize in relation to our hedging activities can also cause our earnings to fluctuate. The level of hedging expenses that we recognize in a particular period is impacted by the changes in interest rate spreads between the foreign currencies that we hedge and the U.S. dollar.

We face significant competition.

We face significant competition from large pharmaceutical and biotechnology companies, most of whom have substantially greater resources than we do. In addition, our competitors have more products and have operated in the fields in which we compete for longer than we have. Our HIV products compete primarily with products from the joint venture established by GlaxoSmithKline Inc. (GSK) and Pfizer Inc. (Pfizer) which markets fixed-dose combination products that compete with Truvada and Atripla. In May 2010, the compound patent covering Epivir (lamivudine) itself will expire. Lamivudine, marketed by the joint venture established by GSK and Pfizer, is competitive with emtricitabine, the active pharmaceutical ingredient of Emtriva and a component of both Truvada and Atripla. Certain third party payors or plans may use the entry of generic lamivudine as a reason to exert pricing pressure on our HIV products.

For Hepsera and Viread for treatment of chronic hepatitis B, we compete primarily with products produced by GSK, Bristol-Myers Squibb Company (BMS) and Novartis Pharmaceuticals Corporation (Novartis) in the United States, the European Union and China. For AmBisome, we compete primarily with products produced by Merck & Co., Inc. (Merck) and Pfizer. In addition, we are aware of at least two lipid formulations that claim similarity to AmBisome becoming available outside of the United States, including the possible entry of one such formulation in Greece. These formulations may reduce market demand for AmBisome. Furthermore, the manufacture of lipid formulations of amphotericin B is very complex and if any of these formulations are found to be unsafe, sales of AmBisome may be negatively impacted by association. Letairis competes directly with Actelion Pharmaceuticals US, Inc. (Actelion) and indirectly with PAH products from United Therapeutics Corporation and Pfizer. Ranexa competes predominantly with generic compounds from three distinct classes of drugs, beta-blockers, calcium channel blockers and long-acting nitrates for the treatment of chronic angina in the United States. Cayston competes with a product marketed by Novartis. Tamiflu competes with products sold by GSK and generic competitors.

In addition, a number of companies are pursuing the development of technologies which are competitive with our existing products or research programs. These competing companies include specialized pharmaceutical firms and large pharmaceutical companies acting either independently or together with other pharmaceutical

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companies. Furthermore, academic institutions, government agencies and other public and private organizations conducting research may seek patent protection and may establish collaborative arrangements for competitive products or programs.

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

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

Our product Letairis, which was approved by the U.S. Food and Drug Administration (FDA) in June 2007, is a member of a class of compounds called endothelin receptor antagonists (ERAs) which pose specific risks, including serious risks of liver injury and birth defects. Because of these risks, Letairis is available only through the Letairis Education and Access Program (LEAP), a restricted distribution program intended to help physicians and patients learn about the risks associated with the product and assure appropriate use of the product. As the product is used by additional patients, we may discover new risks associated with Letairis which may result in changes to the distribution program and additional restrictions on the use of Letairis which may decrease demand for the product. 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, Letairis, Ranexa and Cayston for currently approved and additional uses. We anticipate that we will file for marketing approval in additional countries and for additional indications and products over the next several years. These products may fail to receive such marketing approvals on a timely basis, or at all.

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

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;

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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 and our operating results may be adversely affected.

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

We are required to demonstrate the safety and efficacy of products that we develop for each intended use through extensive preclinical studies and clinical trials. The results from preclinical and early clinical studies do not always accurately predict results in later, large-scale clinical trials. Even successfully completed large-scale clinical trials may not result in marketable products. If any of our product candidates fails to achieve its primary endpoint in clinical trials, if safety issues arise or if the results from our clinical trials are otherwise inadequate to support regulatory approval of our product candidates, commercialization of that product candidate could be delayed or halted. For example, in December 2009, we announced our Phase 3 clinical trial evaluating darusentan for the treatment of resistant hypertension did not achieve its co-primary efficacy endpoints and as a result of this outcome, we decided to discontinue the development of darusentan for the treatment of resistant hypertension. In addition, we may also face challenges in clinical trial protocol design. If the clinical trials for any of the product candidates in our pipeline are delayed or terminated, our prospects for future revenue growth would be adversely impacted. For example, we face numerous risks and uncertainties with our product candidates, including elvitegravir, our novel HIV integrase inhibitor for the treatment of HIV infection; the fixed-dose regimen of Truvada and TMC278 for the treatment of HIV infection; and ambrisentan for the treatment of idiopathic pulmonary fibrosis (IPF), each currently in Phase 3 clinical trials that could prevent completion of development of these product candidates. These risks include our ability to enroll patients in clinical trials, the possibility of unfavorable results of our clinical trials, the need to modify or delay our clinical trials or to perform additional trials and the risk of failing to obtain FDA and other regulatory body approvals. As a result, our product candidates may never be successfully commercialized. Further, we may make a strategic decision to discontinue development of our product candidates if, for example, we believe commercialization will be difficult relative to other opportunities in our pipeline. If these programs and others in our pipeline cannot be completed on a timely basis or at all, then our prospects for future revenue growth may be adversely impacted. In addition, clinical trials involving our commercial products could raise new safety issues for our existing products, which could in turn decrease our revenues and harm our business.

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

We extensively outsource our clinical trial activities and usually perform only a small portion of the start-up activities in-house. We rely on independent third party contract research organizations (CROs), to perform most of our clinical studies, including document preparation, site identification, screening and preparation, pre-study visits, training, program management and bioanalytical analysis. Many important aspects of the services performed for us by the CROs are out of our direct control. If there is any dispute or disruption in our relationship with our CROs, our clinical trials may be delayed. Moreover, in our regulatory submissions, we rely on the quality and validity of the clinical work performed by third party CROs. If any of our CROs processes, methodologies or results were determined to be invalid or inadequate, our own clinical data and results and related regulatory approvals could be adversely impacted.

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Our results of operations could be adversely affected by current and potential 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 clear, 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 payers 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. 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.

Both President Obama s Administration and the United States Congress have made healthcare reform a top priority and have proposed reforms to extend coverage to millions of uninsured Americans and to reduce the rate of growth in the costs of government-sponsored healthcare programs. Impending reform legislation in Congress may include reducing the coverage and reimbursement of our products and additional healthcare reform costs being borne by pharmaceutical and biotechnology companies, including us, which could have an adverse impact on our business.

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 the risk that:

- we are unable to control the resources our corporate partners devote to our programs or products;
- disputes may arise with respect to the ownership of rights to technology developed with our corporate partners;
- disagreements with our corporate partners could cause delays in, or termination of, the research, development or commercialization of product candidates or result in litigation or arbitration;
- contracts with our corporate partners may fail to provide significant protection or may fail to be effectively enforced if one of these partners fails to perform;
- our corporate partners have considerable discretion in electing whether to pursue the development of any additional products and may pursue alternative technologies or products either on their own or in collaboration with our competitors;

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

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

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

Under our April 2002 licensing agreement with GSK, we gave GSK the right to control clinical and regulatory development and commercialization of Hepsera in territories in Asia, Africa and Latin America. These include major markets for Hepsera, such as China, Japan, Taiwan and South Korea. In November 2009, we entered into an agreement with GSK that provided GSK with exclusive commercialization rights and registration responsibilities for Viread for the treatment of chronic HBV in China. The success of Hepsera and Viread for the treatment of chronic HBV in these territories depends almost entirely on the efforts of GSK. In this regard, GSK promotes Epivir-HBV/Zeffix, a product that competes with Hepsera. Consequently, GSK s marketing strategy for Hepsera and Viread for the treatment of chronic HBV may be influenced by its promotion of Epivir-HBV/Zeffix. We receive royalties from GSK equal to a percentage of GSK s net sales of Hepsera and Viread for the treatment of chronic HBV as well as net sales of GSK s Epivir-HBV/Zeffix. If GSK fails to devote sufficient resources to, or does not succeed in developing or commercializing Hepsera or Viread for the treatment of chronic HBV in its territories, our potential revenues in these territories may be substantially reduced.

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

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

not effectively sell or support Cayston or Letairis;

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

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

cease operations.

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

Further, Cayston may only be taken by patients using a specific inhalation device that delivers the drug to the lungs of patients. Our commercial launch of Cayston and ongoing distribution of Cayston are entirely reliant upon the manufacturer of that device. For example, the manufacturer could encounter other issues with regulatory agencies related to the device or be unable to supply sufficient quantities of this device at the time of commercial launch or following a commercial launch. In addition, the manufacturer may not be able to provide

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adequate warranty support for the device after it has been distributed to patients. With respect to distribution of the drug and device to patients, we are reliant on the capabilities of specialty pharmacies. For example, the distribution channel for drug and device is complicated and requires coordination. The reimbursement approval processes associated with both drug and device are similarly complex. If the device manufacturer is unable to obtain reimbursement approval or receives approval at a lower-than-expected price, sales of Cayston may be adversely affected. Any of the previously described issues may limit or further delay the commercial launch of Cayston, 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 payer reimbursement for the cost of such products and related treatments. Government health administration authorities, private health insurers and other organizations generally provide reimbursement. In the United States, the European Union and other significant or potentially significant markets for our products and product candidates, government authorities and third party payers are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. For example, a significant portion of our sales of the majority of our products are subject to significant discounts from list price and rebate obligations. In addition, 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.

In Europe, the success of our commercialized products, and any other product candidates we may develop, will depend largely on obtaining and maintaining government reimbursement, because in many European countries patients are unlikely to use prescription drugs that are not reimbursed by their governments. In addition, negotiating prices with governmental authorities can delay commercialization by 12 months or more. Reimbursement policies may adversely affect our ability to sell our products on a profitable basis. In many international markets, governments control the prices of prescription pharmaceuticals, including through the implementation of reference pricing, price cuts, rebates, revenue-related taxes and profit control, and expect prices of prescription pharmaceuticals to decline over the life of the product or as volumes increase. Recently, many countries in the European Union have increased the amount of discounts required on our products, and we expect 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.

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

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

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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.

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

Although we were successful in responding to the PTO office actions in the instance above, similar organizations may still challenge our patents in foreign jurisdictions. For example, in April 2008, the Brazilian Health Ministry, citing the U.S. patent re-examination proceedings as grounds for rejection, requested that the Brazilian patent authority issue a decision that is not supportive of our patent application for tenofovir disoproxil fumarate in Brazil. In August 2008, an examiner in the Brazilian patent authority issued a final rejection of our fumarate salt patent application, the only patent application for tenofovir disoproxil fumarate we have filed in Brazil. We then filed an appeal within the patent authority responding to the questions raised in the rejection. In July 2009, the Brazilian patent authority again rejected the application. This was the highest level of appeal available to us within the Brazilian patent authority. We have filed a civil action in Brazilian federal court to further appeal the action of the Brazilian patent authority. We cannot predict the outcome of this proceeding on our tenofovir disoproxil fumarate patent application. If we are unable to successfully appeal the decision by the patent authority in the courts, the Brazilian government would likely purchase generic tenofovir disoproxil fumarate, which would significantly reduce our sales of HIV products in Brazil. As another example, the Patent Office of India initially allowed our claims covering tenofovir disoproxil and tenofovir disoproxil fumarate. However, under Indian civil procedure, prior to the official grant of the allowed applications, several parties filed legal actions to protest the decision to grant the patents. In August 2009, the Indian Patent Office announced that it had decided these actions against us and would not therefore allow the patents to be granted. We have filed an

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appeal within the Indian Patent Office on both of these applications. We cannot predict the outcome of these proceedings. If we are unable to successfully appeal these decisions, any further appeals will have to be pursued in the Indian court system, and may ultimately prove unsuccessful. In the meantime, any competitor is able to sell generic tenofovir disoproxil fumarate in India. In addition, if we are unable to successfully appeal any further negative decisions by the Indian Patent Office in the Indian courts, these competitors would be able to continue to sell generic tenofovir disoproxil fumarate, which could reduce the amount of royalties we receive from our Indian generic licenses.

In 2009, the Brazilian government purchased approximately $50 million of our HIV products. For 2010, we anticipate that purchases of our HIV products by the Brazilian government will be at a similar level.

Patents do not cover ranolazine, the active ingredient of Ranexa. Instead, when it was discovered that only a sustained release formulation of ranolazine would achieve therapeutic plasma levels, patents were obtained on those formulations and the characteristic plasma levels they achieve. Patents do not cover the active ingredients in AmBisome. In addition, we do not have patent filings in China or certain other Asian countries covering all forms of adefovir dipivoxil, the active ingredient in Hepsera. Asia is a major market for therapies for hepatitis B, the indication for which Hepsera has been developed.

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 submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Truvada. In the notice, Teva alleges that two of the patents associated with emtricitabine are invalid, unenforceable and/or will not be infringed by Teva s manufacture, use or sale of a generic version of Truvada. In December 2008, we filed a lawsuit against Teva for infringement of the two emtricitabine patents. In March 2009, we received notice that Teva submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Atripla. In the notice, Teva challenged the same two emtricitabine patents. In May 2009, we filed another lawsuit against Teva for infringement of the two emtricitabine patents, and this lawsuit was consolidated with the lawsuit filed in December 2008. In January 2010, we received notice that Teva submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Viread. In the notice, Teva challenged four of the tenofovir patents protecting Viread. In January 2010, we also received notices from Teva amending its ANDAs related to Truvada and Atripla. In the notice related to Truvada, Teva challenged four patents related to tenofovir and two additional patents related to emtricitabine. In the notice related to Atripla, Teva challenged four patents related to tenofovir, two additional patents related to emtricitabine and two patents related to efavirenz. We expect to file a lawsuit against Teva for infringement of the four Viread patents and two additional emtricitabine patents. BMS and Merck have the rights to enforce and defend the patents related to efavirenz. We cannot predict the ultimate outcome of these actions, and we may spend significant resources enforcing these patents. If we are unsuccessful in these lawsuits, some or all of our original claims in the patents may be narrowed or invalidated and the patent protection for Truvada, Atripla and Viread in the United States could be substantially shortened. Further, if all of the patents covering those products are invalidated, the FDA could approve Teva s request to manufacture a generic version of such products.

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

In May 2009, we filed another lawsuit against Teva for infringement of the two emtricitabine patents.

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

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

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

We depend on third parties to perform manufacturing activities effectively and on a timely basis for the majority of our solid dose products. In addition, Roche, either by itself or through third parties, is responsible for manufacturing Tamiflu. The manufacturing process for pharmaceutical products is highly regulated and regulators may shut down manufacturing facilities that they believe do not comply with regulations. We, our third party manufacturers and our corporate partners are subject to the FDA s current Good Manufacturing Practices (GMP), which are extensive regulations governing manufacturing processes, stability testing, record keeping and quality standards. Similar regulations are in effect in other countries. Our 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 Cayston will depend upon our ability to manufacture in a multi-product facility.

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

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

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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 Cayston and fill and finish Macugen exclusively at our facilities in San Dimas, California. In the event of a disaster, including an earthquake, equipment failure or other difficulty, we may be unable to replace this manufacturing capacity in a timely manner and may be unable to manufacture AmBisome, Cayston and Macugen to meet market needs.

Cayston is dependent on three different third party single-source suppliers. First, aztreonam, the active pharmaceutical ingredient in aztreonam for inhalation solution, is manufactured by a single supplier at a single site. Second, it is administered to the lungs of patients through a device that is made by a single supplier at a single site. Third, the diluent for Cayston is manufactured by a single manufacturer at a single site. Disruptions or delays with any of these single suppliers could adversely affect our ability to produce Cayston in adequate quantities to support our commercial launch of Cayston, and we cannot be sure that alternative suppliers can be identified in a timely manner, or at all.

In addition, we depend on a single supplier for high quality cholesterol, which is used in the manufacture of AmBisome. We also depend on single suppliers for the active pharmaceutical ingredient of Vistide, Ranexa and Cayston and for the tableting of Emtiva and Letairis. Astellas US LLC, which markets Lexiscan in the United States, is responsible for the commercial manufacture and supply of product in United States and is dependent on a single supplier for the active pharmaceutical ingredient of Lexiscan. Problems with any of the single suppliers we depend on may negatively impact our development and commercialization efforts.

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 $753.6 million as of December 31, 2009, of which $289.4 million was more than 120 days past due based on contractual payment terms. Historically, receivables balances with certain government owned hospitals accumulated over a period of time and were then subsequently settled as large lump sum payments. If significant changes were to occur in the reimbursement practices of these European governments or if government funding becomes unavailable, we may not be able to collect on amounts due to us from these customers and our results of operations would be adversely affected. For example, at December 31, 2009, we had $100.8 million due from publicly-owned hospitals in Greece. In the event that the Greek government defaulted on its debt, we may be unable to collect some or all of these amounts due.

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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 130 countries participating in our Gilead Access Program, or Atripla, which Merck distributes at substantially reduced prices to HIV infected patients in developing countries under our August 2006 agreement, our revenues would be adversely affected. In addition, we have established partnerships with thirteen Indian generic manufacturers to distribute high-quality, low-cost generic versions of tenofovir disoproxil fumarate to 95 developing world countries, including India. If generic versions of our medications under these licenses are then re-exported to the United States, Europe or other markets outside of these 95 countries, our revenues would be adversely affected.

In addition, purchases of our products in countries where our selling prices are relatively low for resale in countries in which our selling prices are relatively high may adversely impact our revenues and gross margin and may cause our sales to fluctuate from quarter to quarter. For example, in the European Union, we are required to permit products purchased in one country to be sold in another country. Purchases of our products in countries where our selling prices are relatively low for resale in countries in which our selling prices are relatively high affect the inventory level held by our wholesalers and can cause the relative sales levels in the various countries to fluctuate from quarter to quarter and not reflect the actual consumer demand in any given quarter. These quarterly fluctuations may impact our earnings, which could adversely affect our stock price and harm our business.

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

In a number of developing countries, government officials and other interested groups have suggested that pharmaceutical companies should make drugs for HIV infection available at low cost. Alternatively, governments in those developing countries could require that we grant compulsory licenses to allow competitors to manufacture and sell their own versions of our products, thereby reducing our product sales. For example, in the past, certain offices of the government of Brazil have expressed concern over the affordability of our HIV products and declared that they were considering issuing compulsory licenses to permit the manufacture of otherwise patented products for HIV infection, including Viread. In July 2009, the Brazilian patent authority rejected our patent application for tenofovir disoproxil fumarate, the active pharmaceutical ingredient in Viread. This was the highest level of appeal available to us within the Brazilian patent authority. We have filed a civil action in Brazilian federal court to further appeal the action of the Brazilian patent authority. If we are unable to successfully appeal the decision by the patent authority in the courts, the Brazilian government would likely purchase generic tenofovir disoproxil fumarate, which would significantly reduce our sales of HIV products in Brazil. In 2009, the Brazilian government purchased approximately $50 million of our HIV products. For 2010, we anticipate that purchases of our HIV products by the Brazilian government will be at a similar level.

In addition, concerns over the cost and availability of Tamiflu related to a potential avian flu pandemic and H1N1 influenza have generated international discussions over compulsory licensing of our Tamiflu patents. For example, the Canadian government may allow Canadian manufacturers to manufacture and export the active ingredient in Tamiflu to eligible developing and least developed countries under Canada s Access to Medicines Regime. Furthermore, Roche has issued voluntary licenses to permit third party manufacturing of Tamiflu. For example, Roche has granted a sublicense to Shanghai Pharmaceutical (Group) Co., Ltd. for China and a sublicense to India s Hetero Drugs Limited for India and certain developing countries. Should one or more compulsory licenses be issued permitting generic manufacturing to override our Tamiflu patents, or should Roche issue additional voluntary licenses to permit third party manufacturing of Tamiflu, those developments could reduce royalties we receive from Roche s sales of Tamiflu. Certain countries do not permit enforcement of

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our patents, and third party manufacturers are able to sell generic versions of our products in those countries. Compulsory licenses or sales of generic versions of our products could significantly reduce our sales and adversely affect our results of operations, particularly if generic versions of our products are imported into territories where we have existing commercial sales.

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

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

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

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

Expensive litigation and government investigations may reduce our earnings.

In November 2008, we received notice that Teva submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Truvada. In the notice, Teva alleges that two of the patents associated with emtricitabine are invalid, unenforceable and/or will not be infringed by Teva s manufacture, use or sale of a generic version of Truvada. In December 2008, we filed a lawsuit against Teva for infringement of the two emtricitabine patents. In March 2009, we received notice that Teva submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Atripla. In the notice, Teva challenged the same two emtricitabine patents. In May 2009, we filed another lawsuit against Teva for infringement of the two emtricitabine patents, and this lawsuit was consolidated with the lawsuit filed in December 2008. In January 2010, we received notice that Teva submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Viread. In the notice, Teva challenged four of the tenofovir patents protecting Viread. In January 2010, we also received notices from Teva amending its ANDAs related to Truvada and Atripla. In the notice related to Truvada, Teva challenged four patents related to tenofovir and two additional patents related to emtricitabine. In the notice related to Atripla, Teva challenged four patents related to tenofovir, two additional patents related to emtricitabine and two patents related to efavirenz. We expect to file a lawsuit against Teva for infringement of the four Viread patents and two additional emtricitabine patents. BMS and Merck have the rights to enforce and defend the patents related to efavirenz. We cannot predict the ultimate outcome of these actions, and we may spend significant resources enforcing these patents. If we are unsuccessful in these lawsuits, some or all of our original claims in the patents may be narrowed or invalidated and the patent protection for Truvada, Atripla and Viread in the United States could be substantially shortened. Further, if all of the patents covering those products are invalidated, the FDA could approve Teva s request to manufacture a generic version of such products.

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. Further, in August 2009, we received a subpoena from the Office of the Inspector General of the U.S. Department of Health and Human Services requesting documents regarding the development, marketing and sales of Ranexa. We have been cooperating and will continue to cooperate with any related governmental inquiry.

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The outcome of the lawsuits above, any other lawsuits that may be brought against us, the investigation or any other such investigations brought against us, are inherently uncertain, and adverse developments or outcomes can result in significant expenses, monetary damages, penalties or injunctive relief against us that could significantly reduce our earnings and cash flows and harm our business.

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 resolution of federal, state and foreign income tax audits. The impact on our income tax provision resulting from the above mentioned factors may be significant and could have a negative impact on our net income.

Our income tax returns are audited by federal, state and foreign tax authorities. We are currently under examination by the Internal Revenue Service for the 2005, 2006 and 2007 tax years and by various state and foreign jurisdictions. There are differing interpretations of tax laws and regulations, and as a result, significant disputes may arise with these tax authorities involving issues of the timing and amount of deductions and allocations of income among various tax jurisdictions. Resolution of one or more of these exposures in any reporting period could have a material impact on the results of operations for that period.

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

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

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

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

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, where we own 18 buildings.

We lease facilities in Foster City, Palo Alto 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 utilize our manufacturing facility in Cork, Ireland, primarily for solid dose tablet manufacturing of our antiviral products, as well as product packaging activities. We also lease and own facilities in the Dublin area of Ireland to house distribution activities.

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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, Ireland, Italy, Netherlands, Portugal, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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 (Teva) submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Truvada. In the notice, Teva alleges that two of the patents associated with emtricitabine, owned by Emory University and licensed exclusively to us, are invalid, unenforceable and/or will not be infringed by Teva s manufacture, use or sale of a generic version of Truvada. In December 2008, we filed a lawsuit in U.S. District Court in New York against Teva for infringement of the two emtricitabine patents. In March 2009, we received notice that Teva submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Atripla. In the notice, Teva challenged the same two emtricitabine patents. In May 2009, we filed another lawsuit in U.S. District Court in New York against Teva for infringement of the two emtricitabine patents, and this lawsuit was consolidated with the lawsuit filed in December 2008. In January 2010, we received notice that Teva submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Viread. In the notice, Teva challenged four of the tenofovir patents protecting Viread. In January 2010, we also received notices from Teva amending its ANDAs related to Truvada and Atripla. In the notice related to Truvada, Teva challenged four patents related to tenofovir and two additional patents related to emtricitabine. In the notice related to Atripla, Teva challenged four patents related to tenofovir, two additional patents related to emtricitabine and two patents related to efavirenz. We expect to file a lawsuit against Teva for infringement of the four Viread patents and two additional emtricitabine patents. BMS and Merck have the rights to enforce and defend the patents related to efavirenz. We cannot predict the ultimate outcome of these actions, and we may spend significant resources enforcing these patents. If we are unsuccessful in these lawsuits, some or all of our original claims in the patents may be narrowed or invalidated and the patent protection for Truvada, Atripla and Viread in the United States could be substantially shortened. Further, if all of the patents covering those products are invalidated, the FDA could approve Teva s request to manufacture a generic version of such products.

Information pertaining to certain of our other legal proceedings can be found under the heading Legal Proceedings in Item 8, Note 11 to our Consolidated Financial Statements included in this Annual Report on Form 10-K and is incorporated by reference herein.

ITEM 4. RESERVED

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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 the high and low intra-day sale prices per share of our common stock on The Nasdaq Global Select Market for the periods indicated. 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
2009		
First Quarter	$ 53.28	$ 40.62
Second Quarter	$ 48.45	$ 41.31
Third Quarter	$ 50.00	$ 43.81
Fourth Quarter	$ 47.53	$ 42.31
2008		
First Quarter	$ 51.65	$ 42.16
Second Quarter	$ 56.95	$ 49.58
Third Quarter	$ 57.63	$ 39.80
Fourth Quarter	$ 52.26	$ 35.60

As of February 19, 2010, we had 903,378,986 shares of common stock outstanding held by approximately 479 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. As of December 31, 2009, we completed share repurchases under this program. In January 2010, our Board authorized a new program for the repurchase of our common stock in an amount of up to $1.00 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 January 2011. See Item 8, Note 12 to our Consolidated Financial Statements included in this Annual Report on Form 10-K for more information regarding our stock repurchase program.

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Performance Graph[1]

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[2]

(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, 2004.

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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. As of December 31, 2009, we completed share repurchases under this program. In January 2010, our Board authorized a new program for the repurchase of our common stock in an amount of up to $1.00 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 January 2011.

The table below summarizes our stock repurchase activity for the three months ended December 31, 2009 (in thousands, except per share amounts):

	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Programs	Maximum Fair Value of Shares that May Yet Be Purchased Under the Program
October 1 October 31, 2009	2,261	$ 44.85	2,260	$ 140,523
November 1 November 30, 2009	2,020	$ 46.12	2,020	$ 47,353
December 1 December 31, 2009	1,020	$ 46.43	1,020	$
Total	5,301[(1)]	$ 45.64	5,300[(1)]	

(1) The difference between the total number of shares purchased and the total number of shares purchased as part of publicly announced programs is due to shares of common stock withheld by us from employee restricted stock awards in order to satisfy our applicable tax withholding obligations.

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ITEM 6. SELECTED FINANCIAL DATA

GILEAD SCIENCES, INC.

SELECTED CONSOLIDATED FINANCIAL DATA

(in thousands, except per share data)

	Year Ended December 31,				
	2009	2008	2007	2006	2005
CONSOLIDATED STATEMENT OF OPERATIONS DATA:					
Total revenues[2]	$ 7,011,383	$ 5,335,750	$ 4,230,045	$ 3,026,139	$ 2,028,400
Purchased in-process research and development[1]	$	$ 10,851	$	$ 2,394,051	$
Total costs and expenses[3]	$ 3,482,162	$ 2,657,209	$ 2,065,538	$ 3,784,892	$ 919,333
Income (loss) from operations	$ 3,529,221	$ 2,678,541	$ 2,164,507	$ (758,753)	$ 1,109,067
Provision for income taxes[1][2][3]	$ 876,364	$ 702,363	$ 635,355	$ 538,857	$ 347,878
Net income (loss) attributable to Gilead[3]	$ 2,635,755	$ 1,978,899	$ 1,584,902	$ (1,209,866)	$ 813,914
Net income (loss) per share attributable to Gilead common stockholders basic[3]	$ 2.91	$ 2.15	$ 1.71	$ (1.32)	$ 0.90
Shares used in per share calculation basic	904,604	920,693	929,133	918,212	908,677
Net income (loss) per share attributable to Gilead common stockholders diluted[3]	$ 2.82	$ 2.06	$ 1.64	$ (1.32)	$ 0.86
Shares used in per share calculation diluted	934,109	958,825	964,356	918,212	948,569

	As of December 31,				
	2009	2008	2007	2006	2005
CONSOLIDATED BALANCE SHEET DATA:					
Cash, cash equivalents and marketable securities	$ 3,904,846	$ 3,239,639	$ 2,722,422	$ 1,389,566	$ 2,311,033
Working capital	$ 2,940,927	$ 3,057,416	$ 2,271,344	$ 1,644,886	$ 2,627,045
Total assets[4]	$ 9,698,559	$ 6,936,831	$ 5,731,055	$ 3,961,612	$ 3,764,651
Other long-term obligations[5]	$ 35,918	$ 21,462	$ 11,604	$ 91,847	$ 240,650
Convertible senior notes[3][5]	$ 1,155,443	$ 1,098,025	$ 1,043,998	$ 992,894	$
Retained earnings (accumulated deficit)	$ 1,995,272	$ 300,314	$ 198,775	$ (911,272)	$ 809,642
Total stockholders equity[3]	$ 6,505,158	$ 4,465,583	$ 3,752,630	$ 2,051,546	$ 3,026,113

(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

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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.

(2)

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).

(3)

We adopted guidance for measuring and recognizing share-based payments to employees and directors, including grants of stock options beginning on January 1, 2006. See Notes 1 and 13 to our Consolidated Financial Statements of this Annual Report on Form 10-K.

On January 1, 2009, we adopted guidance for our convertible senior notes on a retrospective basis. The guidance required us to bifurcate the conversion option from the debt instrument by 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. See Item 8, Note 1 to our Consolidated Financial Statements included in this Annual Report on Form 10-K.

On January 1, 2009, we adopted guidance for our joint ventures with BMS on a retrospective basis. As a result of adopting this guidance, we presented the noncontrolling interest on our Consolidated Statements of Income as net loss attributable to noncontrolling interest, a component of consolidated net income, on a retrospective basis. See Item 8, Note 1 to our Consolidated Financial Statements included in this Annual Report on Form 10-K.

(4)

During 2009, we completed the acquisition of CV Therapeutics, Inc. We recognized consideration transferred of $1.39 billion which was primarily recorded in intangible assets. See Item 8, Note 5 to our Consolidated Financial Statements included in this Annual Report on Form 10-K.

(5)

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.

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ITEM 7. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following Management s Discussion and Analysis of Financial Condition and Results of Operations (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 products in the HIV/AIDS, liver diseases, respiratory and cardiovascular/metabolic therapeutic areas. Our products comprise 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; AmBisome® (amphotericin B liposome for injection) for the treatment of severe fungal infections; Letairis® (ambrisentan) for the treatment of pulmonary arterial hypertension (PAH); Ranexa® (ranolazine) for the treatment of chronic angina; Vistide® (cidofovir injection) for the treatment of cytomegalovirus infection and Cayston® (aztreonam for inhalation solution) as a treatment to improve respiratory symptoms in cystic fibrosis (CF) patients with *Pseudomonas aeruginosa* (*P. aeruginosa*). F. Hoffmann-La Roche Ltd (together with Hoffmann-La Roche Inc., Roche) markets Tamiflu® (oseltamivir phosphate) for the treatment and prevention of influenza under a royalty-paying collaborative agreement with us. Eyetech 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. Menarini International Operations Luxembourg SA markets Ranexa outside of the United States under a royalty-paying collaborative agreement with us. Astellas US LLC markets Lexiscan® (regadenoson) injection in the United States for use as a pharmacologic stress agent in radionuclide myocardial perfusion imaging (MPI) under a royalty-paying collaborative agreement with us.

Business Highlights

During 2009, we grew our business significantly and achieved record total revenues of $7.01 billion while strengthening our product portfolio and pipeline programs.

Our commercial achievements for 2009 comprised the continued rollout of Atripla in the European Union including the launch of Atripla in France, the growth of Atripla and Truvada product sales in the United States and Canada, making gains in the PAH market with Letairis, as well as continuing the expansion of our sales and marketing infrastructure.

We grew our product sales significantly and continued to strengthen our worldwide organization and infrastructure to support our expanded international footprint and business activities. In addition, we added Ranexa to our product portfolio through the acquisition of CV Therapeutics, Inc. (CV Therapeutics) in April 2009. In February 2010, we received marketing approval from the U.S. Food and Drug Administration (FDA) for Cayston as a treatment to improve respiratory symptoms in CF patients with *P. aeruginosa*. Cayston was conditionally approved in Europe and Canada in September 2009. Cayston is delivered via a specific inhalation device developed by PARI Pharma GmbH.

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We also made significant advances on the compounds and product candidates in our research and development (R&D) pipeline, including:

In the HIV area, in January 2010, we announced that both of the Phase 2 clinical studies of cobicistat (formerly GS 9350), our pharmacoenhancer that is in development as a boosting agent for certain HIV medicines, and a complete single-tablet fixed-dose regimen containing elvitegravir, cobicistat and Truvada in treatment-naïve patients met their primary objectives of non-inferiority. Pending discussion with the FDA, we expect to initiate three Phase 3 studies before the middle of 2010: two studies for the single-tablet fixed-dose regimen mentioned above and one study for cobicistat. In December 2009, we completed enrollment in the Phase 3 study evaluating elvitegravir in treatment-experienced patients. In addition, in collaboration with Tibotec Pharmaceuticals (Tibotec), we are developing a new once-daily fixed-dose combination containing our Truvada and Tibotec s investigational non-nucleoside reverse transcriptase inhibitor, TMC278 (25 mg rilpivirine hydrochloride), which is currently in Phase 3 clinical trials. Subject to positive outcome of this study, we intend to submit marketing applications for the fixed-dose combination of Truvada and TMC278 in the United States and Europe during the second half of 2010.

In the liver disease area, we completed the Phase 2a studies of GS 9450, the caspase inhibitor we licensed from LG Life Sciences, Ltd. in 2007, that is in development for the treatment of hepatitis C and nonalcoholic steatohepatitis and expect to present the results in the second quarter of 2010. We are continuing the Phase 2b study of GS 9450 for the treatment of hepatitis C. We are also continuing our Phase 2 study of GS 9190, a non-nucleoside polymerase inhibitor being evaluated for the treatment of hepatitis C infection, and expect to complete the study in the second half of 2010.

In the cardiovascular and metabolic areas, we expanded our product candidate portfolio through the acquisition of CV Therapeutics. We anticipate commencing patient enrollment in a Phase 2 study of ranolazine for the treatment of diastolic heart failure in patients with preserved ejection fraction in the second quarter of 2010. We are continuing our Phase 3 study of ambrisentan in patients with pulmonary hypertension secondary to idiopathic pulmonary fibrosis (IPF). We are also collaborating with GSK to develop a clinical trial to study combination therapy versus monotherapy in a first-line treatment setting for PAH. The study, AMBITION, will evaluate first-line combination use with ambrisentan, an endothelin receptor antagonist (ERA), and tadalafil, a PDE5 inhibitor, in patients with PAH. We are continuing our Phase 2 study of cicletanine hydrochloride, an oral agent in development for the treatment of PAH. We announced plans to terminate development of darusentan for the treatment of resistant hypertension after our second Phase 3 study of the compound failed to meet its co-primary efficacy endpoints. In May 2009, we announced that our marketing authorization application for regadenoson, an investigational pharmacologic stress agent for radionuclide MPI, was validated by the European Medicines Agency (EMEA). Following validation of the marketing authorization application, the dossier is distributed to members of the Committee for Medicinal Products for Human Use (CHMP) for formal review to determine whether regadenoson is a safe and efficacious pharmacologic stress agent in humans.

In the respiratory area, we are continuing the Phase 3 study of ambrisentan for the treatment of IPF and anticipate completing enrollment of patients in this study by the end of 2010. We are continuing the Phase 2 study of GS 9310/11, an inhaled co-formulation of fosfomycin and tobramycin, for the treatment of bacterial infections associated with CF, the Phase 2 study of aztreonam for inhalation solution for the treatment of bronchiectasis and the Phase 1 study of GS 9411, an oral epithelial sodium channel blocker designed to increase airway hydration for the treatment of pulmonary disease.

Acquisition of CV Therapeutics and Restructuring

In April 2009, we completed the acquisition of CV Therapeutics, a publicly-held biopharmaceutical company based in Palo Alto, California, primarily focused on the discovery, development and commercialization of small molecule drugs for the treatment of cardiovascular, metabolic and pulmonary diseases. CV Therapeutics

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had two marketed products as well as several product candidates in clinical development for the treatment of cardiovascular, metabolic and pulmonary diseases. We believe the acquisition will provide us with an opportunity to further expand into the cardiovascular therapeutic area.

We adopted the new business combinations guidance for recognizing and measuring assets acquired, liabilities assumed and any noncontrolling interests in the acquiree and applied it to the CV Therapeutics acquisition. As a result, we recognized consideration transferred of $1.39 billion and recorded $951.2 million and $138.9 million in intangible assets relating to marketed products and in-process research and development (IPR&D) projects, respectively, which constituted a significant portion of the assets acquired from CV Therapeutics. The results of operations of CV Therapeutics beginning on April 15, 2009, the acquisition date, were included in our Consolidated Financial Statements for the year ended December 31, 2009.

During the second quarter of 2009, we approved a plan to realize certain synergies between CV Therapeutics and us, re-align our cardiovascular operations and eliminate certain redundancies. The restructuring plan included consolidation and re-alignment of the cardiovascular R&D organization, our exit from certain facilities and the termination of certain contractual obligations. As a result of this restructuring plan, we recorded $26.2 million and $25.7 million in selling, general and administrative (SG&A) expenses and R&D expenses, respectively, in 2009, primarily related to employee severance, relocation and termination benefits, lease termination costs and other facilities-related expenses. We expect to incur an additional $20.2 million in 2010 bringing the total amount to be incurred in connection with the significant activities of our restructuring plan to be approximately $38.8 million for employee severance, relocation and termination benefits and $33.3 million for facilities-related expenses.

Financial Highlights

Our operating results for the year were led by total product sales of $6.47 billion. Antiviral product sales (Truvada, Atripla, Viread, Hepsera and Emtriva) increased 25% to $5.84 billion in 2009 from $4.67 billion in 2008, and were the key drivers for total product sales growth of 27% for 2009 as compared to 2008. With the continued uptake of Atripla in the United States and Europe, Atripla contributed $2.38 billion, or 41%, to our total 2009 antiviral product sales. The growth of Atripla product sales and its increased proportion to overall product sales caused total product gross margin to decrease to 75% in 2009 from 78% in 2008, due primarily to the efavirenz component of Atripla sales at zero gross margin. Truvada product sales for 2009 comprised $2.49 billion, or 43% of our total 2009 antiviral product sales. Truvada product sales for 2009 increased 18% from 2008 primarily due to continued sales volume growth in the United States and Europe. Foreign currency fluctuations in 2009 had an unfavorable impact of approximately $98.5 million on total revenues and $33.6 million on pre-tax income when compared to 2008.

Royalty revenues that we recognized from our collaborations with corporate partners were $491.8 million in 2009, an increase of 125% from royalty revenues of $218.2 million in 2008. The increase in royalty revenues was due primarily to increased Tamiflu sales by Roche related to pandemic planning initiatives worldwide.

Operating expenses increased $825.0 million in 2009, or 31%, compared to 2008, 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.

Cash, cash equivalents and marketable securities increased by $665.2 million during the year, driven primarily by our operating cash flows of $3.08 billion partially offset by cash used to acquire CV Therapeutics of $1.13 billion, net of cash, cash equivalents and marketable securities acquired from CV Therapeutics of $245.4 million, and $998.5 million used to repurchase approximately 21.8 million shares of our common stock through open market purchases under the now completed $3.00 billion stock repurchase program authorized by our Board of Directors (Board) in October 2007.

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2010 Outlook

Our operating objectives for 2010 include increasing the market share of our commercial products, 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, we have a number of internal and external initiatives intended to promote the continued growth of our franchises. In the HIV area, we expect a favorable impact from our updated Atripla label that includes data from Study 073 supporting switching patients from other HIV regimens to Atripla, revised U.S. Department of Health and Human Services treatment guidelines that recommend earlier treatment for patients with HIV and the extension of the Ryan White Treatment Act which should provide stable funding for AIDS Drug Assistance Programs in the United States through 2013. In the hepatitis B virus (HBV) area, we will continue to support educational and promotional activities focused on Asian communities, highlighting the need to screen, diagnose and link patients to care. As part of those efforts, we will have a larger hepatitis B field team in 2010 in the United States. In the cardiovascular area, we will continue in our efforts to raise awareness of Gilead in the PAH and cardiology communities and believe this will help grow revenues of Letairis and Ranexa in 2010.

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 potential healthcare reform in the United States, continued government pricing pressures internationally and the potential volatility in foreign currency exchange rates. We will continue to monitor these factors and will adjust our business processes to mitigate these risks to our business.

The successes we experienced in 2009 have helped us maintain and build a financially sound business model that we believe will allow us to continue to further expand our commercial, collaborative and R&D activities and to maintain quality and compliance. 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 2010.

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, intangible assets, 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.

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 collectability is reasonably assured. We record estimated reductions to revenues for government rebates such as Medicaid reimbursements, customer

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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 reductions to our revenues for 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. These reductions are settled either by the company being invoiced directly or through charge-backs from our wholesalers. 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 contractual government 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 channel inventory data obtained from our major U.S. wholesalers in accordance with our inventory management agreements. During 2009, 2008 and 2007, U.S government rebates of $885.5 million, $625.0 million and $423.3 million, respectively, representing 12%, 10% and 10% of total gross product sales, respectively, were deducted from gross product sales. We believe that the methodology that we use to estimate our sales allowances for government price reductions is reasonable and appropriate given the current facts and circumstances. However, actual results may differ. 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, 2009 and 2008, we had accrued U.S. government rebates of $242.9 million and $173.4 million, respectively, in other accrued liabilities and an allowance of $41.8 million and $32.8 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
Year ended December 31, 2009:				
Government rebates allowances and accrued liabilities				
Activity related to 2009 sales	$	$ 878,593	$ 594,579	$ 284,014
Activity related to sales prior to 2009	206,273	6,902	212,547	628
Total	$ 206,273	$ 885,495	$ 807,126	$ 284,642
Year ended December 31, 2008:				
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
Total	$ 139,370	$ 624,970	$ 558,067	$ 206,273

Intangible Assets

In conjunction with business combinations that we have completed, we have recorded intangible assets primarily related to marketed products, IPR&D projects and goodwill as part of our recognition and measurement of assets acquired and liabilities assumed in a business combination. Identifiable intangible assets, such as those

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related to marketed products or IPR&D projects, are measured at their respective fair values as of the acquisition date. We believe the fair values assigned to our acquired intangible assets are based on reasonable estimates and assumptions given the available facts and circumstances as of the acquisition dates. Discounted cash flow models are used in valuing these intangible assets, and these models require the use of significant estimates and assumptions including but not limited to:

- estimates of revenues and operating profits related to the products or product candidates;
- the probability of success for unapproved product candidates considering their stages of development;
- the time and resources needed to complete the development and approval of product candidates;
- the life of the potential commercialized products and associated risks, including the inherent difficulties and uncertainties in developing a product candidate such as obtaining FDA and other regulatory approvals; and
- risks related to the viability of and potential alternative treatments in any future target markets.

Goodwill represents the excess of the consideration transferred over the estimated fair values of assets acquired and liabilities assumed in a business combination. Goodwill and intangible assets determined to have indefinite useful lives are not amortized, but are required to be tested for impairment at least annually. We test goodwill and other indefinite-lived intangible assets 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 values of the assets below their carrying amounts. As of December 31, 2009, we had $601.5 million of indefinite-lived intangible assets consisting of $462.6 million of goodwill resulting from various business combinations and $138.9 million of intangible assets related to the IPR&D projects that we acquired from CV Therapeutics.

Of the $138.9 million of IPR&D intangible assets that we acquired from CV Therapeutics, $93.4 million related to GS 9667 (formerly CVT-3619), a product candidate in Phase 1 clinical studies for the treatment of hypertriglyceridemia. The remaining balance of the intangible assets related to the IPR&D projects represented various other in-process projects with no single project comprising a significant portion of the total value. The estimated fair value of the IPR&D intangible assets acquired from CV Therapeutics was determined using the income approach, which discounts expected future cash flows to present value. We estimated the fair value of these intangible assets using a present value discount rate of 9%, which is based on the estimated weighted-average cost of capital for companies with profiles substantially similar to that of CV Therapeutics. This is comparable to the estimated internal rate of return for CV Therapeutics operations and represents the rate that market participants would use to value the intangible assets. We compensated for the differing phases of development of each project by probability-adjusting our estimation of the expected future cash flows associated with each project. We then determined the present value of the expected future cash flows using the discount rate of 9%. The projected cash flows from the IPR&D projects were based on various estimates and assumptions including those noted above.

Intangible assets with finite useful 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. We are amortizing the intangible asset related to the Ranexa product, which we acquired from CV Therapeutics, over its estimated useful life using an amortization rate derived from our forecasted future product sales for Ranexa. 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, we will prospectively update the rate used to amortize our intangible asset related to Ranexa which may increase future cost of goods sold, as that is where we record the amortization expense. We are amortizing the intangible asset related to the Lexiscan product, which we also acquired from CV Therapeutics, over its estimated useful life to cost of goods sold on a

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straight-line basis. Given that current Lexiscan revenues consist of royalties received from a collaboration partner and we will have limited ongoing access and visibility into that partner s future sales forecasts, we cannot make a reasonable estimate of the amortization rate utilizing a forecasted product sales approach. As of December 31, 2009, we had $923.3 million of net unamortized finite-lived intangible assets consisting primarily of intangible assets related to the marketed products that we acquired from CV Therapeutics.

Our judgment regarding the existence of impairment indicators is based on our historical and projected future operating results, our extent or manner of use of the acquired assets, legal and regulatory factors and events, our overall business strategy and market and economic trends. If events occur in the future that cause us to conclude that impairment indicators exist and that certain intangible assets are impaired, our financial condition and results of operations may be adversely impacted.

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, 2008 to December 31, 2009. 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 periodically 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.

We amortize our prepaid royalties based on an effective royalty rate that we derive from forecasted future 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 cost of goods sold, as that is where we record the amortization expense. As of December 31, 2009 and 2008, we had a prepaid royalty asset relating to the emtricitabine royalties we paid to Emory of $245.0 million and $275.0 million, respectively. Amortization expense relating to this prepaid royalty asset was $29.9 million, $31.8 million and $14.3 million for the years ended December 31, 2009, 2008 and 2007, respectively.

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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 2009, 2008 and 2007, we incurred CRO costs of $109.9 million, $111.8 million and $65.6 million, respectively. We accrue costs for clinical studies performed by CROs 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 2009, 2008 and 2007 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, Letairis and Ranexa. 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, 2009, 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.

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 2009 and 2008 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 $14.0 million and $15.5 million for 2009 and 2008, 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.

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At December 31, 2009 and 2008, we had total federal, state and foreign unrecognized tax benefits of $93.3 million and $119.3 million, respectively, including interest of $5.4 million and $10.1 million, respectively. Of the total unrecognized tax benefits, $74.7 million and $111.1 million at December 31, 2009 and 2008, respectively, if recognized, would reduce our effective tax rate in the period of recognition.

In 2009, we reached agreement with the Internal Revenue Service (IRS) on several issues related to the examinations of our federal income tax returns for 2003 through 2007. We also amended our California income tax returns for 2003 through 2007 based on the resolution of certain tax positions with the IRS. As a result, we reduced our unrecognized tax benefits by $76.2 million in 2009.

As of December 31, 2009, we believe it is reasonably possible that our unrecognized tax benefits will decrease by approximately $5.0 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 tax authorities.

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

Our income tax returns are audited by federal, state and foreign tax authorities. We are currently under examination by the IRS for the 2005, 2006 and 2007 tax years and by various state and foreign jurisdictions. There are differing interpretations of tax laws and regulations, and as a result, significant disputes may arise with these tax authorities involving issues of the timing and amount of deductions and allocations of income among various tax jurisdictions. We periodically evaluate our exposures associated with our tax filing positions.

We record liabilities related to uncertain tax positions in accordance with the guidance that clarifies the accounting for uncertainty in income taxes recognized in an enterprise s financial statements by prescribing a minimum recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. We do not believe any such uncertain tax positions currently pending will have a material adverse effect on our Consolidated Financial Statements, although an adverse resolution of one or more of these uncertain tax positions in any period could have a material impact on the results of operations for that period.

Stock-based Compensation

We measure all share-based payments to employees and directors, including grants of stock options, based on their relative fair values. Fair values of awards granted under our stock option plans and Employee Stock Purchase Plan 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.

Stock-based compensation is recognized as expense over the requisite service periods in our Consolidated Statements of Income using a graded vesting expense attribution approach for non-vested stock options granted prior to January 1, 2006, and using the straight-line expense attribution approach for stock options granted after our adoption of new guidance for share-based payments to employees and directors on January 1, 2006. As stock-based compensation expenses related to stock options recognized on adoption of the new guidance is based on awards ultimately expected to vest, gross expense has been reduced for estimated forfeitures. The guidance requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual

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forfeitures differ from those estimates. We estimated forfeitures based on our historical experience. Prior to the adoption of this guidance, pro forma information that was required to be disclosed included forfeitures as they occurred. As a result of the guidance adopted on January 1, 2006, we 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 our Consolidated Statements of Income rather than through APIC.

During the years ended December 31, 2009, 2008 and 2007, we recognized stock-based compensation expenses of $185.8 million, $153.4 million and $184.6 million, respectively, in operating expenses, and we capitalized $11.4 million, $9.9 million and $9.8 million, respectively, to inventory. As of December 31, 2009, we had unrecognized stock-based compensation expenses of $347.4 million related to non-vested stock options, which we expect to expense over an estimated weighted-average period of 2.7 years.

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

Results of Operations

Total Revenues

We had total revenues of $7.01 billion in 2009, $5.34 billion in 2008 and $4.23 billion in 2007. Included in total revenues were product sales, royalty revenues and contract and other revenues.

Product Sales

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

	2009	Change	2008	Change	2007
Antiviral products:					
Truvada	$ 2,489,682	18%	$ 2,106,687	33%	$ 1,589,229
Atripla	2,382,113	51%	1,572,455	74%	903,381
Viread	667,510	7%	621,187	1%	613,169
Hepsera	271,595	(20)%	341,023	13%	302,722
Emtriva	27,974	(10)%	31,080	(1)%	31,493
Total antiviral products	5,838,874	25%	4,672,432	36%	3,439,994
AmBisome	298,597	3%	289,651	10%	262,571
Letairis	183,949	63%	112,855	437%	21,020
Ranexa	131,062				
Other	16,829	71%	9,858	4%	9,524
Total product sales	$ 6,469,311	27%	$ 5,084,796	36%	$ 3,733,109

Total product sales increased by 27% in 2009 compared to 2008 and 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 loss from the appreciation of the U.S. dollar of approximately $98.5 million for 2009 compared to 2008, and a net benefit from the depreciation of the U.S. dollar of approximately $148.2 million for 2008 compared to 2007. A significant percentage of our product sales continued to be denominated in foreign currencies. We used foreign currency exchange 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.

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Antiviral Products

Antiviral product sales increased 25% in 2009 compared to 2008 and by 36% in 2008 compared to 2007, driven primarily by sales volume growth of Atripla and Truvada. The increase in 2008 compared to 2007 was also due to a favorable foreign currency exchange impact.

Truvada

Truvada sales increased by 18% in 2009 compared to 2008, driven primarily by sales volume growth in the United States and Europe, partially offset by an unfavorable foreign currency exchange impact. 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 accounted for 43%, 45% and 46% of our total antiviral product sales for 2009, 2008 and 2007, respectively.

Atripla

Atripla sales increased by 51% in 2009 compared to 2008, driven primarily by sales volume growth in the United States and Europe. The European growth benefited from the launch of Atripla in France in the second quarter of 2009. 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 include the efavirenz portion at zero product gross margin. The efavirenz portion of our Atripla sales was approximately $880.7 million, $576.0 million and $334.3 million in 2009, 2008 and 2007, respectively. Atripla sales accounted for 41%, 34% and 26% of our total antiviral product sales for 2009, 2008 and 2007, respectively.

Other Antiviral Products

Other antiviral product sales, which include product sales of Viread, Hepsera and Emtriva decreased by 3% for 2009 compared to 2008, driven primarily by sales volume decreases in Hepsera, partially offset by sales volume increases in Viread for the treatment of patients with chronic hepatitis B. Other antiviral product sales increased by 5% in 2008 compared to 2007, driven primarily by a 13% increase in Hepsera sales which benefited from a favorable foreign currency exchange impact as well as sales volume growth in certain European countries.

AmBisome

Sales of AmBisome increased 3% in 2009 compared to 2008, driven primarily by sales volume growth in certain European markets, partially offset by an unfavorable foreign currency exchange impact. Sales of AmBisome increased 10% in 2008 compared to 2007, driven primarily by a favorable foreign currency exchange impact and sales volume growth in certain European markets. AmBisome product sales in the United States and Canada relate solely to our sales of AmBisome to Astellas Pharma US, Inc. which are recorded at our manufacturing cost.

Letairis

Sales of Letairis for the treatment of PAH increased by 63% for 2009 compared to 2008, driven primarily by sales volume growth in the United States. Sales of Letairis increased 437% in 2008 compared to 2007, driven primarily by sales volume growth in the United States as Letairis was launched in June of 2007.

Ranexa

Sales of Ranexa were $131.1 million for the period from April 15, 2009 (the date of our acquisition of CV Therapeutics) to December 31, 2009.

We expect total product sales to continue to grow in 2010 as we continue to expand our sales and marketing efforts.

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Royalty Revenues

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

	2009	Change	2008	Change	2007
Royalty revenues	$ 491,818	125%	$ 218,180	(53)%	$ 468,155

Our most significant source of royalty revenues for 2009, 2008 and 2007 was from sales of Tamiflu by Roche.

Royalty revenues for 2009 were $491.8 million, an increase of 125% compared to 2008, driven primarily by the recognition of Tamiflu royalties from Roche of $392.7 million in 2009 compared to Tamiflu royalties from Roche of $155.5 million in 2008. The higher Tamiflu royalties for 2009 were due to increased Tamiflu sales by Roche related primarily to pandemic planning initiatives worldwide. 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. 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:

	2009	Change	2008	Change	2007
Total product sales	$ 6,469,311	27%	$ 5,084,796	36%	$ 3,733,109
Cost of goods sold	$ 1,595,558	42%	$ 1,127,246	47%	$ 768,771
Product gross margin	75%		78%		79%

Our product gross margin for 2009 was 75%, compared to 78% for 2008. The lower product gross margin in 2009 was due primarily to the higher proportion of Atripla sales, which include the efavirenz portion at zero product gross margin, as well as the amortization associated with the intangible assets acquired in our acquisition of CV Therapeutics. Our product gross margin for 2008 was 78% compared to 79% for 2007. The decrease in product gross margin was due primarily to the higher 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 Bristol-Myers Squibb Company (BMS) at BMS s net selling price of efavirenz.

We expect our product gross margin in 2010 to be lower compared to 2009, due primarily to a higher proportion of expected Atripla sales.

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Research and Development Expenses

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

	2009	Change	2008	Change	2007
Research	$ 185,019	16%	$ 159,148	21%	$ 131,019
Clinical development	615,041	37%	449,598	25%	361,091
Pharmaceutical development	139,858	24%	113,022	14%	98,916
Total research and development	$ 939,918	30%	$ 721,768	22%	$ 591,026

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

R&D expenses in 2009 increased by $218.2 million or 30%, compared to 2008, due primarily to increased compensation and benefits expenses of $88.8 million driven by higher headcount related to the growth of our business, the R&D expense reimbursement related to our Tibotec TMC278 collaboration of $52.4 million and increased clinical study expenses of $23.9 million. The increase in compensation and benefits expenses was also driven by severance and termination benefits associated with our restructuring activities related to our acquisition of CV Therapeutics.

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 benefits expenses of $50.7 million due primarily to higher headcount.

In general, significant collaboration payments, like those made to Tibotec, will cause our R&D expenses to fluctuate period over period. In 2010, we expect R&D expenses to increase over 2009 levels due to increased spending on our internal and collaborative R&D efforts as we anticipate that some of our product candidates will progress 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):

	2009	Change	2008	Change	2007
Selling, general and administrative	$ 946,686	19%	$ 797,344	13%	$ 705,741

SG&A expenses in 2009 increased by $149.3 million or 19%, compared to 2008, due primarily to increased compensation and benefits expenses of $75.4 million driven by higher headcount related to the growth of our business, increased contract and professional services expenses of $46.6 million driven primarily by our expanding sales and marketing activities and $5.8 million related to certain contract termination costs. The increase in compensation and benefits expenses was also driven by severance and termination benefits associated with our restructuring activities related to our acquisition of CV Therapeutics.

SG&A expenses for 2008 increased by $91.6 million or 13%, compared to 2007, due primarily to increased compensation and benefits expenses of $41.6 million due largely to higher headcount, increased marketing and

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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, and costs of $12.4 million associated with certain employee termination-related disputes in our international operations.

In 2010, we expect SG&A expenses to increase over 2009 levels due to increased investment to support the growth in our HIV franchise, the full year impact of sales and marketing activities for Ranexa and the commercialization of Cayston. We believe we have the appropriate infrastructure to support the growth of our business in 2010.

Purchased In-process Research and Development Expenses

In connection with our acquisition of the cicletanine assets from Navitas Assets, LLC in 2008, we recorded IPR&D expense of $10.9 million during the year ended December 31, 2008. As we do not consider the acquisition to be a material purchase, we have not made further disclosures regarding the related purchased IPR&D.

In connection with our acquisition of Myogen in 2006, we recorded purchased IPR&D expenses of $2.06 billion during the year ended December 31, 2006 related to the ambrisentan and darusentan IPR&D projects that we acquired. The purchased IPR&D expense represented the estimated fair value of Myogen s incomplete R&D projects that had not yet reached technological feasibility and had no alternative future uses as of the acquisition date and, therefore, was expensed upon acquisition. With respect to ambrisentan, in June 2007, the FDA approved Letairis for the treatment of PAH in the United States. Additionally, in April 2008, the European Commission granted our collaboration partner, GSK, marketing authorization for ambrisentan for the treatment of PAH, which is marketed under the name Volibris by GSK. With respect to darusentan, in December 2009, we announced plans to terminate the development of darusentan for the treatment of resistant hypertension after our second Phase 3 study of the compound failed to meet its co-primary efficacy endpoints.

In connection with our acquisition of Corus Pharma, Inc. (Corus) in 2006, we recorded purchased IPR&D expenses of $335.6 million during the year ended December 31, 2006 related to the aztreonam for inhalation solution for CF IPR&D project that we acquired. The purchased IPR&D expense represented the estimated fair value of Corus s incomplete R&D project that had not yet reached technological feasibility and had no alternative future use as of the acquisition date and, therefore, was expensed upon acquisition. In February 2010, we received marketing approval from the FDA for Cayston as a treatment to improve respiratory symptoms in CF patients with *P. aeruginosa*. Cayston was conditionally approved in Europe and Canada in September 2009.

Interest and Other Income, Net

We recorded interest and other income, net, of $42.4 million, $59.4 million and $109.8 million in 2009, 2008 and 2007, respectively. The decrease in 2009 compared to 2008 was due primarily to decreased interest income of $40.6 million driven by a reduction in the average yield of our investment portfolio as a result of lower interest rates, partially offset by an increase in net foreign currency exchange gains of $15.7 million. 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 exchange 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.

Interest Expense

On January 1, 2009, we adopted guidance for our convertible senior notes due in 2011 (2011 Notes) and convertible senior notes due in 2013 (2013 Notes) (collectively, the Notes) on a retrospective basis. The guidance requires us to bifurcate the conversion option from the debt instrument by 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. As a result of the retrospective adoption of this guidance, we reflected additional interest expense of

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$53.1 million and $50.1 million, respectively, and a related benefit from income taxes of $20.9 million and $19.7 million, respectively, in 2008 and 2007. We recorded additional interest expense of $56.2 million and a related benefit from income taxes of $21.9 million in 2009.

Our interest expense was $69.7 million, $65.2 million and $63.2 million in 2009, 2008 and 2007, respectively. The increases in 2009 compared to 2008 and in 2008 compared to 2007 were due primarily to the effect of accreting the debt discount on the Notes as additional interest expense over the expected life of the debt as discussed above.

Provision for Income Taxes

Our provision for income taxes was $876.4 million, $702.4 million and $635.4 million in 2009, 2008 and 2007, respectively. The 2009 effective tax rate of 25.0% differed from the U.S. federal statutory rate of 35% due primarily to tax credits, the resolution of certain tax positions with tax authorities and certain operating earnings from non-U.S. subsidiaries that are considered indefinitely invested outside the United States, partially offset by state taxes and the revaluation of certain state tax assets related to the integration of CV Therapeutics. We do not provide for U.S. income taxes on undistributed earnings of our foreign operations that are intended to be permanently reinvested.

The 2008 effective tax rate of 26.3% differs from the U.S. federal statutory rate of 35% due primarily to tax credits, the resolution of certain tax positions with tax authorities and certain operating earnings from non-U.S. subsidiaries that are considered indefinitely invested outside the United States, partially offset by state taxes.

The 2007 effective tax rate of 28.7% 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, partially offset by state taxes.

As of December 31, 2009 and 2008, we had total federal, state and foreign unrecognized tax benefits of $93.3 million and $119.3 million, respectively, including interest of $5.4 million and $10.1 million, respectively. Of the total unrecognized tax benefits, $74.7 million and $111.1 million at December 31, 2009 and 2008, respectively, if recognized, would reduce our effective tax rate in the period of recognition. 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 Income.

In 2009, we reached agreement with the IRS on several issues related to the examinations of our federal income tax returns for 2003 through 2007. We also amended our California income tax returns for 2003 through 2007 based on the resolution of certain tax positions with the IRS. As a result, we reduced our unrecognized tax benefits by $76.2 million in 2009.

As of December 31, 2009, we believe it is reasonably possible that our unrecognized tax benefits will decrease by approximately $5.0 million in the next 12 months as we expect to have clarification from the IRS and other tax authorities 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 tax authorities.

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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):

	2009	2008	2007
As of December 31:			
Cash, cash equivalents and marketable securities	$ 3,904,846	$ 3,239,639	$ 2,722,422
Working capital	$ 2,940,927	$ 3,057,416	$ 2,271,344
Year Ended December 31:			
Cash provided by (used in):			
Operating activities	$ 3,080,054	$ 2,143,384	$ 1,669,082
Investing activities	$ (2,215,900)	$ (178,819)	$ (1,302,467)
Financing activities	$ (1,051,438)	$ (1,474,569)	$ (170,983)

Cash, Cash Equivalents and Marketable Securities

Cash, cash equivalents and marketable securities totaled $3.90 billion at December 31, 2009, an increase of $665.2 million or 21% from December 31, 2008. This increase was primarily attributable to net cash provided by operations of $3.08 billion and proceeds from issuances of common stock under our employee stock plans of $222.7 million, partially offset by the following:

- cash used to acquire CV Therapeutics of $1.13 billion, net of cash, cash equivalents and marketable securities acquired from CV Therapeutics of $245.4 million;
- $998.5 million used to repurchase our common stock under our stock repurchase program; and
- $305.5 million used to extinguish the convertible senior notes we assumed in our acquisition of CV Therapeutics.

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 $2.14 billion in 2008; and
- proceeds from issuances of common stock under our employee stock plans of $246.1 million in 2008.

This increase from 2007 to 2008 was partially offset by our repurchases of $1.97 billion of our common stock under our stock repurchase program during 2008.

Working Capital

Working capital was $2.94 billion at December 31, 2009, a decrease of $116.5 million or 4% from working capital as of December 31, 2008. This decrease was primarily attributable to:

- an increase of $209.3 million in accounts payable due primarily to the purchases of efavirenz at its estimated market value from BMS; and

a decrease of $133.1 million in cash, cash equivalents and short-term marketable securities since we held a higher proportion of long-term marketable securities as of December 31, 2009 compared to December 31, 2008.

This decrease from 2008 to 2009 was partially offset by an increase of $366.1 million in our accounts receivable, net, driven primarily by increased product sales.

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Working capital at December 31, 2008 was $3.06 billion, an increase of $786.1 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 its estimated market value from BMS;
- an increase of $228.3 million in accounts receivable, net, driven primarily by increased product sales; and
- an increase of $618.1 million in cash, cash equivalents and short-term marketable securities.

This increase from 2007 to 2008 was partially offset by a $310.9 million increase in accounts payable due primarily to the purchases of efavirenz at its estimated market value from BMS.

Cash Provided by Operating Activities

Cash provided by operating activities of $3.08 billion in 2009 primarily related to net income of $2.63 billion, adjusted for non-cash items such as $180.7 million of stock-based compensation expenses and $148.4 million of amortization expenses. As a result of our adoption of the guidance for our joint ventures with BMS on January 1, 2009, we reclassified the change in noncontrolling interest from cash provided by operating activities to cash used in financing activities.

Cash provided by operating activities of $2.14 billion in 2008 primarily related to net income of $1.97 billion, 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 expenses. This was partially offset by $191.9 million of excess tax benefits from stock option exercises which we reclassified to cash used in financing activities.

Cash provided by operating activities of $1.67 billion in 2007 primarily related to net income of $1.58 billion, adjusted for non-cash items such as $184.6 million of stock-based compensation expenses, $113.4 million of deferred income taxes and $110.7 million of tax benefits related to employee stock plans. This was partially offset by a $332.4 million net cash outflow related to changes in operating assets and liabilities.

Cash Used in Investing Activities

Cash used in investing activities in 2009 was $2.22 billion, driven by cash used for our acquisition of CV Therapeutics of $1.25 billion (net of cash acquired), a net use of $738.0 million in purchases of marketable securities and $230.1 million of capital expenditures for the year. Capital expenditures made in 2009, 2008 and 2007 related primarily to the expansion of our manufacturing capabilities, upgrades to our facilities and spending on computer and laboratory equipment, as well as enterprise software, to accommodate our continued business growth. Capital expenditures in 2009 also included the purchase of an office building and approximately 30 acres of land located in Foster City, California.

Cash used in investing activities in 2008 was $178.8 million, driven primarily by a net use of $53.0 million in purchases of marketable securities and $115.0 million of capital expenditures for the year.

Cash used in investing activities in 2007 was $1.30 billion, driven primarily by a net use of $1.17 billion in purchases of marketable securities, cash used in our acquisition of Nycomed Limited of $46.4 million (net of cash acquired) and $78.6 million of capital expenditures for the year. Capital expenditures in 2007 included the construction of a new building at our Foster City, California headquarters.

As of December 31, 2009, we had capital expenditure commitments of $24.8 million, which consisted primarily of enterprise software purchase commitments. We expect to fulfill such commitments from funds generated from our operating cash flows.

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Cash Used in Financing Activities

Cash used in financing activities in 2009 was $1.05 billion, driven primarily by the $998.5 million used to repurchase our common stock under our stock repurchase program and the $305.5 million used to extinguish the convertible senior notes assumed from the acquisition of CV Therapeutics. The cash outflows were partially offset by proceeds of $222.7 million from issuances of common stock under our employee stock plans.

As a result of our adoption of the guidance for our joint ventures with BMS on January 1, 2009, we reclassified the change in noncontrolling interest from cash provided by operating activities to cash used in financing activities, as discussed above.

Under our amended and restated credit agreement, we, along with our wholly-owned subsidiary, Gilead Biopharmaceutics Ireland Corporation, may borrow up to an aggregate of $1.25 billion in revolving credit loans. The credit agreement also includes a sub-facility for swing-line loans and letters of credit. Loans under the credit agreement bear interest at an interest rate of either LIBOR plus a margin ranging from 0.20 percent to 0.32 percent or the base rate, as described in the credit agreement. In April 2009, in connection with the acquisition of CV Therapeutics, we borrowed $400.0 million under the credit agreement to partially fund the acquisition and had fully repaid the amount as of December 31, 2009. The credit agreement will terminate in December 2012 and all unpaid borrowings thereunder shall be due and payable at that time. We may reduce the commitments and may prepay loans under the credit agreement in whole or in part without penalty, subject to certain conditions. As of December 31, 2009, approximately $1.25 billion was available to be drawn down under this credit agreement.

Cash used in financing activities in 2008 was $1.47 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. In 2008, under this stock repurchase program, 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 and October 2008, we entered into accelerated share repurchase agreements with a financial institution to repurchase our common stock on an accelerated basis. For the February 2008 transaction, we paid $500.0 million to settle the initial purchase and received 9,373,548 shares of our common stock at a price of $53.34 per share. In June 2008, upon termination 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 total number of shares repurchased and retired under this accelerated share repurchase agreement was 9,613,160 shares at an average purchase price of $52.01 per share. For the October 2008 transaction, we paid $750.0 million to settle the initial purchase and received 14,874,519 shares of our common stock at a price of $50.42 per share. In March 2009, upon termination of the agreement we received an additional 1,356,337 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 total number of shares repurchased and retired under this accelerated share repurchase agreement was 16,230,856 shares at an average purchase price of $46.21 per share.

As of December 31, 2009, we completed share repurchases under our $3.00 billion stock repurchase program. In January 2010, our Board authorized a new program for the repurchase of our common stock in an aggregate amount of up to $1.00 billion through open market and private block transactions pursuant to Rule 10b5-1 plans, privately negotiated purchases or other means. This stock repurchase plan will expire in January 2011.

Cash used in financing activities in 2007 was $171.0 million, driven primarily by the $487.5 million used to repurchase our common stock under our stock repurchase program and $99.0 million used to pay off all

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remaining amounts due on our term loan, partially offset by proceeds from issuances of common stock under our employee stock plans of $243.4 million, distributions from noncontrolling interest of $96.3 million as well as $76.3 million of excess tax benefits from stock option exercises.

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.

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.

Contractual Obligations

Our contractual obligations consist of debt obligations, operating leases, 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, 2009 (in thousands):

		Payments due by Period			
Contractual Obligations	**Total**	**Less than one year**	**1-3 years**	**3-5 years**	**More than 5 years**

Convertible senior notes[1]	$ 1,299,854	$	$ 649,987	$ 649,867	$
Operating lease obligations	244,010	46,514	80,554	46,824	70,118
Capital commitments[2]	24,780	14,518	10,262		
Purchase obligations[3][4]	1,117,862	820,058	249,110	48,694	
Clinical trials[5]	201,814	95,478	76,186	26,793	3,357
Total	$ 2,888,320	$ 976,568	$ 1,066,099	$ 772,178	$ 73,475

(1) At December 31, 2009, we had outstanding principal of $1.16 billion under the Notes that we issued in April 2006.

(2) At December 31, 2009, we had firm capital project commitments of approximately $24.8 million primarily relating to enterprise software purchase commitments.

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(3) At December 31, 2009, we had firm purchase commitments related to active pharmaceutical ingredients and certain inventory-related items. These amounts represent minimum purchase requirements and 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, collaboration and development arrangements. 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 Sheets and have not been included in the table above.

(5) At December 31, 2009, we had several clinical studies in various clinical trial phases. Our most significant clinical trial expenditures are to CROs. Although all of our material contracts with CROs are cancelable, we historically have not cancelled such contracts. These amounts reflect commitments based on existing contracts and do not reflect any future modifications to, or terminations of, existing contracts or anticipated or potential new contracts.

We had total gross unrecognized tax benefit liabilities of $116.0 million as of December 31, 2009. We believe that it is reasonably possible that our unrecognized tax benefits will decrease by approximately $5.0 million in the next 12 months as we expect to have clarification from the tax authorities 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 tax authorities. Such amounts were included in long-term income taxes payable and non current deferred tax assets on our Consolidated Balance Sheet and have not been included in the table above.

Recent Accounting Pronouncements

In June 2009, the Financial Accounting Standards Board (FASB) issued amended standards for determining whether to consolidate a variable interest entity under Accounting Standards Codification (ASC) section 810-10-25. These amended standards eliminate a mandatory quantitative approach to determine whether a variable interest gives the entity a controlling financial interest in a variable interest entity in favor of a qualitatively focused analysis, and require an ongoing reassessment of whether the entity is a primarily beneficiary. The amended standards are effective for us beginning in the first quarter of 2010. We have been consolidating our joint ventures with BMS because we are the primary beneficiary. We are still evaluating whether the revised standard will have any impact on our Consolidated Financial Statements.

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

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,

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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 and 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.

The following table summarizes the notional amounts, weighted-average currency exchange rates and fair values of our open foreign currency exchange forward contracts at December 31, 2009. We had no foreign currency exchange option contracts outstanding at December 31, 2009. 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, 2009 (notional amounts and fair values in U.S. dollars and in thousands):

Foreign Currency Exchange Forward Contracts

Currency	Notional Amount	Weighted-Average Settlement Price	Fair Value
Euro	$ 2,728,279	1.43	$ (4,430)
British Pound	311,293	1.60	2,305
Canadian Dollar	153,218	1.12	(11,216)
Australian Dollar	81,632	0.84	(5,228)
Swiss Franc	67,976	1.06	(898)
Danish Krone	35,130	5.22	(318)
Swedish Krone	27,097	7.38	(581)
Norwegian Krone	18,163	6.05	(750)
New Zealand Dollar	16,683	0.81	(366)
Turkish Lira	6,134	1.52	(7)
Total	$ 3,445,605		$ (21,489)

The total notional amount of $3.45 billion and total fair value relating to our net liability of $21.5 million on our open foreign currency exchange forward contracts at December 31, 2009 compares with 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.

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 credit rating, maturity, 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.

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The following table summarizes the expected maturities and average interest rates of our interest-generating assets and interest-bearing liabilities at December 31, 2009 (dollars in thousands):

	Years Ending December 31,							Total Fair Value at December 31, 2009
	2010	2011	2012	2013	2014	Thereafter	Total	
Assets								
Available-for-sale debt securities	$ 442,757	$ 966,140	$ 854,743	$ 102,175	$ 23,020	$ 288,280	$ 2,677,115	$ 2,677,115
Average interest rate	0.5%	1.1%	1.7%	2.4%	3.3%	0.9%		
Liabilities								
Convertible senior notes[1]	$	$ 649,987	$	$ 649,867	$	$	$ 1,299,854	$ 1,577,695
Average interest rate		0.5%		0.6%				

(1) In April 2006, we issued the Notes in a private placement pursuant to Rule 144A of the Securities Act of 1933, as amended. The Notes were issued at par and bear interest rates of 0.50% and 0.625% for the 2011 Notes and 2013 Notes, respectively, and may be converted into shares of our common stock subject to certain circumstances.

Credit Risk

A portion of our marketable securities consist of 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, 2009, we held approximately $104.8 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 3% of our total cash, cash equivalents and marketable securities as of December 31, 2009. All of our auction rate securities, including those subject to the failed auctions, are currently rated AAA, consistent with the high quality rating required by our investment policy, are supported by the federal government as part of the Federal Family Education Loan Program, and are over-collateralized. Our auction rate securities reset every seven to 35 days with maturity dates ranging from 2023 through 2041 and have annual interest rates ranging from 0.4% to 1.2%. As of December 31, 2009, our auction rate securities continued to earn interest.

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

In light of the volatility and developments that we have seen in the financial markets, we continue to review our cash equivalents and marketable securities carefully and strive to invest prudently. We believe that maintaining the primary goals of our investment policy, safety and preservation of principal and diversification of risk, as well as liquidity, has protected us from many 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 strategic opportunities such as the acquisition of CV Therapeutics in 2009.

Our accounts receivable balance at December 31, 2009 was $1.39 billion, compared to $1.02 billion at December 31, 2008. The growth in our accounts receivable balance 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. At December 31,

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2009, our accounts receivable for Greece, Italy, Portugal and Spain totaled $753.6 million, of which $289.4 million was more than 120 days past due based on contractual payment terms. To date, we have not experienced significant losses with respect to the collection of our accounts receivable and believe that our accounts receivable, net of allowances, as reflected in our Consolidated Balance Sheets, are collectible.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required by this item are set forth beginning at page 78 of this Annual Report on Form 10-K 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, 2009 was carried out under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures, which are defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act), as controls and other procedures of a company that are designed to ensure that the information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission s rules and forms, and that such information is accumulated and communicated to the company s management, including its Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at December 31, 2009.

(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 Rule 13a-15(f) of the Exchange Act. 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, 2009.

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, 2009. Their report on the audit of internal control over financial reporting appears below.

(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, 2009, 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.

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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, 2009, 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, 2009, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the 2009 consolidated financial statements of Gilead Sciences, Inc. and our report dated March 1, 2010 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Palo Alto, California

March 1, 2010

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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 Securities and Exchange Commission pursuant to Regulation 14A in connection with our 2010 Annual Meeting of Stockholders (the Proxy Statement) under the headings Nominees, Qualification of 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 sections 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 sections 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.

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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:

(2) Schedule II is included on page 103 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)	2.1	Agreement and Plan of Merger among Registrant, Apex Merger Sub, Inc. and CV Therapeutics, Inc., dated as of March 12, 2009
(1)	2.2	Stockholder Agreement by and between Registrant and Louis G. Lange, dated as of March 12, 2009
(2)	3.1	Restated Certificate of Incorporation of the Registrant, as amended through May 8, 2008
(3)	3.2	Certificate of Designation of the Series A Junior Participating Preferred Stock of Registrant
(4)	3.3	Certificate of Amendment to Certificate of Designation of Series A Junior Participating Preferred Stock of the Registrant
(5)	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
(6)	4.2	Amended and Restated Rights Agreement between the Registrant and ChaseMellon Shareholder Services, LLC, dated October 21, 1999
(7)	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
(8)	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
(9)	4.5	Indenture related to the Convertible Senior Notes, due 2011, between Registrant and Wells Fargo Bank, National Association, as trustee (including form of 0.50% Convertible Senior Note due 2011), dated April 25, 2006
(9)	4.6	Indenture related to the Convertible Senior Notes, due 2013, between Registrant and Wells Fargo Bank, National Association, as trustee (including form of 0.625% Convertible Senior Note due 2013), dated April 25, 2006

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Exhibit Footnote	Exhibit Number	Description of Document
(10)	10.1	Confirmation of OTC Convertible Note Hedge related to 2011 Notes, dated April 19, 2006, as amended and restated as of April 24, 2006, between Registrant and Bank of America, N.A.
(10)	10.2	Confirmation of OTC Convertible Note Hedge related to 2013 Notes, dated April 19, 2006, as amended and restated as of April 24, 2006, between Registrant and Bank of America, N.A.
(10)	10.3	Confirmation of OTC Warrant Transaction, dated April 19, 2006, as amended and restated as of April 24, 2006, between Registrant and Bank of America, N.A. for warrants expiring in 2011
(10)	10.4	Confirmation of OTC Warrant Transaction, dated April 19, 2006, as amended and restated as of April 24, 2006, between Registrant and Bank of America, N.A. for warrants expiring in 2013
(11)	10.5	Amended and Restated Credit Agreement among Registrant, Gilead Biopharmaceutics Ireland Corporation, the lenders parties thereto and Bank of America, N.A., as Administrative Agent, Swing Line Lender and L/C Issuer, dated as of December 18, 2007
(11)	10.6	Parent Guaranty Agreement, dated as of December 18, 2007, by Registrant
(12)	10.7	Master Confirmation by and between Registrant and Citibank N.A., together with the Supplemental Confirmation, dated as of October 21, 2008
*(13)	10.8	Gilead Sciences, Inc. 1991 Stock Option Plan, as amended through January 29, 2003
*(14)	10.9	Form of option agreements used under the 1991 Stock Option Plan
*(13)	10.10	Gilead Sciences, Inc. 1995 Non-Employee Directors Stock Option Plan, as amended through January 30, 2002
*(15)	10.11	Form of option agreement used under the Gilead Sciences, Inc. 1995 Non-Employee Directors Stock Option Plan
*(16)	10.12	Gilead Sciences, Inc. 2004 Equity Incentive Plan, as amended through May 6, 2009
*(17)	10.13	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants prior to February 2008)
*(18)	10.14	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants made February 2008 through April 2009)
*(19)	10.15	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants made May 2009 through January 2010)
*	10.16	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants commencing in February 2010)
*(17)	10.17	Form of non-employee director stock option agreement used under 2004 Equity Incentive Plan (for grants prior to 2008)
*(18)	10.18	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for initial grants made in 2008)
*(18)	10.19	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for annual grants made in May 2008)
*(19)	10.20	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for annual grants commencing in May 2009)
*(19)	10.21	Form of restricted stock agreement used under 2004 Equity Incentive Plan (for annual grants to non-employee directors commencing in May 2009)
*(19)	10.22	Form of restricted stock agreement used under 2004 Equity Incentive Plan (for annual grants to certain non-employee directors)

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Exhibit Footnote	Exhibit Number	Description of Document
*(20)	10.23	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for grants made in 2007)
*(21)	10.24	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for grants made in 2008)
*(19)	10.25	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for grants made in 2009)
*	10.26	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for grants made in 2010)
*(22)	10.27	Form of restricted stock unit issuance agreement used under the 2004 Equity Incentive Plan (for grants made prior to May 2009)
*(19)	10.28	Form of restricted stock unit issuance agreement used under the 2004 Equity Incentive Plan (for grants commencing in May 2009)
*	10.29	Gilead Sciences, Inc. Employee Stock Purchase Plan, amended and restated on November 3, 2009
*(23)	10.30	Gilead Sciences, Inc. International Employee Stock Purchase Plan, adopted November 3, 2009
*(24)	10.31	Gilead Sciences, Inc. Deferred Compensation Plan Basic Plan Document
*(24)	10.32	Gilead Sciences, Inc. Deferred Compensation Plan Adoption Agreement
*(24)	10.33	Addendum to the Gilead Sciences, Inc. Deferred Compensation Plan
*(25)	10.34	Gilead Sciences, Inc. 2005 Deferred Compensation Plan, as amended and restated on October 23, 2008
*	10.35	Gilead Sciences, Inc. Severance Plan, as amended through January 28, 2010
*(17)	10.36	Gilead Sciences, Inc. Corporate Bonus Plan
*(17)	10.37	Gilead Sciences, Inc. Code Section 162(m) Bonus Plan
*(26)	10.38	2010 Base Salaries for the Named Executive Officers
*(27)	10.39	Offer Letter dated April 16, 2008 between Registrant and Robin Washington
*(14)	10.40	Form of Indemnity Agreement entered into between the Registrant and its directors and executive officers
*(14)	10.41	Form of Employee Proprietary Information and Invention Agreement entered into between Registrant and certain of its officers and key employees
*(20)	10.42	Form of Employee Proprietary Information and Invention Agreement entered into between Registrant and certain of its officers and key employees (revised in September 2006)
+(28)	10.43	Amended and Restated Collaboration Agreement by and among Registrant, Gilead Holdings, LLC, Bristol-Myers Squibb Company, E.R. Squibb & Sons, L.L.C., and Bristol-Myers Squibb & Gilead Sciences, LLC, dated September 28, 2006
+(18)	10.44	Commercialization Agreement by and between Gilead Sciences Limited and Bristol-Myers Squibb Company, dated December 10, 2007
+(29)	10.45	Amendment Agreement, dated October 25, 1993, between Registrant, the Institute of Organic Chemistry and Biochemistry (IOCB) and Rega Stichting v.z.w. (REGA), together with the following exhibits: the License Agreement, dated December 15, 1991, between Registrant, IOCB and REGA (the 1991 License Agreement), the License Agreement, dated October 15, 1992, between Registrant, IOCB and REGA (the October 1992 License Agreement) and the License Agreement, dated December 1, 1992, between Registrant, IOCB and REGA (the December 1992 License Agreement)

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Exhibit Footnote	Exhibit Number	Description of Document
(30)	10.46	Amendment Agreement between Registrant and IOCB/REGA, dated December 27, 2000 amending the 1991 License Agreement and the December 1992 License Agreement
(28)	10.47	Sixth Amendment Agreement to the License Agreement, between IOCB/REGA and Registrant, dated August 18, 2006 amending the October 1992 License Agreement and the December 1992 License Agreement
+(28)	10.48	Development and License Agreement among Registrant and F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc., dated September 27, 1996
+(31)	10.49	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
+(32)	10.50	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
+(33)	10.51	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
+(33)	10.52	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.
+(34)	10.53	License Agreement between Japan Tobacco Inc. and Registrant, dated March 22, 2005
+(35)	10.54	License Agreement between Registrant (as successor to Myogen, Inc.) and Abbott Deutschland Holding GmbH dated October 8, 2001
+(35)	10.55	License Agreement between Registrant (as successor to Myogen, Inc.) and Abbott Laboratories, dated June 30, 2003
+(36)	10.56	License Agreement between Registrant (as successor to CV Therapeutics, Inc.) and Syntex (U.S.A.) Inc., dated March 27, 1996
+(36)	10.57	First Amendment to License Agreement between Registrant (as successor to CV Therapeutics, Inc.) and Syntex (U.S.A.) Inc., dated July 3, 1997
(36)	10.58	Amendment No. 2 to License Agreement between Registrant (as successor to CV Therapeutics, Inc.) and Syntex (U.S.A.) Inc., dated November 30. 1999
+(37)	10.59	Amendment No. 4 to Collaboration and License Agreement with Registrant (as successor to CV Therapeutics, Inc.) and Roche Palo Alto LLC, dated June 20, 2006
+(38)	10.60	License and Collaboration Agreement by and among Registrant, Gilead Sciences Limited and Tibotec Pharmaceuticals, dated July 16, 2009
+(39)	10.61	Master Clinical and Commercial Supply Agreement between Gilead World Markets, Limited, Registrant and Patheon Inc., dated January 1, 2003
+(33)	10.62	Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Gilead Sciences Limited and PharmaChem Technologies (Grand Bahama), Ltd., dated July 17, 2003
+(40)	10.63	Addendum to Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Gilead Sciences Limited and PharmaChem Technologies (Grand Bahama) Ltd., dated May 10, 2007
+(25)	10.64	Addendum to Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Gilead Sciences Limited and PharmaChem Technologies (Grand Bahama) Ltd., dated December 5, 2008

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Exhibit Footnote	Exhibit Number	Description of Document
+(21)	10.65	Tenofovir Disoproxil Fumarate Manufacturing Supply Agreement by and between Registrant and Ampac Fine Chemicals LLC, dated March 6, 2008
+(31)	10.66	Restated and Amended Toll Manufacturing Agreement between Gilead Sciences Limited, Registrant and ALTANA Pharma Oranienburg GmbH, dated November 7, 2005
+(11)	10.67	Emtricitabine Manufacturing Supply Agreement between Gilead Sciences Limited and Degussa AG, dated June 6, 2006
(25)	10.68	Purchase and Sale Agreement and Escrow Instructions between Electronics for Imaging, Inc. and Registrant, dated October 23, 2008
	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)
	101***	The following materials from Registrant s Annual Report on Form 10-K for the year ended December 31, 2009, formatted in Extensible Business Reporting Language (XBRL) includes: (i) Consolidated Balance Sheets at December 31, 2009 and 2008, (ii) Consolidated Statements of Income for the years ended December 31, 2009, 2008 and 2007, (iii) Consolidated Statements of Cash Flows for the years ended December 31, 2009, 2008 and 2007, and (iv) Notes to Consolidated Financial Statements, tagged as blocks of text.

(1) Filed as an exhibit to Registrant s Current Report on Form 8-K filed on March 12, 2009, and incorporated herein by reference.

(2) Filed as an exhibit to Registrant s Current Report on Form 8-K filed on May 9, 2008, and incorporated herein by reference.

(3) Filed as an exhibit to Registrant s Current Report on Form 8-K filed on November 22, 1994, and incorporated herein by reference.

(4) Filed as an exhibit to Registrant s Current Report on Form 8-K filed on May 11, 2006, and incorporated herein by reference.

(5) Filed as an exhibit to Registrant s Current Report on Form 8-K filed on October 28, 2008, and incorporated herein by reference.

(6) Filed as an exhibit to Registrant s Current Report on Form 8-K filed on October 22, 1999, and incorporated herein by reference.

(7) Filed as an exhibit to Registrant s Current Report on Form 8-K filed on October 31, 2003, and incorporated herein by reference.

(8) Filed as an exhibit to Registrant s Registration Statement on Form S-8 (No. 333-135412) filed on June 28, 2006, and incorporated herein by reference.

(9) Filed as an exhibit to Registrant s Current Report on Form 8-K filed on April 25, 2006, and incorporated herein by reference.

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(10) Filed as an exhibit to Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2006, and incorporated herein by reference.

(11) Filed as an exhibit to Registrant s Current Report on Form 8-K also filed on December 19, 2007, and incorporated herein by reference.

(12) Filed as an exhibit to Registrant s Current Report on Form 8-K filed on October 21, 2008, and incorporated herein by reference.

(13) Filed as an exhibit to Registrant s Registration Statement on Form S-8 (No. 333-102912) filed on January 31, 2003, and incorporated herein by reference.

(14) Filed as an exhibit to Registrant s Registration Statement on Form S-1 (No. 33-55680), as amended, and incorporated herein by reference.

(15) Filed as an exhibit to Registrant s Annual Report on Form 10-K/A for the fiscal year ended December 31, 1998, and incorporated herein by reference.

(16) Filed as an exhibit to Registrant s Current Report on Form 8-K filed on May 11, 2009, and incorporated herein by reference.

(17) Filed as an exhibit to Registrant s Current Report on Form 8-K/A filed on February 22, 2006, and incorporated herein by reference.

(18) Filed as an exhibit to Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2007, and incorporated herein by reference.

(19) Filed as an exhibit to Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2009, and incorporated herein by reference.

(20) Filed as an exhibit to Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2006, and incorporated herein by reference.

(21) 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.

(22) Filed as an exhibit to Registrant s Current Report on Form 8-K first filed on December 19, 2007, and incorporated herein by reference.

(23) Filed as an exhibit to Registrant s Registration Statement on Form S-8 (No. 333-163871) filed on December 21, 2009, and incorporated herein by reference.

(24) 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.

(25) Filed as an exhibit to Registrant s Annual Report on Form 10-K for the fiscal year ended December 31, 2008, and incorporated herein by reference.

(26) Information is included in Registrant s Current Report on Form 8-K filed on February 1, 2010, and incorporated herein by reference.

(27) 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.

(28) 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.

(29) 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.

(30) 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.

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(31) 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.

(32) 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.

(33) 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.

(34) 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.

(35) 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.

(36) Filed as an exhibit to CV Therapeutics, Inc. s Registration Statement on Form S-3 (No. 333-59318), as amended, originally filed on April 20, 2001, and incorporated herein by reference.

(37) Filed as an exhibit to CV Therapeutics, Inc. s Quarterly Report on Form 10-Q for the quarter ended June 30, 2006, and incorporated herein by reference.

(38) Filed as an exhibit to Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2009, and incorporated herein by reference.

(39) 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.

(40) 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.

*** XBRL information is furnished and not filed or a part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections.

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

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GILEAD SCIENCES, INC.

CONSOLIDATED FINANCIAL STATEMENTS

Years ended December 31, 2009, 2008, and 2007

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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, 2009 and 2008, and the related consolidated statements of income, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2009. 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, 2009 and 2008, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2009, 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.

As discussed in Notes 1 and 5 to the consolidated financial statements, the Company changed its method of accounting for its convertible senior notes that may be settled in cash upon conversion, its method of accounting for and presentation of noncontrolling interest, and its method of accounting for business combinations effective January 1, 2009.

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, 2009, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 1, 2010 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Palo Alto, California

March 1, 2010

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GILEAD SCIENCES, INC.

Consolidated Balance Sheets

(in thousands, except per share amounts)

	December 31, 2009	2008
Assets		
Current assets:		
Cash and cash equivalents	$ 1,272,958	$ 1,459,302
Short-term marketable securities	384,017	330,760
Accounts receivable, net of allowances of $132,810 at December 31, 2009 and $90,694 at December 31, 2008	1,389,534	1,023,397
Inventories	1,051,771	927,868
Deferred tax assets	295,080	140,882
Prepaid taxes	274,196	198,318
Prepaid expenses	78,111	71,815
Other current assets	66,891	126,066
Total current assets	4,812,558	4,278,408
Property, plant and equipment, net	699,970	528,799
Noncurrent portion of prepaid royalties	226,250	257,208
Noncurrent deferred tax assets	101,498	226,728
Long-term marketable securities	2,247,871	1,449,577
Intangible assets	1,524,777	123,008
Other noncurrent assets	85,635	73,103
Total assets	$ 9,698,559	$ 6,936,831
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 810,544	$ 601,200
Accrued government rebates	248,660	176,939
Accrued compensation and employee benefits	132,481	103,840
Income taxes payable	167,623	44,757
Other accrued liabilities	384,015	245,662
Deferred revenues	122,721	42,963
Current portion of other long-term obligations	5,587	5,631
Total current liabilities	1,871,631	1,220,992
Long-term deferred revenues	43,026	74,181
Convertible senior notes, net	1,155,443	1,098,025
Long-term income taxes payable	87,383	56,588
Other long-term obligations	35,918	21,462
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; 899,753 and 909,819 shares issued and outstanding at December 31, 2009 and 2008, respectively	900	910
Additional paid-in capital	4,376,651	3,930,109
Accumulated other comprehensive income (loss)	(5,758)	41,240
Retained earnings	1,995,272	300,314
Total Gilead stockholders equity	6,367,065	4,272,573

Noncontrolling interest	138,093	193,010
Total stockholders equity	6,505,158	4,465,583
Total liabilities and stockholders equity	$ 9,698,559	$ 6,936,831