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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2010

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 ☒ No ☐

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

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

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

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

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

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, 2010 was $25,450,411,375.*

The number of shares outstanding of the registrant's Common Stock on February 18, 2011 was 795,264,644.

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 2011 Annual Meeting of Stockholders, to be held on May 12, 2011, are incorporated by reference into Part III of this Report.

*Based on a closing price of $34.28 per share on June 30, 2010. Excludes 96,205,183 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, 2010. 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.

2010 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.

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 28. 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.

PART I

ITEM 1. BUSINESS

Overview

Gilead Sciences, Inc. (Gilead, we or us), 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 Asia Pacific. 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 a product acquisition and in-licensing strategy.

Our Products

- ***Atripla*** (efavirenz 600 mg/ emtricitabine 200 mg/ tenofovir disoproxil fumarate 300 mg) is an oral formulation dosed once a day for the treatment of human immunodeficiency virus (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 antiretroviral medications, Viread (tenofovir disoproxil fumarate) and Emtriva (emtricitabine), and Bristol Myers-Squibb Company's (BMS) non-nucleoside reverse transcriptase inhibitor, Sustiva (efavirenz).
- ***Truvada*** (emtricitabine and tenofovir disoproxil fumarate) is an oral formulation dosed once a day as part of combination therapy to treat HIV infection in adults. It is a fixed-dose combination of our antiretroviral medications, Viread and Emtriva.
- ***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, Japan and Saudi Arabia.
- ***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.
- ***Ranexa*** (ranolazine) 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):

	2010	% of Total Product Sales	2009	% of Total Product Sales	2008	% of Total Product Sales
Antiviral products:						
Atripla	$2,926,579	40%	$2,382,113	37%	$1,572,455	31%
Truvada	2,649,908	36%	2,489,682	38%	2,106,687	41%
Viread	732,240	10%	667,510	10%	621,187	12%
Hepsera	200,592	3%	271,595	4%	341,023	7%
Emtriva	27,679	0%	27,974	0%	31,080	1%
Total antiviral products	6,536,998	88%	5,838,874	90%	4,672,432	92%
AmBisome	305,856	4%	298,597	5%	289,651	6%
Letairis	240,279	3%	183,949	3%	112,855	2%
Ranexa	239,832	3%	131,062	2%	—	—
Other	66,956	1%	16,829	0%	9,858	0%
Total product sales	$7,389,921	100%	$6,469,311	100%	$5,084,796	100%

See Item 8, Note 16 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/Rapiscan*** (regadenoson) 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 sell regadenoson under the name Lexiscan in the United States, subject to its obligations to pay us royalties based on sales of Lexiscan in the United States. In September 2010, our marketing authorization application for regadenoson for MPI in the European Union was approved by the European Medicines Agency. Rapidscan Pharma Solutions, Inc. (Rapidscan) holds the exclusive right to manufacture and sell regadenoson under the name Rapiscan in Europe and certain territories outside the United States. We will receive royalties from Rapidscan for sales in these territories.

Commercialization and Distribution

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.

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, Poland, Portugal, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States.

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, BMS. We distribute Atripla, Truvada, 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, 2010, 2009 and 2008. On a combined basis, in 2010, these wholesalers accounted for approximately 82% of our product sales in the United States and approximately 43% of our total worldwide 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, Japan and Saudi Arabia. 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. Menarini International Operations Luxembourg SA markets Ranexa in certain territories outside of the United States for the treatment of chronic angina. Rapidscan Pharma Solutions, Inc. markets Rapiscan (regadenoson) in certain territories outside of the United States for the inducement of pharmacological stress and/or vasodilation of the coronary vasculature strictly for purposes of diagnosing cardiovascular disease.

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 per capita (GNI) and HIV prevalence. This approach allows us to price our therapies based on a country's ability to pay.

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, called the DART (Development of AntiRetroviral Therapy) study, was 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 provided Viread at no cost for the DART study. In addition, we donated tenofovir for the Centre for the AIDS Programme of Research in South Africa (CAPRISA) 004 microbicide trial, which assessed the effectiveness and the safety of a tenofovir-based microbicide gel for the prevention of HIV infection in South African women. We also provide drugs for a number of innovative international studies investigating whether Viread or Truvada can prevent HIV transmission among at-risk, uninfected adults. This is a potential HIV prevention strategy called pre-exposure prophylaxis, or PrEP.

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 to our products in the developing world, which include:

- **PharmaChem Technologies (Grand Bahama), Ltd (PharmaChem).** In 2005, PharmaChem, one of our commercial 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 Atripla and Truvada, 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.** 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.

- **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 of certain formulations of tenofovir for use as a topical microbicide to prevent HIV infection.

Competition

Our products 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. Our HIV products also compete broadly with HIV products from Abbott Laboratories, Inc., Boehringer Ingelheim GmbH, Merck, Roche and Tibotec Pharmaceuticals.

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.

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 Atripla and Truvada. In May 2010, the compound patent covering Epivir (lamivudine) itself expired in the United States, and we expect to see generic lamivudine in the United States in the near future. Generic lamivudine has been available in Spain since March 2010. We expect that generic versions of lamivudine will be launched in other countries within the European Union as early as the first quarter of 2011.

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), which was developed by GSK in collaboration with Shire Pharmaceuticals Group PLC and is 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.

Our Cardiovascular Products.

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

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.

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 3 clinical trials. These stress agents and product candidates could also compete with Lexiscan.

Our Other Products.

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.

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 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 competes with Relenza (zanamivir), an anti-influenza drug that is sold by GSK. Relenza is a neuraminidase inhibitor that is delivered as an orally-inhaled dry powder. Generic competitors include amantadine and rimantadine, both oral tablets that only inhibit the replication of the influenza A virus. BioCryst Pharmaceuticals, Inc. is developing injectable formulations of peramivir, an influenza neuraminidase inhibitor, for the treatment of influenza, which are currently in Phase 3 clinical trials.

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

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

Collaborative Relationships

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

- **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.

- **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 Gilead. Starting in the second quarter of 2011, except for a limited number of activities that will be jointly managed, the parties will no longer coordinate detailing and promotional activities in the United States. The parties will continue to collaborate on activities such as manufacturing, regulatory, compliance and pharmacovigilance. The daily operations of the joint venture are governed by four primary joint committees formed by both BMS and Gilead. We are responsible for accounting, financial reporting, tax reporting and product distribution for the joint venture. In September 2006, we and BMS amended the joint venture's collaboration agreement to allow the joint venture to sell Atripla into Canada. The agreement will continue until terminated by the mutual agreement of the parties. In addition, either party may terminate the other party's participation in the collaboration within 30 days after the launch of at least one generic version of such other party's single agent products (or the double agent products). The non-terminated party then has the right to continue to sell Atripla and a short-term obligation to pay royalties to the terminated party.

  In December 2007, we entered into a collaboration with BMS which sets forth the terms and conditions under which we and BMS commercialize Atripla in the European Union, 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.

- **GSK.** In March 2006, we sublicensed to GSK exclusive rights to market ambrisentan (the active pharmaceutical ingredient in Letairis) under the name Volibris 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, 2010, we have received $45.0 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, 2010, 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). 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 reimburse 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 completion of bioequivalence studies. Through December 31, 2010, we recorded €53.6 million (approximately $74.5 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 prices of Truvada and TMC278 components. 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

Our product development efforts cover a wide range of medical conditions, including HIV/AIDS, liver disease, cardiovascular disease and respiratory disease.

We have research scientists in Foster City, Palo Alto and San Dimas, California; Branford, Connecticut; 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.

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 Candidates for the Treatment of HIV

Product Candidates	Description
Marketing Application Pending	
Truvada/TMC278 Single-Tablet Regimen	In September 2010, we announced that we had submitted a new drug application to the European Medicines Agency for marketing approval of the single-tablet regimen of tenofovir disoproxil fumarate, emtricitabine and TMC278 for the treatment of HIV/AIDS in treatment-naive patients. In November 2010, we submitted a new drug application to the U.S. Food and Drug Administration (FDA) for this single-tablet regimen. In January 2011, we received a "refuse to file" notification from the FDA regarding our application. The FDA requested additional information with respect to the Chemistry, Manufacturing and Controls section of the application. In February 2011, we re-filed our new drug application, which included the requested information, and are awaiting the FDA's response as to whether it is substantially complete to permit a substantive review.
Phase 3	
Cobicistat	Cobicistat is a pharmacoenhancer that is under evaluation as a boosting agent for certain HIV medicines in treatment-naïve patients.
Elvitegravir	Elvitegravir is an oral integrase inhibitor that is being evaluated as part of combination therapy for HIV in treatment-experienced patients.
Integrase Single-Tablet Regimen "Quad"	The once-daily, single-tablet "Quad" regimen of elvitegravir, cobicistat, tenofovir disoproxil fumarate and emtricitabine is under evaluation for the treatment of HIV/AIDS in treatment-naïve patients.
Phase 1	
GS 7340	GS 7340 is a nucleotide reverse transcriptase inhibitor being evaluated for the treatment of HIV/AIDS.

Product Candidates for the Treatment of Liver Diseases

Product Candidates	Description
Phase 2	
GS 9190	GS 9190 is an oral NS5B non-nucleoside polymerase inhibitor being evaluated for the treatment of hepatitis C.
GS 9256	GS 9256 is an NS3 oral protease inhibitor being evaluated for the treatment of hepatitis C.
GS 9451	GS 9451 is an oral NS3 protease inhibitor being evaluated for the treatment of hepatitis C.
Phase 1	
GS 5885	GS 5885 is an oral NS5A inhibitor under evaluation for the treatment of hepatitis C.
GS 6620	GS 6620 is an oral nucleotide NS5B polymerase inhibitor under evaluation for the treatment of hepatitis C.
GS 9620	GS 9620 is an oral TLR-7 agonist for the treatment of hepatitis B and hepatitis C.

Product Candidates for the Treatment of Cardiovascular/Metabolic Diseases

Product Candidates	Description
Phase 2	
Cicletanine	Cicletanine is an oral antihypertensive agent under evaluation for the treatment of PAH.
Ranolazine	Ranolazine is a late sodium current inhibitor approved for the treatment of chronic angina, which will also be evaluated for the treatment of coronary artery disease in patients with diabetes.

Product Candidates for the Treatment of Respiratory Diseases

Product Candidates	Description
Phase 3	
Aztreonam for inhalation solution	Aztreonam for inhalation solution, approved for the treatment of cystic fibrosis (CF) patients with *Pseudomonas aeruginosa,* is also being evaluated for the treatment of CF in patients with *Burkholderia spp.*
Phase 2	
Aztreonam for inhalation solution	Aztreonam for inhalation solution is also being evaluated for the treatment of bronchiectasis.

Product Candidates for the Treatment of Inflammation/Oncology Diseases

Product Candidates	Description
Phase 1	
GS 6624	GS 6624 is a monoclonal antibody being evaluated for the treatment of idiopathic pulmonary fibrosis and solid tumors.

In total, our R&D expenses for 2010 were $1.07 billion compared with $939.9 million for 2009 and $721.8 million for 2008.

In addition to our internal discovery and clinical development programs, we seek to add to our portfolio of products through product acquisitions. The following table shows some of our recent acquisitions:

Year	Company	Therapeutic area
2006	Myogen, Inc.	Cardiopulmonary disease and other cardiovascular disorders
2006	Corus Pharma, Inc.	Respiratory and infectious diseases
2008	Navitas Assets, LLC	Cicletanine as a potential treatment for PAH
2009	CV Therapeutics, Inc.	Cardiovascular disorders
2010	CGI Pharmaceuticals, Inc.	Serious inflammatory diseases
2011	Arresto Biosciences, Inc.	Fibrotic diseases and cancer

In February 2011, we entered into an agreement to acquire Calistoga Pharmaceuticals, Inc., a privately-held, biotechnology company focused on the development of medicines to treat cancer and inflammatory diseases.

Patents and Proprietary Rights

U.S. and European Patent Expiration

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:

Products	U.S. Patent Expiration	European Patent 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 (3)	2021 (7)

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

(2) SPC protection has been obtained in certain European countries that confer 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 allowed. An SPC can be applied for upon grant of the European patent.

Patent Protection and Certain Challenges

Patents and other proprietary rights are very important to our business. If we have a properly designed and enforceable patent, it can be more difficult for our competitors to use our technology to create competitive products and more difficult for our competitors to obtain a patent that prevents us from using technology we create. As part of our business strategy, we actively seek patent protection both in the United States and internationally and file additional patent applications, when appropriate, to cover improvements in our compounds, products and technology. We also rely on trade secrets, internal know-how, technological innovations and agreements with third parties to develop, maintain and protect our competitive position. Our ability to be competitive will depend on the success of this strategy.

Patents covering the active pharmaceutical ingredients of Atripla, Truvada, 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 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 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.

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 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 Atripla, Truvada and Viread. The PTO granted these requests and issued non-final rejections for the four patents, which is a step common in a proceeding to initiate the re-examination process. In 2008, the PTO confirmed the patentability of all four patents.

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

within the Brazilian patent authority. We have filed a civil action in Brazilian federal court to further appeal the action of the Brazilian patent authority. We cannot predict the outcome of this proceeding on our tenofovir disoproxil fumarate patent application. If we are unsuccessful in our appeal to the courts of the decision by the patent authority, the Brazilian government would likely purchase generic tenofovir disoproxil fumarate, which would significantly reduce our sales of HIV products in Brazil. In 2010, the Brazilian government purchased approximately $50 million of our HIV products. Further, we are aware of applications from two generic companies to sell a generic version of Viread in Brazil. If one or both of these generic applicants are able to compete for this contract for 2011, we would not expect the Brazilian government to purchase any of our HIV products in 2011.

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

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 provide effective enforcement of our patents, and third-party manufacturers are able to sell generic versions of our products in those countries.

Abbreviated New Drug Applications Filed by Generic Manufacturers

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

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

patents related to tenofovir disoproxil fumarate and two additional patents related to emtricitabine. In the notice related to Atripla, Teva challenged four patents related to tenofovir disoproxil fumarate, two additional patents related to emtricitabine and two patents related to efavirenz. In March 2010, we filed a lawsuit against Teva for infringement of the four Viread patents and two additional emtricitabine patents. In March 2010, BMS and Merck filed a lawsuit against Teva for infringement of the patents related to efavirenz.

In June 2010, we received notice that Lupin Limited (Lupin) submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Ranexa. In the notice, Lupin alleges that ten of the patents associated with Ranexa are invalid, unenforceable and/or will not be infringed by Lupin's manufacture, use or sale of a generic version of Ranexa. In July 2010, we filed a lawsuit against Lupin for infringement of our patents for Ranexa.

In August 2010, we received notice that Sigmapharm Labs (Sigmapharm) submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Hepsera. In the notice, Sigmapharm alleges that both of the patents associated with Hepsera are invalid, unenforceable and/or will not be infringed by Sigmapharm's manufacture, use or sale of a generic version of Hepsera. In September 2010, we filed a lawsuit against Sigmapharm for infringement of our patents for Hepsera. One of the patents challenged by Sigmapharm is also being challenged by Ranbaxy, Inc. (Ranbaxy) pursuant to a notice received in October 2010. The patent challenged by Ranbaxy expires in July 2018. We are considering our options for enforcing our patent.

In February 2011, we received notice that Natco Pharma Limited (Natco) submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Tamiflu. In the notice, Natco alleges that a patent associated with Tamiflu is invalid, unenforceable and/or will not be infringed by Natco's manufacture, use or sale of a generic version of Tamiflu. We are currently reviewing the notice letter and have 45 days from the date of receipt to commence a patent infringement lawsuit against Natco.

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 Atripla, Truvada, Viread, Hepsera, Ranexa and Tamiflu in the United States could be substantially shortened. Further, if all of the patents covering those products are invalidated, the FDA could approve the requests to manufacture a generic version of such products prior to the expiration date of those patents.

Trade Secrets

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 active pharmaceutical ingredients and 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.

Manufacturing of our Products

We contract with third parties to manufacture certain products for clinical and commercial purposes, including Atripla, Truvada, 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 Atripla and Truvada; and emtricitabine, the active pharmaceutical ingredient in Emtriva and one of the active pharmaceutical ingredients in Atripla and Truvada. We rely on a single third-party manufacturer to manufacture the active pharmaceutical ingredients of Ranexa and Cayston. We are in the process of validating a second manufacturer for Ranexa and Cayston.

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

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 US LLC, our corporate partner for Lexiscan in the United States, is responsible for the commercial manufacture and supply of product in the United States and is dependent on a single supplier for the active pharmaceutical ingredient of Lexiscan. 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.

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.

Our Manufacturing Facilities

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 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 Atripla, Truvada, Viread, Emtriva, Hepsera and Ranexa in their finished forms at our facilities in San Dimas. 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.

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 Vistide, 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 Atripla, Truvada, 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 final release 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. We distribute our products to the European Union and other international markets from our Dublin, Ireland site.

Third-party Manufacturers

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.

Regulation of Manufacturing Process

The manufacturing process for pharmaceutical products is highly regulated and regulators may shut down manufacturing facilities that they believe do not comply with regulations. We, our third-party manufacturers and our corporate partners are subject to current Good Manufacturing Practices, which are extensive regulations governing manufacturing processes, stability testing, record keeping and quality standards as defined by the FDA and the European Medicines Agency. Similar regulations are in effect in other countries.

In January and February 2010, the FDA conducted a routine inspection of our San Dimas, California, manufacturing and distribution facility, where we manufacture AmBisome and Cayston, fill and finish Macugen, and package solid dosage form products. At the conclusion of that inspection, the FDA issued Form 483 Inspectional Observations stating concerns over: the maintenance of aseptic processing conditions in the manufacturing suite for our AmBisome product; environmental maintenance issues in the San Dimas warehousing facility; batch sampling; and the timeliness of completion of annual product quality reports. On September 24, 2010, our San Dimas manufacturing facility received a Warning Letter from the FDA further detailing the FDA's concerns over the AmBisome manufacturing environment, including control systems and monitoring, procedures to prevent microbiological contamination and preventative cleaning and equipment maintenance. Referencing certain Viread lots, the letter also stated concerns connected with quality procedures, controls and investigation procedures, and a generalized concern over the effectiveness of the San Dimas quality unit in carrying out its responsibilities.

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

Unless and until we receive confirmation from the FDA that it is satisfied we have corrected outstanding issues, the FDA may withhold permission to export AmBisome and Cayston manufactured at San Dimas to certain countries outside the United States and Europe. The FDA may also withhold approval of pending drug applications listing the San Dimas facility. Since, as required, we have notified appropriate international regulatory authorities of the letter's issuance, it is possible that the letter may impact our ability to supply our aseptic products manufactured at San Dimas (AmBisome, Cayston and Macugen) outside the United States. If as a result of a Warning Letter, we are unable to receive export or regulatory approvals for AmBisome or any other products at issue, we may be unable to sell sufficient quantities of these products to meet market demand, which would decrease our revenues and harm our business. We do not believe the Warning Letter will impact our ability to supply any of the solid dosage form products that we package at the San Dimas facility, which include Atripla, Truvada, Viread, Emtriva, Hepsera, Letairis and Ranexa. In the event our solid dosage form products were affected, we have alternate sites from which we could supply such products

Access to Supplies and Materials

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. For example, a significant portion of the raw materials and intermediates used to manufacture our HIV products (Atripla, Truvada, Viread and Emtriva) are supplied by Chinese-based companies. As a result, an international trade dispute between China and the United States or any other actions by the Chinese government that would limit or prevent Chinese companies from supplying these materials would adversely affect our ability to manufacture and supply our HIV products to meet market needs and have a material and adverse effect on our operating results.

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 2010 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 its approval to test the compound in humans.

Clinical Trials

If the FDA accepts the investigational new drug 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, 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 a new drug application (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 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. In addition, changes 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 may adversely affect our product revenues and profitability.

Legislative and regulatory changes to government prescription drug procurement and reimbursement programs occur relatively frequently in the United States. 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.

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 they expect prices of prescription pharmaceuticals to decline over the life of the product or as volumes increase. Recently, many countries in the European Union have increased the amount of discounts required on our products, and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the European Union. For example, in June 2010, Spain imposed an incremental discount on all branded drugs and in August 2010, Germany increased the rebate on prescription pharmaceuticals. Other countries have recently imposed or could impose similar discounts on our products. As generic drugs come to market, we may face price decreases for our products in some countries in the European Union.

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. For example, recent HIV treatment guidelines in the United States and abroad have endorsed earlier diagnosis and treatment.

United States Healthcare Reform

In March 2010, healthcare reform legislation was adopted in the United States. As a result, we are required to further rebate or discount products reimbursed or paid for by various public payers, including Medicaid and other entities eligible to purchase discounted products through the 340B Drug Pricing Program under the Public Health Service Act, such as AIDS Drug Assistance Programs (ADAPs). The discounts, rebates and fees in the legislation that impacted us include:

- effective January 1, 2010, our minimum base rebate amount owed to Medicaid on products reimbursed by Medicaid was increased by 8%, and the discounts or rebates we owe to ADAPs and other Public Health Service entities which reimburse or purchase our products were also increased by 8%;
- effective March 23, 2010, we are required to extend rebates to patients receiving our products through Medicaid managed care organizations;
- effective January 1, 2011, we are required to provide a 50% discount on products sold to patients while they are in the Medicare Part D “donut hole;” and
- effective 2011, we, along with other pharmaceutical manufacturers of branded drug products, are required to pay a portion of a new industry fee (also known as the pharmaceutical excise tax), calculated based on select government sales during the 2010 calendar year as a percentage of total industry government sales.

Starting in 2014, as the number of people with access to healthcare coverage is expected to increase, we could experience a positive impact on the sales of our products. Further, the expansion of healthcare coverage may decrease the reliance of patients on state ADAPs that currently rely on the availability of federal and state funding.

The full impact of healthcare reform for 2010 was a reduction of approximately $200 million in U.S. net product sales. The majority of this impact began in the third quarter and continued throughout the fourth quarter of 2010 since some of the new discount and rebate requirements took two quarters to fully take effect. For 2011, excluding the impact of the new pharmaceutical excise tax, we estimate that the impact of healthcare reform on product sales will be approximately 5–6% of our U.S. net product sales.

Many of the specific determinations necessary to implement the healthcare reform legislation have yet to be decided and communicated by the federal government. For example, we do not know how many or how quickly patients receiving our product under the Medicare Part D program will reach the "donut hole" or how details of the pharmaceutical excise tax will be calculated. Based on the information that we have to date, we estimate the 2011 impact of the pharmaceutical excise tax to be between $30-50 million, which will be classified as selling, general and administrative (SG&A) expense. The excise tax is not tax deductible. In calculating the anticipated financial impacts of healthcare reform described above, we made several estimates and assumptions with respect to our expected payer mix and how the reforms will be implemented.

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.

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. In 2010, the Brazilian government purchased approximately $50 million of our HIV products. We are aware of applications from two generic companies to sell a generic version of Viread in Brazil. If one or both of