GILEAD SCIENCES INC
Form 10-K
February 23, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2011

or

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

Commission File No. 0-19731

GILEAD SCIENCES, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

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

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

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

Large accelerated filer x	Accelerated filer ¨	Non-Accelerated filer ¨	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 x

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant based upon the closing price of its Common Stock on the Nasdaq Global Select Market on June 30, 2011 was $ 29,933,970,092.*

The number of shares outstanding of the registrant s Common Stock on February 10, 2012 was 757,315,361.

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 2012 Annual Meeting of Stockholders, to be held on May 10, 2012, are incorporated by reference into Part III of this Report.

* Based on a closing price of $41.41 per share on June 30, 2011. Excludes 48,586,996 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, 2011. 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.

2011 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®, COMPLERA®, EVIPLERA®, VISTIDE®, LETAIRIS®, VOLIBRIS®, RANEXA®, CAYSTON® and RAPISCAN®. ATRIPLA® is a registered trademark belonging to Bristol-Myers Squibb & Gilead Sciences, LLC. LEXISCAN® is a registered trademark belonging to Astellas U.S. LLC. MACUGEN® is a registered trademark belonging to Eyetech Inc. SUSTIVA® is a registered trademark of Bristol-Myers Squibb Pharma Company. TAMIFLU® is a registered trademark belonging to Hoffmann-La Roche Inc. This report also includes other trademarks, service marks and trade names of other companies.

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This Annual Report on Form 10-K, including the section entitled Management s Discussion and Analysis of Financial Condition and Results of Operations, contains forward-looking statements regarding future events and our future results that are subject to the safe harbors created under the Securities Act of 1933, as amended (the Securities Act), and the Securities Exchange Act of 1934, as amended (the Exchange Act). Words such as expect, anticipate, target, goal, project, hope, intend, plan, believe, seek, estimate, continue, may, could, should, might, variations of such words and similar expressions are intended to identify such forward-looking statements. In addition, any statements other than statements of historical fact are forward-looking statements, including statements regarding overall trends, operating cost and revenue trends, liquidity and capital needs and other statements of expectations, beliefs, future plans and strategies, anticipated events or trends and similar expressions. We have based these forward-looking statements on our current expectations about future events. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Our actual results may differ materially from those suggested by these forward-looking statements for various reasons, including those identified below under Risk Factors, beginning at page 30. Given these risks and uncertainties, you are cautioned not to place undue reliance on forward-looking statements. The forward-looking statements included in this report are made only as of the date hereof. Except as required under federal securities laws and the rules and regulations of the Securities and Exchange Commission (SEC), we do not undertake, and specifically decline, any obligation to update any of these statements or to publicly announce the results of any revisions to any forward-looking statements after the distribution of this report, whether as a result of new information, future events, changes in assumptions or otherwise.

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PART I

ITEM 1. BUSINESS

Overview

Gilead Sciences, Inc. (Gilead, we or us), incorporated in Delaware on June 22, 1987, is a research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of unmet medical need. With each new discovery and experimental drug candidate, we seek to improve the care of patients suffering from life-threatening diseases around the world. Gilead s primary areas of focus include human immunodeficiency virus (HIV)/AIDS, liver diseases such as hepatitis B and C and serious cardiovascular/metabolic and respiratory conditions. Headquartered in Foster City, California, we have operations in North America, Europe and Asia Pacific. 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.

Over the past year, we executed our philosophy and strategy to bring best-in-class drugs to market. In keeping with this strategy, we completed several acquisitions and licensing transactions to enhance our pipeline. We also expanded our single-tablet regimen product offerings for the treatment of HIV with the launch of Complera/Eviplera (emtricitabine/rilpivirine/tenofovir disoproxil fumarate) and the anticipated 2012 launch of Quad, which combines four of our HIV medicines in a once-daily single-tablet regimen and is pending Food and Drug Administration (FDA) approval.

Our largest transaction was the acquisition of Pharmasset, Inc. in January 2012 for $11.1 billion. For several years, we have focused a large proportion of our research and development effort on discovering and advancing direct-acting antivirals for the treatment of chronic hepatitis C virus (HCV). The HCV therapeutic market has been and continues to be vastly underserved. Due to the limitations of available therapies, only a small fraction of individuals who are infected with HCV are diagnosed, and an even smaller fraction of those patients are treated. Prior to May 2011, when the first protease inhibitors were approved, only about half of the patients responded to the standard of care combination of pegylated interferon and ribavirin. The addition of protease inhibitors to the standard of care has resulted in incremental response rates for patients with genotype 1 infection; however, this regimen causes substantial side effects such as fatigue, bone marrow suppression, potentially debilitating rash, anemia and neuropsychiatric effects. As such, discontinuation rates with these triple therapy combinations have significantly increased.

Over the last two years, we have progressed several early stage HCV molecules with various mechanisms of action into clinical development. During 2011, the field of HCV research evolved rapidly, and it became clear our HCV portfolio of oral antiviral development compounds would have difficulty competing because it was behind the development programs of many of our competitors. Through our acquisition of Pharmasset, we gained ownership of GS-7977, the most advanced, and to date the most potent, nucleotide analog that acts to inhibit the replication of HCV with limited safety or resistance concerns detected thus far. The compound has been studied extensively in Phase 2 studies in genotype 2 and 3 infected patients in combination with ribavirin with or without pegylated interferon and is currently being studied in genotype 1 infected patients. The first of two Phase 3 trials, known as FISSION, evaluating GS-7977 in genotype 2 and 3 patients is currently enrolling. A second Phase 3 study of genotype 2 and 3 patients is scheduled to begin enrolling in the next few weeks. If Phase 3 data for genotype 2 and 3 patients is consistent with data from our Phase 2 trials, we would expect to file a new drug application (NDA) for the treatment of genotype 2 and 3 patients in 2013 for potential approval in late 2013 or early 2014.

Two thirds of HCV-infected individuals in the United States and Europe are infected with HCV genotype 1. We are conducting Phase 2 studies to determine the efficacy of GS-7977 plus ribavirin in this population. Results from these studies will be available over the next several months. We expect the first data evaluating GS-7977 plus ribavirin for 12 weeks in genotype 1 treatment-naïve patients from an arm of the QUANTUM study with 25 patients will be available at the end of the first quarter of 2012. We expect that this will be followed in the second quarter by data from an arm of the ELECTRON study involving 25 treatment-naïve patients treated for 12 weeks and, early in the third quarter, data on GS-7977 and ribavirin treatment for 24 weeks from an arm of the QUANTUM study will become available.

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On February 17, 2012, we announced that the majority of HCV genotype 1 patients with a prior null response to an interferon-containing regimen enrolled in an arm of our ongoing ELECTRON study experienced viral relapse within four weeks of completing 12 weeks of treatment with GS-7977 plus ribavirin. Ten patients were randomized to this arm of the ELECTRON study and data were available for eight of the ten patients at the time of the announcement. Among these eight patients, six experienced viral relapse. Two patients had not relapsed; however, they had only reached the two week post-treatment time point. These data indicate that treatment of genotype 1 patients classified as null responders with GS-7977 plus ribavirin for 12 weeks will not be sufficient to cure their disease. Regulatory authorities require that patients have a sustained viral response for 12 weeks after the cessation of therapy to be considered cured of the disease.

To the extent data from the ELECTRON and QUANTUM studies indicate genotype 1 treatment-naïve patients can be effectively treated using GS-7977 and ribavirin, larger Phase 3 studies in genotype 1 patients are expected to commence in 2012. If we are able to commence Phase 3 trials on that timeline and the results of those trials are positive, we expect to file a NDA that includes data for genotype 1 patients in 2013 for potential approval in 2014. If GS-7977 with ribavirin is not sufficiently effective in treating genotype 1 treatment-naïve patients, we would need to explore combination therapy using GS-7977 and other direct acting antiviral compounds from our or others portfolios, which would delay development and approval of GS-7977 for use in genotype 1 treatment-naïve patients. We expect to begin clinical studies evaluating GS-7977 in combination with our GS-5885 NS5A inhibitor in genotype 1 treatment-naïve patients in the second quarter of 2012.

See the Risk Factor entitled The public announcement of data from clinical studies evaluating GS-7977 in HCV-infected patients is likely to cause significant volatility in our stock price on page 30.

Our Products

HIV/AIDS

Atripla (efavirenz 600 mg/ emtricitabine 200 mg/ tenofovir disoproxil fumarate 300 mg) is an oral formulation dosed once a day for the treatment of HIV infection in adults. Atripla is the first once-daily single-tablet regimen for HIV intended as a stand alone therapy or in combination with other antiretrovirals. It is a fixed-dose combination of our 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 analog reverse transcriptase inhibitor, dosed once a day as part of combination therapy to treat HIV infection in patients 2 years of age and older. Viread is also approved for the treatment of chronic hepatitis B in adults.

Complera/Eviplera is an oral formulation dosed once a day for the treatment of HIV-1 infection in treatment-naïve adults. The product, marketed in the United States as Complera and in Europe as Eviplera, is the second complete single-tablet regimen for the treatment of HIV and is a fixed-dose combination of our antiretroviral medications, Viread and Emtriva, and Tibotec Pharmaceuticals non-nucleoside reverse transcriptase inhibitor, Edurant (rilpivirine).

Emtriva is an oral formulation of a nucleoside analog 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 available as an oral solution approved as part of combination therapy to treat HIV infection in children.

Liver Disease

Viread is an oral formulation of a nucleotide analog reverse transcriptase inhibitor, dosed once a day for the treatment of chronic hepatitis B in adults with compensated and decompensated liver disease.

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We have licensed to GlaxoSmithKline Inc. (GSK) the rights to commercialize Viread for the treatment of chronic hepatitis B in Asia and certain other territories. As noted above, Viread is also approved for the treatment of HIV infection in patients 2 years of age and older in combination with other antiretroviral agents.

Hepsera (adefovir dipivoxil) is an oral formulation of a nucleotide analog polymerase inhibitor, dosed once a day to treat chronic hepatitis B in patients 12 years of age and older. 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.

Cardiovascular

Letairis (ambrisentan) is an oral formulation of 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 an extended-release tablet 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.

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. Rapidscan Pharma Solutions, Inc. (RPS) holds the exclusive right to manufacture and sell regadenoson under the name Rapiscan in Europe and certain territories outside the United States. We receive royalties from Astellas and RPS for sales in these territories.

Respiratory

Cayston (aztreonam for inhalation solution) is an inhaled antibiotic for the treatment of respiratory systems in cystic fibrosis (CF) patients 7 years of age and older with *Pseudomonas aeruginosa (P. aeruginosa).*

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.

Other

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 in adults. 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.

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

Macugen (pegaptanib sodium injection) is an intravitreal injection of an anti-angiogenic oligonucleotide for the treatment of neovascular age-related macular degeneration. Macugen was

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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.

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

	2011	% of Total Product Sales	2010	% of Total Product Sales	2009	% of Total Product Sales
Antiviral products:						
Atripla	$ 3,224,518	40%	$ 2,926,579	40%	$ 2,382,113	37%
Truvada	2,875,141	35%	2,649,908	36%	2,489,682	38%
Viread	737,867	9%	732,240	10%	667,510	10%
Hepsera	144,679	2%	200,592	3%	271,595	4%
Complera/Eviplera	38,747	0%				
Emtriva	28,764	0%	27,679	0%	27,974	0%
Total antiviral products	7,049,716	87%	6,536,998	88%	5,838,874	90%
AmBisome	330,156	4%	305,856	4%	298,597	5%
Letairis	293,426	4%	240,279	3%	183,949	3%
Ranexa	320,004	4%	239,832	3%	131,062	2%
Other	109,057	1%	66,956	1%	16,829	0%
Total product sales	$ 8,102,359	100%	$ 7,389,921	100%	$ 6,469,311	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.

Commercialization and Distribution

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

Our products are marketed through our commercial teams and/or in conjunction with third-party distributors and corporate partners. Our commercial teams promote our products through direct field contact with physicians, hospitals, clinics and other healthcare providers. We generally grant our third-party distributors the exclusive right to promote our product in a territory for a specified period of time. Most of our agreements with these distributors provide for collaborative efforts between the distributor and Gilead in obtaining and maintaining regulatory approval for the product in the specified territory.

We sell and distribute Atripla, Truvada, Viread, Hepsera, Complera, Emtriva, Ranexa and Vistide in the United States exclusively through the wholesale channel. Our product sales to three large wholesalers, Cardinal Health, Inc., McKesson Corp. and AmerisourceBergen Corp., each accounted for more than 10% of total revenues for each of the years ended December 31, 2011, 2010 and 2009. On a combined basis, in 2011, these wholesalers accounted for approximately 79% of our product sales in the United States and approximately 43% of our total worldwide revenues. Letairis and Cayston are distributed exclusively by specialty pharmacies. These specialty pharmacies dispense medications for complex or chronic conditions that require a high level of patient education and ongoing counseling. We sell and distribute Atripla, Truvada, Viread, Hepsera, Emtriva, Complera/Eviplera, and AmBisome in Asia, Australia, Canada, Europe, Latin America, the Middle East and New Zealand either through our commercial teams, third-party distributors or corporate partners.

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We also rely on our corporate partners to help promote and sell our products under collaboration agreements. For example, BMS has rights to promote Atripla in the United States. BMS also has rights to promote Atripla in a majority of the countries in Europe. 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. We have licensed to GSK the right to promote and sell Viread and Hepsera for the treatment of hepatitis B in certain countries outside the United States. We licensed the rights to manufacture and sell Tamiflu, Macugen and Lexiscan/Rapiscan worldwide to third parties, subject to our corporate partners obligation to pay us royalties based on a percentage of the sales of these products.

Access in the Developing World

Through the Gilead Access Program, established in 2003, certain of our HIV and other products are available at substantially reduced prices in 134 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, 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. In December 2011, we announced the submission of a supplemental NDA (sNDA) to the FDA for the approval of once-daily Truvada for PrEP to reduce the risk of HIV-1 infection among uninfected adults. If the sNDA is approved, Truvada would be the first agent indicated for uninfected individuals to reduce the risk of acquiring HIV through sex.

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 also support clinical research studies aimed at identifying the best treatment course for visceral leishmaniasis and donated AmBisome to support clinical studies assessing combination therapies and the cost-effectiveness of multiple visceral leishmaniasis treatment interventions. In December 2011, we signed a partnership agreement with World Health Organization to donate 445,000 vials of AmBisome over five years. This donation will be used to treat more than 50,000 patients in resource-limited countries.

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. This partnership increases manufacturing capacity for our HIV medicines, and improve delivery efficiency, since the medicines are produced in or near the markets where they are needed most.

Aspen Pharmacare Holdings Ltd (Aspen). In 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 2007, we amended our agreement with Aspen. Under the amended

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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.

Licenses with Generic Manufacturers. In 2006, we 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 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. In 2011, we expanded these non-exclusive license agreements to increase the number of countries included in the license, and also to include rights to our future pipeline products elvitegravir, an investigational integrase inhibitor; cobicistat, an investigational antiretroviral boosting agent; and Quad, which combines four of our HIV medicines in a once-daily single-tablet regimen and is pending FDA approval. To expand access to Viread for the treatment of hepatitis B treatment in developing countries, we also included in these non-exclusive license agreements the ability to manufacture and distribute generic versions of tenofovir disoproxil fumarate for the treatment of hepatitis B in the same countries where they are authorized to sell generic versions of tenofovir disoproxil fumarate for HIV.

Merck. In 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 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.

Medicines Patent Pool (the Pool). In 2011, we entered into an agreement with the Pool, an organization that was established by the United Nations to increase global access to high-quality, low-cost antiretroviral therapy through the sharing of patents. We granted the Pool a non-exclusive license to identify generic pharmaceutical manufacturers in India who specialize in high-quality production of generic medicines and grant sublicenses to those Indian manufacturers to manufacture and distribute generic versions of our antiretrovirals in the developing world. Sublicensees through the Pool will be free to develop combination products and pediatric formulations of our HIV medicines. We also granted the Pool the right to grant sublicenses to our future pipeline products elvitegravir, cobicistat and Quad to those same generic pharmaceutical manufacturers in India for distribution in the developing world.

Tibotec Pharmaceuticals (Tibotec). In 2011, we expanded our agreement with Tibotec to provide for distribution of Complera/Eviplera for the treatment of HIV in less developed countries and to enable the commercialization of generic versions of the product.

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Competition

Our products target a number of areas, including viral, cardiovascular, respiratory and fungal 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. Competition from current and expected competitors may erode the revenues we receive from sales of our HIV products. Of the 35 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, ViiV, that was 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.

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. Lamivudine, marketed by ViiV, is competitive with emtricitabine, the active pharmaceutical ingredient of Emtriva and a component of Atripla, Truvada and Complera/Eviplera. In May 2010, the

compound patent covering Epivir (lamivudine) itself expired in the United States, and generic lamivudine is now available in the United States, Spain and Portugal, and recently received pricing approval in Italy. We expect that generic versions of lamivudine will be launched in other countries within the European Union. In May 2011, a generic version of Combivir (lamivudine and zidovudine) was approved and was recently launched in the United States. In addition, in late 2011, generic tenofovir also became available in Turkey. To date, there has not been a significant impact from generic didanosine, zidovudine, stavudine, lamivudine, the generic version of Combivir or generic tenofovir in Turkey on the price of our HIV products; however, price decreases for all HIV products may result in the longer term.

Our Liver Disease Products

Our hepatitis B virus (HBV) products, Viread and Hepsera, face significant competition from existing and expected therapies for treating patients with chronic hepatitis B, which may erode the revenues we receive from sales of our HBV products. Our HBV products face competition from Baraclude (entecavir), an oral nucleoside

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analog developed by BMS and launched in the United States in 2005, and Tyzeka/Sebivo (telbivudine), an oral nucleoside analog 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.

Viread and Hepsera 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