GILEAD SCIENCES INC
Form 10-K
February 27, 2013

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

FORM 10-K
(Mark One)

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

For the fiscal year ended December 31, 2012
or

o 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 29, 2012 was $32,606,069,397.*

The number of shares outstanding of the registrant's Common Stock on February 15, 2013 was 1,522,392,518.

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 2013 Annual Meeting of Stockholders, to be held on May 8, 2013, are incorporated by reference into Part III of this Report.

* Based on a closing price of $25.64 per share on June 29, 2012. Excludes 226,596,532 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 29, 2012. 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.

GILEAD SCIENCES, INC.
2012 Form 10-K Annual Report
Table of Contents

We own or have rights to various trademarks, copyrights and trade names used in our business, including the following: GILEAD®, GILEAD SCIENCES®, STRIBILD®, COMPLERA®, EVIPLERA®, TRUVADA®, VIREAD®, HEPSERA®, AMBISOME®, EMTRIVA®, 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.

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,” varia 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 31. 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 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), liver diseases such as hepatitis B virus (HBV) and hepatitis C virus (HCV), serious cardiovascular and respiratory conditions, and oncology/inflammation. Headquartered in Foster City, California, we have operations in North America, Europe and Asia. We continue 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.

2012 Highlights

Over the past year, we executed on our strategy to bring best-in-class drugs to market. We completed our acquisition of Pharmasset, Inc. (Pharmasset), which accelerated our timeline to develop the first all-oral HCV regimen and entered into an agreement to acquire YM Biosciences Inc. (YM Biosciences), which closed in February 2013 and expands our growing oncology/inflammation pipeline. We also expanded our single tablet regimen product offerings for the treatment of HIV with the launch of Stribild in the United States, which combines four of our medicines in a once-daily single tablet regimen, and expanded worldwide access to Complera/Eviplera, which is now available in 21 countries. We also advanced our research and development pipeline, with over 50 active Phase 3 clinical trials at the end of 2012 and filed marketing applications for two of the components of Stribild, elvitegravir and cobicistat, as single agents.

HIV Program

A substantial portion of our revenues is derived from our six marketed HIV products. In 2012, we continued to be at the forefront of advancing HIV treatment through the development of new single tablet regimens. Our long-term goal is to ensure that all HIV patients have the option to choose a single tablet regimen that is right for them. Single tablet regimens allow patients to adhere to a fully suppressive course of therapy more easily and consistently, which is critical for the successful management of the disease. Because of this, we continue to focus on the development of new HIV medicines and co-formulations. With the launch of Stribild in the United States in 2012, Complera/Eviplera in 2011 and Atripla in 2006, we now have three single tablet regimens available.

During 2012, we submitted marketing applications in the United States and European Union for elvitegravir, an integrase inhibitor for the treatment of HIV-1 infection in treatment-experienced adults, and cobicistat, a pharmacoenhancing or "boosting" agent that increases blood levels to allow once-daily dosing of certain HIV medicines. The U.S. Food and Drug Administration (FDA) has set target review dates of April 2013 under the Prescription Drug User Fee Act.

In 2012, we also obtained FDA approval for once-daily oral Truvada, in combination with safer sex practices, for pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection among uninfected adults. Truvada is the first antiretroviral has been approved for the prevention of HIV infection in adults.

We also made important progress with the clinical development of tenofovir alafenamide (TAF), formerly known as GS-7340. A Phase 2 study showed that TAF is efficacious at one-tenth the dose of Viread and provides potential safety advantages. Based on these results, a Phase 3 trial evaluating the single tablet regimen of TAF, elvitegravir, cobicistat and emtricitabine treatment of HIV infection in treatment-naïve adults commenced earlier this year. Under an agreement with Janssen R&D Ireland (Janssen), we are also conducting Phase 2 trials evaluating a single tablet regimen of TAF, cobicistat, darunavir and emtricitabine for the treatment of HIV infection.

HCV Program

In January 2012, we acquired Pharmasset. Through the acquisition, we acquired sofosbuvir (formerly known as GS-7977), an investigational nucleotide analog that acts to inhibit the replication of HCV. This product candidate is currently in Phase 2 and Phase 3 clinical trials. 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 (peg-IFN) 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.

During 2013, we expect to receive a significant amount of data from clinical trials evaluating sofosbuvir, alone or in combination with other direct acting antivirals in HCV-infected individuals across all genotypes. Our initial new drug application (NDA) for sofosbuvir will be supported by four Phase 3 studies named Fission, Positron, Fusion and Neutrino. Fission is a study in genotype 2 and 3-treatment naïve patients comparing 12 weeks of sofosbuvir and ribavirin to the current standard of care of 24 weeks of treatment with interferon and ribavirin. Positron compares 12 weeks of treatment with sofosbuvir and ribavirin in genotype 2 and 3 interferon intolerant/ineligible patients to placebo. The Fusion study explores 12 or 16 weeks duration of treatment with sofosbuvir and ribavirin among genotype 2 and 3 treatment-experienced patients. Neutrino is a single arm study evaluating a 12-week course of sofosbuvir, interferon and ribavirin in genotype 1, 4, 5 and 6 infected-patients. We announced data from the four studies in late 2012 and during the first quarter of 2013.

We anticipate filing for regulatory approvals for sofosbuvir by the second quarter of 2013. We expect the initial indication to be for 12 to 16 weeks of treatment with sofosbuvir and ribavirin in treatment-naive, interferon-intolerant and experienced genotype 2 and 3 patients and for 12 weeks of treatment with sofosbuvir, peg-IFN and ribavirin in treatment-naive genotype 1, 4, 5 and 6 patients.

In parallel, we are also advancing a fixed-dose combination of sofosbuvir and ledipasvir (formerly GS-5885) for the treatment of genotype 1 patients. Our NDA for the fixed dose combination of sofosbuvir and ledipasvir will be supported by two clinical trials. The first study, named ION-1, evaluates the fixed-dose combination of sofosbuvir and ledipasvir with and without ribavirin for either 12 or 24 weeks in treatment-naïve genotype 1 infected patients. Pending a review of results from the two 12-week arms of an initial enrollment of 200 patients, by the second quarter of 2013, we expect to enroll additional patients in the ION-1 study to assess the fixed dose combination of sofosbuvir and ledipasvir in a total of 800 individuals. In January 2013, we also started screening patients for the second Phase 3 study, named ION-2, which evaluates the fixed-dose combination with ribavirin for 12 weeks and with and without ribavirin for 24 weeks of therapy among treatment-experienced genotype 1 HCV patients.

See the Risk Factor entitled “The public announcement of data from clinical studies evaluating sofosbuvir and the fixed dose combination of sofosbuvir and ledipasvir in HCV-infected patients is likely to cause significant volatility in our stock price” on page 31.

Oncology/Inflammation

Over the last five years we have worked to advance our oncology franchise. Idelalisib, is a PI3K delta inhibitor antibody formerly known as GS-1101, that advanced into five Phase 3 trials during 2012. The compound is being evaluated for the treatment of chronic lymphocytic leukemia and indolent non-Hodgkin's lymphoma. Simtuzumab, a monoclonal antibody formerly known as GS-6624, is being evaluated in various Phase 2 trials for the treatment of myelofibrosis, colorectal cancer and pancreatic cancer. With the acquisition of YM Biosciences, we acquired momelotinib or GS-0387, formerly known as CYT387. Momelotinib is a JAK inhibitor being evaluated in Phase 2 clinical trials for the treatment of myelofibrosis. We expect to advance the compound to Phase 3 trials later in 2013.

Our Products

HIV/AIDS

- Stribild (elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) is a complete once-daily single tablet regimen for HIV-1 infection for treatment-naive adults. Stribild combines four

compounds in one daily tablet and was approved by the FDA in August 2012. We filed a marketing authorization application for Stribild with the European Medicines Agency (EMA) in December 2011. We expect to receive approval from the European Commission in the second quarter of 2013.

- 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 (tenofovir disoproxil fumarate) and Emtriva (emtricitabine), and Janssen's non-nucleoside reverse transcriptase inhibitor, Edurant (rilpivirine).
- 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 and Emtriva and Bristol Myers-Squibb Company's 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. In 2012, the FDA also approved Truvada, in combination with safer sex practices, to reduce the risk of sexually acquired HIV-1 infection in adults at high risk, a strategy called pre-exposure prophylaxis (PrEP).
- 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. In 2012, the European Commission also approved the use of Viread in combination with other antiretroviral agents for the treatment of HIV-1 infected pediatric patients aged 2 to less than 18 years with nucleoside reverse transcriptase inhibitor resistance or toxicities precluding the use of first line pediatric agents. Viread is also approved for the treatment of chronic HBV in adults.
- 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 HBV in adults with compensated and decompensated liver disease. We licensed to GlaxoSmithKline Inc. (GSK) the rights to commercialize Viread for the treatment of chronic HBV in China, Japan and Saudi Arabia. In 2012, the European Commission approved the use of Viread for the treatment of chronic HBV infection in adolescent patients aged 12 to less than 18 years with compensated liver disease and evidence of immune active disease. 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 HBV in patients 12 years of age and older. We licensed to GSK the rights to commercialize Hepsera for the treatment of chronic HBV 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 U.S. 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 developed by Eyetech Inc. (Eyetech) using technology licensed from us and is now promoted in the United States by Valeant Pharmaceuticals, Inc. (Valeant), which acquired Eyetech in 2012. Valeant 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 Valeant and Pfizer based on sales of Macugen worldwide.

Sales of our antiviral products, which include products in our HIV/AIDS and Liver Disease areas described above, were $8.14 billion in 2012, $7.05 billion in 2011 and $6.54 billion in 2010. This represented 84% of our total revenues in 2012 and 2011 and 82% in 2010. Sales of our other products, which include Letairis, Ranexa, AmBisome and Cayston, were $1.26 billion in 2012, $1.05 billion in 2011 and $852.9 million in 2010. This represented 13% of our total revenues in 2012 and 2011 and 11% in 2010. Please see Item 7, Management's Discussion and Analysis included in this Annual Report on Form 10-K for more information regarding our revenues.

Commercialization and Distribution

We have U.S. and international commercial sales operations, with marketing subsidiaries in Australia, Austria, Belgium, Canada, the Czech Republic, Denmark, Finland, France, Germany, Greece, Hong Kong, Ireland, Italy, Japan, the Netherlands, New Zealand, Norway, Poland, Portugal, Russia, 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 Stribild, Complera, Atripla, Truvada, Viread, Hepsera, 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, 2012, 2011 and 2010. On a combined basis, in 2012, these wholesalers accounted for approximately 81% of our product sales in the United States and approximately 46% 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 Complera/Eviplera, Atripla, Truvada, Viread, Hepsera, Emtriva 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.

Access in the Developing World

Through the Gilead Access Program, established in 2003, certain of our products for the treatment of HIV, chronic HBV and visceral leishmaniasis are available at substantially reduced prices in the developing world. Gilead delivers its medicines in these countries by working with regional business partners to distribute brand-name Viread and Truvada at prices that are based on a country's ability to pay and represent little or no profit to Gilead. We also have partnerships with India-based companies to expand access to generic versions of our HIV medications in the least-developed countries of the world (see below).

We work closely with the World Health Organization and with non-governmental organizations to provide AmBisome for the treatment of leishmaniasis 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 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 HIV prevention strategy called pre-exposure prophylaxis, or PrEP. With the FDA approval in 2012, Truvada became the first agent indicated for uninfected individuals to reduce the risk of acquiring HIV through sex.

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 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 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. We have entered into non-exclusive license agreements with Indian generic manufacturers, granting them 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 and quality 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 Stribild and our future product candidates, elvitegravir, an investigational integrase inhibitor; and cobicistat, a pharmacoenhancing or "boosting" agent that increases blood levels to allow once-daily dosing of certain HIV medicines. To expand access to Viread for the treatment of HBV 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 HBV in the same countries where they are authorized to sell generic versions of tenofovir disoproxil fumarate for HIV. In August 2012, we announced new collaborations with Indian partners to produce and distribute generic emtricitabine in the developing world, including single tablet regimens containing emtricitabine and fixed-dose combinations of emtricitabine co-formulated with other Gilead HIV medicines.

- 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 granted 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 generic versions of Stribild and to our product candidates, elvitegravir and cobicistat, to those same generic pharmaceutical manufacturers in India for distribution in the developing world.
- Janssen. In 2011, we expanded our agreement with Janssen, formerly Tibotec Pharmaceuticals, 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.

Competition

Our marketed 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 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 Janssen.

BMS's Videx EC (didanosine, ddI) became the first generic HIV product in the United States in 2004. GSK's Retrovir (zidovudine) faces generic competition in the United States as a result of the launch of generic zidovudine in 2005. BMS's Zerit (stavudine) faces generic competition in the United States as a result of the launch of generic stavudine in 2008. Epivir (lamivudine), marketed by ViiV, is competitive with emtricitabine, the active pharmaceutical ingredient of Emtriva and a component of Atripla, Truvada, Complera/Eviplera and Stribild. In May 2010, the compound patent covering Epivir (lamivudine) itself expired in the United States and Europe, and generic lamivudine is now available in the United States, Spain, Portugal and 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, which resulted in an increase in the rebate for Viread 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.

We currently also expect competition from a generic version of Sustiva (efavirenz), a component of our Atripla, to be available in Europe and Canada in 2013 and the United States in 2014, which may negatively impact sales of our HIV products. We also expect the launch of dolutegravir, an integrase inhibitor, in the fourth quarter of 2013 by GSK which could impact the sales of our HIV products.

Our Liver Disease Products

Our HBV products, Viread and Hepsera, face significant competition from existing and expected therapies for treating patients with chronic HBV, which may erode the revenues we receive from sales of our HBV products. Our HBV products face competition from Baraclude (entecavir), an oral nucleoside analog developed by BMS and launched in the United States in 2005 and Europe in 2011, 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 major countries throughout North and South America, Europe and Asia.

Viread and Hepsera for the treatment of chronic HBV 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 HBV.

Our Cardiovascular Products

Letairis competes directly with Tracleer (bosentan) sold by Actelion Pharmaceuticals US, Inc. (Actelion) and indirectly with Adcirca (tadalafil) 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.

There are numerous marketed generic and/or branded pharmacologic stress agents that compete with Lexiscan/Rapiscan.

Our Respiratory Products

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

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 approved in Japan and South Korea.

Our Other Products

AmBisome faces strong competition from several current and expected competitors. 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 three lipid formulations that claim similarity to AmBisome becoming available outside of the United States, including the possible entry of such formulations in Greece and Taiwan. 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, respectively, 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.

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. in the United States and Novartis in territories outside the United States.

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 pro