GILEAD SCIENCES INC
Form 10-K
February 25, 2015

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, 2014
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 30, 2014 was $99,821,731,329.*

The number of shares outstanding of the registrant's Common Stock on February 13, 2015 was 1,489,401,683.

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 2015 Annual Meeting of Stockholders, to be held on May 6, 2015, are incorporated by reference into Part III of this Report.

* Based on a closing price of $82.91 per share on June 30, 2014. Excludes 310,054,509 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, 2014. 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.
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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®, SOVALDI®, TRUVADA®, HARVONI®, COMPLERA®, EVIPLERA®, STRIBILD®, VIREAD®, LETAIRIS®, RANEXA®, AMBISOME®, ZYDELIG®, EMTRIVA®, TYBOST®, HEPSERA®, VITEKTA®, CAYSTON®, VOLIBRIS® 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 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.

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 investigational drug candidate, we strive to transform and simplify care for people with life-threatening illnesses around the world. Gilead's primary areas of focus include human immunodeficiency virus (HIV), liver diseases such as chronic hepatitis C virus (HCV) infection and chronic hepatitis B virus (HBV) infection, oncology and inflammation, and serious cardiovascular and respiratory conditions. We have operations in more than 30 countries worldwide, with headquarters in Foster City, California. 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.

2014 Highlights

Over the past year, we brought best-in-class drugs to market that advanced the standard of care by offering enhanced modes of delivery, more convenient treatment regimens, improved resistance profiles, reduced side effects and greater efficacy. In the liver diseases area, we received approval from the U.S. Food and Drug Administration (FDA) and the European Commission of Harvoni®, the first once-daily single tablet regimen for the treatment of HCV genotype 1 infection in adults. Harvoni combines the NS5A inhibitor ledipasvir with the nucleotide analog polymerase inhibitor sofosbuvir, which was approved under the tradename Sovaldi® in December 2013. The approval of Harvoni represents a significant improvement in the treatment paradigm for the majority of HCV genotype 1 infected patients because it eliminates the need for pegylated interferon (peg-IFN) injections and ribavirin (RBV). In clinical studies, Harvoni demonstrated very high cure rates of 94% to 99% in eight or twelve weeks. In the HIV area, we submitted a new drug application (NDA) for a once-daily single tablet regimen containing elvitegravir 150 mg, cobicistat 150 mg, emtricitabine 200 mg and tenofovir alafenamide (TAF) 10 mg (E/C/F/TAF) for the treatment of HIV-1 infection in adults. We also received approval in the United States of Tybost® (cobicistat) and Vitekta® (elvitegravir 85 mg and 150 mg), each a component of Stribild®. In the oncology area, we received approval of Zydelig® (idelalisib), a first-in-class, targeted, oral inhibitor of PI3K delta, in combination with rituximab for the treatment of certain patients with chronic lymphocytic leukemia (CLL), small lymphocytic lymphoma (SLL) and follicular lymphoma (FL), the most common type of indolent non-Hodgkin's lymphoma (iNHL). We also advanced our research and development pipeline, with 225 active clinical studies at the end of 2014, of which more than 54 were Phase 3 clinical trials.

In addition to advancing treatment options across therapeutic areas, we also enabled access to our medications for people who need them around the world. During 2014, we signed non-exclusive license agreements with seven India-based generic drug companies to manufacture Sovaldi and Harvoni for distribution in 91 developing countries. We also announced an agreement with the Medicines Patent Pool (the MPP) under which the MPP can sublicense TAF to generic drug companies in India and China for manufacturing and distribution in 112 developing countries. These efforts extend ongoing programs to enable access for people in the most resource-limited parts of the world, where diseases like HIV and HCV affect the highest numbers of individuals.

HIV Program

Our goal is to ensure that all HIV patients can 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. We are focused on the development of new HIV medicines and co-formulations of products into complete regimens. With the launch of Stribild in the United States in 2012 and in Europe in 2013, Complera®/Eviplera® (emtricitabine 200 mg/rilpivirine 25 mg/tenofovir disoproxil fumarate 300 mg) in 2011 and Atripla® (efavirenz 600 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) in 2006, we now have three single tablet regimens available for the treatment of HIV.

In 2014, we advanced the development of a new single tablet regimen, E/C/F/TAF, for the treatment of HIV-1 infection in adults. Marketing applications for E/C/F/TAF are pending in the United States and European Union. The FDA has established a target review date, under the Prescription Drug User Fee Act, of November 5, 2015.

Phase 3 clinical studies demonstrated that patients taking E/C/F/TAF experienced favorable renal and bone safety compared to Stribild patients. We are also conducting Phase 3 clinical trials of the fixed-dose co-formulation of TAF and emtricitabine. Under an agreement with Janssen R&D Ireland (Janssen), formerly Tibotec Pharmaceuticals, we are evaluating a single tablet regimen of TAF, cobicistat, darunavir and emtricitabine for the treatment of HIV infection. We also amended our agreement with Janssen to collaborate on a single tablet regimen of rilpivirine, emtricitabine and TAF.

In 2014, we received FDA approval for Tybost, a pharmacokinetic enhancer that boosts blood levels of certain HIV medicines. Tybost is indicated as a boosting agent for the HIV protease inhibitors atazanavir (300 mg once daily) and darunavir (800 mg once daily) as part of antiretroviral combination therapy in adults with HIV-1 infection. In 2014, the FDA also approved Vitekta, an integrase inhibitor for the treatment of HIV-1 infection in adults without known mutations associated with resistance to elvitegravir. Vitekta is indicated for use as part of HIV treatment regimens that include a ritonavir-boosted protease inhibitor.

Liver Diseases

Our goal is to advance the treatment options and standard of care for the underserved HCV market. In 2013, we received approval of Sovaldi for the treatment of HCV as a component of a combination antiviral treatment regimen. Sovaldi's efficacy has been established in patients with HCV genotypes 1, 2, 3 or 4 infection (in United States and Europe) and genotypes 5 and 6 infection (in Europe), including those with hepatocellular carcinoma meeting Milan criteria (awaiting liver transplantation) and those with HCV/HIV-1 co-infection. Compared to the prior standard of care of up to 48 weeks, Sovaldi has shortened the duration of treatment to as few as 12 weeks and reduced or completely eliminated the need for peg-IFN injections in certain viral genotype populations.

In 2014, we received FDA and European Commission approval of Harvoni, the first once-daily single tablet regimen for the treatment of HCV genotype 1 infected patients, the most prevalent genotype in the United States. Harvoni combines the NS5A inhibitor ledipasvir with sofosbuvir and is indicated for an eight, 12 or 24 week treatment duration depending on prior treatment history, cirrhosis status and baseline viral load and eliminates the need for peg-IFN and RBV, which can be challenging to take and tolerate.

Marketing applications for sofosbuvir and the fixed-dose combination of ledipasvir and sofosbuvir are pending in Japan.

Our long term goal is to develop an oral therapy for all HCV patients across genotypes. Our fixed-dose combination of sofosbuvir and GS-5816, a pan-genotypic NS5A inhibitor, is currently in Phase 3 clinical trials. We are also evaluating a single tablet regimen of GS-9857, GS-5816 and sofosbuvir in Phase 2 trials for the potential treatment of HCV genotype 1 and 3 infected patients in four and six weeks.

We are evaluating TAF for the treatment of HBV and have completed enrollment of Phase 3 clinical trials. We are also conducting Phase 2 clinical studies of GS-4774, a Tarmogen T cell immunity stimulator, and GS-9620, an oral TLR-7 agonist, being evaluated as a potential cure for HBV.

We are evaluating simtuzumab for nonalcoholic steatohepatitis (NASH) in Phase 2 clinical trials. In December 2014, we also entered into an agreement with Phenex Pharmaceuticals AG (Phenex) under which we acquired Phenex's Farnesoid X Receptor (FXR) program comprised of small molecule FXR agonists for the treatment of liver diseases including NASH.

Oncology and Inflammation

In the oncology area, in 2014 we received FDA and European Commission approval of Zydelig (idelalisib), a first-in-class PI3K delta inhibitor, in combination with rituximab, for the treatment of patients with certain blood cancers. In the fourth quarter of 2014, we also initiated Phase 3 clinical studies to evaluate idelalisib as a treatment for patients with iNHL and a frontline treatment for patients with CLL.

In December 2014, we entered into an exclusive license agreement with ONO Pharmaceutical Co., Ltd. for the development and commercialization of ONO-4059 (now known as GS-4059), an oral Bruton's tyrosine kinase inhibitor for the treatment of B-cell malignancies and other diseases.

Cardiovascular

In 2014, we released positive results from the AMBITION study (a randomized, double-blind, multicenter study of first-line combination therapy with Letairis® (ambrisentan) and tadalafil in patients with pulmonary arterial hypertension), which was conducted in collaboration with GlaxoSmithKline plc. In AMBITION, first-line treatment of pulmonary arterial hypertension with the combination of ambrisentan 10 mg and tadalafil 40 mg reduced the risk of clinical failure by 50 percent compared to the pooled ambrisentan and tadalafil monotherapy arm. The combination was also statistically significant versus the individual ambrisentan and tadalafil monotherapy groups for the primary endpoint. We have filed a supplemental NDA in the United States to cover the use of ambrisentan in combination with tadalafil.

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Our Products

HIV

- Stribild is an oral formulation dosed once a day for the treatment of HIV-1 infection in treatment-naive adults. Stribild is our third complete single tablet regimen for the treatment of HIV and is a fixed-dose combination of our antiretroviral medications, Vitekta, Tybost, Viread® and Emtriva® (emtricitabine). Stribild was approved by the FDA in August 2012 and the European Commission in May 2013.
- Complera/Eviplera is an oral formulation dosed once a day for the treatment of HIV-1 infection in adults. The product, marketed in the United States as Complera and in Europe as Eviplera, is our second complete single tablet regimen for the treatment of HIV and is a fixed-dose combination of our antiretroviral medications, Viread and Emtriva, and Janssen's non-nucleoside reverse transcriptase inhibitor, Edurant (rilpivirine).
- Atripla is an oral formulation dosed once a day for the treatment of HIV infection in adults. Atripla is our first 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 (BMS'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 two years of age and older. In 2012, the European Commission approved the use of Viread in combination with other antiretroviral agents for the treatment of HIV-1 infected adolescent patients aged two 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.
- 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.
- Tybost is a pharmacokinetic enhancer dosed once a day that boosts blood levels of certain HIV medicines. Tybost is indicated as a boosting agent for the HIV protease inhibitors atazanavir and darunavir as part of antiretroviral combination therapy in adults with HIV-1 infection.
- Vitekta is an oral formulation of an integrase inhibitor, dosed once a day as part of combination therapy to treat HIV infection in adults without known mutations associated with resistance to elvitegravir, the active ingredient of Vitekta. Vitekta is indicated for use as part of HIV treatment regimens that include a ritonavir-boosted protease inhibitor.

Liver Diseases

- Harvoni is an oral formulation of the NS5A inhibitor with a nucleotide analog polymerase inhibitor dosed once a day for the treatment of HCV genotype 1 infection in adults. Harvoni was approved by the FDA in October 2014 and by the European Commission in November 2014. In Europe, Harvoni is also indicated for certain patients with HCV genotype 4 infection, HCV genotype 3 infection with cirrhosis and/or prior treatment failure and those with HCV/HIV-1 co-infection.
- Sovaldi is an oral formulation of a nucleotide analog polymerase inhibitor dosed once a day for the treatment of HCV as a component of a combination antiviral treatment regimen. Sovaldi was approved by the FDA in December 2013 and by the European Commission in January 2014. Sovaldi’s efficacy has been established in patients with HCV genotypes 1, 2, 3 or 4 infection (in United States and Europe) and genotypes 5 and 6 infection (in Europe), including those with hepatocellular carcinoma meeting Milan criteria (awaiting liver transplantation) and those with HCV/HIV-1 co-infection.
- 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.

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- 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 Pacific, Latin America and certain other territories.

Oncology

- Zydelig is a first-in-class PI3K delta inhibitor, in combination with rituximab, for the treatment of certain blood cancers. In July 2014, the FDA approved Zydelig for relapsed CLL, FL and SLL. In September 2014, the European Commission approved Zydelig for CLL and FL.

Cardiovascular

- Letairis (ambrisentan) is an oral formulation of an endothelin receptor antagonist (ERA) indicated for the treatment of pulmonary arterial hypertension (PAH) (World Health Organization (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 (Astellas) has exclusive rights to manufacture and sell regadenoson under the name 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 seven 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.
- 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 worldwide sales of Macugen.

Sales of our antiviral products, which include products in our HIV and liver diseases areas described above, were $22.8 billion in 2014, $9.3 billion in 2013 and $8.1 billion in 2012. This represented 91% of our total revenues in 2014, 83% of our total revenues in 2013 and 84% of our total revenues in 2012. Sales of our other products were $1.7 billion in 2014, $1.5 billion in 2013 and $1.3 billion in 2012. This represented 7% of our total revenues in 2014 and 13% of our total revenues in 2013 and 2012. See Item 7, Management's Discussion and Analysis and Item 8, Note 15 Segment Information in our Consolidated Financial Statements included in this Annual Report on Form 10-K.

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Commercialization and Distribution

We have U.S. and international commercial sales operations, with marketing subsidiaries in Argentina, Australia, Austria, Belgium, Brazil, Canada, the Czech Republic, Denmark, Finland, France, Germany, Greece, Hong Kong, India, Ireland, Israel, Italy, Japan, Malaysia, Mexico, the Netherlands, New Zealand, Norway, Panama, Poland, Portugal, Russia, Singapore, Slovakia, South Africa, South Korea, Spain, Sweden, Switzerland, Taiwan, Turkey, the United Arab Emirates, 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 Sovaldi, Atripla, Truvada, Harvoni, Complera, Stribild, Viread, Emtriva, Ranexa, Zydelig, Tybost and Hepsera and 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, 2014, 2013 and 2012. On a combined basis, in 2014, these wholesalers accounted for approximately 87% of our product sales in the United States and approximately 63% 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 Stribild, Eviplera, Atripla, Truvada, Sovaldi, Harvoni, Viread, Hepsera, Emtriva, Vitekta, Tybost and AmBisome in Europe and countries outside the United States, where the product is approved, either through our commercial teams, third-party distributors or corporate partners.

U.S. Patient Access

We make it a priority to increase access to our medicines for people who can benefit from them, regardless of their ability to pay. In the United States, our U.S. patient assistance programs help make our therapies accessible for uninsured individuals and those who need financial assistance. We also support programs for those unable to afford the co-payments associated with health insurance programs. Half of all patients taking our HIV medicines in the United States already receive them through federal and state programs at substantially discounted prices. We have a long history of working with state AIDS Drug Assistance Programs (ADAPs) to provide lower pricing for our HIV medicines. The price freeze we instituted for ADAPs in 2008 was extended in 2013 through the end of 2014, providing important support to these critical programs as they evolve in the changing U.S. healthcare environment.

Access in the Developing World

Through the Gilead Access Program, established in 2003, certain of our products for the treatment of HIV, HBV, HCV and visceral leishmaniasis are available at substantially reduced prices in the developing world. We deliver our medicines in these countries by working with regional business partners to distribute brand-name Truvada and Viread at prices that are based on a country's ability to pay and represent little or no profit to us. We also have partnerships with India-based companies to expand access to generic versions of our HIV and HCV 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 have 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 the World Health Organization to donate 445,000 vials of AmBisome over five years. This donation is being 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 FDA approval for PrEP 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 Acquisition Company 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, including 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 Truvada and Viread 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 Truvada and Viread for the treatment of HIV infection in these developing world countries. Aspen has the right to purchase Truvada and Viread in unlabeled bottles from us for distribution in such countries, and also has the right to manufacture Truvada and Viread 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 Truvada and Viread, 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 include India and many 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 cobicistat and elvitegravir, including generic versions of our combination product containing the four active ingredients of cobicistat, elvitegravir, tenofovir disoproxil fumarate and emtricitabine. 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 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 our other HIV medicines. In 2014, we granted certain of our Indian partners direct licenses to produce and distribute generic tenofovir alafenamide in the developing world, including single tablet regiments containing emtricitabine and fixed-dose combinations of tenofovir alafenamide and emtricitabine co-formulated with our other HIV medicines. In 2014, we also entered into eight new collaborations with our Indian partners to produce and distribute generic versions of sofosbuvir and the fixed-dose combination of ledipasvir/sofosbuvir for distribution in 91 developing countries. In early 2015, we expanded our collaborations to allow our Indian partners to manufacture GS-5816 and the single tablet regimen of sofosbuvir/GS-5815, once approved.
- Merck & Co., Inc. (Merck). In 2006, we entered into an agreement with an affiliate of Merck pursuant to which we 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. In 2008,

we also entered into an agreement with Merck to commercialize Atripla in over 30 low-middle income countries, including Brazil, Egypt and Mexico.

- 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 MPP). In 2011, we entered into an agreement with the MPP, 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 MPP 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 MPP will be free to develop combination products and pediatric formulations of our HIV medicines. We also granted the MPP the right to grant sublicenses to generic versions of the single tablet regimen consisting of elvitegravir, cobicistat, tenofovir disoproxil fumarate and emtricitabine and to our product candidates, elvitegravir and cobicistat, to those same generic pharmaceutical manufacturers in India for distribution in the developing world. In 2014, we entered into a new agreement with the MPP to expand access to TAF for HIV and HBV to developing countries, contingent on the medicine's U.S. regulatory approval. Under the agreement, the MPP can sub-license to generic drug companies in India and China the right to manufacture generic versions of products containing TAF, including fixed-dose combinations of TAF co-formulated with certain of our other HIV medicines and distribute such generic versions in 112 developing countries.

- Janssen. In 2011, we expanded our agreement with Janssen to provide for distribution of Complera/Eviplera for the treatment of HIV in less developed countries. In 2014, the agreement was amended to include a product in clinical development containing Janssen's rilpivirine and our emtricitabine and TAF.

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 39 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 ViiV Healthcare (ViiV). These products compete with Stribild, Complera/Eviplera, Atripla and Truvada. For Tybost, we compete with ritonavir, marketed by AbbVie Inc. (AbbVie). Our HIV products also compete broadly with HIV products from AbbVie, Boehringer Ingelheim GmbH, Merck, Roche and Janssen. In addition, Tivicay (dolutegravir), an integrase inhibitor launched in 2013 by ViiV, and Triumeq (dolutegravir/abacavir/lamivudine), a single tablet antiretroviral regimen launched in the third quarter of 2014 by ViiV, could adversely impact sales of our HIV products.

We also face competition from generic HIV products. BMS's Videx EC (didanosine, ddI) became the first generic HIV product in the United States in 2004. GSK's Retrovir (zidovudine) faces competition in the United States as a result of the launch of generic zidovudine in 2005. BMS's Zerit (stavudine) faces 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 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 (lamivud