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

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2014

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to
Commission File No. 0-19731

GILEAD SCIENCES, INC.
(Exact name of registrant as specified in its charter)

Delaware	**94-3047598**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
333 Lakeside Drive, Foster City, California	**94404**
(Address of principal executive offices)	**(Zip Code)**

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

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

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

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

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

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

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

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

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

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

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

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

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

2014 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 ®, 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," 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.

Cipla v. Gilead **IPR2025-00033** **Petitioner Exhibit 1030**

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.

Cipla v. Gilead IPR2025-00033 Petitioner Exhibit 1030

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,

Cipla v. Gilead IPR2025-00033 Petitioner Exhibit 1030

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.

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- **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

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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. Generic efavirenz, the active pharmaceutical ingredient in Sustiva and a component of our Atripla, is now available in Canada and Europe and we expect competition from generic efavirenz in the United States in December 2017. This may put pricing pressure on our HIV products.

Our Liver Diseases Products

Our HCV products, Sovaldi and Harvoni, compete with AbbVie's Viekira Pak and Janssen's Olysio (simeprevir) in the United States.

Our HBV products, Viread and Hepsera, face significant competition from existing and expected therapies for treating patients with 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 as well as generic entecavir. Our HBV products also compete with Tyzeka/Sebivo (telbivudine), an oral nucleoside analog developed by Novartis Pharmaceuticals Corporation (Novartis), and Epivir-HBV/Zeffix (lamivudine), which was developed by GSK in collaboration with Shire plc.

Viread and Hepsera for the treatment of HBV also compete with established immunomodulatory therapies, including Intron-A (interferon alfa-2b), which is sold by Merck 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 HBV.

Our Cardiovascular Products

Letairis competes directly with Tracleer (bosentan) and Opsumit (macitentan). Both drugs are sold by Actelion Pharmaceuticals US, Inc. Letairis also competes 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, which 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

Zydelig competes with Imbruvica (ibrutinib) marketed by Pharmacyclics, Inc. for the treatment of relapsed CLL.

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.

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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 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.

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 programs.

Collaborative Relationships

As part of our business strategy, we establish collaborations with other companies, universities and medical research institutions to assist in the clinical development and/or commercialization of certain of our products and product candidates and to provide support for our research programs. We also evaluate opportunities for acquiring products or rights to products and technologies that are complementary to our business from other companies, universities and medical research institutions. For more information regarding certain of these relationships, including their ongoing financial and accounting impact on our business, see Item 8, Note 9 Collaborative Arrangements in our Consolidated Financial Statements included in this Annual Report on Form 10-K.

Commercial Collaborations

Although we currently have a number of collaborations with corporate partners for the manufacture, sale, distribution and/or marketing of our products in various territories worldwide, the following commercial collaborations are those that are most significant to us from a financial statement perspective and where significant ongoing collaboration activity exists.

- **BMS.** In 2004, we entered into a collaboration arrangement with BMS to develop and commercialize a single tablet regimen containing our Truvada and BMS's Sustiva (efavirenz) in the United States. This combination was approved for use in the United States in 2006 and is sold under the brand name Atripla. We and BMS structured this collaboration as a joint venture that operates as a limited liability company named Bristol-Myers Squibb & Gilead Sciences, LLC, which we consolidate. We and BMS granted royalty-free sublicenses to the joint venture for the use of our respective company owned technologies and, in return, were granted a license by the joint venture to use any intellectual property that results from the collaboration. In 2006, we and BMS amended the joint venture's collaboration agreement to allow the joint venture to sell Atripla in Canada. The economic interests of the joint venture held by us and BMS (including share of revenues and out-of-pocket expenses) are based on the portion of the net selling price of Atripla attributable to efavirenz and Truvada. Since the net selling price for Truvada may change over time relative to the net selling price of efavirenz, both our and BMS's respective economic interests in the joint venture may vary annually. We and BMS shared marketing and sales efforts. Starting in 2011, except for a limited number of activities that are jointly managed, the parties no longer coordinate detailing and promotional activities in the United States, and the parties have reduced their joint promotional efforts since we launched Complera in August 2011 and Stribild in August 2012. The agreement will continue until terminated by the mutual agreement of the parties. In addition, either party may terminate the other party's participation in the collaboration within 30 days after the launch of at least one generic version of such other party's single agent products (or the double agent products). The terminating party then has the right to continue to sell Atripla and become the continuing party, but will be obligated to pay the terminated party certain royalties for a three-year period following the effective date of the termination.

  In 2007, Gilead Sciences Ireland Unlimited Company, our wholly-owned subsidiary formerly known as Gilead Sciences Limited, and BMS entered into a collaboration agreement under which we and BMS commercialize and distribute Atripla in the European Union, Iceland, Liechtenstein, Norway and Switzerland (collectively, the European Territory). The parties formed a limited liability company which we consolidate, to manufacture Atripla for distribution in the European Territory using efavirenz that it purchases from BMS at BMS's estimated net selling price of efavirenz in the European Territory. Starting in 2012, except for a limited number of activities that are jointly managed, the parties no longer coordinate detailing and promotional activities in the region. As of December 31, 2014 and 2013 , efavirenz purchased from BMS at BMS's estimated net selling price of efavirenz in the European Territory is included in inventories on our Consolidated Balance Sheets. The agreement will

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terminate upon the expiration of the last-to-expire patent which affords market exclusivity to Atripla or one of its components in the European Territory. In addition, starting December 31, 2013, either party may terminate the agreement for any reason and such termination will be effective two calendar quarters after notice of termination. The non-terminating party has the right to continue to sell Atripla and become the continuing party, but will be obligated to pay the terminating party certain royalties for a three-year period following the effective date of the termination. In the event the continuing party decides not to sell Atripla, the effective date of the termination will be the date Atripla is withdrawn in each country or the date on which a third party assumes distribution of Atripla, whichever is earlier.

- **Janssen.** In 2009, we entered into a collaboration agreement with Janssen to develop and commercialize a fixed-dose combination of our Truvada and Janssen's rilpivirine. The agreement was amended in 2011, 2013 and 2014. The combination was approved in the United States and European Union in 2011 and is sold under the brand name Complera in the United States and Eviplera in the European Union. The 2014 amendment expanded the collaboration to include another single tablet regimen containing Janssen's rilpivirine and our emtricitabine and tenofovir alafenamide (RFTAF). Under the agreement, Janssen granted us an exclusive license to Complera/Eviplera and RFTAF worldwide but has the right to distribute both combination products in 18 countries including Mexico, Russia and Japan. Neither party is restricted from combining its drugs with any other drug products except those which are similar to the components of Complera/Eviplera and RFTAF.

  In December 2011, we recorded €72 million (approximately $100 million) in reimbursable research and development (R&D) expenses incurred by Janssen in the development of rilpivirine. This represented the maximum amount reimbursable under the terms of the agreement. We are responsible for manufacturing Complera/Eviplera and RFTAF and have the lead role in registration, distribution and commercialization of both products except in the countries where Janssen distributes. Janssen has exercised a right to co-detail the combination product in some of the countries where Gilead is the selling party.

  The selling party sets the price of the products and the parties share revenues based on the ratio of the net selling prices of the party's component(s), subject to certain restrictions and adjustments. We retain a specified percentage of Janssen's share of revenues, up to 30% in major markets.

  Either party may terminate the collaboration agreement with respect to a product and a country if the product is withdrawn from the market in such country or with respect to a product in all countries if the other party materially breaches the agreement with respect to a product. The agreement and the parties' obligation to share revenues will expire on a product-by-product and country-by-country basis as Janssen patents providing exclusivity for the product expire or, if later, on the tenth anniversary of the commercial launch for such product. We may terminate the agreement without cause with respect to the countries where we sell the products in which case Janssen has the right to become the selling party for such country if the product has launched but has been on the market for fewer than 10 years.

- **Japan Tobacco.** In 2005, we entered into a licensing agreement with Japan Tobacco, under which Japan Tobacco granted us exclusive rights to develop and commercialize elvitegravir, a novel HIV integrase inhibitor, in all countries of the world, excluding Japan, where Japan Tobacco retains such rights. Under the agreement, we are responsible for seeking regulatory approval in our territories and are required to use diligent efforts to commercialize elvitegravir-containing products for the treatment of HIV infection. We bear all costs and expenses associated with such commercialization efforts. Under the terms of the agreement, we paid an up-front license fee of $15 million and total milestone payments of $90 million for the achievement of certain clinical, regulatory and commercial objectives. Additionally, we are obligated to pay royalties based on any net sales of products containing elvitegravir in the territories where we market them. The agreement and our obligation to pay royalties to Japan Tobacco will terminate on a product-by-product basis as patents providing exclusivity for the product expire or, if later, on the tenth anniversary of the commercial launch for such product. We may terminate the agreement for any reason in which case the license granted by Japan Tobacco to us would terminate. Either party may terminate the agreement in response to a material breach by the other party.

Research Collaborations

We also have a number of collaborations with partners for the R&D of certain compounds and drug candidates. None of our research collaborations rose to a level that is significant to us from a financial statement perspective and where significant ongoing collaboration activity exists.

Research and Development

Our R&D philosophy and strategy is to develop best-in-class drugs that improve safety or efficacy for unmet medical needs. We intend to continue committing significant resources to R&D opportunities and business development activity.

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Our product development efforts cover a wide range of medical conditions, including HIV/AIDS and liver diseases such as HBV and HCV, inflammation/oncology and serious cardiovascular and respiratory conditions. We have research scientists in Foster City, Fremont, San Dimas and Oceanside, California; Branford, Connecticut; Seattle, Washington; and Alberta, Canada engaged in the discovery and development of new molecules and technologies that we hope will lead to the approval of new medicines addressing unmet needs.

The development of our product candidates is subject to various risks and uncertainties. These risks and uncertainties include our ability to enroll patients in clinical trials, the possibility of unfavorable results of our clinical trials, the need to modify or delay our clinical trials or to perform additional trials and the risk of failing to obtain regulatory approvals. As a result, our product candidates may never be successfully commercialized. Drug development is inherently risky and many product candidates fail during the drug development process.

Below is a summary of our key product candidates and their corresponding current stages of development. For additional information on our development pipeline, visit our website at www.gilead.com.

Product Candidates for the Treatment of HIV

Product Candidates	Description
Marketing Application Pending	
Single tablet regimen of elvitegravir, cobicistat, emtricitabine and TAF	A single tablet regimen of elvitegravir, cobicistat, emtricitabine and TAF is being evaluated for the treatment of HIV infection.
Products in Phase 3	
Fixed-dose co-formulation of emtricitabine and TAF	A fixed-dose co-formulation of emtricitabine and TAF is being evaluated for the treatment of HIV infection.
Single tablet regimen of emtricitabine, rilpivirine and TAF	Under an agreement with Janssen, a single tablet regimen of emtricitabine, rilpivirine and TAF is being evaluated for the treatment of HIV infection.

Product Candidates for the Treatment of Liver Diseases

Product Candidates	Description
Products in Phase 3	
Fixed-dose combination of sofosbuvir and GS-5816	A fixed-dose combination of sofosbuvir and GS-5816, a nucleotide NS5B inhibitor/pan-genotypic NS5A inhibitor, is being evaluated for the treatment of HCV.
TAF	TAF is a nucleotide reverse transcriptase inhibitor being evaluated for the treatment of HBV.
Products in Phase 2	
Fixed-dose combination of GS-9857, sofosbuvir and GS-5816	GS-9857 is a pan-genotypic NS3 protease inhibitor being evaluated in combination with sofosbuvir and GS-5816 for the treatment of HCV.
GS-4774	GS-4774 is a Tarmogen T cell immunity stimulator being evaluated for the treatment of HBV.
GS-9620	GS-9620 is an oral TLR-7 agonist being evaluated as a potential cure of HBV.
Simtuzumab	Simtuzumab is a monoclonal antibody being evaluated for the treatment of liver fibrosis, NASH and primary sclerosing cholangitis.
Products in Phase 1	
GS-4997	GS-4997 is an ASK-1 inhibitor being evaluated for the treatment of diabetic nephropathy and NASH.
GS-6637	GS-6637 is an ALDH-2 inhibitor being evaluated for the treatment of drug addiction.

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Product Candidates for the Treatment of Oncology and Inflammation

Product Candidates	Description
Products in Phase 3	
Idelalisib	Idelalisib is a PI3K delta inhibitor being evaluated for the treatment of iNHL and frontline and relapsed refractory CLL.
Momelotinib	Momelotinib is a JAK inhibitor being evaluated for the treatment of myelofibrosis.
Products in Phase 2	
GS-9973	GS-9973 is a spleen tyrosine kinase (Syk) inhibitor being evaluated with hematological malignancies.
Idelalisib	Idelalisib is also being evaluated for the treatment of frontline iNHL.
Momelotinib	Momelotinib is also being evaluated for the treatment of pancreatic cancer.
Products in Phase 1	
GS-4059	GS-4059 is a Bruton's tyrosine kinase inhibitor being evaluated for B-cell malignancies.
GS-5745	GS-5745 is a MMP9 maB inhibitor being evaluated for the treatment of solid tumors and ulcerative colitis.
GS-9901	GS-9901 is a PI3K delta inhibitor being evaluated for the treatment of hematological malignancies.

Product Candidates for the Treatment of Cardiovascular Diseases

Product Candidates	Description
Products in Phase 3	
Ranolazine	Ranolazine is a late sodium current inhibitor approved for the treatment of chronic angina, which is being evaluated for the treatment of incomplete revascularization post-percutaneous coronary intervention.
GS-6615	GS-6615 is a late sodium current inhibitor being evaluated for the treatment of LQT-3 Syndrome.
Products in Phase 2	
Fixed-dose combination of ranolazine and dronedarone	A fixed-dose combination of ranolazine and dronedarone is being evaluated for the treatment of paroxysmal atrial fibrillation.
GS-4997	GS-4997 is also being evaluated for the treatment of pulmonary arterial hypertension.
GS-6615	GS-6615 is a late sodium current inhibitor being evaluated for the treatment of LQT-3 Syndrome and hypertrophic cardiomyopathy.

Product Candidates for the Treatment of Respiratory Diseases

Product Candidates	Description
Products in Phase 2	
GS-5806	GS-5806 is an inhalable small molecule antiviral fusion inhibitor being evaluated for the treatment of respiratory syncytial virus.
Simtuzumab	Simtuzumab is also being evaluated for the treatment of idiopathic pulmonary fibrosis.

In total, our R&D expenses for 2014 were $2.9 billion compared with $2.1 billion for 2013 and $1.8 billion for 2012 . In addition to our internal discovery and clinical development programs, we seek to add to our portfolio of products through product acquisitions, licenses and collaborations.

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. In December 2014, we entered into an agreement with Phenex

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Pharmaceuticals AG (Phenex) under which we acquired Phenex's Farnesoid X Receptor program comprised of small molecule FXR agonists for the treatment of liver diseases including NASH.

Patents and Proprietary Rights

U.S. and European Patent Expiration

We have a number of U.S. and foreign patents, patent applications and rights to patents related to our compounds, products and technology, but we cannot be certain that issued patents will be enforceable or provide adequate protection or that pending patent applications will result in issued patents.

The following table shows the estimated expiration dates (including Patent Term Extension, Supplementary Protection Certificates and/or Pediatric exclusivity where granted) in the United States and Europe for the primary (typically compound) patents for our Phase 3 product candidates. Patents do not cover the ranolazine compound, the active ingredient of Ranexa. Instead, when it was discovered that only a sustained-release formulation of ranolazine would achieve therapeutic plasma levels, patents were obtained on those formulations and the characteristic plasma levels they achieve. For our product candidates that are single tablet regimens, the estimated patent expiration date provided corresponds to the latest expiring compound patent for one of the active ingredients in the single tablet regimen.

Phase 3 Product Candidates	Patent Expiration	
Product Candidates for the Treatment of HIV	**U.S.**	**E.U.**
Single tablet regimen of elvitegravir, cobicistat, emtricitabine and TAF	2029	(2027)
Single tablet regimen of emtricitabine and TAF	2022	(2021)
Single tablet regimen of darunavir, cobicistat, emtricitabine and TAF	2029	(2027)
Single tablet regimen of emtricitabine, rilpivirine and TAF	2023	2022
Product Candidates for the Treatment of Liver Diseases		
Single tablet regimen of sofosbuvir and GS-5816 for the treatment of HCV	2030	(2032)
Single agent TAF for the treatment of HBV	2022	(2021)
Product Candidates for the Treatment of Oncology/Inflammation		
Idelalisib for the treatment of iNHL and frontline and relapsed refractory CLL	2025	(2025)
Momelotinib for the treatment of myelofibrosis	2030	(2028)
Product Candidates for the Treatment of Cardiovascular Diseases		
Ranolazine for the treatment of incomplete revascularization post-percutaneous coronary intervention and the treatment of type II diabetes	2019	2023
GS-6615 for the treatment of LQT-3 Syndrome	2032	(2032)

Dates in parentheses reflect the estimated expiration date of patents which may issue from currently pending applications. The estimated expiration dates do not include any potential additional exclusivity (e.g., patent term extension, supplementary protection certificates or pediatric exclusivity) that has not yet been granted.

The following table shows the actual or estimated expiration dates (including Patent Term Extension, Supplementary Protection Certificates and/or Pediatric exclusivity where granted) in the United States and Europe for the primary (typically compound) patents for our marketed products. For our product that are single tablet regimens (e.g., Truvada, Atripla, Complera/Eviplera and Stribild), the estimated patent expiration dates provided correspond to the latest expiring compound patent for one of the active ingredients in the single tablet regimen.

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Products	Patent Expiration	
	U.S.	E.U.
Hepsera	2014	2016
AmBisome	2016	2008
Macugen	2017	2017
Tamiflu	2017	2016
Letairis	2018	2020
Viread	2018*	2018
Ranexa	2019**	2023
Atripla	2021	2018
Cayston	2021	2021
Emtriva	2021	2016
Truvada	2021	2018
Lexiscan	2022	2025
Complera/Eviplera	2023	2022
Vitekta	2023	2023
Zydelig	2025	2025
Sovaldi	2029	2028
Stribild	2029	2027
Tybost	2029	2027
Harvoni	2030	(2030)

Dates in parentheses reflect the estimated expiration date of patents which may issue from currently pending applications. The estimated expiration dates do not include any potential additional exclusivity (e.g., patent term extension, supplementary protection certificates or pediatric exclusivity) that has not yet been granted.

* In 2013, Gilead and Teva Pharmaceuticals (Teva) reached an agreement in principle to settle the ongoing patent litigation concerning the four patents that protect tenofovir disoproxil fumarate in our Viread, Truvada and Atripla products. Under the agreement, Teva will be allowed to launch a generic version of Viread on December 15, 2017.

** In 2013, Gilead and Lupin Limited (Lupin) reached an agreement to settle the patent litigation prior to issuance of the court's decision. Under the agreement, Lupin will be allowed to launch a generic version of Ranexa on February 27, 2019.

Patent Protection and Certain Challenges

Patents and other proprietary rights are very important to our business. If we have a properly drafted and enforceable patent, it can be more difficult for our competitors to use our technology to create competitive products and more difficult for our competitors to obtain a patent that prevents us from using technology we create. As part of our business strategy, we actively seek patent protection both in the United States and internationally and file additional patent applications, when appropriate, to cover improvements in our compounds, products and technology.

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

We may obtain patents for certain products many years before marketing approval is obtained for those products. Because patents have a limited life, which may begin to run prior to the commercial sale of the related product, the commercial value of the patent may be limited. However, we may be able to apply for patent term extensions or supplementary protection certificates in some countries. For example, extensions for the patents or supplementary protection certificates on many of our products have been granted in the United States and in a number of European countries, compensating in part for delays in obtaining marketing approval. Similar patent term extensions may be available for other products that we are developing, but we cannot be certain we will obtain them in some countries.

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It is also important that we do not infringe the valid patents of third parties. If we infringe the valid patents of third parties, we may be prevented from commercializing products or may be required to obtain licenses from these third parties. We may not be able to obtain alternative technologies or any required license on reasonable terms or at all. If we fail to obtain these licenses or alternative technologies, we may be unable to develop or commercialize some or all of our products. For example, we are aware of a body of patents that may relate to our operation of Letairis Education and Access Program (LEAP), our restricted distribution program designed to support Letairis and we are aware of patents and patent applications owned by other parties that may claim to cover the use of sofosbuvir and the use of the combination of sofosbuvir and ledipasvir.

Because patent applications are confidential for a period of time until a patent is issued, we may not know if our competitors have filed patent applications for technology covered by our pending applications or if we were the first to invent or first to file an application directed toward the technology that is the subject of our patent applications. Competitors may have filed patent applications or received patents and may obtain additional patents and proprietary rights that block or compete with our products. In addition, if competitors file patent applications covering our technology, we may have to participate in interference/derivation proceedings or litigation to determine the right to a patent. Litigation and interference/derivation proceedings are unpredictable and expensive, such that, even if we are ultimately successful, our results of operations may be adversely affected by such events.

Patents relating to pharmaceutical, biopharmaceutical and biotechnology products, compounds and processes such as those that cover our existing compounds, products and processes and those that we will likely file in the future, do not always provide complete or adequate protection. Future litigation or other proceedings regarding the enforcement or validity of our existing patents or any future patents could result in the invalidation of our patents or substantially reduce their protection. From time to time, certain individuals or entities may challenge our patents.

Our pending patent applications and the patent applications filed by our collaborative partners may not result in the issuance of any patents or may result in patents that do not provide adequate protection. As a result, we may not be able to prevent third parties from developing compounds or products that are closely related to those which we have developed or are developing. In addition, certain countries in South America, Africa and Asia, including Brazil and China, do not provide effective enforcement of our patents, and third-party manufacturers may be able to sell generic versions of our products in those countries.

Litigation Regarding Sofosbuvir

In January 2012, we acquired Pharmasset, Inc. (Pharmasset). Through the acquisition, we acquired sofosbuvir, a nucleotide analog that acts to inhibit the replication of the HCV. In December 2013, we received FDA approval of sofosbuvir, now known commercially as Sovaldi. In October 2014, we also received approval of the fixed-dose combination of ledipasvir and sofosbuvir, now known commercially as Harvoni. We have received a number of intellectual property claims regarding sofosbuvir. We have carefully considered these claims both prior to and following the acquisition and believe they are without merit.

We own patents and patent applications that claim sofosbuvir (Sovaldi) as a chemical entity and its metabolites and the fixed-dose combination of ledipasvir and sofosbuvir (Harvoni). Third parties may have, or may obtain rights to, patents that allegedly could be used to prevent or attempt to prevent us from commercializing Sovaldi or Harvoni. For example, we are aware of patents and patent applications owned by other parties that may be alleged by such parties to cover the use of Sovaldi and Harvoni. We cannot predict the ultimate outcome of intellectual property claims related to Sovaldi or Harvoni, and we have spent, and will continue to spend, significant resources defending against these claims.

If these parties successfully obtain valid and enforceable patents, and successfully prove infringement of those patents by Sovaldi and/or Harvoni, we could be prevented from selling these products unless we were able to obtain a license under such patents. Such a license may not be available on commercially reasonable terms or at all.

Interference Proceedings and Litigation with Idenix Pharmaceuticals, Inc. (Idenix)

In February 2012, we received notice that the U.S. Patent and Trademark Office (USPTO) had declared Interference No. 105,871 (First Idenix Interference) between our U.S. Patent No. 7,429,572 (the ‘572 patent) and Idenix's pending U.S. Patent Application No. 12/131,868. An interference is an administrative proceeding before the USPTO designed to determine who was the first to invent the subject matter claimed by both parties. Our patent covers metabolites of sofosbuvir. Idenix is attempting to patent a class of compounds, including these metabolites. The purpose of the First Idenix Interference was to determine who was first to invent these compounds and therefore who is entitled to the patent claiming these compounds. In March 2013, the USPTO Patent Trial and Appeal Board (the Board) determined that Idenix is not entitled to the benefit of any of its early application filing dates because none of those patent applications, including the application granted as

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Idenix's U.S. Patent No. 7,608,600 (the '600 patent), taught how to make the compounds in dispute. The Board also determined that because we are entitled to the filing date of our earliest application, we were first to file the patent application on the compounds in dispute, and we were therefore the "senior party" in the First Idenix Interference. On January 29, 2014, the Board determined that Pharmasset and not Idenix was the first to invent the compounds in dispute and accordingly Gilead prevailed in the First Idenix Interference. In its decision, the Board held that Idenix failed to prove that it was first to conceive of any of the compounds in dispute. Specifically, Idenix failed to prove that the Idenix inventors had identified the structure, a method of making and a use for any of the disputed compounds. The Board went on to conclude that Idenix failed to work diligently toward making and testing the compounds in dispute during the relevant time period. Idenix has appealed the Board's decisions to the U.S. District Court for the District of Delaware.

In December 2013, after receiving our request to do so, the USPTO declared Interference No. 105,981 (Second Idenix Interference) between our pending U.S. Patent Application No. 11/854,218 and the '600 patent. The '600 patent includes claims directed to methods of treating HCV with nucleoside compounds similar to those which were involved in the First Idenix Interference. The Second Idenix Interference will determine who was first to invent the claimed methods of treating HCV. On January 16, 2015 the Board issued a decision in favor of Gilead in the first phase of the Second Idenix Interference. The Board decided that we were first to file the patent application on the disputed methods of treating HCV, designated Gilead as the senior party in the Second Idenix Interference, and invalidated the patent claims of the Idenix '600 patent that are involved in the Second Idenix Interference. As the senior party, we are presumed to be the first to have invented the disputed methods of treating HCV. Because Idenix failed to teach how to make and use the invention in its '600 patent, the Board invalidated the Idenix claims involved in the Second Idenix Interference for lack of enablement. The Board has also placed Idenix under an Order to Show Cause requiring Idenix to explain why judgment should not be entered against it in the Second Idenix Interference based upon the decision by the Board in the First Idenix Interference. The decision in the Second Idenix Interference is consistent with the Board's earlier rulings in March 2013 and January 2014 in the First Idenix Interference in which Gilead was declared the senior party and the first to invent certain 2'-fluoro, methyl nucleoside compounds. These compounds are relevant to the methods of treating HCV at issue in the Second Idenix Interference.

We believe that the Idenix claims involved in the First and Second Idenix Interferences, and similar U.S. and foreign patents claiming the same compounds, metabolites and uses thereof, are invalid. As a result, we filed an Impeachment Action in the Federal Court of Canada to invalidate Idenix Canadian Patent No. 2,490,191 (the '191 patent), which is the Canadian patent that corresponds to the '600 patent and the Idenix patent application that was the subject of the First Idenix Interference. Idenix has asserted that the commercialization of Sovaldi in Canada will infringe its '191 patent and that our Canadian Patent No. 2,527,657, corresponding to the '572 patent involved in the First Idenix Interference, is invalid. A trial on these issues commenced in January 2015.

We filed a similar legal action in Norway in the Oslo District Court seeking to invalidate Idenix's Norwegian patent corresponding to the '600 patent. In September 2013, Idenix filed an invalidation action in the Norwegian proceedings against our Norwegian Patent No. 333700 patent, which corresponds to the '572 patent. On March 21, 2014, the Norwegian court found all claims in the Idenix Norwegian patent to be invalid and upheld the validity of all claims in the challenged Gilead patent. On April 30, 2014, Idenix appealed the March 21, 2014 decision to the Norwegian Court of Appeal. Idenix's obligation to pay our attorneys' fees will be stayed during the pendency of the appeal. The appeal from the March 2014 decision is scheduled to commence in February 2016.

In August 2013 and April 2014, Idenix filed two separate requests for invalidation with the Chinese Patent Office of our Chinese Patent CN ZL200480019148.4, which corresponds to our '572 patent. In August 2014 Idenix withdrew its invalidation requests and the Chinese proceedings were terminated with our challenged patent remaining valid and enforceable.

In January 2013, we filed a legal action in the Federal Court of Australia seeking to invalidate Idenix's Australian patent corresponding to the '600 patent. In April 2013, Idenix asserted that the commercialization of Sovaldi in Australia will infringe the Australian patent corresponding to the '600 patent. A trial on these issues is scheduled to commence in September 2015 in Sydney. On March 12, 2014 the European Patent Office (EPO) granted Idenix European Patent No. 1 523 489 (the '489 patent), which corresponds to the '600 patent. The same day that the '489 patent granted, we filed an opposition with the EPO seeking to revoke the '489 patent. Also on that day, Idenix initiated infringement proceedings against Gilead in the United Kingdom (UK), Germany and France alleging that the commercialization of Sovaldi in those countries would infringe the respective national counterparts of the '489 patent. In the United Kingdom, a trial was held in October 2014 to determine the issues of infringement and validity of the Idenix UK patent. In December 2014, the High Court of Justice of England and Wales (UK Court) invalidated all claims of the '489 patent on multiple grounds. Specifically, the UK Court held that the '489 patent lacked novelty over our earlier filed patent application teaching some of the same compounds, the '489 patent lacked an inventive step because it did not add anything to the knowledge existing at the time

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and the disclosure in the Idenix's patent application was insufficient because it did not teach how to make the compounds or show which of the claimed compounds would have activity against viruses like the hepatitis C virus. On January 22, 2015, the UK Court held a hearing at which the court ordered Idenix to pay 92% of Gilead's costs, with an interim payment due within 28 days of the hearing. The UK Court granted Idenix permission to appeal the December 1, 2014 judgment. On February 3, 2015, the German court in Düsseldorf held a hearing to determine the issue of infringement of the Idenix German patent. We expect a decision in mid-March 2015. We do not have a trial date for the French lawsuit.

Idenix has not been awarded patents corresponding to the '600 patent in Japan or China. In the event such patents issue, we expect to challenge them in proceedings similar to those we invoked in other countries.

In December 2013, Idenix, Universita Degli Studi di Cagliari (UDSG), Centre National de la Recherche Scientifique and L'Université Montpellier II sued us in U.S. District Court for the District of Delaware alleging that the commercialization of sofosbuvir will infringe the '600 patent and that an interference exists between the '600 patent and our U.S. Patent No. 8,415,322. Also in December 2013, Idenix and UDSG sued us in the U.S. District Court for the District of Massachusetts alleging that the commercialization of sofosbuvir will infringe U.S. Patent Nos. 6,914,054 and 7,608,597. On June 30, 2014, the court in Massachusetts granted our request and transferred the Massachusetts litigation to the U.S. District Court for the District of Delaware. We believe that Idenix's patents are invalid and would not be infringed by our commercialization of sofosbuvir and that we have the sole right to commercialize sofosbuvir. The district court has set trial dates in October 2016 and December 2016 for resolution of these issues. A decision by the district court can be appealed by either party to the U.S. Court of Appeals for the Federal Circuit (CAFC).

Idenix was acquired by Merck in August 2014. While the acquisition does not change our view of the lack of merit in the claims made by Idenix, Merck has greater resources than Idenix and may therefore choose to fund the litigation at higher levels than Idenix.

Litigation with Merck

In August 2013, Merck contacted us requesting that we pay royalties on the sales of sofosbuvir and obtain a license to U.S. Patent Nos. 7,105,499 and 8,481,712, which it co-owns with Isis Pharmaceuticals, Inc. We believe that Merck's patents are invalid and are not infringed by our commercialization of sofosbuvir and that we have the sole right to commercialize sofosbuvir. In August 2013, we filed a lawsuit in the U.S. District Court for the Northern District of California seeking a declaratory judgment that the Merck patents are invalid and not infringed. Merck's U.S. Patent Nos. 7,105,499 and 8,481,712 cover compounds which do not include, but may relate to, sofosbuvir. During patent prosecution, Merck amended its patent application in an attempt to cover compounds related to sofosbuvir with the apparent goal of ultimately extracting royalty payments for sofosbuvir's commercialization, or eliminating competition by excluding it from the market. If the court determines that Merck's patents are valid and that we have infringed those claims, we may be required to obtain a license from and pay royalties to Merck to commercialize sofosbuvir. Either party can appeal a decision by the District Court to the CAFC. The court has set a trial date of March 7, 2016 for this lawsuit.

Litigation with AbbVie, Inc. (AbbVie)

AbbVie has obtained U.S. Patent Nos. 8,466,159, 8,492,386, 8,680,106, 8,685,984, and 8,809,265 (AbbVie Patents) which purport to cover the use of a combination of ledipasvir/sofosbuvir (or Harvoni) for the treatment of HCV. Gilead is aware that AbbVie has pending patent applications in the United States and other countries. We own published and pending patent applications directed to the use of combinations for the treatment of HCV, and, specifically, to the combination of ledipasvir and sofosbuvir. Certain of our applications were filed before the AbbVie Patents. For this reason and others, we believe the AbbVie Patents are invalid.

Accordingly, in December 2013, we filed a lawsuit in the U.S. District Court for the District of Delaware seeking declaratory judgment that the AbbVie Patents are invalid and unenforceable, as well as other relief. We believe that Abbott Laboratories, Inc. and AbbVie conspired to eliminate competition in the HCV market by falsely representing to the USPTO that they, and not Gilead, invented methods of treating HCV using a combination of ledipasvir/sofosbuvir. In February and March 2014, AbbVie responded to our lawsuit by filing two lawsuits also in the U.S. District Court for the District of Delaware alleging that our fixed-dose combination of ledipasvir/sofosbuvir will infringe its patents. All of those lawsuits have been consolidated into a single action. In the United States, either party can appeal a decision by the District Court to the CAFC. The AbbVie Patents have not blocked or delayed the commercialization of our combination product in the United States or Europe. We do not expect any other foreign patents to block or delay the commercialization around the world. If a court determines that the AbbVie Patents are valid and that we have infringed those claims, we may be required to obtain a license from and pay royalties to AbbVie to commercialize sofosbuvir combination products.

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Litigation with Generic Manufacturers

As part of the approval process for some of our products, the FDA granted us a New Chemical Entity (NCE) exclusivity period during which other manufacturers' applications for approval of generic versions of our product will not be approved. Generic manufacturers may challenge the patents protecting products that have been granted NCE exclusivity one year prior to the end of the NCE exclusivity period. Generic manufacturers have sought and may continue to seek FDA approval for a similar or identical drug through an abbreviated new drug application (ANDA), the application form typically used by manufacturers seeking approval of a generic drug.

Tenofovir Disoproxil Fumarate, Emtricitabine and Fixed-dose Combination of Emtricitabine, Tenofovir Disoproxil Fumarate and Efavirenz

In 2008 and 2009, we received notices that Teva Pharmaceuticals (Teva) submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Truvada. In April 2013, we and Teva reached an agreement to settle the ongoing patent litigation concerning the patents that protect tenofovir disoproxil fumarate in Atripla, Truvada and Viread. Under the agreement, Teva will be allowed to launch a generic version of Viread on December 15, 2017. In April 2014, we and Teva entered into an agreement to settle the ongoing patent litigation concerning the emtricitabine patents that protect Atripla and Truvada. Terms of the settlement are confidential.

In November 2011, we received notice that Teva submitted an ANDS to the Canadian Minister of Health requesting permission to manufacture and market a generic fixed-dose combination of emtricitabine and tenofovir disoproxil fumarate. In the notice, Teva alleges that three of the patents associated with Truvada are invalid, unenforceable and/or will not be infringed by Teva's manufacture, use or sale of a generic version of Truvada. In January 2012, we filed a lawsuit against Teva in the Federal Court of Canada seeking an order of prohibition against approval of this ANDS.

In December 2011, we received notice that Teva submitted an ANDS to the Canadian Minister of Health requesting permission to manufacture and market a generic fixed-dose combination of emtricitabine, tenofovir disoproxil fumarate and efavirenz. In the notice, Teva alleges that three of our patents associated with Atripla and two of Merck's patents associated with Atripla are invalid, unenforceable and/or will not be infringed by Teva's manufacture, use or sale of a generic fixed-dose combination of emtricitabine, tenofovir disoproxil fumarate and efavirenz. In February 2012, we filed a lawsuit against Teva in the Federal Court of Canada seeking an order of prohibition against approval of this ANDS. In August 2012, we received notice that Teva submitted an ANDS to the Canadian Minister of Health requesting permission to manufacture and market a generic version of Viread. In the notice, Teva alleges that two patents associated with tenofovir disoproxil fumarate are invalid, unenforceable and/or will not be infringed by Teva's manufacture, use or sale of a generic version of Viread, Truvada, and Atripla. In September 2012, we filed a lawsuit against Teva in the Federal Court of Canada seeking an order of prohibition against approval of this ANDS. Also in August 2012, Teva filed an Impeachment Action in the Federal Court of Canada seeking invalidation of our two Canadian patents associated with Viread. We are currently defending that Impeachment Action. The requests for orders of prohibition in connection with all three of Teva's ANDS filings (for Teva's generic versions of Viread, Truvada and Atripla) were consolidated and in December 2013, the court issued our requested order prohibiting the Canadian Minister of Health from issuing a Notice of Compliance for Teva's generic versions of our Viread, Truvada and Atripla products until expiry of our patent in July 2017. Teva has appealed that decision. That decision did not rule on the validity of the patents and accordingly the only issue on appeal is whether the Minister of Health should be prohibited from issuing the Notices of Compliance for Teva's products. Separately, the court will determine the validity of the patents in the pending Impeachment Action. A trial in the Impeachment Action is scheduled for September 2016. If Teva is successful in invalidating our patents, Teva may be able to launch generic versions of our Viread, Truvada and Atripla products in Canada prior to the expiry of our patents.

In 2012, we received notice that Lupin Limited (Lupin) submitted an ANDA to the FDA requesting permission to manufacture and market generic versions of Truvada and Viread. In May 2014, Lupin amended its ANDAs to certify that it is no longer seeking approval to market generic versions of Truvada and Viread prior to the expiration of the four patents associated with tenofovir disoproxil fumarate in January 2018 (including pediatric exclusivity). In September 2014, we reached agreement with Lupin to settle the lawsuit related to the emtricitabine patents that protect Truvada and Atripla. Terms of the settlement are confidential.

In July 2012, we received notice that Cipla Ltd. (Cipla) submitted an ANDA to the FDA requesting permission to manufacture and market generic versions of Emtriva and Viread. In July 2014, we and Cipla reached agreement to settle those lawsuits. Terms of the settlement are confidential.

In April 2014, we received notice that Mylan Inc. (Mylan) submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Truvada. In the notice, Mylan alleges that two of the patents associated with emtricitabine and one of our patents associated with the fixed-dose combination of emtricitabine with tenofovir disoproxil fumarate are invalid, unenforceable and/or will not be infringed by Mylan's manufacture, use or sale of a generic version of

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Truvada. In June 2014, we filed a lawsuit against Mylan in U.S. District Court for the Northern District of West Virginia for infringement of our patents.

In June 2014, we received notice that Mylan Inc. submitted petitions for Inter Partes Review (IPR) to the Board alleging that four patents associated with tenofovir disoproxil fumarate are invalid. We opposed Mylan's petitions. In December 2014, the USPTO Patent Trial and Appeal Board (PTAB) issued decisions denying each of Mylan's petitions for IPR against the tenofovir disoproxil fumarate-associated patents on the grounds that Mylan had not established a reasonable likelihood of success that it would prevail in its challenge to each of these patents. Mylan has requested rehearing on the basis that it believes the PTAB decision is wrong.

In June 2014, we received notice that Apotex Inc. (Apotex) submitted an ANDS to the Canadian Minister of Health requesting permission to manufacture and market a generic fixed-dose combination of emtricitabine and tenofovir disoproxil fumarate and a separate ANDS requesting permission to manufacture and market a generic version of Viread. In the notice, Apotex alleges that three of the patents associated with Truvada and two of the patents associated with Viread are invalid, unenforceable and/or will not be infringed by Apotex's manufacture, use or sale of a generic version of Truvada or Viread. In August 2014, we filed a lawsuit against Apotex in the Federal Court of Canada seeking an order of prohibition against approval of this ANDS.

Ranolazine

In 2010, we received notice that Lupin submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of sustained-release ranolazine. In August 2013, the parties reached agreement to settle the patent litigation prior to issuance of the court's decision. Under the agreement, Lupin will be allowed to launch a generic version of Ranexa on February 27, 2019.

Tamiflu

In February 2011, we received notice that Natco Pharma Ltd. (Natco) submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Tamiflu. In the notice, Natco alleges that one of the patents associated with oseltamivir phosphate is invalid, unenforceable and/or will not be infringed by Natco's manufacture, use or sale of a generic version of Tamiflu. In March 2011, we and Roche filed a lawsuit against Natco in U.S. District Court for the District of New Jersey for infringement of one of the patents associated with Tamiflu. In December 2012, the court issued a ruling in favor of Gilead and Roche that our patent is not invalid for the reason stated in Natco's notice letter. Natco appealed this decision to the CAFC which issued its decision on April 22, 2014 allowing Natco's patent invalidity challenge to proceed and remanding to the District Court of New Jersey for a full trial on the merits. On June 30, 2014, we filed a petition for rehearing en banc with the CAFC, which was subsequently denied. We have filed a petition for certiorari to the Supreme Court of the United States and are concurrently proceeding before the District Court.

Letairis

In August 2014, Natco filed a complaint with the U. S. District Court for the District of Minnesota against Gilead and Express Scripts Holding Co., a specialty pharmacy that distributes our Letairis product. We distribute Letairis pursuant to an FDA-mandated Risk Evaluation and Mitigation Strategies (REMS) program. Natco alleges that Gilead, independently and together with Express Scripts, denied Natco access to samples of Letairis, which Natco claims it needs in order to conduct bioequivalence testing and file an ANDA. According to Natco, our conduct therefore violates antitrust laws. Natco is seeking damages and an order restraining Gilead from limiting distribution of Letairis to Natco through use of the REMS program.

In November 2014, Zydus Pharmaceuticals (USA) Inc. (Zydus) and Cadila Healthcare Limited (Cadila) filed a complaint with the U.S. District Court for the District of New Jersey against us relating to Letairis sales. We distribute Letairis pursuant to the REMS program. Zydus and Cadila allege that we denied them access to samples of Letairis, which they claim they need in order to conduct bioequivalence testing and file an ANDA. According to Zydus and Cadila, our conduct therefore violates antitrust laws. Zydus and Cadila are seeking damages and an order enjoining Gilead to provide Zydus with samples of Letairis.

In February 2015, we received notice that Watson Laboratories, Inc. (Watson) submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Letairis. In the notice, Watson alleges that one of the patents associated with ambrisentan tablets is invalid, unenforceable and/or will not be infringed by Watson's manufacture, use or sale of a generic version of Letairis. We are currently evaluating Watson's notice and will file a patent infringement lawsuit as necessary to protect the exclusivity of the product.

Lexiscan

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In December 2014, Astellas informed us that they had received notice that Apotex submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Lexiscan. In the notice, Apotex alleges that one of the patents associated with regadenoson is invalid, unenforceable and/or will not be infringed by Apotex's manufacture, use or sale of a generic version of Lexiscan. Because Apotex has not challenged several of the patents associated with regadenoson, Apotex product would not be eligible for final approval until expiry of the patents that have not been challenged. We and Astellas have the opportunity to file a patent infringement lawsuit against Apotex in the future should we decide that it is necessary to protect the exclusivity of the product.

We cannot predict the ultimate outcome of these actions, and we may spend significant resources enforcing and defending these patents. If we are unsuccessful in these lawsuits, some or all of our claims in the patents may be narrowed or invalidated and the patent protection for Truvada, Viread, Lexiscan and Tamiflu in the United States and Atripla, Truvada and Viread in Canada could be substantially shortened. Further, if all of the patents covering one or more products are invalidated, the FDA or Canadian Minister of Health could approve the requests to manufacture a generic version of such products in the United States or Canada, respectively, prior to the expiration date of those patents. The sale of generic versions of these products earlier than their patent expiration would have a significant negative effect on our revenues and results of operations.

Trade Secrets

We also rely on unpatented trade secrets and improvements, unpatented internal know-how and technological innovation. In particular, a great deal of our liposomal manufacturing expertise, which is a key component of our liposomal technology, is not covered by patents but is instead protected as a trade secret. We protect these rights mainly through confidentiality agreements with our corporate partners, employees, consultants and vendors. These agreements provide that all confidential information developed or made known to an individual during the course of their relationship with us will be kept confidential and will not be used or disclosed to third parties except in specified circumstances. In the case of employees, the agreements provide that all inventions made by an individual while employed by us will be our exclusive property. We cannot be certain that these parties will comply with these confidentiality agreements, that we have adequate remedies for any breach or that our trade secrets will not otherwise become known or be independently discovered by our competitors. Under some of our R&D agreements, inventions become jointly owned by us and our corporate partner and in other cases become the exclusive property of one party. In certain circumstances, it can be difficult to determine who owns a particular invention and disputes could arise regarding those inventions.

Manufacturing and Raw Materials

Our manufacturing strategy is to contract with third parties to manufacture the majority of our active pharmaceutical ingredients and solid dose products. We also rely on our corporate partners to manufacture certain of our products. Additionally, we own or lease manufacturing facilities in Foster City, San Dimas and Oceanside, California; Edmonton, Alberta, Canada and Cork, Ireland, where we manufacture certain products and active pharmaceutical ingredients for clinical and commercial uses.

Manufacturing of our Products

We contract with third parties to manufacture certain products for clinical and commercial purposes, including Sovaldi, Atripla, Truvada, Harvoni, Complera/Eviplera, Stribild, Viread, Emtriva, Hepsera, Tybost, Vitekta, Ranexa, AmBisome, Zydelig and Cayston. We generally use multiple third-party contract manufacturers to manufacture the active pharmaceutical ingredients in our products. We are the exclusive manufacturer of idelalisib, the active pharmaceutical ingredient in Zydelig, and ambrisentan, the active pharmaceutical ingredient of Letairis, although another supplier is qualified to make the active pharmaceutical ingredient in Letairis.

We also rely on third-party contract manufacturers to manufacture our tablet or capsule products. For example, we use multiple third-party contract manufacturers to tablet Sovaldi, Atripla, Truvada, Harvoni, Complera/Eviplera, Stribild, Viread, Hepsera, Tybost, Vitekta, Letairis, Zydelig and Ranexa, and Emtriva encapsulation is also completed by third-party contract manufacturers.

We also have manufacturing agreements with many of our corporate partners. Roche, by itself and through third parties, is responsible for manufacturing Tamiflu. Under our agreement with Roche, through a joint manufacturing committee composed of representatives from Roche and Gilead, we have the opportunity to review Roche's existing manufacturing capacity for Tamiflu and global plans for manufacturing Tamiflu. Astellas US LLC, our corporate partner for Lexiscan in the United States, is responsible for the commercial manufacture and supply of product in the United States and is dependent on a single supplier for the active pharmaceutical ingredient of Lexiscan.

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For our future products, we continue to develop additional manufacturing capabilities and establish additional third-party suppliers to manufacture sufficient quantities of our product candidates to undertake clinical trials and to manufacture sufficient quantities of any product that is approved for commercial sale. If we are unable to develop manufacturing capabilities internally or contract for large scale manufacturing with third parties on acceptable terms for our future products, our ability to conduct large scale clinical trials and meet customer demand for commercial products will be adversely affected. In addition, we rely on third-party contract manufacturers to manufacture our aseptic products such as AmBisome and Cayston.

Our Manufacturing Facilities

At our San Dimas, California manufacturing facility, we package and label solid dosage oral form products, including Sovaldi, Atripla, Truvada, Harvoni, Complera/Eviplera, Stribild, Viread, Ranexa, Zydelig and Emtriva, and label Hepsera at our facilities in San Dimas. We manufacture AmBisome and Cayston at our San Dimas facility. We depend on a single supplier for the high quality cholesterol and the active pharmaceutical ingredient used in the manufacture of AmBisome. Because we are the exclusive supplier of key drug product intermediates of AmBisome, in the event of a disaster, including an earthquake, equipment failure or other difficulty, we may be unable to replace this manufacturing capacity in a timely manner and may be unable to manufacture AmBisome to meet market needs.

We utilize our Cork, Ireland facility primarily for solid dose tablet manufacturing of certain of our antiviral products, as well as product packaging activities. We package and label drug product for Sovaldi, Atripla, Truvada, Harvoni, Complera/Eviplera, Stribild, Viread, Tybost and Vitekta and label Hepsera and Emtriva at our facilities in Cork, Ireland. We also perform quality control testing, final labeling and secondary packaging of both AmBisome and Cayston and final release of many of our products for the European Union and elsewhere at this facility. We distribute our products to the European Union and other international markets from our Dublin, Ireland site.

At our Edmonton, Alberta facility in Canada, we carry out process research and scale-up of our clinical development candidates, manufacture active pharmaceutical ingredients for both investigational and commercial products and conduct chemical development activities to improve existing commercial manufacturing processes. We also manufacture the active pharmaceutical ingredients in Letairis and Hepsera exclusively at our Edmonton site, although another supplier is qualified to make the active pharmaceutical ingredient in Letairis.

Our Oceanside, California facility is designed and equipped to produce biologic compounds for toxicological, Phase 1 and Phase 2 clinical studies. We use the facility for the process development and manufacture of simtuzumab, an investigational monoclonal antibody candidate in development for treatment of certain cancers and respiratory diseases and other biologics.

Third-party Manufacturers

Our third-party manufacturers and corporate partners are independent entities who are subject to their own unique operational and financial risks which are out of our control. If we or any of these third-party manufacturers or corporate partners fail to perform as required, this could impair our ability to deliver our products on a timely basis or receive royalties or cause delays in our clinical trials and applications for regulatory approval. Further, we may have to write-off the costs of manufacturing any batch that fails to pass quality inspection or meet regulatory approval. To the extent these risks materialize and affect their performance obligations to us, our financial results may be adversely affected. In addition, we, our third-party manufacturers and our corporate partners may only be able to produce some of our products at one or a limited number of facilities and, therefore, have limited manufacturing capacity for certain products. For example, in 2012, due to unexpected delays both in qualifying two new external sites and with expanding Cayston manufacturing in San Dimas, we were unable to supply enough Cayston to fulfill our projected demand. From February through September 2012, we suspended access for patients with new prescriptions for Cayston, subject to certain exceptions where specific medical need existed. As a result of our inability to manufacture sufficient Cayston to meet demand, the amount of revenues we received from the sale of Cayston was reduced.

We believe the technology we use to manufacture our products is proprietary. For products manufactured by our third-party contract manufacturers, we have disclosed all necessary aspects of this technology to enable them to manufacture the products for us. We have agreements with these third-party manufacturers that are intended to restrict these manufacturers from using or revealing this technology, but we cannot be certain that these third-party manufacturers will comply with these restrictions. In addition, these third-party manufacturers could develop their own technology related to the work they perform for us that we may need to manufacture our products. We could be required to enter into additional agreements with these third-party manufacturers if we want to use that technology ourselves or allow another manufacturer to use that technology. The third-party manufacturer could refuse to allow us to use their technology or could demand terms to use their technology that are not acceptable to us.

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Regulation of Manufacturing Process

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

Our manufacturing operations are subject to routine inspections by regulatory agencies. For example, in April 2013, the FDA conducted an inspection of our Foster City facility and issued Form 483 Inspectional Observations, which noted deficiencies in documentation and validation of certain quality testing procedures and methods. As a result of the observations, the FDA delivered Complete Response Letters notifying us that it was unable to approve our NDAs for elvitegravir and cobicistat as standalone agents. In mid-October 2013, the FDA completed its sofosbuvir pre-approval inspection of our Foster City facility. Following that inspection, the FDA issued additional Form 483 Inspectional Observations citing deficiencies related to testing and reconciliation of stability samples, testing protocols, testing of shipping samples, and procedures for calibrating test equipment. We completed and filed our responses to these observations with the FDA. In 2014, we received a letter from FDA related to the extent of method revalidations being conducted, stability program oversight, audit trail review/data management and Quality Management System gaps. We have filed our responses to these observations with the FDA. If we are unable to remedy the deficiencies cited by the FDA in these inspections, our currently marketed products and the timing of regulatory approval of products in development could be adversely affected. Further, there is risk that regulatory agencies in other countries where marketing applications are pending will undertake similar additional reviews or apply a heightened standard of review, which could delay the regulatory approvals for products in those countries. If approval of any of our product candidates were delayed or if production of our marketed products was interrupted, our anticipated revenues and our stock price would be adversely affected.

Access to Supplies and Materials

We need access to certain supplies and products to manufacture our products. If we are unable to purchase sufficient quantities of these materials or find suitable alternate materials in a timely manner, our development efforts for our product candidates may be delayed or our ability to manufacture our products would be limited, which would limit our ability to generate revenues. For example, a significant portion of the raw materials and intermediates used to manufacture our antiviral products (Sovaldi, Atripla, Truvada, Harvoni, Complera/Eviplera, Stribild, Viread, Emtriva, Tybost and Vitekta) are supplied by China-based companies. As a result, an international trade dispute between China and the United States or any other actions by the Chinese government that would limit or prevent Chinese companies from supplying these materials would adversely affect our ability to manufacture and supply our HIV and HCV products to meet market needs and have a material and adverse effect on our operating results.

Seasonal Operations and Backlog

Our worldwide product sales do not reflect any significant degree of seasonality.

For the most part, we operate in markets characterized by short lead times and the absence of significant backlogs. We do not believe that backlog information is material to our business as a whole.

Government Regulation

Our operations and activities are subject to extensive regulation by numerous government authorities in the United States and other countries. In the United States, drugs are subject to rigorous FDA regulation. The Federal Food, Drug and Cosmetic Act and other federal and state statutes and regulations govern the testing, manufacture, safety, efficacy, labeling, storage, record keeping, approval, advertising and promotion of our products. As a result of these regulations, product development and product approval processes are very expensive and time consuming.

The FDA must approve a drug before it can be sold in the United States. The general process for this approval is as follows:

Preclinical Testing

Before we can test a drug candidate in humans, we must study the drug in laboratory experiments and in animals to generate data to support the drug candidate's potential benefits and safety. We submit this data to the FDA in an investigational new drug (IND) application seeking its approval to test the compound in humans.

Clinical Trials

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If the FDA accepts the IND, the drug candidate can then be studied in human clinical trials to determine if the drug candidate is safe and effective. These clinical trials involve three separate phases that often overlap, can take many years and are very expensive. These three phases, which are subject to considerable regulation, are as follows:

- Phase 1. The drug candidate is given to a small number of healthy human control subjects or patients suffering from the indicated disease, to test for safety, dose tolerance, pharmacokinetics, metabolism, distribution and excretion.
- Phase 2. The drug candidate is given to a limited patient population to determine the effect of the drug candidate in treating the disease, the best dose of the drug candidate, and the possible side effects and safety risks of the drug candidate. It is not uncommon for a drug candidate that appears promising in Phase 1 clinical trials to fail in the more rigorous Phase 2 clinical trials.
- Phase 3. If a drug candidate appears to be effective and safe in Phase 2 clinical trials, Phase 3 clinical trials are commenced to confirm those results. Phase 3 clinical trials are conducted over a longer term, involve a significantly larger population, are conducted at numerous sites in different geographic regions and are carefully designed to provide reliable and conclusive data regarding the safety and benefits of a drug candidate. It is not uncommon for a drug candidate that appears promising in Phase 2 clinical trials to fail in the more rigorous and extensive Phase 3 clinical trials.

FDA Approval Process

When we believe that the data from our clinical trials show an adequate level of safety and efficacy, we submit the appropriate filing, usually in the form of an NDA or supplemental NDA, with the FDA seeking approval to sell the drug candidate for a particular use. The FDA may hold a public hearing where an independent advisory committee of expert advisors asks additional questions and makes recommendations regarding the drug candidate. This committee makes a recommendation to the FDA that is not binding but is generally followed by the FDA. If the FDA agrees that the compound has met the required level of safety and efficacy for a particular use, it will allow us to sell the drug candidate in the United States for that use. It is not unusual, however, for the FDA to reject an application because it believes that the drug candidate is not safe enough or efficacious enough or because it does not believe that the data submitted is reliable or conclusive.

At any point in this process, the development of a drug candidate can be stopped for a number of reasons including safety concerns and lack of treatment benefit. We cannot be certain that any clinical trials that we are currently conducting or any that we conduct in the future will be completed successfully or within any specified time period. We may choose, or the FDA may require us, to delay or suspend our clinical trials at any time if it appears that the patients are being exposed to an unacceptable health risk or if the drug candidate does not appear to have sufficient treatment benefit.

The FDA may also require Phase 4 non-registrational studies to explore scientific questions to further characterize safety and efficacy during commercial use of our drug. The FDA may also require us to provide additional data or information, improve our manufacturing processes, procedures or facilities or may require extensive surveillance to monitor the safety or benefits of our product candidates if it determines that our filing does not contain adequate evidence of the safety and benefits of the drug. In addition, even if the FDA approves a drug, it could limit the uses of the drug. The FDA can withdraw approvals if it does not believe that we are complying with regulatory standards or if problems are uncovered or occur after approval.

In addition to obtaining FDA approval for each drug, we obtain FDA approval of the manufacturing facilities for any drug we sell, including those of companies who manufacture our drugs for us. All of these facilities are subject to periodic inspections by the FDA. The FDA must also approve foreign establishments that manufacture products to be sold in the United States and these facilities are subject to periodic regulatory inspection. Our manufacturing facilities located in California, including our Oceanside and San Dimas facilities, also must be licensed by the State of California in compliance with local regulatory requirements. Our manufacturing facilities located in Canada, including our Edmonton, Alberta facility, and our facilities located near Dublin and in Cork, Ireland, also must obtain local licenses and permits in compliance with local regulatory requirements.

Drugs that treat serious or life threatening diseases and conditions that are not adequately addressed by existing drugs, and for which the development program is designed to address the unmet medical need, may be designated as fast track candidates by the FDA and may be eligible for accelerated and priority review. Drugs for the treatment of HIV infection that are designated for use under the U.S. President's Emergency Plan for AIDS Relief may also qualify for an expedited or priority review. Sovaldi, Atripla, Truvada, Harvoni, Viread, Complera, Stribild, Viread and Zydelig received accelerated approval and priority reviews. Drugs receiving accelerated approval must be monitored in post-marketing clinical trials in order to confirm the safety and benefits of the drug.

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Drugs are also subject to extensive regulation outside of the United States. In the European Union, there is a centralized approval procedure that authorizes marketing of a product in all countries of the European Union (which includes most major countries in Europe). If this centralized approval procedure is not used, approval in one country of the European Union can be used to obtain approval in another country of the European Union under one of two simplified application processes: the mutual recognition procedure or the decentralized procedure, both of which rely on the principle of mutual recognition. After receiving regulatory approval through any of the European registration procedures, separate pricing and reimbursement approvals are also required in most countries. The European Union also has requirements for approval of manufacturing facilities for all products that are approved for sale by the European regulatory authorities.

Pricing and Reimbursement

Successful commercialization of our products depends, in part, on the availability of governmental and third-party payer reimbursement for the cost of such products and related treatments. Government health administration authorities, private health insurers and other organizations generally provide reimbursement. In the United States, the European Union and other significant or potentially significant markets for our products and product candidates, government authorities and third-party payers are increasingly attempting to limit or regulate the price of medical products and services, which has resulted in lower average selling prices.

In the United States, a significant portion of our sales of the majority of our products are subject to significant discounts from list price and rebate obligations. In the HCV area, we have experienced increased pricing pressure and in certain cases, have provided significant discounts or rebates to private and public payers in order to obtain formulary status. Any change in the formulary coverage, reimbursement levels or discounts or rebates offered on our HCV products to payers may impact our anticipated revenues. We also expect pricing pressure in the HCV market to continue. In addition, state ADAPs, which purchase a significant portion of our HIV products, rely on federal, supplemental federal and state funding to help fund purchases of our products. In the past, we have experienced a shift in our payer mix for HIV as patients previously covered by private insurance move to public reimbursement programs that require rebates or discounts from us or as patients previously covered by one public reimbursement program move to another public reimbursement program that requires greater rebates or discounts from us. If federal and state funds are not available in amounts sufficient to support the number of patients that rely on ADAPs, sales of our HIV products could be negatively impacted which would reduce our revenues. In prior quarters, because of the insufficiency of federal and state funds and as many states reduced eligibility criteria, we saw an increase in the number of patients on state ADAP waitlists, and we may see similar increases in future periods as a result of any reduction in federal and state ADAP support resulting from the sequestration. Until these patients are enrolled in an ADAP, they generally receive product from industry-supported patient assistance programs or are unable to access treatment. The increased emphasis on managed healthcare in the United States will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our product sales and profitability. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies and pricing in general.

In July 2014, we received a letter from the U.S. Senate Committee on Finance requesting information and supporting documentation from us related to Sovaldi and the pricing of Sovaldi in the United States. The letter raised concerns about our approach to pricing Sovaldi, its affordability and its impact on federal government spending and public health. We are cooperating with the inquiries. It is both costly and time-consuming for us to comply with these inquiries. We cannot predict the outcome. It is possible that the inquiries could result in negative publicity or other negative actions that could harm our reputation, reduce demand for Sovaldi, Harvoni or other sofosbuvir containing products and/or reduce coverage of Sovaldi, Harvoni or other sofosbuvir containing products, including by federal health care programs such as Medicare and Medicaid. If any or all of these events occur, our business and stock price could be materially and adversely affected.

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

Recently, many countries in the European Union have increased the level of discounting required on our products, and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the European Union. Some countries have instituted clawbacks and enacted taxes on specific products. As generic drugs come to market, we may face price decreases for our products in some countries in the European Union. Further, cost containment pressures in the European Union, especially in Southern Europe, could lead

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to delays in the treatment of patients and also delay pricing approval, which could negatively impact the commercialization of new products.

Government agencies also issue regulations and guidelines directly applicable to us and to our products. In addition, from time to time, professional societies, practice management groups, private health/science foundations and organizations publish guidelines or recommendations directed to certain health care and patient communities. Such recommendations and guidelines may relate to such matters as product usage, dosage, route of administration, and use of related or competing therapies and can consequently result in increased or decreased usage of our products.

United States Healthcare Reform

Legislative and regulatory changes to government prescription drug procurement and reimbursement programs occur relatively frequently in the United States and foreign jurisdictions. In March 2010, healthcare reform legislation was adopted in the United States, requiring us to further rebate or discount products reimbursed or paid for by various public payers, including Medicaid and other entities eligible to purchase discounted products through the 340B Drug Pricing Program under the Public Health Service Act, such as ADAPs. As a result of the 2010 legislation, the discounts, rebates and fees that impacted us include:

- our minimum base rebate amount owed to Medicaid on products reimbursed by Medicaid increased by 8%, and the discounts or rebates we owe to ADAPs and other Public Health Service entities which reimburse or purchase our products also increased by 8%;
- we are required to extend rebates to patients receiving our products through Medicaid managed care organizations;
- we are required to provide a 50% discount on products sold to patients while they are in the Medicare Part D “donut hole;” and
- we, along with other pharmaceutical manufacturers of branded drug products, are required to pay a portion of a new industry fee (also known as the Branded Prescription Drug fee (the BPD fee)), of $3.0 billion for 2014, calculated based on select government sales during the 2012 calendar year as a percentage of total industry government sales.

The amount of the annual industry fee imposed on the pharmaceutical industry as a whole will be $3.0 billion in 2014 through 2016, increase to $4.0 billion in 2017, increase to a peak of $4.1 billion in 2018, and then decrease to $2.8 billion in 2019 and thereafter. We expect our portion of the BPD fee to increase as our revenues grow and as the amount of the annual industry fee increases through 2018 and drug patents expire on major drugs of other companies. In addition, during the third quarter of 2014, the Internal Revenues Service (IRS) issued final regulations which indicated that a manufacturer’s obligation to pay its portion of the BPD fee in any given calendar year is triggered by the qualifying sales in the previous year, instead of the first qualifying sale in the current calendar year. As a result of the final IRS regulations, we were required to recognize our 2014 fee of $460 million and 2013 fee of $142 million in our 2014 Consolidated Statement of Income. Our BPD fees were approximately $590 million, $110 million and $85 million in 2014, 2013 and 2012, respectively. The BPD fee is not tax deductible. Further, even though not addressed in the healthcare reform legislation, discussions continue at the federal level on legislation that would either allow or require the federal government to directly negotiate price concessions from pharmaceutical manufacturers or set minimum requirements for Medicare Part D pricing.

In addition, state Medicaid programs could request additional supplemental rebates on our products as a result of the increase in the federal base Medicaid rebate. Private insurers could also use the enactment of these increased rebates to exert pricing pressure on our products, and to the extent that private insurers or managed care programs follow Medicaid coverage and payment developments, the adverse effects may be magnified by private insurers adopting lower payment schedules.

Health Care Fraud and Abuse Laws and Anti-Bribery Laws

We are subject to various federal and state laws pertaining to health care “fraud and abuse,” including anti-kickback laws and false claims laws. Anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug. Due to the breadth of the statutory provisions and the increasing attention being given to them by law enforcement authorities, it is possible that certain of our practices may be challenged under anti-kickback or similar laws. False claims laws generally prohibit anyone from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment by federal and certain state payers (including Medicare and Medicaid), or knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim. Our sales, marketing and medical activities may be subject to scrutiny under these laws. In addition, the U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments for the purpose of obtaining or retaining business. Our policies mandate compliance with these anti-bribery laws. We operate in parts of the world that have experienced governmental corruption to some degree. In certain circumstances, strict compliance with anti-bribery laws may conflict with local customs and practices or may require us to interact with doctors and hospitals, some of which may be state controlled, in a manner that is different than local custom. Despite our training and compliance program,

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our internal control policies and procedures may not protect us from reckless or criminal acts committed by our employees or agents. Violations of fraud and abuse laws or anti-bribery laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from federal health care programs (including Medicare and Medicaid). Violations can also lead to the imposition of a Corporate Integrity Agreement or similar government oversight program. If the government were to allege against or convict us of violating these laws, there could be a disruption on our business and material adverse effect on our results of operations.

Compulsory Licenses

In a number of developing countries, government officials and other interested groups have suggested that pharmaceutical companies should make drugs for HCV or HIV infection available at low cost. Alternatively, governments in those developing countries could require that we grant compulsory licenses to allow competitors to manufacture and sell their own versions of our products, thereby reducing our product sales. For example, there is growing attention on the availability of HCV therapies and some activists are advocating for the increased availability of HCV therapies through means including compulsory licenses. In the past, certain offices of the government of Brazil have expressed concern over the affordability of our HIV products and declared that they were considering issuing compulsory licenses to permit the manufacture of otherwise patented products for HIV infection, including Viread.

In addition, concerns over the cost and availability of Tamiflu related to a potential avian flu pandemic and H1N1 influenza generated international discussions over compulsory licensing of our Tamiflu patents. For example, the Canadian government considered allowing Canadian manufacturers to manufacture and export the active ingredient in Tamiflu to eligible developing and least developed countries under Canada's Access to Medicines Regime. Furthermore, Roche issued voluntary licenses to permit third-party manufacturing of Tamiflu. For example, Roche granted a sublicense to Shanghai Pharmaceutical (Group) Co., Ltd. for China and a sublicense to India's Hetero Drugs Limited for India and certain developing countries. If compulsory licenses permit generic manufacturing to override our product patents for Sovaldi, Harvoni, our HIV products or Tamiflu, or if we are required to grant compulsory licenses for these products, it could reduce our earnings and cash flows and harm our business. In addition, certain countries do not permit enforcement of our patents, and third-party manufacturers are able to sell generic versions of our products in those countries. Compulsory licenses or sales of generic versions of our products could significantly reduce our sales and adversely affect our results of operations, particularly if generic versions of our products are imported into territories where we have existing commercial sales.

Employees

As of January 31, 2015, we had approximately 7,000 full-time employees. We believe we have good relations with our employees.

Environment, Health and Safety

We have evaluated our current level of environmental impact and have identified ways to reduce our energy consumption. Some factors that contribute to our environmental impact include greenhouse gas emissions produced by employee commutes, the energy and water consumed by our facilities, and the use of hazardous materials such as chemicals, viruses and radioactive compounds in our R&D facilities. Pursuant to our evaluation, we have taken some initial measures to address these impacts. For example, we have established employee commuter programs, evaluated the energy efficiency of our buildings, and installed low-flow water fixtures. We have also implemented proactive programs to minimize the occurrence of hazardous materials incidents and to reduce the risk of accidental environmental contamination and worker injury.

We are subject to a number of laws and regulations that require compliance with federal, state, and local regulations regarding workplace safety and protection of the environment. We anticipate additional regulations in the near future. Laws and regulations are implemented and under consideration to mitigate the effects of climate change mainly caused by greenhouse gas emissions. Our business is not energy intensive. Therefore, we do not anticipate being subject to a cap and trade system or other mitigation measure that would materially impact our capital expenditures, operations, or competitive position. Based on current information, and subject to the finalization of proposed regulations, we believe that our primary risk related to climate change is increased energy costs. We use hazardous materials, chemicals, viruses and various radioactive compounds in our R&D activities and cannot eliminate the risk of accidental contamination or injury from these materials. Misuse or accidents involving hazardous materials could lead to significant litigation, fines, and penalties.

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Other Information

We are subject to the information requirements of the Exchange Act. Therefore, we file periodic reports, proxy statements and other information with the SEC. Such reports, proxy statements and other information may be obtained by visiting the Public Reference Room of the SEC at 100 F Street, NE, Washington, D.C. 20549 or by calling the SEC at 1-800-SEC-0330, by sending an electronic message to the SEC at publicinfo@sec.gov or by sending a fax to the SEC at 1-202-777-1027. In addition, the SEC maintains a website (www.sec.gov) that contains reports, proxy and information statements, and other information regarding issuers that file electronically.

The mailing address of our headquarters is 333 Lakeside Drive, Foster City, California 94404, and our telephone number at that location is 650-574-3000. Our website is www.gilead.com. Through a link on the "Investors" section of our website (under "SEC Filings" in the "Financial Information" section), we make available the following filings as soon as reasonably practicable after they are electronically filed with or furnished to the SEC: our Annual Reports on Form 10-K; Quarterly Reports on Form 10-Q; Current Reports on Form 8-K; and any amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act. All such filings are available free of charge upon request.

Transactions with Iran

We did not have any transactions with Iran during 2014 that would require disclosure in this Annual Report on Form 10-K.

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ITEM 1A. RISK FACTORS

In evaluating our business, you should carefully consider the following risks in addition to the other information in this Annual Report on Form 10-K. A manifestation of any of the following risks could materially and adversely affect our business, results of operations and financial condition. We note these factors for investors as permitted by the Private Securities Litigation Reform Act of 1995. It is not possible to predict or identify all such factors and, therefore, you should not consider the following risks to be a complete statement of all the potential risks or uncertainties that we face.

A substantial portion of our revenues is derived from sales of products to treat HCV and HIV. If we are unable to maintain or continue increasing sales of these products, our results of operations may be adversely affected.

During the year ended December 31, 2014, sales of Sovaldi and Harvoni for the treatment of HCV, accounted for approximately 50% of our total product sales. Since Sovaldi and Harvoni were only recently launched, we cannot be certain if 2014 sales of our HCV products are indicative of future sales. With the approval of a competitor's HCV product in December 2014 and the potential entry of other competitive products, we cannot predict whether, and to what extent, our HCV revenues may be adversely affected in the future. As a result of the launch of a competing regimen, we have experienced, and may continue to experience, increased pricing pressure. In certain cases, we have provided significant discounts or rebates to public and private payers in order to obtain formulary status or to expand access for patients to our HCV products. In addition, future sales of Sovaldi and Harvoni are difficult to estimate because demand depends in part on the extent of reimbursement of our HCV products by private and public payers in the United States and countries outside the United States. In light of the continued fiscal and debt crises experienced by several countries in the European Union, several governments have announced or implemented measures to manage healthcare expenditures. We continue to experience pricing pressure such as increases in the amount of discounts required on our products and delayed reimbursement which could negatively impact our future product sales and results of operations. Also, private and public payers can choose to exclude Sovaldi or Harvoni from their formulary or limit the types of patients for whom coverage will be provided, which would negatively impact the demand for, and revenues of, Sovaldi and Harvoni. Any change in the formulary coverage, reimbursement levels or discounts or rebates offered on our HCV products to payers may impact our anticipated revenues. We expect pricing pressure in the HCV market to continue. If we are unable to maintain the current or expected future sales levels of Sovaldi and Harvoni or obtain approval or reimbursement for our HCV product candidates in the currently anticipated timelines, our results of operations and stock price could be negatively affected.

We receive a substantial portion of our revenue from sales of our products for the treatment of HIV infection, particularly our single tablet regimen products, Atripla, Complera/Eviplera and Stribild. During the year ended December 31, 2014, sales of our HIV products accounted for more than 40% of our total product sales. Most of our HIV products contain tenofovir disoproxil fumarate and/or emtricitabine, which belong to the nucleoside class of antiviral therapeutics. If the treatment paradigm for HIV changes, causing nucleoside-based therapeutics to fall out of favor, or if we are unable to maintain or continue increasing our HIV product sales, our results of operations would likely suffer and we would likely need to scale back our operations, including our spending on research and development (R&D) efforts. We may not be able to sustain or increase the growth rate of sales of our HIV products, especially Atripla, Complera/Eviplera and Stribild, for any number of reasons including, but not limited to, the following:

- As our HIV products are used over a longer period of time in many patients and in combination with other products, and additional studies are conducted, new issues with respect to safety, resistance and interactions with other drugs may arise, which could cause us to provide additional warnings or contraindications on our labels, narrow our approved indications or halt sales of a product, each of which could reduce our revenues.
- As our HIV products mature, private insurers and government payers often reduce the amount they will reimburse patients for these products, which increases pressure on us to reduce prices.
- A large part of the market for our HIV products consists of patients who are already taking other HIV drugs. If physicians do not see the benefit of our HIV products, the sales of our HIV products will be limited.
- As generic HIV products are introduced into major markets, our ability to maintain pricing and market share may be affected. For example, generic versions of Sustiva (efavirenz), a component of our Atripla, are now available in Canada and Europe and we anticipate competition from generic efavirenz in the United States in December 2017. We have observed some pricing pressure related to the Sustiva component of our Atripla sales.

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If we fail to commercialize new products or expand the indications for existing products, our prospects for future revenues may be adversely affected.

If we do not introduce new products to market or increase sales of our existing products, we will not be able to increase or maintain our total revenues nor continue to expand our R&D efforts. Drug development is inherently risky and many product candidates fail during the drug development process. For example, we recently announced results from our Phase 2 study of simtuzumab for the treatment of pancreatic cancer, myelofibrosis and colorectal cancer showing that the product candidate did not provide clinical benefit.

In June 2014, we submitted a NDA with Japan's Pharmaceutical and Medical Devices Agency (PMDA) for approval of sofosbuvir for the treatment of HCV and in September 2014, we submitted a NDA with the PMDA for approval of the fixed-dose combination of ledipasvir and sofosbuvir. In the fourth quarter of 2014, we filed our marketing applications for approval of the single tablet regimen of elvitegravir, cobicistat, emtricitabine and TAF for the treatment of HIV-1 infection in adults in the United States and European Union. These marketing applications may not be approved by the regulatory authorities on a timely basis, or at all. Even if marketing approval is granted for these products, there may be significant limitations on their use. Further, we may be unable to file our marketing applications for new products.

Our inability to accurately predict demand for our products, the uptake of new products or the timing of fluctuations in the inventories maintained by customers makes it difficult for us to accurately forecast sales and may cause our revenues and earnings to fluctuate, which could adversely affect our financial results and our stock price.

We may be unable to accurately predict demand for our products, including the uptake of new products, as demand is dependent on a number of factors. For example, our HCV products, Sovaldi and Harvoni, represent a significant change in the treatment paradigm for HCV-infected patients due to the shortened duration of treatment and the reduction or elimination of the need for pegylated interferon injection and ribavirin in certain patient populations. Because these products are in a new therapeutic area for us and product demand is dependent on a number of factors, revenues from these products in 2015 and beyond are difficult for us and investors to estimate. Demand for Sovaldi and Harvoni will depend in part on the extent of reimbursement of our HCV products by private and public payers in the United States and countries outside the United States. Private and public payers can choose to exclude Sovaldi or Harvoni from their formulary or limit the types of patients for whom coverage will be provided, which would negatively impact the demand for and revenues of Sovaldi and Harvoni. Also, because our HCV products represent a significant change in the treatment paradigm of HCV infection and in light of the launch of a competitor's regimen, sales levels or prescription growth rates early in the launch may not be indicative of future sales. As a result of the launch of a competing regimen, we have experienced increased pricing pressure in the United States and in certain cases, have provided significant discounts to private and public payers in order to obtain formulary status or to expand access for patients to our HCV products. Any change in the formulary coverage, reimbursement levels or discounts or rebates offered on our HCV products to payers may negatively impact our anticipated revenues. We expect pricing pressure in the HCV market to continue. Because HCV-related revenues are difficult to predict, investors may have widely varying expectations that may be materially higher or lower than our actual revenues. To the extent our HCV product revenues exceed or fall short of these expectations, our stock price may experience significant volatility.

In the year ended December 31, 2014, approximately 87% of our product sales in the United States were to three wholesalers, AmerisourceBergen Corp., McKesson Corp. and Cardinal Health, Inc. The U.S. wholesalers with whom we have entered into inventory management agreements make estimates to determine end user demand and may not be completely effective in matching their inventory levels to actual end user demand. As a result, changes in inventory levels held by those wholesalers can cause our operating results to fluctuate unexpectedly if our sales to these wholesalers do not match end user demand. In addition, inventory is held at retail pharmacies and other non-wholesaler locations with whom we have no inventory management agreements and no control over buying patterns. Adverse changes in economic conditions or other factors may cause retail pharmacies to reduce their inventories of our products, which would reduce their orders from wholesalers and, consequently, the wholesalers' orders from us, even if end user demand has not changed. For example, during the fourth quarter of 2013, strong wholesaler and sub-wholesaler purchases of our HIV products resulted in inventory draw-down by wholesalers and sub-wholesalers in the first quarter of 2014. As inventory in the distribution channel fluctuates from quarter to quarter, we may continue to see fluctuations in our earnings and a mismatch between prescription demand for our products and our revenues.

In addition, the non-retail sector in the United States, which includes government institutions, including state AIDS Drug Assistance Programs (ADAPs), correctional facilities and large health maintenance organizations, tends to be even less consistent in terms of buying patterns and often causes quarter over quarter fluctuations that do not necessarily mirror patient demand for our products. Federal and state budget pressures, including sequestration, as well as the annual grant cycles for federal and state ADAP funds, may cause ADAP purchasing patterns to not reflect patient demand of our HIV products. For example, in the first quarters of certain prior years, we observed large non-retail purchases of our HIV products by a number

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of state ADAPs that exceeded patient demand. We believe such purchases were driven by the grant cycle for federal ADAP funds. We expect to continue to experience fluctuations in the purchasing patterns of our non-retail customers which may result in fluctuations in our product sales, revenues and earnings in the future. In light of the global economic downturn and budget crises faced by many European countries, we have observed variations in purchasing patterns induced by cost containment measures in Europe. We believe these measures have caused some government agencies and other purchasers to reduce inventory of our products in the distribution channels, which has decreased our revenues and caused fluctuations in our product sales and earnings. We may continue to see this trend in the future.

Our results of operations may be adversely affected by current and potential future healthcare reforms.

Legislative and regulatory changes to government prescription drug procurement and reimbursement programs occur relatively frequently in the United States and foreign jurisdictions. In March 2010, healthcare reform legislation was adopted in the United States, requiring us to further rebate or discount products reimbursed or paid for by various public payers, including Medicaid and other entities eligible to purchase discounted products through the 340B Drug Pricing Program under the Public Health Service Act, such as ADAPs. As a result of the 2010 legislation, the discounts, rebates and fees that impacted us include:

- our minimum base rebate amount owed to Medicaid on products reimbursed by Medicaid increased by 8%, and the discounts or rebates we owe to ADAPs and other Public Health Service entities which reimburse or purchase our products also increased by 8%;
- we are required to extend rebates to patients receiving our products through Medicaid managed care organizations;
- we are required to provide a 50% discount on products sold to patients while they are in the Medicare Part D “donut hole;” and
- we, along with other pharmaceutical manufacturers of branded drug products, are required to pay a portion of a new industry fee (also known as the Branded Prescription Drug (BPD) Fee), of $3.0 billion for 2014, calculated based on select government sales during the 2012 calendar year as a percentage of total industry government sales.

The amount of the annual industry fee imposed on the pharmaceutical industry as a whole will be $3.0 billion in 2014 through 2016, increase to $4.0 billion in 2017, increase to a peak of $4.1 billion in 2018, and then decrease to $2.8 billion in 2019 and thereafter. We expect our portion of the BPD fee to increase as our revenues grow and as the amount of the annual industry fee increases through 2018 and drug patents expire on major drugs of other companies. In addition, during the third quarter of 2014, the Internal Revenues Service (IRS) issued final regulations which indicated that a manufacturer’s obligation to pay its portion of the BPD fee in any given calendar year is triggered by the qualifying sales in the previous year, instead of the first qualifying sale in the current calendar year. As a result of the final IRS regulations, we were required to recognize our 2014 fee of $460 million and 2013 fee of $142 million in our 2014 Consolidated Statement of Income. Our BPD fees were approximately $590 million, $110 million and $85 million in 2014, 2013 and 2012, respectively. The BPD fee is not tax deductible. Further, even though not addressed in the healthcare reform legislation, discussions continue at the federal level on legislation that would either allow or require the federal government to directly negotiate price concessions from pharmaceutical manufacturers or set minimum requirements for Medicare Part D pricing.

In addition, state Medicaid programs could request additional supplemental rebates on our products as a result of the increase in the federal base Medicaid rebate. Private insurers could also use the enactment of these increased rebates to exert pricing pressure on our products, and to the extent that private insurers or managed care programs follow Medicaid coverage and payment developments, the adverse effects may be magnified by private insurers adopting lower payment schedules.

Our existing products are subject to reimbursement from government agencies and other third parties. Pharmaceutical pricing and reimbursement pressures may reduce profitability.

Successful commercialization of our products depends, in part, on the availability of governmental and third-party payer reimbursement for the cost of such products and related treatments. Government health administration authorities, private health insurers and other organizations generally provide reimbursement. In the United States, the European Union and other significant or potentially significant markets for our products and product candidates, government authorities and third-party payers are increasingly attempting to limit or regulate the price of medical products and services, which has resulted in lower average selling prices.

A significant portion of our sales of the majority of our products are subject to significant discounts from list price and rebate obligations. In the United States, state ADAPs, which purchase a significant portion of our HIV products, rely on federal, supplemental federal and state funding to help fund purchases of our products. In the past, we have experienced a shift in our payer mix for HIV as patients previously covered by private insurance move to public reimbursement programs that require rebates or discounts from us or as patients previously covered by one public reimbursement program move to another

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public reimbursement program that requires greater rebates or discounts from us. If federal and state funds are not available in amounts sufficient to support the number of patients that rely on ADAPs, sales of our HIV products could be negatively impacted which would reduce our revenues. In prior quarters, because of the insufficiency of federal and state funds and as many states reduced eligibility criteria, we saw an increase in the number of patients on state ADAP waitlists, and we may see similar increases in future periods as a result of any reduction in federal and state ADAP support resulting from the sequestration. Until these patients are enrolled in an ADAP, they generally receive product from industry-supported patient assistance programs or are unable to access treatment. The increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the European Union will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our product sales and profitability. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies and pricing in general.

We have also experienced increased pricing pressure in the United States and in certain cases, have provided discounts to private payers in order to obtain formulary status or to expand access for patients to our HCV products. See also our risk factor "A substantial portion of our revenues is derived from sales of products to treat HCV and HIV. If we are unable to maintain or continue increasing sales of these products, our results of operations may be adversely affected."

In July 2014, we received a letter from the U.S. Senate Committee on Finance requesting information and supporting documentation from us related to Sovaldi and the pricing of Sovaldi in the United States. The letter raised concerns about our approach to pricing Sovaldi, its affordability and its impact on federal government spending and public health. We are cooperating with the inquiries. It is both costly and time-consuming for us to comply with these inquiries. We cannot predict the outcome. It is possible that the inquiries could result in negative publicity or other negative actions that could harm our reputation, reduce demand for Sovaldi, Harvoni or other sofosbuvir containing products and/or reduce coverage of Sovaldi, Harvoni or other sofosbuvir containing products, including by federal health care programs such as Medicare and Medicaid. If any or all of these events occur, our business and stock price could be materially and adversely affected.

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

Recently, many countries in the European Union have increased the level of discounting required on our products, and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the European Union. Some countries have instituted clawbacks and enacted taxes on specific products. As generic drugs come to market, we may face price decreases for our products in some countries in the European Union. Further, cost containment pressures in the European Union, especially in Southern Europe, could lead to delays in the treatment of patients and also delay pricing approval, which could negatively impact the commercialization of new products.

Government agencies also issue regulations and guidelines directly applicable to us and to our products. In addition, from time to time, professional societies, practice management groups, private health/science foundations and organizations publish guidelines or recommendations directed to certain health care and patient communities. Such recommendations and guidelines may relate to such matters as product usage, dosage, route of administration, and use of related or competing therapies and can consequently result in increased or decreased usage of our products.

Approximately 26% of our product sales occur outside the United States, and currency fluctuations and hedging expenses may cause our earnings to fluctuate, which could adversely affect our stock price.

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

We use foreign currency exchange forward and option contracts to hedge a percentage of our forecasted international sales, primarily those denominated in the Euro. We also hedge certain monetary assets and liabilities denominated in foreign

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currencies, which reduces but does not eliminate our exposure to currency fluctuations between the date a transaction is recorded and the date that cash is collected or paid. We cannot predict future fluctuations in the foreign currency exchange rate of the U.S. dollar. If the U.S. dollar appreciates significantly against certain currencies and our hedging program does not sufficiently offset the effects of such appreciation, our results of operations will be adversely affected and our stock price may decline.

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

We face significant competition.

We face significant competition from large global pharmaceutical and biotechnology companies, specialized pharmaceutical firms and generic drug manufacturers.

Our HCV products, Sovaldi and Harvoni, compete with a product marketed by AbbVie Inc. (Abbvie) and Janssen R&D Ireland's Olysio (simeprevir) in the United States.

Our HIV products compete primarily with products from ViiV Healthcare (ViiV), which markets fixed-dose combination products that compete with Stribild, Complera/Eviplera, Atripla and Truvada. For example, lamivudine, marketed by this joint venture, competes with emtricitabine, the active pharmaceutical ingredient of Emtriva and a component of Complera/Eviplera, Atripla and Truvada. For Tybost, we compete with ritonavir marketed by AbbVie. In addition, Tivicay (dolutegravir), an integrase inhibitor, launched in the fourth quarter of 2013 by ViiV, and Triumeq, a single-tablet triple-combination 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. In May 2010, the compound patent covering Epivir (lamivudine) 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 (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. Generic versions of Sustiva (efavirenz), a component of our Atripla, are now available in Canada and Europe and we anticipate competition from generic efavirenz to be in the United States in December 2017. We have observed some pricing pressure related to the Sustiva component of our Atripla sales.

For Viread and Hepsera for treatment of chronic hepatitis B virus (HBV) infection, we face competition from Baraclude (entecavir) marketed by Bristol-Myers Squibb Company as well as generic entecavir. Our HBV products also compete with Tyzeka/Sebivo (telbivudine) marketed by Novartis Pharmaceuticals Corporation (Novartis).

AmBisome competes predominantly with 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. In addition, 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 Taiwan. These formulations may reduce market demand for AmBisome. Furthermore, the manufacture of lipid formulations of amphotericin B is very complex and if any of these formulations are found to be unsafe, sales of AmBisome may be negatively impacted by association.

Letairis competes directly with Tracleer (bosentan) and Opsumit (macitentan) produced by Actelion Pharmaceuticals US, Inc. and also with Adcirca (tadalafil) from United Therapeutics Corporation and Pfizer.

Ranexa competes predominantly with generic compounds from three distinct classes of drugs, beta-blockers, calcium channel blockers and long-acting nitrates for the treatment of chronic angina in the United States.

Cayston competes with Tobi (tobramycin inhalation solution) marketed by Novartis.

Tamiflu competes with Relenza (zanamivir) sold by GSK and products sold by generic competitors.

In relapsed chronic lymphocytic leukemia, Zydelig competes with Imbruvica (ibrutinib) marketed by Pharmacyclics, Inc.

In addition, a number of companies are pursuing the development of technologies which are competitive with our existing products or research programs. These competing companies include specialized pharmaceutical firms and large pharmaceutical companies acting either independently or together with other pharmaceutical companies. Furthermore, academic institutions, government agencies and other public and private organizations conducting research may seek patent protection and may establish collaborative arrangements for competitive products or programs. If any of these competitors gain market share on our products, it could adversely affect our results of operations and stock price.

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

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

Our product Letairis, which was approved by the U.S. Food and Drug Administration (FDA) in June 2007, is a member of a class of compounds called endothelin receptor antagonists which pose specific risks, including serious risks of birth defects. Because of these risks, Letairis is available only through the Letairis Education and Access Program (LEAP), a restricted distribution program intended to help physicians and patients learn about the risks associated with the product and assure appropriate use of the product. As the product is used by additional patients, we may discover new risks associated with Letairis which may result in changes to the distribution program and additional restrictions on the use of Letairis which may decrease demand for the product.

Regulatory authorities have been moving towards more active and transparent pharmacovigilance and are making greater amounts of stand-alone safety information and clinical trial data directly available to the public through websites and other means, e.g. periodic safety update report summaries, risk management plan summaries and various adverse event data. Safety information, without the appropriate context and expertise, may be misinterpreted and lead to misperception or legal action which may potentially cause our product sales or stock price to decline.

Further, if serious safety, resistance or drug interaction issues arise with our marketed products, sales of these products could be limited or halted by us or by regulatory authorities and our results of operations would be adversely affected.

Our operations depend on compliance with complex FDA and comparable international regulations. Failure to obtain broad approvals on a timely basis or to maintain compliance could delay or halt commercialization of our products.

The products we develop must be approved for marketing and sale by regulatory authorities and, once approved, are subject to extensive regulation by the FDA, the EMA and comparable regulatory agencies in other countries. We are continuing clinical trials for Sovaldi, Atripla, Truvada, Harvoni, Complera/Eviplera, Stribild, Viread, Emtriva, Hepsera, Tybost, Vitekta, Letairis, Ranexa, Cayston and Zydelig for currently approved and additional uses. We anticipate that we will file for marketing approval in additional countries and for additional indications and products over the next several years. These products may fail to receive such marketing approvals on a timely basis, or at all.

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

For example, under FDA rules, we are often required to conduct post-approval clinical studies to assess a known serious risk, signals of serious risk or to identify an unexpected serious risk and implement a Risk Evaluation and Mitigation Strategy for our products, which could include a medication guide, patient package insert, a communication plan to healthcare providers or other elements as the FDA deems are necessary to assure safe use of the drug, which could include imposing certain restrictions on the distribution or use of a product. Failure to comply with these or other requirements, if imposed on a sponsor by the FDA, could result in significant civil monetary penalties and our operating results may be adversely affected.

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

We are required to demonstrate the safety and efficacy of products that we develop for each intended use through extensive preclinical studies and clinical trials. The results from preclinical and early clinical studies do not always accurately predict results in later, large-scale clinical trials. Even successfully completed large-scale clinical trials may not result in marketable products. If any of our product candidates fails to achieve its primary endpoint in clinical trials, if safety issues arise or if the results from our clinical trials are otherwise inadequate to support regulatory approval of our product candidates, commercialization of that product candidate could be delayed or halted. For example, we recently announced results from our

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Phase 2 study of simtuzumab for the treatment of pancreatic cancer, myelofibrosis and colorectal cancer showing that the product candidate did not provide clinical benefit. In addition, we may also face challenges in clinical trial protocol design.

If the clinical trials for any of the product candidates in our pipeline are delayed or terminated, our prospects for future revenue growth would be adversely impacted. For example, we face numerous risks and uncertainties with our product candidates, including the fixed-dose combination of sofosbuvir and GS-5816 for HCV; the fixed-dose combination of emtricitabine with TAF for HIV; idelalisib for the treatment of indolent non-Hodgkin lymphoma and frontline and relapsed refractory chronic lymphocytic leukemia; momelotinib for the treatment of myelofibrosis, ranolazine for the treatment of incomplete revascularization post-percutaneous coronary intervention; GS-6615 for the treatment of LQT-3; and TAF as a standalone agent, each currently in Phase 3 clinical trials, that could prevent completion of development of these product candidates. These risks include our ability to enroll patients in clinical trials, the possibility of unfavorable results of our clinical trials, the need to modify or delay our clinical trials or to perform additional trials and the risk of failing to obtain FDA and other regulatory body approvals. As a result, our product candidates may never be successfully commercialized. Further, we may make a strategic decision to discontinue development of our product candidates if, for example, we believe commercialization will be difficult relative to other opportunities in our pipeline. If these programs and others in our pipeline cannot be completed on a timely basis or at all, then our prospects for future revenue growth may be adversely impacted. In addition, clinical trials involving our commercial products could raise new safety issues for our existing products, which could in turn decrease our revenues and harm our business.

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

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

We depend on relationships with other companies for sales and marketing performance, development and commercialization of product candidates and revenues. Failure to maintain these relationships, poor performance by these companies or disputes with these companies could negatively impact our business.

We rely on a number of significant collaborative relationships with major pharmaceutical companies for our sales and marketing performance in certain territories. These include collaborations with BMS for Atripla in the United States, Europe and Canada; F. Hoffmann-La Roche Ltd. (together with Hoffmann-La Roche Inc., Roche) for Tamiflu worldwide; and GSK for ambrisentan in territories outside of the United States. In some countries, we rely on international distributors for sales of Truvada, Viread, Hepsera, Emtriva and AmBisome. Some of these relationships also involve the clinical development of these products by our partners. Reliance on collaborative relationships poses a number of risks, including the risk that:

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

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

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

- not provide us with accurate or timely information regarding their inventories, patient data or safety complaints;
- not effectively sell or support Letairis or Cayston;
- not devote the resources necessary to sell Letairis or Cayston in the volumes and within the time frames that we expect;
- not be able to satisfy their financial obligations to us or others; or
- cease operations.

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

Further, Cayston may only be taken by patients using a specific inhalation device that delivers the drug to the lungs of patients. Our ongoing distribution of Cayston is entirely reliant upon the manufacturer of that device. This manufacturer could encounter other issues with regulatory agencies related to the device or be unable to supply sufficient quantities of this device. In addition, the manufacturer may not be able to provide adequate warranty support for the device after it has been distributed to patients. With respect to distribution of the drug and device to patients, we are reliant on the capabilities of specialty pharmacies. For example, the distribution channel for drug and device is complicated and requires coordination. The reimbursement approval processes associated with both drug and device are similarly complex. If the device manufacturer is unable to obtain reimbursement approval or receives approval at a lower-than-expected price, sales of Cayston may be adversely affected. Any of the previously described issues may limit the sales of Cayston, which would adversely affect our financial results.

Our success will depend to a significant degree on our ability to defend our patents and other intellectual property rights both domestically and internationally. We may not be able to obtain effective patents to protect our technologies from use by competitors and patents of other companies could require us to stop using or pay for the use of required technology.

Patents and other proprietary rights are very important to our business. Our success will depend to a significant degree on our ability to:

- obtain patents and licenses to patent rights;
- preserve trade secrets;
- defend against infringement and efforts to invalidate our patents; and
- operate without infringing on the intellectual property of others.

If we have a properly drafted and enforceable patent, it can be more difficult for our competitors to use our technology to create competitive products and more difficult for our competitors to obtain a patent that prevents us from using technology we create. As part of our business strategy, we actively seek patent protection both in the United States and internationally and file additional patent applications, when appropriate, to cover improvements in our compounds, products and technology.

We have a number of U.S. and foreign patents, patent applications and rights to patents related to our compounds, products and technology, but we cannot be certain that issued patents will be enforceable or provide adequate protection or that pending patent applications will result in issued patents. Patent applications are confidential for a period of time before a patent is issued. As a result, we may not know if our competitors filed patent applications for technology covered by our pending applications or if we were the first to invent or first to file an application directed toward the technology that is the subject of our patent applications. Competitors may have filed patent applications or received patents and may obtain additional patents and proprietary rights that block or compete with our products. In addition, if competitors file patent applications covering our technology, we may have to participate in litigation, interference or other proceedings to determine the right to a patent. Litigation, interference or other proceedings are unpredictable and expensive, such that, even if we are ultimately successful, our results of operations may be adversely affected by such events.

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

We may obtain patents for certain products many years before marketing approval is obtained for those products. Because patents have a limited life, which may begin to run prior to the commercial sale of the related product, the commercial value of the patent may be limited. However, we may be able to apply for patent term extensions or supplementary protection certificates in some countries.

Generic manufacturers have sought, and may continue to seek, FDA approval to market generic versions of our products through an abbreviated new drug application (ANDA), the application form typically used by manufacturers seeking approval of a generic drug. See a description of our ANDA litigation in "Legal Proceedings" beginning on page 47 and risk factor entitled "Litigation with generic manufacturers has increased our expenses which may continue to reduce our earnings. If we are unsuccessful in all or some of these lawsuits, some or all of our claims in the patents may be narrowed or invalidated and generic versions of our products could be launched prior to our patent expiry." beginning on page 42 .

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

If we infringe the valid patents of third parties, we may be prevented from commercializing products or may be required to obtain licenses from these third parties. We may not be able to obtain alternative technologies or any required license on reasonable terms or at all. If we fail to obtain these licenses or alternative technologies, we may be unable to develop or commercialize some or all of our products. For example, we are aware of patents that may relate to our operation of LEAP, our restricted distribution program designed to support Letairis and we are aware of patents and patent applications owned by other parties that may claim to cover the use of sofosbuvir. See a description of our litigation regarding sofosbuvir in the risk factor entitled "If any party is successful in establishing exclusive rights to Sovaldi and/or Harvoni, our expected revenues and earnings from the sale of Sovaldi and/or Harvoni could be adversely affected" beginning on page 38 .

Furthermore, we also rely on unpatented trade secrets and improvements, unpatented internal know-how and technological innovation. In particular, a great deal of our liposomal manufacturing expertise, which is a key component of our liposomal technology, is not covered by patents but is instead protected as a trade secret. We protect these rights mainly through confidentiality agreements with our corporate partners, employees, consultants and vendors. These agreements provide that all confidential information developed or made known to an individual during the course of their relationship with us will be kept confidential and will not be used or disclosed to third parties except in specified circumstances. In the case of employees, the agreements provide that all inventions made by an individual while employed by us will be our exclusive property. We cannot be certain that these parties will comply with these confidentiality agreements, that we have adequate remedies for any breach or that our trade secrets will not otherwise become known or be independently discovered by our competitors. Under some of our R&D agreements, inventions become jointly owned by us and our corporate partner and in other cases become the exclusive property of one party. In certain circumstances, it can be difficult to determine who owns a particular invention and disputes could arise regarding those inventions. If our trade secrets or confidential information become known or independently discovered by competitors or if we enter into disputes over ownership of inventions, our business and results of operations could be adversely affected.

If any party is successful in establishing exclusive rights to Sovaldi and/or Harvoni, our expected revenues and earnings from the sale of Sovaldi and/or Harvoni could be adversely affected.

We own patents and patent applications that claim sofosbuvir (Sovaldi) as a chemical entity and its metabolites and the fixed-dose combination of ledipasvir and sofosbuvir (Harvoni). Third parties may have, or may obtain rights to, patents that allegedly could be used to prevent or attempt to prevent us from commercializing Sovaldi or Harvoni. For example, we are aware of patents and patent applications owned by other parties that may be alleged by such parties to cover the use of Sovaldi and Harvoni. We cannot predict the ultimate outcome of intellectual property claims related to Sovaldi or Harvoni, and we have spent, and will continue to spend, significant resources defending against these claims. If these parties successfully obtain valid and enforceable patents, and successfully prove infringement of those patents by Sovaldi and/or Harvoni, we could be prevented from selling sofosbuvir unless we were able to obtain a license under such patents. Such a license may not be available on commercially reasonable terms or at all.

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Interference Proceedings and Litigation with Idenix Pharmaceuticals, Inc. (Idenix)

In February 2012, we received notice that the U.S. Patent and Trademark Office (USPTO) had declared Interference No. 105,871 (First Idenix Interference) between our U.S. Patent No. 7,429,572 (the ‘572 patent) and Idenix's pending U.S. Patent Application No. 12/131,868. An interference is an administrative proceeding before the USPTO designed to determine who was the first to invent the subject matter claimed by both parties. Our patent covers metabolites of sofosbuvir. Idenix is attempting to patent a class of compounds, including these metabolites. The purpose of the First Idenix Interference was to determine who was first to invent these compounds and therefore who is entitled to the patent claiming these compounds. In March 2013, the USPTO Patent Trial and Appeal Board (the Board) determined that Idenix is not entitled to the benefit of any of its early application filing dates because none of those patent applications, including the application granted as Idenix’s U.S. Patent No. 7,608,600 (the ‘600 patent), taught how to make the compounds in dispute. The Board also determined that because we are entitled to the filing date of our earliest application, we were first to file the patent application on the compounds in dispute, and we were therefore the “senior party” in the First Idenix Interference. On January 29, 2014, the Board determined that Pharmasset and not Idenix was the first to invent the compounds in dispute and accordingly Gilead prevailed in the First Idenix Interference. In its decision, the Board held that Idenix failed to prove that it was first to conceive of any of the compounds in dispute. Specifically, Idenix failed to prove that the Idenix inventors had identified the structure, a method of making and a use for any of the disputed compounds. The Board went on to conclude that Idenix failed to work diligently toward making and testing the compounds in dispute during the relevant time period. Idenix has appealed the Board’s decisions to the U.S. District Court for the District of Delaware.

In December 2013, after receiving our request to do so, the USPTO declared Interference No. 105,981 (Second Idenix Interference) between our pending U.S. Patent Application No. 11/854,218 and the ‘600 patent. The ‘600 patent includes claims directed to methods of treating HCV with nucleoside compounds similar to those which were involved in the First Idenix Interference. The Second Idenix Interference will determine who was first to invent the claimed methods of treating HCV. On January 16, 2015 the Board issued a decision in favor of Gilead in the first phase of the Second Idenix Interference. The Board decided that we were first to file the patent application on the disputed methods of treating HCV, designated Gilead as the senior party in the Second Idenix Interference, and invalidated the patent claims of the Idenix ‘600 patent that are involved in the Second Idenix Interference. As the senior party, we are presumed to be the first to have invented the disputed methods of treating HCV. Because Idenix failed to teach how to make and use the invention in its ‘600 patent, the Board invalidated the Idenix claims involved in the Second Idenix Interference for lack of enablement. The Board has also placed Idenix under an Order to Show Cause requiring Idenix to explain why judgment should not be entered against it in the Second Idenix Interference based upon the decision by the Board in the First Idenix Interference. The decision in the Second Idenix Interference is consistent with the Board’s earlier rulings in March 2013 and January 2014 in the First Idenix Interference in which Gilead was declared the senior party and the first to invent certain 2’-fluoro, methyl nucleoside compounds. These compounds are relevant to the methods of treating HCV at issue in the Second Idenix Interference.

We believe that the Idenix claims involved in the First and Second Idenix Interferences, and similar U.S. and foreign patents claiming the same compounds, metabolites and uses thereof, are invalid. As a result, we filed an Impeachment Action in the Federal Court of Canada to invalidate Idenix Canadian Patent No. 2,490,191 (the ‘191 patent), which is the Canadian patent that corresponds to the ‘600 patent and the Idenix patent application that was the subject of the First Idenix Interference. Idenix has asserted that the commercialization of Sovaldi in Canada will infringe its ‘191 patent and that our Canadian Patent No. 2,527,657, corresponding to the ‘572 patent involved in the First Idenix Interference, is invalid. A trial on these issues commenced in January 2015.

We filed a similar legal action in Norway in the Oslo District Court seeking to invalidate Idenix's Norwegian patent corresponding to the ‘600 patent. In September 2013, Idenix filed an invalidation action in the Norwegian proceedings against our Norwegian Patent No. 333700 patent, which corresponds to the ‘572 patent. On March 21, 2014, the Norwegian court found all claims in the Idenix Norwegian patent to be invalid and upheld the validity of all claims in the challenged Gilead patent. On April 30, 2014, Idenix appealed the March 21, 2014 decision to the Norwegian Court of Appeal. Idenix’s obligation to pay our attorneys’ fees will be stayed during the pendency of the appeal. The appeal from the March 2014 decision is scheduled to commence in February 2016.

In August 2013 and April 2014, Idenix filed two separate requests for invalidation with the Chinese Patent Office of our Chinese Patent CN ZL200480019148.4, which corresponds to our '572 patent. In August 2014 Idenix withdrew its invalidation requests and the Chinese proceedings were terminated with our challenged patent remaining valid and enforceable.

In January 2013, we filed a legal action in the Federal Court of Australia seeking to invalidate Idenix’s Australian patent corresponding to the ‘600 patent. In April 2013, Idenix asserted that the commercialization of Sovaldi in Australia will infringe the Australian patent corresponding to the ‘600 patent. A trial on these issues is scheduled to commence in September

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2015 in Sydney. On March 12, 2014 the European Patent Office (EPO) granted Idenix European Patent No. 1 523 489 (the ‘489 patent), which corresponds to the ‘600 patent. The same day that the ‘489 patent granted, we filed an opposition with the EPO seeking to revoke the ‘489 patent. Also on that day, Idenix initiated infringement proceedings against Gilead in the United Kingdom (UK), Germany and France alleging that the commercialization of Sovaldi in those countries would infringe the respective national counterparts of the ‘489 patent. In the United Kingdom, a trial was held in October 2014 to determine the issues of infringement and validity of the Idenix UK patent. In December 2014, the High Court of Justice of England and Wales (UK Court) invalidated all claims of the ‘489 patent on multiple grounds. Specifically, the UK Court held that the ‘489 patent lacked novelty over our earlier filed patent application teaching some of the same compounds, the ’489 patent lacked an inventive step because it did not add anything to the knowledge existing at the time and the disclosure in the Idenix’s patent application was insufficient because it did not teach how to make the compounds or show which of the claimed compounds would have activity against viruses like the hepatitis C virus. On January 22, 2015, the UK Court held a hearing at which the court ordered Idenix to pay 92% of Gilead’s costs, with an interim payment due within 28 days of the hearing. The UK Court granted Idenix permission to appeal the December 1, 2014 judgment. On February 3, 2015, the German court in Düsseldorf held a hearing to determine the issue of infringement of the Idenix German patent. We do not have a trial date for the French lawsuit.

Idenix has not been awarded patents corresponding to the ‘600 patent in Japan or China. In the event such patents issue, we expect to challenge them in proceedings similar to those we invoked in other countries.

In December 2013, Idenix, Universita Degli Studi di Cagliari (UDSG), Centre National de la Recherche Scientifique and L’Université Montpellier II sued us in U.S. District Court for the District of Delaware alleging that the commercialization of sofosbuvir will infringe the ‘600 patent and that an interference exists between the ‘600 patent and our U.S. Patent No. 8,415,322. Also in December 2013, Idenix and UDSG sued us in the U.S. District Court for the District of Massachusetts alleging that the commercialization of sofosbuvir will infringe U.S. Patent Nos. 6,914,054 and 7,608,597. On June 30, 2014, the court in Massachusetts granted our request and transferred the Massachusetts litigation to the U.S. District Court for the District of Delaware. We believe that Idenix’s patents are invalid and would not be infringed by our commercialization of sofosbuvir and that we have the sole right to commercialize sofosbuvir. The district court has set trial dates in October 2016 and December 2016 for resolution of these issues. A decision by the district court can be appealed by either party to the U.S. Court of Appeals for the Federal Circuit (CAFC).

Idenix was acquired by Merck in August 2014. While the acquisition does not change our view of the lack of merit in the claims made by Idenix, Merck has greater resources than Idenix and may therefore choose to fund the litigation at higher levels than Idenix.

Litigation with Merck

In August 2013, Merck contacted us requesting that we pay royalties on the sales of sofosbuvir and obtain a license to U.S. Patent Nos. 7,105,499 and 8,481,712, which it co-owns with Isis Pharmaceuticals, Inc. We believe that Merck’s patents are invalid and would not be infringed by our commercialization of sofosbuvir and that we have the sole right to commercialize sofosbuvir. Accordingly, in August 2013, we filed a lawsuit in the U.S. District Court for the Northern District of California seeking a declaratory judgment that the Merck patents are invalid and not infringed. Merck’s U.S. Patent Nos. 7,105,499 and 8,481,712 cover compounds which do not include, but may relate to, sofosbuvir. During patent prosecution, Merck amended its patent application in an attempt to cover compounds related to sofosbuvir and ultimately extract royalty payments for sofosbuvir’s commercialization, or to exclude it from the market. If the court determines that Merck’s patents are valid and that we have infringed those claims, we may be required to obtain a license from and pay royalties to Merck to commercialize sofosbuvir. Either party can appeal a decision by the District Court to the CAFC. The court has set a trial date of March 7, 2016 for this litigation.

Litigation with AbbVie

AbbVie has obtained U.S. Patent Nos. 8,466,159, 8,492,386, 8,680,106, 8,685,984 and 8,809,265 (AbbVie Patents), which purport to cover the use of a combination of ledipasvir/sofosbuvir (or Harvoni) for the treatment of HCV. We are aware that AbbVie has pending patent applications in other countries. We own published and pending patent applications directed to the use of combinations for the treatment of HCV, and, specifically, to the combination of ledipasvir and sofosbuvir. Certain of those applications were filed before the AbbVie Patents. For this reason and others, we believe the AbbVie Patents are invalid.

Accordingly, in December 2013, we filed a lawsuit in the U.S. District Court for the District of Delaware seeking declaratory judgment that the AbbVie Patents are invalid and unenforceable, as well as other relief. We believe that Abbott Laboratories, Inc. and AbbVie conspired to eliminate competition in the HCV market by falsely representing to the USPTO that they, and not Gilead, invented methods of treating HCV using a combination of ledipasvir/sofosbuvir. In February and March 2014, AbbVie responded to our lawsuit by filing two lawsuits also in the U.S. District Court for the District of

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Delaware alleging that our fixed-dose combination of ledipasvir/sofosbuvir will infringe its patents. A ll of those lawsuits have been consolidated into a single action. Either party can appeal a decision by the District Court to the CAFC. The AbbVie Patents have not blocked or delayed the commercialization of our combination product in the United States, and we do not expect any other foreign patents to block or delay the commercialization around the world. If a court determines that the AbbVie Patents are valid and that we have infringed those claims, we may be required to obtain a license from and pay royalties to AbbVie to commercialize sofosbuvir combination products.

Manufacturing problems, including at our third-party manufacturers and corporate partners, could cause inventory shortages and delay product shipments and regulatory approvals, which may adversely affect our results of operations.

In order to generate revenue from our products, we must be able to produce sufficient quantities of our products to satisfy demand. Many of our products are the result of complex manufacturing processes. The manufacturing process for pharmaceutical products is also highly regulated and regulators may shut down manufacturing facilities that they believe do not comply with regulations.

Our products are either manufactured at our own facilities or by third-party manufacturers or corporate partners. We depend on third parties to perform manufacturing activities effectively and on a timely basis for the majority of our solid dose products. In addition, Roche, either by itself or through third parties, is responsible for manufacturing Tamiflu. We, our third-party manufacturers and our corporate partners are subject to Good Manufacturing Practices (GMP), which are extensive regulations governing manufacturing processes, stability testing, record keeping and quality standards as defined by the FDA and the EMA. Similar regulations are in effect in other countries.

Our third-party manufacturers and corporate partners are independent entities who are subject to their own unique operational and financial risks which are out of our control. If we or any of these third-party manufacturers or corporate partners fail to perform as required, this could impair our ability to deliver our products on a timely basis or receive royalties or cause delays in our clinical trials and applications for regulatory approval. Further, we may have to write-off the costs of manufacturing any batch that fails to pass quality inspection or meet regulatory approval. To the extent these risks materialize and affect their performance obligations to us, our financial results may be adversely affected.

In addition, we, our third-party manufacturers and our corporate partners may only be able to produce some of our products at one or a limited number of facilities and, therefore, have limited manufacturing capacity for certain products. For example, in 2012, due to unexpected delays both in qualifying two new external sites and with expanding Cayston manufacturing in San Dimas, we were unable to supply enough Cayston to fulfill our projected demand. From February through September 2012, we suspended access for patients with new prescriptions for Cayston, subject to certain exceptions where specific medical need existed. As a result of our inability to manufacture sufficient Cayston to meet demand, the amount of revenues we received from the sale of Cayston was reduced.

Our manufacturing operations are subject to routine inspections by regulatory agencies. For example, in April 2013, the FDA conducted an inspection of our Foster City facility and issued Form 483 Inspectional Observations, which noted deficiencies in documentation and validation of certain quality testing procedures and methods. As a result of the observations, the FDA delivered Complete Response Letters notifying us that it was unable to approve our NDAs for elvitegravir and cobicistat as standalone agents. In mid-October 2013, the FDA completed its sofosbuvir pre-approval inspection of our Foster City facility. Following that inspection, the FDA issued additional Form 483 Inspectional Observations citing deficiencies related to testing and reconciliation of stability samples, testing protocols, testing of shipping samples, and procedures for calibrating test equipment. We completed and filed our responses to these observations with the FDA. In 2014, we received a letter from FDA related to the extent of method revalidations being conducted, stability program oversight, audit trail review/data management and Quality Management System gaps. We have filed our responses to these observations with the FDA. If we are unable to remedy the deficiencies cited by the FDA in these inspections, our currently marketed products and the timing of regulatory approval of products in development could be adversely affected. Further, there is risk that regulatory agencies in other countries where marketing applications are pending will undertake similar additional reviews or apply a heightened standard of review, which could delay the regulatory approvals for products in those countries. If approval of any of our product candidates were delayed or if production of our marketed products was interrupted, our anticipated revenues and our stock price would be adversely affected.

We may not be able to obtain materials or supplies necessary to conduct clinical trials or to manufacture and sell our products, which would limit our ability to generate revenues.

We need access to certain supplies and products to conduct our clinical trials and to manufacture our products. If we are unable to purchase sufficient quantities of these materials or find suitable alternate materials in a timely manner, our development efforts for our product candidates may be delayed or our ability to manufacture our products would be limited, which would limit our ability to generate revenues.

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Suppliers of key components and materials must be named in an NDA filed with the FDA, EMA or other regulatory authority for any product candidate for which we are seeking marketing approval, and significant delays can occur if the qualification of a new supplier is required. Even after a manufacturer is qualified by the regulatory authority, the manufacturer must continue to expend time, money and effort in the area of production and quality control to ensure full compliance with GMP. Manufacturers are subject to regular, periodic inspections by the regulatory authorities following initial approval. If, as a result of these inspections, a regulatory authority determines that the equipment, facilities, laboratories or processes do not comply with applicable regulations and conditions of product approval, the regulatory authority may suspend the manufacturing operations. If the manufacturing operations of any of the single suppliers for our products are suspended, we may be unable to generate sufficient quantities of commercial or clinical supplies of product to meet market demand, which would in turn decrease our revenues and harm our business. In addition, if delivery of material from our suppliers were interrupted for any reason, we may be unable to ship certain of our products for commercial supply or to supply our products in development for clinical trials. In addition, some of our products and the materials that we utilize in our operations are made at only one facility. For example, we manufacture certain drug product intermediates utilized in AmBisome exclusively at our facilities in San Dimas, California. In the event of a disaster, including an earthquake, equipment failure or other difficulty, we may be unable to replace this manufacturing capacity in a timely manner and may be unable to manufacture AmBisome to meet market needs.

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

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

Litigation with generic manufacturers has increased our expenses which may continue to reduce our earnings. If we are unsuccessful in all or some of these lawsuits, some or all of our claims in the patents may be narrowed or invalidated and generic versions of our products could be launched prior to our patent expiry.

As part of the approval process for some of our products, the FDA granted us a New Chemical Entity (NCE) exclusivity period during which other manufacturers' applications for approval of generic versions of our product will not be approved. Generic manufacturers may challenge the patents protecting products that have been granted NCE exclusivity one year prior to the end of the NCE exclusivity period. Generic manufacturers have sought and may continue to seek FDA approval for a similar or identical drug through an ANDA, the application form typically used by manufacturers seeking approval of a generic drug. Current legal proceedings of significance with some of our generic manufacturers include:

Mylan

In April 2014, we received notice that Mylan Inc. (Mylan) submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Truvada. In the notice, Mylan alleges that two of the patents associated with emtricitabine and one of our patents associated with the fixed-dose combination of emtricitabine with tenofovir disoproxil fumarate are invalid, unenforceable and/or will not be infringed by Mylan's manufacture, use or sale of a generic version of Truvada. In June 2014, we filed a lawsuit against Mylan in U.S. District Court for the Northern District of West Virginia for infringement of our patents. In June 2014, we received notice that Mylan Inc. submitted petitions for Inter Partes Review (IPR) to the Board alleging that four patents associated with tenofovir disoproxil fumarate are invalid. We opposed Mylan’s petitions. In December 2014, the PTAB issued decisions denying each of Mylan’s petitions for IPR against the tenofovir disoproxil fumarate-associated patents on the grounds that Mylan had not established a reasonable likelihood of success that it would prevail in its challenge to each of these patents. Mylan has requested a rehearing on the basis that it believes the PTAB decision is wrong.

Apotex

In June 2014, we received notice that Apotex Inc. (Apotex) submitted an abbreviated new drug submission (ANDS) to the Canadian Minister of Health requesting permission to manufacture and market a generic fixed-dose combination of emtricitabine and tenofovir disoproxil fumarate and a separate ANDS requesting permission to manufacture and market a generic version of Viread. In the notice, Apotex alleges that three of the patents associated with Truvada and two of the patents

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associated with Viread are invalid, unenforceable and/or will not be infringed by Apotex's manufacture, use or sale of a generic version of Truvada or Viread. In August 2014, we filed a lawsuit against Apotex in the Federal Court of Canada seeking an order of prohibition against approval of this ANDS.

Natco

In March 2011, we and F. Hoffmann-La Roche Ltd. (Roche) filed a lawsuit against Natco Pharma Ltd. (Natco) in U.S. District Court for the District of New Jersey for infringement of one of the patents associated with Tamiflu. In December 2012, the court issued a ruling in favor of Gilead and Roche, that our patent is not invalid for the reason stated in Natco's notice letter. Natco has appealed this decision to the CAFC. In April 2014, the CAFC issued a decision which will allow Natco's patent invalidity challenge to proceed if the case is remanded to the District Court for a full trial on the merits. On June 30, 2014, we filed a petition for rehearing *en banc* with the CAFC, which was subsequently denied. We have submitted a request for an extension of time to submit our petition for certiorari to the Supreme Court of the United States and are concurrently proceeding before the District Court.

Teva

In August 2012, Teva Pharmaceuticals (Teva) filed an Impeachment Action in the Federal Court of Canada seeking invalidation of our two Canadian patents associated with Viread. In September 2013, a hearing on the consolidated requests for orders of prohibition in connection with all three of Teva's ANDS filings to the Canadian Minister of Health (for Teva's generic versions of Viread, Truvada, and Atripla) took place. In December 2013, the court issued our requested order prohibiting the Canadian Ministry of Health from issuing a Notice of Compliance for Teva's generic versions of our Viread, Truvada, and Atripla products until expiry of our patent in July 2017. Teva appealed the decision of the court prohibiting the Minister of Heath from issuing the Notices of Compliance until expiry of our patent in July 2017. This decision did not rule on the validity of the patents and accordingly the only issue on appeal is whether the Minister of Health should be prohibited from issuing the Notices of Compliance for Teva's products. Separately, the court will determine the validity of the patents in the pending Impeachment Action. A trial in the Impeachment Action is scheduled for September 2016. If Teva is successful in invalidating our patents, Teva may be able to launch generic versions of our Viread, Truvada and Atripla products in Canada prior to the expiry of our patents.

Watson

In February 2015, we received notice that Watson Laboratories, Inc. (Watson) submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Letairis. In the notice, Watson alleges that one of the patents associated with ambrisentan tablets is invalid, unenforceable and/or will not be infringed by Watson's manufacture, use or sale of a generic version of Letairis. We are currently evaluating Watson's notice and will file a patent infringement lawsuit as necessary to protect the exclusivity of the product.

Astellas/Apotex

In December 2014, Astellas informed us that they had received notice that Apotex submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Lexiscan. In the notice, Apotex alleges that one of the patents associated with regadenoson is invalid, unenforceable and/or will not be infringed by Apotex's manufacture, use or sale of a generic version of Lexiscan. Because Apotex has not challenged several of the patents associated with regadenoson, Apotex product would not be eligible for final approval until expiry of the patents that have not been challenged. We and Astellas have the opportunity to file a patent infringement lawsuit against Apotex in the future should we decide that it is necessary to protect the exclusivity of the product.

We cannot predict the ultimate outcome of the foregoing actions and other litigation with generic manufacturers, and we may spend significant resources enforcing and defending these patents. If we are unsuccessful in these lawsuits, some or all of our original claims in the patents may be narrowed or invalidated and the patent protection for Truvada, Viread and Tamiflu in the United States and Atripla, Truvada and Viread in Canada could be substantially shortened. Further, if all of the patents covering one or more products are invalidated, the FDA or Canadian Minister of Health could approve the requests to manufacture a generic version of such products in the United States or Canada, respectively, prior to the expiration date of those patents. The sale of generic versions of these products earlier than their patent expiration would have a significant negative effect on our revenues and results of operations.

We face credit risks from our Emerging Market and Southern European customers that may adversely affect our results of operations.

We have exposure to customer credit risks in Emerging Markets and Southern Europe. Southern European product sales to government-owned or supported customers in Southern Europe, specifically Spain, Italy, Portugal and Greece have

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historically been and continue to be subject to significant payment delays due to government funding and reimbursement practices. This has resulted and may continue to result in days sales outstanding being significantly higher in these countries due to the average length of time that accounts receivable remain outstanding. As of December 31, 2014 , our accounts receivable in these countries totaled approximately $504 million of which $157 million were past due greater than 120 days and $44 million were past due greater than 365 days.

Historically, receivable balances with certain publicly-owned hospitals accumulate over a period of time and are then subsequently settled as large lump sum payments. This pattern is also experienced by other pharmaceutical companies that sell directly to hospitals. If significant changes were to occur in the reimbursement practices of these European governments or if government funding becomes unavailable, we may not be able to collect on amounts due to us from these customers and our results of operations would be adversely affected.

Our revenues and gross margin could be reduced by imports from countries where our products are available at lower prices.

Prices for our products are based on local market economics and competition and sometimes differ from country to country. Our sales in countries with relatively higher prices may be reduced if products can be imported into those or other countries from lower price markets. There have been cases in which other pharmaceutical products were sold at steeply discounted prices in the developing world and then re-exported to European countries where they could be re-sold at much higher prices. If this happens with our products, particularly Truvada and Viread, which we have agreed to make available at substantially reduced prices to more than 125 countries participating in our Gilead Access Program, or Atripla, which Merck distributes at substantially reduced prices to HIV infected patients in developing countries under our 2006 agreement, our revenues would be adversely affected. In addition, we have established partnerships with India-based generic manufacturers to distribute generic versions of tenofovir disoproxil fumarate to 112 developing world countries, including India. We expanded these agreements to include rights to Stribild, Tybost and Vitekta. We also entered into agreements with certain India-based generic manufacturers 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 September 2014, we entered into licensing agreements with India-based generic manufacturers to produce and distribute generic sofosbuvir and the fixed-dose combination of ledipasvir/sofosbuvir to 91 developing countries. If generic versions of our HIV and HCV medications under these licenses are then re-exported to the United States, Europe or other markets outside of these 112 countries, our revenues would be adversely affected. As part of our commitment to make Sovaldi available in the developing world at discounted prices, we entered into an agreement to make Sovaldi available in Egypt, a country that has among the highest HCV prevalence in the world. If the discounted Sovaldi is re-exported from these developing countries into the United States or other higher price markets, our revenues could be adversely affected.

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

Expensive litigation and government investigations have increased our expenses which may continue to reduce our earnings.

We are involved in a number of litigation, investigation and other dispute-related matters that require us to expend substantial internal and financial resources. We expect these matters will continue to require a high level of internal and financial resources for the foreseeable future. These matters have reduced and will continue to reduce our earnings. Please see a description of our Litigation Regarding Sofosbuvir and Litigation with Generic Manufacturers in "Legal Proceedings" beginning on page 47 . The outcome of such lawsuits or any other lawsuits that may be brought against us, the investigation or any other investigations that may be initiated, are inherently uncertain, and adverse developments or outcomes can result in significant expenses, monetary damages, penalties or injunctive relief against us that could significantly reduce our earnings and cash flows and harm our business.

In some countries, we may be required to grant compulsory licenses for our products or our patents may not be enforced.

In a number of developing countries, government officials and other interested groups have suggested that pharmaceutical companies should make drugs for HCV or HIV infection available at low cost. Alternatively, governments in

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those developing countries could require that we grant compulsory licenses to allow competitors to manufacture and sell their own versions of our products, thereby reducing our product sales. For example, there is growing attention on the availability of HCV therapies and some activists are advocating for the increased availability of HCV therapies through means including compulsory licenses. In the past, certain offices of the government of Brazil have expressed concern over the affordability of our HIV products and declared that they were considering issuing compulsory licenses to permit the manufacture of otherwise patented products for HIV infection, including Viread. In addition, concerns over the cost and availability of Tamiflu related to a potential avian flu pandemic and H1N1 influenza generated international discussions over compulsory licensing of our Tamiflu patents. For example, the Canadian government considered allowing Canadian manufacturers to manufacture and export the active ingredient in Tamiflu to eligible developing and least developed countries under Canada's Access to Medicines Regime. Furthermore, Roche issued voluntary licenses to permit third-party manufacturing of Tamiflu. For example, Roche granted a sublicense to Shanghai Pharmaceutical (Group) Co., Ltd. for China and a sublicense to India's Hetero Drugs Limited for India and certain developing countries. If compulsory licenses permit generic manufacturing to override our product patents for Sovaldi, Harvoni, our HIV products or Tamiflu, or if we are required to grant compulsory licenses for these products, it could reduce our earnings and cash flows and harm our business.

In addition, certain countries do not permit enforcement of our patents, and third-party manufacturers are able to sell generic versions of our products in those countries. For example, in July 2009, the Brazilian patent authority rejected our patent application for tenofovir disoproxil fumarate, the active pharmaceutical ingredient in Viread. This was the highest level of appeal available to us within the Brazilian patent authority. Because we do not currently have a patent in Brazil, the Brazilian government now purchases its supply of tenofovir disoproxil fumarate from generic manufacturers. Sales of generic versions of our products could significantly reduce our sales and adversely affect our results of operations, particularly if generic versions of our products are imported into territories where we have existing commercial sales.

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

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

Business disruptions from natural or man-made disasters may harm our future revenues.

Our worldwide operations could be subject to business interruptions stemming from natural or man-made disasters for which we may be self-insured. Our corporate headquarters and Fremont locations, which together house a majority of our R&D activities, and our San Dimas and Oceanside manufacturing facilities are located in California, a seismically active region. As we do not carry earthquake insurance and significant recovery time could be required to resume operations, our financial condition and operating results could be materially adversely affected in the event of a major earthquake.

We are dependent on information technology systems, infrastructure and data.

We are dependent upon information technology systems, infrastructure and data. The multitude and complexity of our computer systems make them inherently vulnerable to service interruption or destruction, malicious intrusion and random attack. Likewise, data privacy or security breaches by employees or others may pose a risk that sensitive data, including our intellectual property, trade secrets or personal information of our employees, patients, customers or other business partners may be exposed to unauthorized persons or to the public. Cyberattacks are increasing in their frequency, sophistication and intensity. Cyberattacks could include the deployment of harmful malware, denial-of-service, social engineering and other means to affect service reliability and threaten data confidentiality, integrity and availability. Our business partners face similar risks and any security breach of their systems could adversely affect our security posture. While we have invested, and continue to invest, in the protection of our data and information technology infrastructure, there can be no assurance that our efforts will prevent service interruptions, or identify breaches in our systems, that could adversely affect our business and operations and/or result in the loss of critical or sensitive information, which could result in financial, legal, business or reputational harm to us. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyberattacks and other related breaches.

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Changes in our effective income tax rate could reduce our earnings.

We are subject to income taxes in both the United States and various foreign jurisdictions including Ireland. Due to economic and political conditions various countries are actively considering changes to existing tax laws. We cannot predict the form or timing of potential legislative changes that could have a material adverse impact on our results of operations. In addition, significant judgment is required in determining our worldwide provision for income taxes. Various factors may have favorable or unfavorable effects on our income tax rate including, but not limited to, changes in forecasted demand for our HCV products, our portion of the non-tax deductible BPD fee (also known as the pharmaceutical excise tax), the accounting for stock options and other share-based awards, mergers and acquisitions, the ability to manufacture product in our Cork, Ireland facility, the amortization of certain acquisition related intangibles for which we receive no tax benefit, expiration of the federal research tax credit, future levels of R&D spending, changes in the mix of earnings in the various tax jurisdictions in which we operate, changes in overall levels of pre-tax earnings and resolution of federal, state and foreign income tax audits. The impact on our income tax provision resulting from the above mentioned factors may be significant and could have a negative impact on our consolidated results of operations.

Our income tax returns are audited by federal, state and foreign tax authorities. We are currently under examination by the Internal Revenue Service for the 2010, 2011 and 2012 tax years and by various state and foreign jurisdictions. There are differing interpretations of tax laws and regulations, and as a result, significant disputes may arise with these tax authorities involving issues of the timing and amount of deductions and allocations of income among various tax jurisdictions. Resolution of one or more of these exposures in any reporting period could have a material impact on the results of operations for that period.

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

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

There can be no assurance that we will pay dividends or continue to repurchase stock.

In February 2015, we announced that our Board of Directors authorized a dividend program under which we intend to pay quarterly dividends of $0.43 per share, beginning in the second quarter of 2015, subject to quarterly declarations by our Board of Directors and that our Board of Directors also approved the repurchase of up to an additional $15.0 billion of our common stock. The declaration, amount and timing of such dividends and/or the amount and timing of such stock repurchases are subject to capital availability and determinations by our Board of Directors that cash dividends and/or stock repurchases are in the best interest of our stockholders and are in compliance with all respective laws and our agreements applicable to the declaration and payment of cash dividends and the repurchase of stock. Our ability to pay dividends and/or repurchase stock will depend upon, among other factors, our cash balances and potential future capital requirements for strategic transactions, including acquisitions, debt service requirements, results of operations, financial condition and other factors beyond our control that our Board of Directors may deem relevant. A reduction in or elimination of our dividend payments, our dividend program and/or stock repurchases could have a negative effect on our stock price.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

Our corporate headquarters is located in Foster City, California, where we house our administrative, manufacturing and R&D activities. We also have R&D facilities in Oceanside and Fremont, California; Seattle, Washington; Branford, Connecticut; and Alberta, Canada and manufacturing facilities in San Dimas, California and Cork, Ireland. Our global commercial operations include 20 offices throughout Europe, seven in Asia, one in South America and one in North America.

We believe that our existing properties, including both owned and leased sites, are in good condition and suitable for the conduct of our business. We believe our capital resources are sufficient to purchase, lease or construct any additional facilities required to meet our expected long-term growth needs.

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ITEM 3. LEGAL PROCEEDINGS

Litigation Regarding Sofosbuvir

In January 2012, we acquired Pharmasset, Inc. (Pharmasset). Through the acquisition, we acquired sofosbuvir, a nucleotide analog that acts to inhibit the replication of the HCV. In December 2013, we received FDA approval of sofosbuvir, now known commercially as Sovaldi. In October 2014, we also received approval of the fixed-dose combination of ledipasvir and sofosbuvir, now known commercially as Harvoni. We have received a number of contractual and intellectual property claims regarding sofosbuvir. We have carefully considered these claims both prior to and following the acquisition and believe they are without merit.

We own patents and patent applications that claim sofosbuvir (Sovaldi) as a chemical entity and its metabolites and the fixed-dose combination of ledipasvir and sofosbuvir (Harvoni). Third parties may have, or may obtain rights to, patents that allegedly could be used to prevent or attempt to prevent us from commercializing Sovaldi or Harvoni. For example, we are aware of patents and patent applications owned by other parties that may be alleged by such parties to cover the use of Sovaldi and Harvoni. We cannot predict the ultimate outcome of intellectual property claims related to Sovaldi or Harvoni, and we have spent, and will continue to spend, significant resources defending against these claims.

If these parties successfully obtain valid and enforceable patents, and successfully prove infringement of those patents by Sovaldi and/or Harvoni, we could be prevented from selling these products unless we were able to obtain a license under such patents. Such a license may not be available on commercially reasonable terms or at all.

Interference Proceedings and Litigation with Idenix Pharmaceuticals, Inc. (Idenix)

In February 2012, we received notice that the U.S. Patent and Trademark Office (USPTO) had declared Interference No. 105,871 (First Idenix Interference) between our U.S. Patent No. 7,429,572 (the ‘572 patent) and Idenix's pending U.S. Patent Application No. 12/131,868. An interference is an administrative proceeding before the USPTO designed to determine who was the first to invent the subject matter claimed by both parties. Our patent covers metabolites of sofosbuvir. Idenix is attempting to patent a class of compounds, including these metabolites. The purpose of the First Idenix Interference was to determine who was first to invent these compounds and therefore who is entitled to the patent claiming these compounds. In March 2013, the USPTO Patent Trial and Appeal Board (the Board) determined that Idenix is not entitled to the benefit of any of its early application filing dates because none of those patent applications, including the application granted as Idenix’s U.S. Patent No. 7,608,600 (the ‘600 patent), taught how to make the compounds in dispute. The Board also determined that because we are entitled to the filing date of our earliest application, we were first to file the patent application on the compounds in dispute, and we were therefore the “senior party” in the First Idenix Interference. On January 29, 2014, the Board determined that Pharmasset and not Idenix was the first to invent the compounds in dispute and accordingly Gilead prevailed in the First Idenix Interference. In its decision, the Board held that Idenix failed to prove that it was first to conceive of any of the compounds in dispute. Specifically, Idenix failed to prove that the Idenix inventors had identified the structure, a method of making and a use for any of the disputed compounds. The Board went on to conclude that Idenix failed to work diligently toward making and testing the compounds in dispute during the relevant time period. Idenix has appealed the Board’s decisions to the U.S. District Court for the District of Delaware.

In December 2013, after receiving our request to do so, the USPTO declared Interference No. 105,981 (Second Idenix Interference) between our pending U.S. Patent Application No. 11/854,218 and the ‘600 patent. The ‘600 patent includes claims directed to methods of treating HCV with nucleoside compounds similar to those which were involved in the First Idenix Interference. The Second Idenix Interference will determine who was first to invent the claimed methods of treating HCV. On January 16, 2015 the Board issued a decision in favor of Gilead in the first phase of the Second Idenix Interference. The Board decided that we were first to file the patent application on the disputed methods of treating HCV, designated Gilead as the senior party in the Second Idenix Interference, and invalidated the patent claims of the Idenix ‘600 patent that are involved in the Second Idenix Interference. As the senior party, we are presumed to be the first to have invented the disputed methods of treating HCV. Because Idenix failed to teach how to make and use the invention in its ‘600 patent, the Board invalidated the Idenix claims involved in the Second Idenix Interference for lack of enablement. The Board has also placed Idenix under an Order to Show Cause requiring Idenix to explain why judgment should not be entered against it in the Second Idenix Interference based upon the decision by the Board in the First Idenix Interference. The decision in the Second Idenix Interference is consistent with the Board’s earlier rulings in March 2013 and January 2014 in the First Idenix Interference in which Gilead was declared the senior party and the first to invent certain 2’-fluoro, methyl nucleoside compounds. These compounds are relevant to the methods of treating HCV at issue in the Second Idenix Interference.

We believe that the Idenix claims involved in the First and Second Idenix Interferences, and similar U.S. and foreign patents claiming the same compounds, metabolites and uses thereof, are invalid. As a result, we filed an Impeachment Action in the Federal Court of Canada to invalidate Idenix Canadian Patent No. 2,490,191 (the ‘191 patent), which is the Canadian

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patent that corresponds to the ‘600 patent and the Idenix patent application that was the subject of the First Idenix Interference. Idenix has asserted that the commercialization of Sovaldi in Canada will infringe its ‘191 patent and that our Canadian Patent No. 2,527,657, corresponding to the ‘572 patent involved in the First Idenix Interference, is invalid. A trial on these issues commenced in January 2015.

We filed a similar legal action in Norway in the Oslo District Court seeking to invalidate Idenix's Norwegian patent corresponding to the ‘600 patent. In September 2013, Idenix filed an invalidation action in the Norwegian proceedings against our Norwegian Patent No. 333700 patent, which corresponds to the ‘572 patent. On March 21, 2014, the Norwegian court found all claims in the Idenix Norwegian patent to be invalid and upheld the validity of all claims in the challenged Gilead patent. On April 30, 2014, Idenix appealed the March 21, 2014 decision to the Norwegian Court of Appeal. Idenix’s obligation to pay our attorneys’ fees will be stayed during the pendency of the appeal. The appeal from the March 2014 decision is scheduled to commence in February 2016.

In August 2013 and April 2014, Idenix filed two separate requests for invalidation with the Chinese Patent Office of our Chinese Patent CN ZL200480019148.4, which corresponds to our '572 patent. In August 2014 Idenix withdrew its invalidation requests and the Chinese proceedings were terminated with our challenged patent remaining valid and enforceable.

In January 2013, we filed a legal action in the Federal Court of Australia seeking to invalidate Idenix’s Australian patent corresponding to the ‘600 patent. In April 2013, Idenix asserted that the commercialization of Sovaldi in Australia will infringe the Australian patent corresponding to the ‘600 patent. A trial on these issues is scheduled to commence in September 2015 in Sydney. On March 12, 2014 the European Patent Office (EPO) granted Idenix European Patent No. 1 523 489 (the ‘489 patent), which corresponds to the ‘600 patent. The same day that the ‘489 patent granted, we filed an opposition with the EPO seeking to revoke the ‘489 patent. Also on that day, Idenix initiated infringement proceedings against Gilead in the United Kingdom (UK), Germany and France alleging that the commercialization of Sovaldi in those countries would infringe the respective national counterparts of the ‘489 patent. In the United Kingdom, a trial was held in October 2014 to determine the issues of infringement and validity of the Idenix UK patent. In December 2014, the High Court of Justice of England and Wales (UK Court) invalidated all claims of the ‘489 patent on multiple grounds. Specifically, the UK Court held that the ‘489 patent lacked novelty over our earlier filed patent application teaching some of the same compounds, the ’489 patent lacked an inventive step because it did not add anything to the knowledge existing at the time and the disclosure in the Idenix’s patent application was insufficient because it did not teach how to make the compounds or show which of the claimed compounds would have activity against viruses like the hepatitis C virus. On January 22, 2015, the UK Court held a hearing at which the court ordered Idenix to pay 92% of Gilead’s costs, with an interim payment due within 28 days of the hearing. The UK Court granted Idenix permission to appeal the December 1, 2014 judgment. On February 3, 2015, the German court in Düsseldorf held a hearing to determine the issue of infringement of the Idenix German patent. We do not have a trial date for the French lawsuit.

Idenix has not been awarded patents corresponding to the ‘600 patent in Japan or China. In the event such patents issue, we expect to challenge them in proceedings similar to those we invoked in other countries.

In December 2013, Idenix, Universita Degli Studi di Cagliari (UDSG), Centre National de la Recherche Scientifique and L’Université Montpellier II sued us in U.S. District Court for the District of Delaware alleging that the commercialization of sofosbuvir will infringe the ‘600 patent and that an interference exists between the ‘600 patent and our U.S. Patent No. 8,415,322. Also in December 2013, Idenix and UDSG sued us in the U.S. District Court for the District of Massachusetts alleging that the commercialization of sofosbuvir will infringe U.S. Patent Nos. 6,914,054 and 7,608,597. On June 30, 2014, the court in Massachusetts granted our request and transferred the Massachusetts litigation to the U.S. District Court for the District of Delaware. We believe that Idenix’s patents are invalid and would not be infringed by our commercialization of sofosbuvir and that we have the sole right to commercialize sofosbuvir. The district court has set trial dates in October 2016 and December 2016 for resolution of these issues. A decision by the district court can be appealed by either party to the U.S. Court of Appeals for the Federal Circuit (CAFC).

Idenix was acquired by Merck in August 2014. While the acquisition does not change our view of the lack of merit in the claims made by Idenix, Merck has greater resources than Idenix and may therefore choose to fund the litigation at higher levels than Idenix.

Litigation with Merck & Co, Inc. (Merck)

In August 2013, Merck contacted us requesting that we pay royalties on the sales of sofosbuvir and obtain a license to U.S. Patent Nos. 7,105,499 and 8,481,712, which it co-owns with Isis Pharmaceuticals, Inc. We believe that Merck’s patents are invalid and are not infringed by our commercialization of sofosbuvir and that we have the sole right to commercialize

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sofosbuvir. In August 2013, we filed a lawsuit in the U.S. District Court for the Northern District of California seeking a declaratory judgment that the Merck patents are invalid and not infringed. Merck's U.S. Patent Nos. 7,105,499 and 8,481,712 cover compounds which do not include, but may relate to, sofosbuvir. During patent prosecution, Merck amended its patent application in an attempt to cover compounds related to sofosbuvir with the apparent goal of ultimately extracting royalty payments for sofosbuvir's commercialization, or eliminating competition by excluding it from the market. If the court determines that Merck's patents are valid and that we have infringed those claims, we may be required to obtain a license from and pay royalties to Merck to commercialize sofosbuvir. Either party can appeal a decision by the District Court to the CAFC. The court has set a trial date of March 7, 2016 for this lawsuit.

Litigation with AbbVie, Inc. (AbbVie)

AbbVie has obtained U.S. Patent Nos. 8,466,159, 8,492,386, 8,680,106, 8,685,984, and 8,809,265 (AbbVie Patents) which purport to cover the use of a combination of ledipasvir/sofosbuvir (or Harvoni) for the treatment of HCV. Gilead is aware that AbbVie has pending patent applications in the United States and other countries. We own published and pending patent applications directed to the use of combinations for the treatment of HCV, and, specifically, to the combination of ledipasvir and sofosbuvir. Certain of our applications were filed before the AbbVie Patents. For this reason and others, we believe the AbbVie Patents are invalid.

Accordingly, in December 2013, we filed a lawsuit in the U.S. District Court for the District of Delaware seeking declaratory judgment that the AbbVie Patents are invalid and unenforceable, as well as other relief. We believe that Abbott Laboratories, Inc. and AbbVie conspired to eliminate competition in the HCV market by falsely representing to the USPTO that they, and not Gilead, invented methods of treating HCV using a combination of ledipasvir/sofosbuvir. In February and March 2014, AbbVie responded to our lawsuit by filing two lawsuits also in the U.S. District Court for the District of Delaware alleging that our fixed-dose combination of ledipasvir/sofosbuvir will infringe its patents. All of those lawsuits have been consolidated into a single action. In the United States, either party can appeal a decision by the District Court to the CAFC. The AbbVie Patents have not blocked or delayed the commercialization of our combination product in the United States or Europe. We do not expect any other foreign patents to block or delay the commercialization around the world. If a court determines that the AbbVie Patents are valid and that we have infringed those claims, we may be required to obtain a license from and pay royalties to AbbVie to commercialize sofosbuvir combination products.

Litigation with Generic Manufacturers

As part of the approval process for some of our products, the FDA granted us a New Chemical Entity (NCE) exclusivity period during which other manufacturers' applications for approval of generic versions of our product will not be approved. Generic manufacturers may challenge the patents protecting products that have been granted NCE exclusivity one year prior to the end of the NCE exclusivity period. Generic manufacturers have sought and may continue to seek FDA approval for a similar or identical drug through an abbreviated new drug application (ANDA), the application form typically used by manufacturers seeking approval of a generic drug.

Tenofovir Disoproxil Fumarate, Emtricitabine and Fixed-dose Combination of Emtricitabine, Tenofovir Disoproxil Fumarate and Efavirenz

In 2008 and 2009, we received notices that Teva Pharmaceuticals (Teva) submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Truvada. In April 2013, we and Teva reached an agreement to settle the ongoing patent litigation concerning the patents that protect tenofovir disoproxil fumarate in Atripla, Truvada and Viread. Under the agreement, Teva will be allowed to launch a generic version of Viread on December 15, 2017. In April 2014, we and Teva entered into an agreement to settle the ongoing patent litigation concerning the emtricitabine patents that protect Atripla and Truvada. Terms of the settlement are confidential.

In November 2011, we received notice that Teva submitted an ANDS to the Canadian Minister of Health requesting permission to manufacture and market a generic fixed-dose combination of emtricitabine and tenofovir disoproxil fumarate. In the notice, Teva alleges that three of the patents associated with Truvada are invalid, unenforceable and/or will not be infringed by Teva's manufacture, use or sale of a generic version of Truvada. In January 2012, we filed a lawsuit against Teva in the Federal Court of Canada seeking an order of prohibition against approval of this ANDS.

In December 2011, we received notice that Teva submitted an ANDS to the Canadian Minister of Health requesting permission to manufacture and market a generic fixed-dose combination of emtricitabine, tenofovir disoproxil fumarate and efavirenz. In the notice, Teva alleges that three of our patents associated with Atripla and two of Merck's patents associated with Atripla are invalid, unenforceable and/or will not be infringed by Teva's manufacture, use or sale of a generic fixed-dose combination of emtricitabine, tenofovir disoproxil fumarate and efavirenz. In February 2012, we filed a lawsuit against Teva in the Federal Court of Canada seeking an order of prohibition against approval of this ANDS. In August 2012, we received notice that Teva submitted an ANDS to the Canadian Minister of Health requesting permission to manufacture and market a

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generic version of Viread. In the notice, Teva alleges that two patents associated with tenofovir disoproxil fumarate are invalid, unenforceable and/or will not be infringed by Teva's manufacture, use or sale of a generic version of Viread, Truvada, and Atripla. In September 2012, we filed a lawsuit against Teva in the Federal Court of Canada seeking an order of prohibition against approval of this ANDS. Also in August 2012, Teva filed an Impeachment Action in the Federal Court of Canada seeking invalidation of our two Canadian patents associated with Viread. We are currently defending that Impeachment Action. The requests for orders of prohibition in connection with all three of Teva's ANDS filings (for Teva's generic versions of Viread, Truvada and Atripla) were consolidated and in December 2013, the court issued our requested order prohibiting the Canadian Minister of Health from issuing a Notice of Compliance for Teva's generic versions of our Viread, Truvada and Atripla products until expiry of our patent in July 2017. Teva has appealed that decision. That decision did not rule on the validity of the patents and accordingly the only issue on appeal is whether the Minister of Health should be prohibited from issuing the Notices of Compliance for Teva's products. Separately, the court will determine the validity of the patents in the pending Impeachment Action. A trial in the Impeachment Action is scheduled for September 2016. If Teva is successful in invalidating our patents, Teva may be able to launch generic versions of our Viread, Truvada and Atripla products in Canada prior to the expiry of our patents.

In 2012, we received notice that Lupin Limited (Lupin) submitted an ANDA to the FDA requesting permission to manufacture and market generic versions of Truvada and Viread. In May 2014, Lupin amended its ANDAs to certify that it is no longer seeking approval to market generic versions of Truvada and Viread prior to the expiration of the four patents associated with tenofovir disoproxil fumarate in January 2018 (including pediatric exclusivity). In September 2014, we reached agreement with Lupin to settle the lawsuit related to the emtricitabine patents that protect Truvada and Atripla. Terms of the settlement are confidential.

In July 2012, we received notice that Cipla Ltd. (Cipla) submitted an ANDA to the FDA requesting permission to manufacture and market generic versions of Emtriva and Viread. In July 2014, we and Cipla reached agreement to settle those lawsuits. Terms of the settlement are confidential.

In April 2014, we received notice that Mylan Inc. (Mylan) submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Truvada. In the notice, Mylan alleges that two of the patents associated with emtricitabine and one of our patents associated with the fixed-dose combination of emtricitabine with tenofovir disoproxil fumarate are invalid, unenforceable and/or will not be infringed by Mylan's manufacture, use or sale of a generic version of Truvada. In June 2014, we filed a lawsuit against Mylan in U.S. District Court for the Northern District of West Virginia for infringement of our patents.

In June 2014, we received notice that Mylan Inc. submitted petitions for Inter Partes Review (IPR) to the Board alleging that four patents associated with tenofovir disoproxil fumarate are invalid. We opposed Mylan's petitions. In December 2014, the USPTO Patent Trial and Appeal Board (PTAB) issued decisions denying each of Mylan's petitions for IPR against the tenofovir disoproxil fumarate-associated patents on the grounds that Mylan had not established a reasonable likelihood of success that it would prevail in its challenge to each of these patents. Mylan has requested rehearing on the basis that it believes the PTAB decision is wrong.

In June 2014, we received notice that Apotex Inc. (Apotex) submitted an ANDS to the Canadian Minister of Health requesting permission to manufacture and market a generic fixed-dose combination of emtricitabine and tenofovir disoproxil fumarate and a separate ANDS requesting permission to manufacture and market a generic version of Viread. In the notice, Apotex alleges that three of the patents associated with Truvada and two of the patents associated with Viread are invalid, unenforceable and/or will not be infringed by Apotex's manufacture, use or sale of a generic version of Truvada or Viread. In August 2014, we filed a lawsuit against Apotex in the Federal Court of Canada seeking an order of prohibition against approval of this ANDS.

Ranolazine

In 2010, we received notice that Lupin submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of sustained-release ranolazine. In August 2013, the parties reached agreement to settle the patent litigation prior to issuance of the court's decision. Under the agreement, Lupin will be allowed to launch a generic version of Ranexa on February 27, 2019.

Tamiflu

In February 2011, we received notice that Natco Pharma Ltd. (Natco) submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Tamiflu. In the notice, Natco alleges that one of the patents associated with oseltamivir phosphate is invalid, unenforceable and/or will not be infringed by Natco's manufacture, use or sale of a generic version of Tamiflu. In March 2011, we and Roche filed a lawsuit against Natco in U.S. District Court for the District of New Jersey for infringement of one of the patents associated with Tamiflu. In December 2012, the court issued a

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ruling in favor of Gilead and Roche that our patent is not invalid for the reason stated in Natco's notice letter. Natco appealed this decision to the CAFC which issued its decision on April 22, 2014 allowing Natco's patent invalidity challenge to proceed and remanding to the District Court of New Jersey for a full trial on the merits. On June 30, 2014, we filed a petition for rehearing en banc with the CAFC, which was subsequently denied. We have filed a petition for certiorari to the Supreme Court of the United States and are concurrently proceeding before the District Court.

Letairis

In August 2014, Natco filed a complaint with the U.S. District Court for the District of Minnesota against Gilead and Express Scripts Holding Co., a specialty pharmacy that distributes our Letairis product. We distribute Letairis pursuant to an FDA-mandated Risk Evaluation and Mitigation Strategies (REMS) program. Natco alleges that Gilead, independently and together with Express Scripts, denied Natco access to samples of Letairis, which Natco claims it needs in order to conduct bioequivalence testing and file an ANDA. According to Natco, our conduct therefore violates antitrust laws. Natco is seeking damages and an order restraining Gilead from limiting distribution of Letairis to Natco through use of the REMS program.

In November 2014, Zydus Pharmaceuticals (USA) Inc. (Zydus) and Cadila Healthcare Limited (Cadila) filed a complaint with the U.S. District Court for the District of New Jersey against us relating to Letairis sales. We distribute Letairis pursuant to the REMS program. Zydus and Cadila allege that we denied them access to samples of Letairis, which they claim they need in order to conduct bioequivalence testing and file an ANDA. According to Zydus and Cadila, our conduct therefore violates antitrust laws. Zydus and Cadila are seeking damages and an order enjoining Gilead to provide Zydus with samples of Letairis.

In February 2015, we received notice that Watson Laboratories, Inc. (Watson) submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Letairis. In the notice, Watson alleges that one of the patents associated with ambrisentan tablets is invalid, unenforceable and/or will not be infringed by Watson's manufacture, use or sale of a generic version of Letairis. We are currently evaluating Watson's notice and will file a patent infringement lawsuit as necessary to protect the exclusivity of the product.

Lexiscan

In December 2014, Astellas informed us that they had received notice that Apotex submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Lexiscan. In the notice, Apotex alleges that one of the patents associated with regadenoson is invalid, unenforceable and/or will not be infringed by Apotex's manufacture, use or sale of a generic version of Lexiscan. Because Apotex has not challenged several of the patents associated with regadenoson, Apotex product would not be eligible for final approval until expiry of the patents that have not been challenged. We and Astellas have the opportunity to file a patent infringement lawsuit against Apotex in the future should we decide that it is necessary to protect the exclusivity of the product.

We cannot predict the ultimate outcome of these actions, and we may spend significant resources enforcing and defending these patents. If we are unsuccessful in these lawsuits, some or all of our claims in the patents may be narrowed or invalidated and the patent protection for Truvada, Viread, Lexiscan and Tamiflu in the United States and Atripla, Truvada and Viread in Canada could be substantially shortened. Further, if all of the patents covering one or more products are invalidated, the FDA or Canadian Minister of Health could approve the requests to manufacture a generic version of such products in the United States or Canada, respectively, prior to the expiration date of those patents. The sale of generic versions of these products earlier than their patent expiration would have a significant negative effect on our revenues and results of operations.

Department of Justice Investigation

In June 2011, we received a subpoena from the U.S. Attorney's Office for the Northern District of California requesting documents related to the manufacture, and related quality and distribution practices, of Complera, Atripla, Truvada, Viread, Emtriva, Hepsera and Letairis. We cooperated with the government's inquiry. In April 2014, the United States Department of Justice informed us that, following an investigation, it declined to intervene in a False Claims Act lawsuit filed by two former employees. In April 2014, the former employees served a First Amended Complaint. In January 2015, the federal district court issued an order granting in its entirety, without prejudice, our motion to dismiss the First Amended Complaint. In February 2015, the former employees served a Second Amended Complaint. We will move to dismiss the Second Amended Complaint.

Other Matters

We are a party to various legal actions that arose in the ordinary course of our business. We do not believe that these other legal actions will have a material adverse impact on our consolidated business, financial position or results of operations.

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ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

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PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock is traded on The Nasdaq Global Select Market under the symbol “GILD”. The following table sets forth the high and low intra-day sale prices per share of our common stock on The Nasdaq Global Select Market for the periods indicated. These prices represent quotations among dealers without adjustments for retail mark-ups, markdowns or commissions and may not represent prices of actual transactions.

	High	Low
2014		
First Quarter	$84.88	$67.63
Second Quarter	$84.45	$63.50
Third Quarter	$110.64	$83.32
Fourth Quarter	$116.83	$85.95
2013		
First Quarter	$49.48	$36.94
Second Quarter	$58.07	$46.53
Third Quarter	$64.74	$51.42
Fourth Quarter	$76.11	$58.81

As of February 13, 2015 , we had 1,489,401,683 shares of common stock outstanding held by approximately 375 stockholders of record, which include shares held by a broker, bank or other nominee.

We have not paid cash dividends on our common stock since our inception. On February 3, 2015, we announced the initiation of a quarterly dividend of $0.43 per share that will begin in the second quarter of 2015 subject to a declaration by the Board of Directors. The quarterly dividend is equivalent to $1.72 per share on an annual basis.

Performance Graph [(1)]

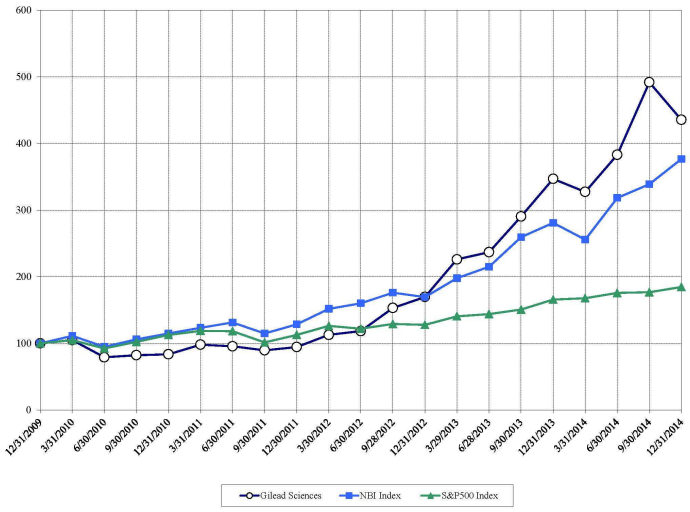
The following graph compares our total stockholder returns for the past five years to two indices: the Standard & Poor's 500 Stock Index, labeled S&P 500 Index; and the Nasdaq Biotechnology Index, labeled NBI Index. The total return for each index assumes the reinvestment of all dividends, if any, paid by companies included in these indices and are calculated as of December 31 of each year.

We are a composite member of each of the S&P 500 Index and the NBI Index, and we intend to use these indices as comparators for our stock performance for the purposes of the following graph going forward. As a composite member of the S&P 500 Index, we are required under applicable regulations to use this index as a comparator, and we believe the NBI Index is a relevant comparator since it is composed of peer companies in lines-of-business similar to ours.

The stockholder return shown on the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns.

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Comparison of Cumulative Total Return on Investment for the Past Five Years [2]



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[1] This section is not "soliciting material," is not deemed "filed" with the SEC and is not to be incorporated by reference in any of our filings under the Securities Act or the Exchange Act whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

[2] Shows the cumulative return on investment assuming an investment of $100 in our common stock, the NBI Index and the S&P 500 Index on December 31, 2009.

Issuer Purchases of Equity Securities

During the third quarter of 2014, we completed the $5.0 billion stock repurchase program announced in 2011 (2011 Program). During 2014, we repurchased $3.3 billion of the 2011 Program. In May 2014, our Board of Directors authorized a new three-year $5.0 billion stock repurchase program (2014 Program). This program will expire in September 2017. As of December 31, 2014 , we repurchased $2.0 billion of our common stock under the 2014 Program. On February 3, 2015, we announced that our Board of Directors authorized a new $15 billion five-year share repurchase program, which we will initiate in 2015 on the completion of our 2014 Program.

In 2014, we spent a total of $5.3 billion to repurchase and retire approximately 59 million shares of our common stock at an average purchase price of $90.30 per share. See Item 8, Note 12 Stockholders' Equity in our Consolidated Financial Statements included in this Annual Report on Form 10-K for more information regarding our stock repurchase programs. The table below summarizes our stock repurchase activity for the three months ended December 31, 2014 :

	Total Number of Shares Purchased (in thousands)	Average Price Paid per Share (in dollars)	Total Number of Shares Purchased as Part of Publicly Announced Program (in thousands) [1]	Maximum Fair Value of Shares that May Yet Be Purchased Under the Program (in millions) [1]
October 1 - October 31, 2014	6,693	$ 105.53	6,633	$ 4,300
November 1 - November 30, 2014	6,562	$ 104.50	6,227	$ 3,650
December 1 - December 31, 2014	6,417	$ 101.66	6,394	$ 3,000
Total	19,672 [2]	$ 103.93	19,254 [2]	

[1] Stock repurchases were made under the 2014 Program.

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

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ITEM 6. SELECTED FINANCIAL DATA

GILEAD SCIENCES, INC.
SELECTED CONSOLIDATED FINANCIAL DATA
(in millions, except per share data)

	Year Ended December 31,				
	2014	2013	2012	2011	2010
CONSOLIDATED STATEMENT OF INCOME DATA:					
Total revenues [1]	$ 24,890	$ 11,202	$ 9,702	$ 8,385	$ 7,949
Total costs and expenses [1]	$ 9,625	$ 6,678	$ 5,692	$ 4,596	$ 3,987
Income from operations	$ 15,265	$ 4,524	$ 4,010	$ 3,790	$ 3,962
Provision for income taxes	$ 2,797	$ 1,151	$ 1,038	$ 862	$ 1,024
Net income attributable to Gilead	$ 12,101	$ 3,075	$ 2,592	$ 2,804	$ 2,901
Net income per share attributable to Gilead common stockholders - basic	$ 7.95	$ 2.01	$ 1.71	$ 1.81	$ 1.69
Shares used in per share calculation-basic	1,522	1,529	1,515	1,550	1,712
Net income per share attributable to Gilead common stockholders - diluted	$ 7.35	$ 1.81	$ 1.64	$ 1.77	$ 1.66
Shares used in per share calculation-diluted	1,647	1,695	1,583	1,580	1,747

	December 31,				
	2014	2013	2012	2011	2010
CONSOLIDATED BALANCE SHEET DATA:					
Cash, cash equivalents and marketable securities [3]	$ 11,726	$ 2,571	$ 2,582	$ 9,964	$ 5,318
Working capital [2]	$ 11,953	$ 590	$ 1,918	$ 11,432	$ 3,271
Total assets [2]	$ 34,664	$ 22,579	$ 21,240	$ 17,303	$ 11,593
Other long-term obligations	$ 535	$ 179	$ 250	$ 175	$ 56
Convertible senior notes, senior unsecured notes and credit facility [3]	$ 12,404	$ 6,636	$ 8,224	$ 7,606	$ 3,478
Retained earnings	$ 12,732	$ 6,106	$ 3,705	$ 1,777	$ 1,184
Total stockholders' equity	$ 15,819	$ 11,745	$ 9,544	$ 6,867	$ 6,122

[1] See Item 7, Management's Discussion and Analysis for a description of our results of operations for 2014.

[2] During 2012, we completed the acquisition of Pharmasset and we recognized consideration transferred of $11.1 billion which was primarily recorded in intangible assets. We financed the transaction with approximately $5.2 billion in cash on hand, $2.2 billion in bank debt issued in January 2012 and $3.7 billion in senior unsecured notes issued in December 2011.

[3] During 2014, we issued senior unsecured notes for a total aggregate principal amount of $8.0 billion. We also repaid $912 million of principal balance of convertible senior notes, $2.5 billion in cash related to the conversion spread of the notes, $750 million for senior unsecured notes and $600 million for a revolving credit facility.

During 2013, we repaid $1.5 billion of principal balance of convertible senior notes and repaid $150 million under the five-year revolving credit facility credit agreement (the Five-Year Revolving Credit Agreement).

During 2012, we borrowed $750 million under our Five-Year Revolving Credit Agreement.

During 2011, we issued $4.7 billion principal amount of senior unsecured notes in registered offerings.

During 2010, we issued $2.5 billion principal amount of convertible senior notes in a private placement.

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

The following Management's Discussion and Analysis of Financial Condition and Results of Operations (MD&A) is intended to help the reader understand our results of operations and financial condition. MD&A is provided as a supplement to, and should be read in conjunction with, our audited Consolidated Financial Statements and the accompanying Notes to Consolidated Financial Statements and other disclosures included in this Annual Report on Form 10-K (including the disclosures under Item 1A, Risk Factors). Our Consolidated Financial Statements have been prepared in accordance with U.S. generally accepted accounting principles and are presented in U.S. dollars.

Management Overview

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.

Our portfolio of marketed products includes Sovaldi ®, Atripla ®, Truvada ®, Harvoni ®, Complera ®/Eviplera ®, Stribild ®, Viread ®, Letairis ®, Ranexa ®, AmBisome ®, Zydelig ®, Cayston ®, Hepsera ®, Emtriva ®, Tybost ®, Vitekta ® and Tamiflu ®. We have U.S. and international commercial sales operations, with marketing subsidiaries in North and South America, Europe and Asia-Pacific. We also sell and distribute certain products through our corporate partners under royalty-paying collaborative agreements.

Business Highlights

During 2014, we continued to advance our product pipeline across our therapeutic areas with the goal of delivering best-in-class drugs that advance the current standard of care and/or address unmet medical needs. Highlights of our 2014 announcements include:

Antiviral Program

- received approval from the U.S. Food and Drug Administration (FDA) in October 2014 and the European Commission in November 2014 for Harvoni (ledipasvir 90mg/sofosbuvir 400mg), the first once-daily single tablet regimen for the treatment of HCV genotype 1 infection in adults;
- received approval from the European Commission for Sovaldi in combination with other antiviral agents ribavirin and pegylated interferon alpha in all 28 countries of the European Union (EU) in January 2014;
- submitted a new drug application (NDA) to Japan’s Pharmaceutical and Medical Devices Agency for approval of sofosbuvir and our single tablet regimen of ledipasvir/sofosbuvir for the treatment of chronic genotype 1 HCV infection in adults;
- received approval from the FDA for Tybost, a pharmacokinetic enhancer that boosts blood levels of certain HIV medicines, and Vitekta, an integrase inhibitor for the treatment of HIV infection in adults without known mutations associated with resistance to elvitegravir;
- submitted a NDA to the FDA for approval of a single tablet regimen containing elvitegravir, cobicistat, emtricitabine and tenofovir alafenamide (E/C/F/TAF) for the treatment of HIV infection in adults;
- announced an expansion to our agreement with Janssen R&D Ireland Limited (Janssen) for the development and commercialization of a new single tablet regimen containing our TAF and emtricitabine, and Janssen's rilpivirine (RFTAF). We also amended our agreement with Janssen to collaborate on a single tablet regimen for HIV infection containing our TAF, emtricitabine and cobicistat and Janssen's darunavir;

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- entered into an agreement with Phenex Pharmaceuticals AG (Phenex) in December 2014 under which we acquired Phenex's Farnesoid X Receptor (FXR) program comprised of small molecule FXR agonists for the treatment of liver diseases, including nonalcoholic steatohepatitis (NASH);
- announced non-exclusive licensing agreements with India-based generic pharmaceutical manufacturers to expand access to our chronic HCV medicines in developing countries;
- announced a new agreement with the Medicines Patent Pool to expand access to TAF for HIV and HBV, contingent on FDA approval.

Oncology Program

- received approval from the FDA in July 2014 and the European Commission in September 2014 for Zydelig for the treatment of three B-cell blood cancers. Zydelig is indicated in combination with rituximab for patients with relapsed chronic lymphocytic leukemia and as a monotherapy for patients with relapsed follicular lymphoma and small lymphocytic lymphoma;
- entered into an exclusive license agreement with ONO Pharmaceutical Co., Ltd. (ONO), for the development and commercialization of ONO's oral Bruton's tyrosine kinase inhibitor for the treatment of B-cell malignancies and other diseases.

Cardiovascular Program

- announced 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. We have filed a supplemental NDA in the United States to cover the use of ambrisentan in combination with tadalafil.

Outlook 2015

In 2015 , we will continue to focus on our key operating objectives which include the progression of our product pipeline and continued uptake of our commercial products. From a research and development (R&D) perspective, we will continue to invest in conducting new and ongoing clinical studies, which support both our existing products and our product candidates. We expect to move forward on a number of late-stage clinical studies for new product candidates and plan to file marketing applications for product candidates in various therapeutic areas.

From a commercial perspective, we will continue to focus on supporting the uptake of our single tablet regimens for the treatment of HIV, prepare for the launch of our new single tablet regimen containing TAF in the United States and continue to promote the use of Sovaldi, Harvoni and Zydelig in the United States and Europe. We plan to further build-out and expand our international commercial infrastructure in Asia, in particular Japan, and other international markets to support the anticipated launch of Sovaldi and Harvoni in those regions.

As a result of the launch of Sovaldi and Harvoni in the United States and Sovaldi in parts of Europe, our business more than doubled in 2014. While we do not expect this level of growth in 2015, we do anticipate overall net product sales growth as we expect expanded access to Sovaldi and Harvoni in the United States and the launch of Harvoni in additional European Union countries and other international markets. However, this growth is subject to a number of uncertainties. These uncertainties include the continuation of a challenging macroeconomic environment in Europe inclusive of the potential adoption of additional pricing measures to reduce healthcare spending, particularly in HCV, the potential for continued volatility in foreign currency exchange rates, the number of HCV patients treated, an increase in discounts, chargebacks and rebates due to ongoing private and public payer negotiations, a larger than anticipated shift in payer mix to more highly discounted payer segments and the regulatory approval and commercial launches of Sovaldi and Harvoni in Japan.

We expect that our product pipeline investments and expanding commercial infrastructure will enable us to execute on our 2015 operating objectives.

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2014 Financial Highlights

During 2014, total revenues increased to $24.9 billion and total product sales increased to $24.5 billion , compared to $11.2 billion and $10.8 billion respectively, in 2013 , driven primarily by sales of Sovaldi and Harvoni and increased sales of our HIV single tablet regimen products, Stribild and Complera/Eviplera. Sovaldi was approved in the United States in December 2013 and in the European Union in January 2014. Sovaldi is now available in over 40 countries. Harvoni was approved in the United States in October 2014 and in the European Union in November 2014.

R&D expenses increased 35% to $2.9 billion for 2014 compared to 2013 due to continued investment in the progression and expansion in our product pipeline. Selling, general and administrative (SG&A) expenses increased 76% to $3.0 billion for 2014 compared to 2013 due to increased costs to support our business expansion related primarily to liver diseases and oncology and an increase in the Branded Prescription Drug fee (the BPD fee).

Net income attributable to Gilead for 2014 was $12.1 billion or $7.35 per diluted share, compared to $3.1 billion or $1.81 per diluted share in 2013 , due primarily to the launch of Sovaldi and Harvoni, partially offset by the increases in operating expenses.

As of December 31, 2014, our cash, cash equivalents and marketable securities totaled $11.7 billion . During 2014, we generated $12.8 billion in operating cash flows, issued $8.0 billion in senior unsecured notes and repaid $2.3 billion in debt.

Results of Operations

Total Revenues

Total revenues include product sales and royalty, contract and other revenues. Total revenues were $24.9 billion in 2014 , compared to $11.2 billion in 2013 and $9.7 billion in 2012 . Product sales represented 98% , 96% and 97% of total revenues in 2014 , 2013 and 2012 , respectively.

Product Sales

Total product sales were $24.5 billion in 2014 , compared to $10.8 billion in 2013 and $9.4 billion in 2012, driven primarily by an increase in antiviral product sales. Antiviral product sales were $22.8 billion in 2014, $9.3 billion in 2013 and $8.1 billion in 2012. The increase in antiviral product sales in 2014 was driven primarily by sales of Sovaldi and Harvoni and in 2013 was driven primarily by the continued uptake of our HIV single tablet regimen products, primarily Stribild and Complera/Eviplera. Other product sales which include Letairis, Ranexa, AmBisome and Zydelig, our first oncology product which launched in 2014, were $1.7 billion in 2014, an increase of 15% compared to $1.5 billion in 2013, an increase of 16% over other product sales of $1.3 billion in 2012. In 2014 approximately 26% of our product sales were generated outside the United States. We face exposure to adverse movements in foreign currency exchange rates, primarily in the Euro. We used foreign currency exchange contracts to hedge a percentage of our foreign currency exposure. Foreign currency exchange, net of hedges, had a favorable impact of $39 million on our 2014 revenues compared to 2013 and an unfavorable impact of $65 million on our 2013 revenues compared to 2012 .

We record product sales net of estimated mandatory and supplemental discounts to government payers, in addition to discounts to private payers, and other related costs. These deductions are generally referred to as gross-to-net deductions and totaled $7.3 billion in 2014, $3.9 billion in 2013, and $3.1 billion in 2012. As a percentage of gross product sales, gross-to-net deductions were 23% in 2014, 26% in 2013 and 25% in 2012. The decline in gross-to-net deductions as a percentage of gross product sales in 2014 compared to 2013 was primarily due to change in our payer mix reflecting a higher proportion of private payers compared to the prior year given the launch of Sovaldi in December 2013 and Harvoni in October 2014. The increase in gross-to-net deductions as a percentage of gross product sales in 2013 compared to 2012 resulted primarily from changes in payer mix, while the dollar increase resulted from payer mix and a higher level of gross product sales.

Product sales in the United States increased to $18.1 billion for 2014 compared to $6.6 billion in 2013 , due primarily to sales of Sovaldi and Harvoni and increases in sales of Stribild and Complera. Product sales in the United States increased 20% for 2013 compared to $5.5 billion in 2012, driven by sales growth of our single tablet regimen products, specifically Stribild and Complera as well as the launch of Sovaldi. During the fourth quarters of 2014 and 2013, we noted inventory levels at the high end of the inventory management agreement range. As we have seen in years past, we believe that inventory could draw down in the first quarter of 2015 and then track more normally with demand through the rest of 2015.

Product sales in Europe increased by 54% in 2014 to $5.1 billion compared to $3.3 billion in 2013 , due primarily to sales of Sovaldi and increases in sales of Stribild and Eviplera. Product sales in Europe increased 6% in 2013 to $3.3 billion compared to $3.1 billion in 2012, driven primarily by higher underlying demand for our antiviral products, specifically Eviplera, partially offset by decreases in the average net selling price of our HIV products. Foreign currency exchange, net of

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hedges, had a favorable impact of $72 million on our European product sales for 2014 compared to 2013 and an unfavorable impact of $55 million on our European product sales in 2013 compared to 2012.

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

(In millions, except percentages)	2014	Change	2013	Change	2012
Antiviral products:					
Sovaldi	$ 10,283	*	$ 139	*	$ —
Atripla	3,470	(5)%	3,648	2 %	3,574
Truvada	3,340	7 %	3,136	(1)%	3,181
Harvoni	2,127	*	—	*	—
Complera/Eviplera	1,228	52 %	810	137 %	342
Stribild	1,197	122 %	539	*	58
Viread	1,058	10 %	959	13 %	849
Other antiviral	88	(21)%	111	(20)%	138
Total antiviral products	22,791	144 %	9,342	15 %	8,142
Other products:					
Letairis	595	14 %	520	27 %	410
Ranexa	510	14 %	449	20 %	373
AmBisome	388	10 %	352	1 %	346
Zydelig	23	*	—	*	—
Other	167	18 %	141	13 %	127
Total product sales	$ 24,474	127 %	$ 10,804	15 %	$ 9,398

* Percentage not meaningful

Antiviral Products

Antiviral product sales increased by 144% in 2014 compared to 2013 and by 15% in 2013 compared to 2012 . The following is additional discussion of our results by product:

- *HCV Products*

  In 2014, sales of Sovaldi and Harvoni (HCV products) were $12.4 billion. HCV product sales accounted for 54% of our total antiviral product sales for the year. HCV product sales were $10.5 billion in the United States and $1.6 billion in Europe in 2014. Since the launch of Sovaldi in December 2013 and Harvoni in October 2014, more than 170,000 patients around the world have been treated with a sofosbuvir-based regimen.

- *Atripla*

  Atripla sales accounted for 15% , 39% and 44% of our total antiviral product sales for 2014 , 2013 and 2012 , respectively, and decreased by 5% in 2014 compared to 2013, due primarily to declines in volume as doctors prescribed newer treatments such as Complera/Eviplera and Stribild. The efavirenz component of Atripla, which has a gross margin of zero, comprised $1.3 billion , $1.4 billion and $1.3 billion of our Atripla sales in 2014 , 2013 and 2012 , respectively.

  A generic version of Bristol-Myers Squibb Company's Sustiva (efavirenz), a component of Atripla, was made available in Canada and Europe in 2013 and will be made available in the United States in 2017. While we have observed some pricing pressure related to the efavirenz component of our Atripla sales, we have not yet observed any meaningful splitting of the Atripla single tablet regimen.

- *Truvada*

  In 2014 , Truvada sales increased by 7% compared to 2013 due primarily to an increase in the average net selling price and sales volume growth in the United States. In 2013, decreases in Truvada sales were due to lower sales volume, partially offset by an increase in average net selling price. Truvada sales accounted for 15% , 34% and 39% of our total antiviral product sales for 2014 , 2013 and 2012 , respectively.

- *Complera/Eviplera*

  In 2014 , sales of Complera/Eviplera were $1.2 billion an increase of 52% compared to 2013. Increases in sales of Complera/Eviplera in both 2014 and 2013 were driven primarily by sales volume growth in Europe and the United States. In 2012 , Complera/Eviplera sales increased due primarily to sales volume growth in the United States.

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- *Stribild*

  In 2014, sales of Stribild were $1.2 billion , an increase of 122% compared to 2013, due primarily to increased sales volume in the United States and Europe. In 2013 and 2012, increases in sales of Stribild were driven primarily by sales volume growth in the United States.

Other Products

Other products which include Letairis, Ranexa, AmBisome and Zydelig, our first oncology product which launched in 2014, were $1.7 billion in 2014 compared to $1.5 billion in 2013. The increase in other product sales is due primarily to increased sales volume.

Royalty, Contract and Other Revenues

The following table summarizes the period over period changes in our royalty, contract and other revenues:

(In millions, except percentages)	2014	Change	2013	Change	2012
Royalty, contract and other revenues	$ 416	5%	$ 398	31%	$ 304

Royalty, contract and other revenues includes royalty revenues from F. Hoffman-La Roche Ltd (Roche) for sales of Tamiflu. The majority of our royalties are recognized in the quarter following the quarter in which the corresponding product sales occur.

Cost of Goods Sold and Product Gross Margin

The following table summarizes the period over period changes in our product sales, cost of goods sold and product gross margin:

(In millions, except percentages)	2014	Change	2013	Change	2012
Total product sales	$ 24,474	127%	$ 10,804	15%	$ 9,398
Cost of goods sold	$ 3,788	32%	$ 2,859	16%	$ 2,471
Product gross margin	85%		74%		74%

Our product gross margin for 2014 increased compared to 2013 primarily due to changes in product mix, resulting from the launches of Sovaldi and Harvoni. Our product gross margin for 2013 was consistent with our product gross margin for 2012.

Research and Development Expenses

The following table summarizes the period over period changes in R&D expenses:

(In millions, except percentages)	2014	Change	2013	Change	2012
Research and development	$ 2,854	35%	$ 2,120	20%	$ 1,760

R&D expenses summarized above consist primarily of clinical studies performed by contract research organizations, materials and supplies, licenses and fees, milestone payments under collaboration arrangements, personnel costs, including salaries, benefits and stock-based compensation and overhead allocations consisting of various support and facilities-related costs.

We do not track total R&D expenses by product candidate, therapeutic area or development phase. However, we manage our R&D expenses by identifying the R&D activities we anticipate will be performed during a given period and then prioritizing efforts based on scientific data, probability of successful development, market potential, available human and capital resources and other considerations. We continually review our R&D pipeline and the status of development and, as necessary, reallocate resources among the R&D portfolio that we believe will best support the future growth of our business.

The following table provides a breakout of R&D expenses by major cost type:

(In millions, except percentages)	2014	2013	2012
Clinical studies and outside services	$ 1,688	$ 1,147	$ 828
Personnel and infrastructure expenses	900	714	686
Facilities, IT and other costs	266	259	246
Total	$ 2,854	$ 2,120	$ 1,760

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In 2014 , R&D expenses increased $734 million or 35% compared to 2013 , due primarily to an increase in clinical studies and outside services. The increase in clinical studies and outside services includes one-time items of $350 million for collaboration and acquisition related expenses and the purchase of a FDA priority review voucher and $191 million for expenses related to the progression of clinical study activity, primarily in the oncology and HIV areas. Personnel and infrastructure expenses increased $186 million to support our ongoing clinical study activity, geographic expansion and marketed product support.

In 2013, R&D expenses increased $360 million or 20% compared to 2012, due primarily to a $319 million increase in clinical studies and a $28 million increase in personnel and infrastructure expenses to support the continued progression of our clinical studies, particularly Phase 3 studies in oncology, liver diseases and HIV. These increases were partially offset by a $100 million decrease in stock-based compensation expense due to the acceleration of vested stock options related to our acquisition of Pharmasset, Inc. (Pharmasset) in January 2012.

In 2012, clinical studies and outside services increased $258 million compared to 2011 due to progression and expansion of our Phase 3 studies, particularly in liver diseases and oncology. Additionally, personnel expenses increased $274 million due to higher headcount to support our product pipeline and study progression.

In 2015 , we expect R&D expenses to increase over 2014 to support the expansion of our clinical studies in various therapeutic areas including liver disease, HIV and oncology.

Selling, General and Administrative Expenses

The following table summarizes the period over period changes in SG&A expenses:

(In millions, except percentages)	2014	Change	2013	Change	2012
Selling, general and administrative	$ 2,983	76%	$ 1,699	16%	$ 1,461

SG&A expenses relate to sales and marketing, finance, human resources, legal and other administrative activities. Expenses are primarily comprised of facilities and overhead costs, outside marketing, advertising and legal expenses and other general and administrative costs.

In 2014 , SG&A expenses increased $1.3 billion or 76% compared to 2013 due primarily to an increase in headcount-related and other expenses of $542 million to support the ongoing growth and expansion of our business, including commercial expansion related to the launches of Sovaldi and Harvoni and an increase in the BPD fee. During the third quarter of 2014, the Internal Revenues Service (IRS) issued final regulations which indicated that a manufacturer’s obligation to pay its portion of the BPD fee in any given calendar year is triggered by the qualifying sales in the previous year, instead of the first qualifying sale in the current calendar year. As a result of the final IRS regulations, we were required to recognize our 2014 fee of $460 million and 2013 fee of $142 million in our 2014 Consolidated Statement of Income. Our BPD fees were approximately $590 million, $110 million and $85 million in 2014, 2013 and 2012, respectively. The BPD fee is not tax deductible.

In 2013 , SG&A expenses increased $238 million or 16% compared to 2012 . The increase was due primarily to a $308 million increase in headcount-related and other expenses to support the ongoing growth of our business, legal expenses and the BPD fee. This increase was partially offset by a $98 million decrease in stock-based compensation due to the acceleration of vested stock options related to our acquisition of Pharmasset in January 2012.

In 2015 we expect SG&A expenses to increase compared to 2014 to support our continued build-out and expansion of our commercial infrastructure in Europe and Asia to support our products.

Interest Expense

In 2014 , interest expense increased to $412 million compared to $307 million in 2013 . The increase was primarily a result of the issuance of our senior unsecured notes in registered offerings in March 2014 and November 2014, offset by repayment of our senior unsecured notes due in December 2014 (the December 2014 Notes), conversion and maturity of our convertible senior notes due in May 2014 (the May 2014 Notes) and partial conversion of our convertible senior notes due in May 2016 (the May 2016 Notes). In 2013 , interest expense decreased to $307 million compared to $361 million in 2012 . The decrease was due primarily to the repayment of our convertible senior notes due in May 2013 (the May 2013 Notes), conversion of the May 2014 Notes, partial conversion of the May 2016 Notes and the repayment of revolving credit facilities.

Other Income (Expense), Net

Other income (expense), net was not significant for 2014. During 2013 as compared to 2012, the changes in other income (expense), net were due primarily to a $40 million loss on Greek bonds related to Greece's restructuring of its sovereign debt in the first quarter of 2012.

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Provision for Income Taxes

Our provision for income taxes was $2.8 billion , $1.2 billion and $1.0 billion in 2014 , 2013 and 2012 , respectively. The 2014 effective tax rate of 18.8% differed from the U.S. federal statutory rate of 35% due primarily to certain operating earnings from non-U.S. subsidiaries that are considered indefinitely reinvested and tax credits, partially offset by state taxes, our portion of the non-tax deductible BPD fee and amortization expense of the intangible asset related to sofosbuvir for which we receive no tax benefit. We do not provide for U.S. income taxes on undistributed earnings of our foreign operations that are intended to be indefinitely reinvested in our foreign subsidiaries.

The 2013 effective tax rate of 27.3% differed from the U.S. federal statutory rate of 35% due primarily to the retroactive extension of the 2012 federal research tax credit in January 2013, the 2013 federal research tax credit and certain operating earnings from non-U.S. subsidiaries that are considered indefinitely reinvested, partially offset by state taxes, our portion of the non-tax deductible BPD fee, amortization expense of the intangible asset related to sofosbuvir and contingent consideration expense related to certain acquisitions for which we receive no tax benefit.

The 2012 effective tax rate of 28.7% differed from the U.S. federal statutory rate of 35% due primarily to tax credits and certain operating earnings from non-U.S. subsidiaries that are considered indefinitely reinvested, partially offset by state taxes, the stock-based compensation expense related to the Pharmasset acquisition and contingent consideration expense related to certain acquisitions for which we receive no tax benefit.

Acquisitions

YM Biosciences Inc.

We completed the acquisition of YM BioSciences Inc. (YM), based in Canada, for total consideration transferred of $488 million on February 8, 2013, at which time YM became a wholly-owned subsidiary of Gilead. YM was a drug development company primarily focused on advancing momelotinib, an orally administered, once-daily candidate for hematologic cancers.

The fair values of acquired assets and assumed liabilities included primarily in-process research and development (IPR&D) of $363 million , goodwill of $127 million, deferred tax assets of $53 million with a full unrecognized tax benefit, deferred tax liabilities of $109 million and cash acquired of $109 million . Pro forma results of operations for the acquisition of YM have not been presented because this acquisition is not material to our consolidated results of operations. See Item 8, Note 8 Intangible Assets and Goodwill in our Consolidated Financial Statements included in this Annual Report on Form 10-K for a description of the IPR&D acquired.

Pharmasset, Inc.

In January 2012, we completed the acquisition of Pharmasset, a publicly-held clinical-stage pharmaceutical company committed to discovering, developing and commercializing novel drugs to treat viral infections. Pharmasset's primary focus was the development of oral therapeutics for the treatment of HCV infection. Pharmasset's lead compound, sofosbuvir (formerly referred to as GS-7977), is a nucleotide analog which, in December 2013, was approved by the FDA under the name Sovaldi, as a once-daily oral regimen for the treatment of HCV in patients with genotypes 1, 2, 3 or 4 infection, including those with hepatocellular carcinoma meeting Milan criteria (awaiting liver transplantation) and those with HCV/HIV-1 co-infection. In October 2014, Harvoni, which combines the NS5A inhibitor ledipasvir with sofosbuvir, received approval from the FDA for the treatment of chronic HCV genotype 1 infection in adults. The acquisition of Pharmasset has allowed us to advance our effort to develop all-oral regimens for the treatment of HCV.

We acquired all of the outstanding shares of common stock of Pharmasset for $137 per share in cash through a tender offer and subsequent merger under the terms of an agreement and plan of merger entered into in November 2011. The aggregate cash payment to acquire all of the outstanding shares of common stock was $11.1 billion . We financed the transaction with approximately $5.2 billion in cash on hand, $3.7 billion in senior unsecured notes issued in December 2011 and $2.2 billion in bank debt issued in January 2012.

The Pharmasset acquisition was accounted for as a business combination. The results of operations of Pharmasset have been included in our Consolidated Statements of Income since January 13, 2012 , the date on which we acquired approximately 88% of the outstanding shares of common stock of Pharmasset and cash consideration was transferred, and as a result, we obtained effective control of Pharmasset. The acquisition was completed on January 17, 2012, at which time Pharmasset became a wholly-owned subsidiary of Gilead and was integrated into our operations. As we do not track earnings results by product candidate or therapeutic area, we do not maintain separate earnings results for the acquired Pharmasset business.

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The following table summarizes the components of the cash paid to acquire Pharmasset (in millions):

Total consideration transferred	$	10,858
Stock-based compensation expense		194
Total cash paid	$	11,052

The $11.1 billion cash payment consisted of a $10.4 billion cash payment to the outstanding common stockholders as well as a $668 million cash payment to option holders under the Pharmasset stock option plans. The $10.4 billion cash payment to the outstanding common stockholders and $474 million of the cash payment to vested option holders under the Pharmasset stock option plans were accounted for as consideration transferred. The remaining $194 million of cash payment was accounted for as stock-based compensation expense resulting from the accelerated vesting of Pharmasset employee options immediately prior to the acquisition.

The following table summarizes the acquisition date fair values of assets acquired and liabilities assumed, and the consideration transferred (in millions):

Identifiable intangible assets	$	10,738
Cash and cash equivalents		107
Other assets acquired (liabilities assumed), net		(43)
Total identifiable net assets		10,802
Goodwill		56
Total consideration transferred	$	10,858

Refer to Item 8, Note 5 Acquisitions in our Consolidated Financial Statements included in this Annual Report on Form 10-K for more detailed information.

Liquidity and Capital Resources

We believe that our existing capital resources, supplemented by our cash flows generated from operating activities will be adequate to satisfy our capital needs for the foreseeable future. Our cash, cash equivalents and marketable securities and working capital increased significantly in 2014 compared to 2013 as we issued a total of $8.0 billion in senior unsecured notes in registered offerings in March 2014 and November 2014. The following table summarizes our cash, cash equivalents and marketable securities, our working capital and our cash flow activities as of the end of, and for each of, the periods presented:

(in millions)	2014	2013	2012
As of December 31:			
Cash, cash equivalents and marketable securities	$ 11,726	$ 2,571	$ 2,582
Working capital [1]	$ 11,953	$ 590	$ 1,918
Year Ended December 31:			
Cash provided by (used in):			
Operating activities	$ 12,818	$ 3,105	$ 3,195
Investing activities	$ (1,823)	$ (254)	$ (11,846)
Financing activities	$ (3,025)	$ (2,544)	$ 563

[1] Certain prior period amounts have been reclassified to conform to the current presentation.

Cash, Cash Equivalents and Marketable Securities

Cash, cash equivalents and marketable securities totaled $11.7 billion at December 31, 2014 , an increase of $9.2 billion or 356% when compared to $2.6 billion at December 31, 2013 . During 2014 , we generated $12.8 billion in cash flows from operations; received $7.9 billion from the issuance of senior unsecured notes in registered offerings in March 2014 and November 2014; repaid $2.3 billion in debt, net of convertible note hedges; repurchased $5.3 billion of common stock; and paid approximately $4.1 billion to settle the warrants expiring in 2014 (the 2014 Warrants) related to our May 2014 Notes, which were retired in May 2014.

Cash, cash equivalents and marketable securities remained relatively flat at $2.6 billion at December 31, 2013 , when compared to $2.6 billion at December 31, 2012. During 2013, we generated $3.1 billion in operating cash flows, paid $1.0 billion for warrants related to our May 2013 Notes that were settled in August 2013, repaid $1.7 billion in debt net of proceeds from convertible note hedges and utilized $379 million for the acquisition of YM, net of cash acquired.

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Of the total cash, cash equivalents and marketable securities at December 31, 2014 , approximately $3.2 billion was generated from operations in foreign jurisdictions and is intended for use in our foreign operations. We do not rely on unrepatriated earnings as a source of funds for our domestic business as we expect to have sufficient cash flow and borrowing capacity in the United States to fund our domestic operational and strategic needs.

Working Capital

Working capital was $12.0 billion at December 31, 2014 . The increase of $11.4 billion from working capital as of December 31, 2013 was driven primarily by positive cash flows from operations and an increase in cash and cash equivalents due to the issuance of senior unsecured notes in March 2014 and November 2014, partially offset by cash paid to settle convertible senior notes and the 2014 Warrants, repayment of our bank debt, and repurchases of common stock.

Working capital was $590 million at December 31, 2013 . The decrease of $1.3 billion from working capital as of December 31, 2012 was due to an increase in the current portion of long-term debt and other accrued liabilities, partially offset by increases in accounts receivable, inventories and cash and cash equivalents.

Cash Provided by Operating Activities

Cash provided by operating activities was $12.8 billion in 2014 , consisting primarily of net income of $12.1 billion , adjusted for non-cash items such as $1.1 billion of depreciation and amortization expenses, $360 million for stock-based compensation expense and $518 million of net cash outflow related to changes in operating assets and liabilities.

Cash provided by operating activities was $3.1 billion in 2013 , consisting primarily of net income of $3.1 billion , adjusted for non-cash items such as $345 million of depreciation and amortization expenses and $252 million of stock-based compensation expenses. This was partially offset by $562 million of net cash outflow related to changes in operating assets and liabilities.

Cash provided by operating activities was $3.2 billion in 2012 , consisting primarily of net income of $2.6 billion , adjusted for non-cash items such as $278 million of depreciation and amortization expenses, $209 million of stock-based compensation expenses, $108 million of net cash inflow related to changes in operating assets and liabilities.

Cash Used in Investing Activities

Cash used in investing activities in 2014 was $1.8 billion , consisting primarily of $1.2 billion in net purchases of marketable securities and $557 million in capital expenditures related to the expansion of our business.

Cash used in investing activities in 2013 was $254 million , consisting primarily of $379 million used in our acquisition of YM, net of cash acquired and $190 million of capital expenditures primarily related to construction in progress associated with new facilities at our headquarters to support the ongoing growth of our business. This was partially offset by $315 million of net proceeds from sales of marketable securities.

Cash used in investing activities in 2012 was $11.8 billion , consisting primarily of $10.8 billion used for our acquisition of Pharmasset, net of the stock-based compensation expense and cash acquired, $672 million of net purchases of marketable securities and $397 million of capital expenditures, related primarily to the purchase of an office building for $180 million and a $156 million increase in construction in progress associated with new facilities at our headquarters to support the ongoing growth of our business.

Cash Provided by (Used in) Financing Activities

Cash used in financing activities in 2014 was $3.0 billion , consisting primarily of $2.3 billion used to repay debt, net of convertible notes hedges, $5.3 billion used to repurchase common stock under our stock repurchase programs and $4.1 billion to settle the warrants related to our May 2014 Notes. These payments were primarily offset by $7.9 billion in net proceeds from the issuances of our senior unsecured notes due in April 2019 (the April 2019 Notes), senior unsecured notes due in April 2024 (the April 2024 Notes) and senior unsecured notes due in April 2044 (the April 2044 Notes, and together with the April 2019 Notes and the April 2024 Notes, the April Notes) in a registered offering for a total aggregate principal amount of $4.0 billion and from the issuances of our senior unsecured notes due in February 2020 (the February 2020 Notes), senior unsecured notes due in February 2025 (the February 2025 Notes) and senior unsecured notes due in February 2045 (February 2045 Notes, and together with the February 2020 Notes and the February 2025 Notes, the February Notes) in a registered offering for an aggregate principal amount of $4.0 billion .

Cash used in financing activities in 2013 was $2.5 billion , consisting primarily of $4.4 billion used to repay debt financing which includes the maturity of our May 2013 Notes and conversions of our May 2014 Notes and May 2016 Notes,

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$1.0 billion to settle the warrants related to our May 2013 Notes that settled in August 2013 and $582 million used to repurchase common stock under our stock repurchase program. This cash outflow was partially offset by proceeds of $2.8 billion related to our convertible note hedges.

Cash provided by financing activities in 2012 was $563 million , driven primarily by net proceeds of $2.1 billion from the issuance of bank debt in conjunction with the Pharmasset acquisition, proceeds of $466 million from issuances of common stock under our employee stock plans and $214 million from proceeds received related to our convertible note hedges. The cash proceeds were partially offset by the $1.8 billion used to repay debt financing during the year and $667 million used to repurchase common stock under our stock repurchase programs.

Debt and Credit Facility

Debt Financing

In March 2014, we issued senior unsecured notes in a registered offering for a total aggregate principal amount of $4.0 billion. We issued the April 2019 Notes for $500 million which pay interest at a fixed annual rate of 2.05% , the April 2024 Notes for $1.8 billion which pay interest at a fixed annual rate of 3.70% and the April 2044 Notes for $1.8 billion which pay interest at a fixed annual rate of 4.80%.

In November 2014, we issued senior unsecured notes in a registered offering for a total aggregate principal amount of $4.0 billion . We issued the February 2020 Notes for $500 million which pay interest at a fixed annual rate of 2.35% , the February 2025 Notes for $1.8 billion which pay interest at a fixed annual rate of 3.50% and the February 2045 Notes for $1.8 billion which pay interest at a fixed annual rate of 4.50% .

Bank Debt

In January 2012, in conjunction with the acquisition of Pharmasset, we entered into a five-year $1.3 billion revolving credit facility credit agreement (the Five-Year Revolving Credit Agreement). In 2012, we borrowed $750 million under the Five-Year Revolving Credit Agreement upon the close of the acquisition. The Five-Year Revolving Credit Agreement contains customary representations, warranties, affirmative, negative and financial maintenance covenants and events of default. The loan bears interest at either (i) the Eurodollar Rate plus the Applicable Margin or (ii) the Base Rate plus the Applicable Margin, each as defined in the credit agreement. We may reduce the commitments and may prepay the loan in whole or in part at any time without premium or penalty. We are required to comply with certain covenants under the credit agreement and note indentures and as of December 31, 2014 , we were not in violation of any covenants.

In 2013, we repaid $150 million under the Five-Year Revolving Credit Agreement. During 2014, we repaid the remaining balance of $600 million that was outstanding under the Five-Year Revolving Credit Agreement. The Five-Year Revolving Credit Agreement will terminate and all amounts owed under the agreement shall be due and payable in January 2017.

Convertible Senior Notes

During 2014, our May 2014 Notes matured and a portion of our May 2016 Notes (together, the May Notes) was converted. During 2014, we repaid $912 million of principal balance relating to the May Notes. We also paid $2.5 billion in cash related to the conversion spread of the May Notes, which represents the conversion value in excess of the principal amount, and received $2.5 billion in cash from the convertible note hedges related to the May Notes.

During the year ended December 31, 2014 , we exercised our option to settle in cash the 2014 Warrants. As a result, we paid $4.1 billion to settle the warrants as the market value of our common stock at the time of the exercise of the warrants exceeds their strike price. There were 56 million shares of our common stock underlying the 2014 Warrants, which had a strike price of $28.38 per share and expired during the 40 trading-day period commencing August 1, 2014 and ending on September 26, 2014. Because the warrants could have been settled, at our option, in cash or shares of our common stock, and the related contracts met all of the applicable criteria for equity classification, the settlement was recorded as a reduction of additional paid-in capital in our Consolidated Balance Sheets.

As of December 31, 2014, the May 2016 Notes were classified as current given that their conversion criteria had been met. As a result, the related unamortized discount of $15 million was classified as equity component of currently redeemable convertible notes on our Consolidated Balance Sheets.

There are 55 million shares of our common stock underlying our warrants expiring in 2016 (the 2016 Warrants). The 2016 Warrants have a strike price of $30.05 per share and are exercisable only on their expiration date. If the market value of our common stock at the time of the exercise of the warrants exceeds their strike price, we will be required to net settle in cash or shares of our common stock, at our option, for the value of the warrants in excess of the warrant strike price.

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Stock Repurchase Programs

Under our stock repurchase program authorized in January 2011 (2011 Program), we repurchased a total of $3.3 billion or 40 million shares of common stock during 2014. In May 2014, our Board of Directors authorized a new $5.0 billion stock repurchase program (2014 Program) through open market and private block transactions pursuant to Rule 10b5-1 plans, privately negotiated transactions or other means. This new program expires three years after the completion of the 2011 Program. We began repurchases under the 2014 Program in October 2014 and repurchased a total of $2.0 billion or 19 million shares. We intend to use the additional authorization to repurchase shares opportunistically and to offset the dilution created by shares issued under employee stock plans. On February 3, 2015, we announced that our Board of Directors authorized a new $15 billion five-year share repurchase program, which we will initiate in 2015 on the completion of our 2014 Program.

Long-Term Obligations

The summary of our borrowings under various financing arrangements is included in Item 8, Note 10 Debt and Credit Facility in our Consolidated Financial Statements included in this Annual Report on Form 10-K.

We believe our existing capital resources, supplemented by cash flows generated from our operations, will be adequate to satisfy our capital needs for the foreseeable future. Our future capital requirements will depend on many factors, including but not limited to the following:

- the commercial performance of our current and future products;
- the progress and scope of our R&D efforts, including preclinical studies and clinical trials;
- the cost, timing and outcome of regulatory reviews;
- the expansion of our sales and marketing capabilities;
- administrative expenses;
- the possibility of acquiring additional manufacturing capabilities or office facilities;
- the possibility of acquiring other companies or new products;
- costs associated with the settlement and conversion of our convertible senior notes and related warrants;
- the establishment of additional collaborative relationships with other companies; and
- costs associated with the defense, settlement and adverse results of litigation and government investigations.

We may in the future require additional funding, which could be in the form of proceeds from equity or debt financings. If such funding is required, we cannot guarantee that it will be available to us on favorable terms, if at all.

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Critical Accounting Policies, Estimates and Judgments

The discussion and analysis of our financial condition and results of operations is based on our Consolidated Financial Statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosures. On an ongoing basis, we evaluate our estimates, including those related to revenue recognition, allowance for doubtful accounts, valuation of intangible assets and contingent consideration liabilities resulting from business combinations and our tax provision. We base our estimates on historical experience and on various other market specific and other relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ significantly from these estimates.

We believe the following critical accounting policies reflect the more significant judgments and estimates used in the preparation of our Consolidated Financial Statements.

Revenue Recognition

Product Sales

We recognize revenues from product sales when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed or determinable and collectability is reasonably assured. We record product sales net of estimated mandatory and supplemental discounts to government payers, in addition to discounts to private payers, and other related charges. These are generally referred to as gross-to-net deductions and are recorded in the same period the related sales occur. Government and other rebates and chargebacks represent the majority of our gross-to-net deductions and require complex and significant judgment by management. Estimates are assessed each period and updated to reflect current information.

Government and Other Rebates and Chargebacks

Government and other rebates and chargebacks include amounts paid to payers and healthcare providers in the United States, including Medicaid rebates, ADAPs, Veterans Administration and Public Health Service discounts, and other rebates, as well as foreign government rebates. Rebates and chargebacks are based on contractual arrangements or statutory requirements which may vary by product, by payer and individual payer plans.

For qualified programs that can purchase our products through wholesalers or other distributors at a lower contractual price, the wholesalers or distributors charge back to us the difference between their acquisition cost and the lower contractual price. Our consolidated allowances for government and other chargebacks that are payable to our direct customers are classified as reductions of accounts receivable, and totaled $220 million as of December 31, 2014 and $149 million as of December 31, 2013.

Our consolidated allowance for government and other rebates that will be paid to parties other than our direct customers are recorded in accrued government and other rebates on our Consolidated Balance Sheets, and totaled $2.3 billion as of December 31, 2014 and $1.0 billion as of December 31, 2013.

Our allowances for government and other rebates and chargebacks are estimated based on products sold, historical utilization rates, pertinent third party industry information, estimated patient population, known market events or trends, channel inventory and/or other market data. We also take into consideration new information regarding changes in programs' regulations and guidelines that would impact the amount of the actual rebates and/or our expectations regarding future utilization rates for these programs. We believe that the methodology that we use to estimate our government and other rebates and chargebacks is reasonable and appropriate given the current facts and circumstances. However, actual results may differ significantly from our estimates. During the last three years, our actual government rebates and chargebacks claimed for prior periods have varied by less than 5% from our estimates.

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The following table summarizes the consolidated activity in our government and other rebates and chargebacks accounts (in millions):

Accrued government and other rebates and chargebacks:	Balance at Beginning of Year	Decrease/(Increase) to Product Sales	Payments	Balance at End of Year
Year ended December 31, 2014:				
Activity related to 2014 sales	$ —	$ 6,113	$ (3,650)	$ 2,463
Activity related to sales prior to 2014	1,167	(109)	(985)	73
Total	$ 1,167	$ 6,004	$ (4,635)	$ 2,536
Year ended December 31, 2013:				
Activity related to 2013 sales	$ —	$ 3,430	$ (2,357)	$ 1,073
Activity related to sales prior to 2013	886	(121)	(671)	94
Total	$ 886	$ 3,309	$ (3,028)	$ 1,167

Allowance for Doubtful Accounts

We maintain an allowance for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. This allowance is based on our analysis of several factors, including, but not limited to, contractual payment terms, historical payment patterns of our customers and individual customer circumstances, an analysis of days sales outstanding by geographic region and a review of the local economic environment and its potential impact on government funding and reimbursement practices. If the financial condition of our customers or the economic environment in which they operate were to deteriorate, resulting in an inability to make payments, additional allowances may be required. We believe that the allowance for doubtful accounts is adequate; however, significant deterioration in any of the above factors could materially change these expectations and may result in an increase to our allowance for doubtful accounts. As of December 31, 2014 and 2013 , our allowance for doubtful accounts was $31 million and $59 million, respectively.

Valuation of Intangible Assets

In conjunction with our business combinations, we have recorded intangible assets primarily related to IPR&D projects. We had total intangible assets of $11.1 billion as of December 31, 2014 and $11.9 billion as of December 31, 2013.

The identifiable intangible assets are measured at their respective fair values as of the acquisition date. The models used in valuing these intangible assets require the use of significant estimates and assumptions including but not limited to:

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

We believe the fair values used to record intangible assets acquired in connection with a business combination are based upon reasonable estimates and assumptions given the facts and circumstances as of the related valuation dates.

Intangible assets related to IPR&D projects are considered to be indefinite-lived until the completion or abandonment of the associated R&D efforts. If and when development is complete, which generally occurs if and when regulatory approval to market a product is obtained, the associated assets would be deemed finite-lived and would then be amortized based on their respective estimated useful lives at that point in time. During the period the assets are considered indefinite-lived, they will not be amortized but will be tested for impairment on an annual basis as well as between annual tests if we become aware of any events or changes that would indicate that it is more likely than not that the fair value of the IPR&D projects below their respective carrying amounts. The fair value of our indefinite-lived intangible assets is dependent on assumptions such as the expected timing or probability of achieving the specified milestones, changes in projected revenues or changes in discount rates. Significant judgment is employed in determining these assumptions and changes to our assumptions could have a significant impact on our results of operations in any given period.

Intangible assets with finite useful lives are amortized over their estimated useful lives primarily on a straight-line basis. Intangible assets with finite useful lives are reviewed for impairment when facts or circumstances suggest that the carrying value of these assets may not be recoverable.

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Valuation of Contingent Consideration Liabilities Resulting from Business Combinations

In conjunction with our business combinations and consolidation of a variable interest entity for which we are the primary beneficiary, we have recorded contingent consideration liabilities payable upon the achievement of specified development, regulatory approval, sales-based milestone events or financial results. The contingent consideration liabilities are measured at their respective fair values as of the acquisition or initial consolidation date. The models used in valuing these contingent consideration liabilities require the use of significant estimates and assumptions including but not limited to:

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

W e revalue contingent consideration obligations each reporting period and record changes in their fair value in R&D expense within our Consolidated Statement of Income.

Changes in the fair value of our contingent consideration liabilities can result from updates to one or multiple assumptions such as the expected timing or probability of achieving the specified milestones, changes in projected revenues or changes in discount rates. Significant judgment is employed in determining these assumptions as of the acquisition date and for each subsequent reporting period. Updates to assumptions could have a significant impact on our results of operations in any given period. Actual results may differ from estimates.

We had total contingent consideration liabilities of $133 million as of December 31, 2014 and $264 million as of December 31, 2013.

Tax Provision

We estimate our income tax provision, including deferred tax assets and liabilities, based on significant management judgment. We evaluate the realization of all or a portion of our deferred tax assets on a quarterly basis. We record a valuation allowance to reduce our deferred tax assets to the amounts that are more likely than not to be realized. We consider future taxable income, ongoing tax planning strategies and our historical financial performance in assessing the need for a valuation allowance.

If we expect to realize deferred tax assets for which we have previously recorded a valuation allowance, we will reduce the valuation allowance in the period in which such determination is first made.

We are subject to income taxes in both the United States and various foreign jurisdictions including Ireland. Due to economic and political conditions, various countries are actively considering changes to existing tax laws. We cannot predict the form or timing of potential legislative changes that could have a material adverse impact on our results of operations. In addition, significant judgment is required in determining our worldwide provision for income taxes.

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

At December 31, 2014 and 2013 , we had total federal, state and foreign unrecognized tax benefits of $661 million and $237 million , respectively. Of the total unrecognized tax benefits, $602 million and $195 million at December 31, 2014 and 2013 , respectively, if recognized, would reduce our effective tax rate in the period of recognition. As of December 31, 2014 , we believe that it is reasonably possible that our unrecognized tax benefits will decrease by approximately $12 million in the next 12 months as we expect to have clarification from the IRS and other tax authorities regarding our uncertain tax positions. With respect to the remaining unrecognized tax benefits, we are currently unable to make a reasonable estimate as to the period of cash settlement, if any, with the respective tax authorities.

We file federal, state and foreign income tax returns in many jurisdictions in the United States and abroad. For federal income tax purposes, the statute of limitations is open for 2010 and onwards. For certain acquired entities, the statute of

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limitations is open for all years from inception due to our utilization of their net operating losses and credits carried over from prior years. For California income tax purposes, the statute of limitations is open for 2008 and onwards.

Our income tax returns are audited by federal, state and foreign tax authorities. We are currently under examination by the IRS for the 2010, 2011 and 2012 tax years and by various state and foreign jurisdictions. There are differing interpretations of tax laws and regulations, and as a result, significant disputes may arise with these tax authorities involving issues of the timing and amount of deductions and allocations of income among various tax jurisdictions. We periodically evaluate our exposures associated with our tax filing positions.

Branded Prescription Drug Fee

We, along with other pharmaceutical manufacturers of branded drug products, are required to pay a portion of the BPD fee, which is calculated based on select government sales during each calendar year as a percentage of total industry government sales. The fee is determined by estimating our total sales to government agencies along with an assumption of the total pharmaceutical industry sales to government agencies. Our estimates are based on past history along with expectations of future branded drug sales activity by us along with other pharmaceutical companies. Judgment is employed in determining these assumptions. Updates to assumptions could have an impact on our results of operations. Adjustments to our estimates in the past have not been material.

In 2014, the IRS issued final regulations related to the BPD fee which indicate that an entity's obligation to pay its portion of the BPD fee in any given calendar year is triggered by the qualifying sales in the previous year, instead of the first qualifying sale in the current calendar year. As a result of the final IRS regulations, we were required to recognize our 2014 fee of $460 million and 2013 fee of $142 million in our 2014 Consolidated Statement of Income. Our BPD fees were approximately $590 million, $110 million and $85 million in 2014, 2013 and 2012, respectively. The IRS is expected to communicate the final BPD fee amounts due for 2013 sales during the third quarter of 2015 and for 2014 sales during the third quarter of 2016. Our BPD fee accrual totaled $500 million as of December 31, 2014 and $38 million as of December 31, 2013.

Off Balance Sheet Arrangements

We do not have any off balance sheet arrangements as defined in Item 303(a)(4)(ii) of Regulation S-K.

Contractual Obligations

Our contractual obligations consist of debt obligations, operating leases, capital commitments, purchase obligations for active pharmaceutical ingredients and inventory-related items and clinical trials contracts. The following table summarizes our significant enforceable and legally binding obligations, future commitments and obligations related to all contracts that we are likely to continue regardless of the fact that certain of these obligations may be cancelable as of December 31, 2014 (in millions):

	Payments due by Period				
Contractual Obligations	**Total**	**Less than one year**	**1-3 years**	**3-5 years**	**More than 5 years**
Debt [1]	$ 20,912	$ 453	$ 2,159	$ 1,429	$ 16,871
Operating lease obligations	302	58	102	69	73
Capital commitments [2]	399	323	76	—	—
Purchase obligations [3][4]	2,809	2,252	296	261	—
Clinical trials [5]	1,207	581	453	118	55
Total	$ 25,629	$ 3,667	$ 3,086	$ 1,877	$ 16,999

[1] Our debt obligations include convertible senior notes and senior unsecured notes. Interest payments are incurred and calculated based on terms of the related notes. For further information, see Item 8, Note 10 Debt and Credit Facility in our Consolidated Financial Statements included in this Annual Report on Form 10-K.

[2] At December 31, 2014 , we had firm capital project commitments of approximately $399 million primarily relating to construction of new buildings.

[3] At December 31, 2014 , we had firm purchase commitments related to active pharmaceutical ingredients and certain inventory-related items. These amounts include minimum purchase requirements.

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(4) In addition to the above, we have committed to make potential future milestone payments to third parties as part of licensing, collaboration and development arrangements. Payments under these agreements generally become due and payable only upon achievement of certain developmental, regulatory and/or commercial milestones. Because the achievement of these milestones is neither probable nor reasonably estimable, such contingencies have not been recorded on our Consolidated Balance Sheets and have not been included in the table above.

(5) At December 31, 2014 , we had several clinical studies in various clinical trial phases. Our most significant clinical trial expenditures are to contract research organizations (CROs). Although all of our material contracts with CROs are cancelable, we historically have not canceled such contracts. These amounts reflect commitments based on existing contracts and do not reflect any future modifications to, or terminations of, existing contracts or anticipated or potential new contracts.

We had total gross unrecognized tax benefit liabilities including interest and penalties of $685 million as of December 31, 2014 . We believe that it is reasonably possible that our unrecognized tax benefits will decrease by approximately $12 million in the next 12 months as we expect to have clarification from the IRS and other tax authorities regarding our uncertain tax positions. With respect to the remaining unrecognized tax benefits, we are currently unable to make a reasonable estimate as to the period of cash settlement, if any, with the respective tax authorities. The unrecognized tax benefits were included in current and long-term income taxes payable and long-term deferred tax assets on our Consolidated Balance Sheets and have not been included in the table above.

Recent Accounting Pronouncements

The information required by this item is included in Item 8, Note 1 Organization and Summary of Significant Accounting Policies in our Consolidated Financial Statements included in this Annual Report on Form 10-K.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risks that may result from changes in foreign currency exchange rates, interest rates and credit risks. To reduce certain of these risks, we enter into various types of foreign currency or interest rate derivative hedging transactions, follow investment guidelines and monitor outstanding receivables as part of our risk management program.

Foreign Currency Exchange Risk

Our operations include manufacturing and sales activities in the United States, Canada and Ireland as well as sales activities in countries outside the United States, including Europe and Asia Pacific. As a result, our financial results could be significantly affected by factors such as changes in foreign currency exchange rates or weak economic conditions in the foreign markets in which we distribute our products. Our operating results are exposed to changes in foreign currency exchange rates between the U.S. dollar and various foreign currencies, the most significant of which is the Euro. When the U.S. dollar strengthens against these currencies, the relative value of sales made in the respective foreign currency decreases. Conversely, when the U.S. dollar weakens against these currencies, the relative amounts of such sales increase. Overall, we are a net receiver of foreign currencies and, therefore, benefit from a weaker U.S. dollar and are adversely affected by a stronger U.S. dollar relative to those foreign currencies in which we transact significant amounts of business.

Approximately 26% of our product sales were denominated in foreign currencies during 2014 . To partially mitigate the impact of changes in currency exchange rates on net cash flows from our foreign currency denominated sales, we may enter into foreign currency exchange forward and option contracts. We also hedge certain monetary assets and liabilities denominated in foreign currencies, which reduces but does not eliminate our exposure to currency fluctuations between the date a transaction is recorded and the date that cash is collected or paid. In general, the market risks of these contracts are offset by corresponding gains and losses on the transactions being hedged.

As of December 31, 2014 and 2013 , we had open foreign currency forward contracts with notional amounts of $6.4 billion and $4.3 billion , respectively. A hypothetical 10% adverse movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates at December 31, 2014 would have resulted in a reduction in fair value of these contracts of approximately $600 million on this date and, if realized, would negatively affect earnings over the remaining life of the contracts. The same hypothetical movement in foreign currency exchange rates compared with the U.S. dollar relative to exchange rates at December 31, 2013 , would have resulted in a reduction in fair value of these contracts of approximately $435 million on this date and, if realized, would negatively affect earnings over the remaining life of the contracts. The analysis does not consider the impact that hypothetical changes in foreign currency exchange rates would have on anticipated transactions that these foreign currency sensitive instruments were designed to offset.

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Interest Rate Risk

Our portfolio of available-for-sale marketable securities and our fixed and variable rate liabilities create an exposure to interest rate risk. With respect to our investment portfolio, we adhere to an investment policy that requires us to limit amounts invested in securities based on credit rating, maturity, industry group and investment type and issuer, except for securities issued by the U.S. government. The goals of our investment policy, in order of priority, are as follows:

- safety and preservation of principal and diversification of risk;
- liquidity of investments sufficient to meet cash flow requirements; and
- competitive after-tax rate of return.

The following table summarizes the expected maturities and average interest rates of our interest-generating assets and fixed interest-bearing liabilities at December 31, 2014 (in millions, except percentages):

	Expected Maturity							
	2015	2016	2017	2018	2019	Thereafter	Total	Total Fair Value at December 31, 2014
Assets								
Available-for-sale debt securities	$ 101	$ 606	$ 831	$ 108	$ 35	$ 18	$ 1,699	$ 1,699
Average interest rate	0.45%	0.71%	1.26%	0.97%	1.13%	1.66%		
Liabilities								
Debt (1)	$ —	$ 1,199	$ —	$ —	$ 500	$ 10,750	$ 12,449	$ 15,000
Average interest rate	—%	2.46%	—%	—%	2.05%	4.25%		

(1) In December 2011, we issued senior unsecured notes due in December 2016, 2021 and 2041 in a registered offering. The notes pay interest at fixed annual rates ranging from 3.05% to 5.65%. In March 2011, we issued senior unsecured notes due in April 2021 in a registered offering. The notes pay interest at a fixed annual rate of 4.50%.

In March and November 2014, we issued the April Notes and the February Notes, respectively, with interest rates ranging from 2.05% to 4.80%.

In July 2010, we issued the May 2016 Notes in a private placement pursuant to Rule 144A of the Securities Act of 1933, as amended. The May 2016 Notes were issued at par and bear an interest rate of 1.625%, and may be converted into shares of our common stock subject to certain circumstances.

In 2012, in connection with our acquisition of Pharmasset, we entered into credit agreements that are subject to variable interest rates. During 2014 , the portion of interest expense related to variable interest totaled $3 million .

Credit Risk

We are subject to credit risk from our portfolio of cash equivalents and marketable securities. Under our investment policy, we limit amounts invested in such securities by credit rating, maturity, industry group, investment type and issuer, except for securities issued by the U.S. government. We are not exposed to any significant concentrations of credit risk from these financial instruments. The goals of our investment policy, in order of priority, are as follows: safety and preservation of principal and diversification of risk; liquidity of investments sufficient to meet cash flow requirements; and a competitive after-tax rate of return.

We are also subject to credit risk from our accounts receivable related to our product sales. The majority of our trade accounts receivable arises from product sales in the United States and Europe.

As of December 31, 2014 , our accounts receivable in Southern Europe, specifically Greece, Italy, Portugal and Spain, totaled approximately $504 million , of which $157 million were greater than 120 days past due and $44 million were greater than 365 days past due. As of December 31, 2013 , our accounts receivable in Southern Europe, specifically Greece, Italy, Portugal and Spain, totaled approximately $846 million , of which $402 million were greater than 120 days past due and $176 million were greater than 365 days past due. To date, we have not experienced significant losses with respect to the collection of our accounts receivable. We believe that our allowance for doubtful accounts was adequate at December 31, 2014 .

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

GILEAD SCIENCES, INC.
CONSOLIDATED FINANCIAL STATEMENTS
Years ended December 31, 2014 , 2013 and 2012

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of Gilead Sciences, Inc.

We have audited the accompanying consolidated balance sheets of Gilead Sciences, Inc. as of December 31, 2014 and 2013 , and the related consolidated statements of income, comprehensive income, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2014 . Our audits also included the financial statement schedule listed in the Index at Item 15(a). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Gilead Sciences, Inc. at December 31, 2014 and 2013 , and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2014 , in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Gilead Sciences, Inc.'s internal control over financial reporting as of December 31, 2014 , based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated February 25, 2015 expressed an unqualified opinion thereon.

/s/ E RNST & Y OUNG LLP

Redwood City, California
February 25, 2015

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GILEAD SCIENCES, INC.

Consolidated Balance Sheets
(in millions, except per share amounts)

	December 31,	
	2014	2013
Assets		
Current assets:		
Cash and cash equivalents	$ 10,027	$ 2,113
Short-term marketable securities	101	19
Accounts receivable, net of allowances of $356 at December 31, 2014 and $252 at December 31, 2013	4,635	2,182
Inventories	1,386	1,697
Deferred tax assets	508	331
Prepaid taxes	391	398
Prepaid expenses	194	166
Other current assets	472	91
Total current assets	17,714	6,997
Property, plant and equipment, net	1,674	1,166
Long-term portion of prepaid royalties	466	199
Long-term deferred tax assets	236	190
Long-term marketable securities	1,598	439
Intangible assets, net	11,073	11,900
Goodwill	1,172	1,169
Other long-term assets	731	519
Total assets	$ 34,664	$ 22,579
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 955	$ 1,256
Accrued government and other rebates	2,316	1,018
Accrued compensation and employee benefits	316	243
Income taxes payable	105	11
Other accrued liabilities	1,452	1,071
Deferred revenues	134	111
Current portion of long-term debt and other obligations, net	483	2,697
Total current liabilities	5,761	6,407
Long-term debt, net	11,921	3,939
Long-term income taxes payable	562	162
Long-term deferred tax liabilities	51	83
Other long-term obligations	535	179
Commitments and contingencies (Note 11)		
Equity component of currently redeemable convertible notes	15	64
Stockholders' equity:		
Preferred stock, par value $0.001 per share; 5 shares authorized; none outstanding	—	—
Common stock, par value $0.001 per share; shares authorized of 5,600 at December 31, 2014 and December 31, 2013; shares issued and outstanding of 1,499 at December 31, 2014 and 1,534 at December 31, 2013	2	2
Additional paid-in capital	2,391	5,386
Accumulated other comprehensive income (loss)	301	(124)
Retained earnings	12,732	6,106
Total Gilead stockholders' equity	15,426	11,370
Noncontrolling interest	393	375
Total stockholders' equity	15,819	11,745
Total liabilities and stockholders' equity	$ 34,664	$ 22,579

See accompanying notes.

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GILEAD SCIENCES, INC.

Consolidated Statements of Income
(in millions, except per share amounts)

	Year Ended December 31,		
	2014	2013	2012
Revenues:			
Product sales	$ 24,474	$ 10,804	$ 9,398
Royalty, contract and other revenues	416	398	304
Total revenues	24,890	11,202	9,702
Costs and expenses:			
Cost of goods sold	3,788	2,859	2,471
Research and development expenses	2,854	2,120	1,760
Selling, general and administrative expenses	2,983	1,699	1,461
Total costs and expenses	9,625	6,678	5,692
Income from operations	15,265	4,524	4,010
Interest expense	(412)	(307)	(361)
Other income (expense), net	3	(9)	(37)
Income before provision for income taxes	14,856	4,208	3,612
Provision for income taxes	2,797	1,151	1,038
Net income	12,059	3,057	2,574
Net loss attributable to noncontrolling interest	42	18	18
Net income attributable to Gilead	$ 12,101	$ 3,075	$ 2,592
Net income per share attributable to Gilead common stockholders—basic	$ 7.95	$ 2.01	$ 1.71
Shares used in per share calculation—basic	1,522	1,529	1,515
Net income per share attributable to Gilead common stockholders—diluted	$ 7.35	$ 1.81	$ 1.64
Shares used in per share calculation—diluted	1,647	1,695	1,583

See accompanying notes.

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GILEAD SCIENCES, INC.
Consolidated Statements of Comprehensive Income
(in millions)

	Year Ended December 31,		
	2014	2013	2012
Net income	$ 12,059	$ 3,057	$ 2,574
Other comprehensive income (loss):			
Net foreign currency translation gain (loss), net of tax	(9)	(44)	11
Available-for-sale securities:			
Net unrealized gain, net of tax impact of $0, $4, $(1)	1	5	1
Reclassifications to net income, net of tax impact of $0, $0, and $1	(1)	—	33
Net change	—	5	34
Cash flow hedges:			
Net unrealized gain (loss), net of tax impact of $16, $4 and $2	430	(60)	(62)
Reclassification to net income, net of tax impact of $(4), $(1), and $(2)	4	21	(87)
Net change	434	(39)	(149)
Other comprehensive income (loss)	425	(78)	(104)
Comprehensive income	12,484	2,979	2,470
Comprehensive loss attributable to noncontrolling interest	42	18	18
Comprehensive income attributable to Gilead	$ 12,526	$ 2,997	$ 2,488

See accompanying notes.

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GILEAD SCIENCES, INC.

Consolidated Statements of Stockholders' Equity

(in millions)

	Gilead Stockholders' Equity						
	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Retained Earnings	Noncontrolling Interest	Total Stockholders' Equity
	Shares	Amount					
Balance at December 31, 2011	1,506	$ 2	$ 4,902	$ 58	$ 1,777	$ 128	$ 6,867
Contributions from noncontrolling interest	—	—	—	—	—	131	131
Net income (loss)	—	—	—	—	2,592	(18)	2,574
Other comprehensive income, net of tax	—	—	—	(104)	—	—	(104)
Issuances under employee stock purchase plan	2	—	31	—	—	—	31
Issuances under equity incentive plans	32	—	436	—	—	—	436
Tax benefits from employee stock plans	—	—	113	—	—	—	113
Stock-based compensation	—	—	208	—	—	—	208
Repurchases of common stock	(21)	—	(41)	—	(664)	—	(705)
Convertible notes settlement	—	—	(214)	—	—	—	(214)
Convertible notes hedge settlement	—	—	214	—	—	—	214
Reclassification to equity component of currently redeemable convertible notes	—	—	(7)	—	—	—	(7)
Balance at December 31, 2012	1,519	2	5,642	(46)	3,705	241	9,544
Contributions from noncontrolling interest	—	—	—	—	—	152	152
Net income (loss)	—	—	—	—	3,075	(18)	3,057
Other comprehensive income, net of tax	—	—	—	(78)	—	—	(78)
Issuances under employee stock purchase plan	3	—	55	—	—	—	55
Issuances under equity incentive plans	24	—	258	—	—	—	258
Tax benefits from employee stock plans	—	—	285	—	—	—	285
Stock-based compensation	—	—	254	—	—	—	254
Repurchases of common stock	(12)	—	(14)	—	(674)	—	(688)
Warrants settlement	—	—	(1,040)	—	—	—	(1,040)
Convertible notes settlement	—	—	(2,771)	—	—	—	(2,771)
Convertible notes hedge settlement	—	—	2,774	—	—	—	2,774
Reclassification to equity component of currently redeemable convertible notes	—	—	(57)	—	—	—	(57)
Balance at December 31, 2013	1,534	2	5,386	(124)	6,106	375	11,745
Change in noncontrolling interest	—	—	—	—	—	60	60
Net income (loss)	—	—	—		12,101	(42)	12,059
Other comprehensive income, net of tax	—	—	—	425	—	—	425
Issuances under employee stock purchase plan	3	—	72	—	—	—	72
Issuances under equity incentive plans	24	—	260	—	—	—	260
Tax benefits from employee stock plans	—	—	484	—	—	—	484
Stock-based compensation	—	—	362	—	—	—	362
Repurchases of common stock	(62)	—	(133)	—	(5,475)	—	(5,608)
Warrants settlement	—	—	(4,093)	—	—	—	(4,093)
Convertible notes settlement	—	—	(2,513)	—	—	—	(2,513)
Convertible notes hedge settlement	—	—	2,543	—	—	—	2,543
Purchases of convertible note hedges	—	—	(26)	—	—	—	(26)
Reclassification to equity component of currently redeemable convertible notes	—	—	49	—	—	—	49
Balance at December 31, 2014	1,499	$ 2	$ 2,391	$ 301	$ 12,732	$ 393	$ 15,819

See accompanying notes.

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GILEAD SCIENCES, INC.

Consolidated Statements of Cash Flows
(in millions)

	Year Ended December 31,		
	2014	2013	2012
Operating Activities:			
Net income	$ 12,059	$ 3,057	$ 2,574
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation expense	125	103	83
Amortization expense	925	242	195
Stock-based compensation expense	360	252	209
Excess tax benefits from stock-based compensation	(482)	(279)	(114)
Tax benefits from exercise and vesting of stock-based awards	484	285	113
Deferred income taxes	(236)	(98)	(39)
Change in fair value of contingent consideration	22	59	69
Other	79	46	(3)
Changes in operating assets and liabilities:			
Accounts receivable, net	(2,578)	(315)	198
Inventories	143	(343)	(350)
Prepaid expenses and other assets	(371)	(170)	(129)
Accounts payable	(289)	(98)	117
Income taxes payable	533	30	(68)
Accrued liabilities	2,013	312	317
Deferred revenues	31	22	23
Net cash provided by operating activities	12,818	3,105	3,195
Investing Activities:			
Purchases of marketable securities	(2,107)	(257)	(1,245)
Proceeds from sales of marketable securities	807	494	528
Proceeds from maturities of marketable securities	52	78	45
Other investments	(18)	—	(25)
Acquisitions, net of cash acquired	—	(379)	(10,752)
Capital expenditures	(557)	(190)	(397)
Net cash used in investing activities	(1,823)	(254)	(11,846)
Financing Activities:			
Proceeds from debt financing, net of issuance costs	7,932	—	2,144
Proceeds from convertible note hedges	2,543	2,774	214
Purchases of convertible note hedges	(26)	—	—
Proceeds from issuances of common stock	331	313	466
Repurchases of common stock	(5,349)	(582)	(667)
Repayments of debt and other long-term obligations	(4,779)	(4,440)	(1,839)
Payments to settle warrants	(4,093)	(1,040)	—
Excess tax benefits from stock-based compensation	482	279	114
Payment of contingent consideration	(101)	—	—
Contributions from noncontrolling interest	35	152	131
Net cash provided by (used in) financing activities	(3,025)	(2,544)	563
Effect of exchange rate changes on cash and cash equivalents	(56)	2	8
Net change in cash and cash equivalents	7,914	309	(8,080)
Cash and cash equivalents at beginning of period	2,113	1,804	9,884
Cash and cash equivalents at end of period	$ 10,027	$ 2,113	$ 1,804
Supplemental disclosure of cash flow information:			
Interest paid, net of amounts capitalized	$ 330	$ 238	$ 249
Income taxes paid	$ 2,060	$ 1,051	$ 1,101

See accompanying notes.

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1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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.

Our product portfolio is comprised of Sovaldi ®, Atripla ®, Truvada ®, Harvoni ®, Complera ®/Eviplera ®, Stribild ®, Viread ®, Letairis ®, Ranexa ®, AmBisome ®, Zydelig ®, Cayston ®, Hepsera ®, Emtriva ®, Tybost ® and Vitekta ®. We have global commercial sales operations and marketing subsidiaries in North and South America, Europe and Asia-Pacific. In addition, we also sell and distribute certain products through our corporate partners under royalty-paying collaborative agreements.

Basis of Presentation

The accompanying Consolidated Financial Statements include the accounts of Gilead, our wholly-owned subsidiaries and certain variable interest entities for which we are the primary beneficiary. For consolidated entities where we own or are exposed to less than 100% of the economics, we record net income (loss) attributable to noncontrolling interests in our Consolidated Statements of Income equal to the percentage of the economic or ownership interest retained in such entities by the respective noncontrolling parties. All intercompany transactions have been eliminated. The Consolidated Financial Statements include the results of companies acquired by us from the date of each acquisition for the applicable reporting periods.

On January 25, 2013, we completed a two-for-one stock split in the form of a stock dividend to stockholders of record as of January 7, 2013, as declared on December 10, 2012. Accordingly, all share and per share amounts for all periods presented in these Consolidated Financial Statements and notes have been adjusted retroactively to reflect this stock split.

Significant Accounting Policies, Estimates and Judgments

The preparation of these Consolidated Financial Statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures. On an ongoing basis, management evaluates its significant accounting policies and estimates. We base our estimates on historical experience and on various market specific and other relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ significantly from these estimates. Estimates are assessed each period and updated to reflect current information such as actual experience.

Revenue Recognition

Product Sales

We recognize revenue from product sales when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed or determinable and collectability is reasonably assured. Upon recognition of revenue from product sales, provisions are made for government and other rebates such as Medicaid reimbursements, customer incentives such as cash discounts for prompt payment, distributor fees and expected returns of expired products, as appropriate.

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Items Deducted from Gross Product Sales

Rebates and Chargebacks

We estimate reductions to our revenues for amounts paid to payers and healthcare providers in the United States, including Medicaid rebates, ADAPs, Veterans Administration and Public Health Service discounts, and other rebates, as well as foreign government rebates. Rebates and chargebacks are based on contractual arrangements or statutory requirements which may vary by product, by payer and individual payer plans. Our estimates are based on products sold, historical utilization rates, and as available, pertinent third party industry information, estimated patient population, known market events or trends, and for our U.S. product sales, channel inventory data obtained from our major U.S. wholesalers in accordance with our inventory management agreements. We also take into consideration, as available, new information regarding changes in programs' regulations and guidelines that would impact the amount of the actual rebates and/or our expectations regarding future utilization rates for these programs. Government and other chargebacks that are payable to our direct customers are classified as reductions of accounts receivable on our Consolidated Balance Sheets. Government and other rebates that are invoiced directly to us are recorded in accrued government and other rebates on our Consolidated Balance Sheets.

Cash Discounts

We estimate cash discounts based on contractual terms, historical utilization rates, as available, and our expectations regarding future utilization rates.

Distributor Fees

Under our inventory management agreements with our significant U.S. wholesalers, we pay the wholesalers a fee primarily for the compliance of certain contractually determined covenants such as the maintenance of agreed upon inventory levels. These distributor fees are based on a contractually determined fixed percentage of sales.

Product Returns

We do not provide our customers with a general right of product return, but typically permit returns if the product is damaged or defective when received by the customer, or in the case of product sold in the United States and certain countries outside the United States, if the product has expired. We will accept returns for product that will expire within six months or that have expired up to one year after their expiration dates. Our estimates for expected returns of expired products are based primarily on an ongoing analysis of our historical return patterns, historical industry information reporting the return rates for similar products and contractual agreements intended to limit the amount of inventory maintained by our wholesalers.

Royalty, Contract and Other Revenues

Royalty revenue from sales of our other products is generally recognized when received, which is generally in the quarter following the quarter in which the corresponding sales occur or in the month following the month in which the corresponding sales occur.

Revenue from non-refundable up-front license fees and milestone payments, such as under a development collaboration or an obligation to supply product, is recognized as performance occurs and our obligations are completed. In accordance with the specific terms of our obligations under these arrangements, revenue is recognized as the obligation is fulfilled or ratably over the development or manufacturing period. Revenue associated with substantive at-risk milestones is recognized based upon the achievement of the milestones set forth in the respective agreements. Advance payments received in excess of amounts earned are classified as deferred revenue on our Consolidated Balance Sheets.

Research and Development Expenses

Research and development (R&D) expenses consist primarily of personnel costs, including salaries, benefits and stock-based compensation, clinical studies performed by contract research organizations (CROs), materials and supplies, licenses and fees, milestone payments under collaboration arrangements and overhead allocations consisting of various support and facility-related costs.

We charge R&D costs, including clinical study costs, to expense when incurred . Clinical study costs are a significant component of R&D expenses. Most of our clinical studies are performed by third-party CROs. We monitor levels of performance under each significant contract including the extent of patient enrollment and other activities through communications with our CROs. We accrue costs for clinical studies performed by CROs over the service periods specified in the contracts and adjust our estimates, if required, based upon our ongoing review of the level of effort and costs actually incurred by the CROs. All of our material CRO contracts are terminable by us upon written notice and we are generally only

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liable for actual services completed by the CRO and certain non-cancelable expenses incurred at any point of termination. Amounts paid in advance related to uncompleted services will be refunded to us if a contract is terminated.

Advertising Expenses

We expense the costs of advertising, including promotional expenses, as incurred. Advertising expenses were $393 million in 2014 , $216 million in 2013 and $160 million in 2012 .

Stock-Based Compensation

We utilize share based compensation in the form of various types of equity-based awards, including restricted stock units (RSUs), performance-based restricted stock units (PSUs) and stock options. Compensation expense is recognized in the Consolidated Statements of Income based on the estimated fair value at grant date. The estimated fair values of RSUs are based on the closing price of our common stock. For PSUs, estimated fair values are based on either the Monte Carlo valuation methodology or the stock price on the date of grant. For stock option awards, estimated fair values are based on the Black-Scholes option valuation model.

Cash and Cash Equivalents

We consider highly liquid investments with insignificant interest rate risk and an original maturity of three months or less on the purchase date to be cash equivalents. Eligible instruments under our investment policy that are included in cash equivalents include commercial paper, money market funds, overnight repurchase agreements (repos) with major banks and authorized dealers and other bank obligations.

Marketable and Nonmarketable Securities

We determine the appropriate classification of our marketable securities, which consist primarily of debt securities, at the time of purchase and reevaluate such designation at each balance sheet date. All of our marketable securities are considered as available-for-sale and carried at estimated fair values and reported in cash equivalents, short-term marketable securities or long-term marketable securities. Unrealized gains and losses on available-for-sale securities are excluded from net income and reported in accumulated other comprehensive income (loss) as a separate component of stockholders' equity. Other income (expense), net, includes interest, dividends, amortization of purchase premiums and discounts, realized gains and losses on sales of securities and other-than-temporary declines in the fair value of securities, if any. The cost of securities sold is based on the specific identification method. We regularly review all of our investments for other-than-temporary declines in fair value. Our review includes the consideration of the cause of the impairment, including the creditworthiness of the security issuers, the number of securities in an unrealized loss position, the severity and duration of the unrealized losses, whether we have the intent to sell the securities and whether it is more likely than not that we will be required to sell the securities before the recovery of their amortized cost basis. When we determine that the decline in fair value of an investment is below our accounting basis and this decline is other-than-temporary, we reduce the carrying value of the security we hold and record a loss for the amount of such decline.

As a result of entering into collaborations, from time to time, we may hold investments in non-public companies. We record these nonmarketable securities at cost in other long-term assets, less any amounts for other-than-temporary impairment. We regularly review our securities for indicators of impairment. Investments in nonmarketable securities are not material for the periods presented.

Concentrations of Risk

We are subject to credit risk from our portfolio of cash equivalents and marketable securities. Under our investment policy, we limit amounts invested in such securities by credit rating, maturity, industry group, investment type and issuer, except for securities issued by the U.S. government. We are not exposed to any significant concentrations of credit risk from these financial instruments. The goals of our investment policy, in order of priority, are as follows: safety and preservation of principal and diversification of risk; liquidity of investments sufficient to meet cash flow requirements; and a competitive after-tax rate of return.

We are also subject to credit risk from our accounts receivable related to our product sales. The majority of our trade accounts receivable arises from product sales in the United States and Europe.

As of December 31, 2014 , our accounts receivable in Southern Europe, specifically Greece, Italy, Portugal and Spain, totaled approximately $504 million , of which $157 million were greater than 120 days past due and $44 million were greater than 365 days past due. To date, we have not experienced significant losses with respect to the collection of our accounts receivable. We believe that our allowance for doubtful accounts was adequate at December 31, 2014 .

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Certain of the raw materials and components that we utilize in our operations are obtained through single suppliers. Certain of the raw materials that we utilize in our operations are made at only one facility. Since the suppliers of key components and raw materials must be named in a new drug application (NDA) filed with the U.S. Food and Drug Administration (FDA) for a product, significant delays can occur if the qualification of a new supplier is required. If delivery of material from our suppliers were interrupted for any reason, we may be unable to ship our commercial products or to supply our product candidates for clinical trials.

Accounts Receivable

Trade accounts receivable are recorded net of allowances for wholesaler chargebacks related to government and other programs, cash discounts for prompt payment and doubtful accounts. Estimates for wholesaler chargebacks for government and other programs and cash discounts are based on contractual terms, historical trends and our expectations regarding the utilization rates for these programs. Estimates of our allowance for doubtful accounts are determined based on existing contractual payment terms, historical payment patterns of our customers and individual customer circumstances, an analysis of days sales outstanding by geographic region and a review of the local economic environment and its potential impact on government funding and reimbursement practices. Historically, the amounts of uncollectible accounts receivable that have been written off have been insignificant and consistent with management's expectations.

Inventories

Inventories are recorded at the lower of cost or market, with cost determined on a first-in, first-out basis. We periodically review the composition of our inventories in order to identify obsolete, slow-moving or otherwise unsaleable items. If unsaleable items are observed and there are no alternate uses for the inventory, we will record a write-down to net realizable value in the period that the impairment is first recognized.

When future commercialization is considered probable and the future economic benefit is expected to be realized, based on management's judgment, we capitalize pre-launch inventory costs prior to regulatory approval. A number of factors are taken into consideration, including the current status in the regulatory approval process, potential impediments to the approval process such as safety or efficacy, anticipated research and development initiatives that could impact the indication in which the compound will be used, viability of commercialization and marketplace trends. As of December 31, 2014 and 2013 , the amount of pre-launch inventory on our Consolidated Balance Sheets was not significant.

Property, Plant and Equipment

Property, plant and equipment is stated at cost less accumulated depreciation and amortization. Depreciation and amortization are recognized using the straight-line method. Repairs and maintenance costs are expensed as incurred. Estimated useful lives in years are as follows:

Description	Estimated Useful Life
Buildings and improvements	20-35
Laboratory and manufacturing equipment	4-10
Office and computer equipment	3-7
Leasehold improvements	Shorter of useful life or lease term

Office and computer equipment includes capitalized software. We had unamortized capitalized software costs on our Consolidated Balance Sheets of $80 million as of December 31, 2014 and $84 million as of December 31, 2013 . Leasehold improvements are amortized over the shorter of the lease term or the asset's useful life. Capitalized interest on construction in-progress is included in property, plant and equipment. Interest capitalized in 2014 , 2013 and 2012 was not significant.

Goodwill and Intangible Assets

Goodwill represents the excess of the consideration transferred over the estimated fair value of assets acquired and liabilities assumed in a business combination. Intangible assets with indefinite useful lives are related to purchased in-process research and development (IPR&D) projects and are measured at their respective fair values as of the acquisition date. We do not amortize goodwill and intangible assets with indefinite useful lives. Intangible assets related to IPR&D projects are considered to be indefinite-lived until the completion or abandonment of the associated R&D efforts. If and when development is complete, which generally occurs if and when regulatory approval to market a product is obtained, the associated assets are deemed finite-lived and are amortized based on their respective estimated useful lives at that point in time. We test goodwill

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and other indefinite-lived intangible assets for impairment on an annual basis and in between annual tests if we become aware of any events or changes that would indicate the fair values of the assets are below their carrying amounts.

Intangible assets with finite useful lives are amortized over their estimated useful lives, primarily on a straight-line basis, and are reviewed for impairment when facts or circumstances suggest that the carrying value of these assets may not be recoverable.

Impairment of Long-Lived Assets

The carrying value of long-lived assets is reviewed on a regular basis for the existence of facts or circumstances both internally and externally that may suggest impairment. Specific potential indicators of impairment include a significant decrease in the fair value of an asset, a significant change in the extent or manner in which an asset is used or a significant physical change in an asset, a significant adverse change in legal factors or in the business climate that affects the value of an asset, an adverse action or assessment by the FDA or another regulator, an accumulation of costs significantly in excess of the amount originally expected to acquire or construct an asset and operating or cash flow losses combined with a history of operating or cash flow losses or a projection or forecast that demonstrates continuing losses associated with an income producing asset.

Should there be an indication of impairment, we will test for recoverability by comparing the estimated undiscounted future cash flows expected to result from the use of the asset or asset group and its eventual disposition to the carrying amount of the asset or asset group. Any excess of the carrying value of the asset or asset group over its estimated fair value will be recognized as an impairment loss.

Valuation of Contingent Consideration Resulting from a Business Combination

In connection with certain business combinations, we may be required to pay future consideration that is contingent upon the achievement of specified development, regulatory approval or sales-based milestone events. We record contingent consideration resulting from a business combination at its fair value on the acquisition date. In connection with the consolidation of a variable interest entity for which we are a primary beneficiary, we record contingent consideration related to future earn-out payments based upon percentage of gross margin of the entity. Each reporting period thereafter, we revalue these obligations and record changes in their fair value within our Consolidated Statement of Income. We record changes in fair value related to future milestone payments as R&D expense until such time that the related product candidate receives marketing approval.

Changes in fair value of the contingent consideration liabilities can result from updates to assumptions such as the expected timing or probability of achieving the specified milestones, changes in projected revenues or changes in discount rates. Significant judgment is employed in determining these assumptions as of the acquisition or consolidation date and for each subsequent period. Updates to assumptions could have a significant impact on our results of operations in any given period. Actual results may differ from estimates.

Foreign Currency Translation, Transaction Gains and Losses, and Hedging Contracts

Non-U.S. entity operations are recorded in the functional currency of each entity. Results of operations for non-U.S. dollar functional currency entities are translated into U.S. dollars using average currency rates. Assets and liabilities are translated using currency rates at period end. Foreign currency translation adjustments are recorded as a component of other comprehensive income (loss) within stockholders' equity. Foreign currency transaction gains and losses are recorded in other income (expense), net on our Consolidated Statements of Income. Net foreign currency transaction gains totaled $4 million in 2014 , and losses totaled $4 million in 2013 and $11 million in 2012 .

We hedge a portion of our foreign currency exposures related to outstanding monetary assets and liabilities as well as forecasted product sales using foreign currency exchange forward and option contracts. In general, the market risk related to these contracts is offset by corresponding gains and losses on the hedged transactions. The credit risk associated with these contracts is driven by changes in interest and currency exchange rates and, as a result, varies over time. By working only with major banks and closely monitoring current market conditions, we seek to limit the risk that counterparties to these contracts may be unable to perform. We also seek to limit our risk of loss by entering into contracts that permit net settlement at maturity. Therefore, our overall risk of loss in the event of a counterparty default is limited to the amount of any unrecognized gains on outstanding contracts (i.e., those contracts that have a positive fair value) at the date of default. We do not enter into derivative contracts for trading purposes, nor do we hedge our net investment in any of our foreign subsidiaries.

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Fair Value of Financial Instruments

We apply fair value accounting for all financial assets and liabilities and non-financial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis. We define fair value as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining the fair value measurements for assets and liabilities which are required to be recorded at fair value, we consider the principal or most advantageous market in which we would transact and the market-based risk measurements or assumptions that market participants would use in pricing the asset or liability, such as risks inherent in valuation techniques, transfer restrictions and credit risks.

Derivative Financial Instruments

We recognize all derivative instruments as either assets or liabilities at fair value in our Consolidated Balance Sheets. Changes in the fair value of derivatives are recorded each period in current earnings or accumulated other comprehensive income (loss), depending on whether a derivative is designated as part of a hedge transaction and, if it is, the type of hedge transaction. We classify the cash flows from these instruments in the same category as the cash flows from the hedged items. We do not hold or issue derivative instruments for trading or speculative purposes.

We assess, both at inception and on an ongoing basis, whether the derivatives that are used in hedging transactions are highly effective in offsetting the changes in cash flows or fair values of the hedged items. We also assess hedge ineffectiveness on a quarterly basis and record the gain or loss related to the ineffective portion to current earnings to the extent significant. If we determine that a forecasted transaction is no longer probable of occurring, we discontinue hedge accounting for the affected portion of the hedge instrument, and any related unrealized gain or loss on the contract is recognized in current earnings.

Income Taxes

Our income tax provision is computed under the liability method. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Significant estimates are required in determining our provision for income taxes. Some of these estimates are based on interpretations of existing tax laws or regulations.

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

Branded Prescription Drug Fee

We, along with other pharmaceutical manufacturers of branded drug products, are required to pay a portion of the BPD fee, which is calculated based on select government sales during each calendar year as a percentage of total industry government sales. In 2014, the Internal Revenue Service (IRS) issued final regulations related to the BPD fee which indicate that an entity's obligation to pay its portion of the BPD fee in any given calendar year is triggered by the qualifying sales in the previous year, instead of the first qualifying sale in the current calendar year. As a result of the final IRS regulations, we were required to recognize our 2014 fee of $460 million and 2013 fee of $142 million in our 2014 Consolidated Statement of Income. The IRS is expected to communicate the final BPD fee amounts due for 2013 sales during the third quarter of 2015 and for 2014 sales during the third quarter of 2016. Our BPD fee accrual totaled $500 million as of December 31, 2014 and $38 million as of December 31, 2013 on our Consolidated Balance Sheets.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, jointly with the International Accounting Standards Board, issued a comprehensive new standard on revenue recognition from contracts with customers. The standard's core principle is that a reporting entity will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In applying this new guidance to contracts within its scope, an entity will: (1) identify the contract(s) with a customer, (2) identify the performance obligations in the contract, (3) determine the transaction price, (4) allocate the transaction price to the performance obligations in the contract, and (5) recognize revenue when (or as) the entity satisfies a performance obligation. Additionally, this new guidance will require significantly expanded revenue recognition disclosures. This guidance will become effective for us beginning in the first quarter of 2017. Early application is not permitted. Entities have the option of using either a full

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retrospective or a modified retrospective approach to adopt this new guidance. We are currently evaluating the impact of our adoption of this standard on our Consolidated Financial Statements.

2. FAIR VALUE MEASUREMENTS

We determine the fair value of financial and non-financial assets and liabilities using the fair value hierarchy, which establishes three levels of inputs that may be used to measure fair value, as follows:

- Level 1 inputs which include quoted prices in active markets for identical assets or liabilities;
- Level 2 inputs which include observable inputs other than Level 1 inputs, such as quoted prices for similar assets or liabilities; quoted prices for identical or similar assets or liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the asset or liability. For our marketable securities, we review trading activity and pricing as of the measurement date. When sufficient quoted pricing for identical securities is not available, we use market pricing and other observable market inputs for similar securities obtained from various third-party data providers. These inputs either represent quoted prices for similar assets in active markets or have been derived from observable market data; and
- Level 3 inputs which include unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the underlying asset or liability. Level 3 assets and liabilities include those whose fair value measurements are determined using pricing models, discounted cash flow methodologies or similar valuation techniques and significant management judgment or estimation.

Our financial instruments consist principally of cash and cash equivalents, marketable securities, accounts receivable, foreign currency exchange contracts, accounts payable and short-term and long-term debt. Cash and cash equivalents, marketable securities and foreign currency exchange contracts that hedge accounts receivable and forecasted sales are reported at their respective fair values on our Consolidated Balance Sheets. Short-term and long-term debt are reported at their amortized cost on our Consolidated Balance Sheets. The remaining financial instruments are reported on our Consolidated Balance Sheets at amounts that approximate current fair values.

The following table summarizes, for assets or liabilities recorded at fair value, the respective fair value and the classification by level of input within the fair value hierarchy (in millions):

	December 31, 2014				December 31, 2013			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Assets:								
Money market funds	$ 7,926	$ —	$ —	$ 7,926	$ 1,491	$ —	$ —	$ 1,491
Corporate debt securities	—	938	—	938	—	220	—	220
U.S. treasury securities	363	—	—	363	86	—	—	86
Residential mortgage and asset-backed securities	—	269	—	269	—	47	—	47
U.S. government agencies securities	—	113	—	113	—	93	—	93
Municipal debt securities	—	16	—	16	—	12	—	12
Foreign currency derivative contracts	—	349	—	349	—	14	—	14
Deferred compensation plan (1)	54	—	—	54	44	—	—	44
	$ 8,343	$ 1,685	$ —	$ 10,028	$ 1,621	$ 386	$ —	$ 2,007
Liabilities:								
Contingent consideration	$ —	$ —	$ 133	$ 133	$ —	$ —	$ 264	$ 264
Deferred compensation plan (1)	54	—	—	54	44	—	—	44
Foreign currency derivative contracts	—	—	—	—	—	99	—	99
	$ 54	$ —	$ 133	$ 187	$ 44	$ 99	$ 264	$ 407

(1) We maintain a deferred compensation plan under which our directors and key employees may defer compensation for income tax purposes. Amounts deferred by participants are deposited in a rabbit trust and the amount is periodically adjusted to reflect earnings or (losses) based on the participant's investment elections among a select group of investment funds which consists of money market funds and mutual funds.

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Level 2 Inputs

We estimate the fair values of our government related debt, corporate debt, residential mortgage and asset-backed securities by taking into consideration valuations obtained from third-party pricing services. The pricing services utilize industry standard valuation models, including both income- and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities; issuer credit spreads; benchmark securities; prepayment/default projections based on historical data; and other observable inputs.

Substantially all of our foreign currency derivatives contracts have maturities primarily over an 18 month time horizon and all are with counterparties that have a minimum credit rating of A- or equivalent by Standard & Poor's, Moody's Investors Service, Inc. or Fitch, Inc. We estimate the fair values of these contracts by taking into consideration valuations obtained from a third-party valuation service that utilizes an income-based industry standard valuation model for which all significant inputs are observable, either directly or indirectly. These inputs include foreign currency rates, London Interbank Offered Rates (LIBOR) and swap rates. These inputs, where applicable, are at commonly quoted intervals.

The fair values of our convertible senior notes and senior unsecured notes were determined using Level 2 inputs based on their quoted market values. The following table summarizes the carrying values and fair values of the convertible senior notes and senior unsecured notes (in millions):

		December 31, 2014		December 31, 2013	
Type of Borrowing	Description	Carrying Value	Fair Value	Carrying Value	Fair Value
Convertible Senior	May 2014 Notes	$ —	$ —	$ 234	$ 784
Convertible Senior	May 2016 Notes	483	2,097	1,113	3,872
Senior Unsecured	April 2021 Notes	995	1,108	994	1,075
Senior Unsecured	December 2014 Notes	—	—	750	763
Senior Unsecured	December 2016 Notes	700	727	699	741
Senior Unsecured	December 2021 Notes	1,248	1,377	1,248	1,337
Senior Unsecured	December 2041 Notes	998	1,229	998	1,119
Senior Unsecured	April 2019 Notes	499	500	—	—
Senior Unsecured	April 2024 Notes	1,747	1,836	—	—
Senior Unsecured	April 2044 Notes	1,747	1,954	—	—
Senior Unsecured	February 2020 Notes	499	504	—	—
Senior Unsecured	February 2025 Notes	1,748	1,797	—	—
Senior Unsecured	February 2045 Notes	1,740	1,872	—	—

Level 3 Inputs

As of December 31, 2014 and 2013 , the only assets or liabilities that were measured using Level 3 inputs were contingent consideration liabilities. Our policy is to recognize transfers into or out of Level 3 classification as of the actual date of the event or change in circumstances that caused the transfer.

Contingent Consideration Liabilities

In connection with certain acquisitions, we may be required to pay future consideration that is contingent upon the achievement of specified development, regulatory approval, sales-based milestone events, or other financial results. We estimate the fair value of the contingent consideration liabilities on the acquisition date or initial consolidation date and each reporting period thereafter using a probability-weighted income approach, which reflects the probability and timing of future payments. This fair value measurement is based on significant Level 3 inputs such as the anticipated timelines and probability of achieving development, regulatory approval or sales-based milestone events and projected revenues. The resulting probability-weighted cash flows are discounted using credit-risk adjusted interest rates.

Each reporting period thereafter, we revalue these obligations by performing a review of the assumptions listed above and record increases or decreases in the fair value of these contingent consideration obligations within our Consolidated Statements of Income. We record fair value related to future milestone payments in R&D expense until such time that the related product candidate receives marketing approval. The change in the fair value of future earn-out payments is recorded in selling, general and administrative (SG&A) expense. In the absence of any significant changes in key assumptions, the quarterly determination of fair values of these contingent consideration obligations would primarily reflect the passage of time.

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Significant judgment is employed in determining Level 3 inputs and fair value measurements as of the acquisition date or initial consolidation date and for each subsequent period. Updates to assumptions could have a significant impact on our results of operations in any given period and actual results may differ from estimates. For example, significant increases in the probability of achieving a milestone or projected revenues would result in a significantly higher fair value measurement while significant decreases in the estimated probability of achieving a milestone or projected revenues would result in a significantly lower fair value measurement. Significant increases in the discount rate or in the anticipated timelines would result in a significantly lower fair value measurement while significant decreases in the discount rate or anticipated timelines would result in a significantly higher fair value measurement.

The potential contingent consideration payments required upon achievement of development or regulatory approval-based milestones related to our acquisitions of CGI Pharmaceuticals, Inc. and Calistoga Pharmaceuticals, Inc. (Calistoga) ranged from no payment if none of the milestones were achieved to an estimated maximum of $254 million (undiscounted). In July 2014, upon receiving FDA approval of Zydelig, certain regulatory approval-based milestones related to our Calistoga acquisition were met and as a result, we made contingent consideration payments totaling $175 million in the third quarter of 2014. As of December 31, 2014 and December 31, 2013 , we had accrued $55 million and $221 million , respectively, related to these acquisitions.

The remainder of the contingent consideration liabilities as of December 31, 2014 and 2013 primarily relate to the potential future payments resulting from the acquisition of Arresto Biosciences, Inc. for royalty obligations on future sales once specified sales-based milestones are achieved.

The following table provides a rollforward of our contingent consideration liabilities, which are recorded as part of other accrued liabilities and other long-term obligations in our Consolidated Balance Sheets (in millions):

	Year Ended December 31,	
	2014	2013
Balance, beginning of period	$ 264	$ 205
Milestone payments - Calistoga	(175)	—
Net changes in valuation	32	59
Addition from consolidation of variable interest entity	12	—
Balance, end of period	$ 133	$ 264

3. AVAILABLE-FOR-SALE SECURITIES

Estimated fair values of available-for-sale securities are generally based on prices obtained from commercial pricing services. The following table is a summary of available-for-sale securities recorded in cash and cash equivalents or marketable securities in our Consolidated Balance Sheets (in millions):

	December 31, 2014				December 31, 2013			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds	$ 7,926	$ —	$ —	$ 7,926	$ 1,491	$ —	$ —	$ 1,491
Corporate debt securities	941	—	(3)	938	219	1	—	220
U.S. treasury securities	363	—	—	363	86	—	—	86
Residential mortgage and asset-backed securities	269	—	—	269	47	—	—	47
U.S. government agencies securities	113	—	—	113	93	—	—	93
Municipal debt securities	16	—	—	16	12	—	—	12
Total	$ 9,628	$ —	$ (3)	$ 9,625	$ 1,948	$ 1	$ —	$ 1,949

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The following table summarizes the classification of the available-for-sale securities on our Consolidated Balance Sheets (in millions):

	December 31, 2014	December 31, 2013
Cash and cash equivalents	$ 7,926	$ 1,491
Short-term marketable securities	101	19
Long-term marketable securities	1,598	439
Total	$ 9,625	$ 1,949

Cash and cash equivalents in the table above exclude cash of $2.1 billion as of December 31, 2014 and $622 million as of December 31, 2013 .

The following table summarizes our portfolio of available-for-sale securities by contractual maturity (in millions):

	December 31, 2014	
	Amortized Cost	Fair Value
Less than one year	$ 8,027	$ 8,027
Greater than one year but less than five years	1,583	1,580
Greater than five years but less than ten years	14	14
Greater than ten years	4	4
Total	$ 9,628	$ 9,625

The following table summarizes the gross realized gains and losses related to sales of marketable securities (in millions):

	Year Ended December 31,		
	2014	2013	2012
Gross realized gains on sales	$ 1	$ 1	$ 10
Gross realized losses on sales	$ —	$ (1)	$ (44)

The following table summarizes our available-for-sale debt securities that were in a continuous unrealized loss position, but were not deemed to be other-than-temporarily impaired (in millions):

	Less Than 12 Months		12 Months or Greater		Total	
	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value
December 31, 2014						
Debt securities:						
Corporate debt securities	$ (3)	$ 802	$ —	$ —	$ (3)	$ 802
Residential mortgage and asset-backed securities	—	227	—	1	—	228
U.S. treasury securities	—	206	—	—	—	206
U.S. government agencies securities	—	22	—	—	—	22
Municipal debt securities	—	2	—	—	—	2
Total	$ (3)	$ 1,259	$ —	$ 1	$ (3)	$ 1,260
December 31, 2013						
Debt securities:						
Corporate debt securities	$ —	$ 37	$ —	$ 2	$ —	$ 39
Residential mortgage and asset-backed securities	—	19	—	6	—	25
U.S. treasury securities	—	25	—	—	—	25
U.S. government agencies securities	—	11	—	—	—	11
Municipal debt securities	—	—	—	—	—	—
Total	$ —	$ 92	$ —	$ 8	$ —	$ 100

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We held a total of 468 positions as of December 31, 2014 and 40 positions as of December 31, 2013 that were in an unrealized loss position. The unrealized losses were immaterial both individually and in aggregate. Based on our review of these securities, we believe we had no other-than-temporary impairments on these securities as of December 31, 2014 and 2013 because we do not intend to sell these securities and we believe it is not more likely than not that we will be required to sell these securities before the recovery of their amortized cost basis.

4. DERIVATIVE FINANCIAL INSTRUMENTS

We operate in foreign countries, which exposes us to market risk associated with foreign currency exchange rate fluctuations between the U.S. dollar and various foreign currencies, the most significant of which is the Euro. In order to manage this risk, we may hedge a portion of our foreign currency exposures related to outstanding monetary assets and liabilities as well as forecasted product sales using foreign currency exchange forward or option contracts. In general, the market risk related to these contracts is offset by corresponding gains and losses on the hedged transactions. The credit risk associated with these contracts is driven by changes in interest and currency exchange rates and, as a result, varies over time. By working only with major banks and closely monitoring current market conditions, we seek to limit the risk that counterparties to these contracts may be unable to perform. We also seek to limit our risk of loss by entering into contracts that permit net settlement at maturity. Therefore, our overall risk of loss in the event of a counterparty default is limited to the amount of any unrecognized gains on outstanding contracts (i.e., those contracts that have a positive fair value) at the date of default. We do not enter into derivative contracts for trading purposes.

We hedge our exposure to foreign currency exchange rate fluctuations for certain monetary assets and liabilities of our foreign subsidiaries that are denominated in a non-functional currency. The derivative instruments we use to hedge this exposure are not designated as hedges, and as a result, changes in their fair value are recorded in other income (expense), net on our Consolidated Statements of Income.

We hedge our exposure to foreign currency exchange rate fluctuations for forecasted product sales that are denominated in a non-functional currency. The derivative instruments we use to hedge this exposure are designated as cash flow hedges and have maturity dates of 18 months or less. Upon executing a hedging contract and quarterly thereafter, we assess prospective hedge effectiveness using a regression analysis which calculates the change in cash flow as a result of the hedge instrument. On a monthly basis, we assess retrospective hedge effectiveness using a dollar offset approach. We exclude time value from our effectiveness testing and recognize changes in the time value of the hedge in other income (expense), net. The effective component of our hedge is recorded as an unrealized gain or loss on the hedging instrument in accumulated other comprehensive income (OCI) within stockholders' equity. When the hedged forecasted transaction occurs, the hedge is de-designated and the unrealized gains or losses are reclassified into product sales. The majority of gains and losses related to the hedged forecasted transactions reported in accumulated OCI at December 31, 2014 will be reclassified to product sales within 12 months.

The cash flow effects of our derivative contracts for the three years ended December 31, 2014 , 2013 and 2012 are included within net cash provided by operating activities in the Consolidated Statements of Cash Flows.

We had notional amounts on foreign currency exchange contracts outstanding of $6.4 billion at December 31, 2014 and $4.3 billion at December 31, 2013 .

While all of our derivative contracts allow us the right to offset assets or liabilities, we have presented amounts on a gross basis. Under the International Swap Dealers Association, Inc. master agreements with the respective counterparties of the foreign currency exchange contracts, subject to applicable requirements, we are allowed to net settle transactions of the same currency with a single net amount payable by one party to the other. The following table summarizes the classification and fair values of derivative instruments on our Consolidated Balance Sheets (in millions):

	December 31, 2014			
	Asset Derivatives		Liability Derivatives	
	Classification	Fair Value	Classification	Fair Value
Derivatives designated as hedges:				
Foreign currency exchange contracts	Other current assets	$ 314	Other accrued liabilities	$ —
Foreign currency exchange contracts	Other long-term assets	35	Other long-term obligations	—
Total derivatives		$ 349		$ —

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	December 31, 2013			
	Asset Derivatives		Liability Derivatives	
	Classification	Fair Value	Classification	Fair Value
Derivatives designated as hedges:				
Foreign currency exchange contracts	Other current assets	$ 13	Other accrued liabilities	$ 86
Foreign currency exchange contracts	Other long-term assets	1	Other long-term obligations	13
Total derivatives		$ 14		$ 99

As of December 31, 2014 and December 31, 2013 , there were no material derivatives not designated as hedges.

The following table summarizes the effect of our foreign currency exchange contracts on our Consolidated Financial Statements (in millions):

	Year Ended December 31,		
	2014	2013	2012
Derivatives designated as hedges:			
Gains (losses) recognized in accumulated OCI (effective portion)	$ 446	$ (55)	$ (62)
Gains (losses) reclassified from accumulated OCI into product sales (effective portion)	$ —	$ (20)	$ 89
Gains (losses) recognized in other income (expense), net (ineffective portion and amounts excluded from effectiveness testing)	$ (7)	$ 2	$ (8)
Derivatives not designated as hedges:			
Gains (losses) recognized in other income (expense), net	$ 135	$ (17)	$ (1)

From time to time, we may discontinue cash flow hedges and as a result, record related amounts in other income (expense), net on our Consolidated Statements of Income. There were no material amounts recorded in other income (expense), net for the years ended December 31, 2014 , 2013 and 2012 as a result of the discontinuance of cash flow hedges.

As of December 31, 2014 and 2013 , we held one type of financial instrument, derivative contracts related to foreign currency exchange contracts. The following table summarizes the potential effect of offsetting derivatives by type of financial instrument on our Consolidated Balance Sheets (in millions):

As of December 31, 2014 Offsetting of Derivative Assets/Liabilities						
				Gross Amounts Not Offset in the Consolidated Balance Sheet		
Description	Gross Amounts of Recognized Assets/Liabilities	Gross Amounts Offset in the Consolidated Balance Sheet	Amounts of Assets/Liabilities Presented in the Consolidated Balance Sheet	Derivative Financial Instruments	Cash Collateral Received/Pledged	Net Amount (Legal Offset)
Derivative assets	$ 349	$ —	$ 349	$ —	$ —	$ 349
Derivative liabilities	—	—	—	—	—	—

As of December 31, 2013 Offsetting of Derivative Assets/Liabilities						
				Gross Amounts Not Offset in the Consolidated Balance Sheet		
Description	Gross Amounts of Recognized Assets/Liabilities	Gross Amounts Offset in the Consolidated Balance Sheet	Amounts of Assets/Liabilities Presented in the Consolidated Balance Sheet	Derivative Financial Instruments	Cash Collateral Received/Pledged	Net Amount (Legal Offset)
Derivative assets	$ 14	$ —	$ 14	$ (14)	$ —	$ —
Derivative liabilities	(99)	—	(99)	14	—	(85)

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5. ACQUISITIONS

YM BioSciences Inc.

In February 2013, we completed the acquisition of YM BioSciences Inc. (YM), based in Canada, for total consideration transferred of $488 million , at which time YM became a wholly-owned subsidiary of Gilead. YM was a drug development company primarily focused on advancing momelotinib, an orally administered, once-daily candidate for hematologic cancers.

The YM acquisition was accounted for as a business combination. The fair values of acquired assets and assumed liabilities primarily included IPR&D of $363 million , goodwill of $127 million , deferred tax assets of $53 million with a full unrecognized tax benefit, deferred tax liabilities of $109 million and cash acquired of $109 million . Pro forma results of operations for the acquisition of YM have not been presented because this acquisition is not material to our consolidated results of operations. See Note 8, Intangible Assets and Goodwill for a description of the IPR&D acquired.

Pharmasset, Inc.

In January 2012, we completed the acquisition of Pharmasset, Inc. (Pharmasset) a publicly-held clinical-stage pharmaceutical company committed to discovering, developing and commercializing novel drugs to treat viral infections. Pharmasset's primary focus was the development of oral therapeutics for the treatment of HCV infection. Pharmasset's lead compound, sofosbuvir, is a nucleotide analog which, in December 2013, was approved by the FDA under the name Sovaldi, as a once-daily oral regimen for the treatment of HCV in patients with genotypes 1, 2, 3 or 4 infection, including those with hepatocellular carcinoma meeting Milan criteria (awaiting liver transplantation) and those with HCV/HIV-1 co-infection. In October 2014, Harvoni, which combines the NS5A inhibitor ledipasvir with sofosbuvir, received approval from the FDA for the treatment of chronic HCV genotype 1 infection in adults. The acquisition of Pharmasset has allowed us to advance our effort to develop all-oral regimens for the treatment of HCV.

We acquired all of the outstanding shares of common stock of Pharmasset for $137 per share in cash through a tender offer and subsequent merger under the terms of an agreement and plan of merger entered into in November 2011. The aggregate cash payment to acquire all of the outstanding shares of common stock was $11.1 billion . We financed the transaction with approximately $5.2 billion in cash on hand, $3.7 billion in senior unsecured notes issued in December 2011 and $2.2 billion in bank debt issued in January 2012.

The Pharmasset acquisition was accounted for as a business combination. The results of operations of Pharmasset have been included in our Consolidated Statements of Income since January 13, 2012 , the date on which we acquired approximately 88% of the outstanding shares of common stock of Pharmasset.

The following table summarizes the components of the cash paid to acquire Pharmasset (in millions):

Total consideration transferred	$	10,858
Stock-based compensation expense		194
Total cash paid	$	11,052

The $11.1 billion cash payment consisted of a $10.4 billion cash payment to the outstanding common stockholders and a $668 million cash payment to option holders under the Pharmasset stock option plans. The $10.4 billion cash payment to the outstanding common stockholders and $474 million of the cash payment to vested option holders under the Pharmasset stock option plans were accounted for as consideration transferred. The remaining $194 million of cash payment was accounted for as stock-based compensation expense resulting from the accelerated vesting of Pharmasset employee options immediately prior to the acquisition.

The following table summarizes the acquisition date fair values of assets acquired and liabilities assumed, and the consideration transferred (in millions):

Identifiable intangible assets	$	10,738
Cash and cash equivalents		107
Other assets acquired (liabilities assumed), net		(43)
Total identifiable net assets		10,802
Goodwill		56
Total consideration transferred	$	10,858

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Identifiable Intangible Assets

We acquired intangible assets, primarily comprised of the sofosbuvir IPR&D compound, which had an estimated fair value of $10.7 billion as of the date of acquisition. The fair value of the asset was determined using a probability-weighted income approach that discounts expected future cash flows to present value. The estimated net cash flows were discounted using a discount rate of 12% , which is based on the estimated weighted-average cost of capital for companies with profiles similar to that of Pharmasset. This rate was comparable to the estimated internal rate of return for the acquisition and represents the rate that market participants would have used to value the intangible asset. The projected cash flow from sofosbuvir was based on key assumptions such as: estimates of revenues and operating profits related to each project considering its stage of development on the acquisition date; the time and resources needed to complete the development and approval of the product candidate; the life of the potential commercialized product and associated risks, including the inherent difficulties and uncertainties in developing a product candidate such as obtaining marketing approval from the FDA and other regulatory agencies; and risks related to the viability of and potential alternative treatments in any future target markets. Intangible assets related to IPR&D projects are considered to be indefinite-lived assets until the completion or abandonment of the associated R&D efforts. In December 2013, the $10.7 billion purchased IPR&D project for sofosbuvir was completed and reclassified as a finite-lived intangible asset. We are amortizing this asset over its estimated useful life, utilizing the straight-line method.

Goodwill

The $56 million of goodwill represents the excess of the consideration transferred over the fair values of assets acquired and liabilities assumed and is attributable to the synergies expected from combining our R&D operations with Pharmasset's operations. None of the goodwill is expected to be deductible for income tax purposes.

Stock-Based Compensation Expense

The stock-based compensation expense recognized for the accelerated vesting of employee options immediately prior to the acquisition was reported in our Consolidated Statements of Income as follows (in millions):

	Year Ended December 31, 2012
Research and development expense	$ 100
Selling, general and administrative expense	94
Total stock-based compensation expense	$ 194

Other Costs

Other costs incurred in connection with the acquisition include (in millions):

	Year Ended December 31,	
	2012	2011
Transaction costs (e.g. investment advisory, legal and accounting fees)	$ 11	$ 28
Bridge financing costs	7	24
Restructuring costs	15	—
Total other costs	$ 33	$ 52

The following table summarizes these costs by the line item in our Consolidated Statements of Income in which these costs were recognized (in millions):

	Year Ended December 31,	
	2012	2011
Research and development expense	$ 8	$ —
Selling, general and administrative expense	18	28
Interest expense	7	24
Total other costs	$ 33	$ 52

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Pro Forma Information

The following unaudited pro forma information presents the combined results of operations of Gilead and Pharmasset as if the acquisition of Pharmasset had been completed on January 1, 2011, with adjustments to give effect to pro forma events that are directly attributable to the acquisition. The unaudited pro forma results do not reflect any operating efficiencies or potential cost savings which may result from the consolidation of the operations of Gilead and Pharmasset. Accordingly, these unaudited pro forma results are presented for informational purposes only and are not necessarily indicative of what the actual results of operations of the combined company would have been if the acquisition had occurred at the beginning of the period presented, nor are they indicative of future results of operations (in millions):

	Year Ended December 31,	
	2012	2011
Total revenues	$ 9,703	$ 8,385
Net income attributable to Gilead	$ 2,746	$ 2,389

The unaudited pro forma consolidated results include non-recurring pro forma adjustments that assume the acquisition occurred on January 1, 2011. Stock-based compensation expenses of $194 million incurred in 2012 were included in the net income attributable to Gilead for the year ended December 31, 2011 . Other costs of $18 million incurred during the year ended December 31, 2012 were included in the net income attributable to Gilead for the year ended December 31, 2011 .

6. INVENTORIES

Inventories are summarized as follows (in millions):

	December 31,	
	2014	2013
Raw materials	$ 909	$ 1,050
Work in process	500	413
Finished goods	466	593
Total	$ 1,875	$ 2,056
Recognized as:		
Inventories	$ 1,386	$ 1,697
Other long-term assets	489	359
Total	$ 1,875	$ 2,056

Amounts reported as other long-term assets are comprised almost entirely of raw materials as of December 31, 2014 and December 31, 2013. Prior period amounts have been reclassified to conform to the current presentation.

The joint ventures formed by Gilead Sciences, LLC and Bristol-Myers Squibb (BMS) (See Note 9, Collaborative Arrangements), which are included in our Consolidated Financial Statements, held efavirenz active pharmaceutical ingredient in inventory. This efavirenz inventory was purchased from BMS at BMS's estimated net selling price of efavirenz and totaled $806 million as of December 31, 2014 and $1.3 billion as of December 31, 2013 .

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7. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment are summarized as follows (in millions):

	December 31,	
	2014	2013
Property, plant and equipment, net:		
Buildings and improvements (including leasehold improvements)	$ 997	$ 835
Laboratory and manufacturing equipment	327	250
Office and computer equipment	305	258
Construction in progress	411	129
Subtotal	2,040	1,472
Less accumulated depreciation and amortization (including $2 for 2014 and 2013 relating to capitalized leased equipment)	(620)	(502)
Subtotal	1,420	970
Land	254	196
Total	$ 1,674	$ 1,166

8. INTANGIBLE ASSETS AND GOODWILL

Intangible Assets

The following table summarizes the carrying amount of our intangible assets (in millions):

	December 31,	
	2014	2013
Finite-lived intangible assets	$ 10,641	$ 11,326
Indefinite-lived intangible assets	432	574
Total intangible assets	$ 11,073	$ 11,900

Finite-Lived Intangible Assets

The following table summarizes our finite-lived intangible assets (in millions):

	December 31, 2014		December 31, 2013	
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Intangible asset - sofosbuvir	$ 10,720	$ 757	$ 10,720	$ 58
Intangible asset - Ranexa	688	277	688	191
Other	455	188	306	139
Total	$ 11,863	$ 1,222	$ 11,714	$ 388

Upon FDA approval and commercial launch of Sovaldi in December 2013, we reclassified the IPR&D related to sofosbuvir to finite-lived intangible assets. Amortization expense related to finite-lived intangible assets included primarily in cost of goods sold in our Consolidated Statements of Income totaled $818 million in 2014 , $143 million in 2013 and $63 million in 2012 . As of December 31, 2014 , the estimated future amortization expense associated with our finite-lived intangible assets for each of the five succeeding fiscal years is as follows (in millions):

Fiscal Year	Amount
2015	$ 826
2016	832
2017	846
2018	853
2019	741
Total	$ 4,098

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Indefinite-Lived Intangible Assets

In 2013, we completed our acquisition of YM. Of the total $488 million fair value of acquired assets and assumed liabilities for YM, we attributed $363 million to IPR&D related to momelotinib on our Consolidated Balance Sheets. The following table summarizes our indefinite-lived intangible assets (in millions):

	December 31,	
	2014	2013
Indefinite-lived intangible asset - momelotinib (formerly CYT387)	$ 308	363
Indefinite-lived intangible assets - Other	117	266
	425	629
Foreign currency translation adjustment	7	(55)
Total	$ 432	$ 574

Goodwill

The following table summarizes the changes in the carrying amount of goodwill (in millions):

Balance at December 31, 2013	$ 1,169
Foreign currency translation adjustment	3
Balance at December 31, 2014	$ 1,172

9. COLLABORATIVE ARRANGEMENTS

We enter into collaboration arrangements with third parties for the development and commercialization of certain products. Both parties are active participants in the operating activities of the collaboration and are exposed to significant risks and rewards depending on the commercial success of the activities. Collaboration arrangements are assessed at their inception, and at each reporting date, to determine whether we are the primary beneficiary of an entity determined to be a VIE and therefore would be required to consolidate the third party.

For VIEs, we may be required to consolidate an entity if the contractual terms of the arrangement essentially provide us with control over the entity, even if we do not have a majority voting interest. We assess whether we are the primary beneficiary of a VIE based on our power to direct the activities of the VIE that most significantly impact the VIE's economic performance and our obligation to absorb losses or the right to receive benefits from the VIE that could potentially be significant to the VIE. As such, we have consolidated those entities in our consolidated financial statements. As of December 31, 2014, the only material VIE was our joint venture with BMS which is described below.

Bristol-Myers Squibb Company

North America

In 2004, we entered into a collaboration arrangement with BMS to develop and commercialize a single tablet regimen containing our Truvada and BMS's Sustiva (efavirenz) in the United States. This combination was approved for use in the United States in 2006 and is sold under the brand name Atripla. We and BMS structured this collaboration as a joint venture that operates as a limited liability company named Bristol-Myers Squibb & Gilead Sciences, LLC, which we consolidate. We and BMS granted royalty-free sublicenses to the joint venture for the use of our respective company owned technologies and, in return, were granted a license by the joint venture to use any intellectual property that results from the collaboration. In 2006, we and BMS amended the joint venture's collaboration agreement to allow the joint venture to sell Atripla in Canada. The economic interests of the joint venture held by us and BMS (including a share of revenues and out-of-pocket expenses) are based on the portion of the net selling price of Atripla attributable to efavirenz and Truvada. Since the net selling price for Truvada may change over time relative to the net selling price of efavirenz, both our and BMS's respective economic interests in the joint venture may vary annually.

We and BMS shared marketing and sales efforts. Starting in the second quarter of 2011, except for a limited number of activities that will be jointly managed, the parties no longer coordinate detailing and promotional activities in the United States, and the parties reduced their joint promotional efforts since we launched Complera in August 2011 and Stribild in August 2012. The parties will continue to collaborate on activities such as manufacturing, regulatory, compliance and pharmacovigilance. The daily operations of the joint venture are governed by four primary joint committees formed by both BMS and Gilead. We are responsible for accounting, financial reporting, tax reporting, manufacturing and product distribution for the joint venture. Both parties provide their respective bulk active pharmaceutical ingredients to the joint venture at their approximate market

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values. The agreement will continue until terminated by the mutual agreement of the parties. In addition, either party may terminate the other party's participation in the collaboration within 30 days after the launch of at least one generic version of such other party's single agent products (or the double agent products). The terminating party then has the right to continue to sell Atripla and become the continuing party, but will be obligated to pay the terminated party certain royalties for a three-year period following the effective date of the termination.

As of December 31, 2014 and 2013 , the joint venture held efavirenz active pharmaceutical ingredient which it purchased from BMS at BMS's estimated net selling price of efavirenz in the U.S. market. These amounts are included in inventories on our Consolidated Balance Sheets. As of December 31, 2014 , total assets held by the joint venture were $2.1 billion and consisted primarily of cash and cash equivalents of $250 million , accounts receivable of $297 million and inventories of $1.6 billion ; total liabilities were $1.2 billion and consisted primarily of accounts payable of $750 million and other accrued expenses of $408 million . As of December 31, 2013 , total assets held by the joint venture were $2.2 billion and consisted primarily of cash and cash equivalents of $246 million , accounts receivable of $275 million and inventories of $1.7 billion ; total liabilities were $1.3 billion and consisted primarily of accounts payable of $915 million and other accrued expenses of $341 million . These asset and liability amounts do not reflect the impact of intercompany eliminations that are included in our Consolidated Balance Sheets. Although we consolidate the joint venture, the legal structure of the joint venture limits the recourse that its creditors will have over our general credit or assets. Similarly, the assets held in the joint venture can be used only to settle obligations of the joint venture.

Europe

In 2007, Gilead Sciences Ireland Unlimited Company, our wholly-owned subsidiary, formerly known as Gilead Sciences Limited, and BMS entered into a collaboration agreement with BMS which sets forth the terms and conditions under which we and BMS commercialize and distribute Atripla in the European Union, Iceland, Liechtenstein, Norway and Switzerland (collectively, the European Territory). The parties formed a limited liability company which we consolidate, to manufacture Atripla for distribution in the European Territory using efavirenz that it purchases from BMS at BMS's estimated net selling price of efavirenz in the European Territory. We are responsible for manufacturing, product distribution, inventory management and warehousing. Through our local subsidiaries, we have primary responsibility for order fulfillment, collection of receivables, customer relations and handling of sales returns in all the territories where we and BMS promote Atripla. In general, the parties share revenues and out-of-pocket expenses in proportion to the net selling prices of the components of Atripla, Truvada and efavirenz.

Starting in 2012, except for a limited number of activities that will be jointly managed, the parties no longer coordinate detailing and promotional activities in the region. We are responsible for accounting, financial reporting and tax reporting for the collaboration. As of December 31, 2014 and 2013 , efavirenz purchased from BMS at BMS's estimated net selling price of efavirenz in the European Territory is included in inventories on our Consolidated Balance Sheets.

The parties also formed a limited liability company to hold the marketing authorization for Atripla in Europe. We have primary responsibility for regulatory activities. In the major market countries, both parties have agreed to independently continue to use commercially reasonable efforts to promote Atripla.

The agreement will terminate upon the expiration of the last-to-expire patent which affords market exclusivity to Atripla or one of its components in the European Territory. In addition, since December 31, 2013, either party may terminate the agreement for any reason and such termination will be effective two calendar quarters after notice of termination. The non-terminating party has the right to continue to sell Atripla and become the continuing party, but will be obligated to pay the terminating party certain royalties for a three-year period following the effective date of the termination. In the event the continuing party decides not to sell Atripla, the effective date of the termination will be the date Atripla is withdrawn in each country or the date on which a third party assumes distribution of Atripla, whichever is earlier. As of December 31, 2014, neither party had elected to terminate the agreement.

Japan Tobacco Inc.

In 2005, Japan Tobacco Inc. (Japan Tobacco) granted us exclusive rights to develop and commercialize elvitegravir, a novel HIV integrase inhibitor, in all countries of the world, excluding Japan, where Japan Tobacco retained such rights. Under the agreement, we are responsible for seeking regulatory approval in our territories and are required to use diligent efforts to commercialize elvitegravir for the treatment of HIV infection. We bear all costs and expenses associated with such commercialization efforts.

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We received approval of Stribild (an elvitegravir-containing product) from the FDA in August 2012 and from the European Commission in May 2013. We capitalized $20 million related to the milestone incurred in connection with the FDA approval of Stribild and $12 million related to the milestone we incurred in connection with the European Commission approval. Both milestones are being amortized over the useful patent life of elvitegravir, which is approximately 10 years, expiring in 2023.

The agreement and our obligation to pay royalties to Japan Tobacco will terminate on a product-by-product basis as patents providing exclusivity for the product expire or, if later, on the tenth anniversary of commercial launch for such product. We may terminate the agreement for any reason in which case the license granted by Japan Tobacco to us would terminate. Either party may terminate the agreement in response to a material breach by the other party.

Janssen

In 2009, we entered into a license and collaboration agreement with Janssen Sciences Ireland UC (Janssen), formerly Tibotec Pharmaceuticals, to develop and commercialize a fixed-dose combination of our Truvada and Janssen's non-nucleoside reverse transcriptase inhibitor rilpivirine. This combination was approved in the United States and European Union in 2011 and is sold under the brand name Complera in the United States and Eviplera in the European Union. Under this original agreement, Janssen granted us an exclusive license to Complera/Eviplera worldwide excluding certain middle income and developing world countries and Japan.

In 2011 and 2013, we amended the agreement to include distribution of Complera/Eviplera to the rest of the world. In 2014, we amended the agreement to expand the collaboration to include another product containing Janssen’s rilpivirine and our emtricitabine and tenofovir alafenamide (RFTAF). Under the amended agreement, Janssen granted us an exclusive license to Complera/Eviplera and RFTAF worldwide, but retained rights to distribute both combination products in 18 countries including Mexico, Russia and Japan. Neither party is restricted from combining its drugs with any other drug products except those which are similar to the components of Complera/Eviplera and RFTAF.

We are responsible for manufacturing Complera/Eviplera and RFTAF and have the lead role in registration, distribution and commercialization of both products except in the countries where Janssen distributes. Janssen has exercised a right to co-detail the combination product in some of the countries where Gilead is the selling party.

Under the initial agreement, the price of Complera/Eviplera was expected to be the sum of the price of Truvada and the price of rilpivirine purchased separately. The cost of rilpivirine purchased by us from Janssen for Complera/Eviplera was approximately the market price of rilpivirine, less a specified percentage of up to 30% in major markets. The 2014 amendment, effective in 2015, enables the selling party to set the price of the combined products and the parties share revenues based on the ratio of the net selling prices of the party’s component(s), subject to certain restrictions and adjustments. Gilead will continue to retain a specified percentage of Janssen’s share of revenues, up to 30% in major markets.

Either party may terminate the collaboration agreement with respect to a product and a country if the product is withdrawn from the market in such country or with respect to a product in all countries if the other party materially breaches the agreement with respect to a product. The agreement and the parties’ obligation to share revenues will expire on a product-by-product and country-by-country basis as Janssen patents providing exclusivity for the product expire or, if later, on the tenth anniversary of commercial launch for such product. We may terminate the agreement without cause with respect to the countries where we sell the products in which case Janssen has the right to become the selling party for such country if the product has launched but has been on the market for fewer than 10 years.

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10. DEBT AND CREDIT FACILITY

Financing Arrangements

The following table summarizes the carrying amount of our borrowings under various financing arrangements (in millions):

Type of Borrowing	Description	Issue Date	Due Date	Interest Rate	December 31, 2014	December 31, 2013
Convertible Senior	May 2014 Notes	July 2010	May 2014	1.00%	$ —	$ 234
Convertible Senior	May 2016 Notes	July 2010	May 2016	1.625%	483	1,113
Senior Unsecured	April 2021 Notes	March 2011	April 2021	4.50%	995	994
Senior Unsecured	December 2014 Notes	December 2011	December 2014	2.40%	—	750
Senior Unsecured	December 2016 Notes	December 2011	December 2016	3.05%	700	699
Senior Unsecured	December 2021 Notes	December 2011	December 2021	4.40%	1,248	1,248
Senior Unsecured	December 2041 Notes	December 2011	December 2041	5.65%	998	998
Senior Unsecured	April 2019 Notes	March 2014	April 2019	2.05%	499	—
Senior Unsecured	April 2024 Notes	March 2014	April 2024	3.70%	1,747	—
Senior Unsecured	April 2044 Notes	March 2014	April 2044	4.80%	1,747	—
Senior Unsecured	February 2020 Notes	November 2014	February 2020	2.35%	499	—
Senior Unsecured	February 2025 Notes	November 2014	February 2025	3.50%	1,748	—
Senior Unsecured	February 2045 Notes	November 2014	February 2045	4.50%	1,740	—
Credit Facility	Five-Year Revolver	January 2012	January 2017	Variable	—	600
Total debt, net					12,404	6,636
Less current portion					483	2,697
Total long-term debt, net					$ 11,921	$ 3,939

May 2014 and May 2016 Convertible Senior Notes

In July 2010, we issued $1.3 billion of convertible senior notes due in May 2014 (the May 2014 Notes) and $1.3 billion of convertible senior notes due in May 2016 (the May 2016 Notes, and collectively with the May 2014 Notes, the May Notes) in a private placement pursuant to Rule 144A of the Securities Act of 1933, as amended.

The May 2014 Notes and May 2016 Notes were issued at par. The May 2014 Notes bore an annual interest rates of 1.00% and the May 2016 Notes bear an annual interest rate of 1.625% . Debt issuance costs of $35 million were recorded in other long-term assets and are being amortized to interest expense over the contractual terms of the May Notes. The aggregate principal amount of the May Notes sold reflects the full exercise by the initial purchasers of their option to purchase additional notes to cover over-allotments. The initial conversion rate for the May 2014 Notes was 44.3690 shares per $1,000 principal amount (which represented an initial conversion price of approximately $22.54 per share), and the initial conversion rate for the May 2016 Notes is 44.0428 shares per $1,000 principal amount (which represents an initial conversion price of approximately $22.71 per share). The conversion rates are subject to customary anti-dilution adjustments.

The May 2016 Notes may be converted prior to April 1, 2016 only under the following circumstances: 1) during any calendar quarter commencing after September 30, 2010, if the closing price of the common stock for at least 20 trading days (whether or not consecutive) during the period of 30 consecutive trading days ending on the last trading day of the preceding calendar quarter is greater than 130% of the applicable conversion price on each applicable trading day, or 2) during the five business day period after any measurement period of ten consecutive trading days in which, for each trading day of such period, the trading price per $1,000 principal amount of notes was less than 98% of the product of the last reported sale price of our common stock and the applicable conversion rate on such trading day, or 3) upon the occurrence of specified corporate transactions, such as the distribution of certain stock rights, cash amounts, or other assets to all of our shareholders or the occurrence of a change in control. On and after April 1, 2016, in the case of the May 2016 Notes, holders may convert their notes at any time, regardless of the foregoing circumstances. Generally, upon conversion, a holder would receive an amount in cash equal to the lesser of (i) the principal amount of the note or (ii) the conversion value for such note, as measured under the indenture governing the relevant notes. If the conversion value exceeds the principal amount, we may also deliver, at our option, cash or common stock or a combination of cash and common stock for the conversion value in excess of the principal amount.

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During the year ended December 31, 2014 , the May 2014 Notes matured and a portion of the May 2016 Notes were converted. During the year ended December 31, 2014, we repaid $912 million of principal balance related to the May Notes. We also paid $2.5 billion in cash related to the conversion spread of the May Notes, which represents the conversion value in excess of the principal amount, and received $2.5 billion in cash from the convertible note hedges related to the May Notes.

As of December 31, 2014 and 2013, the May 2016 Notes were classified as current given that their conversion criteria were met. As of December 31, 2013, given their maturity date, the May 2014 Notes were classified as current. As a result, the related unamortized discounts of $15 million and $64 million as of December 31, 2014 and 2013, respectively, were classified as an equity component of currently redeemable convertible notes on our Consolidated Balance Sheets.

If the May 2016 Notes are converted in connection with a change in control, we may be required to provide a make whole premium in the form of an increase in the conversion rate, subject to a stated maximum amount. In addition, in the event of a change in control, the holders may require us to purchase all or a portion of their notes at a purchase price equal to 100% of their principal amount, plus accrued and unpaid interest, if any. As of December 31, 2014 , the if-converted value of the May 2016 Notes would exceed the principal amounts of the May 2016 Notes by $1.6 billion .

Concurrent with the issuance of the May Notes, we purchased convertible note hedges in private transactions at a cost of $363 million , which is tax deductible over the life of the notes. We also sold warrants in private transactions to acquire 111 million shares of our common stock and received net proceeds of $155 million from the sale of the warrants. The convertible note hedges and warrants are intended to reduce the potential economic dilution upon future conversions of the May Notes by effectively increasing our conversion price to $28.38 per share for the May 2014 Notes and $30.05 per share for the May 2016 Notes. The net cost of $207 million of the convertible note hedge and warrant transactions was recorded in stockholders' equity on our Consolidated Balance Sheets. In addition, because both of these contracts are classified in stockholders’ equity and are indexed to our common stock, they are not accounted for as derivatives.

The convertible note hedges covered, subject to customary anti-dilution adjustments, 111 million shares of our common stock at strike prices that initially correspond to the initial conversion prices of the May Notes and are subject to adjustments similar to those applicable to the conversion price of the related notes. If the market value per share of our common stock at the time of conversion of the May Notes is above the strike price of the applicable convertible note hedges, we will be entitled to receive from the counterparties in the transactions shares of our common stock or, to the extent we have made a corresponding election with respect to the related convertible notes, cash or a combination of cash and shares of our common stock, at our option, for the excess of the market value of the common stock over the strike price of the convertible note hedges. The convertible note hedges will terminate upon the maturity of the May Notes or when none of the May Notes remain outstanding due to conversion or otherwise. There were 111 million shares of our common stock underlying the warrants, subject to customary anti-dilution adjustments. The warrants had a strike price of $28.38 per share (for the warrants that expired in 2014) and $30.05 per share (for the warrants expiring in 2016). Both the warrants that expired in 2014 and the warrants that will expire in 2016 had terms whereby they were or will be exercisable only on their respective expiration dates. If the market value of our common stock at the time of the exercise of the applicable warrants exceeds their respective strike prices, we will be required to net settle in cash or shares of our common stock, at our option, with the respective counterparties for the value of the warrants in excess of the warrant strike prices.

During the year ended December 31, 2014, we exercised our option to settle in cash the warrants expiring in 2014 (the 2014 Warrants) related to the May 2014 Notes. As result, we paid $4.1 billion to settle the 2014 Warrants as the market value of our common stock at the time of the exercise of the 2014 Warrants exceeded their strike price. There were 56 million shares of our common stock underlying the 2014 Warrants, which had a strike price of $28.38 per share and expired during the 40 trading-day period commencing August 1, 2014 and ending on September 26, 2014. Because the 2014 Warrants could have been settled, at our option, in cash or shares of our common stock, and the related contracts met all of the applicable criteria for equity classification, the settlement was recorded as a reduction of additional paid-in capital in our Consolidated Balance Sheets.

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Under current accounting guidance, we bifurcated the conversion option of the May Notes from the debt instrument, classified the conversion option in equity and are accreting the resulting debt discount as interest expense over the contractual terms of the May Notes. The following table summarizes information about the equity and liability components of the May Notes (in millions):

	Carrying Value of Equity Component		Net Carrying Amount of Liability Component		Unamortized Discount of Liability Component	
	December 31,		December 31,		December 31,	
	2014	2013	2014	2013	2014	2013
May 2014 Notes	$ —	$ 20	$ —	$ 234	$ —	$ (2)
May 2016 Notes	61	143	483	1,113	(15)	(62)
Total May Notes	$ 61	$ 163	$ 483	$ 1,347	$ (15)	$ (64)

We recognized $38 million in 2014 , $107 million in 2013 and $87 million in 2012 in interest expense related to the contractual coupon rates and amortization of the debt discount and issuance costs for the May Notes. The effective interest rates on the liability components of the May 2014 Notes and May 2016 Notes were 3.50% and 4.00% , respectively.

We used the net proceeds for general corporate purposes, which include the repayment of existing indebtedness and to repurchase shares of our common stock.

April 2021 Senior Unsecured Notes

In March 2011, we issued senior unsecured notes due in April 2021 (the April 2021 Notes) in a registered offering for an aggregate principal amount of $1.0 billion . The April 2021 Notes will pay interest at a fixed annual rate of 4.50% . Debt issuance costs incurred in connection with the issuance of this debt totaled approximately $6 million and are being amortized to interest expense over the contractual term of the April 2021 Notes. We recognized $46 million in 2014 , 2013 and 2012 in interest expense related to the contractual coupon rates and amortization of the debt discount and issuance costs for the April 2021 Notes.

The April 2021 Notes may be redeemed at our option at any time or from time to time, at a redemption price equal to the greater of (i) 100% of the principal amount of the notes to be redeemed and (ii) the sum, as determined by an independent investment banker, of the present values of the remaining scheduled payments of principal and interest on the notes to be redeemed (exclusive of interest accrued to the date of redemption) discounted to the redemption date on a semiannual basis at the Treasury Rate plus 20 basis points, plus, in each case, accrued and unpaid interest on the notes to be redeemed to the date of redemption. At any time on or after January 1, 2021, we may redeem the April 2021 Notes, in whole or in part, at 100% of the principal amount of the notes to be redeemed, plus accrued and unpaid interest to the date of redemption. In addition, in the event of the occurrence of both a change in control and a downgrade in the rating of the April 2021 Notes below investment grade by Standard & Poor's Ratings Services and Moody's Investors Service, Inc., the holders may require us to purchase all or a portion of their notes at a price equal to 101% of their principal amount, plus accrued and unpaid interest.

We used the net proceeds for general corporate purposes, which include the repayment of existing indebtedness and to repurchase shares of our common stock.

December 2014, 2016, 2021 and 2041 Senior Unsecured Notes

In December 2011, we issued senior unsecured notes due in December 2014, December 2016, December 2021 and December 2041 (the December 2014 Notes, the December 2016 Notes, the December 2021 Notes and the December 2041 Notes, respectively, and collectively, the December Notes) in a registered offering for $750 million , $700 million , $1.3 billion and $1.0 billion , respectively, for an aggregate principal amount of $3.7 billion . The December 2014 Notes paid interest at a fixed annual rate of 2.40% and matured in December 2014, and the remaining notes will mature in December 2016, 2021 and 2041, respectively, and pay interest at fixed annual rates of 3.05% , 4.40% and 5.65% , respectively. Debt issuance costs incurred in connection with the issuance of this debt totaled approximately $20 million and are being amortized to interest expense over the contractual term of each of the respective notes. We recognized $153 million in 2014 , $155 million in 2013 and $155 million in 2012 in interest expense related to the contractual coupon rates and amortization of the debt discount and issuance costs for the December Notes.

The outstanding December Notes may be redeemed at our option at any time or from time to time, at a redemption price equal to the greater of (i) 100% of the principal amount of the notes to be redeemed and (ii) the sum, as determined by an Independent Investment Banker, of the present values of the remaining scheduled payments of principal and interest on the notes to be redeemed (exclusive of interest accrued to the date of redemption) discounted to the redemption date on a

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semiannual basis at the Treasury Rate plus 35 basis points in the case of the December 2016 Notes and 40 basis points in the case of the December 2021 Notes and December 2041 Notes plus, in each case, accrued and unpaid interest on the notes to be redeemed to the date of redemption.

At any time on or after the date that is three months prior to the maturity date of the December 2021 Notes, we may redeem the December 2021 Notes, in whole or in part, at 100% of the principal amount of the notes to be redeemed, plus accrued and unpaid interest to the date of redemption. At any time on or after the date that is six months prior to the maturity date of the December 2041 Notes, we may redeem the December 2041 Notes, in whole or in part, at 100% of the principal amount of the notes to be redeemed, plus accrued and unpaid interest to the date of redemption.

In the event of the occurrence of a change in control and a downgrade in the rating of a series of the outstanding December Notes below investment grade by Standard & Poor's Ratings Services and Moody's Investors Service, Inc., the remaining holders of such series may require us to purchase all or a portion of their notes of such series at a price equal to 101% of the aggregate principal amount of the notes repurchased, plus accrued and unpaid interest to the date of repurchase.

We used the net proceeds from the December Notes to fund the acquisition of Pharmasset which was completed in January 2012 (See Note 5).

April 2019, 2024 and 2044 Senior Unsecured Notes

In March 2014, we issued senior unsecured notes due in April 2019, April 2024 and April 2044 (the April 2019 Notes, the April 2024 Notes and the April 2044 Notes, respectively, and collectively, the April Notes) in a registered offering for a total aggregate principal amount of $4.0 billion . We issued the April 2019 Notes for $500 million that pay interest at a fixed annual rate of 2.05% , the April 2024 Notes for $1.8 billion that pay interest at a fixed annual rate of 3.70% and the April 2044 Notes for $1.8 billion that pay interest at a fixed annual rate of 4.80% . Debt issuance costs incurred in connection with the issuance of this debt totaled approximately $28 million and are being amortized to interest expense over the contractual term of each of the respective notes. We recognized $132 million in interest expense in 2014 related to the contractual coupon rates and amortization of the debt discount and issuance costs for the April Notes.

The April Notes may be redeemed at our option at any time or from time to time, at a redemption price equal to the greater of (i) 100% of the principal amount of the notes to be redeemed and (ii) the sum, as determined by an Independent Investment Banker, of the present values of the remaining scheduled payments of principal and interest on the notes to be redeemed (exclusive of interest accrued to the date of redemption), discounted to the redemption date on a semiannual basis at the Treasury Rate plus 10 basis points in the case of the April 2019 Notes, 15 basis points in the case of the April 2024 Notes and 20 basis points in the case of the April 2044 Notes plus, in each case, accrued and unpaid interest on the notes to be redeemed to the date of redemption.

At any time on or after the date that is three months prior to the maturity date of the April 2024 Notes, we may redeem the April 2024 Notes, in whole or in part, at 100% of the principal amount of the notes to be redeemed, plus accrued and unpaid interest to the date of redemption. At any time on or after the date that is six months prior to the maturity date of the April 2044 Notes, we may redeem the April 2044 Notes, in whole or in part, at 100% of the principal amount of the notes to be redeemed, plus accrued and unpaid interest to the date of redemption.

In the event of the occurrence of both a change in control and a downgrade in the rating of the April Notes below investment grade by Standard & Poor's Ratings Services and Moody's Investors Service, Inc., the holders may require us to purchase all or a portion of their notes at a price equal to 101% of the aggregate principal amount of the notes repurchased, plus accrued and unpaid interest to the date of repurchase.

We used the net proceeds for general corporate purposes, which include the repayment of existing indebtedness and repurchases of our common stock.

February 2020, 2025 and 2045 Senior Unsecured Notes

In November 2014, we issued senior unsecured notes due in February 2020, February 2025 and February 2045 (the February 2020 Notes, the February 2025 Notes and the February 2045 Notes, respectively, and collectively, the February Notes) in a registered offering for $500 million , $1.8 billion and $1.8 billion , respectively for an aggregate principal amount of $4.0 billion . The February 2020 Notes, February 2025 Notes and February 2045 Notes will pay interest at fixed annual rates of 2.35% , 3.50% and 4.50% , respectively. Debt issuance costs incurred in connection with the issuance of this debt totaled approximately $22 million and are being amortized to interest expense over the contractual term of each of the respective notes. We recognized $19 million in 2014 in interest expense related to the contractual coupon rates and amortization of the debt discount and issuance costs for the February Notes.

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The February Notes may be redeemed at our option at any time or from time to time, at a redemption price equal to the greater of (i) 100% of the principal amount of the notes to be redeemed and (ii) the sum, as determined by an independent investment banker, of the present values of the remaining scheduled payments of principal and interest on the notes to be redeemed (exclusive of interest accrued to the date of redemption) discounted to the redemption date on a semiannual basis at the Treasury Rate plus 12.5 basis points in the case of the February 2020 Notes, 20 basis points for the February 2025 Notes and 25 basis points for the February 2045 Notes. In each case, accrued and unpaid interest will also be redeemed to the date of redemption.

At any time on or after the date that is three months prior to the maturity date of the February 2025 Notes, we may redeem the February 2025 Notes, in whole or in part, at 100% of the principal amount of the notes to be redeemed, plus accrued and unpaid interest to the date of redemption.

At any time on or after the date that is six months prior to the maturity date of the February 2045 Notes, we may redeem the February 2045 Notes, in whole or in part, at 100% of the principal amount of the notes to be redeemed, plus accrued and unpaid interest to the date of redemption.

In the event of the occurrence of a change in control and a downgrade in the rating of the February Notes below investment grade by Standard & Poor's Ratings Services and Moody's Investors Service, Inc., the holders may require us to purchase all or a portion of their February Notes at a price equal to 101% of the aggregate principal amount of the notes repurchased, plus accrued and unpaid interest to the date of repurchase.

We will use the net proceeds for general corporate purposes, which include the repayment of existing indebtedness and repurchases of our common stock.

Credit Facilities

In January 2012, in conjunction with our acquisition of Pharmasset, we entered into a five -year $1.3 billion revolving credit facility credit agreement (the Five-Year Revolving Credit Agreement), a $750 million short-term revolving credit facility credit agreement (the Short-Term Revolving Credit Agreement) and a $1.0 billion term loan facility (the Term Loan Credit Agreement). We borrowed $750 million under the Five-Year Revolving Credit Agreement, $400 million under the Short-Term Revolving Credit Agreement and $1.0 billion under the Term Loan Credit Agreement, upon the close of the acquisition. In 2012, we fully repaid the outstanding debt under the Term Loan Credit Agreement and the Short-Term Revolving Credit Agreement, at which time both agreements terminated. During 2013, we repaid $150 million under the Five-Year Revolving Credit Agreement. During 2014, we repaid the remaining balance of $600 million that was outstanding under the Five-Year Revolving Credit Agreement.

The Five-Year Revolving Credit Agreement contains customary representations, warranties, affirmative, negative and financial maintenance covenants and events of default. The loan bears interest at either (i) the Eurodollar Rate plus the Applicable Margin or (ii) the Base Rate plus the Applicable Margin, each as defined in the credit agreement. We may reduce the commitments and may prepay the loan in whole or in part at any time without premium or penalty. We are required to comply with certain covenants under the credit agreement and notes indentures and as of December 31, 2014 , we were not in violation with any covenants.

The Five-Year Revolving Credit Agreement was inclusive of a $30 million swing line loan sub-facility and a $25 million letter of credit sub-facility. The Five-Year Revolving Credit Agreement will terminate and all amounts owed under the agreement shall be due and payable in January 2017.

Contractual Maturities of Financing Obligations

Based on the contractual due dates, the aggregate maturities of financing obligations due subsequent to December 31, 2014 , are as follows (in millions):

Maturity Date	Amount
2015	$ —
2016	1,199
2017	—
2018	—
2019	500
Total	$ 1,699

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11. COMMITMENTS AND CONTINGENCIES

Lease Arrangements

We have entered into various long-term non-cancelable operating leases for equipment and facilities. We lease facilities in Foster City, Fremont, La Verne, Palo Alto, Rancho Cucamonga, and San Dimas, California; Branford, Connecticut; and Seattle, Washington; the Dublin and Cork areas of Ireland and the London area of the United Kingdom; and Dubai, United Arab Emirates. We also have operating leases for sales, marketing and administrative facilities in Europe, Canada, South America and Asia-Pacific. Our leases expire on various dates between 2015 and 2030, with many of our leases containing options to renew. Certain facility leases also contain rent escalation clauses. Our most significant rent escalation clause is in a lease related to a facility in Seattle, Washington, which expires in 2020 and has a 10-year term. The lease provides us with three consecutive rights to extend the term of the lease through 2035 and contains an annual three percent rent escalation clause. The lease also requires us to pay additional amounts for operating expenses and maintenance. We also have leases for four corporate aircraft, with varying terms, with renewal options upon expiration of the initial lease terms.

Lease expense under our operating leases was approximately $66 million in 2014 , $54 million in 2013 and $54 million in 2012 . Aggregate non-cancelable future minimum rental payments under operating leases are as follows (in millions):

2015	$ 58
2016	53
2017	49
2018	36
2019	33
Thereafter	73
Total	$ 302

Legal Proceedings

We are a party to various legal actions. The most significant of these are described below. It is not possible to determine the outcome of these matters, and we cannot reasonably estimate the maximum potential exposure or the range of possible loss.

Litigation Related to Sofosbuvir

In January 2012, we acquired Pharmasset. Through the acquisition, we acquired sofosbuvir, a nucleotide analog that acts to inhibit the replication of the HCV. In December 2013, we received FDA approval of sofosbuvir, now known commercially as Sovaldi. In October 2014, we also received approval of the fixed-dose combination of ledipasvir and sofosbuvir, now known commercially as Harvoni. We own patents and patent applications that claim sofosbuvir (Sovaldi) as a chemical entity and its metabolites and the fixed-dose combination of ledipasvir and sofosbuvir (Harvoni). Third parties may have, or may obtain rights to, patents that allegedly could be used to prevent or attempt to prevent us from commercializing Sovaldi or Harvoni. For example, we are aware of patents and patent applications owned by other parties that may be alleged by such parties to cover the use of Sovaldi and Harvoni. We cannot predict the ultimate outcome of intellectual property claims related to Sovaldi or Harvoni, and we have spent, and will continue to spend, significant resources defending against these claims. If these parties successfully obtain valid and enforceable patents, and successfully prove infringement of those patents by Sovaldi and/or Harvoni, we could be prevented from selling sofosbuvir unless we were able to obtain a license under such patents. Such a license may not be available on commercially-reasonable terms or at all. We cannot predict the ultimate outcome of the intellectual property claims related to sofosbuvir and may spend significant resources enforcing and defending our patents. Any range of loss cannot be estimated at this time.

Current legal proceedings of significance regarding sofosbuvir include:

Arbitration with F. Hoffman-La Roche Ltd and Hoffman-La Roche Inc. (collectively, Roche)

Gilead (as successor to Pharmasset) is a party to a collaboration agreement with Roche. The agreement granted Roche rights to develop PSI-6130, a cytidine analog, and its prodrugs, for the treatment of HCV infection. The collaborative research efforts under the agreement ended in 2006. In March 2013, Roche served an arbitration against us and Pharmasset, predecessor to Gilead Pharmasset LLC. In the arbitration demand, Roche asserted that it had an exclusive license to sofosbuvir pursuant to the collaboration agreement because sofosbuvir, a prodrug of a uridine analog, is allegedly a prodrug of PSI-6130, a cytidine analog. Roche further claimed that, because it had exclusive rights to sofosbuvir, it also had an exclusive license to a patent covering sofosbuvir, and that we infringed that patent by selling and offering for sale products containing sofosbuvir. Gilead and Gilead Pharmasset LLC filed their response to Roche's arbitration demand in April 2013. The arbitration hearing was held in June 2014. In August 2014, the arbitration panel determined that Roche failed to establish any of their claims and ruled in our favor. As a result, Roche is not entitled to any damages or other relief.

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Interference Proceedings and Litigation with Idenix Pharmaceuticals, Inc.

In February 2012, we received notice that the U.S. Patent and Trademark Office (USPTO) had declared Interference No. 105,871 (First Idenix Interference) between our U.S. Patent No. 7,429,572 (the ‘572 patent) and Idenix's pending U.S. Patent Application No. 12/131,868. An interference is an administrative proceeding before the USPTO designed to determine who was the first to invent the subject matter claimed by both parties. Our patent covers metabolites of sofosbuvir. Idenix is attempting to patent a class of compounds, including these metabolites. The purpose of the First Idenix Interference was to determine who was first to invent these compounds and therefore who is entitled to the patent claiming these compounds. In March 2013, the USPTO Patent Trial and Appeal Board (the Board) determined that Idenix is not entitled to the benefit of any of its early application filing dates because none of those patent applications, including the application granted as Idenix’s U.S. Patent No. 7,608,600 (the ‘600 patent), taught how to make the compounds in dispute. The Board also determined that because we are entitled to the filing date of our earliest application, we were first to file the patent application on the compounds in dispute, and we were therefore the “senior party” in the First Idenix Interference. On January 29, 2014, the Board determined that Pharmasset and not Idenix was the first to invent the compounds in dispute and accordingly Gilead prevailed in the First Idenix Interference. In its decision, the Board held that Idenix failed to prove that it was first to conceive of any of the compounds in dispute. Specifically, Idenix failed to prove that the Idenix inventors had identified the structure, a method of making and a use for any of the disputed compounds. The Board went on to conclude that Idenix failed to work diligently toward making and testing the compounds in dispute during the relevant time period. Idenix has appealed the Board’s decisions to the U.S. District Court for the District of Delaware.

In December 2013, after receiving our request to do so, the USPTO declared Interference No. 105,981 (Second Idenix Interference) between our pending U.S. Patent Application No. 11/854,218 and the ‘600 patent. The ‘600 patent includes claims directed to methods of treating HCV with nucleoside compounds similar to those which were involved in the First Idenix Interference. The Second Idenix Interference will determine who was first to invent the claimed methods of treating HCV. On January 16, 2015 the Board issued a decision in favor of Gilead in the first phase of the Second Idenix Interference. The Board decided that we were first to file the patent application on the disputed methods of treating HCV, designated Gilead as the senior party in the Second Idenix Interference, and invalidated the patent claims of the Idenix ‘600 patent that are involved in the Second Idenix Interference. As the senior party, we are presumed to be the first to have invented the disputed methods of treating HCV. Because Idenix failed to teach how to make and use the invention in its ‘600 patent, the Board invalidated the Idenix claims involved in the Second Idenix Interference for lack of enablement. The Board has also placed Idenix under an Order to Show Cause requiring Idenix to explain why judgment should not be entered against it in the Second Idenix Interference based upon the decision by the Board in the First Idenix Interference. The decision in the Second Idenix Interference is consistent with the Board’s earlier rulings in March 2013 and January 2014 in the First Idenix Interference in which Gilead was declared the senior party and the first to invent certain 2’-fluoro, methyl nucleoside compounds. These compounds are relevant to the methods of treating HCV at issue in the Second Idenix Interference.

We believe that the Idenix claims involved in the First and Second Idenix Interferences, and similar U.S. and foreign patents claiming the same compounds, metabolites and uses thereof, are invalid. As a result, we filed an Impeachment Action in the Federal Court of Canada to invalidate Idenix Canadian Patent No. 2,490,191 (the ‘191 patent), which is the Canadian patent that corresponds to the ‘600 patent and the Idenix patent application that was the subject of the First Idenix Interference. Idenix has asserted that the commercialization of Sovaldi in Canada will infringe its ‘191 patent and that our Canadian Patent No. 2,527,657, corresponding to the ‘572 patent involved in the First Idenix Interference, is invalid. A trial on these issues commenced in January 2015.

We filed a similar legal action in Norway in the Oslo District Court seeking to invalidate Idenix's Norwegian patent corresponding to the ‘600 patent. In September 2013, Idenix filed an invalidation action in the Norwegian proceedings against our Norwegian Patent No. 333700 patent, which corresponds to the ‘572 patent. On March 21, 2014, the Norwegian court found all claims in the Idenix Norwegian patent to be invalid and upheld the validity of all claims in the challenged Gilead patent. On April 30, 2014, Idenix appealed the March 21, 2014 decision to the Norwegian Court of Appeal. Idenix’s obligation to pay our attorneys’ fees will be stayed during the pendency of the appeal. The appeal from the March 2014 decision is scheduled to commence in February 2016.

In January 2013, we filed a legal action in the Federal Court of Australia seeking to invalidate Idenix’s Australian patent corresponding to the ‘600 patent. In April 2013, Idenix asserted that the commercialization of Sovaldi in Australia will infringe the Australian patent corresponding to the ‘600 patent. A trial on these issues is scheduled to commence in September 2015 in Sydney. On March 12, 2014 the European Patent Office (EPO) granted Idenix European Patent No. 1 523 489 (the ‘489 patent), which corresponds to the ‘600 patent. The same day that the ‘489 patent granted, we filed an opposition with the EPO seeking to revoke the ‘489 patent. Also on that day, Idenix initiated infringement proceedings against Gilead in the United Kingdom (UK), Germany and France alleging that the commercialization of Sovaldi in those countries would infringe the respective national counterparts of the ‘489 patent. In the United Kingdom, a trial was held in October 2014 to determine the issues of

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infringement and validity of the Idenix UK patent. In December 2014, the High Court of Justice of England and Wales (UK Court) invalidated all claims of the ‘489 patent on multiple grounds. Specifically, the UK Court held that the ‘489 patent lacked novelty over our earlier filed patent application teaching some of the same compounds, the ’489 patent lacked an inventive step because it did not add anything to the knowledge existing at the time and the disclosure in the Idenix’s patent application was insufficient because it did not teach how to make the compounds or show which of the claimed compounds would have activity against viruses like the hepatitis C virus. The UK Court granted Idenix permission to appeal the December 1, 2014 judgment. On February 3, 2015, the German court in Düsseldorf held a hearing to determine the issue of infringement of the Idenix German patent. We do not have a trial date for the French lawsuit.

Idenix has not been awarded patents corresponding to the ‘600 patent in Japan or China. In the event such patents issue, we expect to challenge them in proceedings similar to those we invoked in other countries.

In December 2013, Idenix, Universita Degli Studi di Cagliari (UDSG), Centre National de la Recherche Scientifique and L’Université Montpellier II sued us in U.S. District Court for the District of Delaware alleging that the commercialization of sofosbuvir will infringe the ‘600 patent and that an interference exists between the ‘600 patent and our U.S. Patent No. 8,415,322. Also in December 2013, Idenix and UDSG sued us in the U.S. District Court for the District of Massachusetts alleging that the commercialization of sofosbuvir will infringe U.S. Patent Nos. 6,914,054 and 7,608,597. On June 30, 2014, the court in Massachusetts granted our request and transferred the Massachusetts litigation to the U.S. District Court for the District of Delaware. We believe that Idenix’s patents are invalid and would not be infringed by our commercialization of sofosbuvir and that we have the sole right to commercialize sofosbuvir. The district court has set trial dates in October 2016 and December 2016 for resolution of these issues. A decision by the district court can be appealed by either party to the U.S. Court of Appeals for the Federal Circuit (CAFC).

Idenix was acquired by Merck in August 2014. While the acquisition does not change our view of the lack of merit in the claims made by Idenix, Merck has greater resources than Idenix and may therefore choose to fund the litigation at higher levels than Idenix.

Litigation with Merck & Co., Inc.

In August 2013, Merck contacted us requesting that we pay royalties on the sales of sofosbuvir and obtain a license to U.S. Patent Nos. 7,105,499 and 8,481,712, which it co-owns with Isis Pharmaceuticals, Inc. We believe that Merck’s patents are invalid and are not infringed by our commercialization of sofosbuvir and that we have the sole right to commercialize sofosbuvir. In August 2013, we filed a lawsuit in the U.S. District Court for the Northern District of California seeking a declaratory judgment that the Merck patents are invalid and not infringed. Merck’s U.S. Patent Nos. 7,105,499 and 8,481,712 cover compounds which do not include, but may relate to, sofosbuvir. During patent prosecution, Merck amended its patent application in an attempt to cover compounds related to sofosbuvir with the apparent goal of ultimately extracting royalty payments for sofosbuvir’s commercialization, or eliminating competition by excluding it from the market. If the court determines that Merck’s patents are valid and that we have infringed those claims, we may be required to obtain a license from and pay royalties to Merck to commercialize sofosbuvir. Either party can appeal a decision by the District Court to the CAFC. The court has set a trial date of March 7, 2016 for this lawsuit.

Litigation with AbbVie, Inc. (AbbVie)

AbbVie has obtained U.S. Patent Nos. 8,466,159, 8,492,386, 8,680,106, 8,685,984, and 8,809,265 (AbbVie Patents) which purport to cover the use of a combination of ledipasvir/sofosbuvir (or Harvoni) for the treatment of HCV. Gilead is aware that AbbVie has pending patent applications in the United States and other countries. We own published and pending patent applications directed to the use of combinations for the treatment of HCV, and, specifically, to the combination of ledipasvir and sofosbuvir. Certain of our applications were filed before the AbbVie Patents. For this reason and others, we believe the AbbVie Patents are invalid.

Accordingly, in December 2013, we filed a lawsuit in the U.S. District Court for the District of Delaware seeking declaratory judgment that the AbbVie Patents are invalid and unenforceable, as well as other relief. We believe that Abbott Laboratories, Inc. and AbbVie conspired to eliminate competition in the HCV market by falsely representing to the USPTO that they, and not Gilead, invented methods of treating HCV using a combination of ledipasvir/sofosbuvir. In February and March 2014, AbbVie responded to our lawsuit by filing two lawsuits also in the U.S. District Court for the District of Delaware alleging that our fixed-dose combination of ledipasvir/sofosbuvir will infringe its patents. All of those lawsuits have been consolidated into a single action. In the United States, either party can appeal a decision by the District Court to the CAFC. The AbbVie Patents have not blocked or delayed the commercialization of our combination product in the United States or Europe. We do not expect any other foreign patents to block or delay the commercialization around the world. If a court determines that

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the AbbVie Patents are valid and that we have infringed those claims, we may be required to obtain a license from and pay royalties to AbbVie to commercialize sofosbuvir combination products.

Litigation with Generic Manufacturers

As part of the approval process for some of our products, the FDA granted us a New Chemical Entity (NCE) exclusivity period during which other manufacturers' applications for approval of generic versions of our product will not be approved. Generic manufacturers may challenge the patents protecting products that have been granted NCE exclusivity one year prior to the end of the NCE exclusivity period. Generic manufacturers have sought and may continue to seek FDA approval for a similar or identical drug through an abbreviated new drug application (ANDA), the application form typically used by manufacturers seeking approval of a generic drug. The sale of generic versions of our products earlier than their patent expiration would have a significant negative effect on our revenues and results of operations.

Current legal proceedings of significance with some of our generic manufacturers include:

Mylan Inc. (Mylan)

In April 2014, we received notice that Mylan submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Truvada. In the notice, Mylan alleges that two of the patents associated with emtricitabine and one of our patents associated with the fixed-dose combination of emtricitabine with tenofovir disoproxil fumarate are invalid, unenforceable and/or will not be infringed by Mylan's manufacture, use or sale of a generic version of Truvada. In June 2014, we filed a lawsuit against Mylan in U.S. District Court for the Northern District of West Virginia for infringement of our patents. In June 2014, we received notice that Mylan Inc. submitted petitions for Inter Partes Review (IPR) to the Board alleging that four patents associated with tenofovir disoproxil fumarate are invalid. We opposed Mylan’s petitions. In December 2014, the USPTO Patent Trial and Appeal Board (PTAB) issued decisions denying each of Mylan’s petitions for IPR against the tenofovir disoproxil fumarate-associated patents on the grounds that Mylan had not established a reasonable likelihood of success that it would prevail in its challenge to each of these patents. Mylan has requested a rehearing on the basis that it believes the PTAB decision is wrong.

Apotex Corp. (Apotex)

In June 2014, we received notice that Apotex submitted an ANDS to the Canadian Minister of Health requesting permission to manufacture and market a generic fixed-dose combination of emtricitabine and tenofovir disoproxil fumarate and a separate ANDS requesting permission to manufacture and market a generic version of Viread. In the notice, Apotex alleges that three of the patents associated with Truvada and two of the patents associated with Viread are invalid, unenforceable and/or will not be infringed by Apotex's manufacture, use or sale of a generic version of Truvada or Viread. In August 2014, we filed a lawsuit against Apotex in the Federal Court of Canada seeking an order of prohibition against approval of this ANDS.

Teva Pharmaceuticals (Teva)

In 2011 and 2012, we received notice that Teva submitted ANDSs to the Canadian Minister of Health requesting permission to manufacture and market a generic fixed-dose combination of our Atripla, Truvada and Viread. Teva filed an Impeachment Action in the Federal Court of Canada seeking invalidation of certain of our patents associated with Atripla, Truvada and Viread. In December 2013, the court issued our requested order prohibiting the Canadian Minister of Health from issuing a Notice of Compliance for Teva’s generic versions of our Viread, Truvada and Atripla products until expiry of our patent in July 2017. Teva has appealed that decision. That decision did not rule on the validity of the patents and accordingly the only issue on appeal is whether the Minister of Health should be prohibited from issuing the Notices of Compliance for Teva’s products. Separately, the court will determine the validity of the patents in the pending Impeachment Action. A trial in the Impeachment Action is scheduled for September 2016. If Teva is successful in invalidating our patents, Teva may be able to launch generic versions of our Viread, Truvada and Atripla products in Canada prior to the expiry of our patents.

Department of Justice Investigation

In June 2011, we received a subpoena from the U.S. Attorney's Office for the Northern District of California requesting documents related to the manufacture, and related quality and distribution practices, of Complera, Atripla, Truvada, Viread, Emtriva, Hepsera and Letairis. We cooperated with the government’s inquiry. In April 2014, the United States Department of Justice informed us that, following an investigation, it declined to intervene in a False Claims Act lawsuit filed by two former employees. In April 2014, the former employees served a First Amended Complaint. In January 2015, the federal district court issued an order granting in its entirety, without prejudice, our motion to dismiss the First Amended Complaint. In February 2015, the former employees served a Second Amended Complaint. We will move to dismiss the Second Amended Complaint.

Other Matters

We are a party to various legal actions that arose in the ordinary course of our business. We do not believe that these other legal actions will have a material adverse impact on our consolidated business, financial position or results of operations.

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Other Commitments

In the normal course of business, we enter into various firm purchase commitments primarily related to active pharmaceutical ingredients and certain inventory related items. As of December 31, 2014 , these commitments for the next five years were approximately $2.0 billion in 2015, $139 million in 2016, $136 million in 2017, $69 million in 2018 and $187 million in 2019. The amounts related to active pharmaceutical ingredients represent minimum purchase requirements. Actual payments for the purchases related to these active pharmaceutical ingredients were $1.8 billion in 2014 , $2.1 billion in 2013 and $1.9 billion in 2012 .

12. STOCKHOLDERS' EQUITY

Stock Repurchase Programs

In January 2011, our Board authorized a three -year, $5.0 billion stock repurchase program (2011 Program). Under the 2011 Program we spent a total of $667 million to repurchase and retire 23 million shares of our common stock at an average purchase price of $28.93 per share in 2012; $582 million to repurchase and retire 10 million shares of our common stock at an average purchase price of $60.78 per share in 2013 and $3.3 billion to repurchase and retire 40 million shares of our common stock at an average purchase price of $83.75 per share in 2014. During the third quarter of 2014, we completed the 2011 Program.

In May 2014, our Board of Directors authorized a new stock repurchase program (2014 Program) of up to $5.0 billion of our common stock. Under the 2014 Program we spent a total of $2.0 billion to repurchase and retire 19 million shares of our common stock at an average purchase price of $103.87 per share in 2014. As of December 31, 2014 , the remaining authorized amount of stock repurchases that may be made under the 2014 Program was $3.0 billion .

During 2014, we spent $5.3 billion to repurchase 59 million shares of our common stock in total at an average price of $90.29 .

We use the par value method of accounting for our stock repurchases. Under the par value method, common stock is first charged with the par value of the shares involved. The excess of the cost of shares acquired over the par value is allocated to additional paid-in capital (APIC) based on an estimated average sales price per issued share with the excess amounts charged to retained earnings.

In addition to repurchases from our stock repurchase program, we repurchased shares of common stock withheld by us from employee restricted stock awards to satisfy our applicable tax withholding obligations. The following table summarizes the reduction of common stock and APIC and the charge to retained earnings as a result of our stock repurchases (in millions):

	Year ended December 31,		
	2014	2013	2012
Reduction of common stock and APIC	$ 133	$ 14	$ 41
Charge to retained earnings	$ 5,475	$ 674	$ 664

Preferred Stock

We have 5 million shares of authorized preferred stock issuable in series. Our Board is authorized to determine the designation, powers, preferences and rights of any such series. There was no preferred stock outstanding as of December 31, 2014 and 2013 .

Rights Plan

In September 2012, we terminated our Rights Plan which provided for the distribution of a preferred stock purchase right as a dividend for each share of our common stock.

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Accumulated Other Comprehensive Income

The following table summarizes the changes in accumulated OCI by component, net of tax (in millions):

	Foreign Currency Items	Unrealized Gains and Losses on Available-for-Sale Securities	Unrealized Gains and Losses on Cash Flow Hedges	Total
Balance at December 31, 2012	$ (1)	$ 7	$ (52)	$ (46)
Other comprehensive income (loss) before reclassifications	(44)	5	(60)	(99)
Amounts reclassified from accumulated other comprehensive income	—	—	21	21
Net current period other comprehensive income (loss)	(44)	5	(39)	(78)
Balance at December 31, 2013	(45)	12	(91)	(124)
Other comprehensive income (loss) before reclassifications	(9)	—	430	421
Amounts reclassified from accumulated other comprehensive income	—	—	4	4
Net current period other comprehensive income (loss)	(9)	—	434	425
Balance at December 31, 2014	$ (54)	$ 12	$ 343	$ 301

The amounts reclassified for gains (losses) on cash flow hedges were recorded as part of product sales on our Consolidated Statements of Income. Amounts reclassified for unrealized gains (losses) on available-for-sale securities were recorded as part of other income (expense), net on our Consolidated Statements of Income.

13. EMPLOYEE BENEFITS

2004 Equity Incentive Plan

In May 2004, our stockholders approved and we adopted the Gilead Sciences, Inc. 2004 Equity Incentive Plan (the 2004 Plan). The 2004 Plan is a broad based incentive plan that provides for the grant of equity-based awards, including stock options, restricted stock units, restricted stock awards and performance awards, to employees, directors and consultants. Under the 2004 Plan, we are authorized to issue a maximum of 50 million shares of full-value awards, such as restricted stock, restricted stock units, performance shares, performance units (to the extent settled in common stock) and phantom shares over the term of the plan. The 2004 Plan authorizes the issuance of a total of 243 million shares of common stock. As of December 31, 2014 , a total of 72 million shares remain available for future grant under the 2004 Plan.

Stock Options

The 2004 Plan provides for option grants designated as either non-qualified or incentive stock options. Prior to January 1, 2006, we granted both non-qualified and incentive stock options, but all stock options granted after January 1, 2006 have been non-qualified stock options. Under the 2004 Plan, employee stock options granted prior to 2011 generally vest over five years and stock options granted starting in 2011 generally vest over four years. All options are exercisable over a period not to exceed the contractual term of ten years from the date the stock options are issued and are granted at prices not less than the fair market value of our common stock on the grant date. Stock option exercises are settled with common stock from the 2004 Plan's previously authorized and available pool of shares.

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The following table summarizes activity and related information under our stock option plans. All option grants presented in the table had exercise prices not less than the fair value of the underlying common stock on the grant date:

	Shares (in thousands)	Weighted-Average Exercise Price (in dollars)	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in millions)
Outstanding at December 31, 2013	54,703	$ 19.34		
Granted	1,184	$ 81.19		
Forfeited	(249)	$ 36.00		
Expired	(4)	$ 21.92		
Exercised	(16,490)	$ 15.73		
Outstanding at December 31, 2014	39,144	$ 22.63	3.8	$ 2,804
Exercisable at December 31, 2014	35,188	$ 20.18	3.3	$ 2,607
Expected to vest, net of estimated forfeitures at December 31, 2014	3,846	$ 43.85	7.7	$ 194

Aggregate intrinsic value represents the value of the Company's closing stock price on the last trading day of the period in excess of the weighted-average exercise price multiplied by the number of options outstanding or exercisable. Total intrinsic value of options exercised was $1.2 billion during 2014 , $837 million during 2013 and $500 million during 2012 .

The weighted-average grant date fair values of the stock options granted was $27.63 per share during 2014 , $12.41 per share during 2013 and $7.60 per share during 2012 .

As of December 31, 2014 , there was $45 million of unrecognized compensation cost related to stock options, which is expected to be recognized over an estimated weighted-average period of 1.8 years.

Performance-Based Restricted Stock Units

Under the 2004 Plan, we grant PSUs which vest upon the achievement of specified market or performance goals, which could include achieving a total shareholder return compared to a pre-determined peer group or achieving revenue targets. The actual number of common shares ultimately issued is calculated by multiplying the number of PSUs by a payout percentage ranging from 0% to 200% and these awards generally vest only when a committee (or subcommittee) of our Board has determined that the specified market and performance goals have been achieved. The fair value of each PSU is estimated at the date of grant or when performance objectives are defined for the grants. Depending on the terms of the award, fair value on the date of grant is determined based on either the Monte Carlo valuation methodology or the stock price on the date of grant.

In addition, we have also granted other PSUs to certain of our employees under the 2004 Plan. The vesting of these awards is subject to the achievement of specified individual performance goals, typically within a one year period. The fair value of such an award is equal to the closing price of our common stock on the grant date.

The following table summarizes activity and related information for all of our PSUs:

	Shares (in thousands)	Weighted-Average Grant-Date Fair Value Per Share [1] (in dollars)
Outstanding at December 31, 2013	2,028	$ 27.20
Granted	602	$ 56.38
Vested	(1,780)	$ 25.58
Forfeited	(23)	$ 42.16
Outstanding at December 31, 2014	827	$ 51.52

[1] Weighted-average grant-date fair value per share excludes shares related to grants that currently have no grant-date fair value as the performance objectives have not yet been defined.

The weighted-average grant date fair values of our PSUs granted was $56.38 per share during 2014 , $30.16 per share during 2013 and $20.67 per share during 2012 . The total fair value of our PSUs vested was $46 million during 2014 , $11 million during 2013 and $20 million during 2012 .

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We recognized stock-based compensation expenses of $57 million during 2014 , $25 million during 2013 and $24 million during 2012 related to these PSUs. As of December 31, 2014 , there was $10 million of unrecognized compensation costs related to these PSUs, which is expected to be recognized over an estimated weighted-average period of 0.8 years.

Restricted Stock Units

We grant time-based RSUs to certain employees as part of our annual employee equity compensation review program as well as to new hire employees and to non-employee members of our Board. RSUs are share awards that entitle the holder to receive freely tradable shares of our common stock upon vesting. For awards granted prior to 2011to employees, RSUs vest ratably on an annual basis over five years from the date of grant. Starting January 1, 2011, RSUs vest over four years from the date of grant.

The fair value of an RSU is equal to the closing price of our common stock on the grant date. The following table summarizes our RSU activities and related information:

	Shares (in thousands)	Weighted-Average Grant-Date Fair Value Per Share (in dollars)
Outstanding at December 31, 2013	17,353	$ 32.89
Granted and assumed	4,225	$ 86.75
Vested	(6,110)	$ 29.74
Forfeited	(985)	$ 41.13
Outstanding at December 31, 2014	14,483	$ 49.37

The weighted-average grant date fair values of RSUs granted was $86.75 per share during 2014 , $48.61 per share during 2013 and $27.75 per share during 2012.The total fair value of RSUs that vested was $182 million during 2014 , $118 million during 2013 and $60 million during 2012 .

As of December 31, 2014 , there was $481 million of unrecognized compensation cost related to unvested RSUs which is expected to be recognized over a weighted-average period of 2.1 years.

Employee Stock Purchase Plan

Under our Employee Stock Purchase Plan, as amended, and the International Employee Stock Purchase Plan (together, the ESPP), employees can purchase shares of our common stock based on a percentage of their compensation subject to certain limits. The purchase price per share is equal to the lower of 85% of the fair market value of our common stock on the offering date or the purchase date. The ESPP offers a two-year look-back feature as well as an automatic reset feature that provides for an offering period to be reset to a new lower-priced offering if the offering price of the new offering period is less than that of the current offering period. ESPP purchases are settled with common stock from the ESPP's previously authorized and available pool of shares. During 2014, 2 million shares were issued under the ESPP for $72 million . A total of 67 million shares of common stock have been reserved for issuance under the ESPP, and there were 4 million shares available for issuance under the ESPP as of December 31, 2014 .

As of December 31, 2014 , there was $29 million of unrecognized compensation cost related to the ESPP, which is expected to be recognized over an estimated weighted-average period of 0.7 years.

Stock-Based Compensation

The following table summarizes the stock-based compensation expenses included in our Consolidated Statements of Income (in millions):

	Year Ended December 31,		
	2014	2013	2012
Cost of goods sold	$ 10	$ 7	$ 7
Research and development expenses	152	109	187
Selling, general and administrative expenses	198	136	209
Stock-based compensation expense included in total costs and expenses	360	252	403
Income tax effect	(64)	(67)	(56)
Stock-based compensation expense, net of tax	$ 296	$ 185	$ 347

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We capitalized stock-based compensation costs to inventory totaling $12 million in 2014 , $9 million in 2013 and $7 million in 2012 . The capitalized stock-based compensation costs remaining in inventory were $6 million as of December 31, 2014 , $4 million as of December 31, 2013 and $2 million as of December 31, 2012 . Total stock-based compensation for the year ended December 31, 2012 included $100 million and $94 million in R&D and SG&A expenses, respectively, related to the acceleration of unvested stock options in connection with the acquisition of Pharmasset, which closed during the first quarter of 2012.

Stock-based compensation is recognized as expense over the requisite service periods in our Consolidated Statements of Income using a graded vesting expense attribution approach for unvested stock options granted prior to January 1, 2006, and using the straight-line expense attribution approach for stock options granted after our adoption of new guidance for share-based payments to employees and directors on January 1, 2006. As stock-based compensation expenses related to stock options recognized on adoption of the new guidance is based on awards ultimately expected to vest, gross expense has been reduced for estimated forfeitures. The guidance requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. We estimated forfeitures based on our historical experience. Prior to the adoption of this guidance, pro forma information that was required to be disclosed included forfeitures as they occurred. As a result of the guidance adopted on January 1, 2006, we only recognize a tax benefit from stock-based compensation in APIC if an incremental tax benefit is realized after all other tax attributes currently available to us have been utilized. In addition, we have elected to account for the indirect benefits of stock-based compensation on the research tax credit and the extraterritorial income deduction through the Consolidated Statements of Income rather than through APIC.

Valuation Assumptions

Fair values of options granted under our 2004 Plan and purchases under our ESPP were estimated at grant or purchase dates using a Black-Scholes option valuation model. The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options, which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions, including expected stock price volatility and expected award life. We used the following assumptions to calculate the estimated fair value of the awards:

	Year Ended December 31,		
	2014	2013	2012
Expected volatility:			
Stock options	34%	29%	30%
ESPP	32%	31%	32%
Expected term in years:			
Stock options	5.5	5.7	5.9
ESPP	1.2	1.2	1.3
Risk-free interest rate:			
Stock options	1.8%	1.1%	1.1%
ESPP	1.5%	1.1%	0.7%
Expected dividend yield	—%	—%	—%

The fair value of stock options granted was calculated using the single option approach. We use a blend of historical volatility along with implied volatility for traded options on our common stock to determine our expected volatility. The expected term of stock-based awards represents the weighted-average period the awards are expected to remain outstanding. We estimate the weighted-average expected term based on historical cancellation and historical exercise data related to our stock options as well as the contractual term and vesting terms of the awards. The risk-free interest rate is based upon observed interest rates appropriate for the term of the stock-based awards. The dividend yield is based on our history and expectation of dividend payouts.

Deferred Compensation

We maintain a retirement saving plan under which eligible U.S. employees may defer compensation for income tax purposes under Section 401(k) of the Internal Revenue Code (Gilead Plan). In certain foreign subsidiaries, we maintain defined benefit plans as required by local regulatory requirements. Our total matching contribution expense under the Gilead Plan and other defined benefit plans was $40 million during 2014 , $32 million during 2013 and $27 million during 2012 .

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14. NET INCOME PER SHARE ATTRIBUTABLE TO GILEAD COMMON STOCKHOLDERS

Basic net income per share attributable to Gilead common stockholders is calculated based on the weighted-average number of shares of our common stock outstanding during the period. Diluted net income per share attributable to Gilead common stockholders is calculated based on the weighted-average number of shares of our common stock outstanding and other dilutive securities outstanding during the period. The potential dilutive shares of our common stock resulting from the assumed exercise of outstanding stock options, PSUs and the assumed exercise of warrants relating to our convertible senior notes, including the May 2013 Notes, the May 2014 Notes and the May 2016 Notes are determined under the treasury stock method.

Because the principal amount of the May 2013 Notes, May 2014 Notes and May 2016 Notes have been or will be settled in cash, only the conversion spread relating to the respective notes is included in our calculation of diluted net income per share attributable to Gilead common stockholders. Our common stock resulting from the assumed settlement of the conversion spread of the May 2014 Notes and May 2016 Notes has a dilutive effect when the average market price of our common stock during the period exceeds the conversion price of $22.54 for the May 2014 Notes and $22.71 for the May 2016 Notes. Warrants relating to the May 2014 Notes and May 2016 Notes have a dilutive effect when the average market price of our common stock during the period exceeds the warrants' exercise price of $28.38 for the May 2014 Notes and $30.05 for the May 2016 Notes.

Our May 2013 Notes and May 2014 Notes matured and as a result, we have only included their impact for the periods they were outstanding on our net income per share calculations for the periods shown. Our common stock resulting from the assumed settlement of the conversion spread of the May 2013 Notes and May 2014 Notes had a dilutive effect when the average market price of our common stock during the period exceeded the conversion price of $19.05 for the May 2013 Notes and $22.54 for the May 2014 Notes. Warrants related to our May 2013 Notes and May 2014 Notes settled and as a result, we have only included their impact for the period they were outstanding on our net income per share calculations. The related warrants had a dilutive effect when the average market price of our common stock during the period exceeded the warrants' exercise price of $26.95 for the May 2013 Notes and $28.38 for the May 2014 Notes.

We have excluded stock options to purchase approximately 1 million weighted-average shares of our common stock that were outstanding during 2014 , less than 1 million weighted-average shares during 2013 and 5 million weighted-average shares during 2012 in the computation of diluted net income per share attributable to Gilead common stockholders because their effect was antidilutive.

The following table is a reconciliation of the numerator and denominator used in the calculation of basic and diluted net income per share attributable to Gilead common stockholders (in millions):

	Year Ended December 31,		
	2014	2013	2012
Net income attributable to Gilead	$ 12,101	$ 3,075	$ 2,592
Shares used in per share calculation — basic	1,522	1,529	1,515
Effect of dilutive securities:			
Stock options and equivalents	33	40	33
Conversion spread related to the May 2013 Notes	—	4	11
Conversion spread related to the May 2014 Notes	2	27	11
Conversion spread related to the May 2016 Notes	28	32	11
Warrants related to the May Notes	62	63	2
Shares used in per share calculation — diluted	1,647	1,695	1,583
Net income per share attributable to Gilead common stockholders — basic	$ 7.95	$ 2.01	$ 1.71
Net income per share attributable to Gilead common stockholders — diluted	$ 7.35	$ 1.81	$ 1.64

15. SEGMENT INFORMATION

Product Sales

We operate in one business segment, which primarily focuses on the discovery, development and commercialization of innovative medicines in areas of unmet medical need. All products are included in one segment, because the majority of our products have similar economic and other characteristics, including the nature of the products and production processes, type of customers, distribution methods and regulatory environment.

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Product sales consist of the following (in millions):

	Year Ended December 31,		
	2014	2013	2012
Antiviral products:			
Sovaldi	$ 10,283	$ 139	$ —
Atripla	3,470	3,648	3,574
Truvada	3,340	3,136	3,181
Harvoni	2,127	—	—
Complera/Eviplera	1,228	810	342
Stribild	1,197	539	58
Viread	1,058	959	849
Other antiviral	88	111	138
Total antiviral products	22,791	9,342	8,142
Other products:			
Letairis	595	520	410
Ranexa	510	449	373
AmBisome	388	352	346
Zydelig	23	—	—
Other	167	141	127
Total product sales	$ 24,474	$ 10,804	$ 9,398

The following table summarizes total revenues from external customers and collaboration partners by geographic region (in millions). Product sales and product-related contract revenue are attributed to regions based on ship-to location. Royalty and non-product related contract revenue are attributed to regions based on the location of the collaboration partner.

	Year Ended December 31,		
	2014	2013	2012
Revenues:			
United States	$ 18,182	$ 6,695	$ 5,592
Europe	5,442	3,614	3,333
Other countries	1,266	893	777
Total revenues	$ 24,890	$ 11,202	$ 9,702

The following table summarizes revenues from each of our customers who individually accounted for 10% or more of our total revenues (as a percentage of total revenues):

	Year Ended December 31,		
	2014	2013	2012
AmerisourceBergen Corp.	25%	13%	11%
McKesson Corp.	24%	16%	16%
Cardinal Health, Inc.	14%	17%	19%

Long-lived Assets

At December 31, 2014 , the net book value of our property, plant and equipment (less office and computer equipment) in the United States, Ireland and Canada was $1.3 billion , $127 million , and $86 million , respectively. At December 31, 2013 , the net book value of our property, plant and equipment (less office and computer equipment) in the United States, Ireland and Canada was $883 million , $118 million and $55 million , respectively.

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16. INCOME TAXES

The provision for income taxes consists of the following (in millions):

	Year Ended December 31,		
	2014	2013	2012
Federal:			
Current	$ 2,810	$ 1,156	$ 1,003
Deferred	(190)	(71)	(25)
	2,620	1,085	978
State:			
Current	152	62	49
Deferred	(30)	(22)	(15)
	122	40	34
Foreign:			
Current	85	46	28
Deferred	(30)	(20)	(2)
	55	26	26
Provision for income taxes	$ 2,797	$ 1,151	$ 1,038

Foreign pre-tax income was $8.2 billion in 2014 , $738 million in 2013 and $885 million in 2012 . The cumulative unremitted foreign earnings that are considered indefinitely reinvested in our foreign subsidiaries and for which no U.S. taxes have been provided, were approximately $15.6 billion as of December 31, 2014 and $8.6 billion as of December 31, 2013 . The residual U.S. tax liability, if such amounts were remitted, would be approximately $5.5 billion as of December 31, 2014 and $3.0 billion as of December 31, 2013 .

The reconciliation between the federal statutory tax rate applied to income before taxes and our effective tax rate is summarized as follows:

	Year Ended December 31,		
	2014	2013	2012
Federal statutory rate	35.0 %	35.0 %	35.0 %
State taxes, net of federal benefit	0.6 %	0.5 %	0.5 %
Foreign earnings at different rates	(16.9)%	(6.6)%	(8.5)%
Research and other credits	(0.9)%	(3.0)%	(0.4)%
Net unbenefitted stock compensation	0.2 %	0.6 %	0.3 %
Other	0.8 %	0.8 %	1.8 %
Effective tax rate	18.8 %	27.3 %	28.7 %

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Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of our deferred tax assets and liabilities are as follows (in millions):

	December 31,	
	2014	2013
Deferred tax assets:		
Net operating loss carryforwards	$ 215	$ 228
Stock-based compensation	157	149
Reserves and accruals not currently deductible	383	256
Deferred revenue	46	42
Depreciation related	55	51
Research and other credit carryforwards	91	56
Other, net	125	73
Total deferred tax assets before valuation allowance	1,072	855
Valuation allowance	(9)	(9)
Total deferred tax assets	1,063	846
Deferred tax liabilities:		
Intangibles	(328)	(368)
Unremitted foreign earnings	(16)	(16)
Other	(34)	(25)
Total deferred tax liabilities	(378)	(409)
Net deferred tax assets	$ 685	$ 437

The valuation allowance was $9 million as of December 31, 2014 , December 31, 2013 and December 31, 2012 . We have concluded, based on the standard set forth in the Financial Accounting Standards Board Accounting Standards Codification related to Income Taxes, that it is more likely than not that we will not realize any benefit from the deferred tax assets related to certain state net operating loss and credit carryforwards.

At December 31, 2014 , we had U.S. federal net operating loss carryforwards of approximately $397 million . The federal net operating loss carryforwards will start to expire in 2019, if not utilized. We also had federal tax credit carryforwards of approximately $9 million which will start to expire in 2017, if not utilized. In addition, we had state net operating loss and tax credit carryforwards of approximately $1.2 billion and $163 million , respectively. The state net operating loss and tax credit carryforwards will start to expire in 2015 if not utilized.

Utilization of net operating losses and tax credits may be subject to an annual limitation due to ownership change limitations provided in the Internal Revenue Code of 1986, as amended, and similar state provisions. This annual limitation may result in the expiration of the net operating losses and credits before utilization.

We file federal, state and foreign income tax returns in many jurisdictions in the United States and abroad. For federal income tax purposes, the statute of limitations is open for 2010 and onwards. For certain acquired entities, the statute of limitations is open for all years from inception due to our utilization of their net operating losses and credits carried over from prior years. For California income tax purposes, the statute of limitations is open for 2008 and onwards.

Our income tax returns are audited by federal, state and foreign tax authorities. We are currently under examination by the IRS for the 2010, 2011 and 2012 tax years and by various state and foreign jurisdictions. There are differing interpretations of tax laws and regulations, and as a result, significant disputes may arise with these tax authorities involving issues of the timing and amount of deductions and allocations of income among various tax jurisdictions. We periodically evaluate our exposures associated with our tax filing positions.

We have total federal, state and foreign unrecognized tax benefits of $661 million as of December 31, 2014 and $237 million as of December 31, 2013 . Of the total unrecognized tax benefits, $602 million and $195 million at December 31, 2014 and 2013 , respectively, if recognized, would reduce our effective tax rate in the period of recognition. We have continued to classify interest and penalties related to unrecognized tax benefits as part of our income tax provision in our Consolidated Statements of Income. We had accrued interest and penalties related to unrecognized tax benefits of $18 million as of December 31, 2014 and 2013 .

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As of December 31, 2014 , we believe that it is reasonably possible that our unrecognized tax benefits will decrease by approximately $12 million in the next 12 months as we expect to have clarification from the IRS and other tax authorities regarding our uncertain tax positions. With respect to the remaining unrecognized tax benefits, we are currently unable to make a reasonable estimate as to the period of cash settlement, if any, with the respective tax authorities.

The following is a rollforward of our total gross unrecognized tax benefit liabilities for the years ended December 31, 2014 , 2013 and 2012 (in millions):

	December 31,		
	2014	2013	2012
Balance, beginning of period	$ 237	$ 157	$ 147
Tax positions related to current year:			
Additions	430	112	26
Reductions	—	—	—
Tax positions related to prior years:			
Additions	21	13	2
Reductions	(20)	—	(13)
Settlements	(5)	(39)	—
Lapse of statute of limitations	(2)	(6)	(5)
Balance, end of period	$ 661	$ 237	$ 157

17. SUBSEQUENT EVENTS

On February 3, 2015 , we announced that our Board of Directors authorized a new $15.0 billion five -year share repurchase program, which we will initiate in 2015 on the completion of our 2014 Program.

On February 3, 2015 , we also announced that the initiation of a quarterly dividend of $0.43 per share that will begin in the second quarter of 2015 subject to a declaration by our Board of Directors. The quarterly dividend is equivalent to $1.72 per share on an annual basis.

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SELECTED QUARTERLY FINANCIAL INFORMATION (UNAUDITED)

The following amounts are in millions, except per share amounts:

	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
2014				
Total revenues	$ 4,999	$ 6,535	$ 6,042	$ 7,314
Gross profit on product sales	$ 4,058	$ 5,488	$ 4,981	$ 6,159
Net income	$ 2,223	$ 3,650	$ 2,724	$ 3,462
Net income attributable to Gilead	$ 2,227	$ 3,656	$ 2,731	$ 3,487
Net income per share attributable to Gilead common stockholders-basic	$ 1.45	$ 2.39	$ 1.80	$ 2.32
Net income per share attributable to Gilead common stockholders-diluted	$ 1.33	$ 2.20	$ 1.67	$ 2.18
2013				
Total revenues	$ 2,532	$ 2,767	$ 2,783	$ 3,120
Gross profit on product sales	$ 1,759	$ 1,973	$ 2,028	$ 2,185
Net income	$ 718	$ 768	$ 784	$ 787
Net income attributable to Gilead	$ 722	$ 773	$ 789	$ 791
Net income per share attributable to Gilead common stockholders-basic	$ 0.47	$ 0.51	$ 0.51	$ 0.52
Net income per share attributable to Gilead common stockholders-diluted	$ 0.43	$ 0.46	$ 0.47	$ 0.47

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GILEAD SCIENCES, INC.

Schedule II: Valuation and Qualifying Accounts
(in millions)

	Balance at Beginning of Period	Additions/Charged to Expense	Deductions	Balance at End of Period
Year ended December 31, 2014:				
Accounts receivable allowances [1]	$ 252	$ 2,867	$ 2,763	$ 356
Sales return allowance	$ 82	$ 104	$ 15	$ 171
Valuation allowances for deferred tax assets [2]	$ 9	$ —	$ —	$ 9
Year ended December 31, 2013:				
Accounts receivable allowances [1]	$ 188	$ 1,870	$ 1,806	$ 252
Sales return allowance	$ 73	$ 21	$ 12	$ 82
Valuation allowances for deferred tax assets [2]	$ 9	$ —	$ —	$ 9
Year ended December 31, 2012:				
Accounts receivable allowances [1]	$ 154	$ 1,379	$ 1,345	$ 188
Sales return allowance	$ 52	$ 31	$ 10	$ 73
Valuation allowances for deferred tax assets [2]	$ 9	$ —	$ —	$ 9

[1] Allowances are for doubtful accounts, cash discounts and chargebacks.

[2] Valuation allowance for deferred tax assets includes $6 million and $7 million as of December 31, 2014 and 2013, respectively, related to our acquisitions.

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ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures

An evaluation as of December 31, 2014 was carried out under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our "disclosure controls and procedures," which are defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act), as controls and other procedures of a company that are designed to ensure that the information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to the company's management, including its Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at December 31, 2014 .

(b) Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) of the Exchange Act. Our internal control system is designed to provide reasonable assurance regarding the preparation and fair presentation of financial statements for external purposes in accordance with generally accepted accounting principles. All internal control systems, no matter how well designed, have inherent limitations and can provide only reasonable assurance that the objectives of the internal control system are met.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting, based on criteria established by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in its 2013 Internal Control-Integrated Framework. Based on our evaluation, we concluded that our internal control over financial reporting was effective as of December 31, 2014 .

Our independent registered public accounting firm, Ernst & Young LLP, has audited our Consolidated Financial Statements included in this Annual Report on Form 10-K and have issued a report on our internal control over financial reporting as of December 31, 2014 . Their report on the audit of internal control over financial reporting appears below.

(c) Changes in Internal Control over Financial Reporting

Our management, including our Chief Executive Officer and Chief Financial Officer, has evaluated any changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2014 , and has concluded that there was no change during such quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of Gilead Sciences, Inc.

We have audited Gilead Sciences, Inc.'s internal control over financial reporting as of December 31, 2014 , based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). Gilead Sciences, Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Gilead Sciences, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2014 , based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the 2014 consolidated financial statements of Gilead Sciences, Inc. and our report dated February 25, 2015 expressed an unqualified opinion thereon.

/s/ E RNST & Y OUNG LLP

Redwood City, California
February 25, 2015

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ITEM 9B. OTHER INFORMATION

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item concerning our directors and executive officers is incorporated by reference to the sections of our Definitive Proxy Statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A in connection with our 2015 Annual Meeting of Stockholders (the Proxy Statement) under the headings "Nominees," "Board Committees and Meetings," "Executive Officers," and "Section 16(a) Beneficial Ownership Reporting Compliance."

Our written Code of Ethics applies to all of our directors and employees, including our executive officers, including without limitation our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions. The Code of Ethics is available on our website at http://www.gilead.com in the Investors section under "Corporate Governance." Changes to or waivers of the Code of Ethics will be disclosed on the same website. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding any amendment to, or waiver of, any provision of the Code of Ethics by disclosing such information on the same website.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is incorporated by reference to the sections of the Proxy Statement under the headings "Executive Compensation," "Compensation Committee Interlocks and Insider Participation," "Compensation Committee Report," and "Compensation of Non-Employee Board Members."

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item is incorporated by reference to the sections of the Proxy Statement under the headings "Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance under Equity Compensation Plans."

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this Item is incorporated by reference to the sections of the Proxy Statement under the headings "Nominees," and "Certain Relationships and Related Party Transactions."

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item is incorporated by reference to the section of the Proxy Statement under the heading "Principal Accountant Fees and Services."

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PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this Annual Report on Form 10-K:

(1) Index list to Consolidated Financial Statements:

Report of Independent Registered Public Accounting Firm	74
Audited Consolidated Financial Statements	
Consolidated Balance Sheets	75
Consolidated Statements of Income	76
Consolidated Statements of Comprehensive Income	77
Consolidated Statements of Stockholders' Equity	78
Consolidated Statements of Cash Flows	79
Notes to Consolidated Financial Statements	80

(2) Schedule II is included on page 119 of this report. All other schedules are omitted because they are not required or the required information is included in the financial statements or notes thereto.

(3) Exhibits.

The following exhibits are filed herewith or incorporated by reference:

ITEM 15. EXHIBITS

Exhibit Footnote	Exhibit Number	Description of Document
(1)	1.1	Underwriting Agreement, dated March 4, 2014, among Registrant and Merrill Lynch, Pierce, Fenner & Smith Incorporated and J.P. Morgan Securities LLC, as representatives of the several underwriters listed in Schedule 1 thereto
†(2)	2.1	Agreement and Plan of Merger among Registrant, Merger Sub and Pharmasset, Inc., dated as of November 21, 2011
*(3)	3.1	Restated Certificate of Incorporation of Registrant
*(4)	3.2	Amended and Restated Bylaws of Registrant, as amended and restated on May 7, 2014
	4.1	Reference is made to Exhibit 3.1, Exhibit 3.2 and Exhibit 3.3
*(5)	4.2	Indenture related to the Convertible Senior Notes due 2016 (2016 Notes), between Registrant and Wells Fargo Bank, National Association, as trustee (including form of 1.625% Convertible Senior Note due 2016), dated July 30, 2010
*(6)	4.3	Indenture related to Senior Notes, dated as of March 30, 2011, between Registrant and Wells Fargo, National Association, as Trustee
*(6)	4.4	First Supplemental Indenture related to Senior Notes, dated as of March 30, 2011, between Registrant and Wells Fargo, National Association, as Trustee (including form of Senior Notes)
*(7)	4.5	Second Supplemental Indenture related to Senior Notes, dated as of December 13, 2011, between Registrant and Wells Fargo, National Association, as Trustee (including Form of 2014 Note, Form of 2016 Note, Form of 2021 Note, Form of 2041 Note)
(1)	4.6	Third Supplemental Indenture related to Senior Notes, dated as of March 7, 2014, between Registrant and Wells Fargo, National Association, as Trustee (including Form of 2019 Note, Form of 2024 Note, Form of 2044 Note)
*(8)	10.1	Confirmation of OTC Convertible Note Hedge related to 2016 Notes, dated July 26, 2010, between Registrant and Goldman, Sachs & Co.
*(8)	10.2	Confirmation of OTC Convertible Note Hedge related to 2016 Notes, dated July 26, 2010, between Registrant and JPMorgan Chase Bank, National Association
*(8)	10.3	Confirmation of OTC Warrant Transaction, dated July 26, 2010, between Registrant and Goldman, Sachs & Co. for warrants expiring in 2016
*(8)	10.4	Confirmation of OTC Warrant Transaction, dated July 26, 2010, between Registrant and JPMorgan Chase Bank, National Association for warrants expiring in 2016

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*(9)	10.5	Confirmation of OTC Additional Convertible Note Hedge related to 2016 Notes, dated August 5, 2010, between Registrant and Goldman, Sachs & Co.
*(9)	10.6	Confirmation of OTC Additional Convertible Note Hedge related to 2016 Notes, dated August 5, 2010, between Registrant and JPMorgan Chase Bank, National Association
*(9)	10.7	Confirmation of OTC Additional Warrant Transaction, dated August 5, 2010, between Registrant and Goldman, Sachs & Co. for warrants expiring in 2016
*(9)	10.8	Confirmation of OTC Additional Warrant Transaction, dated August 5, 2010, between Registrant and JPMorgan Chase Bank, National Association for warrants expiring in 2016
*(9)	10.9	Amendment to Confirmation of OTC Convertible Note Hedge related to 2016 Notes, dated August 30, 2010, between Registrant and Goldman, Sachs & Co.
*(9)	10.10	Amendment to Confirmation of OTC Convertible Note Hedge related to 2016 Notes, dated August 30, 2010, between Registrant and JPMorgan Chase Bank, National Association
*(9)	10.11	Amendment to Confirmation of OTC Additional Convertible Note Hedge related to 2016 Notes, dated August 30, 2010, between Registrant and Goldman, Sachs & Co.
*(9)	10.12	Amendment to Confirmation of OTC Additional Convertible Note Hedge related to 2016 Notes, dated August 30, 2010, between Registrant and JPMorgan Chase Bank, National Association
*(10)	10.13	5-Year Revolving Credit Facility Credit Agreement among Registrant and Gilead Biopharmaceutics Ireland UC (formerly Gilead Biopharmaceutics Ireland Corporation), as Borrowers, Bank of America, N.A., as Administrative Agent, Swing Line Lender and L/C Issuer, certain other lenders parties thereto, Barclays Capital, as Syndication Agent, and Goldman Sachs Bank USA, JPMorgan Chase Bank, N.A., Royal Bank of Canada and Wells Fargo Bank, N.A., as Co-Documentation Agents, dated as of January 12, 2012
*(10)	10.14	Parent Guaranty Agreement (5-Year Revolving Credit Facility), dated as of January 12, 2012, by Registrant
*(3)	10.15	Gilead Sciences, Inc. 2004 Equity Incentive Plan, as amended through May 8, 2013
*(11)	10.16	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants prior to February 2008)
*(12)	10.17	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants made February 2008 through April 2009)
*(13)	10.18	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants commencing in May 2009)
*(14)	10.19	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants commencing in February 2010)
*(15)	10.20	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for 2011 and subsequent year grants)
*(12)	10.21	Form of non-employee director stock option agreement used under 2004 Equity Incentive Plan (for grants prior to 2008)
*(12)	10.22	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for initial grants made in 2008)
*(12)	10.23	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for annual grants made in May 2008 and through May 2012)
*(13)	10.24	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for annual grants commencing in May 2009 and through May 2012)
*(16)	10.25	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for annual grants made in May 2013)
*(16)	10.26	Form of non-employee director option agreement (non-U.S.) used under 2004 Equity Incentive Plan (for annual grants made in May 2013)
*(17)	10.27	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for annual grants made in May 2014)
*(18)	10.28	Form of restricted stock unit issuance agreement used under 2004 Equity Incentive Plan (for annual grants to non-employee directors in May 2012)

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*(13)	10.29	Form of restricted stock award agreement used under 2004 Equity Incentive Plan (for annual grants to certain non-employee directors prior to May 2012)
*(16)	10.30	Form of restricted stock unit issuance agreement used under 2004 Equity Incentive Plan (for annual grants to non-employee directors commencing in May 2013)
*(17)	10.31	Form of restricted stock unit issuance agreement used under 2004 Equity Incentive Plan (for annual grants to non-employee directors commencing in May 2014)
*(16)	10.32	Form of restricted stock unit issuance agreement (non-U.S.) used under 2004 Equity Incentive Plan (for annual grants to non-employee directors commencing in May 2013)
*(13)	10.33	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for grants to certain executive officers made in 2009)
*(14)	10.34	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for grants to certain executive officers made in 2010)
*(15)	10.35	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for grants to certain executive officers made in 2011)
*(16)	10.36	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for grants to certain executive officers made in 2012)
*(19)	10.37	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for TSR Goals in 2013 and 2014)
*(20)	10.38	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for Revenue Goals in 2013 and 2014)
*(21)	10.39	Form of restricted stock unit issuance agreement used under the 2004 Equity Incentive Plan (for grants to certain executive officers made prior to May 2009)
*(13)	10.40	Form of restricted stock unit issuance agreement used under the 2004 Equity Incentive Plan (for grants to certain executive officers commencing in May 2009)
*(22)	10.41	Form of restricted stock unit issuance agreement used under the 2004 Equity Incentive Plan (service-based vesting for certain executive officers commencing in November 2009)
*(15)	10.42	Form of restricted stock unit issuance agreement used under the 2004 Equity Incentive Plan (service-based vesting for certain executive officers commencing in 2011)
*(16)	10.43	Gilead Sciences, Inc. Employee Stock Purchase Plan, amended and restated through May 8, 2013
*(23)	10.44	Gilead Sciences, Inc. Deferred Compensation Plan-Basic Plan Document
*(22)	10.45	Gilead Sciences, Inc. Deferred Compensation Plan-Adoption Agreement
*(23)	10.46	Addendum to the Gilead Sciences, Inc. Deferred Compensation Plan
*(24)	10.47	Gilead Sciences, Inc. 2005 Deferred Compensation Plan, as amended and restated on October 23, 2008
*(19)	10.48	Gilead Sciences, Inc. Severance Plan, as amended on January 26, 2012
*(11)	10.49	Gilead Sciences, Inc. Corporate Bonus Plan
*(25)	10.50	Amended and Restated Gilead Sciences, Inc. Code Section 162(m) Bonus Plan
*(26)	10.51	2015 Base Salaries for the Named Executive Officers
*(27)	10.52	Offer Letter dated April 16, 2008 between Registrant and Robin Washington
*(28)	10.53	Form of Indemnity Agreement entered into between Registrant and its directors and executive officers
*(29)	10.54	Form of Employee Proprietary Information and Invention Agreement entered into between Registrant and certain of its officers and key employees

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*(14)	10.55	Form of Employee Proprietary Information and Invention Agreement entered into between Registrant and certain of its officers and key employees (revised in September 2006)
+ (30)	10.56	Amended and Restated Collaboration Agreement by and among Registrant, Gilead Holdings, LLC, Bristol-Myers Squibb Company, E.R. Squibb & Sons, L.L.C., and Bristol-Myers Squibb & Gilead Sciences, LLC, dated September 28, 2006
+ (12)	10.57	Commercialization Agreement by and between Gilead Sciences Limited and Bristol-Myers Squibb Company, dated December 10, 2007
+ (31)	10.58	Amendment Agreement, dated October 25, 1993, between Registrant, the Institute of Organic Chemistry and Biochemistry (IOCB) and Rega Stichting v.z.w. (REGA), together with the following exhibits: the License Agreement, dated December 15, 1991, between Registrant, IOCB and REGA (the 1991 License Agreement), the License Agreement, dated October 15, 1992, between Registrant, IOCB and REGA (the October 1992 License Agreement) and the License Agreement, dated December 1, 1992, between Registrant, IOCB and REGA (the December 1992 License Agreement)
+ (32)	10.59	Amendment Agreement between Registrant and IOCB/REGA, dated December 27, 2000 amending the 1991 License Agreement and the December 1992 License Agreement
+ (30)	10.60	Sixth Amendment Agreement to the License Agreement, between IOCB/REGA and Registrant, dated August 18, 2006 amending the October 1992 License Agreement and the December 1992 License Agreement
+ (33)	10.61	Seventh Amendment Agreement to the License Agreement, between IOCB/REGA and Registrant dated July 1, 2013 amending the October 1992 License Agreement and the December 1992 License Agreement
+ (34)	10.62	Exclusive License Agreement between Registrant (as successor to Triangle Pharmaceuticals, Inc.), Glaxo Group Limited, The Wellcome Foundation Limited, Glaxo Wellcome Inc. and Emory University, dated May 6, 1999
+ (35)	10.63	Royalty Sale Agreement by and among Registrant, Emory University and Investors Trust & Custodial Services (Ireland) Limited, solely in its capacity as Trustee of Royalty Pharma, dated July 18, 2005
+ (35)	10.64	Amended and Restated License Agreement between Registrant, Emory University and Investors Trust & Custodial Services (Ireland) Limited, solely in its capacity as Trustee of Royalty Pharma, dated July 21, 2005
+ (36)	10.65	License Agreement between Japan Tobacco Inc. and Registrant, dated March 22, 2005
+ (37)	10.66	First Amendment to License Agreement between Japan Tobacco Inc. and Registrant, dated May 19, 2005
+ (37)	10.67	Second Amendment to License Agreement between Japan Tobacco Inc. and Registrant, dated May 17, 2010
+ (37)	10.68	Third Amendment to License Agreement between Japan Tobacco Inc. and Registrant, dated July 5, 2011
+ (37)	10.69	Fourth Amendment to License Agreement between Japan Tobacco Inc. and Registrant, dated July 5, 2011
+(38)	10.70	Amendment to License Agreement between Japan Tobacco Inc. and Registrant, dated October 10, 2013
+(39)	10.71	Fifth Amendment to License Agreement between Japan Tobacco Inc. and Registrant, dated September 29, 2014
+	10.76	Amended and Restated Collaboration Agreement by and among Registrant, Gilead Sciences Ireland UC (formerly Gilead Sciences Limited) and Janssen R&D Ireland, dated December 23, 2014
+(40)	10.77	Master Clinical and Commercial Supply Agreement between Gilead World Markets, Limited, Registrant and Patheon Inc., dated January 1, 2003
+(41)	10.78	Restated and Amended Toll Manufacturing Agreement between Gilead Sciences Limited, Registrant and Takeda GmbH (formerly Nycomed GmbH and Altana Pharma Oranienburg GmbH), dated November 7, 2005
	21.1	Subsidiaries of Registrant
	23.1	Consent of Independent Registered Public Accounting Firm
	31.1	Certification of Chief Executive Officer, as required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended
	31.2	Certification of Chief Financial Officer, as required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended

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32.1**	Certifications of Chief Executive Officer and Chief Financial Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350)
101***	The following materials from Registrant's Annual Report on Form 10-K for the year ended December 31, 2014, formatted in Extensible Business Reporting Language (XBRL) includes: (i) Consolidated Balance Sheets at December 31, 2014 and 2013, (ii) Consolidated Statements of Income for the years ended December 31, 2014, 2013 and 2012, (iii) Consolidated Statements of Comprehensive Income for the years ended December 31, 2014, 2013 and 2012, (iv) Consolidated Statements of Stockholders' Equity for the years ended December 31, 2014, 2013 and 2012 (v) Consolidated Statements of Cash Flows for years ended December 31, 2014, 2013 and 2012, and (vi) Notes to Consolidated Financial Statements.

(1) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on March 7, 2014, and incorporated herein by reference.
(2) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on November 25, 2011, and incorporated herein by reference.
(3) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on May 7, 2014, and incorporated herein by reference.
(4) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on May 17, 2011, and incorporated herein by reference.
(5) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on August 2, 2010, and incorporated herein by reference.
(6) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on April 1, 2011, and incorporated herein by reference.
(7) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on December 13, 2011, and incorporated herein by reference.
(8) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2010, and incorporated herein by reference.
(9) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2010, and incorporated herein by reference.
(10) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on January 17, 2012, and incorporated herein by reference.
(11) Filed as an exhibit to Registrant's Current Report on Form 8-K/A filed on February 22, 2006, and incorporated herein by reference.
(12) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2007, and incorporated herein by reference.
(13) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2009, and incorporated herein by reference.
(14) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2009, and incorporated herein by reference.
(15) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2011, and incorporated herein by reference.
(16) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, and incorporated herein by reference
(17) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2014, and incorporated herein by reference.
(18) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2012, and incorporated herein by reference.
(19) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2012, and incorporated herein by reference.
(20) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2013, and incorporated herein by reference.
(21) Filed as an exhibit to Registrant's Current Report on Form 8-K first filed on December 19, 2007, and incorporated herein by reference.
(22) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2010, and incorporated herein by reference.
(23) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2001, and incorporated herein by reference.
(24) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2008, and incorporated herein by reference.
(25) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on May 13, 2013, and incorporated herein by reference.
(26) Information is included in Registrant's Current Report on Form 8-K filed on January 28, 2015, and incorporated herein by reference.
(27) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008, and incorporated herein by reference.
(28) Filed as an exhibit to Registrant's Registration Statement on Form S-1 (No. 33-55680), as amended, and incorporated herein by reference.

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

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

(31) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended March 31, 1994, and incorporated herein by reference.

(32) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2000, and incorporated herein by reference.

(33) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2013, and incorporated herein by reference.

(34) Filed as an exhibit to Triangle Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q/A filed on November 3, 1999, and incorporated herein by reference.

(35) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2005, and incorporated herein by reference.

(36) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2005, and incorporated herein by reference.

(37) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2011, and incorporated herein by reference.

(38) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2013, and incorporated herein by reference.

(39) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, and incorporated herein by reference.

(40) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2003, and incorporated herein by reference.

(41) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2005, and incorporated herein by reference.

† The Agreement and Plan of Merger (the Pharmasset Merger Agreement) contains representations and warranties of Registrant, Merger Sub and Pharmasset, Inc. made solely to each other as of specific dates. Those representations and warranties were made solely for purposes of the Pharmasset Merger Agreement and may be subject to important qualifications and limitations agreed to by Registrant, Merger Sub and Pharmasset, Inc. Moreover, some of those representations and warranties may not be accurate or complete as of any specified date, may be subject to a standard of materiality provided for in the Pharmasset Merger Agreement and have been used for the purpose of allocating risk among Registrant, Merger Sub and Pharmasset, Inc. rather than establishing matters as facts.

* Management contract or compensatory plan or arrangement.

** This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

*** XBRL information is filed herewith.

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

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

GILEAD SCIENCES, INC.

By: /S/ JOHN C. MARTIN

John C. Martin, Ph.D.
Chairman and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints John C. Martin and Gregg H. Alton, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place, and stead, in any and all capacities, to sign any and all amendments to this Report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming that all said attorneys-in-fact and agents, or any of them or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

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Signature	Title	Date
/s/ JOHN C. MARTIN **John C. Martin, Ph.D.**	Chairman and Chief Executive Officer *(Principal Executive Officer)*	February 25, 2015
/s/ ROBIN L. WASHINGTON **Robin L. Washington**	Executive Vice President and Chief Financial Officer *(Principal Financial and Accounting Officer)*	February 25, 2015
/s/ JOHN F. COGAN **John F. Cogan**	Director	February 25, 2015
/s/ ETIENNE F. DAVIGNON **Etienne F. Davignon**	Director	February 25, 2015
/s/ CARLA A. HILLS **Carla A. Hills**	Director	February 25, 2015
/s/ KEVIN E. LOFTON **Kevin E. Lofton**	Director	February 25, 2015
/s/ JOHN W. MADIGAN **John W. Madigan**	Director	February 25, 2015
/s/ NICHOLAS G. MOORE **Nicholas G. Moore**	Director	February 25, 2015
/s/ RICHARD J. WHITLEY **Richard J. Whitley**	Director	February 25, 2015
/s/ GAYLE E. WILSON **Gayle E. Wilson**	Director	February 25, 2015
/s/ PER WOLD-OLSEN **Per Wold-Olsen**	Director	February 25, 2015

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CONFIDENTIAL TREATMENT REQUESTED
UNDER 17 C.F.R. §§ 200.80(b)(4) AND 240.24B-2

AMENDED & RESTATED
COLLABORATION AGREEMENT

(Complera and the R/F/TAF Product)

by and among

GILEAD SCIENCES, INC., GILEAD SCIENCES IRELAND UC

and

JANSSEN R&D IRELAND

Dated as of December 23, 2014

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

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Annexes

Annex list included in attached Annexes.

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AMENDED & RESTATED COLLABORATION AGREEMENT

THIS AMENDED & RESTATED COLLABORATION AGREEMENT (as the same may be amended, modified or supplemented from time to time, this " **Agreement** ") is made as of December 23, 2014 (the " **Restatement Effective Date** "), by and among Gilead Sciences, Inc., a corporation organized and existing under the laws of the State of Delaware and having its principal place of business at 333 Lakeside Drive, Foster City, California 94404 (" **Gilead Parent** "), Gilead Sciences Ireland UC (formerly known as Gilead Sciences Limited), an unlimited liability company existing under the laws of Ireland and wholly-owned subsidiary of Gilead Parent having its principal place of business at IDA Business & Technology Park, Carrigtohill, Co. Cork, Ireland (" **Gilead Sub** " and, collectively with Gilead Parent, " **Gilead** ") and Janssen R&D Ireland, a company organized and existing under the laws of Ireland, having its principal place of business at Eastgate Village, Eastgate, Little Island, County Cork, Ireland (" **Janssen** ," formerly known as Tibotec Pharmaceuticals, " **Tibotec** "). Each of Gilead and Janssen is sometimes referred to individually herein as a " **Party** " and collectively as the " **Parties** ."

RECITALS

WHEREAS, Gilead has developed and is marketing a proprietary reverse transcriptase inhibitor, Viread® (containing TDF (particularly 300 mg Tenofovir Disoproxil Fumarate and lower pediatric doses) as its only active pharmaceutical ingredient) (" **Viread** "), a proprietary nucleoside reverse transcriptase inhibitor, Emtriva® (containing FTC (particularly 200 mg Emtricitabine) as its only active pharmaceutical ingredient) (" **Emtriva** "), and a fixed-dose co-formulated product containing TDF (particularly 300 mg Tenofovir Disoproxil Fumarate) and FTC (particularly 200 mg Emtricitabine) as its only active pharmaceutical ingredients, Truvada® (" **Truvada** "), for the treatment of HIV infection in adults;

WHEREAS, Janssen or one or more of its Affiliates (as defined below) have developed and are marketing a proprietary non-nucleoside reverse transcriptase inhibitor, Edurant® (containing RPV (particularly 27.5 mg rilpivirine hydrochloride equivalent to 25 mg Rilpivirine) as its only active pharmaceutical ingredient) (" **Edurant** "), for the treatment of HIV infection in adults;

WHEREAS, Gilead or one or more of its Affiliates own or otherwise control certain intellectual property and other rights in and to a proprietary reverse transcriptase inhibitor containing TAF (particularly GS-7340) as its only active pharmaceutical ingredient, which inhibitor is being developed for the treatment of HIV infection in adults;

WHEREAS, pursuant to the License and Collaboration Agreement between the Parties dated July 16, 2009 (the " **Original Effective Date** "), as amended prior to the date hereof (the " **Original Agreement** "), the Parties have developed and are marketing Complera (as defined below);

WHEREAS, Gilead desires to develop a fixed-dose co-formulated product containing TAF, FTC and RPV as its only active pharmaceutical ingredients, and the Parties wish

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

to allocate among themselves certain rights and duties relating to the development and commercialization of the R/F/TAF Product (as defined below) in the Territory (as defined below);

WHEREAS, Janssen was the Selling Party for Complera in certain countries under the Original Agreement as of the Restatement Effective Date and will continue to be the Selling Party for Complera in those countries under this Agreement pursuant to the Janssen Distributor Agreement (as defined below), subject to the terms and conditions hereof;

WHEREAS, the Parties believe that Complera is and the R/F/TAF Product will become an important treatment for the HIV community, and that in addition to the therapeutic benefit, Complera does and the R/F/TAF Product will improve health by driving compliance with treatment regimens;

WHEREAS, the Parties desire to amend and restate the Original Agreement to make certain modifications to their rights and obligations with respect to Complera and to set forth their rights and obligations with respect to the R/F/TAF Product; and

WHEREAS, both Complera and the R/F/TAF Product are, in part, the result of the cooperative effort of the Parties as set forth in this Agreement.

NOW, THEREFORE, in consideration of the mutual promises and covenants set forth below and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

1 DEFINITIONS

Unless otherwise specifically provided herein, the following terms shall have the following meanings:

1.1 " **3TC** " shall mean the compound set forth in Annex GG-5 , known as lamivudine.

1.2 " **Accounting Standards** " shall mean United States Generally Accepted Accounting Principles (GAAP) or International Financial Reporting Standards (IFRS) if required in lieu of GAAP for a public company filing financial reports with the U.S. Securities and Exchange Commission, in each case as then current at the relevant time, and as consistently applied by the applicable Party and its Affiliates.

1.3 " **Act** " shall mean the United States Food, Drug and Cosmetic Act, as amended.

1.4 " **ACTG** " shall mean the AIDS Clinical Trials Group.

1.5 " **Actual Percentages** " shall mean (a) with respect to Territory Complera, the Complera Actual Percentage, and (b) with respect to the Territory R/F/TAF Product, the R/F/TAF Product Actual Percentage.

1.6 " **Additional Personnel** " shall have the meaning set forth in Section 1.250.

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1.7 " **Additional Requirement** " shall have the meaning set forth in Section 8.4.

1.8 " **Additional Supply Price** " shall have the meaning set forth in Annex M-1 .

1.9 " **Ad Hoc Operating Committee** " shall have the meaning set forth in Section 2.3.

1.10 " **Affiliate** " of a Person shall mean any other Person that, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with such Person. For purposes of this definition only, "control" and, with correlative meanings, the terms "controlled by" and "under common control with" shall mean (a) the possession, directly or indirectly, of the power to direct the management or policies of a Person, whether through the ownership of voting securities or by contract relating to voting rights or corporate governance, or (b) the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities or other ownership interest of a Person; provided , however , that if local law restricts foreign ownership to fifty percent (50%) or less of such securities or such interest, control shall be established by direct or indirect ownership of the maximum ownership percentage that may, under such local law, be owned by foreign interests. For purposes of this Agreement and the Ancillary Agreements, Bristol-Myers Squibb & Gilead Sciences, LLC shall constitute an Affiliate of Gilead solely when and to the extent that Gilead has voting control with respect to such entity.

1.11 [*].

1.12 " **Agreement** " shall have the meaning set forth in the preamble hereto.

1.13 " **Alliance Manager** " shall have the meaning set forth in Section 2.1.

1.14 " **Amended D/C/F/TAF Agreement** " shall mean that certain Amended and Restated Collaboration Agreement between the Parties, relating to darunavir, cobicistat, FTC and TAF, dated as of even date herewith, as such agreement is amended from time to time.

1.15 " **Ancillary Agreements** " shall mean, collectively, (a) the Janssen Distributor Agreement, (b) the PVA, (c) the Quality Agreement(s), (d) the RPV Supply Agreement, (e) the Co-Detailing LOA's, (f) the Data Sharing LOA, (g) the Master Clinical Trial Material Agreement, and the quality agreement(s) related thereto (as may be amended from time to time), in each case (under this clause (g)) solely as relating to the following supplement(s) to the Master Clinical Trial Material Agreement: that certain Clinical Trial Material Agreement Supplement by and between Janssen R&D Ireland, Janssen Services, LLC, Janssen Infectious Diseases - Diagnostics BVBA, Gilead Sciences, Inc. and Gilead Sciences Ireland UC, dated as of October 23, 2014, as may be amended from time to time, and any other supplements entered into in the future that are designated by the Parties (or their Affiliates that are parties to such supplements) as an Ancillary Agreement hereunder, as may be amended from time to time, and (h) any other agreement that is now or in the future designated in writing to be an Ancillary Agreement by the Parties (or their Affiliates that are parties to such agreements), as may be amended from time to time.

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1.16 " **Annual Manufacturing Fee** " shall have the meaning set forth in Annex M-4 .

1.17 " **Annual Yield Rate** " shall have the meaning set forth in Annex M-1 .

1.18 " **API** " shall mean active pharmaceutical ingredient.

1.19 " **API Conversion Amount** " shall have the meaning set forth in Annex M-1 .

1.20 " **Applicable Law** " shall mean all applicable laws, rules, regulations, guidelines or other requirements of governmental authorities, including those that may be in effect from time to time in the Territory with respect to the validity or enforceability of this Agreement or activities under this Agreement, as may be applicable.

1.21 " **Approved Price** " shall have the meaning set forth Annex M-2 .

1.22 " **Arbitration Matter** " shall mean any Dispute other than a Patent Matter or Expert Dispute, to the extent such Dispute (a) requires a determination as to the validity (including any claim of inducement of this Agreement by fraud or otherwise), application, interpretation or construction of, the compliance with, termination of, or breach of, this Agreement or any Ancillary Agreement or (b) is designated as an Arbitration Matter hereunder or under any Ancillary Agreement, provided that, in each case ((a) and (b)), such Dispute has been referred to, but not resolved by mutual agreement of, the Executives pursuant to Section 20.6 or, in the case of an Arbitration Matter related to the determination of an Estimated Yield Rate, the Manufacturing Executives pursuant to Annex M-1 . For clarity, nothing in this Section 1.22 is intended to impair or nullify either Party's final decision-making authority or right to consent with respect to any matter for which such Party is expressly stated to have final decision-making authority or right to consent under this Agreement.

1.23 " **Atripla** " shall mean that certain fixed-dose, co-formulated combination product containing as its only active pharmaceutical ingredients per single daily dose, TDF (particularly 300 mg Tenofovir Disoproxil Fumarate), FTC (particularly 200 mg Emtricitabine) and 600 mg efavirenz.

1.24 " **Attorney Representative** " shall have the meaning set forth in Section 2.3.1.

1.25 " **Audit** " shall have the meaning set forth in Section 10.8.1.1.

1.26 " **Audited Party** " shall have the meaning set forth in Section 10.8.1.1.

1.27 " **Auditing Party** " shall have the meaning set forth in Section 10.8.1.1.

1.28 " **Average Respective Percentage** " shall mean (a) with respect to Territory Complera, the Complera Average Respective Percentage, and (b) with respect to the Territory R/F/TAF Product, the R/F/TAF Product Average Respective Percentage.

1.29 " **Biannual Month** " shall have the meaning set forth in Annex M-1 .

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1.30 [*].

1.31 " **Branded Region B/C Complera** " shall mean any Territory Complera that is Manufactured by or on behalf of Gilead or its Affiliates in accordance with the applicable Territory Complera Specifications (as such term is defined in the Janssen Distributor Agreement) (including the tablet color and shape set forth therein), which Territory Complera Specifications describe a product intended by the Parties to be sold or otherwise Distributed (or Manufactured for sale or other Distribution) exclusively in Region B and Region C.

1.32 " **Branded Region B/C R/F/TAF Product** " shall mean any Territory R/F/TAF Product that is Manufactured by or on behalf of Gilead or its Affiliates in accordance with the applicable Territory R/F/TAF Product Specifications (as such term is defined in the Janssen Distributor Agreement) (including the tablet color and shape set forth therein), which Territory R/F/TAF Product Specifications describe a product intended by the Parties to be sold or otherwise Distributed (or Manufactured for sale or other Distribution) exclusively in Region B and Region C.

1.33 " **Breaching Party** " shall have the meaning set forth in Section 19.4.1.

1.34 " **Business Day** " shall mean a day that is not a Saturday, Sunday, a day on which banking institutions in New York, New York or San Francisco, California are required by law to remain closed, or December 26 through December 31.

1.35 " **Calculation Period** " shall have the meaning set forth in Annex M-1 .

1.36 " **Calendar Quarter** " shall mean a period of three (3) consecutive calendar months ending on March 31, June 30, September 30 or December 31.

1.37 " **Calendar Year** " shall mean a period of twelve (12) consecutive calendar months commencing on January 1 and ending on December 31, or a portion thereof in the case of a first or last Calendar Year.

1.38 " **Canada Co-Detailing LOA** " shall mean that certain Letter Agreement, dated as of November 30, 2011, by and between Gilead Sciences Canada, Inc. and Janssen Inc., setting forth principles for Detailing by Janssen, Inc. in Canada, as such agreement is amended from time to time.

1.39 " **CDA** " shall mean that certain amended and restated mutual confidential disclosure agreement between Gilead Parent and Janssen entered into as of August 9, 2007.

1.40 " **Cessation** " shall have the meaning set forth in Section 11.6.

1.41 " **Clinical Data** " shall mean, with respect to a Clinical Trial, any and all final clinical study reports, top line results reports and the tables, figures and listings as specified in the statistical analysis plan for such Clinical Trial, to the extent that such reports, tables, figures and listings are Controlled by a Party or any of its Affiliates. For the sake of clarity, Clinical Data shall not include any raw data.

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1.42 " **Clinical Trial** " shall mean (a) any Combination Product Clinical Trial; (b) any clinical trial in humans of any Single Agent Product in the Field; or (c) any clinical trial in humans of any Double Agent Product in the Field.

1.43 " **CMC Data** " shall mean any and all information contained in, as well as data supporting, the "Chemistry, Manufacturing and Control" and facilities sections (or sections corresponding thereto) of a Drug Approval Application, including information contained in, or data supporting, any drug master files referenced therein.

1.44 " **CMO** " shall have the meaning set forth in Annex M-4 .

1.45 " **Co-Detailing LOA's** " shall mean, collectively, the Canada Co-Detailing LOA, the International Co-Detailing LOA and the U.S. Co-Detailing LOA.

1.46 " **Collaboration Inventions** " shall mean any and all Information and Inventions conceived, discovered, developed or otherwise made (as necessary to establish authorship or inventorship under United States copyright or patent law, as the case may be) in the course of, as a result of, or in connection with, (a) the Combination Product Development Activities or (b) the activities relevant to a Combination Product conducted under the MTA or TPA. "Collaboration Inventions" shall include inventions arising from Clinical Data derived or generated from Combination Product Development Activities and shall exclude any Information and Inventions made (x) by Janssen specifically with respect to any RPV Product or the APIs contained therein, and (y) by Gilead specifically with respect to any Gilead Compound Product or the APIs contained therein.

1.47 " **Combination Product** " shall mean each of Complera and the R/F/TAF Product.

1.48 " **Combination Product Clinical Trial** " shall mean any Complera Clinical Trial or any R/F/TAF Product Clinical Trial, as applicable.

1.49 [*].

1.50 " **Combination Product Development Activities** " shall mean any Development Activities with respect to a Territory Combination Product (including any Combination Product Clinical Trials) that are necessary or reasonably expected to be necessary to obtain or maintain Regulatory Approval(s) for such Territory Combination Product in the Field in any or all countries in the Territory, except the term "Combination Product Development Activities" shall exclude (a) any Combination Product Clinical Trials conducted by or on behalf of Janssen or its Affiliates or any Combination Product Clinical Trials conducted by or on behalf of Gilead, its Affiliates or its Sublicensees, in each case other than those necessary or reasonably expected to be necessary to obtain or maintain Regulatory Approval(s) for such Territory Combination Product in the Field in any or all countries in the Territory, (b) any Development Activities relating specifically to RPV (or one or more of the RPV Products) and (c) any Development Activities relating specifically to TDF, TAF or FTC (or one or more of the Gilead Compound Products).

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1.51 " **Combination Product Regulatory Activities** " shall mean all regulatory activities conducted for the applicable Territory Combination Product (and not with respect to any other product) that are necessary or reasonably expected to be necessary to obtain or maintain Regulatory Approval(s) of a Territory Combination Product in the Field in any or all countries in the Territory, but excluding any Development Activities other than regulatory affairs activities with respect to such Territory Combination Product.

1.52 " **Combination Product Regulatory Documentation** " shall mean all Regulatory Documentation that is (a) specifically applicable to a Combination Product or the Combination Product Development Activities and (b) developed by or on behalf of a Party, or any of its Affiliates, Third Party distributors or Sublicensees, pursuant to, and during the term of, this Agreement or any Ancillary Agreement, but excluding (i) any Regulatory Documentation developed, owned, or generated by any Generic Licensee, (ii) any Regulatory Documentation resulting from Development Activities relating specifically to RPV (or any RPV Product), including the Edurant Development Activities, (iii) any Regulatory Documentation resulting from Development Activities relating specifically to one or more of TDF, TAF or FTC (or one or more of the Gilead Compound Products), and (iv) any INDs that a Party that is not the MA Holder with respect to a given country is permitted to hold pursuant to Section 4.4.2.

1.53 " **Combination Product Trademarks** " shall mean the Product Trademark(s) selected by Gilead for use in connection with the Exploitation of a Territory Combination Product in the Field in the Territory in accordance with this Agreement, including (with respect to Territory Complera) COMPLERA ® and EVIPLERA ®, and other Trademarks relating thereto, including any registrations of any of the foregoing or any pending applications relating to any of the foregoing. Notwithstanding the foregoing, the following shall not constitute Combination Product Trademarks: (a) Gilead Licensed Trademarks, (b) Janssen Licensed Trademarks and (c) the names, logos and other Trademarks of the Parties and their respective Affiliates (whether or not included in (a) or (b)).

1.54 " **Commence** " shall mean to administer the first dosing of a subject in the applicable Clinical Trial. " **Commencement** " shall have a corresponding meaning.

1.55 " **Commercial Target Breach** " shall mean Gilead's failure to substantially achieve each or any of the Specific Targets under Section 6.2.2.

1.56 " **Commercialization Activities** " shall mean the marketing, promotion, including Detailing, Distribution, selling and other activities for the commercialization of a Territory Combination Product in the Field (including obtaining and maintaining any pricing approvals under Applicable Law and securing local or national drug plan reimbursement).

1.57 " **Commercially Reasonable Efforts** " shall mean, with respect to a given activity and a Party for a product or compound under this Agreement, the level of effort that would generally be used by such Party to conduct such activity for a product or compound owned by it or to which it has rights, which is of comparable market potential, profit potential or strategic value to such Party and is at a similar stage in its development or product life, taking into account, without limitation, issues of safety and efficacy, product profile, the proprietary

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position, the then-current competitive environment for such product or compound (and any individual agent comprising part of such product or compound), the likely timing of the product's or compound's (and any such individual agent's) entry into the market, the then-current market penetration, the return on investment potential of such product (and any individual agent comprising part of such product), the regulatory environment and status of the product (and any individual agent comprising part of such product), and other relevant scientific, technical and commercial factors, in each case as measured by the facts and circumstances at the time such efforts are due; provided , however , that the R/F/TAF Product shall not be taken into account when determining whether Gilead is using Commercially Reasonable Efforts with respect to a given activity for Complera in a given country until the filing of a Drug Approval Application for the R/F/TAF Product in such country. To the extent that the performance of a Party's obligations hereunder is adversely affected by the other Party's failure to perform its obligations hereunder, the impact of such performance failure will be taken into account in determining whether such Party has used Commercially Reasonable Efforts to perform such affected obligations.

1.58 " **Company Sponsored Trial** " shall mean a clinical trial sponsored by or on behalf of a Party or any of its Affiliates or (sub) licensees, but excluding any (a) investigator initiated studies or (b) ACTG studies, in each case ((a) and (b)), unless the applicable study is used by Janssen or its Affiliates in a Drug Approval Application for any Single Agent Product of Janssen or its Affiliates, or by the Selling Party in a Drug Approval Application for a Territory Combination Product.

1.59 " **Complera** " shall mean the fixed-dose co-formulated product in oral dosage form containing, as its only APIs per single daily dose, TDF, FTC and RPV, which product is either (a) a solid form that contains a dosage form of TDF equivalent to three hundred (300) milligrams Tenofovir Disoproxil Fumarate, FTC equivalent to two hundred (200) milligrams Emtricitabine and RPV equivalent to twenty-five (25) milligrams Rilpivirine; or (b) an age-appropriate pediatric formulation and dosage consistent with the Pediatric Investigation/Study Plan for a product that corresponds to the product described in clause (a) above, which plan is developed by Gilead and approved by Janssen in accordance with this Agreement.

1.60 " **Complera Actual Percentage** " shall have the meaning set forth on Annex I .

1.61 " **Complera Average Respective Percentage** " shall mean, with respect to a given Party and with respect to given Losses, (a) the weighted average of such Party's Complera Actual Percentage for each Calendar Year during the period commencing on the Original Effective Date and ending with the earlier of (i) the last Calendar Year during the Term and (ii) the Calendar Year immediately prior to the Calendar Year in which such Losses are incurred, with the weighting based on the Net Sales of Territory Complera in the Territory during each such Calendar Year or (b) in the case of any Losses incurred in or prior to the Calendar Year in which the First Commercial Sale of Territory Complera in the Territory first occurs, such Party's Complera Working Percentage for the Calendar Year in which such Losses are incurred.

1.62 " **Complera Clinical Trial** " shall mean: (a) any clinical trial in humans of Complera; or (b) any clinical trial in humans of a treatment regimen administered via multiple products that contain, in aggregate, all of RPV, FTC and TDF as its only three (3) APIs, in each

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case ((a) and (b)), conducted in accordance with this Agreement. For clarity, a clinical trial involving a comparison of subjects treated with Complera (or the multiple products described in clause (b) above) to subjects treated with a different combination product or other treatment regimen shall be considered a Complera Clinical Trial. Any clinical trial that only qualifies as a Complera Clinical Trial because of the inclusion of an unspecified background regimen shall not be considered a Complera Clinical Trial.

1.63 " **Complera Key Selling Messages** " shall have the meaning set forth in Section 6.7.1.

1.64 " **Complera Launch Period** " shall have the meaning set forth in Section 6.2.2.1.

1.65 " **Complera PVA** " shall mean that certain Amended Safety Data Exchange Agreement between the Parties dated September 19, 2013, as such agreement is amended from time to time.

1.66 " **Complera Third Party Trial** " shall have the meaning set forth in Section 3.2.2.2a.iii.

1.67 " **Complera Working Percentage** " shall have the meaning set forth on Annex H .

1.68 " **Completed Territory Combination Product** " shall have the meaning set forth in Annex M-1 .

1.69 " **Completion** " shall have the meaning set forth in Annex M-1 .

1.70 " **Confidential Information** " shall have the meaning set forth in Section 15.3.1.

1.71 " **Control** " shall mean, with respect to a grant of any license, sublicense, access, or other right by a Party to the other hereunder relating to any Information and Inventions, Regulatory Documentation, Patents, know-how or other intellectual property rights, the right of such Party, whether by ownership, license or otherwise, to grant a license, sublicense, access, or other right to or under such item, Patent or right as provided for in this Agreement without violating Applicable Law or the terms of any agreement or other binding arrangement with any Third Party (before taking into account the effect of any licenses granted under this Agreement, but after taking into account the effect of Section 14.1).

1.72 " **Corresponding Ratio** " shall have the meaning set forth in Annex M-1 .

1.73 " **Country Monthly Payment** " shall have the meaning set forth in Annex M-1 .

1.74 " **Country Ratio** " shall have the meaning set forth in Annex M-1 .

1.75 " **Court** " shall have the meaning set forth in Section 20.8.1.

1.76 " **Cover** ", " **Covered** " or " **Covering** " shall mean, with respect to a specified subject matter (such as a composition of matter, a method of use or activity), that, in the absence

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of a license granted, the Exploitation of such subject matter would or is reasonably likely to infringe the applicable Patent or Valid Claim.

1.77 " **CTD** " shall mean, with respect to each Combination Product, the portion of Gilead's NDA for such Combination Product filed in accordance with the Common Technical Document requirements, as defined by the International Conference on Harmonization.

1.78 " **Cure Period** " shall have the meaning set forth in Section 19.4.1.

1.79 " **Data Sharing LOA** " shall mean, collectively, (a) that certain Letter Agreement, dated as of March 21, 2011, by and between Janssen, Gilead Sciences, Inc., and Gilead Sciences Limited, and (b) that certain Letter Agreement, dated as of November 21, 2011, by and between Janssen, Gilead Sciences, Inc., and Gilead Sciences Limited, both (a) and (b), setting forth the obligations of the Parties with regards to [*], as such agreement is amended from time to time.

1.80 " **Defending Party** " shall have the meaning set forth in Section 18.7.2.

1.81 " **Detail** " shall mean an in-person presentation to a health care provider who has prescribing authority by a sales representative who is fully equipped with knowledge of, and local promotional materials and the Product Label with respect to, a Combination Product, in which presentation the characteristics of such Combination Product are described by such sales representative in a fair and balanced manner consistent with the requirements of Applicable Law and this Agreement, and in a manner that is customary in the industry for the purpose of promoting a prescription pharmaceutical product, but without regard to the position of the presentation within a call to the health care provider. For the avoidance of doubt, a promotional material drop or product reminder shall not constitute a Detail. When used as a verb, to "Detail" shall mean to engage in a Detail.

1.82 " **Detailing Year** " shall have the meaning set forth in Section 6.2.2.3.

1.83 " **Development Activities** " shall mean pre-clinical or clinical activities relating to any pharmaceutical product, including: pre-clinical testing, toxicology studies, formulation work, clinical studies (including bioequivalence studies), regulatory affairs activities with regard to clinical studies and clinical supplies, process development (including validation and scale-up), CMC Data development activities, pre-clinical and clinical manufacturing, validation, stability testing, and quality assurance technical support activities, test method development, statistical analysis, preparation of documentation and report writing.

1.84 " **Development Record Access Notice** " shall have the meaning set forth in Section 3.4.2.

1.85 " **Disclosing Party** " shall have the meaning set forth in Section 15.1.

1.86 " **Disclosure Statement** " shall mean a separate statement exchanged by the Parties that is identified on its face as the "Disclosure Statement" to this Agreement, is signed by the

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Parties and contains disclosures relating to any representation, warranty or covenant made by a Party under Article 17 as of the Restatement Effective Date.

1.87 " **Dispute** " shall have the meaning set forth in Section 20.6.1.

1.88 " **Distribute** " or " **Distribution** " shall mean, with respect to each country in the Territory, importing, selling, distributing, exporting, transporting and other activities associated with the foregoing listed activities with respect to the distribution of a product, including inventory management and control, warehousing and distribution, invoicing, collection of sales proceeds, preparation of sales records and reports, customer relations and services, and the handling of returns.

1.89 " **Distribution Activities** " shall have the meaning set forth in Section 6.6.

1.90 " **Distribution Subcontractor** " shall mean any Third Party subcontractor that (a) performs storage, warehousing or shipping, or coordination of any of the foregoing or (b) performs any of the Distribution Activities, in each case ((a) and (b)), with respect to a Territory Combination Product on behalf of a Selling Party (or its Affiliates) under this Agreement, other than Third Party Distributors.

1.91 " **Double Agent Product** " shall mean each of the F/TDF Product and the F/TAF Product.

1.92 " **Drug Approval Application** " shall mean, with respect to a product in a particular country, an application to the applicable Regulatory Authority for permission to market and/or sell such product in such country, including an NDA or MAA.

1.93 " **Edurant** " shall have the meaning set forth in the recitals hereto and shall mean such product as of the Restatement Effective Date.

1.94 " **Edurant Development Activities** " shall mean Development Activities with respect to Edurant.

1.95 " **Edurant Regulatory Activities** " shall mean the regulatory activities to be conducted for Edurant as required in order to obtain or maintain Regulatory Approvals of Edurant in the Field in the Territory, but excluding any Edurant Development Activities.

1.96 " **Edurant Study** " shall mean any Company Sponsored Trial that involves Edurant but does not include any other pharmaceutical product except (i) the F/TDF Product, (ii) the F/TAF Product, (iii) TDF and FTC (whether co-administered or co-formulated) or (iv) TAF and FTC (whether co-administered or co-formulated). Notwithstanding the foregoing, any clinical trial that would only qualify as an Edurant Study because of the inclusion of any of the items described in clauses (i) through (iv) in an unspecified background regimen shall not be considered an Edurant Study.

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1.97 " **EMA** " shall mean the European Medicines Agency or any successor entity thereto having review authority over applications for centralized Regulatory Approvals in the European Union.

1.98 " **Emtricitabine** " shall mean the compound set forth in Annex GG-3 , known as emtricitabine.

1.99 " **Emtriva** " shall have the meaning set forth in the recitals hereto and shall mean such product as of the Original Effective Date.

1.100 " **Estimated Yield Rate** " shall have the meaning set forth in Annex M-1 .

1.101 " **European Commission** " shall mean the governing body of the European Union, or such other entity(ies) responsible for proposing legislation, implementing decisions, upholding treaties and the general operation of the European Union, including issuance of Regulatory Approvals in the European Union.

1.102 " **European Union** " or " **EU** " shall mean all countries that are member states of the European Union as constituted from time to time.

1.103 " **Executive(s)** " shall mean (a) in the case of Gilead, the President and Chief Operating Officer of Gilead Parent, and (b) in the case of Janssen, a Worldwide Chairman of Janssen Parent's pharmaceutical group.

1.104 " **Executives Review Period** " shall have the meaning set forth in Section 20.6.2.

1.105 " **Existing Gilead Licenses** " shall mean any of those license agreements on Annex Y .

1.106 " **Existing RPV Licenses** " shall mean any of those license agreements on Annex W .

1.107 " **Expert** " shall have the meaning set forth in Section 20.6.3.

1.108 " **Expert Dispute** " shall mean a matter that is subject to resolution by an Expert in accordance with Section 20.6.2.3.

1.109 " **Exploitation** " or " **Exploit** " shall mean the making, having made, importation, exportation, use, sale, offering for sale, having sold, disposition, research, development, registration, modification, enhancement, Manufacturing, storage, formulation, optimization, transport, distribution, promotion or marketing of a product or process. When used as a verb, "Exploit" shall mean to engage in any of the foregoing activities.

1.110 " **FDA** " shall mean the United States Food and Drug Administration and any successor entity thereto having authority over Regulatory Approvals in the United States.

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1.111 " **Field** " shall mean all human use in the prophylaxis and treatment of HIV infection.

1.112 " **Finance Representative** " shall have the meaning set forth in Section 2.3.1.

1.113 " **Financial Records** " shall have the meaning set forth in Section 10.6.

1.114 " **Financial Reporting Committee** " shall have the meaning set forth in Section 2.3.

1.115 " **Finished Product** " shall have the meaning set forth in Section 9.3.3.

1.116 " **First Calendar Year** " shall have the meaning set forth in Annex M-1 .

1.117 " **First Commercial Sale** " shall mean, with respect to the applicable product in a country, the first sale in an arm's length transaction and shipment of such product to a Third Party by a Party or any of its Affiliates or (sub)licensees in the Field in such country following Marketing Approval of such product in such country. For the avoidance of doubt, a first sale for compassionate use or named patient program sales shall not constitute a First Commercial Sale for purposes of this Agreement.

1.118 " **Force Majeure Event** " shall have the meaning set forth in Section 20.1.

1.119 " **F/TAF Market** " shall mean, [*].

1.120 " **F/TAF NSP** " shall have the meaning set forth in Annex M-1 .

1.121 " **F/TAF Product** " shall mean any fixed-dose co-formulated FTC Product in oral dosage form containing, as its only two (2) APIs, FTC and TAF.

1.122 " **F/TDF NSP** " shall have the meaning set forth in Annex M-1 .

1.123 " **F/TDF Product** " shall mean any fixed-dose co-formulated FTC Product in oral dosage form containing, as its only two (2) APIs, FTC and TDF, including Truvada.

1.124 " **FTC** " shall mean Emtricitabine or any or all of the following: [*].

1.125 " **FTC Product** " shall mean any pharmaceutical product containing FTC, which product is under development or is being sold at any time by Gilead or an Affiliate, subcontractor, (sub)licensee, or Third Party distributor of Gilead or its Affiliates, including any FTC Single Agent Product, F/TDF Product or F/TAF Product; provided , however , that the term "FTC Product" shall not include any Combination Product or any STR (as defined in the Amended D/C/F/TAF Agreement).

1.126 " **FTC Single Agent Product** " shall mean any FTC Product that contains FTC as its only API, including Emtriva.

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1.127 " **Generic Basis** " shall mean, with regard to commercialization of a product, the commercialization of a generic oral version of such product that is approved for marketing by a Third Party in the Field either: (i) pursuant to Section 505(j) of the Act (21 U.S.C. 355(j)) or a foreign equivalent thereof by reference to a Marketing Approval of such product, or (ii) pursuant to any other law or regulation where such approval is based on a demonstration of bio-equivalence or biosimilarity to such product. Under no circumstances shall a product be considered commercialized on a Generic Basis if a Party or its Affiliates or its (sub)licensees (a) transferred a Marketing Approval of such product to such Third Party, (b) transferred an application for Marketing Approval of such product to such Third Party, or (c) provided a Right of Reference to such Third Party in order to enable such Third Party to commercialize such product, except for a right of reference limited to qualifying the generic version for a government and/or nonprofit entity's program for providing medicines at no or low cost to countries in Region C (such as the President's Emergency Plan for AIDS Relief).

1.128 " **Generic Combination Product** " shall mean (a) with respect to Complera, Generic Complera, and (b) with respect to the R/F/TAF Product, Generic R/F/TAF Product.

1.129 " **Generic Competition Period** " shall mean, [*].

1.130 " **Generic Complera** " shall mean an oral product owned or otherwise controlled by a Third Party that (a) contains all three (3) of RPV, FTC and TDF as its only APIs and (b) is approved (or sought to be approved) in the Field either: (i) pursuant to Section 505(j) of the Act (21 U.S.C. 355(j)) or a foreign equivalent thereof by reference to a Marketing Approval of Territory Complera or any RPV Product, FTC Product or TDF Product, or (ii) pursuant to any other law or regulation where such approval is based on a demonstration of bio-equivalence or biosimilarity to any of the foregoing products.

1.131 " **Generic Equivalent** " shall have the meaning set forth in [*].

1.132 " **Generic Exception** " shall have the meaning set forth in Section 17.3.1.

1.133 " **Generic F/TAF Combination** " shall mean a product owned or controlled by a Third Party that (a) is in oral dosage form, (b) contains as its only APIs per single daily dose, TAF equivalent to 25 mg GS-7340 and FTC equivalent to 200 mg Emtricitabine, and (c) is approved (or sought to be approved) in the Field either: (i) pursuant to Section 505(j) of the Act (21 U.S.C. 355(j)) or a foreign equivalent thereof by reference to a Marketing Approval of F/TAF Product or any FTC Product or TAF Product, or (ii) pursuant to any other law or regulation where such approval is based on a demonstration of bio-equivalence or biosimilarity to any of the foregoing products.

1.134 " **Generic F/TAF Combination Threshold** " shall mean, [*].

1.135 " **Generic FTC/TDF Combination** " shall mean a product owned or controlled by a Third Party that (a) is in oral dosage form, (b) contains as its only APIs per single daily dose, TDF equivalent to 300 mg Tenofovir Disoproxil Fumarate and FTC equivalent to 200 mg Emtricitabine, and (c) is approved (or sought to be approved) in the Field either: (i) pursuant to

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Section 505(j) of the Act (21 U.S.C. 355(j)) or a foreign equivalent thereof by reference to a Marketing Approval of Truvada or any FTC Product or TDF Product, or (ii) pursuant to any other law or regulation where such approval is based on a demonstration of bio-equivalence or biosimilarity to any of the foregoing products.

1.136 " **Generic FTC/TDF Combination Threshold** " shall mean, [*].

1.137 " **Generic Licensee** " shall mean a Third Party that is authorized by a Party or a Party's Affiliate to: (a) manufacture a generic version of such Party's Single Agent Product(s) (or with respect to Gilead, its Double Agent Products) or other combination products containing one or more of such API(s), as applicable, on a Generic Basis or the API(s) therein, in order to sell such generic products or to sell such API(s) for use in such generic products; or (b) sell a generic version of any such products on a Generic Basis. With regard to Gilead, the term "Generic Licensee" shall also include MPP or any MPP Licensee(s).

1.138 " **Generic R/F/TAF Product** " shall mean an oral product owned or otherwise controlled by a Third Party that (a) contains all three (3) of RPV, FTC and TAF as its only APIs and (b) is approved (or sought to be approved) in the Field either: (i) pursuant to Section 505(j) of the Act (21 U.S.C. 355(j)) or a foreign equivalent thereof by reference to a Marketing Approval of the Territory R/F/TAF Product or any RPV Product, FTC Product or TAF Product, or (ii) pursuant to any other law or regulation where such approval is based on a demonstration of bio-equivalence or biosimilarity to any of the foregoing products.

1.139 " **Generic Sales** " shall have the meaning set forth in [*].

1.140 " **Generic Threshold** " shall have the meaning set forth in Annex M-2 .

1.141 " **Gilead** " shall have the meaning set forth in the preamble hereto.

1.142 " **Gilead Clinical Data** " shall have the meaning set forth in Section 3.2.4.4.

1.143 " **Gilead Component Characteristics** " shall have the meaning set forth in Section 18.2.1.

1.144 " **Gilead Compound Data Exclusivity** " shall have the meaning set forth in Section 9.2.3.1.

1.145 " **Gilead Compound Infringement** " shall mean an infringement or misappropriation of any Patent or other intellectual property, including trade secrets, of a Third Party resulting from:

(a) the importation of a Territory Combination Product by or on behalf of Janssen or its Affiliates, which infringement or misappropriation directly results from the incorporation into such Territory Combination Product of TAF, TDF or FTC, but [*], or

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(b) the importation of a Territory Combination Product by or on behalf of Janssen or its Affiliates, which infringement or misappropriation directly results from the manufacture of any TAF, TDF or FTC that is incorporated into such Territory Combination Product, but [*],

in each case ((a) and (b)) without reference to the combination of the applicable Gilead Compound Product with RPV. For purposes of the definition of Gilead Compound Infringement, (x) "incorporation" or "incorporated" shall mean the presence of TAF, TDF or FTC, as applicable, in a Territory Combination Product, and not the process of incorporating TAF, TDF or FTC, as applicable, into a Territory Combination Product, and (y) Gilead Compound Infringement shall include only misappropriation by Gilead (or its Affiliates or contract manufacturers) and not by Janssen or any of its Indemnified Persons.

1.146 " **Gilead Compound Product** " shall mean any TDF Product, TAF Product or FTC Product. For the sake of clarity, "Gilead Compound Product" shall include any F/TAF Product or F/TDF Product, but shall exclude any Combination Product and the Duo Combination Product (as defined in the Amended D/C/F/TAF Agreement).

1.147 " **Gilead-Controlled Combination Product Joint Patents** " shall have the meaning set forth in Section 14.2.3.1a.

1.148 " **Gilead Core Technology** " shall mean all Information and Inventions Controlled by Gilead relating specifically to the Exploitation of FTC, TDF or TAF, or any combination of any of FTC, TDF and TAF, or any Gilead Compound Product (including the Double Agent Products and Atripla, but excluding, for clarity, any Combination Product).

1.149 " **Gilead Countries** " shall mean, at any time, any country other than the Janssen Countries (for clarity, including any Gilead Take-Over Countries and excluding any Janssen Take-Over Countries).

1.150 " **Gilead In-License Requirements** " shall have the meaning set forth in Section 9.5.1.

1.151 " **Gilead Know-How** " shall mean any and all Information and Inventions under the Control of Gilead or any of its Affiliates at any time during the period beginning on the Original Effective Date and ending on the last day of the Term (other than pursuant to Section 9.1) that are necessary or reasonably expected to be necessary for the Exploitation of a Territory Combination Product or are disclosed to Janssen or its Affiliates by Gilead or its Affiliates in the course of the performance of this Agreement or under the PVA (or other safety-data exchange provisions contained in any other Ancillary Agreement) and are not generally known to Third Parties, including any such Information and Inventions included in the Gilead-Owned Collaboration Inventions, but excluding any and all (a) such Information and Inventions to the extent disclosed by published Gilead Patents, (b) Joint Know-How and (c) any (i) business information, medical education materials, promotional materials and marketing and strategic studies, or (ii) information relating to the validity or enforceability of any Patents or any freedom to operate analysis. For clarity, Gilead Know-How shall not (x) include any Gilead Regulatory

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Documentation, but shall include Clinical Data Controlled by Gilead or its Affiliates or (y) include any Information and Inventions with respect to any compound other than TDF, TAF, FTC or RPV.

1.152 " **Gilead Licensed Trademarks** " shall mean any Trademarks used by Gilead or its Affiliates in connection with the Exploitation of Viread, Emtriva, Truvada or the F/TAF Product. A list of certain Gilead Licensed Trademarks existing as of the Restatement Effective Date is attached hereto as Annex A-1 , which list Gilead shall update as reasonably requested by Janssen in writing.

1.153 " **Gilead Marketing Approval** " shall have the meaning set forth in Section 4.8.

1.154 " **Gilead-Owned Collaboration Invention** " shall mean any Collaboration Invention pertaining specifically and solely to Gilead Core Technology.

1.155 " **Gilead Parent** " shall have the meaning set forth in the preamble hereto.

1.156 " **Gilead Patents** " shall mean all of the Patents under the Control of Gilead or any of its Affiliates (other than pursuant to Section 9.1) at any time during the period beginning on the Original Effective Date and ending on the last day of the Term that would be infringed by the Exploitation of any Combination Product by a Person Distributing such Combination Product if such Combination Product were not purchased from Gilead. A list of certain Gilead Patents in the Janssen Countries, existing as of the Restatement Effective Date, is attached hereto as Annex B-1 , which list Gilead shall update as reasonably requested by Janssen in writing. The Gilead Patents do not include the Joint Patents. For clarity, the Gilead Patents include Patents Covering the Gilead-Owned Collaboration Inventions.

1.157 " **Gilead Payment Term** " shall have the meaning set forth in Annex M-5 .

1.158 " **Gilead Permitted Use** " shall mean (a) obtaining and maintaining Regulatory Approvals (including the initial Product Label and updates thereto) of any Territory Combination Product in the Gilead Countries, any Single Agent Product of Gilead or any Double Agent Product of Gilead in the Territory (such product(s) alone or in combination with RPV or an RPV Single Agent Product but not in combination with other compounds or products), (b) the performance of Gilead's obligations and exercise of Gilead's rights under this Agreement and (c) compliance with Applicable Law.

1.159 " **Gilead Redactable Information** " shall mean:

[*].

1.160 " **Gilead Regulatory Documentation** " shall mean all Regulatory Documentation that (a) is with respect to (i) TDF, TAF, FTC or a Gilead Compound Product, in each case in the Field, or (ii) a Combination Product and (b) is Controlled by Gilead or its Affiliates at any time during the period beginning on the Original Effective Date and ending on the last day of the Term.

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1.161 " **Gilead Results** " shall have the meaning set forth in Section 3.6.1.

1.162 " **Gilead Specified Rights** " shall have the meaning set forth in Section 19.3.

1.163 " **Gilead Sub** " shall have the meaning set forth in the preamble hereto.

1.164 " **Gilead Take-Over Country** " shall mean, at any time, any country (a) that was a Janssen Country as of the Restatement Effective Date, (b) with respect to which the Janssen Distributor Agreement has terminated and (c) with respect to which Gilead has elected to convert such country to a Gilead Country pursuant to [*].

1.165 " **Gilead Technology** " shall mean, collectively, the Gilead Know-How and the Gilead Patents.

1.166 " **Good Clinical Practice** " or " **GCP** " shall mean the then-current standards for clinical trials for pharmaceutical products, as set forth in Applicable Law, as amended from time to time.

1.167 " **Good Distribution Practice** " or " **GDP** " shall mean the then-current standards for Distribution activities as set forth by the World Health Organization and Applicable Law, as amended from time to time.

1.168 " **Good Laboratory Practice** " or " **GLP** " shall mean the then-current standards for laboratory activities for pharmaceutical products, as set forth in Applicable Law, as amended from time to time.

1.169 " **Good Manufacturing Practice** " or " **GMP** " shall mean applicable current good manufacturing practices for pharmaceutical products (and components thereof) as described in regulations promulgated by the applicable Regulatory Authority, as amended from time to time.

1.170 " **GS-7340** " shall mean the compound set forth in Annex GG-1 , known as GS-7340.

1.171 [*] shall have the meaning set forth in [*].

1.172 " **Hold Criteria** " shall have the meaning set forth in Section 4.8.

1.173 " **IND** " shall mean (a) an Investigational New Drug Application as defined in the Act and regulations promulgated thereunder or any successor application or procedure required to initiate clinical testing of a drug in humans in the United States; (b) a counterpart of such an Investigational New Drug Application that is required in any other country in the Territory before beginning clinical testing of a drug in humans in such country; and (c) all supplements and amendments to any of the foregoing.

1.174 " **Indemnified Party** " shall mean a Party that is seeking, or has an Indemnified Person that is seeking, indemnification (or other reimbursement) for Losses pursuant to Article 18.

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1.175 " **Indemnified Persons** " shall mean, with respect to a Party, such Party, its Affiliates and their respective agents, officers, directors and employees.

1.176 " **Indemnifying Party** " shall mean the Party responsible for indemnifying the Indemnified Party and its Indemnified Persons under Article 18.

1.177 " **Information and Inventions** " shall mean all technical, scientific and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulas, instructions, skills, techniques, procedures, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, results and other material, including Manufacturing procedures, test procedures, and purification and isolation techniques (whether or not confidential, proprietary, patented or patentable) in written, electronic or any other form, and all other discoveries, developments, inventions (whether or not confidential, proprietary, patented or patentable), and tangible embodiments of any of the foregoing. Information and Inventions shall be deemed to exclude Regulatory Documentation, but, for clarity, shall include Clinical Data. Notwithstanding the foregoing, in no event shall Information and Inventions include any (a) promotional or sales materials, or (b) information relating to the validity or enforceability of any Patents or any freedom to operate analysis.

1.178 " **Infringement** " shall have the meaning set forth in Section 14.4.4.

1.179 " **Infringing Combination Product** " shall have the meaning set forth in Section 14.4.4.

1.180 " **Initial Specific Target Breach** " shall mean, with respect to each applicable Major Market Country and each Specific Target, the first failure by Gilead to substantially achieve such Specific Target in such country.

1.181 " **In-License Agreement** " shall mean any Existing RPV License, any Existing Gilead License or any agreement deemed to be an In-License Agreement pursuant to Section 9.5.4.

1.182 " **In-License Requirements** " shall mean the Janssen In-License Requirements or the Gilead In-License Requirements, as applicable.

1.183 " **Input Supplied RPV** " shall have the meaning set forth in Annex M-1 .

1.184 " **International Co-Detailing LOA** " shall mean that certain Amended and Restated Letter Agreement, dated as of November 4, 2013, by and between Janssen R&D Ireland and Gilead Sciences, Inc., which sets forth Detailing principles for the Co-Detailing Territory (defined therein), as such agreement is amended from time to time.

1.185 " **International Public Organization** " shall mean any of the organizations listed on 8 C.F.R. § 316.20, as amended from time to time.

1.186 " **JAMS** " shall have the meaning set forth in Section 20.7.1.

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1.187 " **Janssen** " shall have the meaning set forth in the preamble hereto.

1.188 " **Janssen Blended Ratio** " shall have the meaning set forth in Annex M-3 .

1.189 " **Janssen Clinical Data** " shall have the meaning set forth in Section 3.1.2.

1.190 " **Janssen-Controlled Combination Product Joint Patents** " shall have the meaning set forth in Section 14.2.3.1b.

1.191 " **Janssen Core Technology** " shall mean all Information and Inventions Controlled by Janssen and relating specifically to the Exploitation of RPV or any RPV Product, but excluding for clarity the Combination Products.

1.192 " **Janssen Countries** " shall mean, at any time, each of the countries set forth on Annex AA-2 , but excluding any Gilead Take-Over Countries and including any Janssen Take-Over Countries.

1.193 [*].

1.194 " **Janssen Distributor Agreement** " shall mean the agreement entered into on even date hereof between the Parties in the form set forth in Annex Z , which agreement amends and restates the Janssen Distributor Agreement (as defined in the Original Agreement), and pursuant to which Janssen will act as Gilead's exclusive distributor of Territory Combination Products within the Janssen Countries, as such agreement is amended from time to time.

1.195 " **Janssen In-License Requirements** " shall have the meaning set forth in Section 9.5.1.

1.196 " **Janssen Know-How** " shall mean any and all Information and Inventions under the Control of Janssen or any of its Affiliates at any time during the period beginning on the Original Effective Date and ending on the last day of the Term that are necessary or reasonably expected to be necessary for the Exploitation of a Combination Product or are disclosed to Gilead or its Affiliates by Janssen or its Affiliates in the course of the performance of this Agreement or under the PVA (or other safety-data exchange provisions contained in any other Ancillary Agreement) and are not generally known to Third Parties, including any such Information and Inventions included in the Janssen-Owned Collaboration Inventions, but excluding any and all (a) such Information and Inventions to the extent disclosed by published Janssen Patents, (b) Joint Know-How and (c) (i) business information, medical education materials, promotional materials and marketing and strategic studies, or (ii) information relating to the validity or enforceability of any Patents or any freedom to operate analysis. For clarity, Janssen Know-How shall not include (x) any Janssen Regulatory Documentation, but shall include Clinical Data Controlled by Janssen or its Affiliates or (y) any Information and Inventions with respect to any compound other than RPV, TAF, TDF or FTC.

1.197 " **Janssen Licensed Trademarks** " shall mean any Trademarks used by Janssen or its Affiliates in connection with the Exploitation of the RPV Single Agent Product, including

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Edurant. A list of certain Janssen Licensed Trademarks existing as of the Restatement Effective Date is attached hereto as Annex A-2 , which list Janssen shall update as reasonably requested by Gilead in writing.

1.198 " **Janssen-Owned Collaboration Invention** " shall mean any Collaboration Invention pertaining specifically and solely to Janssen Core Technology.

1.199 " **Janssen Parent** " shall mean Johnson & Johnson, a New Jersey corporation.

1.200 " **Janssen Patents** " shall mean all of the Patents under the Control of Janssen or any of its Affiliates at any time during the period beginning on the Original Effective Date and ending on the last day of the Term that Cover any or all of the following: the composition of matter, method of use, formulation, Manufacture, import or sale of RPV or any Combination Product. A list of certain Janssen Patents existing as of the Restatement Effective Date is attached hereto as Annex B-2 , which list Janssen shall update as reasonably requested by Gilead in writing. The Janssen Patents do not include the Joint Patents. For clarity, the Janssen Patents do include Patents Covering the Janssen-Owned Collaboration Inventions.

1.201 " **Janssen Payment Term** " shall have the meaning set forth in the Janssen Distributor Agreement.

1.202 " **Janssen Percentage** " shall have the meaning set forth in Annex M-1 .

1.203 " **Janssen Permitted Use** " shall mean solely (a) obtaining and maintaining Regulatory Approvals (including the initial Product Label and updates thereto) of any Territory Combination Product in the Janssen Countries or any Single Agent Product of Janssen in the Territory (such Single Agent Product alone or in combination with FTC, TDF or TAF or Truvada, the F/TAF Product, the FTC Single Agent Product, the TDF Single Agent Product or the TAF Single Agent Product, but not in combination with other compounds or products), (b) performing Janssen's obligations or exercising Janssen's rights under this Agreement and (c) compliance with Applicable Law.

1.204 " **Janssen Portion** " shall have the meaning set forth in Annex M-4 .

1.205 " **Janssen Ratio** " shall have the meaning set forth in Annex M-3 .

1.206 " **Janssen Redactable Information** " shall mean:

[*].

1.207 " **Janssen Regulatory Documentation** " shall mean all Regulatory Documentation (a) with respect to any RPV Single Agent Product and (b) that is Controlled by Janssen or any of its Affiliates at any time during the period beginning on the Original Effective Date and ending on the last day of the Term.

1.208 " **Janssen Reliant Country** " shall have the meaning set forth in Section 4.8.

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1.209 " **Janssen Results** " shall have the meaning set forth in Section 3.6.2.

1.210 " **Janssen Share** " shall have the meaning set forth in Annex M-1 .

1.211 " **Janssen Specified Rights** " shall have the meaning set forth in Section 19.3.

1.212 " **Janssen Take-Over Country** " shall mean, at any time, any country that was a Gilead Country as of the Restatement Effective Date, with respect to which Janssen has elected to convert such country to a Janssen Country pursuant to any applicable provision of this Agreement.

1.213 " **Janssen Technology** " shall mean, collectively, the Janssen Know-How and the Janssen Patents.

1.214 " **Joint Collaboration Inventions** " shall mean all Collaboration Inventions, but excluding any Janssen-Owned Collaboration Inventions and Gilead-Owned Collaboration Inventions.

1.215 " **Joint Know-How** " shall mean any and all Information and Inventions included in the Joint Collaboration Inventions that are not generally known, but excluding any Information and Inventions to the extent (a) disclosed by published Joint Patents, or (b) published pursuant to Section 3.6.

1.216 " **Joint Patents** " shall mean any Patents to the extent that such Patents Cover Joint Collaboration Inventions.

1.217 " **Joint Technology** " shall mean, collectively, the Joint Know-How and the Joint Patents.

1.218 " **Key Selling Messages** " shall have the meaning set forth in Section 6.7.1.

1.219 " **Key Territory** " shall mean the following countries: the countries comprising the European Union, [*] and the United States.

1.220 " **Label Characteristics** " shall have the meaning set forth in Section 18.2.2.

1.221 " **Launch Period** " shall mean, in the case of Territory Complera, the Complera Launch Period and, in the case of Territory R/F/TAF Product, the R/F/TAF Launch Period.

1.222 " **Lead Patent Party** " shall have the meaning set forth in Section 14.2.3.2.

1.223 " **Licensor Patent** " shall mean any Janssen Patent that Covers any or all of the following: the composition of matter, method of use, formulation, Manufacture, import or sale of RPV or Supplied RPV or a Combination Product.

1.224 " **Local Promotional Materials** " shall have the meaning set forth in Section 6.7.2.

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1.225 " **Losses** " shall mean judgments, fines, amounts paid in settlement, and reasonable, direct, out-of-pocket costs and expenses (including reasonable attorneys' fees) incurred by a Party (or other indemnitee as provided in Article 18) in a Proceeding. For clarity, Recall Expenses shall not constitute Losses.

1.226 " **Lost Supplied RPV** " shall have the meaning set forth in Annex M-1 .

1.227 " **MAA** " shall mean (a) a marketing authorization application filed with (i) the EMA under the centralized EMA filing procedure or (ii) a Regulatory Authority in any country in the European Union if the centralized EMA filing procedure is not used to obtain Marketing Approval; or (b) any other equivalent or related regulatory submission to gain Marketing Approval in any country in the European Union.

1.228 " **MA Holder** " shall mean the entity that holds the Marketing Approval for a product in a given country.

1.229 " **Major Market Countries** " shall mean the United States, [*], France, Germany, Italy, Spain, the United Kingdom [*].

1.230 " **Mandatory Price Reduction** " shall have the meaning set forth in Annex M-2 .

1.231 " **Manufacture** " or " **Manufacturing** " shall mean, with respect to a product or API, the manufacturing, processing, formulating, packaging, labeling, holding (including storage), and quality control testing (including release) of such product or API.

1.232 " **Manufacturing Completion** " shall have the meaning set forth in Annex M-1 .

1.233 " **Manufacturing Executives** " shall have the meaning set forth in Annex M-1 .

1.234 " **Manufacturing Fee** " shall have the meaning set forth in Annex M-4 .

1.235 " **Manufacturing Fee Percentage** " shall have the meaning set forth in Annex M-3 .

1.236 " **Manufacturing Process** " shall mean any process or step thereof that is necessary or useful for Manufacturing a Territory Combination Product from (a) the Supplied RPV, (b) TDF or TAF, as applicable, and (c) FTC, in each case ((a), (b) and (c)) whether in bulk granulation form or any other form. Manufacturing Process shall not include making RPV in any form.

1.237 " **Marketing Approval** " shall mean, with respect to a given product and a given country or jurisdiction, an approval by the applicable Regulatory Authority of a Drug Approval Application for such product in such country or jurisdiction, including all post-approval commitments, supplements and amendments to such an application, but excluding any pricing and reimbursement approvals or, except in countries where the import license provides a right to market and sell the product, import licenses.

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1.238 " **Master Clinical Trial Material Agreement** " shall mean the Master Clinical Trial Material Agreement, effective as of November 17, 2005, entered into by Janssen and Gilead Parent, as amended by Janssen, Gilead Parent, and Tibotec Therapeutics Clinical Affairs, Division of Ortho Biotech Clinical Affairs LLC (as used in this Section 1.238, "Tibotec Therapeutics") in Amendment #1 to Master Clinical Trial Material Agreement, last dated October 2, 2006, and as amended by Janssen, Gilead Parent, Tibotec Therapeutics, and Tibotec BVBA in Amendment # 2 to the Master Clinical Trial Material Agreement, effective as of November 5, 2010 and as thereafter amended from time to time.

1.239 " **Material** " shall mean RPV, TDF, TAF or FTC, as applicable.

1.240 " **Material Breach** " shall mean (a) with respect to Territory Complera, (i) in the case of Gilead, a Commercial Target Breach, or (ii) in the case of either Party, a breach of this Agreement that goes to the root of this Agreement with respect to Territory Complera and that is so substantial that it defeats the object of the aggrieved Party in making this Agreement with respect to Territory Complera, and (b) with respect to the Territory R/F/TAF Product, in the case of either Party, a breach of this Agreement that goes to the root of this Agreement with respect to the Territory R/F/TAF Product and that is so substantial that it defeats the object of the aggrieved Party in making this Agreement with respect to the Territory R/F/TAF Product. In determining whether a breach is a Material Breach, the arbitrator shall take into particular consideration the special purpose of this Agreement with respect to the applicable Territory Combination Product and the extent to which the injured Party will be deprived of the benefit which it reasonably expected in entering into this Agreement with respect to the applicable Territory Combination Product.

1.241 " **Material Supplier** " shall mean, in the case of RPV, Janssen, or, in the case of TDF, TAF or FTC or Territory Combination Product, Gilead.

1.242 " **Monthly Payment** " shall have the meaning set forth in Annex M-1 .

1.243 " **Monthly Payment Term** " for a given Territory Combination Product and country of the Territory (including the Janssen Countries), shall mean the period that commences as of the date of First Commercial Sale of such applicable Territory Combination Product in such country and expires at the later of: (a) [*] after the date of First Commercial Sale of Territory Complera or the Territory R/F/TAF Product, as applicable, in such country; and (b) expiration or invalidation (as described in the definition of Valid Claim) of the last of the Valid Claims of the Licensor Patent(s) that Covers Exploitation of such applicable Territory Combination Product in such country by Gilead or its Affiliates, Sublicensees or Third Party Distributors.

1.244 " **Monthly Quantity** " shall have the meaning set forth in Annex M-1 .

1.245 " **MPP** " shall mean the Medicines Patent Pool, a non-profit foundation registered under the laws of Switzerland, and having a principal place of business at 150 route de Ferney, P.O. Box 2100, CH-1211 Geneva 2, Switzerland, or any successor thereof.

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1.246 " **MPP License** " shall mean each of (a) the license granted by Gilead to MPP pursuant to that certain license agreement between the MPP and Gilead Parent effective as of July 11, 2011, as amended from time to time (provided that any such amendment may not have the effect of removing any existing requirements (or substantially similar requirements) as set forth in clauses (a) through (c) of Section 1.310 with respect to MPP or its sublicensees as Generic Licensees) and (b) the license granted by Gilead to MPP pursuant to that certain license agreement between the MPP and Gilead Parent effective as of July 22, 2014, as amended from time to time (provided that any such amendment may not have the effect of removing any existing requirements (or substantially similar requirements) as set forth in clauses (a) through (c) of Section 1.310 with respect to MPP or its sublicensees as Generic Licensees).

1.247 " **MPP Licensee(s)** " shall mean any Third Party that enters into a sublicense with MPP under either of the MPP Licenses.

1.248 " **MTA** " shall mean that certain Materials Transfer Agreement by and between Gilead Parent and Janssen dated February 1, 2009, as such agreement is amended from time to time, including Addendum #1 dated April 2, 2014, Addendum #2 dated June 12, 2014, Addendum #3 dated September 15, 2014 and Addendum #4 dated October 30, 2014.

1.249 " **NDA** " shall mean a New Drug Application as defined in the Act and regulations promulgated thereunder or any successor application or procedure required to market or sell a drug in the United States or to export a pharmaceutical product from the United States.

1.250 " **Necessary Personnel** " means, with respect to each Party [*] (such Persons, the " **Additional Personnel** ").

1.251 " **Negotiation Period** " shall have the meaning set forth in Section 6.5.

1.252 " **Net Sales** " shall mean, with respect to a product for any period for a country, expressed in local currency in such country, the gross amount invoiced for commercial sales of such product in such period by the applicable selling Party or any of its Affiliates or Sublicensees (in the case of Territory Combination Product where Gilead is the Selling Party) or (sub)licensees (in the case of any other product) to Third Parties, less charges, if any, to the applicable Third Party for freight, postage, shipping and insurance expenses (if separately identified in such invoice) and less deductions for: (a) normal and customary quantity or cash discounts and sales returns and allowances, including those granted on account of prompt payment, price adjustments, billing errors, permitted customer rejections or returns (including due to a recall or product withdrawal) for a given quantity of the applicable product, administrative fees or reimbursements or similar payments to wholesalers or other distributors, buying groups, pharmacy benefit management organizations, health care insurance carriers or other institutions, and allowances, rebates, fees paid to distributors and chargebacks allowed or given; (b) customs or excise duties or other duties related to the sales making up the gross invoice amount (if separately identified in such invoice); (c) any rebates or similar payments accrued with respect to sales paid for by any governmental or regulatory authority; (d) sales and other taxes and duties directly related to the sale, to the extent that such items are included in the gross invoice amount (but not including taxes assessed against the income derived from such sale); and (e) any other

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item taken as a deduction to determine net sales under the Accounting Standards. Any of the deductions listed above that involves a payment by such Party shall not be taken as a deduction prior to the date accrued in accordance with the Accounting Standards. Further, for purposes of determining Net Sales with respect to a product, the product shall be deemed to be sold when the revenue obtained in connection with the transfer of such product to a Third Party is recognized in accordance with the Accounting Standards. Net Sales with respect to a product for any period for the Territory as a whole (or the Gilead Countries as a whole or the Janssen Countries as a whole, as the case may be) shall be expressed in U.S. Dollars and, in the case of a Territory Combination Product, shall be equal to the sum of Net Sales of such Territory Combination Product (as converted into U.S. Dollars as provided under Section 10.7) in each country in the Territory (or the Gilead Countries or the Janssen Countries, as applicable) for such period.

For purposes of calculating the F/TAF NSP, F/TDF NSP, and RPV NSP or making the analogous calculation pursuant to Section 19.6.3, if (i) the applicable product is sold by a Third Party distributor of a Party, (ii) the applicable agreement between such Party and such Third Party distributor includes the record-keeping and audit provisions required to be included in such agreement under Section 10.8.2.3 and such Third Party distributor has not previously refused to allow an audit, which refusal has prevented such audit of its records under such provisions (or the Parties otherwise agree), and (iii) at the time the calculations in Section F of Annex M-1 or Section E of Exhibit B-1 of the Janssen Distributor Agreement, as applicable, are to be performed, the in-market Net Sales made by such Third Party distributor (calculated *mutatis mutandis*) are available, then such in-market Net Sales may be used in lieu of the Net Sales calculation based on the sale of such product to the Third Party distributor as set forth in this definition.

1.253 " **Net Selling Price** " shall have the meaning set forth in Annex M-1 .

1.254 [*] shall have the meaning set forth in Annex M-1 .

1.255 [*] shall have the meaning set forth in Annex M-1 .

1.256 " **Non-Breaching Party** " shall have the meaning set forth in Section 19.4.1.

1.257 [*] shall have the meaning set forth in [*].

1.258 " **Notice of Allegation** " shall mean (a) with respect to Canada, the filing of a notice of allegation under the Patented Medicines (Notice of Compliance) Regulations (Canada) and (b) with respect to any other country, the filing of a certification that is analogous to a Paragraph (iv) Certification or the filing of a notice that is analogous to a Notice of Allegation described in clause (a).

1.259 " **Notice of Claim** " shall have the meaning set forth in Section 18.7.1.

1.260 " **NSP** " shall have the meaning set forth in Annex M-2 .

1.261 " **Officials** " shall have the meaning set forth in Section 17.1.11.

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1.262 " **Ongoing Edurant Studies** " shall have the meaning set forth in Section 3.1.2.

1.263 " **Original Agreement** " shall have the meaning set forth in the recitals hereto.

1.264 " **Original Effective Date** " shall have the meaning set forth in the recitals hereto.

1.265 " **Other Combination Product** " shall mean [*].

1.266 " **Other Generic Licensee** " shall mean [*].

1.267 " **Other Infringement** " shall have the meaning set forth in Section 14.4.4.

1.268 " **Other Infringing Product** " shall have the meaning set forth in Section 14.4.4.

1.269 " **Other RPV Product** " shall mean an RPV Product containing RPV as its sole API at a dose which is the therapeutic equivalent of 25 mg Rilpivirine.

1.270 " **Paragraph (iv) Certification** " shall have the meaning set forth in Section 14.4.4.

1.271 " **Party** " and " **Parties** " shall have the meanings set forth in the preamble hereto.

1.272 " **Party Product** " shall have the meaning set forth in Annex M-2 .

1.273 " **Party-Specific Recall/Withdrawal** " shall mean, with respect to a Party, any recall or withdrawal that (a) is caused by one or more of the following: (i) such Party's (or its Affiliate's or subcontractors') negligence, gross negligence or willful misconduct or omission, (ii) safety issues with respect to such Party's APIs, (iii) breach by such Party (or its Affiliate or subcontractor) of this Agreement or any Ancillary Agreement, (iv) any event occurring while the applicable Territory Combination Product is under the control of such Party (or its Affiliate) hereunder, including under the Janssen Distributor Agreement, or (v) such Party's determination to withdraw a Territory Combination Product from the market in one or more countries in the Territory pursuant to Section 13.2.3; and (b) is not caused by any of the following: (i) the other Party's (or its Affiliate's or subcontractor's) negligence, gross negligence or willful misconduct or omission, (ii) safety issues with respect to the other Party's APIs, (iii) the breach by the other Party (or its Affiliate or subcontractor) of this Agreement or any Ancillary Agreement, or (iv) any event occurring while such Territory Combination Product is under the control of the other Party (or its Affiliate) hereunder, including under the Janssen Distributor Agreement.

1.274 " **Patent Cooperation Treaty** " or " **PCT** " shall mean the Patent Cooperation Treaty, opened for signature June 19, 1970, 58 U.S.T. 7645.

1.275 " **Patent Matter** " shall mean any Dispute between the Parties that relates to the inventorship, infringement, enforceability or validity of any Joint Patent or any Patent that is licensed hereunder by one Party to the other Party, which Dispute is not resolved by the Executives pursuant to Section 20.6.

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1.276 " **Patents** " shall mean, with respect to a particular inventive subject matter, (a) all applications for certificates of invention, provisional or priority-establishing patent applications and non-provisional or utility patent applications, including patent applications under the Patent Cooperation Treaty and the European Patent Right Convention, claiming such inventive subject matter and all patents and certificates of invention issuing therefrom; together with (b) any renewal, division, continuation (in whole or in part), or request for continued examination of any of such patents, and any reissues, reexaminations, extensions, divisions, renewals, substitutions, confirmations, registrations, revalidations, revisions, and additions of or to any of the foregoing, and any foreign counterparts of any of the foregoing and any other patents and patent applications claiming priority back to any of the foregoing.

1.277 " **Payment** " shall have the meaning set forth in Section 17.1.11.

1.278 " **Pediatric Investigation/Study Plan** " shall mean any requirement for consideration of pediatric investigations required or requested by a Regulatory Authority in connection with obtaining or maintaining a first Marketing Approval, including the EMA requirements for pediatric investigation plan and FDA requirements for pediatric assessment in the Field.

1.279 " **Person** " shall mean an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.

1.280 " **Pharmacovigilance Agreement** " or " **PVA** " shall have the meaning set forth in Section 13.1.

1.281 " **Post-Approval Commitment Studies** " shall mean any studies that are required by the applicable Regulatory Authority to maintain a first Marketing Approval for a product in any of the United States, [*] or by the European Commission.

1.282 " **Post-Conversion Invoice** " shall have the meaning set forth in Annex M-5 .

1.283 " **Post-Conversion Supply Price** " or " **PCSP** " shall have the meaning set forth in Annex M-1 .

1.284 " **Post-Conversion Supply Price Country(ies)** " shall mean any Gilead Countries in the Territory for which a Monthly Payment Term is in effect.

1.285 " **Post-Launch NSP Information** " shall have the meaning set forth in Annex N .

1.286 " **Pre-Conversion Invoice** " shall mean an invoice for the Pre-Conversion Supply Price for Supplied RPV provided by Janssen to Gilead under the RPV Supply Agreement.

1.287 " **Pre-Conversion Supply Price** " shall mean [*].

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1.288 [*] shall have the meaning set forth in [*].

1.289 " **Premarket Launch Activities** " shall mean marketing activities preceding the First Commercial Sale of the applicable Territory Combination Product, including market research, key opinion leader education and product positioning.

1.290 " **Proceeding** " shall mean a civil, criminal, administrative or investigative suit or proceeding initiated or brought by, or a demand made by, a Third Party.

1.291 " **Product Label** " shall mean, with respect to a product, the full prescribing information for such product, as approved by an applicable Regulatory Authority, including any required summary of product characteristics and patient information, and a package insert for such product.

1.292 " **Product Label and Package** " shall mean, with respect to a product, (a) the Product Label for such product and (b) all other labels and other written, printed or graphic matter upon any container or wrapper for such product.

1.293 " **Product Trademark** " shall mean any Trademark specifically selected for a product, but not including any Person's company name, logo or similar Trademark.

1.294 " **Prosecution and Maintenance** " shall have the meaning set forth in Section 14.3.

1.295 " **Publication** " shall have the meaning set forth in Section 3.6.1.

1.296 " **Quality Agreement** " shall have the meaning set forth in the RPV Supply Agreement.

1.297 " **Recalled Product** " shall have the meaning set forth in Section 13.3.

1.298 " **Recall Expenses** " shall mean the reasonable, direct, out-of-pocket costs and expenses incurred by either Party or any of its Affiliates in connection with any recall or withdrawal of a Territory Combination Product in the Territory, including (a) any reasonable, direct, out-of-pocket costs and expenses of notification and destruction or return of the recalled Territory Combination Product, and (b) any direct, out-of-pocket costs and expenses reasonably incurred by a Party (or its Affiliate) in connection with causing a Third Party Distributor to take any action that is required to be taken by such Third Party Distributor pursuant to Article 13.

1.299 " **Recall/Withdrawal Criteria** " shall have the meaning set forth in Section 13.2.2.

1.300 " **Receiving Party** " shall have the meaning set forth in Section 15.1.

1.301 [*] shall have the meaning set forth in [*].

1.302 [*] shall have the meaning set forth in [*].

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1.303 [*] shall have the meaning set forth in [*].

1.304 [*] shall have the meaning set forth in [*].

1.305 " **Region** " shall mean, as applicable, the Specified Percentage Countries, Region A2, Region B or Region C, or any combination of the foregoing, defined subdivision of the foregoing or defined grouping of subdivisions of the foregoing, as the case may be.

1.306 " **Region A** " shall mean the Specified Percentage Countries and Region A2.

1.307 " **Region A2** " shall mean those countries specified as Region A2 on Annex AA-1 .

1.308 " **Region B** " shall mean those countries specified as Region B on Annex AA-1 .

1.309 " **Region C** " shall mean those countries specified as Region C on Annex AA-1 .

1.310 " **Region C Generic Conditions** " shall mean, with respect to a Party or its Affiliates' granting of a license or other rights permitted by such Party's Generic Exception to a Region C Generic Licensee, the following requirements (or substantially similar requirements):

(a) Such Generic Licensee shall agree in writing to comply with the following requirements (or substantially similar or more restrictive requirements), which shall be imposed by way of a covenant or a condition on or limitation in the scope of the rights or licenses granted:

(i) Such Generic Licensee shall not sell (or assist any Third Party in selling) and shall prohibit its Affiliates, distributors and their respective wholesalers and distributors from selling any (A) Generic Combination Product or (B) Other Combination Product (which, in the case of (B), is within the scope of a license that such Generic Licensee has been granted by such Party or its Affiliates) outside of Region C or from assisting any Third Party in doing so, except that the granting Party may, if it desires, include any of the following exceptions to such restrictions as follows:

(A) [*];

(B) [*]; or

(C) [*].

(ii) The Generic Licensee shall agree not to pursue or obtain any regulatory exclusivity for any (A) Generic Combination Product or (B) Other Combination Product (which, in the case of (B), is within the scope of a license that such Generic Licensee has been granted by such Party or its Affiliates) or (C) other product licensed under such agreement with such Party or its Affiliates that contains any of TDF, TAF, FTC or RPV (in each case, other than for pediatric formulations thereof).

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(b) The agreement between the applicable Party (or its Affiliate) and the Generic Licensee shall include essentially the following language (or language substantially similar or more restrictive):

(i) in the case of Generic Licensees of Janssen and its Affiliates, *"Licensee shall only be allowed to manufacture, sell or otherwise exploit RPV in combination with other active pharmaceutical ingredient(s) in a country in its territory if Licensee has the legal right to manufacture, sell and otherwise exploit such other active ingredient(s) in such country."*

(ii) in the case of Generic Licensees of Gilead and its Affiliates, *"Licensee shall only be allowed to manufacture, sell or otherwise exploit TDF, TAF or FTC in combination with other active pharmaceutical ingredient(s) in a country in its territory if Licensee has the legal right to manufacture, sell and otherwise exploit such other active ingredient(s) in such country."*

(c) Each Party, upon request of the other Party, (i) shall provide the other Party a written list of its Region C Generic Licensees (excluding any Generic Licensees that are not licensed under their applicable agreement(s) with such Party or its Affiliates to make, use, sell, have sold, offer for sale, or import any fixed-dose combination product containing all of (x) TDF or TAF, as applicable, (y) FTC and (z) RPV) and (ii) from time to time, as requested by the other Party, shall provide a true and correct copy of the language included in its form generic license agreements for Region C Generic Licensees which agreements cover RPV (in the case of Janssen) or any of TDF, TAF or FTC (in the case of Gilead), excluding, in each case ((i) and (ii)), any license agreement executed with a Generic Licensee prior to the Original Effective Date, which language is sufficient to demonstrate compliance with this Agreement.

Notwithstanding the foregoing, nothing in this Section 1.310 shall require a Party to impose a restriction or other obligation on a Generic Licensee, the imposition of which would violate Applicable Law.

1.311 " **Region C Generic Licensee** " shall mean a Generic Licensee granted a license or other rights by a Party or its Affiliate to engage in any or all of the Region C Generic Rights.

1.312 " **Region C Generic Rights** " shall mean any or all of the following activities: to make, use, sell, have sold, offer for sale or import within Region C, [*] solely for purposes of exporting to Region C solely for use or sale in Region C, any product containing (a) in the case of a Generic Licensee of Janssen or its Affiliates, RPV in combination with any other APIs or (b) in the case of a Generic Licensee of Gilead or its Affiliates, one or more of TDF, TAF or FTC in combination with any other APIs.

1.313 " **Registration Plan** " shall have the meaning set forth in Section 4.2.1.

1.314 " **Regulatory Approval** " shall mean, with respect to a given product and given country, any and all approvals, licenses, registrations or authorizations of any Regulatory

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Authority necessary to develop or commercialize such product in such country, including, where applicable, pre- and post-marketing authorizations (including Marketing Approvals), labeling approvals and technical, medical and scientific licenses, but excluding pricing and reimbursement approvals.

1.315 " **Regulatory Authorities** " shall mean any applicable supra-national, federal, national, regional, state, provincial or local regulatory agencies, departments, bureaus, commissions, councils or other government entities exercising regulatory authority with respect to the Exploitation of a pharmaceutical product in the Territory, including the FDA and EMA.

1.316 " **Regulatory Documentation** " shall mean, with respect to a product, all submissions to Regulatory Authorities in connection with obtaining and maintaining Regulatory Approvals for the Exploitation of such product, including all Drug Approval Applications, INDs, sNDAs, drug master files, summary product characterizations, product circulars, patient product information, packaging components, correspondence with regulatory agencies, registrations and licenses, regulatory drug lists, periodic safety update reports, adverse event files, complaint files, inspection reports and manufacturing records, in each case together with all supporting documents (including documents with respect to Clinical Data).

1.317 [*] shall have the meaning set forth in [*].

1.318 " **Responsible Party** " shall have the meaning set forth in Section 13.3.

1.319 " **Restatement Effective Date** " shall have the meaning set forth in the preamble hereto.

1.320 " **Results** " shall have the meaning set forth in Section 3.6.2.

1.321 " **Revaluation Pre-Conversion Invoice** " shall have the meaning set forth in Annex M-6 .

1.322 " **Revaluation Supplied RPV Supply Price** " shall have the meaning set forth in Annex M-6 .

1.323 " **R/F/TAF Launch Period** " shall mean [*].

1.324 " **R/F/TAF Product** " shall mean the fixed-dose co-formulated product in oral dosage form containing, as its only APIs per single daily dose, TAF, FTC and RPV, which product is either (a) a solid form that contains a dosage form of TAF equivalent to twenty-five (25) milligrams GS-7340, FTC equivalent to two hundred (200) milligrams Emtricitabine and RPV equivalent to twenty-five (25) milligrams Rilpivirine or (b) an age-appropriate pediatric formulation and dosage consistent with the Pediatric Investigation/Study Plan for a product that corresponds to the product described in clause (a) above, which plan is developed by Gilead and approved by Janssen in accordance with this Agreement.

1.325 " **R/F/TAF Product Actual Percentage** " shall have the meaning set forth on Annex I .

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1.326 " **R/F/TAF Product Average Respective Percentage** " shall mean, with respect to a given Party and with respect to given Losses, (a) the weighted average of such Party's R/F/TAF Product Actual Percentage for each Calendar Year during the period commencing on the Restatement Effective Date and ending with the earlier of (i) the last Calendar Year during the Term and (ii) the Calendar Year immediately prior to the Calendar Year in which such Losses are incurred, with the weighting based on the Net Sales of the Territory R/F/TAF Product in the Territory during each such Calendar Year or (b) in the case of any Losses incurred in or prior to the Calendar Year in which the First Commercial Sale of the Territory R/F/TAF Product in the Territory occurs, such Party's R/F/TAF Product Working Percentage for the Calendar Year in which such Losses are incurred.

1.327 " **R/F/TAF Product Clinical Trial** " shall mean: (a) any clinical trial in humans of a R/F/TAF Product; or (b) any clinical trial in humans of a treatment regimen administered via multiple products that contain, in aggregate, all of RPV, FTC and TAF as its only three (3) APIs, in each case ((a) and (b)), conducted in accordance with this Agreement. For clarity, a clinical trial involving a comparison of subjects treated with a R/F/TAF Product (or the multiple products described in clause (b) above) to subjects treated with a different combination product or other treatment regimen shall be considered a R/F/TAF Product Clinical Trial. Any clinical trial that only qualifies as a R/F/TAF Product Clinical Trial because of the inclusion of an unspecified background regimen shall not be considered a R/F/TAF Product Clinical Trial.

1.328 " **R/F/TAF Product Key Selling Messages** " shall have the meaning set forth in Section 6.7.1.

1.329 " **R/F/TAF Product Third Party Trial** " shall have the meaning set forth in Section 3.2.2.2b.i.

1.330 " **R/F/TAF Product Working Percentage** " shall have the meaning set forth on Annex H .

1.331 " **Right of Reference** " shall have the meaning set forth in 21 C.F.R. § 314.3(b) or equivalents thereto under Applicable Law in jurisdictions outside the United States. For the avoidance of doubt, as used in this Agreement, "Right of Reference" shall refer to the right of Regulatory Authorities to rely upon and otherwise use the applicable information, but shall not confer on the Party to which such Right of Reference is granted any right to receive or access such information.

1.332 " **Rilpivirine** " shall mean the compound set forth in Annex GG-4 , known as rilpivirine.

1.333 " **ROFN Period** " shall have the meaning set forth in Section 6.5.

1.334 " **ROFN Trigger Notice** " shall have the meaning set forth in Section 6.5.

1.335 " **RPV** " shall mean Rilpivirine or any or all of the following: [*].

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1.336 " **RPV Characteristics** " shall have the meaning set forth in Section 18.2.2.

1.337 " **RPV Data Exclusivity** " shall have the meaning set forth in Section 9.2.3.2.

1.338 " **RPV Generic Equivalent** " shall mean [*].

1.339 " **RPV Infringement** " shall mean an infringement or misappropriation of any Patent or other intellectual property, including trade secrets, of a Third Party resulting from:

(a) the manufacture or importation of any Supplied RPV by or on behalf of Janssen (including for supply to, or importation to or on behalf of, Gilead or its Affiliates or Sublicensees as Supplied RPV),

(b) the importation of any Supplied RPV by or on behalf of Gilead or its Affiliates or Sublicensees, but only if such importation is into either a country within the Key Territory or a country in which Janssen or its Affiliate, (sub)licensee or Third Party distributor is manufacturing or selling (i) in the case of Janssen or its Affiliate or Third Party distributor, any RPV Product at the time of such importation, or (ii) in the case of Janssen's (sub)licensee, any RPV Single Agent Product at the time of such importation,

(c) the manufacture or importation of a Territory Combination Product by or on behalf of Gilead or its Affiliates or Sublicensees, which infringement or misappropriation directly results from the incorporation into such Territory Combination Product of any Supplied RPV, but [*] or

(d) the manufacture or importation of a Territory Combination Product by or on behalf of Gilead or its Affiliates or Sublicensees, which infringement or misappropriation directly results from the manufacture of any Supplied RPV that is incorporated into such Territory Combination Product, but [*],

in each case ((a) through (d)) without reference to the combination of the applicable RPV Product with TAF, TDF or FTC. For purposes of the definition of RPV Infringement, (x) "incorporation" or "incorporated" shall mean the presence of Supplied RPV in a Territory Combination Product, and not the process of incorporating Supplied RPV into a Territory Combination Product, and (y) RPV Infringement shall include only misappropriation by Janssen (or its Affiliates or contract manufacturers) and not by Gilead or any of its Indemnified Persons.

1.340 " **RPV Invoice** " shall mean, with respect to the RPV that is provided by Janssen to Gilead pursuant to the RPV Supply Agreement, either a Pre-Conversion Invoice or a Post-Conversion Invoice, as applicable, in each case provided by Janssen (or its Affiliate) to Gilead (or its Affiliate) pursuant to the RPV Supply Agreement.

1.341 " **RPV NSP** " shall have the meaning set forth in Annex M-1 .

1.342 " **RPV Product** " shall mean any pharmaceutical product containing RPV, which product is under development or is being sold at any time by Janssen or an Affiliate,

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subcontractor, (sub)licensee, or Third Party distributor of Janssen or its Affiliates, including any RPV Single Agent Product; provided , however , that the term "RPV Product" shall not include any Combination Product.

1.343 " **RPV Single Agent Product** " shall mean any RPV Product that contains RPV as its only API, including Edurant.

1.344 " **RPV Supply Agreement** " shall have the meaning set forth in Section 8.1.1.

1.345 " **RPV Supply Agreement Quantities** " shall have the meaning set forth in Section 8.1.2.

1.346 " **Safety Database Closing Date** " shall mean, with respect to a Territory Combination Product, the day after the expiration of the period during which Gilead or its applicable Affiliate, is required to submit safety update reports pursuant to 21 C.F.R. §314.50(d)(5)(vi) for the first NDA for such Territory Combination Product submitted to the FDA by Gilead or any of its Affiliates (which period expires, per Applicable Law in effect as of the Restatement Effective Date, four (4) months after the initial submission of such NDA).

1.347 " **Selected Product Liability Losses** " shall have the meaning set forth in Section 18.3.

1.348 " **Selected Product Liability Proceedings** " shall have the meaning set forth in Section 18.3.

1.349 " **Selling Party** " shall mean (a) Janssen, in the case of the Janssen Countries, and (b) Gilead, in the case of the Gilead Countries.

1.350 " **Semi-Annual Period** " shall have the meaning set forth in Annex M-5 .

1.351 " **Settlement Agreement** " shall have the meaning set forth in Section 17.3.3.

1.352 " **Shared NSP Information** " shall have the meaning set forth in Annex N .

1.353 " **Single Agent Product** " shall mean (a) with respect to Gilead, any TDF Single Agent Product, any TAF Single Agent Product and any FTC Single Agent Product and (b) with respect to Janssen, any RPV Single Agent Product.

1.354 " **sNDA** " shall mean a Supplemental New Drug Application, as defined in the Act and applicable regulations promulgated thereunder, as amended or supplemented from time to time.

1.355 " **Specific Cure** " shall have the meaning set forth in Section 6.2.2.5.

1.356 " **Specific Targets** " shall have the meaning set forth in Section 6.2.2.4.

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1.357 " **Specified Percentage** " shall mean (a) with respect to Territory Complera, (i) [*] subject to adjustment, on a country-by-country basis, pursuant to Section 11.6, and (ii) [*], and (b) with respect to the Territory R/F/TAF Product, (i) [*] subject to adjustment, on a country-by-country basis, pursuant to Section 11.6, and (ii) [*].

1.358 " **Specified Percentage Countries** " shall mean the countries designated as Specified Percentage Countries on Annex AA-1 .

1.359 " **Standard Cost of Manufacturing** " shall mean, with respect to a given API or product, for a given Calendar Year, the sum (expressed in U.S. Dollars per kilogram) of (a) the direct labor costs incurred by the applicable Material Supplier or its Affiliates in the Manufacture of the applicable Material; (b) the direct material costs for materials used by the Material Supplier or its Affiliates in such Manufacture (including raw materials, intermediate compounds, active compounds, excipients, components and packaging materials, and including shipping and taxes therefor, to the extent borne by such Material Supplier or its Affiliates); (c) a reasonable allocation of overhead costs (including facilities expenses, depreciation over the expected life of the buildings and equipment, and costs for administration and for management of material procurement and other Manufacturing activities, including Quality Control (QC) and Quality Assurance (QA), performed directly in support of the Manufacture or acquisition of Material); (d) the cost of shipping of Material (including inter-plant and inter-location transportation expenses); (e) the cost of Manufacturing trial runs, Manufacturing development expenses, and start-up and new product introduction costs; (f) shut-down costs; (g) costs of unusual and excessive material scrapped; (h) lower of cost or market inventory adjustments, inventory write-downs and write-offs, and physical inventory adjustments; and (i) amounts paid (net of rebates or discounts, if any, and not including amounts paid as royalties or any other Third Party License Payments) to non-Affiliate contract manufacturers or service providers to acquire Material or in connection with the Manufacture of Material; provided , however , that no cost may be counted more than once in such calculation. For clarity, such methodology shall be applied on a standard cost basis for all of the applicable Material that is Manufactured by or on behalf of the Material Supplier across all of its products that contain such Material and such methodology shall be calculated in accordance with reasonable cost accounting methods that comply with the Accounting Standards in effect from time to time, consistently applied.

1.360 " **Sublicensee** " shall mean a Third Party to which Gilead or its Affiliates grants a license or sublicense under its or its Affiliates' rights to a Territory Combination Product, as permitted under this Agreement, but excludes any (i) Third Party Distributors, (ii) Distribution Subcontractors, and (iii) Generic Licensees. For clarity, there are no Sublicensees of Janssen.

1.361 " **(sub)licensee** " shall mean any Third Party to which a Party or its Affiliate grants a license or sublicense, but in each case excluding any Generic Licensee of such Party.

1.362 " **Supplied RPV** " shall mean any RPV supplied to Gilead by Janssen in the form supplied to Gilead by Janssen pursuant to the RPV Supply Agreement (or the Master Clinical Trial Material Agreement, to the extent that it is an Ancillary Agreement). Unless otherwise mutually agreed by the Parties, such RPV supplied shall be specific to Territory Complera or Territory R/F/TAF Product and only used for such product.

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1.363 " **Supplied RPV Annual Revaluation** " shall have the meaning set forth in Annex M-6 .

1.364 " **Supplied RPV Ratio** " shall have the meaning set forth in Annex M-1 .

1.365 " **TAF** " shall mean GS-7340 or any or all of the following: [*].

1.366 " **TAF Product** " shall mean any pharmaceutical product containing TAF, which product is under development or is being sold at any time by Gilead or an Affiliate, subcontractor, (sub)licensee, or Third Party distributor of Gilead or its Affiliates, including any TAF Single Agent Product or F/TAF Product; provided , however , that the term "TAF Product" shall not include any Combination Product or any STR (as defined in the Amended D/C/F/TAF Agreement).

1.367 " **TAF Single Agent Product** " shall mean any TAF Product that contains TAF as its only API.

1.368 " **TDF** " shall mean Tenofovir Disoproxil Fumarate or any or all of the following: [*].

1.369 " **TDF Product** " shall mean any pharmaceutical product containing TDF, which product is under development or is being sold at any time by Gilead or an Affiliate, subcontractor, (sub)licensee, or Third Party distributor of Gilead or its Affiliates, including any TDF Single Agent Product or F/TDF Product; provided , however , that the term "TDF Product" shall not include any Combination Product.

1.370 " **TDF Single Agent Product** " shall mean any TDF Product that contains TDF as its only API, including Viread.

1.371 " **Tenofovir Disoproxil Fumarate** " shall mean the compound set forth in Annex GG-2 , known as tenofovir disoproxil fumarate.

1.372 " **Term** " shall have the meaning set forth in Section 19.1.

1.373 " **Terminated Countries** " shall have the meaning set forth in Section 19.6.1.

1.374 " **Territory** " shall mean all countries of the world.

1.375 " **Territory Combination Product** " shall mean (a) with respect to Complera, Territory Complera, and (b) with respect to the R/F/TAF Product, Territory R/F/TAF Product.

1.376 " **Territory Complera** " shall mean any Complera that is: (a) manufactured by or on behalf of Gilead or any of its Affiliates or Sublicensees from Supplied RPV pursuant to this Agreement; (b) manufactured by or on behalf of Gilead or any of its Affiliates or Sublicensees from RPV that is (i) supplied by a Third Party or (ii) manufactured by Gilead or any of its Affiliates or Sublicensees, in either case ((i) or (ii)) pursuant to Section 19.6.3; or (c)

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manufactured by Janssen or its Affiliate or Third Party supplier following the termination of Gilead's supply obligations to Janssen under the JDA pursuant to Section 8.2.2.1.

1.377 " **Territory R/F/TAF Product** " shall mean any R/F/TAF Product that is: (a) manufactured by or on behalf of Gilead or any of its Affiliates or Sublicensees from Supplied RPV pursuant to this Agreement; (b) manufactured by or on behalf of Gilead or any of its Affiliates or Sublicensees from RPV that is (i) supplied by a Third Party or (ii) manufactured by Gilead or any of its Affiliates or Sublicensees, in either case ((i) or (ii)) pursuant to Section 19.6.3; or (c) manufactured by Janssen or its Affiliate or Third Party supplier following the termination of Gilead's supply obligations to Janssen under the JDA pursuant to Section 8.2.2.1.

1.378 " **Third Party** " shall mean any Person other than Gilead, Janssen and their respective Affiliates.

1.379 " **Third Party Distributor** " shall mean a Third Party distributor that purchases a Territory Combination Product from the Selling Party or any of its Affiliates or, in the case of Gilead, Sublicensees for Distribution in a country in the Territory. For clarity, Third Party Distributor does not include Janssen.

1.380 " **Third Party Distributor Agreement** " shall mean any written agreement between the Selling Party or its Affiliates or, in the case of Gilead, Sublicensees, and a Third Party Distributor pursuant to which the Selling Party (or its Affiliates or, in the case of Gilead, Sublicensees) sells a Territory Combination Product to such Third Party Distributor for Distribution in a country in the Territory, to the extent that such agreement relates to such Territory Combination Product.

1.381 " **Third Party License Payments** " shall have the meaning set forth in Section 9.5.1.

1.382 " **Tibotec** " shall have the meaning set forth in the preamble hereto.

1.383 " **TMC278 Supply Agreement** " shall mean that certain TMC278 Supply Agreement by and between Janssen and Gilead Sub dated June 1, 2010, as amended as of the Restatement Effective Date.

1.384 " **TPA** " shall mean that certain Three Party Confidential Disclosure Agreement by and among [*] Gilead Parent and Janssen dated March 24, 2009, as such agreement is amended from time to time.

1.385 " **Trademark** " shall mean any word, name, symbol, color, designation, slogan, catch phrase or device or any combination thereof used or intended to be used in commerce and indicating the source for a product or service, including any domain name, trademark, trade dress, brand mark, trade name, brand name, logo or business symbol, any registrations of any of the foregoing or any pending applications therefor.

1.386 " **Triangle** " shall have the meaning set forth in Section 17.3.3.

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1.387 " **Triggering Sale** " shall have the meaning set forth in Annex M-1 .

1.388 " **Truvada** " shall have the meaning set forth in the recitals hereto and shall mean such product as of the Original Effective Date.

1.389 " **Truvada Market** " shall mean, with respect to a given period and a given country, the [*] during such period.

1.390 " **Unit** " shall mean a thirty (30)-count bottle (or bottle equivalent) of the applicable product.

1.391 " **Universal Calendar Month** " shall have the meaning set forth in Annex M-1 .

1.392 " **Universal Calendar Quarter** " shall have the meaning set forth in Annex M-1 .

1.393 " **Universal Calendar Year** " shall have the meaning set forth in Annex M-1 .

1.394 " **U.S. Co-Detailing LOA** " shall mean that certain Letter Agreement, dated as of November 24, 2014, by and between Gilead Sciences, Inc. and Janssen Products, LP, acting through its Janssen Therapeutics Division, setting forth Detailing responsibilities for Janssen Therapeutics Division in the United States, as such agreement is amended from time to time.

1.395 " **Valid Claim** " shall mean a claim in any Licensor Patent, which claim has not expired or been held invalid or unenforceable by a non-appealed or unappealable decision by a court or other appropriate body of competent jurisdiction, and which is not admitted to be invalid through disclaimer or dedication to the public, including any claim in a Licensor Patent being prosecuted in a pending Patent application, provided that such claim is not pending for more than [*] after the earliest filing date of the Patent application.

1.396 " **Viread** " shall have the meaning set forth in the recitals hereto and shall mean such product as of the Original Effective Date.

1.397 " **Working Percentages** " shall mean (a) with respect to Territory Complera, the Complera Working Percentage, and (b) with respect to the Territory R/F/TAF Product, the R/F/TAF Product Working Percentage.

2 GOVERNANCE

2.1 Alliance Managers . Gilead and Janssen shall each designate within their respective organizations an alliance manager (an " **Alliance Manager** ") with responsibility for facilitating the interaction and cooperation between the Parties with respect to the activities conducted hereunder. The Alliance Managers as of the Restatement Effective Date shall be as set forth on Annex C .

2.2 Procedural Rules of the Alliance Managers .

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2.2.1 Replacement . Each Party may change its Alliance Manager from time to time upon written notice to the other Party.

2.2.2 Meetings . The Alliance Managers shall meet at least once per Calendar Quarter (or on such other schedule as may be determined by the Alliance Managers) to discuss any issues and concerns relating to the Combination Product Development Activities and any other mutually agreed subject matter relating to the Combination Products. Alliance Managers may attend meetings in person or, as long as each is able to hear the other, by telephone or by video conference equipment.

2.2.3 Agreement on Decisions . The Alliance Managers shall seek to reach agreement on matters requiring decisions by the Parties and shall document any such agreements in written minutes to be approved and signed by each Alliance Manager. If the Alliance Managers are unable to reach agreement on a matter properly presented to them for their consideration, the matter shall be resolved by the procedure set forth in Section 20.6 (except as otherwise provided therein). Any written minutes referred to in this Section 2.2, signed by the Alliance Managers, shall not be deemed to be amendments to this Agreement or any Ancillary Agreement.

2.2.4 Authority . The Alliance Managers shall have the right to make only those determinations expressly enumerated in this Agreement; provided , however that the Alliance Managers shall also have the right to make determinations, consents and approvals on behalf of the Parties within the authority stipulated under this Agreement, provided that such determinations are documented in written minutes that are designated as final and mutually agreed by both Alliance Managers.

2.3 Financial Reporting Committee . In order for the Parties to exchange certain Net Selling Prices for the purposes of calculating revenues and performing other financial calculations described under this Agreement as set forth herein, the Parties shall establish a financial reporting committee (the " **Financial Reporting Committee** "). No non-public information on their respective pricing strategies shall be communicated between the Parties. The role of the Financial Reporting Committee shall be solely ministerial, i.e., to communicate product Net Selling Prices from one Party's Financial Reporting Committee members to the other Party's Financial Reporting Committee members, so that each Party's Necessary Personnel may perform the financial calculations described under this Agreement or use the financial information provided herein for the purposes of financial reporting and auditing pursuant to the Accounting Standards, including pursuant to Articles 10 and 11 and Annex M-1 , Annex M-2 , Annex N and the Janssen Distributor Agreement, and pricing the Territory Combination Products (but no other products) in the countries where such Party is the Selling Party.

2.3.1 Composition of Financial Reporting Committee . The Financial Reporting Committee shall be comprised of the following from each Party: One (1) or more representatives from each Party (each, a " **Finance Representative** ") shall be an employee(s) having responsibility for finance matters of such Party (or any of its Affiliates). One (1) representative from each Party (the " **Attorney Representative** ") shall be an attorney for such Party. Neither the Finance Representative(s) nor the Attorney Representative of a Party shall, at

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the time of his or her appointment to the Financial Reporting Committee or, or at any time during his or her service on the Financial Reporting Committee, be involved, directly or indirectly, in the pricing of such Party's (or any of its Affiliates') antiviral products (other than the Territory Combination Products) used to treat HIV infection, including any such products that are the subject of a collaboration with any Third Party (provided that, for purposes of this Section 2.3.1, duties solely with respect to accounts receivable, accounts payable, bookkeeping and accounting shall not, without more, be deemed involvement in pricing). Such representatives shall have skills reasonably appropriate to their responsibilities and functions as members of the Financial Reporting Committee. Furthermore, each Party covenants that, for twelve (12) months immediately after an individual's service on the Financial Reporting Committee (or for such shorter period as he or she is employed by such Party or its Affiliate), he or she will not be assigned to a function or position that involves, directly or indirectly, the pricing of such Party's (or any of its Affiliates') antiviral products used to treat HIV infection (other than the Territory Combination Products), including any such products that are the subject of a collaboration with any Third Party. Each Party shall have the right to approve the other Party's proposed Finance Representative(s) and Attorney Representative on the Financial Reporting Committee (or any replacement therefor), which approval shall not be unreasonably withheld, conditioned or delayed. Subject to the preceding sentence, each Party shall have the right to replace its Finance Representative(s) or Attorney Representative from time to time during the Term, provided that the composition of the Financial Reporting Committee as so changed meets the requirements set forth above in this Section 2.3.1.

2.3.2 Restricted Access to Non-Public Pricing Information; Additional Restrictions .

2.3.2.1 Each Party shall be responsible for implementing internal procedures and security measures to restrict access to and use of non-public pricing information received from the other Party so as to comply with this Agreement and Applicable Law, including training its Financial Reporting Committee representatives and Necessary Personnel regarding such internal procedures and security measures.

2.3.2.2 A Party's Necessary Personnel shall not be involved, directly or indirectly, in the pricing of such Party's (or its Affiliates') antiviral products used to treat HIV infection, including any such products that are the subject of a collaboration with any Third Party, except solely for the Territory Combination Products. This restriction shall apply at the time of his or her selection to perform activities that would qualify him or her as Necessary Personnel and at all times during which his or her job duties include the performance of activities that qualify him or her as Necessary Personnel.

2.3.2.3 Notwithstanding the foregoing, Additional Personnel of a Selling Party may be involved in the pricing of such Party's (or its Affiliates') antiviral products used to treat HIV infection for a country in addition to the Territory Combination Products to the extent that the Selling Party does not have sufficient personnel in its pricing group to reasonably allow for a Person to be involved in the pricing for that country of the Territory Combination Products and no other products.

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2.3.2.4 Additional Personnel shall only receive [*]. Unless and until the Parties mutually agree[*], the Selling Party shall ensure that none of the other Party's Net Selling Price information is accessed by any Person involved in the pricing of such Party's (or its Affiliates') antiviral products used to treat HIV infection (other than the Territory Combination Products) [*].

2.3.3 Necessary Personnel and Financial Reporting Committee Member Oversight . Each Party shall be responsible for the performance of its Necessary Personnel and its representatives on the Financial Reporting Committee and their compliance with the terms of this Section 2.3. Any issue regarding the activities of the Necessary Personnel or the functioning of the Financial Reporting Committee shall be reviewed jointly by the Parties' respective Attorney Representatives.

2.3.4 Meetings . The Financial Reporting Committee shall meet periodically (which meetings may be conducted by telephone or videoconference, so long as each attendee is able to hear the other attendees) as may be determined by members of the Financial Reporting Committee to determine such matters as are within the jurisdiction of the Financial Reporting Committee as set forth in this Section 2.3.

2.3.5 Authority . The Financial Reporting Committee shall perform only such functions as are assigned to the Financial Reporting Committee hereunder.

2.3.6 Decision-Making . The Financial Reporting Committee shall have no decision-making authority.

2.3.7 Retention of Counsel . The Financial Reporting Committee may determine, by consensus and in its sole discretion, to retain independent legal counsel, in which case the costs and expenses of such counsel shall be shared equally by the Parties.

2.4 Ad Hoc Operating Committees . The Parties may, from time to time, create such ad hoc committees (each, an " **Ad Hoc Operating Committee** ") with such responsibilities and such authority as the Parties may mutually agree in writing. Any Disputes arising in any such Ad Hoc Operating Committee shall be subject to Section 20.6.

2.5 Expenses . Gilead and Janssen shall each bear its own costs and expenses related to the management of its activities under this Article 2, including all costs and expenses relating to the meetings of the Alliance Managers, the Financial Reporting Committee or any Ad Hoc Operating Committee, the participation of its representatives in such meetings, communications with the other Party in connection with such meetings or matters within the authority of the Alliance Managers, the Financial Reporting Committee or any Ad Hoc Operating Committee and travel to and from such meetings.

3 DEVELOPMENT ACTIVITIES

3.1 Development of Edurant .

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3.1.5 Edurant Development Activities . The Parties acknowledge and agree that Janssen obtained a first Marketing Approval of Edurant in the Field in the United States, [*], and by the European Commission prior to the Restatement Effective Date. Janssen shall have no obligation to conduct any further Edurant Development Activities unless otherwise expressly required under this Section 3.1.

3.1.6 Clinical Data . As of the Restatement Effective Date, Janssen is conducting the Edurant Studies in the Field listed in Annex HH (such trial(s), the " **Ongoing Edurant Studies** "). With respect to each such Ongoing Edurant Study, Janssen shall provide to Gilead the Clinical Data from such Ongoing Edurant Study as follows: (A) the tables, figures and listings specified in the statistical analysis plan for the applicable Ongoing Edurant Study, no later than forty-five (45) days after database lock with respect to such study, (B) the top line results report and (C) the final clinical study report, in the case of (B) and (C), promptly following the completion of such report and in any event no later than thirty (30) days following completion, and in all cases ((A)-(C)), which shall be provided in electronic form, provided that Gilead (and its Affiliates) shall be permitted to use such Clinical Data only for the Gilead Permitted Use and Janssen may redact the Janssen Redactable Information from such Clinical Data. Without limitation of the foregoing, in the event that Janssen becomes aware of any clinical data that is reasonably likely to affect the Product Label for Edurant (which data has not previously been disclosed to Gilead), Janssen shall promptly provide to Gilead such clinical data (which clinical data shall be limited to tables, figures and listings specified in the applicable statistical analysis plans, top line results reports and final clinical study reports) and copies of any regulatory submissions made with respect thereto as are in Janssen's or its Affiliates' Control, provided that Gilead (and its Affiliates) shall be permitted to use such clinical data and regulatory submissions only for the Gilead Permitted Use and Janssen may redact any Janssen Redactable Information from such clinical data and regulatory submissions. In the event that Gilead believes that Janssen has failed to provide to Gilead any clinical data (including Clinical Data) or regulatory submissions required to be provided by Janssen to Gilead under this Section 3.1.2, or that Janssen has redacted from any clinical data or regulatory submissions provided by Janssen to Gilead under this Section 3.1.2 any information that is not Janssen Redactable Information, either Party may refer such matter to the Alliance Managers for resolution. If the Alliance Managers do not reach consensus with respect to such matter within the time period set forth in Section 20.6.1, such matter may be escalated by either Party to the Executives pursuant to Section 20.6.1 and, in the event that the Executives do not reach agreement on such matter within the Executives Review Period, such matter shall be an Expert Dispute. All clinical data (including Clinical Data) and regulatory submissions provided by Janssen to Gilead pursuant to this Section 3.1.2 and Section 4.3 shall comprise the " **Janssen Clinical Data** ." The Janssen Clinical Data shall constitute Confidential Information of Janssen to the extent that such information satisfies the criteria set forth in Section 15.3. The Janssen Clinical Data with respect to any Edurant Study shall be deemed to be Janssen Know-How.

3.1.7 Edurant Studies . In the event that Janssen or its Affiliates intend to conduct, sponsor or support, independently or together with one or more Third Parties, any Edurant Studies that would reasonably be expected to affect the Product Label for a Territory Combination Product in the Field, then prior to the commencement of any such Edurant Study,

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Janssen shall provide a high-level summary of the protocol(s) for such Edurant Study to Gilead (it being understood that Gilead shall not have any approval rights with respect to such Edurant Study or protocol(s)); provided , however , that each such summary shall constitute Confidential Information of Janssen to the extent that the information provided in such summary satisfies the criteria set forth in Section 15.3.

3.2 Development of Combination Products .

3.2.8 Formulation and Manufacturing Process Development for Territory Combination Products . Gilead shall use Commercially Reasonable Efforts to perform, at its expense, the formulation and Manufacturing Process development for, and to prepare the CMC Data relating to, the Territory R/F/TAF Product. Janssen shall, at its expense, provide to Gilead, in a timely manner, such technical support relating to RPV as is reasonably required by Gilead in connection with performing the formulation and Manufacturing Process development for, and to prepare the CMC Data relating to, each Territory Combination Product. Such support may include documents, procedures, know-how, and in-person technical assistance. Formulation development shall include conducting the formulation screening, optimization and scale-up for a Territory Combination Product in the Field.

3.2.9 Clinical Development .

3.2.9.1 Diligence .

a. The Parties acknowledge and agree that Gilead obtained a first Marketing Approval of Territory Complera in each of the United States, [*] and by the European Commission prior to the Restatement Effective Date.

b. Gilead shall use Commercially Reasonable Efforts to perform, at its expense, all studies necessary (including bioequivalence studies and Post-Approval Commitment Studies but excluding other human clinical trials) to obtain and maintain a first Marketing Approval of the Territory R/F/TAF Product in the Field in each of the United States, [*] and by the European Commission, in each case, with respect to the RPV portion of the Territory R/F/TAF Product, based on Clinical Data made available to Gilead by Janssen. For the sake of clarity, Gilead shall, subject to the terms and conditions of this Agreement, have the right to perform any Development Activities with respect to the Territory R/F/TAF Product and Territory Complera, regardless of whether such Development Activities are required to obtain a first Marketing Approval of the Territory R/F/TAF Product or Territory Complera, as applicable, in the Field in the United States, [*] or by the European Commission.

3.2.9.2 Combination Product Clinical Trials .

a. *Complera Clinical Trials* .

i. On and after the Restatement Effective Date and subject to the other terms and conditions of this Agreement (including Section 3.2.3), either Party (and its Affiliates and (sub)licensees) may Commence (and thereafter conduct) any

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Complera Clinical Trial, either independently or together with one or more Third Parties. Prior to the Commencement of any Complera Clinical Trial (but excluding any Complera Third Party Trial), the Party (or its Affiliate or (sub)licensee) conducting such Complera Clinical Trial shall provide a high-level summary of the protocol therefor to the other Party and such other Party shall have the right to review and provide comments on such summary to the conducting Party. The conducting Party (or its Affiliate or (sub)licensee) shall reasonably consider such comments, but shall have no obligation to incorporate or respond to such comments; provided , however , that upon the request of the other Party, the Parties shall discuss any reasonable concerns of the other Party that the proposed clinical trial is not designed in accordance with GCP and GLP or could result in the occurrence of a safety or tolerability finding that would raise material concerns regarding the clinical benefit of the Territory Combination Product.

ii. Any protocols or summaries provided by one Party (or its Affiliate or (sub)licensee) to the other Party pursuant to this Section 3.2.2.2.a shall constitute Confidential Information of the providing Party to the extent that such information satisfies the criteria set forth in Section 15.3.

iii. On and after the Restatement Effective Date, either Party may provide (1) Gilead Compound Products, in the case of Gilead, (2) RPV Products, in the case of Janssen, (3) Complera or (4) funding, in each case ((1) through (4)) in support of any Complera Clinical Trial sponsored by a Third Party (e.g., an investigator initiated trial or ACTG clinical trials) (such supported Complera Clinical Trials, " **Complera Third Party Trials** ").

b. *R/F/TAF Product Clinical Trials* .

i. *Prior to Safety Database Closing Date*. Prior to the Safety Database Closing Date for the R/F/TAF Product, except for the trials set forth on Annex EE: (x) [*] Gilead, its Affiliates and Sublicensees may conduct any R/F/TAF Product Clinical Trials that are necessary or reasonably expected to be necessary to obtain a first Marketing Approval(s) for the Territory R/F/TAF Product in the Field in any or all countries in the Territory ([*]); (y) [*].

ii. *On and After Safety Database Closing Date.* On and after the Safety Database Closing Date for the R/F/TAF Product and subject to the other terms and conditions of this Agreement (including Section 3.2.3), either Party (and its Affiliates and (sub)licensees) [*].

iii. Prior to the Commencement of any R/F/TAF Product Clinical Trial (excluding any R/F/TAF Product Third Party Trial), the Party (or its Affiliate or (sub)licensee) conducting such R/F/TAF Product Clinical Trial shall provide a high-level summary of the protocol therefor to the other Party and such other Party shall have the right to review and provide comments on such summary to the conducting Party. Such conducting Party (or its Affiliate or (sub)licensee) shall reasonably consider such comments, but shall have no obligation to incorporate or respond to such comments; provided , however , that upon the request of the other Party, the Parties shall discuss any reasonable concerns of the other Party

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that the proposed clinical trial is not designed in accordance with GCP and GLP or could result in the occurrence of a safety or tolerability finding that would raise material concerns regarding the clinical benefit of the Territory Combination Product. Any protocols or summaries provided by one Party (or its Affiliate or (sub)licensee) to the other Party pursuant to this Section 3.2.2.2.b shall constitute Confidential Information of the providing Party to the extent that such information satisfies the criteria set forth in Section 15.3.

3.2.9.3 Rights to Conduct Other Clinical Trials . For clarity, nothing in this Section 3.2.2 is intended to (a) restrict Gilead or any of its Affiliates, (sub)licensees or Generic Licensees from conducting, independently or together with one or more Third Parties, any clinical trial in humans of any of the Gilead Compound Products that is not a R/F/TAF Product Clinical Trial or Complera Clinical Trial, (b) restrict Janssen or any of its Affiliates, (sub)licensees or Generic Licensees from conducting, independently or together with one or more Third Parties, any clinical trial in humans of any RPV Product that is not a R/F/TAF Product Clinical Trial or Complera Clinical Trial or (c) prevent either Party from exercising its rights under such Party's Generic Exception.

3.2.9.4 Confidentiality . Each summary provided pursuant to Section 3.2.2 shall constitute Confidential Information of the disclosing Party to the extent that the information provided in such summary satisfies the criteria set forth in Section 15.3.

3.2.10 Pediatric Formulation . Gilead shall have the sole right, but not the obligation, to develop a pediatric formulation of each Combination Product. Prior to Gilead's or any of its Affiliates' conducting any Combination Product Development Activities relating to a pediatric dosage form or submitting any Pediatric Investigation/Study Plan for a Combination Product to any Regulatory Authority, Gilead shall consult with Janssen and obtain Janssen's written approval, not to be unreasonably withheld, conditioned or delayed, of (a) such Combination Product Development Activities, including the quantity of RPV contained therein, and (b) any related Pediatric Investigation/Study Plan; provided , however , that the Pediatric Investigation/Study Plan for Complera developed by Gilead as of the Restatement Effective Date and any Combination Product Development Activities described therein, relating to a pediatric dosage form of Complera described therein shall be deemed approved by Janssen. Upon Gilead's request, Janssen shall provide Gilead with clinical supplies of RPV for use in Combination Product Development Activities relating to a pediatric dosage form of a Territory Combination Product, which RPV shall be supplied [*] pursuant to the RPV Supply Agreement (or Gilead may use quantities of RPV in its possession, in which case Section 8.1.3.2 shall apply).

3.2.11 Data from Combination Product Clinical Trials Conducted by Gilead .

3.2.11.1 Data from Combination Product Clinical Trials .

a. Prior to the Safety Database Closing Date . With respect to each Combination Product Clinical Trial conducted by Gilead in accordance with this Agreement that is Commenced prior to the Safety Database Closing Date or is a pediatric Combination Product Clinical Trial, Gilead shall provide to Janssen the Clinical Data from such

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Combination Product Clinical Trial as follows: (i) the top line results report (if generated) and final clinical study report for such Combination Product Clinical Trial, which shall be provided promptly following the completion of the applicable report and in any event no later than thirty (30) days following completion; and (ii) the tables, figures and listings as specified in the statistical analysis plan for such Combination Product Clinical Trial, which shall be provided no later than forty-five (45) days after database lock, in each case ((i) and (ii)), which shall be provided in electronic form, provided that Janssen (and its Affiliates) shall be permitted to use such Clinical Data only for the Janssen Permitted Use or to conduct its activities hereunder with respect to the Territory Combination Products in the Janssen Countries and Gilead may redact the Gilead Redactable Information from such Clinical Data. Janssen may submit a written request to Gilead for additional clinical data generated from a Combination Product Clinical Trial conducted by Gilead in accordance with this Agreement that is Commenced prior to the Safety Database Closing Date or is a pediatric Combination Product Trial, which shall be provided by Gilead if such additional data is necessary for Janssen to exercise its rights and perform its obligations under this Agreement, as determined by Gilead in Gilead's sole discretion, provided that Janssen (and its Affiliates) shall be permitted to use such clinical data only for the Janssen Permitted Use and Gilead may redact the Gilead Redactable Information from such clinical data.

b. On or After the Safety Database Closing Date . With respect to each Combination Product Clinical Trial (other than a pediatric Combination Product Clinical Trial) conducted by Gilead in accordance with this Agreement that is Commenced on or after the Safety Database Closing Date, Gilead shall provide to Janssen the Clinical Data from such Combination Product Clinical Trial solely to the extent that such Clinical Data is required by a Regulatory Authority (i) to obtain or maintain Regulatory Approvals with respect to the Territory Combination Products in the Janssen Countries or (ii) for the Janssen Permitted Use, which Janssen shall be permitted to use, in each case, solely for such purpose, provided that Gilead may redact the Gilead Redactable Information from such Clinical Data. Any such Clinical Data from a Combination Product Clinical Trial to be provided by Gilead to Janssen pursuant to this Section 3.2.4.1 shall be provided as follows: (i) the top line results report (if generated) and final clinical study report for such Combination Product Clinical Trial shall be provided promptly following the completion of the applicable report and in any event no later than thirty (30) days following completion; and (ii) the tables, figures and listings as specified in the statistical analysis plan for such Combination Product Clinical Trial shall be provided no later than forty-five (45) days after database lock, in each case ((x) and (y)), in electronic form.

3.2.11.2 Right of Reference . Notwithstanding the foregoing, Gilead shall not be required to provide any clinical data (including Clinical Data) to Janssen pursuant to this Section 3.2.4 if Gilead grants Janssen a Right of Reference to such clinical data (and maintains such clinical data in a manner) that is sufficient for Janssen to use such clinical data for the Janssen Permitted Use, or to exercise its rights and perform its obligations under this Agreement, as applicable.

3.2.11.3 Disputes Regarding Clinical Data . In the event that Gilead does not agree that any clinical data (including Clinical Data) requested by Janssen under Section

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3.2.4.1 is necessary for Janssen to exercise its rights and perform its obligations under this Agreement, or Janssen believes that Gilead has redacted information from clinical data to be provided by Gilead under Section 3.2.4.1 that is not Gilead Redactable Information, either Party may refer such matter to the Alliance Managers for resolution. If the Alliance Managers do not reach consensus on such matter within the time period set forth in Section 20.6.1, such matter may be escalated by either Party to the Executives pursuant to Section 20.6.1, and in the event that the Executives do not reach agreement on such matter within the Executives Review Period, then such matter shall be an Expert Dispute.

3.2.11.4 Definition of Gilead Clinical Data . All clinical data (including Clinical Data) provided by Gilead to Janssen pursuant to this Section 3.2.4 and Section 4.3 shall comprise the " **Gilead Clinical Data** ." The Gilead Clinical Data shall constitute Confidential Information of Gilead to the extent that such information satisfies the criteria set forth in Section 15.3.

3.2.11.5 Electronic Format for Data . Any raw data sets provided by either Party to the other Party hereunder shall be in the form of SAS output data sets unless otherwise agreed by the Parties.

3.2.12 Combination Product Clinical Data . In the event that either Party becomes aware of any clinical data that is reasonably likely to affect the Product Label for (A) a Territory Combination Product or (B) Edurant, which clinical data is not covered by another provision of Article 3 or Article 4, then such Party shall promptly provide to the other Party such clinical data as are in such Party's or its Affiliates' Control, provided that the receiving Party (and its Affiliates) shall be permitted to use such clinical data only to update the Product Label of the Territory Combination Products or any RPV Product, as applicable, and the providing Party may redact any Gilead Redactable Information (if such providing Party is Gilead) or any Janssen Redactable Information (if such providing Party is Janssen) from such clinical data. The clinical data to be provided under this Section 3.2.5 shall be limited to the final clinical study reports and the tables, figures and listings as specified in the applicable statistical analysis plan.

3.2.13 [*].

3.3 Performance; Subcontracting . In performing the Combination Product Development Activities and Edurant Development Activities, Gilead and Janssen shall perform their respective activities in material compliance with GCP, GLP, and GMP, to the extent applicable, and the requirements of Applicable Law. Either Party may subcontract the performance of its respective development activities under this Article 3; provided , however , that the subcontracting Party shall oversee the performance by its subcontractors of the subcontracted development activities in a manner that would be reasonably expected to result in their timely and successful completion and shall remain responsible for the performance of such development activities in accordance with this Agreement.

3.4 Records .

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3.4.1 Maintenance of Records . Janssen shall maintain, or cause to be maintained, records of (a) any Edurant Development Activities conducted by, or on behalf of, Janssen or its Affiliates, provided that this obligation applies solely to the extent such activities relate to the use of Edurant in combination with the F/TDF Product or F/TAF Product in the Field or are relevant to a Territory Combination Product, and (b) any other activities conducted by, or on behalf of, Janssen or its Affiliates, if relevant to a Territory Combination Product, that result in data disclosed to Gilead under this Agreement. Gilead shall maintain, or cause to be maintained, records of the Combination Product Development Activities and any activities that result in data disclosed to Janssen under this Agreement. The applicable Party shall maintain or cause to be maintained such records in material compliance with GCP, GLP, and GMP, in each case to the extent applicable. Such records shall be complete and accurate and shall fully and properly reflect all work done and results achieved in the performance of such activities in a manner appropriate for any regulatory purpose and, when applicable and permitted under this Agreement, for use in connection with Patent filings, prosecution and maintenance. Such records shall be retained for at least (i) three (3) years following creation or (ii) such longer period as may be required by the In-License Requirements or Applicable Law.

3.4.2 Access to Records . Subject to the terms and conditions of this Section 3.4.2, each Party shall have the right, during normal business hours and upon reasonable prior written notice, to access and copy the development records maintained by the other Party pursuant to Section 3.4.1, subject to each Party's right to redact therefrom any Gilead Redactable Information (if Janssen is the accessing Party) or Janssen Redactable Information (if Gilead is the accessing Party), such access and copying to be solely (a) to the extent necessary or reasonably expected to be necessary to enable the accessing Party to (1) conduct reasonable diligence on matters potentially giving rise to liability on the part of the accessing Party or (2) defend itself with respect to any liability on the part of the accessing Party, in each case ((1) and (2)), if and to the extent that a fact, circumstance or event has arisen that gives the accessing Party a reasonable basis to believe that it has or may incur such liability, and (b) for use by the accessing Party for such purpose. The immediately preceding sentence shall not require any Party to provide access to any records in the event that the Parties' interests in the matter potentially giving rise to liability are or may be adverse in any material respect, in which case Applicable Law, including discovery rules and procedures, shall apply. Each notice delivered under this Section 3.4.2 shall state the reason(s) therefor (each a " **Development Record Access Notice** "). The Party receiving a Development Record Access Notice shall have the right to raise reasonable objections in writing in response to such Development Record Access Notice within five (5) Business Days, including based on such Party's interests in protecting from disclosure trade secrets or other competitive business information. Upon any such objection being asserted, the Parties shall promptly confer in an attempt to address each Party's concerns and reach a resolution with respect to the matter, and in the event that the Parties are unable to agree upon a mutually agreeable resolution within five (5) Business Days of such objection being asserted, either Party shall have the right to refer the matter for resolution pursuant to Section 20.6. In the event that any such Dispute is ultimately referred by a Party to arbitration pursuant to Section 20.6, the arbitrator(s) shall determine as a threshold matter whether and to what extent one or more criteria set forth above have been satisfied by the requesting Party, and, if so, shall make a determination with respect to whether and to what extent the disclosure of such information shall

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be required by balancing, on the one hand, the requesting Party's need to obtain such records, and on the other hand, the objecting Party's interests in protecting such records from disclosure. In making such determination, the arbitrator(s): (x) shall confine their consideration to the facts and arguments set forth in the Development Record Access Notice and the other Party's written response thereto, and (y) shall have the right to require the accessing Party to abide by terms and conditions for the handling, use and non-disclosure (either within such Party's organization or to Third Parties) of such information as may be reasonable under the circumstances.

3.5 Reports . Gilead and Janssen shall each keep the other reasonably informed through their respective Alliance Managers regarding any material developments with respect to the Combination Product Development Activities or Edurant Development Activities, as the case may be, for which it is responsible under Sections 3.1 or 3.2.

3.6 Publication of Results .

3.6.1 By Gilead . Gilead or its Affiliates shall have the right to publish or make a first public presentation, abstract or presentation at a scientific conference (each a " **Publication** ") of the data and findings resulting from its Combination Product Development Activities or any Combination Product Clinical Trials conducted by, or on behalf of, Gilead or its Affiliates (any of the aforesaid data and findings of Gilead described in this Section 3.6.1, " **Gilead Results** "), in each case subject to the remainder of this Section 3.6. The Parties acknowledge and agree that, as of the Restatement Effective Date, certain Publications with respect to data and findings resulting from Complera Clinical Trials completed prior to the Restatement Effective Date have been approved by the Parties and submitted for publication, and are not subject to further review or comment under this Section 3.6.

3.6.2 By Janssen . Janssen or its Affiliates shall have the right to make a Publication of the data and findings resulting from (a) any Edurant Development Activities, to the extent such data and findings relate specifically to one or more Territory Combination Products, TDF, TAF, FTC or one or more Gilead Compound Products, (b) any Combination Product Development Activities or (c) any Combination Product Clinical Trials, in each case ((a) – (c)) conducted by, or on behalf of, Janssen or its Affiliates, in each case subject to the remainder of this Section 3.6 (any of the aforesaid data and findings, collectively, " **Janssen Results** " and, together with Gilead Results, the " **Results** "). For clarity, Development Activities relating to any RPV Product conducted by, or on behalf of, Janssen or its Affiliates, other than Edurant Development Activities that relate specifically to one or more Territory Combination Products, TDF, TAF, FTC or one or more Gilead Compound Products, shall not be subject to this Section 3.6.

3.6.3 Copies . Each Party shall provide to the other Party's Alliance Manager for review copies of any proposed Publication with respect to Results covered by (i) in the case of Janssen, Section 3.6.1 or (ii) in the case of Gilead, Section 3.6.2 that such Party proposes to submit for Publication during the Term (and thereafter to the extent set forth in Section 19.7).

3.6.4 Gilead Right to Comment . Regarding any Publication proposed by Janssen covered by this Section 3.6, Gilead shall have a right to comment on such Publication.

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Written copies of each such proposed Publication required to be provided for review shall be provided to Gilead's Alliance Manager no later than fifteen (15) Business Days before submission for Publication, except that in the case of an abstract and/or presentation, a copy of such abstract and/or presentation shall be provided as soon as reasonably practicable in advance of the submission or presentation thereof to a Third Party (which period may be less than fifteen (15) Business Days). Gilead shall provide its comments, if any, no later than seven (7) Business Days after receipt of such Publication, or in the case of an abstract and/or presentation, no later than four (4) Business Days after receipt. If Janssen does not accept such comments, it shall so notify Gilead and either Party shall have the right to request a meeting of the Alliance Managers to agree upon revisions to such Publication, provided that such request is made within three (3) Business Days after Janssen notifies Gilead that it will not accept Gilead's comments. If so requested, the Parties shall convene such meeting within five (5) Business Days of such request. If the Alliance Managers do not reach consensus upon revisions to such Publication within the time period set forth in Section 20.6.1, such matter may be escalated by either Party to the Executives pursuant to Section 20.6.1 and, in the event that the Executives do not reach agreement on such matter within the Executives Review Period, Janssen shall have final decision-making authority with respect to such matter. During the time in which Gilead, the Alliance Managers or the Executives are reviewing a Publication pursuant to this Section 3.6.4, Janssen shall not make such Publication. If requested by Gilead, Janssen shall provide to Gilead the Clinical Data supporting a Publication by Janssen within three (3) Business Days of the later of such request and Gilead's receipt of the proposed Publication, provided that Janssen may redact any Janssen Redactable Information from such Clinical Data.

3.6.5 Janssen Right to Comment . Regarding any Publications proposed by Gilead covered by this Section 3.6, Janssen shall have a right to comment on such Publication. Written copies of each such proposed Publication required to be provided for review shall be provided to Janssen's Alliance Manager no later than fifteen (15) Business Days before submission for Publication, except that in the case of an abstract and/or presentation, a copy of such abstract and/or presentation shall be provided as soon as reasonably practicable in advance of the submission or presentation thereof to a Third Party (which period may be less than fifteen (15) Business Days). Janssen shall provide its comments, if any, no later than seven (7) Business Days after receipt of such Publication, or in the case of an abstract and/or presentation, no later than four (4) Business Days after receipt. If Gilead does not accept such comments, it shall so notify Janssen and either Party shall have the right to request a meeting of the Alliance Managers to agree upon revisions to such Publication, provided that such request is made within three (3) Business Days after Gilead notifies Janssen that it will not accept Janssen's comments. If so requested, the Parties shall convene such meeting within five (5) Business Days of such request. If the Alliance Managers do not reach consensus upon revisions to such Publication within the time period set forth in Section 20.6.1, then such matter may be escalated by either Party to the Executives pursuant to Section 20.6.1 and, in the event that the Executives do not reach agreement on such matter within the Executives Review Period, Gilead shall have final decision-making authority with respect to such matter. During the time in which Janssen, the Alliance Managers or the Executives are reviewing the Publication pursuant to this Section 3.6.5, Gilead shall not make such Publication. If requested by Janssen, Gilead shall provide to Janssen the Clinical Data supporting a Publication by Gilead within three (3) Business Days of the later of

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such request and Janssen's receipt of the proposed Publication, provided that Gilead may redact any Gilead Redactable Information from such Clinical Data.

3.6.6 Authorship . The Parties shall comply, in any Publication made pursuant to this Section 3.6, with standard academic practice regarding authorship of scientific publications and recognition of contribution of parties. For the avoidance of doubt, nothing contained in this Section 3.6 shall alter or affect a Party's confidentiality obligations pursuant to Article 15.

3.6.7 Limitation . In no event shall either Party be obligated under this Section 3.6 to provide to the other Party any results other than the Results (but without limitation of any other disclosure obligations explicitly set forth in this Agreement). In addition, for clarity, this Section 3.6 does not govern the publication of the results of any Complera Third Party Trial or any R/F/TAF Product Third Party Trial.

3.6.8 Press Releases . Notwithstanding anything to the contrary in this Section 3.6, public announcements (such as press releases) that relate to the Exploitation of any Territory Combination Product in the Territory, other than with respect to Results, are governed by Article 16 and not this Section 3.6.

3.7 Third Party Uses of Combination Product Clinical Data . In the event a Party intends the patient-level data from any Combination Product Clinical Trials, or in the case of Janssen, Edurant Studies, conducted by or on behalf of such Party under this Agreement be made publicly available to the scientific community for further research through one or more industry organizations, the Alliance Managers shall agree upon the timing of release of such data from each such Combination Product Clinical Trial and Edurant Study to such industry organization(s). The proposing Party (or its Affiliate) shall have the right to release such data in an anonymized form to such industry organization(s) of such Party's choosing in a manner that complies with any Regulatory Authority requirements and Applicable Law; provided , however , that if the Alliance Managers do not reach agreement upon the timing of releasing patient-level data from such Combination Product Clinical Trial(s) and Edurant Study(ies) to such industry organization(s) within the time period set forth in Section 20.6.1, the matter shall be referred to the Executives for resolution pursuant to Section 20.6.1 and if the Executives do not resolve the matter within the Executives Review Period, the data in question shall not be released by the proposing Party to such industry organization(s) until the Alliance Managers or Executives later agree on such release or, if earlier, [*] after the end of the Executives Review Period.

3.8 Limitations on Disclosure of [*]. Notwithstanding anything to the contrary herein, if a Party is required to provide data regarding any of its Single Agent Product(s) or Double Agent Product(s) pursuant to this Agreement, such Party shall [*].

4 REGULATORY MATTERS

4.1 General .

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4.1.14 Diligence . For clarity, without limiting a Party's obligations under Article 3, this Section 4.1.1 shall not be construed to require a Party to use any efforts to perform any studies or other development activities (other than regulatory activities).

4.1.14.1 Gilead shall use Commercially Reasonable Efforts to obtain and maintain a first Marketing Approval for each of the Territory Combination Products in the Field from each of the FDA and the European Commission, and the applicable Regulatory Authorities in [*]; provided , however , that such obligation to obtain and maintain with respect to Territory Complera shall [*].

4.1.14.2 Janssen shall use Commercially Reasonable Efforts to obtain and maintain a first Marketing Approval (a) for Edurant in the Field from each of the FDA and the European Commission, and the applicable Regulatory Authorities in [*] and (b) for each of the Territory Combination Products in the Field from the applicable Regulatory Authorities in each Janssen Diligence Country; provided , however , that the obligation in clause (b) of this Section 4.1.1.2 with respect to Territory Complera shall [*]. In the event that Gilead believes that Janssen is in breach of its obligations under clause (b) of this Section 4.1.1.2 with respect to a given Territory Combination Product, Gilead shall have the right to give Janssen written notice specifying the nature of such breach. Janssen shall have a period of [*] after receipt of such written notice to cure such breach. If Janssen does not cure such breach within such [*] period, [*].

4.1.15 Performance; Subcontracting . The Selling Party, in the case of each Territory Combination Product, and Janssen, in the case of Edurant, shall perform, or cause its Affiliates or permitted subcontractors, as applicable, to perform, any activities with respect to obtaining or maintaining Regulatory Approvals for the Territory Combination Products and Edurant, respectively, in the Field in material compliance with the requirements of Applicable Law. The Selling Party, in the case of the Combination Product Regulatory Activities, and Janssen, in the case of Edurant Regulatory Activities, may subcontract the performance of their respective regulatory activities; provided , however , that the subcontracting Party shall oversee the performance by its subcontractors of the subcontracted activities in a manner that would be reasonably expected to result in their timely and successful completion and shall remain responsible for the performance of such activities in accordance with this Agreement.

4.1.16 Limitations . Except as otherwise provided in this Section 4.1, neither Party shall have any obligation under this Agreement to obtain or maintain Regulatory Approvals for the other Party's Single Agent Product(s) or Double Agent Products, as applicable, in any country in the Territory. Gilead shall be relieved of its diligence obligation under the first sentence of Section 4.1.1.1 in any applicable country to the extent that (i) Janssen fails to obtain and maintain a first Marketing Approval for Edurant in the Field in the applicable country or (ii) pursuant to Section 4.3.3, Janssen withholds from the relevant Regulatory Authority any information relating to Edurant that is reasonably requested by Gilead to be provided to such Regulatory Authority in order for Gilead to obtain or maintain a Marketing Approval for a Territory Combination Product in the Field in such country.

4.2 Registration Plan .

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4.2.1 Creation . An initial plan of activities for obtaining and maintaining a first Marketing Approval for the Territory R/F/TAF Product in the Field in each of the Major Market Countries is attached hereto as Annex JJ (such plan, together with the plan existing as of the Restatement Effective Date for obtaining and maintaining first Marketing Approvals for Territory Complera in the Field in each of certain countries in the Territory, the " **Registration Plan** ").

4.2.2 Updates . From time to time during the Term, each Party shall submit any updates it may have to the Registration Plan to the other Party's Alliance Manager.

4.2.3 Purpose . The Registration Plan shall be established and updated solely for the purpose of coordinating logistics regarding filing for Marketing Approvals for the Territory Combination Products in the Field in the Territory. It is not intended to impose any binding obligation on either Party to perform the activities set forth therein.

4.3 Regulatory Documentation to be Provided by the Parties .

4.3.3 Regulatory Documentation for Use by Gilead . Subject to Section 4.3.3, Janssen shall provide Gilead with full access to and copies (in electronic form) of (i) the Janssen Regulatory Documentation and (ii) any other information related to a Territory Combination Product in the possession and Control of Janssen or its Affiliates, in each case, as Gilead may request, solely for the purpose of, and in the case of clause (ii) solely as necessary or reasonably expected to be necessary for the Gilead Permitted Use, provided that Janssen may redact any Janssen Redactable Information from such Janssen Regulatory Documentation or other information. In the event that Janssen does not agree that any information described in clause (ii) above requested by Gilead is necessary or reasonably expected to be necessary for the Gilead Permitted Use, or Gilead believes that Janssen has redacted information from Janssen Regulatory Documentation or other information requested by Gilead under this Section 4.3.1 that is not Janssen Redactable Information, either Party may refer such matter to the Alliance Managers for resolution. If the Alliance Managers do not reach consensus with respect to such matter within the time period set forth in Section 20.6.1, such matter may be escalated by either Party to the Executives pursuant to Section 20.6.1 and, in the event that the Executives do not reach agreement on such matter within the Executives Review Period, such matter shall be an Expert Dispute.

4.3.4 Regulatory Documentation for use by Janssen . The Parties acknowledge and agree that Gilead has previously provided Janssen the CTD for Territory Complera, and Gilead shall hereafter reasonably promptly provide Janssen with any updates by Gilead to the CTD for Territory Complera. Reasonably promptly following the later of the filing of the NDA or the authorization for Marketing Approval with the European Commission for the Territory R/F/TAF Product, Gilead shall provide Janssen the CTD for the Territory R/F/TAF Product for use by Janssen in connection with obtaining and maintaining Regulatory Approvals for the Territory R/F/TAF Product in the Field in the Janssen Countries, and shall thereafter reasonably promptly provide Janssen with any updates by Gilead to the CTD for the Territory R/F/TAF Product. The CTDs for Territory Complera and the Territory R/F/TAF Product, and updates thereto, shall be used by Janssen solely to obtain and maintain Regulatory Approvals for Territory Complera and

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the Territory R/F/TAF Product, as applicable, in the Field in the Janssen Countries. Janssen shall include the applicable CTD (as updated by any updates provided by Gilead pursuant to this Section 4.3.2) in each Drug Approval Application (to the extent required to comply with the requirements for such Drug Approval Application) filed to obtain and maintain a first Marketing Approval in the Field for each Territory Combination Product in any Janssen Country. Janssen's regulatory filings with the Regulatory Authorities, including Drug Approval Applications, with respect to each Territory Combination Product in the Janssen Countries shall be consistent with the applicable CTD and updates thereto. Janssen shall, to the extent required by Applicable Law or otherwise reasonably requested by Gilead, exercise Commercially Reasonable Efforts to update any such filings promptly to reflect any updates to the CTDs as are provided by Gilead to Janssen pursuant to this Section 4.3.2 from time to time after such filings are made. Gilead shall provide electronic versions of the CTDs (including any updates thereto) to Janssen in a mutually agreed-upon format for the purpose of expediting Janssen's activities in preparing and filing Regulatory Documentation for the Janssen Countries.

4.3.5 Additional Regulatory Documentation Provided by Either Party Following Marketing Approval .

4.3.5.1 Once Gilead or any of its Affiliates, Sublicensees or Third Party Distributors has obtained a first Marketing Approval for a Territory Combination Product in the Field in a country, Janssen may not withhold Regulatory Documentation or other information related to such Territory Combination Product or Janssen's Single Agent Product in Janssen's or its Affiliates' Control that Gilead reasonably requires to comply with Applicable Law with regards to such Territory Combination Product in such country. Except as otherwise expressly authorized by Janssen, Gilead (and its Affiliates) shall have the right to use any additional information related to a Territory Combination Product or Janssen's Single Agent Product provided or made available pursuant to the foregoing sentence (and not pursuant to any other provision hereunder) solely to the extent necessary to comply with Applicable Law (solely for regulatory purposes contemplated by this Agreement or any Ancillary Agreement). The provisions of this Section 4.3.3.1 shall survive expiration of this Agreement. Without limitation of the foregoing, if any Regulatory Authority requires, in order for Gilead (or its Affiliate, Sublicensee or Third Party Distributor) to obtain or maintain Regulatory Approval for a Territory Combination Product in any Gilead Country, any Regulatory Documentation or other information (including any analyses of any data relating to RPV and results thereof), and Gilead would have the obligation under the Amended D/C/F/TAF Agreement to provide analogous Regulatory Documentation or information (including analyses and results thereof) to Janssen, then Section 4.3.1.3 or other applicable Section of the Amended D/C/F/TAF Agreement, as applicable, and any defined terms used therein shall apply *mutatis mutandis* with respect to such information or analyses (*e.g.* , references to Gilead shall be changed to Janssen, references to "COBI, FTC or TAF" shall be changed to "RPV (as defined in the Complera Agreement)," references to "DRV" shall be changed to "FTC, TAF or TDF (as defined in the Complera Agreement)", references to "STR Clinical Trial" shall be changed to "Combination Product Clinical Trial" and references to "the Licensed STR" shall be changed to "a Territory Combination Product (as defined in the Complera Agreement)"), except that references to "Gilead Redactable Information" in Section 4.3.1.3 or any other Section of the Amended D/C/F/

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TAF Agreement shall be deemed to be replaced with the term "Janssen Redactable Information" as defined in this Agreement and references to "Regulatory Leads" in Section 4.3.1.1 or any other Section of the Amended D/C/F/TAF Agreement shall be deemed to be replaced with "Alliance Managers (or their designees)."

4.3.5.2 Once Janssen or any of its Affiliates or Third Party Distributors has obtained a first Marketing Approval for a Territory Combination Product in the Field in a country, Gilead may not withhold Regulatory Documentation or other information related to such Territory Combination Product or Gilead's Single Agent Products or Double Agent Products in Gilead's or its Affiliates' Control that Janssen reasonably requires to comply with Applicable Law with regards to such Territory Combination Product in such country. Except as otherwise expressly authorized by Gilead, Janssen (and its Affiliates) shall have the right to use any additional information related to a Territory Combination Product or Gilead's Single Agent Products or Double Agent Products provided or made available pursuant to the foregoing sentence (and not pursuant to any other provision hereunder) solely to the extent necessary to comply with Applicable Law (solely for regulatory purposes contemplated by this Agreement or any Ancillary Agreement). The provisions of this Section 4.3.3.2 shall survive expiration of this Agreement.

4.3.5.3 Limitations . Notwithstanding anything herein to the contrary (other than Section 4.3.3.1 or Section 4.3.3.2), except in the case of the FDA, EMA, the European Commission or any Regulatory Authority in [*], a Party shall have no obligation hereunder to provide to the other Party or any Regulatory Authority, in connection with any filings to obtain Regulatory Approvals of a Territory Combination Product in the Field in the Territory, any information relating to its API or any of its other products (including its Single Agent Product(s) or Double Agent Products), as the case may be, the disclosure of which such first Party reasonably believes may harm its or its Affiliates' business interests with respect to its API or any of its other products (including its Single Agent Product(s) or Double Agent Products).

4.4 Regulatory Filings and Communication .

4.4.1 MA Holder . With respect to each country in the Territory, unless otherwise agreed to in writing by the Parties or prohibited by Applicable Law, the Selling Party, or its designated Affiliate, Sublicensee or (subject to Section 9.3.3 and, in the case of a Janssen Country, the Janssen Distributor Agreement) Third Party Distributor, shall hold any Drug Approval Application or Marketing Approval with respect to a Territory Combination Product with respect to such country. To the extent permitted by Applicable Law, Gilead hereby transfers, and shall cause its Affiliates, Sublicensees or Third Party Distributors to transfer, to Janssen all of its and their right, title and interest in the Marketing Approvals for Territory Complera for Russia and China to Janssen and, following the Restatement Effective Date, the Parties shall coordinate to transfer, subject to the terms of this Agreement and the Ancillary Agreements, such Marketing Approvals to Janssen as promptly as practicable after the Restatement Effective Date. To the extent such transfer is prohibited by Applicable Law, Gilead shall hold the Marketing Authorization(s) for the benefit of Janssen subject to the terms of this

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Agreement and the Ancillary Agreements. For clarity, such transfer of such Marketing Authorization(s) does not convey any ownership interest in the data contained therein. For clarity, Gilead will hold the Import Drug License for China.

4.4.2 Responsibilities With Respect to Combination Product Regulatory Filings . Subject to Section 4.3 and the remainder of this Section 4.4, with respect to each country in the Territory, the Selling Party, on behalf of the applicable entity designated to be the MA Holder with respect to such country, with the cooperation of the non-Selling Party as reasonably required, shall have primary responsibility for preparing and filing all necessary Regulatory Documentation and for acting as liaison for all communications with the Regulatory Authorities in such country for the purpose of obtaining and maintaining Regulatory Approval for the applicable Territory Combination Product in the Field in such country, including, subject to Section 4.4.2.2 below, with respect to any changes to the Product Label for such Territory Combination Product; provided , however , that for each of Russia and China, during any period in which such country is a Janssen Country and Gilead (or its Affiliate) is the MA Holder with respect to a Territory Combination Product with respect to such country, Janssen shall not file any Regulatory Documentation or otherwise communicate with a Regulatory Authority with respect to such Territory Combination Product in such country unless such filing or the substance of such communication has been approved by Gilead in writing, such approval not to be unreasonably withheld, conditioned or delayed. The Parties shall agree in writing on reasonable timeframes and processes to facilitate the foregoing approval process. Notwithstanding anything to the contrary in this Agreement, each Party shall be responsible for preparing and submitting any Regulatory Documentation or other materials with respect to any clinical trial that it or its Affiliate conducts (either solely or with one or more Third Parties) pursuant to this Agreement and the Party that is not the MA Holder for a given country may obtain and maintain INDs for such country in support of Combination Product Clinical Trials that such Party is permitted to conduct under Article 3.

4.4.2.1 Discussion of Single Agent Products or Double Agent Product . Notwithstanding anything contained in this Agreement to the contrary, at any meeting with, or any communication to, Regulatory Authorities in the Territory concerning a Territory Combination Product, the Selling Party shall not engage in any substantive discussions pertaining to the other Party's Single Agent Product(s) or Double Agent Product(s) or the API contained therein, without such other Party's prior written consent.

4.4.2.2 Label Change for Single Agent Products or Double Agent Product . If any communications from Regulatory Authorities in the Territory regarding potential changes to any Product Label for a Territory Combination Product in the Territory are reasonably expected to lead to a change in the Product Label for a Party's Single Agent Product(s) or Double Agent Products, as the case may be, and are not reasonably expected to lead to a change in the Product Label for the other Party's Single Agent Product(s) or Double Agent Products, as the case may be, then, notwithstanding anything in this Agreement to the contrary, the affected Party shall take the lead (in coordination with the Selling Party, if such Party is not the Selling Party) in dealing with such Regulatory Authorities on such matter.

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4.4.2.3 PVA . Notwithstanding the foregoing, the Party which has responsibility for communications with Regulatory Authorities in a country relating to routine safety-related submissions (*e.g.* , individual case reports) pursuant to the PVA, shall have the right to communicate (or to cause one or more of its Affiliates or Third Party distributors to communicate) with Regulatory Authorities in such country in the Territory concerning such submissions in accordance with the terms of the PVA in a manner consistent with any determinations with respect to such communications made pursuant to the PVA.

4.4.3 Price Regulatory Approvals . Notwithstanding anything in this Section 4.4 to the contrary, this Section 4.4 shall not govern the obtaining and maintaining of pricing and reimbursement approvals in the Field in the Territory with respect to the Territory Combination Products, or any communications with any Regulatory Authorities with respect to the foregoing matters. For clarity, such approvals and communications shall be governed by Article 6.

4.4.4 Regulatory Matters Concerning Single/Double Agent Products . Nothing contained in this Section 4.4 shall prohibit or restrict either Party from communicating with the Regulatory Authorities on matters relating to the Exploitation of any of its respective Single Agent Product(s), Double Agent Products or pharmaceutical products other than the Territory Combination Products. Each Party shall promptly notify the other Party of any change proposed by the notifying Party to any Product Label for any of its Single Agent Product(s) or Double Agent Products in the Field in the Territory that is substantive in nature, where such proposed change is reasonably expected to have an impact on any Product Label for a Territory Combination Product, reasonably in advance of the anticipated filing date of such proposed change, by furnishing the other Party with the text of the proposed change and a summary description of the data supporting or basis for such proposed change, and, if requested by the notified Party, existing written summaries of any cumulative review done by or on behalf of the notifying Party, provided that the notifying Party may redact any Gilead Redactable Information (in the case of Gilead as the notifying Party) or Janssen Redactable Information (in the case of Janssen as the notifying Party), as applicable. In addition, promptly after the filing of such proposed change with the applicable Regulatory Authorities in the Territory, the Party that has provided such notice shall furnish the other Party with the text of the proposed change as filed. Any resulting filing with respect to the Product Label for a Territory Combination Product shall be governed by Section 4.4.2 and any documentation required in connection with such filing shall be exchanged to the extent and in the manner set forth in Section 4.3.

4.4.5 Regulatory Matters Concerning a Party's Compliance with Applicable Law . Notwithstanding anything herein to the contrary, as between the Parties, regardless of which Party is the Selling Party, each Party shall have sole responsibility for any submissions to, or communications with, any Regulatory Authority in the Territory with respect to any matter relating to such Party's or any of its Affiliates', subcontractors' or Third Party Distributor's compliance with Applicable Law in connection with its performance of such Party's Commercialization Activities, unless such submissions or communications are made in connection with obtaining or maintaining the applicable Drug Approval Application (in which case the applicable provisions of this Section 4.4 shall control).

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4.4.6 Activities in the EU . This Section 4.4 shall apply to the preparing and filing of all necessary Regulatory Documentation and communications with the Regulatory Authorities of the European Union, including the EMA, as if the European Union were a "country" for purposes of this Section 4.4.

4.5 Activities in Japan . Notwithstanding the foregoing or anything else to the contrary in this Agreement, in the case of Japan, Gilead's rights and obligations under this Agreement may, at Gilead's option, be exercised or performed, as applicable, by its (sub)licensee for Japan; provided , however , that Gilead shall remain fully responsible for the performance of such (sub)licensee.

4.6 Records . Each Party shall maintain, or cause to be maintained, records with respect to its activities pursuant to this Article 4 in material compliance with Applicable Law. Such records shall be retained for at least (a) ten (10) years following creation or (b) such longer period as may be required by the In-License Requirements or Applicable Law.

4.7 Regulatory Costs and Expenses . With respect to each country in the Territory, each Party shall bear its own costs and expenses relating to the Combination Product Regulatory Activities and regulatory filings for the Territory Combination Products in such country. Janssen or its applicable Affiliate shall bear all costs and expenses relating to Edurant Regulatory Activities and any regulatory filings relating to Edurant, and Gilead or its applicable Affiliate shall bear all costs and expenses relating to regulatory activities and filings relating to of Gilead's Single Agent Products or Double Agent Products.

4.8 Regulatory Dependencies . Annex AA-2 sets forth those Janssen Countries in which a Marketing Approval for a Territory Combination Product relies upon or references a Marketing Approval for such Territory Combination Product for the European Union or any Gilead Country (each such Janssen Country, a " **Janssen Reliant Country** "). Gilead shall provide Janssen [*] notice of any voluntary withdrawal or abandonment of a Marketing Approval in any country that is specified in Annex AA-2 as a country that is referenced or relied upon by any Janssen Reliant Country (a " **Gilead Marketing Approval** "). [*]. Notwithstanding the foregoing, this Section 4.8 shall not apply to preclude Gilead from engaging in any withdrawal of a Gilead Marketing Approval due to safety, efficacy or public health reasons or as required or requested by a Regulatory Authority.

5 MEDICAL AFFAIRS; CONFERENCES

5.1 Product Information; Medical Affairs and Medical Communications . Subject to this Article 5 and Section 6.3.2, each Party shall, with respect to the countries in which it is the Selling Party, determine independently how and if to utilize and deploy its medical science liaisons for activities relating to a Territory Combination Product in such countries.

5.2 Responses to Medical Inquiries .

5.2.6 Gilead Countries . Gilead shall apply its standard guidelines and procedures for determining and providing appropriate responses to medical inquiries about each

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Combination Product in the Gilead Countries. Gilead shall ensure that any such response procedures and standard response documents comply with Applicable Law.

5.2.7 Janssen Countries . Gilead shall make available to Janssen a core set of standard response documents for responding to medical inquiries about each Combination Product (" **Core SRDs** "), and Janssen shall use only such Core SRDs or adaptations thereof in responding to medical inquiries about the applicable Combination Product in the Janssen Countries, subject to Janssen's ensuring that such Core SRDs and adaptations comply with Applicable Law. With respect to any Janssen Country for which Gilead (or its Affiliate, Sublicensee or Third Party Distributor) is the MA Holder for a Territory Combination Product, Janssen shall not use any adaptation of the Core SRDs (regardless of whether or not such adaptation reflects a change in the content of the Core SRDs) in responding to medical inquiries about such Territory Combination Product in such Janssen Country unless and until Gilead has approved such adaptation in writing. With respect to any Janssen Country for which Janssen (or its Affiliate or Third Party Distributor) is the MA Holder for a Territory Combination Product, Janssen shall not use any adaptation of the Core SRDs that reflects a change in the content of the Core SRDs in responding to medical inquiries about such Territory Combination Product in such Janssen Country unless and until Gilead has approved such adaptation in writing. Subject to the foregoing, Janssen shall apply its standard guidelines and procedures for determining and providing appropriate responses to medical inquiries about each Combination Product in the Janssen Countries, and Janssen shall ensure that any such response procedures comply with Applicable Law. In the event that Gilead does not provide any Core SRDs to Janssen with respect to a Territory Combination Product, Janssen may respond to any medical inquiries based on the approved Product Label for such Territory Combination Product.

5.2.8 Referrals . With respect to each country, the non-Selling Party shall refer any medical inquiries that it receives about a Territory Combination Product in such country (unless it relates specifically to RPV (if the non-Selling Party is Janssen) or to TAF, TDF or FTC (if the non-Selling Party is Gilead)) to the Selling Party or to such person(s) as the Selling Party shall designate. Each Party shall refer any medical inquiries that it receives about the other Party's Single Agent Products or Double Agent Products to the other Party or to such person(s) as the other Party shall designate.

5.2.9 Procedures . Without limiting the foregoing or anything in the Janssen Distributor Agreement, the Alliance Managers shall ensure that appropriate procedures are in place for the Parties to respond to medical inquiries about a Territory Combination Product that go beyond the information contained in the Product Label for such Territory Combination Product. If at any time a Party has concerns about the other Party's procedures for responding to medical inquiries about a Territory Combination Product or standard response documents for use in responding to medical inquiries about a Territory Combination Product, the concerned Party may refer the matter to the Alliance Managers and the Alliance Managers shall facilitate discussion and resolution of such concerns.

5.3 Conferences and Symposia . Janssen shall not (and shall cause its Affiliates not to) participate in or sponsor any formal presentation or panel or medical booths with respect to a

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Combination Product at any conference or symposia or provide any information with respect to a Combination Product at any conference or symposia without the prior written consent of Gilead; provided , however , that Janssen may participate in or sponsor such presentations or panels or medical booths or provide such information at conferences or symposia (other than international meetings) in the Janssen Countries. Gilead shall not (and shall cause its Affiliates not to) participate in or sponsor any formal presentation or panel or medical booths with respect to any RPV Product at any conference or symposia anywhere in the Territory or with respect to any Combination Product at any conference or symposia (other than international meetings) in the Janssen Countries, or provide any information with respect to any RPV Product at any conference or symposia anywhere in the Territory or with respect to any Combination Product at any conference or symposia (other than international meetings) in the Janssen Countries, without the prior written consent of Janssen.

5.4 Compliance . Each Party shall cause its Affiliates, Sublicensees and Third Party Distributors to comply with the terms of this Article 5 as if such Affiliate, Sublicensee or Third Party Distributor were a Party.

6 COMMERCIALIZATION ACTIVITIES

6.1 Distribution in Region B and Region C . Neither Party nor any of its Affiliates, Sublicensees or Third Party Distributors shall Distribute any Combination Product in Region C other than Branded Region B/C Complera or Branded Region B/C R/F/TAF Product.

6.2 Commercialization Activities .

6.2.7 Diligence . Subject to the terms and conditions of this Agreement, the Selling Party (or its Affiliate, Sublicensee or Third Party Distributor) shall have the sole right to perform Commercialization Activities for a Territory Combination Product with respect to the countries for which it is the Selling Party.

6.2.7.1 Gilead shall use Commercially Reasonable Efforts to perform Commercialization Activities (including through its Affiliates, Sublicensees or Third Party Distributors), including Premarket Launch Activities, for each Territory Combination Product in each of the Major Market Countries; provided , however , that such obligation with respect to Territory Complera shall terminate with respect to each Major Market Country, [*].

6.2.7.2 Janssen shall use Commercially Reasonable Efforts to perform Commercialization Activities (including through its Affiliates or Third Party Distributors), including Premarket Launch Activities, for each Territory Combination Product in each of the Janssen Diligence Countries; provided , however , that such obligation with respect to Territory Complera shall terminate with respect to each Janssen Diligence Country [*]. In the event that Gilead believes that Janssen is in breach of its obligations under this Section 6.2.1.2

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with respect to a given Territory Combination Product in a Janssen Diligence Country, Gilead shall have the right to give Janssen written notice specifying the nature of such breach. Janssen shall have a period of [*] after receipt of such written notice to cure such breach. If Janssen does not cure such breach within such [*] period, [*].

6.2.8 Specific Commercialization Obligations . Without limitation of Section 6.2.1, Gilead agrees to the following solely with respect to each of the Major Market Countries other than [*]:

6.2.8.6 With respect to each Major Market Country other than [*], as of the later of the first Marketing Approval or First Commercial Sale of Territory Complera in the applicable country until the earlier of (x) [*] or (y) [*] (such period, a " **Complera Launch Period** "), Gilead shall ensure (and certify in writing each Calendar Quarter) that the incentive compensation provided by Gilead each Calendar Quarter with respect to Territory Complera to each of the sales representatives of Gilead who are responsible for Detailing Complera in such Major Market Country satisfies the following criteria: the incentive compensation payable to each such sales representative if such sales representative achieves his or her target sales for such Calendar Quarter with respect to Territory Complera shall equal or exceed twenty five percent (25%) of the total incentive compensation such sales representative is eligible to receive if he or she achieves his or her target sales for such Calendar Quarter for all of the products for which such sales representative is responsible for Detailing.

6.2.8.7 [Reserved]

6.2.8.8 For each Detailing Year (as defined below), through the Calendar Quarter that includes the last day of the applicable Launch Period, Gilead shall perform the number of Details of each Territory Combination Product in the specific Major Market Countries set forth in Section 1(a) or 1(b) of Annex F , as applicable, in either the first or second product presentation during the call in which such Detail occurs. Gilead shall use Commercially Reasonable Efforts to ensure that the number of such Details for each such Major Market Country in each Calendar Quarter of each Detailing Year is no less than twenty percent (20%) of the number of Details required for such Major Market Country for such Detailing Year; provided , however , the Parties may by written mutual agreement modify such obligation on a country-by-country basis due to local extrinsic conditions (e.g., seasonality) that may impact the ability of Gilead to fulfill such obligation. Gilead shall certify in writing its compliance with this Section 6.2.2.3 on a quarterly basis. A " **Detailing Year** " for an applicable Major Market Country shall mean, in the case of Territory Complera, (A) in the case of the first Detailing Year, the period beginning on the first day of the first full Calendar Quarter after the later to occur of the First Commercial Sale or the first Marketing Approval of Territory Complera in such Major Market Country through the end of the Calendar Year in which such First Commercial Sale or the first Marketing Approval, as applicable, occurs (in which case, Gilead's obligations under this paragraph with respect to such Detailing Year (but not with respect to any Calendar Quarter in such Detailing Year) shall be prorated accordingly), and (B) in the case of each other Detailing Year, the Calendar Year following the prior Detailing Year, until the end of the Calendar Quarter that includes the last day of the applicable Launch Period (and in the case of the last Detailing

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Year with respect to a Major Market Country, Gilead's obligations under this paragraph with respect to such Detailing Year (but not with respect to any Calendar Quarter in such Detailing Year) shall be prorated accordingly). A " **Detailing Year** " for an applicable Major Market Country shall mean, in the case of Territory R/F/TAF Product, [*]. Notwithstanding anything contained herein to the contrary, the Parties may from time to time mutually agree in writing on adjustments to the number of Details set forth in Annex F .

6.2.8.9 Gilead acknowledges and agrees that Gilead's achievement of each and all of the requirements in Sections 6.2.2.1 and 6.2.2.3 (the " **Specific Targets** ") with respect to each applicable Major Market Country goes to the root of this Agreement and is an essential element of this Agreement, and that Gilead's failure to substantially achieve each or any of the Specific Targets with respect to an applicable Major Market Country is a Material Breach that entitles Janssen to terminate this Agreement with respect to the applicable Territory Combination Product pursuant to Section 19.4 if Gilead fails to cure such failure as provided in Section 19.4 or, with respect to each Initial Specific Target Breach, Section 6.2.2.5.

6.2.8.10 With respect to each Initial Specific Target Breach, Janssen agrees that Gilead shall be deemed to have cured such failure if Gilead complies with the following (each a " **Specific Cure** ") with respect to the applicable failure:

a. in the case of a breach of Section 6.2.2.1 with respect to an applicable Major Market Country, for a number of consecutive Calendar Quarters equal to the number that Gilead was so in breach, starting with the Calendar Quarter immediately following the Calendar Quarter in which Gilead received written notice of such breach, Gilead complies (and on a quarterly basis certifies its compliance in writing) with the requirements of Section 6.2.2.1 in all respects, except that the incentive compensation with respect to Territory Complera for such period shall be thirty percent (30%) instead of twenty-five percent (25%); and

b. in the case of a breach of Section 6.2.2.3 with respect to an applicable Major Market Country for a given Detailing Year (or a given Calendar Quarter within a Detailing Year), no later than ninety (90) days following Gilead's receipt of notice of such breach, Gilead conducts in such country a number of Details of the applicable Territory Combination Product, in either the first or second product presentation during the call in which such Detail occurs, equal to the number of Details by which Gilead fell short of its obligations under Section 6.2.2.3 with respect to such country and such Detailing Year (or Calendar Quarter, as applicable), provided that the Details performed by Gilead in curing said breach shall not count toward Gilead's fulfillment of its Detailing obligations under Section 6.2.2.3 for any Calendar Quarter or Detailing Year other than the Calendar Quarter and Detailing Year in which the breach occurred;

provided , however , that, with respect to each applicable Major Market Country, once Gilead successfully completes a Specific Cure for a given Territory Combination Product with respect to a breach of Sections 6.2.2.1 or 6.2.2.3, no further breach of the same section in such country shall automatically be deemed cured by a Specific Cure with respect to such Territory Combination Product, and the curing of any such further breach shall be governed by the general principles governing cure set forth in Section 19.4 and not by this Section 6.2.2.5.

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6.2.8.11 If there is a modification in Applicable Law or industry guidelines with respect to the compensation of, or activities performed by, pharmaceutical sales representatives, or if Detailing is prohibited at customer facilities, then, to the extent such modification or prohibition would render the achievement of the Specific Targets commercially impracticable or unethical, then the Parties shall negotiate in good faith substitute obligations, which obligations take account of such modification or prohibition.

For clarification, the satisfaction of the obligations of Sections 6.2.2.1 and 6.2.2.3 does not necessarily, in and of itself, constitute satisfaction of Gilead's obligations under Section 6.2.1.

6.2.9 Performance; Subcontracting . Each Party shall comply, and shall cause its Affiliates and any of its permitted subcontractors to comply, with all Applicable Law and the requirements of all Regulatory Approvals for the Territory Combination Products in conducting their respective Commercialization Activities. Either Party may subcontract the performance of Commercialization Activities allocated to it hereunder, including to a contract sales organization or Distribution Subcontractor; provided , however , that (i) Gilead shall not use a contract sales organization in any of the Major Market Countries, (ii) Janssen shall not use a contract sales organization to conduct its Detailing activities with respect to a Territory Combination Product in any Gilead Country and (iii) the subcontracting Party shall oversee the performance by its subcontractors of such subcontracted Commercialization Activities in a manner that would be reasonably expected to result in their timely and successful completion and shall remain responsible for the performance of such Commercialization Activities in accordance with this Agreement.

6.2.10 Co-Detailing LOAs . The Parties acknowledge and agree that the Parties (or their Affiliates) currently have (or may in the future have) certain additional rights and obligations with respect to the Detailing of the Territory Combination Products in certain countries, as set forth in the Co-Detailing LOA's for the applicable countries in each Co-Detailing LOA, or as may be set forth from time to time by other separate written agreements between the Parties. For each Co-Detailing LOA, unless and until such Co-Detailing LOA is amended to cover the Parties' activities with respect to the Territory R/F/TAF Product (or unless otherwise agreed by the Parties in writing), the provisions of such Co-Detailing LOA shall be deemed to apply to the Territory R/F/TAF Product to the same extent as they apply to Territory Complera.

6.3 Co-Detailing; Responses to Unsolicited Questions .

6.3.9 Co-Detailing .

6.3.9.1 Territory Complera . The Parties acknowledge and agree that, as of the Restatement Effective Date, Janssen has made an election under the Original Agreement to commence, at its expense, Detailing of Territory Complera in each country listed in Annex FF , and, during the Term with respect to each such country, subject to the terms and conditions of this Agreement and any Ancillary Agreements, Janssen shall have the non-exclusive right to Detail Territory Complera in such country; provided , however , that such right shall terminate with respect to any country upon the First Commercial Sale of the Territory R/F/

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TAF Product in such country; provided , however , that with respect to any country in which Janssen or its applicable Affiliate is Detailing Territory Complera as of the First Commercial Sale of the Territory R/F/TAF Product in such country, such termination shall be effective at the conclusion of a reasonable wind down period to be agreed by the Parties. For any country listed in Annex FF in which the First Commercial Sale of Territory Complera has not occurred as of the Restatement Effective Date, if Janssen or its applicable Affiliate decides not to commence Detailing Territory Complera in such country upon the First Commercial Sale of Territory Complera in such country, or to commence Detailing Territory Complera in such country at any time after the First Commercial Sale of Territory Complera in such country, Janssen shall notify Gilead of such decision promptly after such decision is made.

6.3.9.2 Territory R/F/TAF Product . During the Term, subject to the terms and conditions of this Agreement and any Ancillary Agreements, Janssen shall have the non-exclusive right to Detail, at its expense, the Territory R/F/TAF Product in each country listed in Annex FF . Subject to the preceding sentence, Detailing by Janssen or its applicable Affiliate under this Section 6.3.1.2 may commence upon or after the First Commercial Sale of the Territory R/F/TAF Product in the applicable country; provided , however , that if Janssen or its applicable Affiliate decides not to commence Detailing the Territory R/F/TAF Product in a country upon the First Commercial Sale of the Territory R/F/TAF Product in such country, or to commence Detailing the Territory R/F/TAF Product in a country at any time after the First Commercial Sale of the Territory R/F/TAF Product in such country, Janssen shall notify Gilead of such decision promptly after such decision is made.

6.3.10 Responses to Unsolicited Questions and Related Matters .

6.3.10.3 Each Party may, with respect to the countries in which it is the Selling Party, respond to unsolicited questions that it receives with respect to any Territory Combination Product in such countries.

6.3.10.4 For any country in Region A, the non-Selling Party with respect to such country (and its Affiliates) may respond to unsolicited questions that it receives with respect to any Territory Combination Product solely in accordance with Applicable Law and based solely upon the Product Label for the applicable Territory Combination Product in such country in Region A and any approved materials the Selling Party provides to the non-Selling Party for responding to such questions in such country, which approved materials may be withdrawn from use by the Selling Party at any time upon notice to the non-Selling Party.

6.3.10.5 For any country in Region B or Region C, the non-Selling Party with respect to such country and its Affiliates shall not respond to any unsolicited question that they receive with respect to any Territory Combination Product and shall use reasonable efforts to refer any such unsolicited questions to the Selling Party for such country.

6.3.10.6 Janssen may not market or promote (other than Detail in accordance with Section 6.3.1) any Territory Combination Product in any Gilead Country. Notwithstanding the foregoing or anything to the contrary in Section 6.3.2.2 or Section 6.3.2.3, Janssen may, in connection with its Detailing of the Territory Combination Products in

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accordance with Section 6.3.1 or its activities relating to Edurant or RPV, respond to unsolicited questions that it receives with respect to the Territory Combination Products, provided that Janssen responds solely in accordance with any approved slide deck or other background materials provided by Gilead to Janssen for the purpose of responding to such questions. Such approved slide deck or other background materials shall comply with Applicable Law and shall be provided by Gilead to Janssen in accordance with procedures to be agreed upon by the Alliance Managers. In the event Gilead does not provide such slide deck or other materials, Janssen may respond to such questions that do not relate specifically to RPV based solely upon the Product Label for the applicable Territory Combination Product in such country. In connection with Gilead's Detailing activities, Gilead shall refer any unsolicited questions with respect to Edurant or RPV to Janssen.

6.3.10.7 For clarity, this Section 6.3 is not intended to (a) apply to medical inquiries about Territory Combination Products, which are governed by Section 5.2, or (b) restrict the ability of Janssen to respond to any unsolicited questions with respect to Edurant or RPV or (c) restrict the ability of Gilead to respond to any unsolicited questions with respect to any Gilead Compound Product or FTC, TDF or TAF. Each Party shall cause its Affiliates, Sublicensees and Third Party Distributors to comply with the terms of this Section 6.3 as if such Affiliate, Sublicensee or Third Party Distributor were a Party.

6.4 [Reserved].

6.5 Third Party Distributors . Gilead shall have the right, with respect to all countries in the Territory other than the Janssen Countries, to engage a Third Party Distributor to Distribute Territory Combination Products. In the event Gilead decides to engage a Third Party Distributor with respect to any Territory Combination Product with respect to any country in Region A (other than a Gilead Take-Over Country) for which Gilead has not previously engaged a Third Party distributor for any of its products and Gilead desires to engage a Third Party Distributor for such country which Third Party Distributor does not already serve as a distributor for any Gilead Products in any country, (a) Gilead shall so notify Janssen in writing (the " **ROFN Trigger Notice** ") and (b) if Janssen notifies Gilead, within [*] after receiving a ROFN Trigger Notice (the " **ROFN Period** "), that it desires to negotiate with Gilead with respect to becoming Gilead's exclusive distributor of one or both Territory Combination Products in such country, the Parties shall negotiate in good faith for [*] (or such longer period as agreed by the Parties) (the " **Negotiation Period** ") an amendment to this Agreement (and, if applicable, the Janssen Distributor Agreement) pursuant to which such country would become a Janssen Country; provided , however , that neither Party will be obligated to enter into such an amendment. If, following receipt of a ROFN Trigger Notice with respect to a country, (i) Janssen notifies Gilead, prior to the expiration of the ROFN Period, that it does not desire to negotiate to become Gilead's exclusive distributor in such country, (ii) the ROFN Period expires without Gilead's receipt of a notification from Janssen that it desires to negotiate to become Gilead's exclusive distributor for the Territory Combination Product in such country or (iii) Janssen notifies Gilead, prior to the expiration of the ROFN Period, that it desires to negotiate to become Gilead's exclusive distributor for the Territory Combination Product in such country, but the Negotiation Period expires before the Parties execute an amendment to this Agreement (and, if applicable, the

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Janssen Distributor Agreement) pursuant to which such country would become a Janssen Country, then Gilead shall thereafter be free to engage a Third Party Distributor to Distribute Territory Combination Products in such Gilead Country.

6.6 Distribution and Related Matters .

6.6.1 Distribution Activities . Subject to the terms and conditions of this Agreement and the Janssen Distributor Agreement, the Parties hereby acknowledge and agree that Gilead (or its Affiliate or Sublicensee or Third Party Distributor) shall have the right to Distribute each Territory Combination Product in each country in the Territory (other than the Janssen Countries). Subject to the Janssen Distributor Agreement, Gilead (or such other Person) shall have the sole responsibility and right to fill orders with respect to such Territory Combination Product in such country and shall have the sole responsibility and right to distribute (or right to cause such other Person to distribute) such Territory Combination Product and to perform distribution activities with respect thereto, including inventory management and control, warehousing and storage, order filling, invoicing, collection of sales proceeds, determination and processing of charge-backs and rebates, preparation of sales records and reports, customer relations and services, and handling of returns (the " **Distribution Activities** "). Gilead shall not (i) grant rights to conduct any Distribution Activities with respect to a Territory Combination Product in any country to any Person other than its Affiliates, Sublicensees, Distribution Subcontractors or Third Party Distributors, (ii) sell or permit its Affiliates, Sublicensees or Third Party Distributors to sell any Territory Combination Product in a country outside of the European Union if Gilead (or such Affiliate, Sublicensee or Third Party Distributor) has reason to believe that such Territory Combination Product will be exported from such country to any Janssen Country, or (iii) export or have exported (other than pursuant to the Janssen Distributor Agreement), or permit its Affiliates, Sublicensees or Third Party Distributors to export, any Territory Combination Product from any country outside of the European Union if Gilead (or such Affiliate, Sublicensee or Third Party Distributor) has reason to believe that such Territory Combination Product will be Distributed (by Gilead or any other Person) in or to any Janssen Country without the written consent of Janssen, unless refusing to so export the Territory Combination Product would violate Applicable Law. Gilead shall perform (or cause to be performed) the Distribution Activities in the Territory consistent with Applicable Law. Janssen shall promptly forward (or cause its Affiliates to forward) to Gilead (or its designee) any order(s) for the purchase of a Territory Combination Product that are received by Janssen or any of its Affiliates (excluding any orders for the purchase of a Territory Combination Product in the Janssen Countries), provided that Janssen's failure to forward any such order to Gilead (or its designee) shall not constitute a breach of this Agreement unless such failure constitutes willful misconduct.

6.6.2 First Expiration, First Out . The Selling Party shall Distribute (and shall cause its Affiliates and Distribution Subcontractors to Distribute) all Territory Combination Product on a first expiration, first out (FEFO) basis.

6.7 Marketing Materials .

6.7.1 Key Selling Messages .

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6.7.1.5 Territory Complera . The Parties acknowledge and agree that, as of the Restatement Effective Date, they have agreed on a set of core messages with respect to Territory Complera, which core messages shall serve as a basis for the promotion of Territory Complera to physicians (the " **Complera Key Selling Messages** "), and from time to time the Parties may develop and propose to each other any updates to the Complera Key Selling Messages, which updates shall be mutually agreed by the Parties. If the Parties cannot reach agreement with respect to a given update to the Complera Key Selling Messages, the Parties shall (on a country-by-country basis if and to the extent appropriate) refer any disputed issues to the Executives for resolution pursuant to Section 20.6. If the Executives are unable to reach agreement with respect thereto within the Executives Review Period, neither Party shall be obligated to use such updated Complera Key Selling Message, but each Party shall be permitted to use such updated Complera Key Selling Message (and include such updated Complera Key Selling Message in its Local Promotional Materials) if such updated Complera Key Selling Message is consistent with both (a) the Product Label for Territory Complera and (b) Applicable Law. This Section 6.7.1.1 shall be effective until the second anniversary of the first date on which the First Commercial Sale of the Territory R/F/TAF Product has occurred in all Major Market Countries.

6.7.1.6 Territory R/F/TAF Product . Before the First Commercial Sale of the Territory R/F/TAF Product in a Major Market Country, Gilead shall develop and propose to Janssen a set of core messages with respect to the Territory R/F/TAF Product, which core messages shall serve as a basis for the promotion of the Territory R/F/TAF Product in such countries to physicians (as updated from time to time, the " **R/F/TAF Product Key Selling Messages** " and, together with the Complera Key Selling Messages, the " **Key Selling Messages** "). From time to time, Gilead may develop and propose to Janssen updates to the R/F/TAF Product Key Selling Messages. All R/F/TAF Product Key Selling Messages, including updates thereto, shall be consistent with the Product Label for the Territory R/F/TAF Product and scientifically accurate. At Janssen's request, the Parties shall discuss such proposed or updated R/F/TAF Product Key Selling Messages and Gilead shall consider Janssen's comments. If the Parties cannot reach agreement with respect to any such R/F/TAF Product Key Selling Message or any updates thereto, the Parties may refer any disputed issues to the Executives for resolution pursuant to Section 20.6. If the Executives are unable to reach agreement with respect thereto within the Executives Review Period, Gilead shall have final decision-making authority with respect to such matter.

6.7.2 Local Promotional Materials . Except as otherwise provided in the Co-Detailing LOA's, all advertising and promotional materials, if any, to be used in connection with the marketing and promotion, including Detailing, of a Territory Combination Product in a given country in the Territory (such advertising and promotional materials for each such country, the " **Local Promotional Materials** ") shall be developed by the Selling Party at its cost and expense. All Local Promotional Materials shall be (a) consistent with the most recent Key Selling Messages (if any) made effective under Section 6.7.1.1 or Section 6.7.1.2, as applicable, for the applicable Territory Combination Product; provided , however , that Janssen shall not be required to conform its Local Promotional Materials to any Key Selling Messages to the extent that Janssen reasonably believes that such Key Selling Messages are inconsistent with the Product

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Label for the applicable Territory Combination Product or that conforming its Local Promotional Materials to such Key Selling Messages would be inconsistent with Applicable Law (for clarity, with respect to Section 6.7.1.1, this clause (a) shall apply during the period Section 6.7.1.1 is effective (as described in the last sentence thereof) and after such period), (b) consistent with the Product Label for the applicable Territory Combination Product, (c) consistent with Applicable Law and (d) in the case of Janssen, consistent with the branding guidance provided by Gilead from time to time, with deviation solely to the extent required by Applicable Law; provided , however , that Janssen shall not be required to conform its Local Promotional Materials to any such branding guidance to the extent that Janssen reasonably believes that such branding guidance is inconsistent with the Product Label for the applicable Territory Combination Product or that conforming its Local Promotional Materials to such branding guidance would be inconsistent with Applicable Law. Any Local Promotional Materials for any Janssen Country in which Gilead (or its applicable Affiliate, Sublicensee or Third Party Distributor) is the MA Holder shall be approved by Gilead in writing prior to their use. In the event of any updates to the applicable Key Selling Messages, or if Gilead notifies Janssen in writing of a modification to Gilead's applicable branding guidance, each Party shall promptly review and update its Local Promotional Materials, if any, to conform such materials thereto. Except as otherwise provided in this Section 6.7.2, each Party (and its Affiliates, Sublicensees and Third Party Distributors) shall use the applicable Local Promotional Materials (and only the Local Promotional Materials) for a given country (as developed in accordance with this Section 6.7), together with Product Label for the applicable Territory Combination Product in such country, in marketing and promoting, including Detailing, a Territory Combination Product in such country; provided , however , that subject to the foregoing, the Selling Party shall have the right to position the applicable Territory Combination Product within its HIV product portfolio in its sole discretion in the countries for which it is the Selling Party.

6.7.3 Regulatory Approval for Promotional Materials . For clarity, in any interactions with a Regulatory Authority with respect to the Local Promotional Materials, the allocation of the Parties' rights and responsibilities shall be as set forth in Section 4.4, except as otherwise provided in the Co-Detailing LOA's, or in any other written agreement between the Parties.

6.7.4 Compliance with Applicable Law . The Parties hereby agree and acknowledge that, notwithstanding the provisions of this Section 6.7, neither Party (nor its Affiliates, Sublicensees and Third Party Distributors) shall be required to market a Territory Combination Product utilizing Local Promotional Materials which such Party believes in good faith do not comply with Applicable Law.

6.7.5 Promotional Materials in Co-Detailing Countries . With respect to each country listed in Annex FF in which Janssen is engaged in Detailing a Territory Combination Product, Gilead shall provide Janssen with copies of promotional materials to be used for Detailing in the applicable country, which materials (and the timelines for providing them) are specified in the applicable Co-Detailing LOA. Gilead may redact from such materials any information relating to Gilead products other than the Territory Combination Products.

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6.8 Selection and Use of Trademarks . The Parties hereby agree and acknowledge that Gilead has selected COMPLERA ® and EVIPLERA ®, and other Trademarks relating thereto, for use in connection with the Exploitation of Territory Complera by the Parties. Gilead shall have the right to select any other Combination Product Trademarks, provided that any such Combination Product Trademark shall comply with Applicable Law. Gilead shall not, and shall not permit its Affiliates to, select or use, as a Combination Product Trademark, any Trademark that is identical to or likely to cause confusion with the Product Trademark for any prescription pharmaceutical product of Janssen or any of its Affiliates or that violates any Applicable Law. Janssen shall not, and shall not permit its Affiliates to, use, in connection with any RPV Product, any Trademark that is identical to or likely to cause confusion with any of the Combination Product Trademarks or the Product Trademarks for any prescription pharmaceutical product of Gilead or any of its Affiliates or that violates any Applicable Law; provided , however , that the foregoing shall not be construed to preclude Janssen or its Affiliates from (a) using any Trademark in connection with the Exploitation of any RPV Product to the extent that Applicable Law requires such Trademark to be so used or (b) using EDURANT®. Gilead shall refrain from, and shall cause its Affiliates, Sublicensees and Third Party Distributors to refrain from, using, directly or indirectly, any Product Trademarks other than the Combination Product Trademarks, the Gilead Licensed Trademarks and the Janssen Licensed Trademarks in connection with the Exploitation of Territory Combination Products for sale or distribution in the Territory; provided , however , that, the foregoing shall not be construed to preclude Gilead or its Affiliates or its Sublicensees or Third Party Distributors from using any Trademark in connection with the Exploitation of Territory Combination Products for sale or distribution in the Territory to the extent that Applicable Law requires such Trademark to be so used.

6.9 [*].

6.10 Patient Assistance Program; Product Donations .

6.10.1 Patient Assistance . For each country in the Territory, the applicable Selling Party shall have the right, but not the obligation, in accordance with its standard practice to respond to requests from individual patients who have or may obtain prescriptions for a Territory Combination Product in such country but may be unable to afford it, and from health care providers on behalf of such patients, including establishing appropriate procedures and response times that shall apply in responding to such requests. The non-Selling Party for any country in the Territory may not conduct any of the activities described in this Section 6.10.1, without the prior written consent of the Selling Party for such country.

6.10.2 Donations . For each country in the Territory, the applicable Selling Party shall have the sole right, but not the obligation, to donate any Territory Combination Product to any Third Party for use in such country; provided , however , that the non-Selling Party's consent, not to be unreasonably withheld, delayed or conditioned, shall be required for any such donation in any country in Region A. Notwithstanding the foregoing, this Section 6.10.2 shall not apply to any Territory Combination Product to be used in any Clinical Trial (which use is addressed in Section 8.3).

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6.10.3 Price of Territory Combination Product for Donation or Patient Assistance . In the event that either Party desires to use a Territory Combination Product in connection with any activities permitted pursuant to Section 6.10.1 or Section 6.10.2, such Party may provide written notice to the other Party of its desire to use such Territory Combination Product in connection with such activities, which notice shall specify the quantity of such Territory Combination Product desired. If Gilead is the requesting Selling Party, then notwithstanding anything to the contrary in this Agreement or the Ancillary Agreements, the compensation due to Janssen (or its Affiliate) from Gilead (or its Affiliate) under the RPV Supply Agreement shall be adjusted so that the quantity of the Supplied RPV corresponding to the applicable quantity of the applicable Territory Combination Product is supplied at the then-current Standard Cost of Manufacturing for RPV. If Janssen is the requesting Selling Party, Gilead shall use reasonable efforts to supply the applicable quantity of the applicable Territory Combination Product for such purpose to Janssen as promptly as practical, taking into account Gilead's Manufacturing capacity and schedule and the availability of TDF or TAF, FTC and the Supplied RPV, at a price that compensates Gilead for the TDF or TAF and FTC contained therein at the then-current Standard Cost of Manufacturing for TDF, TAF and FTC, respectively; provided , however , that the compensation due to Janssen (or its Affiliate) from Gilead (or its Affiliate) under the RPV Supply Agreement shall be adjusted so that the quantity of the Supplied RPV corresponding to such quantity of Territory Complera is provided at the then-current Standard Cost of Manufacturing for such Supplied RPV.

6.11 Commercialization Costs and Expenses . Except as otherwise expressly provided hereunder, each Party or its applicable Affiliate or Third Party Distributor shall bear all of its costs and expenses relating to its Commercialization Activities.

6.12 [Reserved] .

6.13 [Reserved] .

6.14 [Reserved] .

6.15 Pricing for Commercial Sale . With respect to each country in the Territory, the Selling Party for such country and its Affiliates, Sublicensees and Third Party Distributors shall be solely responsible for pricing all Territory Combination Products in such country and obtaining and maintaining price approvals therefor, subject to the terms and conditions of this Agreement. Gilead and Janssen shall each retain sole discretion with respect to price-setting and discounts for its respective Single Agent Products and Double Agent Products. Notwithstanding the foregoing, each Party covenants that it shall, and shall cause its Affiliates to, (a) act in good faith in setting the price and discounts for such Party's Single Agent Product(s) and (in the case of Gilead) Double Agent Products in the Field in the Territory and (b) not directly or indirectly manipulate pricing or discounting arrangements of such Party's Single Agent Product(s) or (in the case of Gilead) Double Agent Products in the Field in the Territory solely or primarily for the purpose of increasing such Party's portion of the revenue from the Territory Combination Products.

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6.16 Janssen Distributor Agreement . Each Party shall (and, notwithstanding anything to the contrary in this Agreement, each Party shall have the right to) exercise its rights and perform its obligations under the Janssen Distributor Agreement in accordance with the terms thereof.

7 [RESERVED]

8 MANUFACTURING AND SUPPLY

8.1 RPV Supply .

8.1.11 The Parties shall work in good faith to negotiate and execute (or cause to be executed) within sixty (60) days after the Restatement Effective Date a new supply agreement with respect to supply of RPV for the Territory Combination Products. The " **RPV Supply Agreement** " shall mean (a) with respect to Supplied RPV for Territory Complera and, if and only to the extent mutually agreed by the Parties in writing, the Territory R/F/TAF Product, unless and until the Parties execute such new supply agreement and such new agreement becomes effective, that certain TMC278 (Rilpivirine (RPV)) Commercial Supply Agreement, dated as of June 1, 2010 and amended as of June 18, 2014, and (b) thereafter such new agreement as amended from time to time. [*]. The Parties acknowledge and agree that, subject to Section 8.3, the Parties' rights and obligations with respect to the supplies of the RPV (in API or other form) for use in the Territory Combination Products for commercial sale in the Territory and Clinical Trial use consistent with this Agreement shall be as set forth in the RPV Supply Agreement or any other applicable Ancillary Agreements.

8.1.12 Without limitation of either Party's (or its Affiliates') rights and obligations under the RPV Supply Agreement, Janssen shall supply quantities of RPV, in such form as supplied under the RPV Supply Agreement or any Ancillary Agreement, to Gilead as promptly as practicable following a reasonable request from Gilead for such RPV for use in any Development Activities with respect to Territory Combination Products that Gilead is permitted to perform under Article 3 and as required to supply Janssen with Territory Combination Product for Development purposes pursuant to Section 8.2. In lieu of such supply, Gilead may use existing quantities of RPV previously supplied under the RPV Supply Agreement for such activities (" **RPV Supply Agreement Quantities** "). Notwithstanding anything to the contrary in the RPV Supply Agreement, Gilead shall have the right to use such quantities of RPV in conducting such activities. If specifically supplied for such purposes, such RPV shall be supplied to Gilead (a) for use in Combination Product Clinical Trials that Commence prior to the Safety Database Closing Date with respect to the applicable Territory Combination Product, [*], and (b) for use in Combination Product Clinical Trials that Commence after the Safety Database Closing Date with respect to the applicable Territory Combination Product, at [*]. If, in the alternative, Gilead uses RPV Supply Agreement Quantities, then the applicable adjustment set forth in Section 8.1.3 shall apply. For clarity, the RPV Supply Agreement shall apply to the supply of RPV under this Section 8.1.2, except that in the case of a conflict with respect to the pricing of such RPV for such purposes, this Agreement shall control.

8.1.13 Adjustments .

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8.1.13.1 Gilead shall promptly notify Janssen in the event that any quantity of RPV (in API or other form) supplied [*] under the MTA or Section 8.1.2 that is incorporated into Territory Combination Product is designated for use in Combination Product Clinical Trials that Commence after the Safety Database Closing Date. Promptly following receipt of any such notice, Janssen shall invoice Gilead [*] for the quantity of RPV (in API or other form) identified in Gilead's notice.

8.1.13.2 Gilead shall promptly notify Janssen in the event that any quantity of RPV (in API or other form) supplied at the Pre-Conversion Supply Price that is incorporated into Territory Combination Product is designated for use in Combination Product Clinical Trials that Commence prior to the Safety Database Closing Date or pursuant to Section 3.2.3. Promptly following receipt of any such notice, Janssen shall [*] for the quantity of RPV (in API or other form) identified in Gilead's notice.

8.1.13.3 Gilead shall promptly notify Janssen in the event that any quantity of RPV (in API or other form) supplied at the Pre-Conversion Supply Price is incorporated into Territory Combination Product is designated for use in Combination Product Clinical Trials that Commence after the Safety Database Closing Date. Promptly following receipt of any such notice, Janssen shall invoice Gilead for an amount [*] for the quantity of RPV (in API or other form) identified in Gilead's notice.

8.1.13.4 Gilead shall promptly notify Janssen in the event that any quantity of RPV (in API or other form) supplied [*] under the MTA or Section 8.1.2 that is incorporated into Territory Combination Product is designated for commercial sale in the Territory. Promptly following receipt of any such notice, Janssen shall invoice Gilead at the Pre-Conversion Supply Price in accordance with the terms of the RPV Supply Agreement for the quantity of RPV (in API or other form) identified in Gilead's notice and such RPV (in API or other form) shall be treated for all purposes (including the invoicing and payment of the Post-Conversion Supply Price) hereunder and under any Ancillary Agreement as though it were supplied by Janssen under the RPV Supply Agreement for commercial sale.

8.1.13.5 Gilead shall promptly notify Janssen in the event that any quantity of RPV (in API or other form) supplied at [*] under Section 8.1.2 is incorporated into Territory Combination Product intended for commercial sale in the Territory. Promptly following receipt of any such notice, Janssen shall [*] for such quantity of RPV, and such RPV (in API or other form) shall be treated for all purposes (including the invoicing and payment of the Post-Conversion Supply Price) hereunder and under any Ancillary Agreement as though it were supplied by Janssen under the RPV Supply Agreement for commercial sale.

8.1.13.6 Invoices issued under this Section 8.1.3 shall be due forty-five (45) days follows receipt by Gilead.

8.2 Territory Combination Product Supply .

8.2.1 Except as otherwise expressly set forth herein, Gilead shall Manufacture (including package and label), or have Manufactured, Territory Combination Products, including

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for clinical use and commercial sale. Except as otherwise set forth in Section 19.6.3, Gilead shall Manufacture (or have Manufactured) such Territory Combination Products (a) solely using Supplied RPV and (b) in accordance with the specifications for the Territory Combination Products, GMP, Applicable Law and the terms and conditions of this Agreement and the RPV Supply Agreement. Gilead covenants to Janssen that it shall not, and shall cause its Affiliates, Sublicensees and Third Party Distributors not to, make any use of the Supplied RPV other than (i) to Manufacture (or have Manufactured) Territory Combination Products as set forth herein and (ii) to conduct Development Activities with respect to a Territory Combination Product permitted under this Agreement (but not to Manufacture (or have Manufactured) any products other than Territory Combination Products).

8.2.2 Supply of Territory Combination Products to Janssen .

8.2.2.4 Gilead's supply of each Territory Combination Product (including Branded Region B/C Complera and Branded Region B/C R/F/TAF Product) to Janssen for Distribution in the Janssen Countries and Janssen's Distribution of Territory Combination Products shall be governed by the Janssen Distributor Agreement; provided , however , that Gilead shall have the right to terminate its supply obligations to Janssen (but, for clarity, not Janssen's Distribution rights or payment obligations) under the Janssen Distributor Agreement (a) with respect to Territory Complera, upon [*] written notice to Janssen, which notice may not be provided until after the First Commercial Sale of the Territory R/F/TAF Product has occurred in each of the Janssen Diligence Countries, and (b) with respect to Territory R/F/TAF Product, upon [*] written notice to Janssen, if (i) Janssen provides Gilead written notice of termination of its supply obligations to Gilead under this Agreement and the RPV Supply Agreement with respect to Territory R/F/TAF Product pursuant to Section 19.5.1 (provided , however , that such termination by Gilead shall not be effective earlier than the effectiveness of such termination by Janssen), (ii) this Agreement expires or terminates with respect to Territory R/F/TAF Product in [*], or (iii) this Agreement expires or terminates with respect to Territory R/F/TAF Product in all of the Janssen Countries.

8.2.2.5 In the case of any termination of Gilead's supply obligations with respect to a Territory Combination Product under Section 8.2.2.1, at the request of Janssen:

c. the Parties shall enter into a supply agreement pursuant to which Gilead would supply such quantities of TAF, TDF or FTC, as applicable, to Janssen at [*] or such other amount as the Parties may agree in writing pursuant to Section 8.2.2.4;

d. the Parties shall negotiate an amendment to this Agreement and the Janssen Distributor Agreement pursuant to which Gilead shall no longer have any obligation to supply such Territory Combination Product for the remainder of the Term, but according to which Janssen may continue to Distribute such Territory Combination Product in the Janssen Countries for the remainder of the Term and following expiration of this Agreement, to the extent otherwise permitted hereunder (other than, for clarity, in any countries with respect to which the Janssen Distributor Agreement has terminated with respect to such Territory

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Combination Product) using quantities of such Territory Combination Product supplied from Third Parties or manufactured by Janssen or an Affiliate of Janssen, which amendment(s) shall (i) grant Janssen such licenses or sublicenses as may be required in order for Janssen to obtain such Territory Combination Product from Third Parties or for Janssen or an Affiliate of Janssen to manufacture such Territory Combination Product from (x) TAF or TDF (as applicable), (y) FTC and (z) RPV (including any such licenses or sublicenses as may be required in the event of any transfer of any Information and Inventions under Section 8.2.2.2c), (ii) include such other commercially reasonable terms and conditions as may be required to reflect the fact that Gilead is no longer the supplier of such Territory Combination Product to Janssen and may be the supplier of Gilead Compounds to Janssen, (iii) subject Janssen to any requirements of any applicable in-license agreements of Gilead or its Affiliates and (iv) permit Janssen to continue to use any Third Party Distributor or Affiliate of Janssen (but excluding any Generic Licensee) as specified in this Agreement; and

e. without limitation of any of the foregoing, at Janssen's sole cost and expense, Gilead shall (i) provide reasonable assistance to Janssen or its Affiliate in sourcing such Territory Combination Product from an alternate Third Party supplier and/or (ii) transfer to Janssen (or an Affiliate thereof) or Janssen's selected Third Party supplier all Information and Inventions Controlled by Gilead that are necessary or useful to enable the manufacture of such Territory Combination Product from its APIs by providing copies or samples of relevant documentation, materials and other embodiments of such Information and Inventions, and by making available Gilead's qualified technical personnel on a reasonable basis to consult with, Janssen (or an Affiliate thereof) or such Third Party supplier, as applicable, with respect to such Information and Inventions and the manufacturing process for such Territory Combination Product. Janssen shall use Commercially Reasonable Efforts to complete any technology transfer required under this Section 8.2.2.2 with respect to Territory R/F/TAF Product within the notice period set forth in Section 8.2.2.1(b).

8.2.2.6 Following any termination of Gilead's supply obligations with respect to a Territory Combination Product under Section 8.2.2.1, Gilead's indemnity obligations hereunder with respect to any quantities of such Territory Combination Product supplied by a Third Party to Janssen or manufactured by Janssen or its Affiliate shall apply only to the extent that any Losses are not attributable to the fault of Janssen or its Affiliate or the Third Party that supplies such Territory Combination Product.

8.2.2.7 In the case of any termination of Gilead's supply obligations with respect to a Territory Combination Product under Section 8.2.2.1, (a) the Parties shall coordinate in good faith to wind down matters relating to the supply of such Territory Combination Product under the Janssen Distributor Agreement and (b) Janssen shall pay to Gilead with respect to any Triggering Sales of such Territory Combination Product manufactured by Janssen or its Affiliate or Third Party supplier an amount of compensation analogous to the compensation that Janssen would have paid to Gilead if such Territory Combination Product had been supplied by Gilead hereunder, adjusted for the fact that Janssen is paying for all of the costs of Manufacturing Territory Combination Product from the APIs contained therein and that there was no corresponding Pre-Conversion Supply Invoice for the RPV contained therein.

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8.3 Supplies of Territory Combination Product for use in Clinical Trials . Gilead shall Manufacture (including package and label), or have Manufactured, Territory Combination Product, including for clinical use. As requested by Janssen for use by Janssen (or its Affiliates or (sub)licensees) solely in Combination Product Clinical Trials performed in accordance with the terms and conditions of this Agreement, for Clinical Trials Commencing after the Safety Database Closing Date for the applicable Territory Combination Product, Janssen shall have the right to order Territory Combination Product for such purpose from Gilead [*] and Gilead shall fill such orders, provided that, Gilead shall have no obligation to fill such orders unless (i) Janssen complies with the provisions of Section 3.2.2.2, (ii) the quantity of Territory Combination Product requested by Janssen is reasonable in light of the number of study subjects described in the protocol summaries for such Combination Product Clinical Trials and (iii) Gilead has sufficient manufacturing capacity to manufacture and supply such quantity. In the event Gilead does not have sufficient manufacturing capacity or available supply of the applicable Territory Combination Product to fill Janssen's orders, Gilead shall allocate its manufacturing capacity or available supply, as between Gilead's obligations under this Section 8.3 to Janssen and the other then-current needs of Gilead and its Affiliates (including contractual obligations to Third Parties) for Territory Combination Product to be used in clinical trials, on a pro-rata basis based on the quantity reasonably requested by Janssen and the good faith forecasted requirements of Gilead and/or its Affiliates (taking into consideration any contractual obligations to Third Parties) for use in clinical trials. Notwithstanding the foregoing, in the event of any such shortage, Gilead shall have no obligation to reallocate or otherwise divert any manufacturing capacity or supply of the Territory Combination Product from (A) the Combination Product Clinical Trials that are necessary or reasonably expected to be necessary to obtain or maintain Marketing Approval(s) of the Territory Combination Products (including any bioequivalence studies or Post-Approval Commitment Studies), (B) any clinical trial conducted by Gilead or its Affiliates or any Third Party with respect to the Territory Combination Product for which Gilead has already committed to supply quantities of the Territory Combination Products, provided that such clinical trial has already commenced at the time of Janssen's request, or (C) the commercial supply of the Territory Combination Product. Janssen covenants to Gilead that it shall not, and shall cause its Affiliates and Third Party distributors not to, make any use of the Territory Combination Product provided by Gilead to Janssen under this Section 8.3 other than use by Janssen solely in the Combination Product Clinical Trials permitted under this Agreement. At the request of either Party, the Parties will discuss in good faith a supplement to the Master Clinical Trial Material Agreement to cover the supply of Territory Combination Product for Combination Product Clinical Trials by Gilead to Janssen hereunder.

8.4 Additional Requirements . In the event that Applicable Law or a Regulatory Authority in the Territory imposes, with respect to the Manufacture of a Territory Combination Product (or TDF, TAF, FTC or the Supplied RPV contained therein) for sale or distribution in one or more countries in the Territory, a requirement that is not imposed by any of the EMA, the European Commission and the FDA with respect to the Manufacture of such Territory Combination Product (or such component) for sale or distribution in the European Union or United States, as applicable (an " **Additional Requirement** "), the Selling Party for such country that imposes the Additional Requirement shall notify the non-Selling Party of such Additional Requirement. The Parties shall consider the relative costs and benefits of complying with such

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Additional Requirement and discuss whether, how and when to implement such Additional Requirement in order to obtain or maintain Regulatory Approvals for such Territory Combination Product in the Field in the applicable country(ies). In the event that the Parties determine to implement such Additional Requirement, the Parties shall establish an implementation plan for such Additional Requirement. Either Party's obligation hereunder or under any Ancillary Agreement to comply with any Additional Requirement, and the allocation between the Parties of costs to be incurred pursuant to such obligations, shall be solely as agreed under such plan. In the event the Selling Party for a country fails to notify the non-Selling Party of any Additional Requirement imposed by such country pursuant to this Section 8.4, the non-Selling Party shall not be liable hereunder or under any Ancillary Agreement for any failure to comply with such Additional Requirement and such a failure shall not constitute a default hereunder or under any Ancillary Agreement.

9 LICENSE GRANTS AND RELATED COVENANTS

9.1 Licenses and Related Rights . Subject to the terms and conditions of this Agreement and any Ancillary Agreements:

9.1.3 Combination Product Development Activities and Commercialization Activities . Janssen hereby grants to Gilead:

a. an exclusive (even as to Janssen and its Affiliates, except for the performance of Janssen's obligations as provided hereunder), royalty-free (except as provided in this Section 9.1) license or sublicense (but without limitation of Gilead's payment obligations under this Agreement), with the right to grant sublicenses to the extent permitted pursuant to Section 9.3, under the Janssen Technology and any and all rights, title and interest that Janssen and its Affiliates may have in and to any Joint Technology, solely to conduct Development Activities with respect to the Territory Combination Product in the Field in the Territory, other than those Development Activities with respect to the Territory Combination Product in the Field in the Territory that Janssen is permitted to conduct under Article 3, and to conduct Combination Product Regulatory Activities;

b. a non-exclusive, royalty-free (except as provided in this Section 9.1) license or sublicense (but without limitation of Gilead's payment obligations under this Agreement), with the right to grant sublicenses to the extent permitted pursuant to Section 9.3, under the Janssen Technology, solely to conduct any Development Activities with respect to the Territory Combination Product in the Field in the Territory that Janssen is also permitted to conduct under Article 3; and

c. an exclusive (even as to Janssen and its Affiliates, except for the performance of Janssen's obligations as provided hereunder), royalty-free (except as provided in this Section 9.1) license or sublicense (but without limitation of Gilead's payment obligations under this Agreement), with the right to grant sublicenses to the extent permitted pursuant to Section 9.3, under the Janssen Technology and any and all rights, title and interest that Janssen and its Affiliates may have in and to any Joint Technology, solely to conduct Commercialization Activities with respect to a Territory Combination Product in the Field in the Territory;

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but in each of (a), (b) and (c), not to Exploit RPV individually or in combination with any other API other than in a Territory Combination Product or as otherwise expressly permitted hereunder, pursuant to and in accordance with the terms of this Agreement (including Section 17.3.6) and any Ancillary Agreements, provided that such license shall not extend to any Exploitation that constitutes a violation of this Agreement, including Sections 17.3.1 or 17.3.6. For clarity, Gilead is not granted any rights to Manufacture RPV under this Agreement except to the limited extent provided in Section 19.6.3. The licenses and sublicenses granted under this Section 9.1.1 shall be paid-up, perpetual and non-exclusive upon the expiration of this Agreement with respect to the applicable country as provided in Section 19.1, but shall remain subject to any royalties or any other payments due under applicable In-License Agreements for sales of a Territory Combination Product after such expiration, which royalties and other payments shall be the responsibility of Gilead (provided that such payment obligations are disclosed to Gilead by Janssen).

9.1.4 Combination Product Manufacturing . Janssen hereby grants to Gilead an exclusive (even as to Janssen and its Affiliates, except for the performance of Janssen's obligations as provided hereunder), royalty-free (except as provided in this Section 9.1) license or sublicense (but without limitation of Gilead's payment obligations under this Agreement), with the right to grant sublicenses to the extent permitted pursuant to Section 9.3, under the Janssen Technology and any and all rights, title and interest that Janssen and its Affiliates may have in and to any Joint Technology, solely to Manufacture and have Manufactured: each Territory Combination Product in the Territory for use in (i) Development Activities with respect to a Combination Product in the Field in the Territory and (ii) Commercialization Activities with respect to a Territory Combination Product in the Field in the Territory but not to Manufacture or have Manufactured RPV individually or in combination with any other API other than in a Territory Combination Product, pursuant to and in accordance with the terms of this Agreement and any Ancillary Agreements, provided that such license shall not extend to any Exploitation that constitutes a violation of this Agreement, including Section 17.3.1 or 17.3.6. Such license or sublicense granted under this Section 9.1.2 shall be paid-up, perpetual and non-exclusive upon the expiration of this Agreement as provided in Section 19.1, but shall remain subject to any royalties or any other payments due under applicable In-License Agreements for sales of a Territory Combination Product after such expiration, which royalties and other payments shall be the responsibility of Gilead (provided that such payment obligations are disclosed to Gilead by Janssen).

9.1.5 To Janssen . Upon request, to the extent required by Applicable Law in connection with Janssen's (or its Affiliates' or Third Party Distributors') Commercialization Activities with respect to a Territory Combination Product in the Janssen Countries, Gilead shall provide written documentation, in a form acceptable to the applicable Regulatory Authority, of Janssen's (or its Affiliate's or applicable Third Party Distributor's) right to engage in Commercialization Activities with respect to such Territory Combination Product (but not to Exploit the TDF or FTC APIs individually or in combination other than in a Territory Combination Product) in the Field in the Janssen Countries pursuant to and in accordance with the terms of this Agreement and any Ancillary Agreements.

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9.2 Rights of Reference and Related Rights .

9.2.1 To Gilead . Subject to the terms and conditions of this Agreement and any Ancillary Agreements, with respect to any Gilead Country and any Janssen Country with respect to which Gilead (or its Affiliate, Sublicensee or Third Party Distributor) is the MA Holder for a Territory Combination Product, Janssen (including on behalf of its Affiliates) hereby grants, and shall cause its (sub)licensees and Third Party distributors for the RPV Single Agent Product to grant, to Gilead (and its Affiliates, Sublicensees, or Third Party Distributors, as applicable), in Janssen's (or its Affiliate's or (sub)licensee's or Third Party Distributor's, as applicable) capacity as the MA Holder of the RPV Single Agent Product, in the Field in such country, a non-exclusive Right of Reference, with the right to grant further Rights of Reference to the extent permitted pursuant to Section 9.3, with regard to the Janssen Regulatory Documentation for the RPV Single Agent Product in the Field in such country, as necessary or reasonably expected to be necessary to, and for the sole purpose of allowing Gilead (or its Affiliates, Third Party Distributors or Sublicensees, as applicable) to, obtain and maintain Regulatory Approvals for such Territory Combination Product in the Field in such country or to comply with Applicable Law. Within ten (10) Business Days following Gilead's request, Janssen shall deliver to Gilead an executed Right of Reference letter with respect to any Right of Reference granted herein. For clarity, such Rights of Reference granted to Gilead under this Section 9.2.1 shall be to the entire item of Janssen Regulatory Documentation (not portions thereof) and shall include those listed as items 1 through 3 (in the case of Territory Complera) or 4 through 6 (in the case of the Territory R/F/TAF Product) in Annex II . Janssen agrees to provide any required signed statement to that effect in accordance with the applicable Regulatory Authority's position on authorization to cross reference. Such Right of Reference granted under this Section 9.2.1 shall be paid-up, perpetual and non-exclusive upon the expiration of this Agreement with respect to the applicable country as provided in Section 19.1.

9.2.2 To Janssen . Subject to the terms and conditions of this Agreement and any Ancillary Agreements, with respect to any Janssen Country for which Janssen (or its Affiliate or Third Party Distributor) is the MA Holder with respect to a Territory Combination Product, Gilead (including on behalf of its Affiliates) hereby grants, and shall cause its (sub)licensees and Third Party distributors for its Single Agent Products and Double Agent Products, as applicable, to grant, to Janssen (and its Affiliates or Third Party Distributors, as applicable), in Gilead's (or its Affiliate's or (sub)licensee's or Third Party distributor's, as applicable) capacity as the MA Holder of any Single Agent Product or Double Agent Product of Gilead, in each case in the Field in such country, a non-exclusive Right of Reference, with the right to grant further Rights of Reference to the extent permitted pursuant to Section 9.3, with regard to the Gilead Regulatory Documentation for, (a) with respect to Territory Complera, Truvada, FTC Single Agent Product or TDF Single Agent Product and (b) with respect to Territory R/F/TAF Product, the F/TAF Product and, only if required by a Regulatory Authority in addition to or in lieu of such Right of Reference with regard to F/TAF Product, FTC Single Agent, in each case in the Field in such country, as necessary or reasonably expected to be necessary to, and for the sole purpose of allowing Janssen (or its Affiliates or Third Party Distributors, as applicable) to, obtain and maintain Regulatory Approvals for such Territory Combination Product in the Field in such country or to comply with Applicable Law. Within ten (10) Business Days following Janssen's

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request, Gilead shall deliver to Janssen an executed Right of Reference letter with respect to any Right of Reference granted herein. For clarity, such Rights of Reference granted to Janssen under this Section 9.2.2 shall be to the entire item of Gilead Regulatory Documentation (not portions thereof) and shall include those listed as items 7 through 9 (in the case of Territory Complera) or 10 through 12 (in the case of the Territory R/F/TAF Product) in Annex II . Gilead agrees to provide any required signed statement to that effect in accordance with the applicable Regulatory Authority's position on authorization to cross reference. Such Right of Reference granted under this Section 9.2.2 shall be paid-up, perpetual and non-exclusive upon the expiration of this Agreement with respect to the applicable country as provided in Section 19.1.

9.2.3 Data Exclusivity .

9.2.3.7 Gilead Compound Data Exclusivity . In the event that (i) Janssen or an Affiliate of Janssen receives Marketing Approval for a Territory Combination Product in a jurisdiction in which any applicable Gilead Compound Products have not received Marketing Approval, and (ii) as a result of such Marketing Approval of such Territory Combination Product, Janssen (or its Affiliate) is the owner of Gilead Compound Data Exclusivity for any of TAF, TDF or FTC, then Janssen (or its Affiliate, as the case may be) shall, at Gilead's request, provide a letter to the applicable Regulatory Authority permitting Gilead and/or Gilead's designee (including any Generic Licensee of Gilead with respect to a Gilead Compound Product (provided that the scope of such letter is consistent with the rights permitted to be granted under the granting Party's Generic Exception)) to file for Marketing Approval of the applicable Gilead Compound Product in that jurisdiction notwithstanding the Gilead Compound Data Exclusivity. For clarity, the foregoing shall not be construed as altering Janssen's rights to control commercialization of each Territory Combination Product in the Janssen Countries or to control Marketing Approval (including Rights of Reference thereto) of each Territory Combination Product as provided for under this Agreement. Notwithstanding the foregoing, Janssen shall not be required to take any action that would result in a loss of the data exclusivity and marketing exclusivity associated with the grant of Marketing Approval for a Territory Combination Product in all other respects. " **Gilead Compound Data Exclusivity** " shall mean, with respect to any of TAF, TDF or FTC, a right or protection, obtained in a jurisdiction, as a result of the fact that a Territory Combination Product contains TAF, TDF or FTC, as applicable, as an active ingredient that has not previously been approved in such jurisdiction, which right or protection provides marketing exclusivity that prevents the Regulatory Authority in such jurisdiction from accepting a Drug Approval Application (whether new or abbreviated), submitted by a Person other than the MA Holder for such Territory Combination Product, of the applicable Gilead Compound Product. The rights afforded to Gilead under this Section 9.2.3.1 shall survive termination or the expiration of this Agreement.

9.2.3.8 RPV Data Exclusivity . In the event that (i) Gilead or an Affiliate or Sublicensee of Gilead receives Marketing Approval for a Territory Combination Product in a jurisdiction in which any applicable RPV Products have not received Marketing Approval, and (ii) as a result of such Marketing Approval of such Territory Combination Product, Gilead (or its Affiliate or Sublicensee) is the owner of RPV Data Exclusivity, then Gilead (or its Affiliate or Sublicensee, as the case may be) shall, at Janssen's request, provide a

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letter to the applicable Regulatory Authority permitting Janssen and/or Janssen's designee (including any Generic Licensee of Janssen with respect to an RPV Product (provided that the scope of such letter is consistent with the rights permitted to be granted under the granting Party's Generic Exception)) to file for Marketing Approval of the applicable RPV Product in that jurisdiction notwithstanding the RPV Data Exclusivity. For clarity, the foregoing shall not be construed as altering Gilead's rights to control commercialization of each Territory Combination Product in the Gilead Countries or to control Marketing Approval (including Rights of Reference thereto) of each Territory Combination Product as provided for under this Agreement. Notwithstanding the foregoing, Gilead shall not be required to take any action that would result in a loss of the data exclusivity and marketing exclusivity associated with the grant of Marketing Approval for a Territory Combination Product in all other respects. " **RPV Data Exclusivity** " shall mean a right or protection, obtained in a jurisdiction, as a result of the fact that a Territory Combination Product contains RPV as an active ingredient that has not previously been approved in such jurisdiction, which right or protection provides marketing exclusivity that prevents the Regulatory Authority in such jurisdiction from accepting a Drug Approval Application (whether new or abbreviated), submitted by a Person other than the MA Holder for such Territory Combination Product, of the applicable RPV Product. The rights afforded to Janssen under this Section 9.2.3.2 shall survive termination or the expiration of this Agreement.

9.3 Sublicenses .

9.3.3 For Manufacturing . Subject to Gilead's payment of amounts due to Janssen under this Agreement, Gilead (and its Affiliates) shall have the right to grant Third Party manufacturers (but excluding any Generic Licensee, [*]) a non-exclusive, royalty-free sublicense anywhere in the world, without the right to further sublicense, under the licenses granted to Gilead in Section 9.1.2, for the sole purpose of Manufacturing any Territory Combination Product (but not the RPV therein) for supply to Gilead or its Affiliates or Sublicensees, or Janssen or its Affiliates pursuant to the Janssen Distributor Agreement, for Exploitation of such Territory Combination Product in the Field (including sale by Gilead, its Affiliates or Sublicensees, or by Janssen or its Affiliates, to a Third Party Distributor) in accordance with this Agreement and the Ancillary Agreements, provided that Gilead shall provide to its Third Party manufacturers only such Janssen Confidential Information and Janssen Regulatory Documentation as is required in order for such Third Party manufacturer to Manufacture the applicable Territory Combination Product in accordance with GMP.

9.3.4 For Development or Commercialization Activities . Subject to Gilead's payment of amounts due to Janssen under this Agreement, Gilead (and its Affiliates) shall have the right to grant any Third Party(ies) (other than a Generic Licensee of Gilead) a sublicense (which may, at the election of Gilead, be non-exclusive or exclusive, to the extent consistent with Gilead's rights hereunder) in any country in the Territory, without the right to further sublicense, under the licenses granted to Gilead in Section 9.1.1 in the Field with respect to any Territory Combination Product in such country, provided that either (i) such Third Party has the same rights with respect to any of Gilead's Single Agent Products or Double Agent Products or another pharmaceutical product of Gilead or its Affiliate, or (ii) Janssen provides its written consent to such sublicense, which consent shall not be unreasonably withheld, conditioned or delayed.

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Gilead shall not have the right to grant any sublicense or further Right of Reference under this Agreement in order to enable any Third Party to sell a Combination Product (A) on a Generic Basis, or (B) in Region C under any Product Trademark other than a Product Trademark Controlled by Gilead or an Affiliate of Gilead.

9.3.5 Limitations on Third Party Distributors . Subject to the Janssen Distributor Agreement, either Party may engage a Third Party Distributor to sell in any country in which such Party is the Selling Party a Territory Combination Product under this Agreement, but in Region C this right shall be subject to each of the following: (i) such Third Party Distributor shall purchase such Territory Combination Product in the form of Finished Product from the applicable Party or its Affiliates, (ii) unless a Party obtains the other Party's prior written approval, such Party or its Affiliate (or a Third Party agent that is not engaged in the business of distribution or manufacturing of pharmaceutical products) shall hold the Marketing Approval for the applicable Territory Combination Product in the applicable country under which such Third Party Distributor sells such Territory Combination Product, and (iii) for clarity, (x) Gilead shall not grant to a Third Party Distributor any access to any Confidential Information of Janssen or Janssen Regulatory Documentation or afford any Right of Reference provided by Janssen to such Third Party Distributor, in each case under this clause (iii)(x), except with Janssen's prior written approval, and (y) Janssen shall not grant to a Third Party Distributor any access to any Confidential Information of Gilead or Gilead Regulatory Documentation or afford any Right of Reference provided by Gilead to such Third Party Distributor, in each case under this clause (iii)(y), except with Gilead's prior written approval. The term " **Finished Product** " shall mean drug product in finished dosage forms.

9.3.6 To Affiliates . Either Party may grant sublicenses under any license granted to it pursuant to Section 9.1 to any of its Affiliates. Either Party may grant a further Right of Reference under any Right of Reference granted to it pursuant to Section 9.2 to any of its Affiliates.

9.4 Trademark Licenses .

9.4.6 Subject to the terms and conditions of this Agreement and any Ancillary Agreement, Gilead hereby grants to Janssen a non-exclusive, royalty-free, fully paid-up license, with the right to sublicense to its Affiliates, Third Party Distributors and permitted subcontractors, to use in the Janssen Countries and any country in which Janssen is Detailing a Territory Combination Product hereunder (i) the Gilead Licensed Trademarks for the sole purpose of exercising its rights under the Janssen Distributor Agreement and Detailing the applicable Territory Combination Product (but not to Exploit the APIs thereof individually or in combination other than in such Territory Combination Product) in the Field and (ii) Gilead's name and company logo/identifiers, in each case ((i) and (ii)) solely for use on the approved Product Label and Package and the Local Promotional Materials for the applicable Territory Combination Product. In its use of any publicly disseminated packaging, labeling, advertising and promotional materials referencing the Gilead Licensed Trademarks, Janssen shall use the Gilead Licensed Trademarks as set forth in standards provided in writing by Gilead from time to time. Any deviation from those standards must be approved in writing by Gilead.

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9.4.7 Subject to the terms and conditions of this Agreement and any Ancillary Agreement, Janssen hereby grants to Gilead a non-exclusive, royalty-free, fully paid-up license, with the right to sublicense to its Affiliates, Third Party Distributors and permitted subcontractors, to use in the Gilead Countries (i) the Janssen Licensed Trademarks for the sole purpose of conducting Commercialization Activities with respect to any Territory Combination Product (but not to Exploit the APIs thereof individually or in combination other than in the Territory Combination Products) in the Field and (ii) Janssen's name and company logo/identifiers, solely for use on the approved Product Label and Package and the Local Promotional Materials for any Territory Combination Product. In its use of any publicly disseminated packaging, labeling, advertising and promotional materials referencing the Janssen Licensed Trademarks, Gilead shall use the Janssen Licensed Trademarks as set forth in standards provided in writing by Janssen from time to time. Any deviation from those standards must be approved in writing by Janssen.

9.4.8 Subject to the terms and conditions of this Agreement and any Ancillary Agreement, Gilead hereby grants to Janssen a non-exclusive, royalty-free, fully paid-up license, with the right to sublicense to its Affiliates, Third Party Distributors and permitted subcontractors, to use in the Janssen Countries and any country in which Janssen is Detailing a Territory Combination Product hereunder the applicable Combination Product Trademarks for the sole purpose of exercising its rights under the Janssen Distributor Agreement and Detailing the applicable Territory Combination Product (but not to Exploit the APIs thereof individually or in combination other than in such Territory Combination Product) in the Field and solely for use on the approved Product Label and Package and the Local Promotional Materials for the applicable Territory Combination Product.

9.4.9 Gilead hereby recognizes Janssen's right, title, and interest in and to the Janssen Licensed Trademarks. Gilead further recognizes that this Agreement, or use of the Janssen Licensed Trademarks in connection with this Agreement, in no way confers to Gilead any right, title, and interest in and to the Janssen Licensed Trademarks or any other Trademarks or intellectual property rights owned by Janssen, except as may otherwise be expressly provided in this Agreement. Janssen hereby recognizes Gilead's right, title, and interest in and to the Gilead Licensed Trademarks and the Combination Product Trademarks. Janssen further recognizes that this Agreement, or use of the Gilead Licensed Trademarks or the Combination Product Trademarks in connection with this Agreement, in no way confers to Janssen any right, title, and interest in and to the Gilead Licensed Trademarks, the Combination Product Trademarks or any other trademarks or intellectual property rights owned by Gilead, except as may otherwise be expressly provided in this Agreement. Janssen agrees that the materials on which it uses the Gilead Licensed Trademarks shall be of similar standard as those materials on which Gilead uses the Gilead Licensed Trademarks and shall comply with Applicable Law. Gilead agrees that the materials on which it uses the Janssen Licensed Trademarks shall be of similar standard as those materials on which Janssen uses the Janssen Licensed Trademarks and shall comply with Applicable Law.

9.5 Sublicensed Rights .

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9.5.1 Third Party License Payments . [*].

9.5.2 Existing RPV License(s) . Gilead acknowledges that it has received a sublicense under this Article 9 with regard to certain Patents or Information and Inventions that are subject to the terms and conditions of the Existing RPV Licenses as applicable to Janssen's sublicensees thereunder and Gilead agrees to comply with such terms and conditions as specified by Janssen in the In-License Requirements established pursuant to this Section 9.5.

9.5.3 In-License Requirements . In order to ensure that Janssen is able to meet its obligations under the Existing RPV Licenses as they relate to the activities under this Agreement, and to ensure Gilead is clear with regard to the requirements on Janssen in order to ensure such compliance, the Parties have agreed upon those obligations, beyond those set forth herein, to which Gilead shall be required to adhere in order to ensure such compliance (such written terms, and any additional written terms the Parties agree upon in good faith under Section 9.5.4, referred to herein the " **Janssen In-License Requirements** "). The Janssen In-License Requirements effective as of the Restatement Effective Date are attached as Annex W . In order to ensure that Gilead is able to meet its obligations under any license agreements entered into by Gilead pursuant to Section 9.5.4, the Parties will agree in good faith upon written terms setting forth those obligations of such license agreements beyond those obligations set forth herein to which Janssen shall be required to adhere, and to ensure Janssen is clear with regard to such obligations (such written terms referred to herein the " **Gilead In-License Requirements** "). The Parties will set forth the Gilead In-License Requirements in a separate signed document.

9.5.4 Additional In-Licenses . In the event that a first Party determines that there is a Patent or other intellectual property that is licensed to such first Party or its Affiliates by a Third Party under a sublicensable license agreement, which Patent or intellectual property is sublicensed to the other Party hereunder (such as, in the case of Janssen as the first Party, the Existing RPV Licenses) or for which such first Party has obligations to such Third Party under such license agreement that would be, to the first Party's good faith knowledge, triggered by any activities conducted hereunder by the other Party (such as, in the case of Gilead, the Existing Gilead Licenses), then such first Party shall promptly notify the other Party and the Parties shall promptly thereafter negotiate and agree on and set forth in writing, (a) either (i) in the case of such a license agreement of Janssen, an amendment to the Janssen In-License Requirements, or (ii) in the case of such a license agreement of Gilead, an amendment to the Gilead In-License Requirements; and (b) an amendment to this Agreement to the extent that a sublicense to the other Party is necessary. For clarity, upon entering into such amendment(s) under this Section 9.5.4, the at-issue Third Party license agreement shall be deemed an " **In-License Agreement** ." Each Party shall only be bound by any In-License Requirement on and after the date on which such In-License Requirement has been disclosed to such Party and only for so long as such Party is a sublicensee under the applicable In-License Agreement or conducting activities in accordance with this Agreement that trigger the other Party's obligations under the applicable In-License Agreement and only for so long as the In-License Requirement is required by the applicable In-License Agreement. [*]. Upon the request of either Party, the other Party shall disclose to the requesting Party the applicable financial terms of any Existing Gilead License (in the case the requested Party is Gilead), any Existing RPV License (in the case the requested

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Party is Janssen) and any In-License Agreement of such requested Party entered into after the Restatement Effective Date that would require the requesting Party to pay a royalty or other monetary compensation after expiration of the Agreement with respect to such country; provided that such request by the requesting Party may be made no earlier [*].

9.5.5 Modifications or Amendments to any In-License Agreement . Modifications or amendments to any In-License Agreement, including the Existing RPV Licenses and the Existing Gilead Licenses, by a Party after the Restatement Effective Date that would materially increase a Party's obligations under the In-License Requirements shall not apply to the obligated Party unless and until such first Party obtains the obligated Party's prior written approval. If a Party modifies or amends any In-License Agreement in a manner that would require modification of the In-License Requirements, the Parties shall negotiate in good faith modifications to the In-License Requirements in order to reflect such modification or amendment, provided that such modification or amendment complies with the preceding sentence, in which case the other Party shall not unreasonably withhold its consent to such modifications or amendments to the In-License Requirements.

9.5.6 Payments . [*].

9.6 Retained Rights . All (sub)license rights not specifically granted in this Article 9 or elsewhere herein or in any Ancillary Agreements are expressly reserved by each licensing Party (or its Affiliates). Any (sub)license granted in this Article 9 which is not sublicensable, may be transferred or assigned by the licensee Party only in connection with a permitted assignment of this Agreement by such Party. Notwithstanding anything contained in this Article 9, none of the licenses granted under this Agreement apply to Generic Combination Product. For clarity, each Party and its Affiliates retains all rights under any intellectual property Controlled by such Party (other than Controlled as a result of the licenses granted in this Article 9) (a) to exercise any of its rights under such Party's Generic Exception, including granting licenses to Generic Licensees permitted thereunder, or any of its rights to conduct clinical trials in accordance with this Agreement, and (b) to perform its obligations hereunder or under any Ancillary Agreement.

10 PAYMENTS

10.1 Payments .

10.1.4 Payment of Pre-Conversion Supply Price . Janssen shall submit an invoice to Gilead at the Pre-Conversion Supply Price for any Supplied RPV used or intended to be used for commercial purposes at the time of delivery to Gilead of such Supplied RPV or promptly thereafter. Payments with respect to each such invoice shall be payable and due in accordance with the terms of the RPV Supply Agreement and the terms of this Agreement, including Section 10.4 and Section 10.5.1. In the event of any inconsistency between the financial provisions of the RPV Supply Agreement and the financial provisions of this Agreement, such terms of this Agreement shall control. For clarity, for each Territory Combination Product, the Pre-Conversion Supply Price shall be invoiced collectively for Region A, Region B and Region C.

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10.1.5 Monthly Payments . Subject to Annex M-1 , for each Territory Combination Product, Gilead shall make a Monthly Payment with respect to all Gilead Countries that are Post-Conversion Supply Price Countries in Region A, Region B and Region C (in a single amount for all such Post-Conversion Supply Price Countries), subject to any adjustments specified hereunder, which payment shall be payable and due in accordance with the terms of this Agreement, including Sections 10.4, 10.5.2 and 10.5.3.

10.2 Post-Conversion and Additional Supply Price Reductions . With respect to Supplied RPV, the Post-Conversion Supply Price or Additional Supply Price, as applicable, for each Territory Combination Product shall be adjusted as set forth in Annex M-2 (provided that, with respect to Section A of Annex M-2 , such adjustments shall apply [*].

10.3 Monthly Payment Term . For each Territory Combination Product, the Monthly Payment shall be made for the Gilead Countries in Region A, Region B and Region C, until the expiration of the last to expire Monthly Payment Term in the Gilead Countries in Region A, Region B and Region C (and the calculations in Annex M-1 shall take account of the exclusion of countries for which the Monthly Payment Term has expired following the end of the applicable Monthly Payment Term).

10.4 Mode of Payment . All payments to Janssen hereunder and under the RPV Supply Agreement shall be made by wire transfer of U.S. Dollars in the requisite amount to the account designated by Janssen; provided , however , that any notice by Janssen of a change in such account shall not be effective until thirty (30) days after receipt thereof by Gilead.

10.5 Reports & Payments .

10.5.1 Pre-Conversion Supply Price Payments and Revaluation Pre-Conversion Payments . Pre-Conversion Invoices shall be due and payable by Gilead or its designated Affiliate in accordance with Annex M-5 . Revaluation Pre-Conversion Invoices shall be due and payable by Gilead in accordance with Annex M-6 .

10.5.2 Monthly Payments . For each Territory Combination Product, Gilead or its designated Affiliate shall make the Monthly Payments collectively for Region A, Region B and Region C, for each calendar month during the Term in accordance with Annex M-5 , subject to prior receipt of an invoice from Janssen for such amount.

10.5.3 Monthly Payment Calculation . For each Territory Combination Product, the calculation of a Monthly Payment shall be based on the total number of Units of such Territory Combination Product sold by Gilead and its Affiliates and Sublicensees to Third Parties during such calendar month (adjusted on a pro rata basis in the event that the applicable Monthly Payment Term has expired during such calendar month) in Gilead Countries that are Post-Conversion Supply Price Countries where the Monthly Payment Term has not yet expired, as provided in Annex M-1 .

10.5.4 Monthly Reports . Gilead shall provide to Janssen the reports described in Annex N on a product-by-product and country-by-country basis setting forth the Units of each

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Territory Combination Product sold and any adjustments to which either Party is entitled hereunder. Such reports shall be due no later than fifteen (15) Business Days after the end of each calendar month. Gilead shall be responsible for making the calculations set forth in Annex M-1. In addition to the aforementioned, each Party shall also provide such other information requested by the other Party and necessary for the other Party (or any of its Affiliates) to comply with such other Party's royalty payment and financial reporting obligations under any In-License Agreement, as specified in the In-License Requirements.

10.5.5 Lost Supplied RPV. Gilead shall notify Janssen in writing on an annual basis of any Supplied RPV that becomes Lost Supplied RPV in such Calendar Year, which notice shall specify the quantity of such Lost Supplied RPV. Such notification shall occur in January of each Calendar Year with regards to Lost Supplied RPV from the prior Calendar Year. Notwithstanding anything to the contrary in this Agreement or the Ancillary Agreements, the compensation due to Janssen (or its Affiliate) from Gilead (or its Affiliate) under the RPV Supply Agreement with respect to any quantity of Lost Supplied RPV shall be adjusted so that it equals the Standard Cost of Manufacturing for such Supplied RPV. Gilead shall pay the then-current Standard Cost of Manufacturing with respect to any quantity of Lost Supplied RPV for a given Calendar Year forty-five (45) days following the receipt of an invoice from Janssen for such Lost Supplied RPV. At the same time, Janssen shall issue to Gilead a credit note for the Pre-Conversion Supply Price with respect to the quantity of Lost Supplied RPV (taking into account any Revaluation Pre-Conversion Invoices with respect to such Pre-Conversion Supply Price).

10.5.6 Other Payments. For all other payments due hereunder or under the RPV Supply Agreement, the invoicing Party shall submit an invoice to the paying Party and such invoices shall be due and payable within forty-five (45) days after receipt unless otherwise provided in this Agreement or the RPV Supply Agreement.

10.5.7 Communication of Non-Public Pricing Information. The Parties shall communicate all non-public Net Selling Price information necessary to perform the financial calculations required by this Agreement solely through their respective representatives on the Financial Reporting Committee or as otherwise approved by such committee.

10.5.8 Other Reports. Without limitation of the foregoing, each Party shall also provide such other financial-related reports as are set forth on Annex N and otherwise comply with the requirements of Annex N.

10.6 Financial Records. Each Party shall keep, and shall cause its Affiliates, (sub)licensees, Third Party distributors and Third Party contractors to keep, accurate records sufficient to support the calculation of the payments due under this Agreement and any Ancillary Agreement (collectively, "**Financial Records**") in accordance with the Accounting Standards and in sufficient detail to enable the amounts due hereunder and thereunder to be determined and verified by the other Party's auditor. Such records shall be retained for at least (i) three (3) years after creation thereof or (ii) such longer period as may be required under any In-License Agreement, as specified in the In-License Requirements, or Applicable Law. Financial Records shall be open for examination, in accordance with Section 10.8, during reasonable business hours for so long as they are required to be maintained under this Section 10.6.

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10.7 Currency Conversion . The Party responsible for making any currency conversions hereunder shall, in a manner consistent with Gilead's then-current standard worldwide currency conversion methodology, convert the applicable amounts incurred or sold, as the case may be, into the applicable currency. Gilead's standard worldwide currency conversion methodology on the Restatement Effective Date is based on a monthly rate that is within the day's trading range during NYC trading hours in Bloomberg Professional service application on the third (3rd) to last Business Day of the prior month. Gilead shall inform Janssen of any changes to its standard worldwide currency conversion methodology prior to any such changes becoming effective. For clarity, all currency conversions required under this Section 10.7 shall use the exchange rate for the applicable month then used by Gilead in accordance with the foregoing.

10.8 Audits .

10.8.1 Audits .

10.8.1.8 Mutually Agreed Audits . Subject to Section 10.8.1.3, within three (3) years after the First Commercial Sale of a Territory Combination Product in the Territory and every three (3) years thereafter (provided that after completion of the initial Audit by each Party pursuant to this Section 10.8.1.1, the Parties may mutually agree to extend the period between subsequent Audits pursuant to this Section 10.8.1.1 to a period greater than three (3) years), each Party (the " **Audited Party** ") shall, and shall cause its Affiliates and Sublicensees (in the case of Gilead) and, to the extent relevant to the revenue share calculations hereunder, Third Party Distributors and other Third Party distributors, if applicable, to permit an independent public accounting firm of national prominence selected by such Party and the other Party (the " **Auditing Party** ") by mutual agreement to have access during normal business hours to those Financial Records of such Audited Party, its Affiliates, Sublicensees (in the case of Gilead), Third Party Distributors and other Third Party distributors as may be reasonably necessary for the sole purpose of verifying the accuracy of the financial reports and calculations hereunder and under any Ancillary Agreement (including all of the components and deductions relating to the payments under Section 10.1 and adjustments under Section 10.2 and analogous payments under the Janssen Distributor Agreement with respect to the Janssen Countries, the Manufacturing Fees and the [*]) and for verifying the accuracy of any information relating to payments due under this Agreement and any Ancillary Agreement (each, an " **Audit** "). For each Audit under this Section 10.8.1.1 with respect to reports and calculations for each Territory Combination Product, [*]. The Parties shall agree on the scope of any such Audit (e.g., whether the Audit shall be one (1), two (2), or three (3) Calendar Years).

10.8.1.9 Party Initiated Audits . Subject to Section 10.8.1.3, and without limitation of Section 10.8.1.1, upon the written request and expense of the Auditing Party, each Audited Party shall, and shall cause its Affiliates and Sublicensees (in the case of Gilead) and , to the extent relevant to the revenue share calculations hereunder, Third Party Distributors and other Third Party distributors, if applicable, to permit an independent public accounting firm of national prominence selected by the Auditing Party and acceptable to the Audited Party to have access during normal business hours to those Financial Records of such

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Audited Party, its Affiliates, Sublicensees (in the case of Gilead) and, to the extent relevant to the revenue share calculations hereunder, Third Party Distributors and other Third Party distributors, if applicable, as may be reasonably necessary for the sole purpose of conducting an Audit. An Auditing Party may not initiate an Audit of the Audited Party under this Section 10.8.1.2 more than once per Calendar Year.

10.8.1.10 Generally . Each Auditing Party may conduct an Audit of the Financial Records relating to a particular Calendar Year of the Audited Party no more than once and there shall be no Audit of the Financial Records relating to a particular Calendar Year of the Audited Party more than once under Section 10.8.1.1 and Section 10.8.1.2, collectively, provided that any Financial Records relating to a particular Calendar Year of a Party that have been Audited may be Audited a second time to the extent that such Financial Records were not included in the scope of the first Audit. Notwithstanding anything herein to the contrary, in no event may an Auditing Party conduct an Audit of the Financial Records of the Audited Party relating to any Calendar Year ending more than three (3) years prior to the date of such Audit. With respect to Third Party Distributors and other Third Party distributors, all Audits shall be conducted solely by the Party that is party to the applicable agreement with such Third Party Distributor or Third Party distributor and in accordance with terms and conditions of such agreement using the independent public accounting firm or other mutually acceptable certified or chartered accountant (in each case as permitted by the terms and conditions of such agreement) and the Auditing Party shall only have the right to review the results of such Audit generated by the contracting Party and such independent public accounting firm or accountant to the extent such Audit results may be revealed pursuant to the applicable agreement with such Third Party Distributor or Third Party distributor; and this Section 10.8 shall not confer rights to any Party that exceed those rights set forth in the applicable agreement with such Third Party Distributor or Third Party distributor. For clarity, any information relating to providing Janssen estimates of amounts to be paid hereunder or under the RPV Supply Agreement shall not be subject to an Audit.

10.8.2 Sublicenses, Distribution Agreements and other Third Party Agreements .

10.8.2.1 With respect to any sublicense agreement entered into after the Restatement Effective Date with respect to a Territory Combination Product, the Parties shall include a provision requiring, among others, the Sublicensee to keep and maintain adequate Financial Records pursuant to such sublicense agreement sufficient to make the calculations hereunder and to grant access to such Financial Records to the extent required under Section 10.6 and Section 10.8.1.

10.8.2.2 With respect to any (sub)license agreement entered into after the Restatement Effective Date with respect to any F/TDF Product, F/TAF Product, RPV Single Agent Product, TDF Single Agent Product or FTC Single Agent Product, to the extent that the sales information generated thereunder is required in order to calculate the F/TAF NSP, F/TDF NSP, FTC NSP or RPV NSP, as applicable, the Party that is a party to such agreement shall include a provision requiring the applicable (sub)licensee to keep and maintain adequate Financial Records pursuant to such sublicense agreement sufficient to make such calculations

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and to grant access to such Financial Records to the extent required under Section 10.6 and Section 10.8.1. With respect to any existing (sub) license agreements, neither Party shall modify such agreements to reduce compliance with the foregoing and, in the event of a modification of such agreements, shall use reasonable efforts to include such provision described in this Section 10.8.2.2.

10.8.2.3 In the event with respect to a country, a Party [*] then the Party that is a party to such agreement shall include a provision requiring the applicable Third Party distributor to keep and maintain adequate Financial Records pursuant to such agreement sufficient to make such calculations and to grant access to such Financial Records to the extent required under Section 10.6 and Section 10.8.1.

10.8.3 Any report prepared by such independent public accounting firm or other accountant, a copy of which shall be sent or otherwise provided to the Auditing Party by such independent public accounting firm or other accountant at the same time as it is sent or otherwise provided to the other Party, shall contain the conclusions of such independent public accounting firm or other accountant regarding the Audit and will specify that the amounts paid by or to the Auditing Party pursuant thereto were correct or, if incorrect, the amount of any underpayment or overpayment.

10.8.4 If such independent public accounting firm's or other accountant's report shows any underpayment, the paying Party shall remit to the other Party within sixty (60) days after receipt of the Audit report, (i) the amount of such underpayment and (ii) if such underpayment exceeds [*] of the total amount owed for the Calendar Year then being audited, the reasonable and necessary fees and expenses of such independent public accounting firm or other accountant performing the Audit, subject to reasonable substantiation thereof. If such independent public accounting firm's report shows any overpayment, the paying Party shall receive a credit equal to such overpayment against future amounts, if any, payable under this Agreement; if no further payments are due under this Agreement, reimbursement of the overpayment shall be due and paid no later than sixty (60) days after receipt of the Audit report (and no invoicing shall be required).

10.9 Interest Due . In case of any delay in payment by a Party to the other Party hereunder or under the RPV Supply Agreement, interest on the overdue payment shall accrue at an annual interest rate equal to the lower of (a) the sum of (i) the prime rate of interest in force on the date the payment is due as published in The Wall Street Journal (Eastern United States Edition) and (ii) [*] and (b) the maximum rate of interest permissible by Applicable Law. The foregoing interest shall be due from the paying Party without any special notice.

10.10 Tax Withholding .

10.10.1 A Party making payments to the other Party under this Agreement or the RPV Supply Agreement shall make such payments without deduction or withholding for taxes except to the extent that any such deduction or withholding is required by Applicable Law in effect at the time of payment.

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10.10.2 Any tax required to be withheld on amounts payable under this Agreement or the RPV Supply Agreement will promptly be paid by the applicable paying Party on behalf of the other Party to the appropriate governmental authority, and such paying Party will furnish the other Party with proof of payment of such tax within sixty (60) days. Any such tax required to be withheld shall be an expense of and borne by such other Party.

10.10.3 Janssen and Gilead shall cooperate with respect to all documentation required by any taxing authority or reasonably requested by Janssen or Gilead to secure a reduction in the rate of applicable withholding taxes.

10.10.4 If the applicable paying Party had a duty to withhold taxes in connection with any payment it made to the other Party under this Agreement or the RPV Supply Agreement but such paying Party failed to withhold, and such taxes were assessed against and paid by such paying Party, then the other Party shall indemnify and hold harmless such paying Party from and against such taxes (including interest, but not including any related penalties). If such paying Party makes a claim under this Section 10.10.4, it shall comply with the obligations imposed by Section 10.10.2 as if such paying Party had withheld taxes from a payment to the other Party.

10.10.5 If either Party assigns in whole or in part this Agreement or the RPV Supply Agreement to an Affiliate or Third Party or grants to an Affiliate or Third Party a sublicense hereunder, in each case in a manner that adversely impacts the other Party economically due to increased withholding taxes on amounts paid by such Party hereunder or under the RPV Supply Agreement, or additional VAT taxes on the transfer of inventory hereunder or thereunder, then such first Party shall pay to such other Party an amount equal to the difference between the amount such other Party owes to the relevant tax authority on payments received or paid hereunder or thereunder, or inventory sold hereunder or thereunder, and the amount such other Party would have owed to such tax authority had this Agreement or the RPV Supply Agreement not been assigned or sublicensed to such Affiliate or Third Party.

10.11 Manufacturing Fees . The Parties shall perform their respective obligations with respect to the Manufacturing Fee as set forth in Annex M-4 .

10.12 Branded Prescription Pharmaceutical Manufacturers Fee . [*].

10.13 Research and Development Reimbursement Payments . The Parties acknowledge and agree that Gilead has paid to Janssen all amounts that are required to be paid by Gilead to Janssen under Section 10.1 of the Original Agreement, and accordingly Gilead shall have no further obligations with respect to the payment of such amounts.

11 FINANCIAL CALCULATIONS AND ADJUSTMENTS

11.1 Calculations . Any obligation of a Party hereunder to make any calculation or to provide the results of such calculation, which calculation requires any information that the other Party is obligated to provide hereunder, shall be subject to receipt of such information from such other Party. In the event that delivery of any such information to the Party performing such

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calculation is delayed, the deadline for performing such calculation and providing the results of such calculation shall be extended for a period of time corresponding to such delay.

11.2 Working Percentages . The Working Percentages for each Calendar Year shall be determined as set forth in Annex H .

11.3 Actual Percentages . Gilead shall calculate the Actual Percentages with respect to each Calendar Year in accordance with Annex I . Gilead shall use reasonable efforts to provide such percentages to Janssen no later than January 31 after the end of such Calendar Year.

11.4 Establishment of Standard Costs of Manufacturing . [*].

11.5 [Reserved] .

11.6 Post-Generic FTC/TDF and F/TAF Combination . For each Calendar Quarter following the occurrence of the Generic FTC/TDF Combination Threshold [*] with respect to a given Specified Percentage Country, this Section 11.6 shall apply with respect to such Specified Percentage Country as follows:

11.6.1 the Specified Percentage with respect to Territory Complera sold in such Specified Percentage Country shall be modified to equal [*] and [*].

11.7 [Reserved] .

11.8 [Reserved] .

11.9 [Reserved] .

11.10 Application of Original Agreement . Notwithstanding anything to the contrary in this Agreement or any Ancillary Agreement, the provisions related to pricing, revenue sharing, payment, currency conversion, financial reporting and audit and committees related to the foregoing (including the Discount Committee (as defined in the Original Agreement) and the Launch Coordination Committee (as defined in the Original Agreement)) of the Original Agreement and not the provisions related to pricing, revenue sharing, payment, currency conversion, financial reporting, audit and committees of this Agreement, shall govern any applicable activities conducted by the Parties (including any Triggering Sales (as defined in the Original Agreement)) with respect to Territory Complera on or before December 31, 2014, as well as any audits hereunder with respect to such period.

12 [RESERVED]

13 SAFETY DATA EXCHANGE AGREEMENT; PRODUCT RECALL AND WITHDRAWAL

13.1 Generally . Subject to the terms of this Agreement, within one hundred and twenty (120) days after the Restatement Effective Date, Janssen and Gilead (under the guidance of their respective pharmacovigilance departments, or equivalents thereof) shall cooperate in

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good faith to discuss and develop mutually acceptable guidelines and procedures for the investigation, exchange, receipt, recordation and communication (as between the Parties and their Affiliates) of safety-related information with respect to the Territory R/F/TAF Product, and to set forth such guidelines and procedures in a written amendment to the Complera PVA or a separate written agreement between the Parties (the Complera PVA as amended by such amendment, or such separate written agreement (as it may be amended from time to time) together with the Complera PVA, the " **Pharmacovigilance Agreement** " or " **PVA** "). In connection with entering into any Third Party Distributor Agreement, the Selling Party shall ensure that it and the applicable Third Party Distributor enter into an appropriate pharmacovigilance agreement consistent with the terms of the PVA. Gilead shall, at its expense, maintain the global safety database with respect to the Territory Combination Products.

13.2 Notification and Recall .

13.2.9 Notification . In the event that either Party becomes aware that any governmental agency or authority has issued or requested a recall or market withdrawal or taken similar action in connection with (a) a Combination Product anywhere in the world, (b) in the case of Janssen, the RPV Single Agent Product, if the reason for such field alert is reasonably likely to affect a Territory Combination Product and Janssen has the right to make such disclosure to Gilead or (c) in the case of Gilead, any of the Gilead Compound Products, if the reason for such field alert is reasonably likely to affect a Territory Combination Product and Gilead has the right to make such disclosure to Janssen, or in the event that either Party determines that such a recall or market withdrawal of a Territory Combination Product may be necessary or advisable, such Party shall notify the other Party thereof by telephone within twenty-four (24) hours after becoming aware of such request, action or determination. Each Party shall also notify the other (i) if such Party issues an FDA field alert or similar alert or foreign equivalent thereof (in which case the Party issuing such field alert shall notify the other Party within twenty-four (24) hours after the decision to issue such field alert, and prior to notification of the applicable governmental agency or authority) with respect to (x) a Territory Combination Product or (y) any of such Party's Single Agent Product(s) (including, in the case of Janssen, any Other RPV Product) or Double Agent Products in the Field, if the reason for such field alert is reasonably likely to affect a Territory Combination Product and the disclosing Party has the right to make such disclosure to the other Party, and (ii) within twenty-four (24) hours after such Party's receipt of any communication from any governmental agency or authority regarding a potential recall or market withdrawal of a Territory Combination Product or any of such Party's aforementioned products anywhere in the world.

13.2.10 Decision to Recall or Withdraw . Within a period of time reasonable under the circumstances after the date of a notice given pursuant to the first sentence of Section 13.2.1 that relates to, or otherwise has implications for, the Exploitation of a Territory Combination Product in any country(ies) in the Territory, for each country in the Territory, the Selling Party with respect thereto shall recall or withdraw such Territory Combination Product in such country if the Recall/Withdrawal Criteria (described below) are met with respect to such country. In such a case, the Selling Party shall determine in its reasonable judgment (i) the extent to which to conduct such recall or withdrawal (where such determination shall be made by

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the Selling Party, in its reasonable judgment, based on the circumstances (e.g., a discrete Manufacturing non-conformity would justify a recall with respect to the applicable quantities of the applicable Territory Combination Product, but not a market withdrawal of such Territory Combination Product from such country)), (ii) the breadth, extent and level of customer to which any such recall or withdrawal shall reach, (iii) the strategies and notifications to be used, and (iv) other related matters with respect to the conduct of such recall or withdrawal. The " **Recall/Withdrawal Criteria** " shall be deemed to have been met in any country in the Territory if (A) the recall or withdrawal is mandated by any Regulatory Authority, (B) the Selling Party reasonably determines to recall or withdraw a Territory Combination Product, or the non-Selling Party reasonably requests such recall or withdrawal in writing, and such determination by the Selling Party, or such request by the non-Selling Party, is made: (v) for failure of such Territory Combination Product to meet the specifications therefor, (w) with a reasonable basis to conclude that material harm to patients may occur in the absence of such recall or withdrawal, (x) in the event the Manufacture of such Territory Combination Product sold in such country does not comply with Applicable Law, (y) on account of safety issues with respect to (1) such Territory Combination Product or (2) any Single Agent Product(s) or Double Agent Product in the Field, including in the event of a withdrawal of any Single Agent Product(s) or Double Agent Product in the Field from markets in the European Union or the United States for safety concerns, or (z) on account of a Regulatory Authority mandating a withdrawal of any Single Agent Product(s) or Double Agent Product in the Field from markets in the European Union or the United States or (C) the applicable Territory Combination Product is recalled or withdrawn in the applicable country(ies) in accordance with Section 13.2.3.

13.2.11 Product Withdrawal .

13.2.11.1 Without limitation of Section 13.2.2, (a) subject to Section 4.8 and Section 13.2.3.2, at any time, Gilead may, for commercial reasons or otherwise determine in its sole discretion, withdraw any Territory Combination Product from the market in any Gilead Country that is not a Major Market Country (and recall such Territory Combination Product in connection therewith, if applicable), (b) at any time after the First Commercial Sale of the Territory R/F/TAF Product has occurred in a Janssen Country, Janssen may, for commercial reasons or otherwise, determine in its sole discretion to withdraw Territory Complera from the market in such Janssen Country (and to recall Territory Complera in connection therewith, if applicable), and (c) at any time after Gilead has withdrawn the Territory R/F/TAF Product in a Major Market Country pursuant to Section 13.2.2, Janssen may, for commercial reasons or otherwise, determine in its sole discretion to withdraw the Territory R/F/TAF Product from any Janssen Country (and to recall the Territory R/F/TAF Product in connection therewith, if applicable). If the reason for such market withdrawal is based on any of the Recall/Withdrawal Criteria (other than clause (C) thereof), such withdrawal shall be conducted in accordance with Section 13.2.2. In all other cases of market withdrawal, the Selling Party shall, upon receiving any necessary or appropriate approval from the applicable Regulatory Authority(ies), cease selling (and cause its subdistributors and Third Party Distributors, as applicable, to cease selling) the applicable Territory Combination Product in the applicable country, and the Selling Party shall determine whether, and if so how, to recall any of such Territory Combination Product already on the market in such country.

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13.2.11.2 If Gilead determines to withdraw the Territory R/F/TAF Product from the market in any Gilead Country that is not a Major Market Country pursuant to Section 13.2.2 or Section 13.2.3.1 for any reason other than a reason described in clause (A) or clause (B) of the Recall/Withdrawal Criteria, Gilead shall promptly notify Janssen in writing and the Parties shall discuss in good faith such Gilead determination to withdraw the Territory R/F/TAF Product. In the event that the Parties are unable to agree on whether Gilead may withdraw the Territory R/F/TAF Product from such country pursuant to Section 13.2.2 or Section 13.2.3.1, either Party shall have the right to refer such matter for resolution by the Alliance Managers pursuant to Section 20.6. If the Alliance Managers do not reach consensus with respect to such matter within the time period set forth in Section 20.6.1, such matter may be escalated by either Party to the Executives pursuant to Section 20.6.1 and, in the event that the Executives do not reach agreement on such matter within the Executives Review Period, Gilead shall have final decision-making authority with respect to such matter.

13.2.12 Conduct of Recall or Withdrawal . Subject to Section 13.3 and the Janssen Distributor Agreement, without limitation of Section 13.2.2, any withdrawal or recall with respect to a Territory Combination Product in any country in the Territory required or agreed upon by the Parties pursuant to this Section 13.2 shall be conducted by the Selling Party with respect to such country or its applicable Affiliate (or in the case of a country in which a Sublicensee or Third Party Distributor is the distributor in such country, the Selling Party shall cause the Sublicensee or Third Party Distributor to conduct such product recall or withdrawal) with reasonable cooperation from the other Party, regardless of whether the other Party requested such withdrawal or recall.

13.2.13 Regulatory Filings; Required Reporting . In the case of any recall or withdrawal of a Territory Combination Product in any country in the Territory, the Selling Party with respect to such country shall make (or cause to be made) such regulatory filings with Regulatory Authorities in such country as may be required to effect such recall or withdrawal.

13.2.14 Reporting and other Actions Required by Applicable Law . Nothing set forth in this Section 13.2 shall be construed as restricting the right of either Party (or its Affiliates, Sublicensees or Third Party Distributors) to make a timely report of any matter relating to an actual or potential recall or similar action to any government agency or take other action that it deems appropriate or required by Applicable Law.

13.3 Recall Expenses . Each Party (the " **Responsible Party** ") shall bear any and all Recall Expenses with respect to any Party-Specific Recall/Withdrawal of such Party. Any Recall Expenses that are not exclusively borne by one of the Parties pursuant to the preceding sentence shall be borne by the Parties in accordance with their applicable Average Respective Percentages with respect to the Territory. In addition, if any existing quantity of Territory Combination Product is rendered unusable as a result of a recall or withdrawal (either by way of a return resulting in unusable Territory Combination Product or an inability to make future sales of Territory Combination Product in inventory) (" **Recalled Product** "), the following shall apply with respect to the Recalled Product (and the quantity of APIs contained therein): (x) for any amounts invoiced by Janssen to Gilead for the Supplied RPV contained in such Recalled

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Product, Janssen shall issue a credit note to Gilead which shall be credited against the outstanding invoice for such Supplied RPV (if not yet due or paid, or otherwise against any other outstanding invoice), (y) solely with respect to Recalled Product supplied by Gilead pursuant to the Janssen Distributor Agreement, for any amounts invoiced by Gilead to Janssen for such Recalled Product, Gilead shall issue a credit note to Janssen which shall be credited against the outstanding invoice for such Recalled Product if not yet due or paid or otherwise against any other outstanding invoice), and (z) solely in the case of a Party-Specific Recall/Withdrawal, the Responsible Party shall pay to the non-Responsible Party (1) for each API of the non-Responsible Party in such Recalled Product, an amount equal to the quantity of such API corresponding to the quantity of such Recalled Product multiplied by the Standard Cost of Manufacturing for such API, and (2) an amount equal to the non-Responsible Party's portion of the applicable Manufacturing Fees for such Recalled Product.

13.4 Recall Records . Each Party shall maintain records of all sales, in countries in which it is the Selling Party, of each Territory Combination Product to direct accounts sufficient to administer a recall until the date that is the latest of (a) three (3) years from the termination or expiration of this Agreement with respect to such Territory Combination Product, (b) three (3) years from the date of the last such sale of such Territory Combination Product in the Territory or (c) the last expiration date of such Territory Combination Product sold by, or on behalf of, such Party, or such longer period as may be required under any In-License Agreement, as specified in the In-License Requirements, or Applicable Law.

13.5 Communication with Regulatory Authorities Regarding Recalls .

13.5.5 Gilead shall make all contacts with any applicable Regulatory Authority in the Gilead Countries relating to the implementation of any recall of the Territory Combination Product, and shall be responsible for coordinating all of the necessary activities in connection with any such recall.

13.5.6 Janssen shall make all contacts with any applicable Regulatory Authority in the Janssen Countries relating to the implementation of any recall of the Territory Combination Product, and shall be responsible for coordinating all of the necessary activities in connection with any such recall.

13.6 Public Statements Regarding Recalls . Gilead shall make all public statements with regard to any recall of the Territory Combination Product in the Gilead Countries and Janssen shall make all public statements with regard to any recall of the Territory Combination Product in the Janssen Countries. Prior to the issue of any press release or making of any other public statement by a Party relating to, connected with or arising out of any recall of the Territory Combination Product that contains the name of or that could reasonably be construed to refer to the other Party or its Affiliate, the other Party's Single Agent Product(s) or Double Agent Products or, in the event such other Party is Gilead, TDF, TAF or FTC, or, in the event such other Party is Janssen, RPV, such Party issuing such press release or making such other public statement shall provide the other Party with a copy of such press release or public statement and reasonably consider the comments of such other Party. Each Party shall make all public

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statements with regard to any recall of its respective Single Agent Product(s) or Double Agent Product.

14 INTELLECTUAL PROPERTY RIGHTS

14.1 Ownership of Intellectual Property .

14.1.15 Gilead Intellectual Property . Janssen shall have no right, title, and interest in and to the Gilead Technology, the Gilead-Owned Collaboration Inventions (including any Patents Covering a Gilead-Owned Collaboration Invention) and the Gilead Regulatory Documentation, except such licenses and other rights as are granted to Janssen in this Agreement and the Ancillary Agreements.

14.1.16 Janssen Intellectual Property . Gilead shall have no right, title, and interest in and to the Janssen Technology, the Janssen-Owned Collaboration Inventions (including any Patents Covering a Janssen-Owned Collaboration Invention) and the Janssen Regulatory Documentation, except such licenses and other rights as are granted to Gilead in this Agreement and the Ancillary Agreements.

14.1.17 Clinical Data . Notwithstanding Sections 14.1.1, 14.1.2 and 14.1.4, subject to the license and other rights granted to the other Party in this Agreement and the Ancillary Agreements, as among the Parties and their Affiliates, each Party shall own all right, title and interest in and to any clinical data generated by or on behalf of such Party or its Affiliates.

14.1.18 Joint Intellectual Property . Subject to the licenses and other rights granted under this Agreement and the Ancillary Agreements, as among the Parties and their Affiliates, the Parties shall jointly own all right, title and interest in and to the Joint Technology and Joint Collaboration Inventions. Subject to the licenses and other rights granted under this Agreement and the Ancillary Agreements and the other terms of this Agreement (including the terms set forth in Section 17.2.1 and 17.3.1), each Party and its Affiliates may independently Exploit its rights in the Joint Technology and Joint Collaboration Inventions without the consent of, or duty of accounting to, the other Party, including the right to assign, license or transfer any of its right, title and ownership in and to any Joint Technology or Joint Collaboration Inventions to (a) any Affiliate, (b) any Third Party that is a permitted assignee of this Agreement, (c) (i) in the case of Gilead or its Affiliates, any of its Third Party (sub)licensees or Generic Licensees to Exploit any Gilead Compound Product or, in the case of a Generic Licensee, a generic version thereof or, in the Gilead Countries, a Territory Combination Product, subject to the terms of this Agreement, or (ii) in the case of Janssen or its Affiliates, any of its Third Party (sub)licensees or Generic Licensees to Exploit any RPV Product or, in the case of a Generic Licensee, a generic version thereof or, in the Janssen Countries, a Territory Combination Product, subject to the terms of this Agreement, or (d) any of its Third Party contract manufacturers, in each case ((a) through (d)), without the consent of the other Party, but any assignment, license or transfer of a Party's (or its Affiliates') right, title or interest in or to any Joint Technology or Joint Collaboration Inventions to any other Third Party shall require the prior written consent of the other Party.

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14.1.19 Disclosure and Assignment of Collaboration Inventions . Each Party shall disclose to the other Party promptly in writing any and all Collaboration Inventions, other than, in the case of Janssen as the disclosing Party, Janssen-Owned Collaboration Inventions and, in the case of Gilead as the disclosing Party, Gilead-Owned Collaboration Inventions, that are conceived, discovered, developed or otherwise made by or on behalf of the disclosing Party. Each Party hereby assigns, and agrees to cause its Affiliates and their respective employees and agents to assign, to the other Party, without payment of additional consideration, such Party's (or its Affiliates') rights, title and interest in and to all Collaboration Inventions to the extent necessary to effect the ownership thereof as set forth in this Section 14.1.

14.1.20 Combination Product Regulatory Documentation . Subject to the licenses and other rights granted by each Party to the other Party pursuant to this Agreement, as between the Parties, Gilead, or its designated Affiliate, Sublicensee, or Third Party Distributor, shall own all right, title and interest in and to the Combination Product Regulatory Documentation; provided , however , that Janssen or its applicable Affiliate shall retain ownership of any Information and Inventions, including Clinical Data, included in the Combination Product Regulatory Documentation developed by or on behalf of Janssen or its Affiliates. Janssen shall, and shall cause its Affiliates and their respective employees and agents to, reasonably cooperate, by the execution of documents and otherwise, to vest ownership of the Combination Product Regulatory Documentation in Gilead (subject to the proviso in the first sentence of this Section 14.1.6).

14.2 Prosecution of Patents .

14.2.4 Gilead Patents . Gilead, through patent attorneys or agents of its choice, shall have the sole right, at its sole cost and expense, to prepare, file, prosecute and maintain the Gilead Patents, including Patents Covering the Gilead-Owned Collaboration Inventions, anywhere in the world in the name of Gilead. Without limitation of Section 14.1.5, Janssen shall, and shall cause its Affiliates and their respective employees and agents to, reasonably cooperate, by the execution of documents and otherwise, to vest ownership of the Gilead-Owned Collaboration Inventions in Gilead.

14.2.5 Janssen Patents . Janssen, through patent attorneys or agents of its choice, shall have the sole right, at its sole cost and expense, to prepare, file, prosecute and maintain the Janssen Patents, including Patents Covering the Janssen-Owned Collaboration Inventions, anywhere in the world in the name of Janssen. Janssen shall use Commercially Reasonable Efforts to prepare, file, prosecute and maintain any Janssen Patent in the Territory that Covers RPV or a Combination Product. Without limitation of Section 14.1.5, Gilead shall, and shall cause its Affiliates and their respective employees and agents to, reasonably cooperate, by the execution of documents and otherwise, to vest ownership of the Janssen-Owned Collaboration Inventions in Janssen.

14.2.6 Joint Patents .

14.2.6.7 Relating to a Combination Product .

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a. Gilead, through patent attorneys or agents of its choice, shall have the first right, but not the obligation, at its sole expense, to prepare, file, prosecute and maintain applications for Patents in the Territory claiming the Joint Know-How, to the extent that such Joint Know-How is (x) related to a Combination Product and (y) would have utility with regard to any Gilead Compound Product and would not have utility with regard to any RPV Product (" **Gilead-Controlled Combination Product Joint Patents** ") and to obtain, prosecute, and maintain such Gilead-Controlled Combination Product Joint Patents in the name of both Parties as assignees throughout the Territory. Gilead shall provide (or shall cause its foreign agents to provide) to Janssen copies of all written official communications correspondence between Gilead or any of its Affiliates or their respective patent counsel and the applicable patent office relating to the prosecution or maintenance of such Gilead-Controlled Combination Product Joint Patents, and Janssen shall have the right, but not the obligation, to provide substantive review and comment on any such correspondence. Without limitation of the foregoing, Janssen shall have the right to request that Gilead file, prosecute and maintain any Gilead-Controlled Combination Product Joint Patent in a particular country. If Gilead declines in writing to do so, or otherwise fails to initiate any such requested action with respect to such Gilead-Controlled Combination Product Joint Patent within sixty (60) days after receiving a request (or to thereafter diligently pursue such action), Janssen shall have the right, but not the obligation, at its sole cost and expense, through counsel of its choosing, to pursue such action with respect to such Gilead-Controlled Combination Product Joint Patent.

b. Janssen, through patent attorneys or agents of its choice, shall have the first right, but not the obligation, at its sole expense, to prepare, file, prosecute and maintain applications for Patents in the Territory claiming the Joint Know-How, to the extent that such Joint Know-How is (x) related to a Combination Product and (y) would have utility with regard to any RPV Product and would not have utility with regard to any Gilead Compound Product (" **Janssen-Controlled Combination Product Joint Patents** ") and to obtain, prosecute, and maintain such Janssen-Controlled Combination Product Joint Patents in the name of both Parties as assignees throughout the Territory. Janssen shall provide (or shall cause its foreign agents to provide) to Gilead copies of all written official communications correspondence between Janssen or any of its Affiliates or their respective patent counsel and the applicable patent office relating to the prosecution or maintenance of such Janssen-Controlled Combination Product Joint Patents and Gilead shall have the right, but not the obligation, to provide substantive review and comment on any such correspondence. Without limitation of the foregoing, Gilead shall have the right to request that Janssen file, prosecute and maintain any Janssen-Controlled Combination Product Joint Patent in a particular country. If Janssen declines in writing to do so, or otherwise fails to initiate any such requested action with respect to such Janssen-Controlled Combination Product Joint Patent within sixty (60) days after receiving a request (or to thereafter diligently pursue such action), Gilead shall have the right, but not the obligation, at its sole cost and expense, through counsel of its choosing, to pursue such action with respect to such Janssen-Controlled Combination Product Joint Patent.

c. Gilead and Janssen shall, and shall cause their respective Affiliates, as applicable, to assist and cooperate with one another in filing, prosecuting and maintaining the Joint Patents under this Section 14.2.3.1 and the reasonable costs and

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expenses of such assistance and cooperation shall be allocated as costs and expenses are otherwise allocated under this Section 14.2.3.1.

14.2.6.8 Other Joint Patents . In the event that either Party desires to prepare and have filed any Patent application in the Territory claiming the Joint Know-How to the extent that such Joint Know-How is either (A) not related to a Combination Product or (B) not covered by Section 14.2.3.1a or Section 14.2.3.1b above, then in either case ((A) or (B)), such Party shall propose such filing to the other Party and the Parties shall discuss and agree in writing on which Party shall take responsibility for preparing and filing the Patent application and the allocation as between the Parties of costs and expenses related to such Joint Patent application. In the event that the Parties fail to reach agreement that such Patent application should be filed, neither Party may file or cause to be filed such Patent application. In the event that the Parties agree that a Patent application for a Joint Patent Covering such Joint Know-How should be filed, the Party designated to lead such application process (the " **Lead Patent Party** ") shall have the sole right and obligation, in consultation with the non-Lead Patent Party, to prepare, file, prosecute, maintain and take any other actions as directed by the Parties with respect to such Joint Patent in the name of both Parties as the assignees in such countries as the Parties shall direct, and the costs and expenses with respect thereto shall be shared by the Parties as agreed pursuant to this Section 14.2.3.2. The Lead Patent Party shall keep the other Party advised of the status of Joint Patent filings pursuant to this Section 14.2.3.2 and shall provide (or shall cause its foreign agents to provide) copies of all written official communications correspondence between such Lead Patent Party or any of its Affiliates or their respective patent counsel and the applicable patent office relating to the prosecution or maintenance of such Joint Patents. For the avoidance of doubt, the Lead Patent Party may elect to use outside patent counsel for the filing, prosecution and maintenance of the Joint Patents. The non-Lead Patent Party may engage outside patent counsel, at its expense, to review any filings to be made with respect to any Joint Patent pursuant to this Section 14.2.3.2. The non-Lead Patent Party shall, and shall cause its Affiliates to, assist and cooperate with the Lead Patent Party in filing, prosecuting and maintaining the Joint Patents pursuant to this Section 14.2.3.2. Costs and expenses with respect to such assistance shall be shared by the Parties as agreed pursuant to this Section 14.2.3.2.

14.2.6.9 Without limitation of Section 14.1.5, each Party shall, and shall cause its Affiliates and their respective employees and agents to, reasonably cooperate, by the execution of documents and otherwise, to vest co-ownership of the Joint Patents in one another.

14.2.7 Extensions . Gilead may file and prosecute to obtain extensions of the Gilead Patents and the Gilead-Controlled Combination Product Joint Patents. Janssen may file and prosecute to obtain extensions of the Janssen Patents and the Janssen-Controlled Combination Product Joint Patents. The Lead Patent Party with respect to any other Joint Patents may file and prosecute to obtain extensions of such Joint Patents. The foregoing rights shall apply in any country in which such extensions are available and each Party may exercise its rights in this Section 14.2.4 in its sole discretion. Each Party shall provide such assistance as may reasonably be required to obtain such extensions.

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14.2.8 Orange Book . Gilead shall have sole discretion to determine which (i) Gilead Patents, including Patents Covering Gilead-Owned Collaboration Inventions, if any, (ii) Janssen Patents, including Patents Covering Janssen-Owned Collaboration Inventions, if any, and (iii) Joint Patents, if any, shall be listed in the "Orange Book" in the U.S., or any analogous or similar listing in the Territory, with respect to a Territory Combination Product in the Field; provided , however , that, in the case of the Janssen Patents and Joint Patents, Gilead shall consult with Janssen in advance, afford Janssen a reasonable opportunity to comment and consider in good faith any comments made by Janssen in good faith with regard to such determination.

14.3 Liability for Prosecution and Maintenance . Each Party acknowledges that the Party responsible for prosecution and maintenance of Patents licensed or co-owned under this Agreement or the Ancillary Agreements (the " **Prosecution and Maintenance** ") does not guarantee the issuance, validity, or enforceability of any such Patent or any claim resulting from its efforts hereunder. Neither Party shall have any liability to the other Party for any negligent acts or misconduct of outside counsel utilized in connection with the Prosecution and Maintenance. The foregoing provisions of this Section 14.3 are without prejudice to either Party's potential liability for breach of its obligations under Section 14.1 or 14.2.

14.4 Enforcement of Patents . Each Party shall promptly notify the other Party in writing of any alleged or threatened Infringement (as defined in Section 14.4.4) of which it becomes aware.

14.4.7 Effect on In-License Agreements . In the event that any Gilead Patents (in the case of Gilead) or Janssen Patents (in the case of Janssen) are subject to an In-License Agreement and such In-License Agreement would restrict or impair the exercise of the other Party of its step-in rights set forth in this Section 14.4 or Section 14.5, then at the request of the step-in Party (which request may only be made if and when such step-in Party intends to exercise such step-in rights), Gilead (in the case of the Gilead Patents) or Janssen (in the case of the Janssen Patents) shall use good faith efforts (a) to reasonably enable such other Party to exercise its such step-in rights, or (b) to achieve an alternate resolution to the exercise of the other Party's step-in rights, provided, however, that the Parties agree that such good faith efforts shall not require Gilead (in the case of the Gilead Patents) or Janssen (in the case of the Janssen Patents) to offer further compensation to a Third Party.

14.4.8 Janssen Patents . As between the Parties, Janssen shall have, with respect to the Major Market Countries, the first right and option, and with respect to the remaining countries in the Territory, the sole right and option, at its sole expense, in each case, to respond to any Infringement (as defined in Section 14.4.4) with respect to any Janssen Patent, including Patents Covering the Janssen-Owned Collaboration Inventions, by appropriate steps, including by filing an infringement suit or taking other similar action. With respect to the Major Market Countries, in the event that Janssen fails to, within forty (40) days following notice of such Infringement, or earlier notifies Gilead in writing of its intent not to, file an infringement suit or other similar action against the infringer with respect to at least one claim of one Janssen Patent, Gilead shall have the right, but not the obligation, to do so at Gilead's sole cost and expense, the foregoing provided that: (i) Janssen has the legal right to allow Gilead to take such steps to

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remove such Infringement, including considering any contractual obligations Janssen may have to Third Parties; (ii) any such steps to respond to such Infringement by Gilead shall only be with respect to claims of Janssen Patents that are directed to a composition-of-matter of RPV alone or in combination with TDF, TAF or FTC or the use in the Field of RPV alone or in combination with TDF, TAF or FTC; and (iii) to the extent that Gilead undertakes steps to remove such Infringement, Gilead shall indemnify Janssen and its Indemnified Persons as set forth in Section 18.5 (and Janssen shall have no obligations of indemnity under Article 18 arising from such enforcement). In the event that Gilead exercises such right, Gilead shall not settle any infringement suit or similar action without the prior written consent of Janssen, which consent shall not be unreasonably withheld; provided , however , that Janssen may in its sole discretion withhold its consent with respect to any settlement that involves an admission of invalidity or unenforceability of any Janssen Patent. The Party not bringing the suit or action shall provide, at such Party's own expense, reasonable assistance to the Party bringing the suit or action, including providing access to relevant documents and other evidence in its possession and control (to the extent it is able to do so without violation of any Third Party agreement), making its employees available at reasonable business hours, and joining the action to the extent necessary to allow the Party bringing the suit or action to maintain the suit or action. In the event of a conflict between Janssen's rights under its Generic Exception and this Section 14.4.2, such rights under Janssen's Generic Exception shall control.

14.4.9 Gilead Patents . As between the Parties, Gilead shall have, with respect to Major Market Countries, the first right and option, and with respect to the remaining countries in the Territory, the sole right and option, at its sole expense, to respond to any Infringement (as defined in Section 14.4.4) with respect to any Gilead Patent, including Patents Covering the Gilead-Owned Collaboration Inventions, by appropriate steps, including by filing an infringement suit or taking other similar action. With respect to Major Market Countries, in the event that Gilead fails to, within forty (40) days following notice of such Infringement, or earlier notifies Janssen in writing of its intent not to, file an infringement suit or other similar action against the infringer with respect to at least one claim of one Gilead Patent, Janssen shall have the right, but not the obligation, to do so at Janssen's sole cost and expense, the foregoing provided that: (i) Gilead has the legal right to allow Janssen to take such steps to remove such Infringement, including considering any contractual obligations Gilead may have to Third Parties; (ii) any such steps to respond to such Infringement by Janssen shall only be with respect to claims of Gilead Patents that are directed to a composition-of-matter of TDF, TAF or FTC alone or in combination with RPV or the use in the Field of TDF, TAF or FTC alone or in combination with RPV; and (iii) to the extent that Janssen undertakes steps to remove such Infringement, Janssen shall indemnify Gilead and its Indemnified Persons as set forth in Section 18.5 (and Gilead shall have no obligations of indemnity under Article 18 arising from such enforcement). In the event that Janssen exercises such right, Janssen shall not settle any infringement suit or similar action without the prior written consent of Gilead, which consent shall not be unreasonably withheld; provided , however , that Gilead may in its sole discretion withhold its consent with respect to any settlement that involves an admission of invalidity or unenforceability of any Gilead Patent. The Party not bringing the suit or action shall provide, at such Party's own expense, reasonable assistance to the Party bringing the suit or action, including providing access to relevant documents and other evidence in its possession and

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control (to the extent it is able to do so without violation of any Third Party agreement), making its employees available at reasonable business hours, and joining the action to the extent necessary to allow the Party bringing the suit or action to maintain such suit or action. In the event of a conflict between Gilead's rights under its Generic Exception and this Section 14.4.3, such rights under Gilead's Generic Exception shall control.

14.4.10 For purposes of this Section 14.4, (i) " **Infringement** " shall mean infringement or potential infringement of any Janssen Patent, Gilead Patent or Joint Patent by the actions of a Third Party in connection with an Combination Product or Other Combination Product (an " **Infringing Combination Product** ") where such infringement or potential infringement relates to the Exploitation of such Combination Product or Other Combination Product in the Territory, (ii) " **Other Infringement** " shall mean infringement or potential infringement of any Joint Patent by the actions of a Third Party in connection with any product that is not an Infringing Combination Product, (an " **Other Infringing Product** ") and (iii) "other similar action" shall include responses to paragraph (iv) certifications under the United States Drug Price Competition and Patent Term Restoration Act (also known as the Hatch-Waxman Act) (a " **Paragraph (iv) Certification** ") or a Notice of Allegation, which Paragraph (iv) Certification or Notice of Allegation relates to any Gilead Patent or Janssen Patent and results from an attempt to market (A) in the case of an Infringing Combination Product, a Generic Combination Product or (B) in the case of an Other Infringing Product, a generic version thereof. For the avoidance of doubt, the Parties acknowledge and agree that infringement of a Gilead Patent or a Janssen Patent, as the case may be, other than by an Infringing Combination Product, is outside the scope of this Agreement and shall not create any rights or impose any obligations on the Parties hereunder, including any right or obligation to take actions to respond to such infringement.

14.4.11 Joint Patents .

14.4.11.1 Right to Respond to Infringements . As between the Parties, Gilead, on behalf of and in the name of both Parties as joint owners, shall have the first right and option, at its sole expense, to respond to any Infringement with respect to any Joint Patent by appropriate steps, including filing an infringement suit or taking other similar action, provided that Gilead shall promptly notify Janssen of such Infringement, consult with Janssen, and consider Janssen's recommended actions, regarding choice of outside counsel and development of litigation strategy regarding any such suit or other action. Gilead shall incur no liability to Janssen as a consequence of such litigation or any unfavorable decision resulting therefrom, including any decision holding such Joint Patent invalid or unenforceable. In the event that Gilead fails to file an infringement suit or other similar action with respect to any Infringement of any Joint Patent within forty (40) days following notice of such Infringement, or notifies Janssen that it will not take action with respect to such Infringement, then Janssen shall have the right, but not the obligation, to take action with respect to such Infringement at Janssen's sole cost and expense. The Party not bringing the suit or action shall provide, at such Party's own expense, reasonable assistance to the Party bringing the suit or action, including providing access to relevant documents and other evidence in its possession and control, to the extent it is able to do so without violation of any Third Party agreement, making its employees available at

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reasonable business hours, and joining the action to the extent necessary to allow the Party to maintain such suit or action.

14.4.11.2 Right to Respond to Other Infringements Related to RPV Products Not Including TDF, TAF or FTC . Janssen, on behalf of and in the name of both Parties as joint owners, shall have the sole right and option, at its sole expense, to respond to any Other Infringement with respect to any Joint Patent to the extent that such Other Infringement relates to any RPV Product that does not contain TDF, TAF or FTC by appropriate steps, including filing an infringement suit or taking other similar action. Janssen shall incur no liability to Gilead as a consequence of such litigation or any unfavorable decision resulting therefrom, including any decision holding such Joint Patent invalid or unenforceable. Gilead, at Janssen's expense, shall provide reasonable assistance to Janssen, including providing access to relevant documents and other evidence in its possession and control, to the extent it is able to do so without violation of any Third Party agreement, making its employees available at reasonable business hours, and joining the action to the extent necessary to allow Janssen to maintain such suit or action.

14.4.11.3 Right to Respond to Other Infringements Related to Gilead Compound Products Not Including RPV . Gilead, on behalf of and in the name of both Parties as joint owners, shall have the sole right and option, at its sole expense, to respond to any Other Infringement with respect to any Joint Patent to the extent that such Other Infringement relates to any of the Gilead Compound Products that does not contain RPV by appropriate steps, including filing an infringement suit or taking other similar action. Gilead shall incur no liability to Janssen as a consequence of such litigation or any unfavorable decision resulting therefrom, including any decision holding such Joint Patent invalid or unenforceable. Janssen, at Gilead's expense, shall provide reasonable assistance to Gilead, including providing access to relevant documents and other evidence in its possession and control, to the extent it is able to do so without violation of any Third Party agreement, making its employees available at reasonable business hours, and joining the action to the extent necessary to allow Gilead to maintain such suit or action.

14.4.11.4 Right to Respond to Other Infringements . To the extent that the right to respond to an Other Infringement of a Joint Patent is not covered by Sections 14.4.5.1, 14.4.5.2 or 14.4.5.3, the Parties shall mutually agree on the rights, procedures and obligations of the Parties with respect to such Other Infringement.

14.4.12 Paragraph (iv) Certifications; Notices of Allegation . Each Party shall notify the other Party in writing within five (5) Business Days of receiving any Paragraph (iv) Certification or Notice of Allegation with respect to a Combination Product or any of its respective Single Agent Product(s) or Double Agent Products. In the event that a Party provides a notice pursuant to this Section 14.4.6 of a Paragraph (iv) Certification or a Notice of Allegation resulting from an attempt to market an Infringing Combination Product or, in the case of the Joint Patents, a generic version of an Other Infringing Product, then the rights and obligations in Sections 14.4.1, 14.4.3 and 14.4.5, if applicable, shall apply with respect to any responses to such Paragraph (iv) Certification or Notice of Allegation to the extent that it relates to any Gilead Patent, Janssen Patent or Joint Patent as if such Paragraph (iv) Certification or Notice of

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Allegation were an enforcement action under this Section 14.4 with respect to such Patents. For clarity, neither Party shall have any right to initiate infringement lawsuits or other similar actions to protect the other Party's Patents or Joint Patents with respect to the other Party's Single Agent Products or Double Agent Products.

14.4.13 Recoveries . As between the Parties, any amounts recovered by either Party pursuant to this Section 14.4 (other than pursuant to Section 14.4.5.2 or 14.4.5.3), whether by settlement or judgment, shall first be used to reimburse the applicable Party(ies) for their costs and expenses in making such recovery (which amounts shall be allocated first to reimburse the costs and expenses of the Party that prosecuted the infringement suit and second to reimburse the costs and expenses of the other Party). Any remaining recovery shall be allocated between the Parties based on the proportion of the Net Sales of the applicable Territory Combination Product to which each Party is entitled hereunder (at the time that the applicable infringement occurred) with regard to the applicable country; provided , however , that any portion of such remaining recovery that constitutes punitive or enhanced damages recovered by judgment (assuming that recoveries constituting punitive or enhanced damages are first applied to the foregoing costs and expenses) shall be retained by the Party that prosecuted the infringement suit. As between the Parties, any amounts recovered by the Party bringing an action under Section 14.4.5.2 or 14.4.5.3 shall be retained by such Party.

14.5 Defense of Patents .

14.5.1 In the event that a Third Party asserts as a counterclaim to an Infringement action or Other Infringement action brought pursuant to Section 14.4 that any Gilead Patent, Janssen Patent or Joint Patent is invalid or unenforceable, the Party controlling such infringement action shall have the right, but not the obligation, at its sole cost and expense, to defend against such assertion (and costs and recoveries shall be apportioned as described in Section 14.4).

14.5.2 In the event that a Third Party asserts, in a declaratory judgment action or similar action or claim filed by such Third Party (other than in an Infringement action brought pursuant to Section 14.4), that any Gilead Patent, Janssen Patent or Joint Patent relating to a Combination Product or Other Combination Product is invalid or unenforceable: (i) Gilead shall have (x) the sole right, but not the obligation, at its sole cost and expense, to defend such action or claim made against any Gilead Patent and (y) the first right, but not the obligation, at its sole cost and expense, to defend such action or claim made against any Joint Patent other than any Janssen-Controlled Combination Product Joint Patent, and (ii) Janssen shall have (x) the sole right, but not the obligation, at its sole cost and expense, to defend such action or claim made against any Janssen Patent and (y) the first right, but not the obligation, at its sole cost and expense, to defend such action or claim made against any Janssen-Controlled Combination Product Joint Patent, and in each case ((x) and (y)) Janssen shall use Commercially Reasonable Efforts to defend such Patents. In the event Janssen fails to take commercially appropriate steps to take action with respect to any declaratory judgment action or similar action or claim alleging that any Janssen-Controlled Combination Product Joint Patent Covering the Manufacture (including formulation), sale or approved use of a Combination Product or an Other Combination

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Product is invalid or unenforceable, to the extent relating to a Combination Product, within [*] following notice of such declaratory judgment action or similar action or claim, or notifies Gilead that it will not take action with respect to such declaratory judgment action or similar action or claim, then if Gilead is a party to such action or claim, Gilead shall have the right, but not the obligation, to take action with respect to such declaratory judgment action or similar action or claim at Gilead's sole cost and expense, provided that such right shall not apply to any Janssen-Controlled Combination Product Joint Patent Covering RPV or its manufacture or sale. In the event Gilead fails to take commercially appropriate steps to take action with respect to any declaratory judgment action or similar action or claim alleging that any Joint Patent other than any Janssen-Controlled Combination Product Joint Patent is invalid or unenforceable, where such claim or action relates to a Combination Product, within [*] following notice of such declaratory judgment action or similar action or claim, or notifies Janssen that it will not take action with respect to such declaratory judgment action or similar action or claim, then Janssen shall have the right, but not the obligation, to take action with respect to such declaratory judgment action or similar action or claim at Janssen's sole cost and expense.

14.6 Trademarks .

14.6.6 Gilead Licensed Trademarks . Gilead shall have the sole right, at its sole cost and expense, to search, clear, file, register, prosecute, maintain and enforce the Gilead Licensed Trademarks in the Territory. Gilead shall have the sole right and option, at its sole cost and expense, to respond to any infringement with respect to any Gilead Licensed Trademark in the Territory by appropriate steps, including by filing an infringement suit or taking other similar action. Gilead shall also have the sole right and option not to prosecute, maintain or enforce Gilead Licensed Trademarks in the Territory or take action to respond to any such infringement in the Territory.

14.6.7 Janssen Licensed Trademarks . Janssen shall have the sole right, at its sole cost and expense, to search, clear, file, register, prosecute, maintain and enforce the Janssen Licensed Trademarks in the Territory. Janssen shall have the sole right and option, at its sole cost and expense, to respond to any infringement with respect to any Janssen Licensed Trademark in the Territory by appropriate steps, including by filing an infringement suit or taking other similar action. Janssen shall also have the sole right and option not to prosecute, maintain or enforce Janssen Licensed Trademarks in the Territory or take action to respond to any such infringement in the Territory.

14.6.8 Combination Product Trademarks .

14.6.8.1 Registration . Subject to the licenses granted in Section 9.4.3, the Parties agree that, as among Gilead and Janssen and their respective Affiliates, Gilead (or its designee) shall own all right, title and interest in and to the Combination Product Trademarks. Gilead (or its designee) shall have the sole right, at its sole cost and expense, to search, clear, file, register, prosecute and maintain the Combination Product Trademarks anywhere in the world in the name of Gilead (or its designee).

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14.6.8.2 Infringement . If Janssen has a reasonable basis to believe that a Third Party is engaging in commercially significant infringement of any Combination Product Trademark in any country in the Territory, Janssen shall use commercially reasonable efforts to notify Gilead in writing and provide it with any evidence of such infringement that is reasonably available. As between the Parties, Gilead shall have the sole right and option, at its sole expense, to respond to any infringement or potential infringement with respect to any Combination Product Trademark by appropriate steps, including filing an infringement suit or taking other similar action, and with respect to any infringement or potential infringement with respect to any Combination Product Trademark in the Janssen Countries, shall notify Janssen of, and consult with Janssen from time to time regarding, any such suit or other action. Janssen shall provide commercially reasonable assistance to Gilead or its designee, at Gilead's expense for any out-of-pocket expenses, with respect to any enforcement activities with respect to the Combination Product Trademarks pursuant to this Section 14.6.3.2, including providing access to relevant documents and other evidence, making its employees available at reasonable business hours, and joining the action to the extent necessary to allow Gilead or its designee to maintain the action. Any amounts recovered pursuant to this Section 14.6.3.2, whether by settlement or judgment, shall first be used to reimburse the applicable Party(ies) for their costs and expenses in making such recovery. Any remaining recovery shall be allocated between the Parties based on the proportion of the Net Sales of the applicable Combination Product to which each Party is entitled hereunder (at the time at which the infringement occurred) with regard to the applicable country; provided , however , that any portion of such remaining recovery that constitutes punitive or enhanced damages recovered by judgment (assuming that recoveries constituting punitive or enhanced damages are first applied to the foregoing costs and expenses) shall be retained by Gilead.

15 CONFIDENTIALITY

15.1 Treatment of Confidential Information . Except as provided in this Article 15, during the Term and for five (5) years thereafter, each Party (the " **Receiving Party** ") (a) shall hold in confidence and shall not publish or otherwise disclose, directly or indirectly, to any Third Party any Confidential Information of the other Party (the " **Disclosing Party** "), (b) shall not directly or indirectly use Confidential Information of the Disclosing Party for any purpose other than performance of its obligations or the enforcement or exercise of its rights under this Agreement or any Ancillary Agreement, and (c) shall use the same level of effort to maintain the confidentiality of Confidential Information of the Disclosing Party as it uses for its own confidential or proprietary information, but in any event at least commercially reasonable efforts.

15.2 Permitted Disclosure . Each Party may disclose Confidential Information of the Disclosing Party to the extent that such disclosure is:

15.2.2 Made as required by Applicable Law; provided , however , that to the extent practicable, the Receiving Party shall first have given notice to the Disclosing Party and given the Disclosing Party a reasonable opportunity to seek any available limitations on, exemptions from or protections available with respect to such disclosure requirement and reasonably cooperate in any efforts by the Disclosing Party to obtain such protections or

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assurances that confidential treatment will be afforded to any Confidential Information so disclosed;

15.2.3 Subject to Section 4.3, made by (i) Janssen or its Affiliates or (sub)licensees or Third Party distributors to Regulatory Authorities as is necessary or reasonably expected to be necessary for Janssen (or its Affiliates, (sub)licensees or Third Party distributors), (A) to engage in the Janssen Permitted Use, or (B) with respect to such Confidential Information disclosed under the PVA (or other safety-data exchange provisions contained in any Ancillary Agreement), and solely to the extent relating to the safety of RPV, (X) to obtain and maintain Regulatory Approvals for any RPV Product or (Y) to update the Product Label for any RPV Product; or (ii) Gilead or its Affiliates or (sub) licensees or Third Party distributors to Regulatory Authorities as is necessary or reasonably expected to be necessary for Gilead (or its Affiliates, (sub)licensees or Third Party distributors) (A) to engage in the Gilead Permitted Use, or (B) with respect to such Confidential Information disclosed under the PVA (or other safety-data exchange provisions contained in any Ancillary Agreement), and solely to the extent relating to the safety of TDF, TAF or FTC, (X) to obtain and maintain Regulatory Approvals for any Gilead Compound Product or (Y) to update the Product Label for any Gilead Compound Product; provided , however , that, in each case ((i) and (ii)), the Receiving Party shall take reasonable measures to assure confidential treatment of such information;

15.2.4 Made by the Receiving Party to its employees, Affiliates, independent contractors, legal counsel, consultants, auditors and advisors who (except in the case of legal counsel) are bound by confidentiality and non-use obligations no less protective than those in this Article 15 and who reasonably require such Confidential Information for the performance of such Party's obligations or the enforcement or exercise of such Party's rights under this Agreement or any Ancillary Agreement; provided , however , that the Receiving Party shall remain responsible for any failure by any such Person to treat such Confidential Information as required by this Article 15;

15.2.5 Made by the Receiving Party or its Affiliates to its licensors (i) listed on Annex W , as applicable, pursuant to contractual obligations to such licensors existing as of the Restatement Effective Date or (ii) otherwise approved in writing by the Disclosing Party such approval not to be unreasonably withheld, conditioned or delayed or (iii) pursuant to any In-License Requirements in accordance with Section 9.5.4, in the case of any In-License Agreement entered into after the Restatement Effective Date, under confidentiality and non-use obligations no less protective than those in this Article 15; provided , however , that the Receiving Party shall remain responsible for any failure by any such Person to treat such Confidential Information as required by this Article 15;

15.2.6 Made by the Receiving Party or its Affiliates as necessary for the filing of its tax returns or pursuant to any audit thereof; provided , however , that the Receiving Party shall take reasonable measures to assure confidential treatment of such information;

15.2.7 Made by the Receiving Party or its Affiliates to Third Party Distributors and its permitted (sub)licensees and subcontractors under confidentiality and non-use obligations no less protective than those in this Article 15; provided , however , that the Receiving Party shall

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remain responsible for any failure by any such Person to treat such Confidential Information as required by this Article 15;

15.2.8 Made by the Receiving Party or its designee to prosecute or defend litigation consistent with this Agreement, or otherwise exercise rights or enforce obligations under this Agreement or any Ancillary Agreement; or

15.2.9 Made by the Receiving Party or its designee as reasonably necessary to file, prosecute or maintain Patents Covering the Collaboration Inventions, consistent with this Agreement; provided , however , that the Receiving Party shall obtain written approval from the Disclosing Party prior to filing any documents that contain the Disclosing Party's Confidential Information in any pending patent application or patent office, which approval shall not be unreasonably withheld, conditioned or delayed.

15.3 Confidential Information .

15.3.14 Defined . " **Confidential Information** " of a Party shall mean the terms of this Agreement and each Ancillary Agreement and all information provided by or on behalf of such Party (or its Affiliates) to the other Party (or its Affiliates) either in connection with the discussions and negotiations pertaining to this Agreement or any Ancillary Agreement, the MTA or the CDA or in the course of performing this Agreement or any such other agreement, including data; knowledge; practices; processes; ideas; research plans; engineering designs and drawings; research data; manufacturing processes and techniques; scientific, manufacturing, marketing and business plans; and financial and personnel matters relating to the Disclosing Party or its Affiliates, or its or their respective present or future products, sales, suppliers, customers, employees, investors or business, including any of the foregoing included in any Annexes or Exhibits to this Agreement or any Ancillary Agreement. Regardless of which Party is the disclosing Party, the Janssen-Owned Collaboration Inventions shall constitute Confidential Information of Janssen, and not Gilead (and Janssen shall be considered the Disclosing Party), the Gilead-Owned Collaboration Inventions shall constitute Confidential Information of Gilead, and not Janssen (and Gilead shall be considered the Disclosing Party), and the Joint Collaboration Inventions shall constitute the Confidential Information of both Parties (and each Party shall be considered the Disclosing Party).

15.3.15 Exclusions . Notwithstanding the foregoing, any information of the Disclosing Party shall not be deemed Confidential Information with respect to the Receiving Party if it:

15.3.15.1 was already known to the Receiving Party or any of its Affiliates, other than to the extent and for so long as the Receiving Party (or its Affiliate) is under an obligation of confidentiality or non-use with respect to such information, at the time of disclosure to such Receiving Party or its Affiliate;

15.3.15.2 was generally available or known, or was otherwise part of the public domain, at the time of disclosure to such Receiving Party or its Affiliate;

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15.3.15.3 became generally available or known, or otherwise became part of the public domain, through no fault of the Receiving Party or any of its Affiliates in violation of this Article 15 or the CDA, after its disclosure to such Receiving Party or its Affiliate;

15.3.15.4 was received by such Receiving Party or any of its Affiliates from a Third Party that, to the knowledge of the Receiving Party, had no obligation to the Disclosing Party (or its Affiliate) not to make such disclosure; or

15.3.15.5 was independently discovered or developed by such Receiving Party or any of its Affiliates, as evidenced by their written records, without the use of Confidential Information of the Disclosing Party.

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of a Party or its Affiliate merely because the Confidential Information is embraced by more general information in the public domain or in the possession of such Party or its Affiliate. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of a Party or its Affiliate merely because individual elements of such Confidential Information are in the public domain or in the possession of such Party or its Affiliate unless the combination and its principles are in the public domain or in the possession of such Party or its Affiliate.

15.4 Notification . Each Party shall notify the other Party immediately, and cooperate with the other Party as the other Party may reasonably request, upon the first Party's discovery of any loss or compromise of the other Party's Confidential Information.

15.5 Data Privacy . Without limitation of its other obligations under this Article 15, each Party shall, and shall cause each of its Affiliates to, comply with Applicable Law, including the applicable national laws implementing the European Union Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data of 24 October 1995, with respect to the collection, use, transfer, storage, deletion, processing (both by computer and manually), combination or other use of subject or other personal data as contemplated by applicable data protection or privacy laws of all data relating to any Person about whom or which data may be collected, retained or exchanged pursuant to this Agreement or any Ancillary Agreement. Without limitation of the foregoing, each Party shall, and shall cause each of its Affiliates to, ensure that it takes any technical and organizational measures required by Applicable Law to protect any such data against accidental or unlawful destruction, loss, damage, alteration, disclosure, access or data processing and against all other unauthorized disclosure, access or forms of data processing.

15.6 Remedies . Each Party agrees that the unauthorized use or disclosure of any material Confidential Information by the Receiving Party in violation of this Agreement may cause severe and irreparable damage to the Disclosing Party, for which money damages may represent an insufficient remedy. In the event of any violation of this Article 15, notwithstanding anything in this Agreement to the contrary, the Disclosing Party shall be authorized and entitled to seek from any court of competent jurisdiction injunctive relief, whether preliminary or

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permanent, with respect to such violation as well as any other relief permitted by Applicable Law.

16 PRESS RELEASES, PUBLICATIONS AND PUBLIC RELATIONS MATTERS

16.1 Initial Statements . Each Party shall have the right to release publicly, upon or after the Restatement Effective Date, that certain press release of such Party attached hereto as Annex S .

16.2 Other Public Disclosures . As between the Parties, subject to Section 3.6 and this Section 16.2, Gilead shall have the primary responsibility for public communications regarding the Exploitation of the Territory Combination Products in the Territory. If either Party or its Affiliates desires to make a public announcement (such as a press release) that relates to the Exploitation of a Territory Combination Product, other than (i) with respect to Results, which are governed by Section 3.6, or (ii) subject to the following sentence, general business updates (even if they include information relating to a Territory Combination Product, so long as they are of the type of updates that are also generally made for such Party's other similar pharmaceutical products generally), the announcing Party (or Affiliate) shall give reasonable advance notice of the proposed text of such announcement (translated into English, if not in English) to the other Party for its prior review. Other than with respect to Results, which are governed by Section 3.6, (a) in the case of Janssen as the announcing Party, any proposed public announcement that refers to the safety, efficacy or other characteristics of a Territory Combination Product or any Gilead Compound Product, shall be subject to prior written approval by Gilead, such approval not to be unreasonably withheld, conditioned or delayed and (b) in the case of Gilead as the announcing Party, any proposed public announcement that refers to the safety, efficacy or other characteristics of a Territory Combination Product or any RPV Product, shall be subject to prior written approval by Janssen, such approval not to be unreasonably withheld, conditioned or delayed. Notwithstanding the foregoing, nothing shall preclude either Party from making any public announcement regarding its generics program that is not specific to the other Party (or its Affiliates) and no such announcement shall be subject to prior review by the other Party hereunder. Further, if any proposed public announcement by either Party that relates to the Exploitation of a Territory Combination Product uses any name or any Trademark of the other Party or its Affiliates (other than a Gilead Licensed Trademark or a Janssen Licensed Trademark used in connection with Territory Combination Product), such public announcement shall be subject to prior approval of such other Party, except to the extent such announcement is required by Applicable Law. If the non-announcing Party with respect to any public announcement provided by the announcing Party for review under this Section 16.2 desires to provide comments or, if applicable, indicate whether the applicable public announcement is approved, it shall do so as soon as reasonably practicable but in any event within three (3) Business Days after receiving the proposed announcement for review. Subject to Section 16.3, neither Party shall be required to have the other Party review or, if applicable, approve the public disclosure of any information that has already been publicly disclosed by either Party in accordance with Section 3.6, Section 15.2 or this Section 16.2. In the event of a legally required press release or other public announcement or disclosure, the Party (or its Affiliate) desiring to make such announcement shall provide the other Party with a copy of the proposed text with as much notice

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as practicable (which shall, to the extent practicable under the circumstances, be no less than three (3) Business Days prior to the proposed disclosure), the other Party shall respond with its comments (if any) as promptly as practicable (but not less than one (1) Business Day prior to the proposed disclosure), and the proposing Party shall take into due consideration any and all reasonable comments that the other Party may provide in a timely manner; provided , however , that, notwithstanding the foregoing, if a Party determines that it or any of its Affiliates must make a legally required disclosure under Applicable Law, then it or its Affiliate, as applicable, shall have the right to make such disclosure at such time as is necessary to comply with Applicable Law, and shall provide the other Party as much notice and opportunity for review and comment as is practicable in the circumstances. Without limitation of any of the foregoing, each Party shall comply, and ensure that its Affiliates and Sublicensees comply with, any press release or other non-disclosure provisions as required by any In-License Agreement, as specified in the In-License Requirements.

16.3 Use of Names . Except as otherwise permitted expressly herein or in any Ancillary Agreement or other written agreement between the Parties (or their respective Affiliates), neither Party shall mention or otherwise use any Trademark, including any name, insignia, symbol, trade name or logotype of the other Party or its Affiliates or of any party to an In-License Agreement of the other Party or its Affiliates (or any abbreviation or adaptation thereof) in any publication, press release, promotional material or other form of publicity without the prior written approval of such other Party in each instance. The restrictions imposed by this Section 16.3 shall not prohibit a Party from making any (a) use of the brand name or brand mark of the other Party's Single Agent Product(s) or Double Agent Product or (b) disclosure identifying the other Party (or such other Party's predecessor) or such other Party's Single Agent Product(s) or Double Agent Product(s), in each case ((a) and (b)), that is required by Applicable Law, nor shall it prohibit Janssen from using the brand name or brand mark for a Territory Combination Product or Combination Product Trademarks in informational materials, provided that any substantive inquiries relating to the Territory Combination Products that arise from such use are referred to the appropriate Party in accordance with Section 5.2 or Section 6.3.2, as applicable, and, further provided that such use shall not be accompanied by any claims regarding the safety or efficacy of such Territory Combination Product, or otherwise describe the characteristics of such Territory Combination Product, other than the identification of the RPV therein, in each case, without such approval.

17 REPRESENTATIONS, WARRANTIES AND COVENANTS; DISCLAIMER

17.1 Mutual Representations, Warranties and Covenants . Except as set forth in the applicable Disclosure Statement with respect to representations, warranties and covenants made as of the Restatement Effective Date, each Party hereby represents and warrants and covenants to the other Party, as of the Original Effective Date and the Restatement Effective Date, as follows:

17.1.16 Good Standing . In the case of Gilead Parent, it (a) is a corporation duly organized and in good standing under the laws of Delaware and (b) has full power and authority and the legal right to own and operate its property and assets and to carry on its business as it is

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now being conducted and as it is contemplated to be conducted by this Agreement. In the case of Gilead Sub, it (i) is a company duly organized and in good standing under the laws of Ireland, and (ii) has full power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as it is contemplated to be conducted by this Agreement. In the case of Janssen, it (x) is a company duly organized and in good standing under the laws of Ireland, and (y) has full power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as it is contemplated to be conducted by this Agreement.

17.1.17 Power and Authority . Such Party (or, in the case of Gilead, each of Gilead Parent and Gilead Sub) (i) has the power and authority and the legal right to enter into this Agreement and any Ancillary Agreements to which it is a party and to perform its obligations hereunder and thereunder, and (ii) has taken (or will take, in the case of the Ancillary Agreements not yet executed) all necessary action on its part required to authorize the execution and delivery of this Agreement and any Ancillary Agreements to which it is a party. This Agreement has been (and all Ancillary Agreements to which it is a party, when executed and delivered, will have been) duly executed and delivered on behalf of such Party (or, in the case of Gilead, each of Gilead Parent and Gilead Sub, as applicable) and constitutes (and all such Ancillary Agreements, when duly executed and delivered by all parties thereto, will constitute) a legal, valid and binding obligation of such Party and is (and in the case of all such Ancillary Agreements, when duly executed and delivered by all parties thereto, will be) enforceable against it in accordance with its terms subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity, whether enforceability is considered in a proceeding at law or equity.

17.1.18 Litigation . Such Party is not aware of any pending or threatened litigation (and has not received any communication) that alleges that such Party's activities related to this Agreement have violated, or that by conducting the activities as contemplated in this Agreement such Party would violate, any of the intellectual property rights of any other Person (after giving effect to the license grants in this Agreement). As of the Original Effective Date, to such Party's knowledge as of such date, and the Restatement Effective Date, to such Party's knowledge as of such date, there is no products liability litigation, with respect to such Party's Single Agent Product(s) or Double Agent Products, as applicable, that is currently pending or that was pending at any time on or after January 1, 2001.

17.1.19 Consents . All necessary consents, approvals and authorizations of all regulatory and governmental authorities and other Persons (i) required to be obtained by such Party in connection with the execution and delivery of this Agreement and any Ancillary Agreements have been obtained (or will have been obtained prior to such execution and delivery) and (ii) required to be obtained by such Party in connection with the performance of its obligations under this Agreement and any Ancillary Agreements have been obtained or will be obtained prior to such performance.

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17.1.20 No Conflicts . With respect to such Party, the execution and delivery of this Agreement and the Ancillary Agreements, and the performance of such Party's obligations hereunder and thereunder (i) do not conflict with or violate in any material way any requirement of Applicable Law, (ii) do not conflict with or violate any provision of the articles of incorporation, bylaws, limited partnership agreement or any similar instrument of such Party or any of its Affiliates, and (iii) do not conflict with, violate, or breach or constitute a default under, any contractual obligation of such Party or any of its Affiliates, including in the case of Gilead, any obligation under any agreement relating to Atripla to which Gilead Parent or Gilead Sub or any of their Affiliates is a party, or any court or administrative order by which such Party (or, in the case of Gilead, either Gilead Parent or Gilead Sub) or any of its Affiliates is bound.

17.1.21 No Adverse Proceedings . There is not pending or, to the knowledge of such Party, threatened, against such Party, any claim, suit, action or governmental proceeding, that would, if adversely determined, materially impair the ability of such Party to perform its obligations under this Agreement or any Ancillary Agreement.

17.1.22 No Debarment . Neither such Party nor any of its Affiliates has been debarred or is subject to debarment, and neither such Party nor any of its Affiliates shall use in any capacity, in connection with the activities to be performed under this Agreement, any Person who has been debarred pursuant to Section 306 of the Act, or who is the subject of a conviction described in such section. Such Party agrees to inform the other Party in writing immediately if it or any Person who is performing activities on its behalf under this Agreement is debarred or is the subject of a conviction described in Section 306, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the knowledge of such first Party, is threatened, relating to the debarment or any such conviction of such Party or any Person performing activities on its behalf under this Agreement.

17.1.23 No Conflicting Grants; Absence of Encumbrance . Such Party has the right to grant the licenses granted by such Party to the other Party hereunder, and has not, prior to the Restatement Effective Date, made a grant to any Third Party of any right or license that would conflict with any grant of rights or licenses granted by such Party to the other Party hereunder. The Patents licensed by such Party hereunder are not subject to any encumbrance or lien by any Third Party (except for any such encumbrances or liens as would not, in the aggregate, have a material adverse effect on the license rights granted to the other Party under this Agreement). Such Party covenants and agrees that it shall not, from and after the Restatement Effective Date and throughout the Term, grant to any Third Party any right or license in respect of the Patents licensed hereunder, including by amending any existing agreement, that would conflict with any grant to the other Party hereunder.

17.1.24 Compliance with Applicable Law . Notwithstanding anything to the contrary in this Agreement, such Party shall, and shall cause its Affiliates, Sublicensees and Third Party Distributors to, comply with all Applicable Law of the country or other jurisdiction, or any court or agency thereof, applicable to the performance of its activities hereunder or any obligation or transaction hereunder, including those pertaining to the production and handling of drug products (which shall also be subject in the case of the Supplied RPV, to the RPV Supply

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Agreement), such as those set forth by the Regulatory Authorities as applicable, and the applicable terms of this Agreement in the performance of its obligations hereunder.

17.1.25 Affiliates . To the extent the intellectual property or Regulatory Documentation licensed under Article 9 by a Party is Controlled by such Party's Affiliates, such Party has the right to use, and has the right to grant sublicenses to the other Party to use, such intellectual property or Regulatory Documentation.

17.1.26 Ethical Business Practices . Neither such Party nor its Affiliates will make any payment, either directly or indirectly, of money or other assets, including the compensation such Party derives from this Agreement (collectively a " **Payment** "), to government or political party officials, officials of International Public Organizations, candidates for public office, or representatives of other businesses or persons acting on behalf of any of the foregoing (collectively " **Officials** ") or other individuals where such Payment would constitute violation of any law, including the Foreign Corrupt Practices Act of 1977, 15 U.S.C. §§ 78dd-1, et seq, and the United Kingdom Bribery Act. In addition regardless of legality, neither such Party nor its Affiliates will make any Payment either directly or indirectly to Officials or other individuals if such Payment is for the purpose of improperly influencing decisions or actions to secure a business advantage, including with respect to the subject matter of this Agreement. Each Party shall have necessary procedures in place to prevent bribery and corrupt conduct by itself and each of its Affiliates and subcontractors. All activities will be conducted in compliance with the U.S. False Claims Act and the U.S. Anti-Kickback Statute. Each Party and each of its Affiliates and subcontractors shall conduct its activities hereunder in accordance with the provisions of Annex T attached hereto.

17.1.27 Cooperation with In-License Agreement Compliance . Each Party shall, at the reasonable request of the other Party, provide reasonable assistance and cooperation to the requesting Party to enable such requesting Party (or any of its Affiliates) to comply with its obligations under any In-License Agreement as specified in the In-License Requirements.

17.2 Additional Representations, Warranties and Covenants of Janssen . Except as set forth in the applicable Disclosure Statement with respect to representations, warranties and covenants made as of the Restatement Effective Date, Janssen hereby represents, warrants and covenants to Gilead as follows:

17.2.3 Without the prior written consent of Gilead: (i) Janssen shall not, and shall cause its Affiliates not to, make, have made, use, sell, have sold, offer for sale, or import, and (ii) Janssen shall not, and shall cause its Affiliates not to, grant any rights to any Third Party to make, have made, use, sell, have sold, offer for sale, or import, in each case ((i) and (ii)) in the Field in the Territory (A) a Combination Product other than pursuant to this Agreement or (B) any Other Combination Product in each case ((A) and (B)) for a period commencing as of the Restatement Effective Date and ending on [*] provided , however that in each case ((A) and (B)):

17.2.3.10 Janssen and its Affiliates shall not be precluded by the foregoing or otherwise under this Agreement from granting licenses or other rights, but, except in the case of the MPP, excluding the right to sublicense, under Janssen's and its Affiliates'

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intellectual property (but, for clarity, not including any of the Gilead Technology or Gilead Regulatory Documentation or Combination Product Regulatory Documentation and in the case of the Joint Technology, solely as permitted under Section 14.1.4), to allow as to any prohibition under this Agreement (a) any Other Generic Licensee to engage in any or all of the following: [*] or (b) any Region C Generic Licensee to engage in the Region C Generic Rights subject to the Region C Generic Conditions; and

17.2.3.11 nothing in this Section 17.2.1 shall preclude Janssen or its Affiliates from conducting any clinical trial that it is permitted to conduct under Article 3 or from granting rights in accordance with Article 3 to one or more Third Party(ies) to conduct any clinical trials as permitted under Article 3; and

17.2.3.12 nothing in this Section 17.2.1 shall require Janssen or its Affiliates to amend any license agreement executed with a Generic Licensee prior to the Restatement Effective Date, provided that nothing in this Section 17.2.1.3 shall excuse Janssen from a failure to comply with one or more of its obligations in the Original Amendment with respect to its Generic Licensees prior to the Restatement Effective Date.

17.2.4 There are no judgments or settlements against, or amounts with respect thereto owed by, Janssen relating to the Janssen Patents. To the knowledge of Janssen, except as was otherwise disclosed in writing by Janssen to Gilead on or before the Original Effective Date, Janssen has not received written notice of any Proceeding in which it is alleged that, with respect to the Territory (i) any of the Janssen Patents that are composition of matter Patents are invalid or unenforceable or (ii) the Exploitation of RPV (in API or other form), whether alone or in combination with either or both of TDF and FTC, infringes any Third Party Patent (other than any such infringement that would arise from the Exploitation of either or both of TDF and FTC in the absence of the RPV (in API or other form)). The representations in this Section 17.2.2 are made as of the Original Effective Date.

17.2.5 There are no judgments or settlements against, or amounts with respect thereto owed by, Janssen relating to the Janssen Patents that are composition of matter Patents. To the knowledge of Janssen, Janssen has not received written notice of any Proceeding in which it is alleged that, with respect to the Territory (i) any of the composition of matter claims in any Janssen Patents are invalid or unenforceable or (ii) the Exploitation in the Field of RPV (in API or other form), whether alone or in combination with TDF, TAF or FTC, or both TDF and FTC or TAF and FTC, infringes any Third Party Patent (other than any such infringement that would arise from the Exploitation of TDF, TAF or FTC, or both TDF and FTC or TAF and FTC, in the absence of the RPV (in API or other form)). Janssen represents and warrants that it shall remain in good standing with regard to any In-License Agreements of Janssen throughout the Term. The representations in this Section 17.2.3 are made as of the Restatement Effective Date.

17.2.6 To the knowledge of Janssen as of the Original Effective Date, the information contained in its INDs for Edurant represents, in all material respects, a complete and accurate reflection of the safety and efficacy profile of Edurant as of such date. As of the date of submission of the NDA for Edurant to the FDA, to the knowledge of Janssen as of such date, the information contained in such NDA as of such date represented, in all material respects, a

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complete and accurate reflection of the safety and efficacy profile of Edurant as of such date. It is understood and agreed that Janssen makes the representation, warranty and covenant to Gilead set forth in this Section 17.2.4 solely for purposes of the Parties' collaboration pursuant to this Agreement, and for no other purpose. The representation in the first sentence of this Section 17.2.4 is made as of the Original Effective Date.

17.2.7 To the knowledge of Janssen, the information contained in the Product Label for Edurant and in the NDA for Edurant represents, in all material respects, a complete and accurate reflection of the safety and efficacy profile of Edurant. To the extent that Edurant remains on the market in a country, Janssen will use reasonable efforts to maintain in such country the Product Label for Edurant and the Janssen Regulatory Documentation through updates as needed to ensure that such information continues to represent a complete and accurate reflection in all material respects of the safety and efficacy profile of Edurant. It is understood and agreed that Janssen makes the representation, warranty and covenant to Gilead set forth in this Section 17.2.5 solely for purposes of the Parties' collaboration pursuant to this Agreement, and for no other purpose. The representation in this Section 17.2.5 is made as of the Restatement Effective Date.

17.2.8 During the Term, except as otherwise expressly provided in the Janssen Distributor Agreement or this Agreement, Janssen and its Affiliates shall only purchase or otherwise acquire, for sale or distribution in the Territory, Combination Products supplied by Gilead and its Affiliates.

17.3 Additional Representations, Warranties and Covenants of Gilead . Except as set forth in the applicable Disclosure Statement with respect to representations, warranties and covenants made as of the Restatement Effective Date, Gilead hereby represents, warrants and covenants to Janssen as follows:

17.3.9 Without the prior written consent of Janssen, [*], (i) Gilead shall not, and shall cause its Affiliates not to, make, have made, use, sell, have sold, offer for sale, or import, and (ii) Gilead shall not, and shall cause its Affiliates not to, grant any rights to any Third Party to make, have made, use, sell, have sold, offer for sale, or import, in each case ((i) and (ii)) in the Field in the Territory (A) a Combination Product other than pursuant to this Agreement or (B) any Other Combination Product; provided , however , that in each case ((A) and (B)):

17.3.9.5 Gilead and its Affiliates shall not be precluded by the foregoing or otherwise under this Agreement from granting licenses or other rights, but, except in the case of the MPP, excluding the right to sublicense, under Gilead's and its Affiliates' intellectual property (but, for clarity, not including any of the Janssen Technology or Janssen Regulatory Documentation or Combination Product Regulatory Documentation and in the case of the Joint Technology, solely as permitted under Section 14.1.4), to allow as to any prohibition under this Agreement (a) any Other Generic Licensee to engage in any or all of the following: [*] or (b) any Region C Generic Licensee to engage in the Region C Generic Rights subject to the Region C Generic Conditions; and

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17.3.9.6 nothing in this Section 17.3.1 shall preclude Gilead or its Affiliates from conducting any clinical trial that it is permitted to conduct in accordance with Article 3 or from granting rights in accordance with Article 3 to one or more Third Party(ies) to conduct any clinical trials as permitted under Article 3; and

17.3.9.7 nothing in this Section 17.3.1 shall require Gilead or its Affiliates to amend any license agreement executed with a Generic Licensee prior to the Restatement Effective Date; provided that nothing in this Section 17.3.1.3 shall excuse Gilead from a failure to comply with one or more of its obligations in the Original Amendment with respect to its Generic Licensees prior to the Restatement Effective Date.

The rights set forth in Section 17.3.1.1 (in the case of Gilead) and Section 17.2.1.1 (in the case of Janssen) shall comprise the " **Generic Exception** " of such Party.

17.3.10 There are no judgments or settlements against, or amounts with respect thereto owed by, Gilead relating to the Gilead Patents. To the knowledge of Gilead, except as was otherwise disclosed in writing by Gilead to Janssen on or before the Original Effective Date, it has not received written notice of any Proceeding in which it is alleged that, with respect to the Territory (i) any of the Gilead Patents that are composition of matter Patents are invalid or unenforceable or (ii) the Exploitation in the Field of either TDF or FTC, whether alone or together and whether or not in combination with RPV, infringes any Third Party Patent (other than any such infringement that would arise from the Exploitation of RPV in the absence of TDF and FTC). The representations in this Section 17.3.2 are made as of the Original Effective Date.

17.3.11 There are no judgments or settlements against, or amounts with respect thereto owed by, Gilead relating to the Gilead Patents that are composition of matter Patents. Gilead represents and warrants that (x) it is in good standing with regard to any In-License Agreements of Gilead and [*], and (y) shall remain in good standing with regard to any In-License Agreements of Gilead and [*] throughout the Term. To the knowledge of Gilead, it has not received written notice of any Proceeding in which it is alleged that, with respect to the Territory (i) any of the composition of matter claims in any Gilead Patents are invalid or unenforceable or (ii) the Exploitation in the Field of TDF, TAF or FTC, or both TDF and FTC or TAF and FTC (all of the foregoing in this (ii) in API or other form), whether or not in combination with RPV, infringes any Third Party Patent (other than any such infringement that would arise from the Exploitation of RPV in the absence of TDF, TAF and FTC (in API or other form)).

17.3.12 To the knowledge of Gilead, the information contained in the Product Labels for Emtriva, Viread and Truvada and in the NDAs for Emtriva, Viread and Truvada represents, in all material respects, a complete and accurate reflection of the safety and efficacy profile of Emtriva, Viread and Truvada. To the extent that Emtriva, Viread and Truvada remain on the market in a country, Gilead will use reasonable efforts to maintain in such country the Product Labels for Emtriva, Viread and Truvada and the Gilead Regulatory Documentation with respect thereto through updates as needed to ensure that such information continues to represent a complete and accurate reflection in all material respects of the safety and efficacy profile of Emtriva, Viread and Truvada. It is understood and agreed that Gilead makes the representation,

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warranty and covenant to Janssen set forth in this Section 17.3.4 solely for purposes of the Parties' collaboration pursuant to this Agreement, and for no other purpose. The representation in this Section 17.3.4 is made as of the Original Effective Date and the Restatement Effective Date.

17.3.13 To the knowledge of Gilead, the information contained in its IND for the F/TAF Product represents, in all material respects, a complete and accurate reflection of the safety and efficacy profile of the F/TAF Product. As of the date of submission of an NDA for the F/TAF Product to the FDA, to the knowledge of Gilead as of such date, the information contained in such NDA as of such date will represent, in all material respects, a complete and accurate reflection of the safety and efficacy profile of the F/TAF Product as of such date. Gilead will seek to obtain a Product Label for the F/TAF Product that represents, in all material respects, a complete and accurate reflection of the safety and efficacy profile of the F/TAF Product as of the date that such Product Label is obtained, to the knowledge of Gilead as of such date based on the information in the possession of Gilead as of such date. Thereafter, to the extent that the F/TAF Product remains on the market in a country, Gilead will use reasonable efforts to maintain in such country the Product Label for the F/TAF Product and the Gilead Regulatory Documentation through updates as needed to ensure that such information continues to represent a complete and accurate reflection in all material respects of the safety and efficacy profile of the F/TAF Product. It is understood and agreed that Gilead makes the representation, warranty and covenant to Janssen set forth in this Section 17.3.5 solely for purposes of the Parties' collaboration pursuant to this Agreement, and for no other purpose.

17.3.14 During the Term, except as otherwise expressly provided in the RPV Supply Agreement and this Agreement, Gilead and its Affiliates shall only purchase or otherwise acquire (and shall only use any contract manufacturers that have purchased or otherwise acquired), for use in the manufacture of the Territory Combination Products for sale or distribution in the Territory, RPV supplied by Janssen and its Affiliates, except that Gilead shall not be precluded by the foregoing from contracting with a potential RPV supplier and qualifying such supplier to supply RPV to Gilead for use in the Combination Products following expiration or termination of this Agreement, but in no event shall this Section 17.3.6 be construed to grant any express or implied license or any other rights to Manufacture RPV from Janssen to Gilead.

17.4 Disclaimer . EXCEPT AS SET FORTH IN SECTIONS 17.1 AND 17.2 AND 17.3 AND AS OTHERWISE EXPRESSLY STATED IN THIS AGREEMENT, EACH PARTY HEREBY DISCLAIMS ANY AND ALL REPRESENTATIONS AND WARRANTIES, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, IN CONNECTION WITH THIS AGREEMENT, INCLUDING WITH RESPECT TO THE SINGLE AGENT PRODUCT(S), THE DOUBLE AGENT PRODUCTS, THE COMBINATION PRODUCTS OR ANY JANSSEN TECHNOLOGY, GILEAD TECHNOLOGY, JOINT TECHNOLOGY OR REGULATORY DOCUMENTATION LICENSED UNDER THIS AGREEMENT, AND INCLUDING ANY WARRANTY OF QUALITY, PERFORMANCE, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE OR NON-INFRINGEMENT OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS. FOR THE AVOIDANCE OF DOUBT, NOTHING CONTAINED IN THIS SECTION 17.4 SHALL OPERATE TO LIMIT OR

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INVALIDATE ANY EXPRESS WARRANTY OR REPRESENTATION CONTAINED IN ANY ANCILLARY AGREEMENT OR THE ORIGINAL AGREEMENT.

18 INDEMNIFICATION AND INSURANCE

18.1 General Indemnification .

18.1.9 By Each Party . Each Party shall indemnify the other Party and such other Party's Indemnified Persons from and against (i) any Proceeding in which such other Party or any of its Indemnified Persons is involved or threatened to be involved to the extent that such Proceeding arises out of or relates to (A) the negligence or willful misconduct of the Indemnifying Party or any of such Indemnifying Party's Affiliates, (sub)licensees or subcontractors, in each case in connection with the exercise of such Indemnifying Party's or any of such Indemnifying Party's Affiliates' rights, or performance of such Indemnifying Party's or any of its Affiliates' obligations, under this Agreement or any Ancillary Agreement, (B) the Indemnifying Party's or any of such Indemnifying Party's Affiliates', (sub)licensees' or subcontractors' failure to comply with or perform one or more of such Indemnifying Party's or such Affiliate's, as applicable, covenants in this Agreement or any Ancillary Agreement, or the breach or inaccuracy of one or more of such Indemnifying Party's or such Affiliate's, as applicable, representations and warranties in this Agreement or any Ancillary Agreement, (C) Exploitation (by the Indemnifying Party or any of its Affiliates, (sub)licensees or subcontractors) of the Joint Technology in connection with such Indemnifying Party's or any of its Affiliates' (x) Single Agent Product(s), (y) Double Agent Products (if any) or (z) other products (other than the Territory Combination Products), (D) the violation of Applicable Law by the Indemnifying Party or any of such Indemnifying Party's Affiliates, (sub)licensees or subcontractors in connection with the exercise of such Indemnifying Party's or any of such Indemnifying Party's Affiliates' rights, or performance of such Indemnifying Party's or any of its Affiliates' obligations, under this Agreement or any Ancillary Agreement, (E) a breach by the Indemnifying Party or any of such Indemnifying Party's Affiliates of any contracts (including In-License Agreements, except to the extent that such breach is due to a breach of such In-License Agreement by such other Party) that such Indemnifying Party or Affiliate has entered into with a Third Party to the extent relating to (x) the Exploitation of a Territory Combination Product or (y) the exercise of such Indemnifying Party's or any of such Indemnifying Party's Affiliates' rights, or performance of such Indemnifying Party's or any of its Affiliates' obligations, in each case under this Agreement or any Ancillary Agreement, or (F) the marketing, sales or promotional activity, relating to a Combination Product or relating to any of such Indemnifying Party's Single Agent Products (or Double Agent Products, if such Indemnifying Party is Gilead) in combination with any of the other Party's Single Agent Products (or Double Agent Products, if such other Party is Gilead), of the employees and agents of the Indemnifying Party or any of its Affiliates, except to the extent resulting from the reasonable reliance on promotional materials or safety information or Regulatory Documentation provided by the Indemnified Party or any of its Indemnified Persons, provided that if any Proceedings or Losses would be covered both by this clause (F) and by Section 18.2.1 or Section 18.2.2, as the case may be, then Section 18.2.1 or Section 18.2.2, as applicable, shall control and this clause (F) shall not apply, and (ii) all Losses

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incurred by the Indemnified Party or any of its Indemnified Persons to the extent arising from any Proceeding covered by the foregoing clause (i).

18.1.10 Limitations . Notwithstanding anything in this Article 18, in no event shall either Party's obligations of indemnity or reimbursement under this Article 18 apply to any Proceeding or Losses to the extent that such Proceeding or Losses were caused by the negligence or willful misconduct of, breach of this Agreement or any Ancillary Agreement by, or violation of Applicable Law by, the other Party or any of its Indemnified Parties. Notwithstanding anything to the contrary hereunder or in any Ancillary Agreement, neither Gilead nor Janssen shall be liable for, nor be obligated to indemnify, hold harmless or defend the other Party or any of its Indemnified Persons with respect to any act or omission of any Generic Licensee and any Losses or Proceedings arising therefrom, provided that such Party has complied with its obligations hereunder with respect to such Generic Licensee.

18.2 Indemnification for Certain Product Liability-Related Matters .

18.2.15 By Gilead . Gilead shall indemnify Janssen and its Indemnified Persons from and against (i) all Proceedings arising anywhere in the world in which Janssen or any of its Indemnified Persons is involved or threatened to be involved to the extent such Proceedings arise from personal injury or death caused by a Territory Combination Product due to defects or the inherent characteristics thereof, where the preponderance of the evidence indicates that such defects or characteristics are the direct result of the incorporation (where, for purposes of this Section 18.2 and Section 18.3, "incorporation" shall be construed to mean the presence of an API in a Territory Combination Product, not the process whereby such API is included in a Territory Combination Product or the formulation of a Territory Combination Product and "incorporated" shall be construed in a corresponding manner) in such Territory Combination Product of TDF, TAF or FTC, or both TDF and FTC or TAF and FTC, in each case without reference to the incorporation in such Territory Combination Product of the Supplied RPV (other than any Selected Product Liability Proceedings, which, for purposes of clarity, are provided for in Section 18.3), irrespective of whether such defects or characteristics (or any associated defects or characteristics of TDF, TAF or FTC) are known as of the Original Effective Date [*] (such defects or characteristics, " **Gilead Component Characteristics** "), and (ii) all Losses (other than Selected Product Liability Losses) incurred by Janssen or any of its Indemnified Persons arising from any Proceeding covered by the foregoing clause (i) to the extent arising from Gilead Component Characteristics.

18.2.16 By Janssen . Janssen shall indemnify Gilead and its Indemnified Persons from and against (i) all Proceedings arising anywhere in the world in which Gilead or any of its Indemnified Persons is involved or threatened to be involved to the extent such Proceedings arise from personal injury or death caused by a Territory Combination Product due to (A) defects or the inherent characteristics thereof, where the preponderance of the evidence indicates that such defects or characteristics are the direct result of the incorporation in such Territory Combination Product of the Supplied RPV without reference to the incorporation in such Territory Combination Product of TDF, TAF or FTC or any combination of the foregoing (other than any Selected Product Liability Proceedings, which, for purposes of clarity, are provided for in

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Section 18.3), irrespective of whether such defects or characteristics (or any associated defects or characteristics of the Supplied RPV) are known as of the Original Effective Date [*] (such defects or characteristics, " **RPV Characteristics** ") or (B) the Label Characteristics (as defined below), and (ii) all Losses (other than Selected Product Liability Losses) incurred by Gilead or any of its Indemnified Persons arising from any Proceeding covered by the foregoing clause (i) to the extent arising from RPV Characteristics or the Label Characteristics. " **Label Characteristics** " shall mean the failure of the Product Label for Janssen's Single Agent Product to represent, in all material respects and to Janssen's knowledge as of the date such Product Label is obtained, a complete and accurate reflection of the safety and efficacy profile of Janssen's Single Agent Product as of such date, which failure leads to the failure of the Product Label for a Territory Combination Product to represent, in all material respects and to Janssen's knowledge as of such date, a complete and accurate reflection of the safety and efficacy profile of the RPV portion of such Territory Combination Product as of such date.

18.3 Selected Product Liability Losses . Any Selected Product Liability Losses shall be borne by Gilead and Janssen in accordance with the applicable Average Respective Percentages with respect to the Territory. " **Selected Product Liability Losses** " shall mean any Losses arising out of any Selected Product Liability Proceeding. " **Selected Product Liability Proceeding** " shall mean any Proceeding arising anywhere in the world in which any Party or any of its Indemnified Persons is involved or threatened to be involved to the extent such Proceedings arise from personal injury or death caused by a Territory Combination Product due to defects or the inherent characteristics of such Territory Combination Product, (a) where the preponderance of the evidence indicates that such defects or characteristics are the direct result of both (i) the Supplied RPV and (ii) TDF, TAF or FTC or any combination of the foregoing being incorporated into such Territory Combination Product, (b) where it ultimately cannot be or is not determined whether such defects or characteristics are the direct result of the Supplied RPV, on the one hand, or the TDF, TAF or FTC or any combination of the foregoing, on the other hand, being incorporated into such Territory Combination Product, or (c) where such defects or characteristics are the direct result of an aspect of such Territory Combination Product other than any of its APIs, except, in each case ((a), (b) and (c)), to the extent such Proceeding arises from personal injury or death caused by a Territory Combination Product due to the Label Characteristics, which Proceeding is covered in Section 18.2.2.

18.4 Third Party Infringement Losses .

18.4.1 By Gilead . Gilead shall indemnify Janssen and its Indemnified Persons from and against (i) any Proceeding arising anywhere in the world in which Janssen or any of its Indemnified Persons is involved or threatened to be involved to the extent that (x) (A) such Proceeding arises out of an allegation that any Exploitation of any Territory Combination Product in a country that, as of the time of such Exploitation, is a Gilead Country infringes or misappropriates, or will infringe or misappropriate, any patent or other intellectual property, including trade secrets, of a Third Party, and (B) such infringement or misappropriation does not directly result from a RPV Infringement, or (y) (A) such Proceeding arises out of an allegation that any Exploitation of any Territory Combination Product in a country that, as of the time of such Exploitation, is a Janssen Country infringes or misappropriates, or will infringe or

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misappropriate, any patent or other intellectual property, including trade secrets, of a Third Party, and (B) such infringement or misappropriation directly results from a Gilead Compound Infringement, and (ii) all Losses arising from such a Proceeding incurred by Janssen or any of its Indemnified Persons, as the case may be, to the extent arising (x) in the case of any Proceeding described in clause (i)(x) above, other than as a direct result of an RPV Infringement, or (y) in the case of any Proceeding described in clause (i)(y) above, as a direct result of a Gilead Compound Infringement.

18.4.2 Combination Product Trademark . Gilead shall indemnify Janssen and its Indemnified Persons from and against (i) any Proceeding arising anywhere in the world where Janssen is licensed by Gilead to use the Combination Product Trademark in which Janssen or any of its Indemnified Persons is involved or threatened to be involved to the extent that such Proceeding arises out of an allegation that the use of the Combination Product Trademark infringes or dilutes the Trademark rights of any Third Party, and (ii) all Losses arising from such a Proceeding incurred by Janssen or any of its Indemnified Persons, as the case may be, to the extent arising as a direct result of such use in accordance with this Agreement.

18.4.3 By Janssen . Janssen shall indemnify Gilead and its Indemnified Persons from and against (i) any Proceeding in which Gilead or any of its Indemnified Persons is involved or threatened to be involved to the extent that (x) (A) such Proceeding arises out of an allegation that any Exploitation of any Territory Combination Product in a country that, as of the time of such Exploitation, is a Gilead Country infringes or misappropriates, or will infringe or misappropriate, any patent or other intellectual property, including trade secrets, of a Third Party and (B) such infringement or misappropriation directly results from an RPV Infringement, or (y) (A) such Proceeding arises out of an allegation that any Exploitation of any Territory Combination Product in a country that, as of the time of such Exploitation, is a Janssen Country infringes or misappropriates, or will infringe or misappropriate, any patent or other intellectual property, including trade secrets, of a Third Party, and (B) such infringement or misappropriation does not directly result from a Gilead Compound Infringement, and (ii) all Losses arising from such a Proceeding incurred by Gilead or any of its Indemnified Persons, as the case may be, to the extent arising (x) in the case of any Proceeding described in clause (i)(x) above, as a direct result of an RPV Infringement, or (y) in the case of any Proceeding described in clause (i)(y) above, other than as a direct result of a Gilead Compound Infringement.

18.5 Enforcement and Defense of Patents . If a Party exercises step-in rights to remove Infringement under Section 14.4.2 or 14.4.3 (as applicable) or to defend an action or claim under Section 14.5.1 or Section 14.5.2, as applicable (each of the foregoing, for the purposes of this Section 18.5, takes an " **Action** "): (a) the Party taking the Action shall indemnify the other Party and the other Party's Indemnified Persons (as applicable) from and against any Proceedings and Losses arising from a claim by a governmental entity of intentional misconduct by either Party as a result of such Action, provided that the Party taking Action had knowledge of alleged intentional misconduct if such intentional misconduct was on the part of the other Party for whom indemnification is provided hereunder.

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18.6 Other Shared Combination Product-Related Losses . With respect to any Losses arising out of any Proceeding brought or made against any Party or any of its Indemnified Persons to the extent arising out of the Exploitation of a Territory Combination Product (including (a) any Manufacture of any Territory Combination Product, and (b) any activities performed by or on behalf of any Party, in its capacity as the MA Holder), except to the extent that either Party has an obligation of indemnification with respect to such Losses pursuant to any of Sections 18.1 through 18.5, Gilead and Janssen shall each bear such portion of such Losses in accordance with its applicable Average Respective Percentage with respect to the Territory.

18.7 Indemnification Procedure . The indemnity and reimbursement obligations of a Party under this Article 18 shall be governed by the following:

18.7.1 Notice . In the case of any Proceeding for which an Indemnifying Party may be liable to an Indemnified Person under this Article 18, the Indemnified Party shall as soon as practicable notify the Indemnifying Party in writing of such Proceeding (a " **Notice of Claim** "). Failure or delay in notifying the Indemnifying Party shall not relieve the Indemnifying Party of any liability it may have to the Indemnified Party, except and only to the extent that such failure or delay causes actual harm to the Indemnifying Party with respect to such Proceeding. The Notice of Claim shall specify in reasonable detail the Proceeding with respect to which such Indemnified Party or any of its Indemnified Persons intends to base a request for indemnification or reimbursement under this Article 18. Failure to provide such reasonable detail will not relieve the Indemnifying Party of any liability it may have to the Indemnified Party, except and only to the extent that such failure causes actual harm to the Indemnifying Party with respect to such Proceeding. The Indemnified Party shall enclose with the Notice of Claim a copy of all papers served with respect to such Proceeding, if any. The Indemnifying Party shall have thirty (30) days from the date on which the Indemnifying Party received the Notice of Claim to notify the Indemnified Party that the Indemnifying Party desires to assume the defense of such Proceeding and any litigation resulting therefrom with counsel of its choice.

18.7.2 Control of the Defense . If the Indemnifying Party has given the Indemnified Party notice pursuant to Section 18.7.1 that it desires to assume control of a Proceeding and the Indemnifying Party has acknowledged in writing an obligation to indemnify or reimburse fully the Indemnified Party or its applicable Indemnified Person(s) for all Losses arising from the Proceeding (to the extent such Losses and Proceedings are covered by such Indemnifying Party's indemnity obligations under Sections 18.1, 18.2, 18.4 or 18.5), then, subject to Section 18.7.4, the Indemnifying Party shall have the right to defend, settle and otherwise dispose of such Proceeding (such Party, " **Defending Party** "). If the Indemnifying Party provides notice that it desires to assume control of the Proceeding, but the Indemnifying Party does not have the right to be the Defending Party pursuant to the preceding sentence, or if Losses are to be allocated under Section 18.3 or 18.6, then the Parties shall confer and negotiate in good faith to determine whether to enter into a joint defense agreement pursuant to which the Parties shall allocate the respective rights and obligations of the Parties with respect to the control of the Proceeding, including whether to designate one of the Parties as the Defending Party. In the event that there are two or more Indemnified Parties or Indemnified Persons that are subject to the same Proceeding, this Section 18.7 shall be construed to apply separately to

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such Proceeding as it applies to each such Indemnified Party or Indemnified Person, provided that the applicable Parties agree to take account of such fact in connection with their negotiations pursuant to this Section 18.7.2 with respect to the defense, control and settlement of such Proceeding as it applies to each such Indemnified Party or Indemnified Person. The out-of-pocket costs and expenses (including reasonable attorneys' fees) reasonably incurred by the Defending Party in connection with its control of a Proceeding shall constitute Losses with respect to such Proceeding.

18.7.3 Interim Control . Unless and until the Defending Party is determined, the Indemnified Party subject to such Proceeding shall have the right to defend and control such Proceeding, but shall not have the right to consent to the entry of any judgment or enter into any settlement with respect to the Proceeding for which it would be seeking indemnification or reimbursement hereunder (including under Section 18.3 or 18.6) without the prior written consent of the other Party (which consent shall not be unreasonably withheld, conditioned or delayed).

18.7.4 Control by the Defending Party . If either Party is the Defending Party, (i) the other Party may retain separate co-counsel at its sole cost and expense (from and after the Defending Party's assumption of control of the Proceeding) and participate in the defense of the Proceeding but the Defending Party shall control the investigation, defense and settlement thereof, (ii) the other Party will not consent to the entry of any judgment or enter into any settlement with respect to the Proceeding for which it would be seeking indemnification or reimbursement hereunder without the prior written consent of the Defending Party (which consent shall not be unreasonably withheld, conditioned or delayed) and (iii) the Defending Party will not, without the prior written consent of the other Party, consent to the entry of any judgment or enter into any settlement with respect to the Proceeding to the extent such judgment or settlement (A) provides for equitable relief (or any other relief other than solely for money damages) or liability or obligation that cannot be assumed and performed by the Defending Party in full (without any recourse to the other Party and its Indemnified Persons), or for any monetary relief that will not be fully discharged by the Defending Party (without any recourse to the other Party and its Indemnified Persons) concurrently with the effectiveness of such judgment or settlement, provided that the other Party's consent shall not be unreasonably withheld, conditioned or delayed to the extent that the sole relief is monetary, (B) does not effect a full and unconditional release of the other Party and its Indemnified Persons with respect to all claims in such Proceeding (or the portion thereof to which the judgment or settlement relates), or (C) contains an admission of wrongdoing on the part of the other Party or its Indemnified Persons. The Parties shall act in good faith in responding to, defending against, settling or otherwise dealing with such Proceeding; provided , however , that (x) an Indemnified Party shall not be obligated pursuant to this sentence to enter into or consent to the entry of any judgment or settlement in relation to any Proceeding and (y) in any event, an Indemnifying Party shall not be relieved of its obligations under this sentence as a result of any breach of this sentence (determined after giving effect to clause (x)) except to the extent that the Indemnifying Party is actually prejudiced by such breach. Notwithstanding anything contained herein to the contrary, an Indemnifying Party shall not be entitled to assume the defense of any Proceeding that seeks an injunction or other equitable relief (or any other relief other than solely money damages) against

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the Indemnified Person. The Parties shall also cooperate in any such defense and give each other reasonable access to all non-privileged information relevant thereto to the extent permitted by Applicable Law.

18.7.5 Election Not to Control . If there is no Defending Party with respect to a given Proceeding, then the Indemnified Party will be entitled to assume control of the Proceeding, at its cost and expense (or to the extent the Indemnified Party is entitled to indemnification or reimbursement with respect thereto pursuant to this Article 18, at the expense of the other Party to such extent) upon delivery of notice to such effect to the other Party; provided that the Indemnifying Party shall have the right to participate in the Proceeding at its sole cost and expense, but the Indemnified Party shall control the investigation, defense and settlement thereof.

18.7.6 Unauthorized Settlements . Whether or not the Indemnifying Party has assumed control of the Proceeding, such Indemnifying Party shall not be obligated to indemnify or reimburse the Indemnified Party hereunder for any settlement entered into, or any judgment that was consented to, by the Indemnified Party without the Indemnifying Party's prior written consent (which consent shall not be unreasonably withheld, conditioned or delayed).

18.7.7 Allocations . The allocation between the Parties (whether by indemnification, reimbursement or otherwise) of any liability for any Losses, if not otherwise determined in a court of law, shall be considered by the Parties and, if the Parties do not reach agreement in writing on such allocation, either Party shall have the right to refer the Dispute to dispute resolution pursuant to Section 20.6. The Parties, the Executives or the arbitrator, as the case may be, shall make such allocation based on the indemnification and reimbursement principles set forth in this Article 18. Notwithstanding the foregoing, the Parties shall not be entitled to refer any Dispute with respect to Losses arising under a Proceeding pursuant to this Section 18.7.7 to arbitration to the extent that the liability of either Party for such Losses is being contested in such Proceeding (or any other Proceeding that would be binding with respect to such first Proceeding).

18.7.8 Third Party Rights . The Parties shall attempt in good faith to coordinate with respect to the rights set forth in this Section 18.7, including any rights with respect to the control of any applicable Proceeding, to take into account the rights of any Third Party (*e.g.* , a subcontractor of a Party) that has an obligation to indemnify any Party (or its Indemnified Persons) with respect to any Losses covered by this Article 18.

18.8 LIMITATION ON DAMAGES . EXCEPT WITH RESPECT TO LIABILITY ARISING FROM BREACHES OF ARTICLE 15 BY A PARTY, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE, MULTIPLIED OR CONSEQUENTIAL DAMAGES (INCLUDING FOR LOST PROFITS), WHETHER IN CONTRACT, WARRANTY, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE, ARISING IN CONNECTION WITH THIS AGREEMENT OR ANY ANCILLARY AGREEMENT. NOTHING IN THIS SECTION 18.8 IS INTENDED TO OR SHALL OPERATE TO LIMIT A PARTY'S OBLIGATIONS OF INDEMNITY OR REIMBURSEMENT OF LOSSES UNDER THIS ARTICLE 18.

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18.9 Insurance . Each Party shall comply with Annex KK .

19 TERM AND TERMINATION

19.1 Term . The term of this Agreement (" Term ") shall commence as of the Restatement Effective Date and shall expire, on a Territory Combination Product-by-Territory Combination Product and country-by-country basis, at the end of the Monthly Payment Term for the applicable Territory Combination Product in the applicable country unless terminated earlier pursuant to this Article 19.

19.2 Challenge by Governmental Authority . In the event that any governmental authority in a country obtains a preliminary injunction or permanent injunction enjoining the transactions between the Parties in connection with entering into this Agreement with respect to a Territory Combination Product, the Parties shall meet and discuss whether to terminate this Agreement with respect to such Territory Combination Product in such country.

19.3 Territory Combination Product Withdrawal . The Selling Party may terminate this Agreement with respect to a Territory Combination Product and a country if such Territory Combination Product is withdrawn from the market in such country pursuant to Section 13.2. In the event of any termination with respect to a Territory Combination Product and a country or countries pursuant to this Section 19.3, such termination with respect to such Territory Combination Product and country(ies) shall be effective immediately upon written notice to the non-Selling Party. For the avoidance of doubt, in the event the Selling Party terminates this Agreement with respect to a Territory Combination Product and a country under this Section 19.3, (a) Gilead may not submit or resubmit any Drug Approval Application or maintain any Regulatory Approval with respect to such Territory Combination Product in such country containing any Confidential Information of Janssen, Janssen Regulatory Documentation or a Right of Reference provided by Janssen under this Agreement or any Ancillary Agreement following such termination; provided , however , that the foregoing shall not preclude the exercise of rights granted to Gilead for any purpose expressly permitted hereunder or under any Ancillary Agreement hereto with respect to products other than such Territory Combination Product, provided that such right survives termination (such rights, the " **Gilead Specified Rights** "), and (b) Janssen may not submit or resubmit any Drug Approval Application or maintain any Regulatory Approval with respect to such Territory Combination Product in such country containing any Confidential Information of Gilead, Gilead Regulatory Documentation or a Right of Reference provided by Gilead under this Agreement or any Ancillary Agreement following such termination; provided , however , that the foregoing shall not preclude the exercise of rights granted to Janssen for any purpose expressly permitted hereunder or under any Ancillary Agreement hereto with respect to products other than such Territory Combination Product, provided that such right survives termination (such rights, the " **Janssen Specified Rights** ").

19.4 Material Breach .

19.4.1 Notice and Cure Period . If a Party (the " **Breaching Party** ") is in Material Breach, the other Party (the " **Non-Breaching Party** ") shall have the right to give the Breaching Party notice specifying the nature of such Material Breach. Except as set forth in

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Section 6.2.2.5 with respect to Initial Specific Target Breaches, the Breaching Party shall have a period of ninety (90) days after receipt of such notice to cure such Material Breach (including Commercial Target Breaches other than Initial Specific Target Breaches) (the " **Cure Period** ") in a manner reasonably acceptable to the Non-Breaching Party. For the avoidance of doubt, this provision is not intended to restrict in any way either Party's right to notify the other Party of any other breach or to demand the cure of any other breach.

19.4.2 Termination Right . The Non-Breaching Party shall have the right to terminate this Agreement with respect to the Territory Combination Product to which the Material Breach relates, upon written notice to the Breaching Party, in the event that the Breaching Party has not, in the case of an Initial Specific Target Breach, cured such Material Breach within the applicable time period set forth in Section 6.2.2.5, or in the case of any other Material Breach, cured such Material Breach within the Cure Period. If a Party contests such termination pursuant to the dispute resolution procedures under Section 20.6, such termination shall not be effective until a conclusion of the dispute resolution procedures in Section 20.6, as applicable, resulting in a determination that there has been an uncured Material Breach (or, if earlier, abandonment of the Dispute by such Party). If the Breaching Party asserts that the Material Breach has been cured, this Agreement with respect to the applicable Territory Combination Product shall not be terminated if the alleged cure has effectively remedied the harm to the Non-Breaching Party caused by the Material Breach.

19.5 Voluntary Termination .

19.5.1 Voluntary Termination of Supply Obligations by Janssen . Janssen may terminate (a) its supply obligations under this Agreement and (b) the RPV Supply Agreement, in each case with respect to a Territory Combination Product, which termination shall be effective [*] after the later of (w) the date Janssen provides Gilead written notice of such termination and (x) the expiration or termination of this Agreement with respect to such Territory Combination Product in [*]. For clarity, in each case, such notice may be provided prior to the applicable expiration or termination of this Agreement. Following the effective date of termination of Janssen's supply obligations with respect to a Territory Combination Product pursuant to this Section 19.5.1, Gilead shall no longer be obligated to purchase RPV from Janssen with respect to such Territory Combination Product. For the avoidance of doubt, Janssen's termination rights under this Section 19.5.1 only relate to its supply obligations (i.e., those under Article 8 and the RPV Supply Agreement). All other provisions of this Agreement, including the license grants to Gilead hereunder, shall remain in full force and effect unless otherwise agreed by the Parties in writing (or until they otherwise expire or terminate pursuant to the terms of this Agreement), and a termination under this Section 19.5.1 shall not be considered a "termination of this Agreement."

19.5.2 Voluntary Termination by Gilead . Gilead may terminate this Agreement (a) with respect to the Territory R/F/TAF Product in a Gilead Country (i) at any time before the First Commercial Sale of the Territory R/F/TAF Product in such Gilead Country, upon [*] advance written notice to Janssen, or (ii) at any time after the First Commercial Sale of the Territory R/F/TAF Product in such Gilead Country, upon [*] advance written notice to Janssen,

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and (b) with respect to Territory Complera in a Major Market Country, subject to Section 4.8, at any time after the termination of Gilead's obligation under Section 4.1.1 to use Commercially Reasonable Efforts to obtain and maintain a first Marketing Approval for Territory Complera in such Major Market Country. In the event Gilead provides a notice of termination of this Agreement under clause (a)(ii) of this Section 19.5.2 with respect to the Territory R/F/TAF Product in a Gilead Country at any time after the First Commercial Sale of the Territory R/F/TAF Product in such country but before the [*] anniversary of the First Commercial Sale of the Territory R/F/TAF Product in such country, Janssen shall have the right to elect to convert such country from a Gilead Country to a Janssen Take-Over Country with respect to all Territory Combination Products by providing notice to Gilead within [*] of Gilead providing Janssen the notice described in clause (a)(ii) of this Section 19.5.2. Thereafter, such country shall be deemed a Janssen Take-Over Country and, if such country is a Specified Percentage Country prior to such election by Janssen, such country shall thereafter no longer be deemed a Specified Percentage Country. In the case of such an election by Janssen, Gilead, upon receiving any necessary or appropriate approval from the applicable Regulatory Authority(ies), shall cease selling (and cause its Affiliates, Sublicensees, Third Party Distributors and subdistributors, as applicable, to cease selling) the Territory Combination Product in the applicable Janssen Take-Over Country, but shall not conduct any withdrawal or recall with respect to the Territory Combination Product in such Janssen Take-Over Country. If Gilead (or its Affiliate or Third Party Distributor) holds any Drug Approval Application or Marketing Approval with respect to any Territory Combination Product with respect to such Janssen Take-Over Country, Gilead shall, [*], as promptly as reasonably practicable after the effective date of such termination, transfer (or cause to be transferred) to Janssen (or its designated Affiliate, Sublicensee or Third Party Distributor) such Drug Approval Application(s) or Marketing Approval(s) and the Parties shall coordinate in good faith to effect such transfer (and, for clarity, until such time as such transfer has been completed, as between the Parties, Gilead shall remain responsible for performing all activities required to be performed by the holder of such Drug Approval Application(s) or Marketing Approval(s) in accordance with Applicable Law), provided that (a) if such Janssen Take-Over Country is in the European Union and not all countries in the European Union have been deemed Janssen Take-Over Countries, Gilead shall continue to hold any Marketing Approval for the Territory Combination Products granted by the European Commission for such Janssen Take-Over Country and the Parties shall coordinate in good faith so that Janssen can operate under such Marketing Approval, and (b) if such Janssen Take-Over Country is in the European Union and all countries in the European Union have been deemed Janssen Take-Over Countries, Gilead shall transfer the Marketing Approvals for the Territory Combination Products by the European Commission as promptly as reasonably practicable and the Parties shall coordinate in good faith to effect such transfer. Gilead shall remain responsible for the performance of its obligations under the Collaboration Agreement with respect to the Janssen Take-Over Country as a Gilead Country for the period during which it was a Gilead Country, including with respect to indemnification with respect to any acts or omissions occurring during such period. For clarity, Jansen shall [*] with respect to the Exploitation of any Territory Combination Product with respect to such Janssen Take-Over Country. For the avoidance of doubt, in the event Gilead terminates this Agreement with respect to a Territory Combination Product in a Gilead Country under this Section 19.5.2, Gilead may not submit or resubmit any Drug Approval Application, or maintain any Regulatory Approval, with respect to

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such Territory Combination Product in such Gilead Country, that contains any Confidential Information of Janssen, Janssen Regulatory Documentation or a Right of Reference provided by Janssen under this Agreement or any Ancillary Agreement following such termination; provided , however , that the foregoing shall not preclude the exercise of the Gilead Specified Rights. Gilead has no right under this Section 19.5.2 to terminate this Agreement with respect to any Janssen Country. For clarity, with respect to Janssen Take-Over Countries, revenue from Triggering Sales in such countries shall be shared between the Parties pursuant to the terms in the Janssen Distributor Agreement.

19.5.3 By Janssen Upon Gilead Failure to Develop . Janssen may, by written notice to Gilead, prior to when first Marketing Approval is first obtained from any of the FDA, [*] or the European Commission for the Territory R/F/TAF Product, terminate this Agreement with respect to the Territory R/F/TAF Product in the event that Gilead has ceased to conduct Combination Product Development Activities with respect to the Territory R/F/TAF Product for a period of [*] or longer, provided that Gilead shall have a period of [*] after receipt of such notice to cure such failure to perform, which termination shall be automatically effective at the end of such cure period if Gilead has not recommenced Combination Product Development Activities with respect to the Territory R/F/TAF Product in good faith and notified Janssen of such recommencement by the end of such period. Gilead shall have a right to contest a termination under this Section 19.5.3 pursuant to the dispute resolution procedures set forth in Section 20.6, in which case such termination shall not be effective until a conclusion of the dispute resolution procedures in Section 20.6 resulting in a determination that there has been an uncured failure to conduct Combination Product Development Activities with respect to the Territory R/F/TAF Product for a period of [*] or longer (or, if earlier, abandonment of the Dispute by Gilead). For the avoidance of doubt, in the event Janssen terminates this Agreement with respect to the Territory R/F/TAF Product under this Section 19.5.3, (a) Gilead may not submit or resubmit any Drug Approval Application or maintain any Regulatory Approval in any country with respect to the Territory R/F/TAF Product that contains any Confidential Information of Janssen, any Janssen Regulatory Documentation or a Right of Reference provided by Janssen under this Agreement or any Ancillary Agreement following such termination; provided , however , that the foregoing shall not preclude the exercise of the Gilead Specified Rights, and (b) Janssen may not submit or resubmit any Drug Approval Application or maintain any Regulatory Approval in any country with respect to the Territory R/F/TAF Product that contains any Confidential Information of Gilead, any Gilead Regulatory Documentation or a Right of Reference provided by Gilead under this Agreement or any Ancillary Agreement following such termination; provided , however , that the foregoing shall not preclude the exercise of the Janssen Specified Rights.

19.6 Consequences of Termination .

19.6.9 Termination For Any Reason . Upon termination of this Agreement in its entirety or with respect to a Territory Combination Product in one or more country(ies) for any reason, the provisions of this Section 19.6.1 shall apply, with respect to the applicable country(ies), in the case of a country-specific termination, or all countries in the Territory, in the case of termination of this Agreement in its entirety (the " **Terminated Countries** ").

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19.6.9.1 The license and other rights granted to a Party in Article 9 with respect to the applicable Territory Combination Product(s) shall survive only to the extent necessary to enable such Party (or its Affiliates) to perform any surviving obligations or exercise any surviving rights of such Party (or its Affiliates).

19.6.9.2 No later than thirty (30) days after the date of such termination, if the applicable Territory Combination Product(s) and any related Drug Approval Application or Regulatory Approval have not yet been withdrawn in the Terminated Countries, they shall be withdrawn promptly from the market or the applicable Regulatory Authority (as the case may be) in the Terminated Countries. For the avoidance of doubt, (a) Gilead may not submit or resubmit any Drug Approval Application with respect to the applicable Territory Combination Product(s) in any of the Terminated Countries, or maintain any Regulatory Approval with respect to the applicable Territory Combination Product(s) in any of the Terminated Countries, that contains any Confidential Information of Janssen, any Janssen Regulatory Documentation or a Right of Reference provided by Janssen under this Agreement or any Ancillary Agreement following such termination in such Terminated Countries; provided , however , that the foregoing shall not preclude the exercise of the Gilead Specified Rights, and (b) Janssen may not submit or resubmit any Drug Approval Application with respect to the applicable Territory Combination Product(s) in any of the Terminated Countries, or maintain any Regulatory Approval with respect to the applicable Territory Combination Product(s) in any of the Terminated Countries, that contains any Confidential Information of Gilead, any Gilead Regulatory Documentation or a Right of Reference provided by Gilead under this Agreement or any Ancillary Agreement following such termination in such Terminated Countries; provided , however , that the foregoing shall not preclude the exercise of the Janssen Specified Rights.

19.6.9.3 No later than thirty (30) days after the date of such termination, each Party shall make arrangements for, at the election of the other Party, either the return or disposal of any Confidential Information of the other Party, whether such Confidential Information is in tangible or intangible form (except for one (1) copy which may be retained solely for archival purposes); provided , however , that the foregoing shall not apply with respect to any such Confidential Information (i) to the extent that this Agreement or any other binding agreement between the Parties (or their respective Affiliates) expressly provides that the returning Party retains the right to use such Confidential Information (e.g., with respect to a Territory Combination Product other than the Territory Combination Product that is subject to such termination, or in the case of a surviving license) following such termination in such Terminated Countries or (ii) in the case of a country-specific termination, to the extent that such Confidential Information is relevant to any country that is not one of the Terminated Countries.

19.6.9.4 No later than thirty (30) days after the date of such termination, the Parties shall coordinate in good faith to wind down matters relating to the Manufacture and supply of the applicable Territory Combination Product(s) with respect to the Terminated Countries, including the appropriate disposition of any quantities of such Territory Combination Product(s) or any unused Supplied RPV for use therein then in Gilead's (or its Affiliates' or Sublicensees') inventory to the extent not usable for commercialization in any country that is not one of the Terminated Countries, if any.

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19.6.10 Termination Due to Material Breach . Except to the extent expressly precluded by this Agreement, the aggrieved Party may also seek damages and other relief for such Material Breach and (for the avoidance of doubt) for any other breach of this Agreement.

19.6.11 Voluntary Termination of Supply Obligations by Janssen .

19.6.11.1 If Janssen voluntarily terminates its supply obligations under this Agreement and the RPV Supply Agreement with respect to a Territory Combination Product pursuant to Section 19.5.1, then, at the request of Gilead, the Parties shall negotiate an amendment to this Agreement pursuant to which Janssen shall no longer have any obligation to supply RPV with respect to such Territory Combination Product for the remainder of the Term, but according to which Gilead may continue to develop and commercialize such Territory Combination Product in the countries in the Territory for the remainder of the Term and following expiration of this Agreement, if applicable (other than, for clarity, in any countries that are Terminated Countries with respect to such Territory Combination Product) using RPV supplied from Third Parties or manufactured by Gilead or an Affiliate of Gilead. Such amendment(s) shall (a) grant Gilead such licenses or sublicenses as may be required in order for Gilead to obtain RPV with respect to the applicable Territory Combination Product from Third Parties or for Gilead or an Affiliate of Gilead to manufacture RPV with respect to the applicable Territory Combination Product (including any such licenses or sublicenses as may be required in the event of any transfer of any Information and Inventions under subsection (ii) of Section 19.6.3.2), (b) provide to Janssen analogous compensation for a given Unit of such Territory Combination Product (taking account of the fact that Janssen will not be paid for supplying RPV with respect to such Territory Combination Product and the fact that Gilead will have to manufacture or contract with a Third Party to manufacture RPV with respect to such Territory Combination Product) and (c) include such other commercially reasonable terms and conditions as may be required to reflect the fact that Janssen is no longer the supplier of RPV to Gilead with respect to such Territory Combination Product. Such amendment(s) shall also permit Gilead to continue to sublicense to, and use, any Third Party Distributor or Affiliate of Gilead (but excluding any Generic Licensee) as specified in this Agreement.

19.6.11.2 Without limitation of any of the foregoing, upon Gilead's request and [*], Janssen shall (i) provide reasonable assistance to Gilead or its Affiliate in sourcing RPV with respect to the applicable Territory Combination Product from an alternate Third Party supplier and/or (ii) transfer to Gilead's selected Third Party supplier or, if Gilead or an Affiliate of Gilead will manufacture RPV with respect to such Territory Combination Product, Gilead or such Affiliate, all Information and Inventions Controlled by Janssen that are necessary or useful to enable the manufacture of RPV with respect to such Territory Combination Product by providing copies or samples of relevant documentation, materials and other embodiments of such Information and Inventions, and by making available Janssen's qualified technical personnel on a reasonable basis to consult with, such Third Party supplier, Gilead or such Affiliate, as applicable, with respect to such Information and Inventions and the manufacturing process for RPV.

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19.6.11.3 Following such termination under Section 19.5.1, Janssen's indemnity obligations hereunder with respect to RPV supplied by a Third Party to Gilead or manufactured by Gilead or its Affiliate with respect to the applicable Territory Combination Product (and its incorporation into such Territory Combination Product) shall apply (a) only with respect to any country for which the Monthly Payment Term for such Territory Combination Product remains in effect at the time of the sale of the at-issue Territory Combination Product, and (b) only to the extent that any Losses are not attributable to the fault of the Third Party that supplies RPV or Gilead or an Affiliate of Gilead that manufactures RPV with respect to the applicable Territory Combination Product. In the case of any termination of Janssen's supply obligations with respect to a Territory Combination Product pursuant to Section 19.5.1, the Parties shall coordinate in good faith to wind down matters relating to the supply of RPV with respect to such Territory Combination Product under the RPV Supply Agreement, including appropriate disposition of any unused RPV then in Gilead's (or its Affiliates' or Sublicensees') inventory to the extent not used or usable for commercialization or otherwise by Gilead.

19.6.12 Expiration . Upon expiration of this Agreement with respect to a Territory Combination Product in a given country, (a) for clarity, the Selling Party shall not be required to withdraw such Territory Combination Product in such country and all rights and licenses granted to the Selling Party under this Agreement (including in Article 9 and in the Janssen Distributor Agreement) with respect to such Territory Combination Product in such country shall remain in effect and shall be fully paid-up and perpetual; provided , however , that such rights and licenses shall remain subject to any Third Party License Payments incurred with respect to sales of such Territory Combination Product in such country after expiration of this Agreement in such country, which Third Party License Payments shall be paid by the Selling Party, and (b) notwithstanding anything to the contrary in this Agreement, (i) with respect to any Supplied RPV used to Manufacture any quantity of such Territory Combination Product that is subject to a Triggering Sale by Gilead or its Affiliate or Sublicensee in such country after such expiration, Gilead shall pay to Janssen an amount equal to [*] and (ii) with respect to any quantity of such Territory Combination Product that is subject to a Triggering Sale by Janssen or its Affiliate in such country after such expiration, Janssen shall pay to Gilead an amount equal to [*].

19.7 Accrued Liabilities; Survival .

19.7.1 Expiration or termination of this Agreement, in whole or in part, shall be without prejudice to any liabilities that shall have accrued prior to such expiration or termination or any remedies to which either Party may be entitled. Such expiration or termination shall not relieve a Party from obligations that are expressly indicated to survive such expiration or termination of this Agreement. In the event that there are any outstanding credit notes that were issued pursuant to this Agreement as of the date of any such expiration or termination, the issuing Party shall pay, promptly and in no event later than forty-five (45) days after such expiration or termination, to the non-issuing Party the amount set forth in such outstanding credit notes and, upon such payment, such notes shall no longer be in effect.

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19.7.2 Without limiting anything contained in Section 19.6, in the event of any termination of this Agreement for any reason, the following sections shall survive such termination: this Section 19.7 ("Accrued Liabilities; Survival"); Article 1 ("Definitions"); Section 2.3 ("Financial Reporting Committee"), to the extent necessary to exchange Net Selling Prices for purposes of calculating payments that accrued under this Agreement prior to the effective date of termination; Section 2.5 ("Expenses"), with respect to any costs and expenses incurred following termination with respect to the Financial Reporting Committee; Section 3.2.2.2a.ii; Section 3.2.2.2b.iii, last sentence only; Section 3.2.2.4 ("Confidentiality"); Section 3.2.4.4 ("Definition of Gilead Clinical Data"); Section 3.4.1("Maintenance of Records"), for the time period set forth therein; Section 3.4.2 ("Access to Records"); Section 3.6 ("Publication of Results") (but solely as it relates to any applicable clinical trials conducted prior to or ongoing at the end of the Term); Section 3.7 ("Third Party Uses of Combination Product Clinical Data") (second sentence only, but not "provided, however," and all language thereafter); Section 3.8 ("Limitations on Disclosure of [*]"), with respect to data required to be disclosed after termination pursuant to any provision that survives termination in accordance with this Section 19.7.2; Section 4.3.3.3 ("Limitations"); Section 4.5 ("Activities in Japan"), solely with respect to any rights or obligations of Gilead that survive termination hereof; Section 4.6 ("Records"), to the extent set forth therein; Section 4.7 ("Regulatory Costs and Expenses"), with respect to costs, expenses and fees incurred prior to the effective date of termination; Section 8.1.3 ("Adjustments"), with respect to any RPV supplied prior to the effective date of termination; Section 9.2.3 ("Data Exclusivity"); Sections 9.5.1 and 9.5.6 ("Third Party License Payments" and "Payments," in each case, solely to the extent relating to Third Party License Payments that accrued prior to the effective date of termination); Section 9.6 ("Retained Rights"); Section 10.1.1 ("Payment of Pre-Conversion Supply Price"), with respect to any Supplied RPV delivered prior to the effective date of termination; Section 10.1.2 ("Monthly Payments") and Annex M-1 ("Financial Calculations for Post-Conversion Supply Price and Additional Supply Price"), with respect to the Monthly Payment(s) in each of (a) the month in which termination occurs, and (b) the immediately preceding month, if the due date for any such Monthly Payment did not occur prior to termination; Section 10.2 ("Post-Conversion and Additional Supply Price Reductions") and Annex M-2 ("Post-Conversion Supply Price Reductions for Gilead Countries"), with respect to any Supplied RPV used to Manufacture any quantity of Territory Combination Product that is subject to a Triggering Sale prior to the effective date of termination; Section 10.3 ("Monthly Payment Term"), with respect to the Monthly Payment(s) in each of (a) the month in which termination occurs, and (b) the immediately preceding month, if the due date for any such Monthly Payment did not occur prior to termination; Section 10.4 ("Mode of Payment"), with respect to any payments that accrued under the Agreement prior to the effective date of termination or that accrue after the effective date of termination pursuant to any provision that survives termination in accordance with this Section 19.7.2; Section 10.5.1 ("Pre-Conversion Supply Price Payments and Revaluation Pre-Conversion Payments"), Annex M-5 ("Payment Terms for Supplied RPV Invoices for Gilead Countries") and Annex M-6 ("Revaluation of API"), with respect to any Supplied RPV delivered prior to the effective date of termination; Section 10.5.2 ("Monthly Payments") with respect to the Monthly Payment(s) in each of (a) the month in which termination occurs, and (b) the immediately preceding month, if the due date for any such Monthly Payment did not occur prior to termination; Section 10.5.3 ("Monthly Payment Calculation") and Annex M-1 ("Financial Calculations for Post-Conversion Supply

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Price and Additional Supply Price"), with respect to Units of Territory Combination Product sold prior to the effective date of termination; Section 10.5.4 ("Monthly Reports"), Annex M-1 ("Financial Calculations for Post-Conversion Supply Price and Additional Supply Price") and Annex N ("Financial Reporting"), with respect to Units of Territory Combination Product for which Triggering Sales occurred prior to the effective date of termination (and any related information required to make revenue share calculations with regard to such Units); Section 10.5.5 ("Lost Supplied RPV"), with respect to Supplied RPV that becomes Lost Supplied RPV during the Calendar Year in which termination occurs; Section 10.5.6 ("Other Payments"), with respect to any payments that accrued under this Agreement or the RPV Supply Agreement prior to the effective date of termination or that accrue after the effective date of termination pursuant to any provision that survives termination in accordance with this Section 19.7.2 or the RPV Supply Agreement; Section 10.5.7 ("Communication of Non-Public Pricing Information"), to the extent necessary to exchange Net Selling Prices for purposes of calculating payments that accrued under this Agreement prior to the effective date of termination; Section 10.5.8 ("Other Reports") and Annex N ("Financial Reporting"), with respect to any obligation under Annex N that survive termination; Section 10.6 ("Financial Records"), to the extent relating to payments made or accrued prior to termination of this Agreement and for the period set forth therein; Section 10.7 ("Currency Conversion"), Section 10.8 ("Audits"), Section 10.9 ("Interest Due") and Section 10.10 ("Tax Withholding"), in each case with regard to payments made or accrued prior to termination of this Agreement, including payments under any In-License Requirements, final Monthly Payment(s) or payments with respect to any surviving sublicensed rights under any In-License Agreement; Section 10.11 ("Manufacturing Fees"); Annex M-3 ("Calculation of Manufacturing Fee Percentage") and Annex M-4 ("Manufacturing Fees"), to the extent necessary to calculate the Manufacturing Fee with respect to Territory Combination Product for which Manufacturing Completion occurred during the Calendar Year in which this Agreement terminated and the Janssen Portion thereof (which shall account for such termination); Section 10.12 ("Branded Prescription Pharmaceutical Manufacturers Fee"), [*]; Article 11 ("Financial Calculations and Adjustments", the Monthly Payment(s) in each of (a) the month in which termination occurs, and (b) the immediately preceding month, if the due date for any such Monthly Payment did not occur prior to termination and any amounts payable that are accrued prior to the effective date of termination; Article 13 ("Pharmacovigilance Agreement; Product Recall and Withdrawal"), solely as it relates to recalls of Territory Combination Product sold during the Term or after termination as necessary to comply with Applicable Law or any In-License Requirements, except with respect to Section 13.4, which shall survive for the time period set forth therein; Section 14.1 ("Ownership of Intellectual Property"), including all subsections thereof; Section 14.2.1 ("Gilead Patents"); Section 14.2.2 ("Janssen Patents"), only the first and last sentences; Section 14.2.3.2 ("Other Joint Patents"), where all Joint Patents shall be governed by such section following termination of this Agreement; Section 14.2.3.3; Section 14.2.4 ("Extensions"), except that all Joint Patents shall be governed by the third sentence thereof; Section 14.3 ("Liability for Prosecution and Maintenance"), to the extent that Section 14.1 and 14.2 survive; Section 14.4 ("Enforcement of Patents"), to the extent that any subsections of Section 14.4 survive; Section 14.4.1 ("Effect on In-License Agreements"), Section 14.4.4 and Section 14.4.7 ("Recoveries"), to the extent that Section 14.4.5 survives; Section 14.4.5 ("Joint Patents"); Section 14.5.1, solely as it relates to actions under Section 14.4.5; Section 14.5.2, solely with respect to Joint Patents; Section 14.6.1 ("Gilead Licensed

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Trademarks"); Section 14.6.2 ("Janssen Licensed Trademarks"), Section 14.6.3.1 ("Combination Product Trademarks; Registration"); Section 14.6.3.2 ("Infringement"), with respect to actions related to infringement commencing prior to the effective date of termination; Article 15 ("Confidentiality"); Section 16.2 ("Other Public Disclosures"), only with respect to Territory Combination Products; Section 16.3 ("Use of Names"); Section 17.1.7 ("No Debarment"), second sentence only; Section 17.1.9 ("Compliance with Applicable Law"), with respect to any activities performed after the effective date of termination pursuant to any provision that survives termination in accordance with this Section 19.7.2; Sections 17.2.1 and 17.3.1, which shall each survive for [*]); Section 17.4 ("Disclaimer"); Article 18 ("Indemnification and Insurance"); Section 19.3 ("Territory Combination Product Withdrawal"), last sentence only and only in the event of termination pursuant to Section 19.3; Section 19.5.2 ("Voluntary Termination by Gilead"), solely with regard to the post-termination consequences set forth therein, if applicable, and only in the event of termination pursuant to Section 19.5.2; Section 19.5.3 ("By Janssen Upon Gilead Failure to Develop"), solely with regard to the post-termination consequences set forth therein, if applicable, and only in the event of termination pursuant to Section 19.5.3; Section 19.6 ("Consequences of Expiration or Termination"); Article 20 ("General Provisions"); the Exhibits, to the extent applicable to the other surviving terms of this Agreement; and such other provisions hereof as are required for the interpretation or enforcement of those Articles and Sections; and any other provisions that by their terms survive termination of this Agreement. In addition to the foregoing, to the extent not surviving as described above, the provisions of Article 3 ("Development Activities") and Article 4 ("Regulatory Matters") shall survive solely as required for each Party to comply with Applicable Law. If this Agreement is terminated with respect to fewer than all of the countries in the Territory, then neither Party shall have any rights hereunder to Exploit any Territory Combination Product in the Terminated Countries, and the Parties' respective rights and obligations under this Agreement as they relate to the Terminated Countries shall remain in effect only as described above in this Section 19.7, but the terms of this Agreement shall remain in full force and effect as they relate to the non-Terminated Countries. Upon termination of this Agreement with respect to all countries in the Territory, this Section 19.7.2 shall apply to all countries that comprised the Territory. For clarity, this Section 19.7.2 does not apply as a result of a termination by Janssen of its supply obligations pursuant to Section 19.5.1.

19.7.3 Without limiting anything contained in Section 19.6, in the event of expiration of this Agreement, the following sections shall survive: this Section 19.7 ("Accrued Liabilities; Survival"); Article 1 ("Definitions"); Section 2.3 ("Financial Reporting Committee"), to the extent necessary to exchange Net Selling Prices for purposes of calculating payments that accrued under this Agreement prior to the effective date of expiration; Section 2.5 ("Expenses"), with respect to any costs and expenses incurred following expiration with respect to the Financial Reporting Committee; Section 3.1.2 ("Clinical Data"); Section 3.2.2.2a.ii; Section 3.2.2.2b.iii, last sentence only; Section 3.2.2.4 ("Confidentiality"); Section 3.2.4.4 ("Definition of Gilead Clinical Data"); Section 3.2.5 ("Combination Product Clinical Data"), only with respect to the Territory Combination Products; Section 3.3 ("Performance; Subcontracting"); Section 3.4.1("Maintenance of Records"), for the time period set forth therein; Section 3.4.2 ("Access to Records"); Section 3.6 ("Publication of Results") (but solely as it relates to any applicable clinical trials conducted prior to or ongoing at the end of the Term); Section 3.7 ("Third Party

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Uses of Combination Product Clinical Data") (second sentence only, but not "provided, however," and all language thereafter); Section 3.8 ("Limitations on Disclosure of [*]"), with respect to data required to be disclosed after expiration pursuant to any provision that survives expiration in accordance with this Section 19.7.2; Section 4.1.2 ("Performance; Subcontracting"); Section 4.3 ("Regulatory Documentation to be Provided by the Parties"), only to the extent necessary to enable the Selling Party to continue conducting Commercialization Activities in countries where such Selling Party is conducting Commercialization Activities on the effective date of expiration and only for so long as the notified Party continues to Commercialize the Territory Combination Product; Section 4.4.2.1 ("Discussion of Single Agent Products or Double Agent Product"); Section 4.4.2.2 ("Label Change for Single Agent Products or Double Agent Product") only to the extent necessary to enable the Selling Party to continue conducting Commercialization Activities in countries where such Selling Party is conducting Commercialization Activities on the effective date of expiration and only for so long as the notified Party continues to Commercialize the Territory Combination Product; Section 4.4.4 ("Regulatory Matters Concerning Single/Double Agent Products"); Section 4.4.5 ("Regulatory Matters Concerning a Party's Compliance with Applicable Law"); Section 4.4.6 ("Activities in the EU"); Section 4.5 ("Activities in Japan"), solely with respect to any rights or obligations of Gilead that survive expiration hereof; Section 4.6 ("Records"), to the extent set forth therein; Section 4.7 ("Regulatory Costs and Expenses"), with respect to costs, expenses and fees incurred prior to the effective date of expiration; Section 4.8 ("Regulatory Dependencies"), only with respect to Marketing Approvals for the Territory Combination Products in Janssen Reliant Countries where Janssen is conducting Commercialization Activities on the effective date of expiration; Article 5 (Medical Affairs; Conferences); Section 6.2.3 ("Performance; Subcontracting"), other than clauses (i) and (ii) thereof; Section 6.5 ("Third Party Distributors"), only the first sentence; Section 6.6.1 ("Distribution Activities"); Section 6.8 ("Selection and Use of Trademarks"); Section 6.16 ("Janssen Distributor Agreement"); Section 8.1.3 ("Adjustments"), with respect to any RPV supplied prior to the effective date of expiration; Section 8.2.2 ("Supply of Territory Combination Products to Janssen"); Section 8.4 ("Additional Requirements"); Sections 9.1.1 and 9.1.2 ("Combination Product Development Activities and Commercialization Activities" and "Combination Product Manufacturing") in each case, only as specified therein and in Section 19.6.4; Section 9.1.3 ("To Janssen"); Sections 9.2.1 and 9.2.2 ("Rights of Reference and Related Rights; to Gilead; to Janssen"), in each case, only as specified therein and in Section 19.6.4; Section 9.2.3 ("Data Exclusivity"); Sections 9.3.1 and 9.3.2 ("Sublicenses; for Manufacturing; for Development or Commercialization Activities"), in each case, only as specified in Section 19.6.4; Section 9.3.3 ("Limitations on Third Party Distributors"); Section 9.3.4 ("Sublicenses; to Affiliates"), as this provision relates to the sublicense of other licenses or other rights granted under Article 9 and solely as such Article relates to surviving licenses or other rights; Section 9.4 ("Trademark Licenses"), only in Section 19.6.4; Sections 9.5.1 and 9.5.6 ("Third Party License Payments" and "Payments," in each case, solely to the extent relating to Third Party License Payments that accrued prior to the effective date of expiration or that become due following expiration of this Agreement with regard to any surviving sublicensed rights under any In-License Agreement); Sections 9.5.2 through 9.5.5 ("Existing RPV Licenses," "In-License Requirements," "Additional In-Licenses," "Modifications or Amendments to any In-License Agreement," with regard to any surviving sublicensed rights under any In-License Agreement); Section 9.6 ("Retained Rights"); Section

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10.1.1 (“Payment of Pre-Conversion Supply Price”), with respect to any Supplied RPV delivered prior to the effective date of expiration or, subject to Section 19.6.4, any Supplied RPV provided following the effective date of expiration; Section 10.1.2 (“Monthly Payments”) and Annex M-1 (“Financial Calculations for Post-Conversion Supply Price and Additional Supply Price”), with respect to the Monthly Payment(s) in each of (a) the month in which expiration occurs, and (b) the immediately preceding month, if the due date for any such Monthly Payment did not occur prior to expiration; Section 10.2 (“Post-Conversion and Additional Supply Price Reductions”) and Annex M-2 (“Post-Conversion Supply Price Reductions for Gilead Countries”), with respect to any Supplied RPV used to Manufacture any quantity of Territory Combination Product that is subject to a Triggering Sale prior to the effective date of expiration; Section 10.3 (“Monthly Payment Term”) and Annex M-1 (“Financial Calculations for Post-Conversion Supply Price and Additional Supply Price”), with respect to the Monthly Payment(s) in each of (a) the month in which expiration occurs, and (b) the immediately preceding month, if the due date for any such Monthly Payment did not occur prior to expiration; Section 10.4 (“Mode of Payment”), with respect to any payments that accrued under the Agreement prior to the effective date of expiration or that accrue after the effective date of expiration pursuant to any provision that survives expiration in accordance with this Section 19.7.3; Section 10.5.1 (“Pre-Conversion Supply Price Payments and Revaluation Pre-Conversion Payments”), Annex M-5 (“Payment Terms for Supplied RPV Invoices for Gilead Countries”) and Annex M-6 (“Revaluation of API”), with respect to any Supplied RPV delivered prior to the effective date of expiration and, subject to Section 19.6.4, after the effective date of expiration; Section 10.5.2 (“Monthly Payments”) with respect to the Monthly Payment(s) in each of (a) the month in which expiration occurs, and (b) the immediately preceding month, if the due date for any such Monthly Payment did not occur prior to expiration; Section 10.5.3 (“Monthly Payment Calculation”) and Annex M-1 (“Financial Calculations for Post-Conversion Supply Price and Additional Supply Price”), with respect to Units of Territory Combination Product sold prior to the effective date of expiration; Section 10.5.4 (“Monthly Reports”), Annex M-1 (“Financial Calculations for Post-Conversion Supply Price and Additional Supply Price”) and Annex N (“Financial Reporting”), with respect to Units of Territory Combination Product for which Triggering Sales occurred prior to the effective date of expiration (and any related information required to make revenue share calculations with regard to such Units); Section 10.5.5 (“Lost Supplied RPV”), with respect to Supplied RPV that becomes Lost Supplied RPV during the Calendar Year in which expiration occurs; Section 10.5.6 (“Other Payments”), with respect to any payments that accrued under this Agreement or the RPV Supply Agreement prior to the effective date of expiration or that accrue after the effective date of expiration pursuant to any provision that survives expiration in accordance with this Section 19.7.2 or the RPV Supply Agreement; Section 10.5.7 (“Communication of Non-Public Pricing Information”), to the extent necessary to exchange Net Selling Prices for purposes of calculating payments that accrued under this Agreement prior to the effective date of expiration; Section 10.5.8 (“Other Reports”) and Annex N (“Financial Reporting”), with respect to any obligation under Annex N that survive expiration; Section 10.6 (“Financial Records”), to the extent relating to payments made or accrued prior to expiration of this Agreement and for the period set forth therein; Section 10.7 (“Currency Conversion”), Section 10.8 (“Audits”), Section 10.9 (“Interest Due”) and Section 10.10 (“Tax Withholding”), in each case with regard to payments made or accrued prior to expiration of this Agreement, including payments under any In-License Requirements, final Monthly Payment(s) or payments

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with respect to any surviving sublicensed rights under any In-License Agreement; Section 10.11 ("Manufacturing Fees"); Annex M-3 ("Calculation of Manufacturing Fee Percentage") and Annex M-4 ("Manufacturing Fees"), to the extent necessary to calculate the Manufacturing Fee with respect to Territory Combination Product for which Manufacturing Completion occurred during the Calendar Year in which this Agreement expired and the Janssen Portion thereof (which shall account for such expiration); Section 10.12 ("Branded Prescription Pharmaceutical Manufacturers Fee"), [*]; Article 11 ("Financial Calculations and Adjustments", the Monthly Payment(s) in each of (a) the month in which expiration occurs, and (b) the immediately preceding month, if the due date for any such Monthly Payment did not occur prior to expiration and any amounts payable that are accrued prior to the effective date of expiration; Article 13 ("Pharmacovigilance Agreement; Product Recall and Withdrawal"), solely as it relates to recalls of Territory Combination Product sold during the Term or after expiration as necessary to comply with Applicable Law or any In-License Requirements, except with respect to Section 13.4, which shall survive for the time period set forth therein; Section 14.1 ("Ownership of Intellectual Property"), including all subsections thereof; Section 14.2.1 ("Gilead Patents"); Section 14.2.2 ("Janssen Patents"), only the first and last sentences; Section 14.2.3.2 ("Other Joint Patents"), where all Joint Patents shall be governed by such section following expiration of this Agreement); Section 14.2.3.3; Section 14.2.4 ("Extensions"), except that all Joint Patents shall be governed by the third sentence thereof; Section 14.2.5 ("Orange Book"); Section 14.3 ("Liability for Prosecution and Maintenance"), to the extent that Section 11.1 and 11.2 survive; Section 14.4 ("Enforcement of Patents"), to the extent that any subsections of Section 14.4 survive; Section 14.4.1 ("Effect on In-License Agreements"), Section 14.4.4 and Section 14.4.7 ("Recoveries"), to the extent that Section 14.4.5 survives; Section 14.4.5 ("Joint Patents"); Section 14.4.6 ("Paragraph (iv) Certifications; Notices of Allegation"); Section 14.5.1, solely as it relates to actions under Section 14.4.5; Section 14.5.2, solely with respect to Joint Patents; Section 14.6.1 ("Gilead Licensed Trademarks"); Section 14.6.2 ("Janssen Licensed Trademarks"), Section 14.6.3.1 ("Combination Product Trademarks; Registration"); Section 14.6.3.2 ("Infringement"); Article 15 ("Confidentiality"); Section 16.2 ("Other Public Disclosures"), only with respect to Territory Combination Products; Section 16.3 ("Use of Names"); Section 17.1.9 ("Compliance with Applicable Law"), with respect to any activities performed after the effective date of expiration pursuant to any provision that survives expiration in accordance with this Section 19.7.3; Section 17.1.11 ("Ethical Business Practices"), with respect to any activities performed after the effective date of expiration pursuant to any provision that survives expiration in accordance with this Section 19.7.3; Section 17.1.12 ("Cooperation with In-License Agreement Compliance"), only with regard to any surviving sublicensed rights under any In-License Agreement; Sections 17.2.1 and 17.3.1, which shall each survive for [*]); Section 17.4 ("Disclaimer"); Article 18 ("Indemnification and Insurance"); Section 19.5.1 ("Voluntary Termination of Supply Obligations by Janssen"); Section 19.5.1 ("Voluntary Termination of Supply Obligations by Janssen"); Section 19.6 ("Consequences of Expiration or Termination"); Article 20 ("General Provisions"), the Annexes, to the extent applicable to the other surviving terms of this Agreement; and such other provisions hereof as are required for the interpretation or enforcement of those Articles and Sections; and any other provisions that expressly survive expiration of this Agreement. In addition to the foregoing, to the extent not surviving as described above, the provisions of Article 3 ("Development Activities") and Article 4 ("Regulatory Matters") shall survive solely as required for each Party to comply with

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Applicable Law. If this Agreement expires with respect to fewer than all of the countries in the Territory, then neither Party shall have any rights hereunder to Exploit the Territory Combination Product in the countries for which this Agreement expired, and the Parties' respective rights and obligations under this Agreement as they relate to such expired countries shall remain in effect only as described above in this Section 19.7, but the terms of this Agreement shall remain in full force and effect as they relate to the non-expired countries. Upon expiration of this Agreement with respect to all countries in the Territory, this Section 19.7.3 shall apply to all countries that comprised the Territory. Notwithstanding the definition of Territory Complera or Territory R/F/TAF Product, any license or other rights granted in Article 9 that survive expiration and apply to Territory Combination Product shall apply regardless of the sources of the RPV contained therein.

20 GENERAL PROVISIONS

20.1 Force Majeure . Neither Party shall be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement, except for the payment of any amounts under this Agreement, when such failure or delay is caused by or results from causes beyond the reasonable control of the non-performing Party, including fires, floods, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not), terrorism, insurrections, riots, civil commotion, acts of God or acts, omissions or delays in acting by any governmental authority (each, a " **Force Majeure Event** "). The non-performing Party shall notify the other Party of such Force Majeure Event within five (5) days after such occurrence by giving written notice to the other Party stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is necessary and the non-performing Party shall use, throughout the period of suspension of performance, commercially reasonable efforts to remedy its inability to perform; provided , however , that in the event the suspension of performance continues for ninety (90) days after the date such Force Majeure Event commences, the Parties shall meet to discuss in good faith how to proceed in order to accomplish the objectives of this Agreement. For purposes of this Agreement a Force Majeure Event shall not include a failure to commit sufficient resources, financial or otherwise, to the activities to be conducted pursuant to this Agreement or general market or economic conditions.

20.2 Notice . All notices, requests, reports, statements and other communications to either Party shall be in writing, shall refer specifically to this Agreement and shall be delivered personally, sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, to the following respective addresses (or to such other address as may be specified by notice from time to time by the relevant Party):

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if to Gilead, to:		
		Gilead Sciences, Inc. 333 Lakeside Drive Foster City, CA 94404 Attn: President & Chief Operating Officer
	with copies to:	
		Gilead Sciences, Inc. 333 Lakeside Drive Foster City, CA 94404 Attn: Senior Vice President & General Counsel
if to Janssen, to:		
		Janssen R&D Ireland EastGate Village EastGate, Little Island Co. Cork, Ireland Attn: President
	with copies to:	
		Janssen R&D Ireland EastGate Village EastGate, Little Island Co. Cork, Ireland Attn: Company Secretary
	and	Office of the General Counsel Johnson & Johnson One Johnson & Johnson Plaza New Brunswick, NJ 08933 Attn: General Counsel

Any such communication shall be deemed to have been given (a) when delivered, if personally delivered during the recipient's normal business hours, (b) on the Business Day after dispatch, if sent by nationally-recognized overnight courier and proof of delivery is obtained, and (c) on the third (3rd) Business Day following the date of mailing, if sent by mail. It is understood and agreed that this Section 20.2 is not intended to govern the day-to-day business communications necessary between the Parties in performing their duties, in due course, under the terms of this Agreement. Whenever this Agreement requires or permits the giving of notice by or to Gilead, such notice may be given by or to Gilead Parent on behalf of Gilead.

20.3 Further Assurances . Each Party shall use commercially reasonable efforts to duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further ministerial, administrative or similar acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary, or as the other Party may reasonably request, to carry out more effectively the provisions and

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purposes hereof, or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

20.4 Successors and Assigns . The terms and provisions hereof shall inure to the benefit of, and be binding upon, the Parties and their respective successors and permitted assigns. Except as expressly permitted in this Agreement, neither Party may, without the prior written consent of the other Party, assign or otherwise transfer any of its rights and interests or subcontract or otherwise delegate any of its obligations under this Agreement. Notwithstanding the foregoing, (i) either Party, without such consent, may assign its rights and delegate its duties under this Agreement to an Affiliate which is a directly or indirectly wholly-owned subsidiary of Gilead Parent or Janssen Parent, as the case may be, provided that, except as set forth in clause (ii) below, such assignment or delegation to an Affiliate shall terminate automatically at such time, if any, as such Affiliate ceases to be wholly-owned, directly or indirectly, by Gilead Parent or Janssen Parent, as the case may be, unless such Affiliate owns substantially all the assets of Gilead or Janssen, as the case may be, that are described in clause (ii)(A) of this Section 20.4, respectively, and (ii) each of Gilead and Janssen, without the prior written consent of the other, may assign its rights and delegate its duties under this Agreement, whether by contract or operation of law, (A) to any Third Party that acquires (through the purchase of assets, stock or otherwise) substantially all of the assets of such Party [*], or (B) in connection with a merger or consolidation of (1) in the case of Gilead as the assigning Party, Gilead Parent, or (2) in the case of Janssen as the assigning Party, Janssen, in each case ((1) and (2)), with or into any Third Party, to such Third Party or to the surviving entity in such merger or consolidation with such Third Party. For purposes of clause (ii)(A) of this Section 20.4, "Party" shall refer to the applicable Party and those of its Affiliates that have been or are anticipated to be engaged in the activities hereunder. Any purported assignment, transfer, subcontract or delegation by either Party in violation of the terms of this Section 20.4 shall be null and void and of no legal effect. In the event that a Party delegates any of its obligations under this Agreement to a subcontractor, or makes any other assignment of this Agreement (other than pursuant to clause (ii)(B) above), the delegating or assigning Party shall remain primarily (and not secondarily or derivatively) liable for the full and timely performance by such subcontractor or assignee of all such Party's obligations under this Agreement. For clarity, for purposes of this Agreement, neither Party nor any of its Affiliates shall constitute a subcontractor of the other Party or any of its Affiliates and no activity performed by a Party or its Affiliates shall be deemed performed "on behalf" of the other Party.

20.5 Governing Law . The interpretation, construction and performance of this Agreement, the rights granted and obligations arising hereunder, shall be governed in accordance with the substantive laws of New York, exclusive of its conflicts of law rules. Notwithstanding anything to the contrary herein, the interpretation and construction of any Patents shall be governed in accordance with the laws of the jurisdiction in which such Patents were filed or granted, as the case may be.

20.6 Dispute Resolution .

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20.6.4 Escalation . If the Parties, their Affiliates or the Alliance Managers do not reach agreement with respect to any matter within five (5) Business Days of such matter being referred to them, and such matter (a) relates to or arises out of this Agreement, including any such matter which requires a determination as to the validity (including any claim of inducement of this Agreement by fraud or otherwise), application, interpretation or construction of, or the compliance with or breach of, or termination of this Agreement or any Ancillary Agreement, (b) requires their mutual agreement hereunder or under an Ancillary Agreement, or (c) is designated hereunder or under any Ancillary Agreement for decision by the Parties or their respective Affiliates or the Alliance Managers (a " **Dispute** "), then, unless this Agreement expressly provides otherwise, either Party may refer such Dispute for resolution to the Executives. For clarity, a decision of the Executives shall not constitute an amendment to this Agreement unless executed in writing and signed by the duly authorized representatives of each Party.

20.6.5 Resolution of Dispute Following Escalation . If the Executives do not reach agreement on a Dispute referred to them within ten (10) Business Days after such referral (the " **Executives Review Period** "), then the following provisions of this Section 20.6.2 shall apply.

20.6.5.1 Disputes Subject to Final Decision-Making Authority . Unless (a) this Agreement or any Ancillary Agreement expressly requires the mutual agreement of the Parties or the Alliance Managers with respect to the matter that is the subject of such Dispute, (b) this Agreement or any Ancillary Agreement expressly requires a Party's or its Alliance Manager's consent or approval with respect to the matter that is the subject of such Dispute, (c) the Dispute is an Arbitration Matter or (d) the Dispute is an Expert Dispute or Patent Matter, then (i) subject to any other provisions of this Agreement and any applicable Ancillary Agreement, Gilead shall have final decision-making authority with respect to such Dispute to the extent (x) [*] and (y) Gilead is granted final decision-making authority in Sections 3.6.5, and, for the Gilead Countries, 13.2.2 (regarding the conduct of the applicable recall or withdrawal); (ii) subject to any other provisions of this Agreement and any applicable Ancillary Agreement, including the RPV Supply Agreement, Janssen shall have final decision-making authority with respect to such Dispute to the extent (x) [*] and (y) Janssen is granted final decision-making authority in Sections 3.6.4 and, for the Janssen Countries, 13.2.2 (regarding the conduct of the applicable recall or withdrawal); and (iii) subject to Article 14, each Party shall have final decision-making authority with respect to the prosecution, maintenance, enforcement and defense of its intellectual property. For clarity, Disputes identified in clauses (a), (b) or (d) of this Section 20.6.2.1 shall not be considered Arbitration Matters subject to resolution under Section 20.7.

20.6.5.2 Matters Requiring Mutual Agreement or Consent . If (a) this Agreement or any Ancillary Agreement expressly requires the mutual agreement of the Parties or the Alliance Managers with respect to the matter that is the subject of such Dispute or (b) this Agreement or any Ancillary Agreement expressly requires a Party's or its Alliance Manager's consent or approval with respect to the matter that is the subject of such Dispute, then such Dispute shall remain unresolved to the extent such Dispute requires such mutual agreement,

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consent or approval unless and until the Parties or Alliance Managers reach mutual agreement, or the Party or its Alliance Manager gives its consent or approval, as applicable. For avoidance of doubt, an impasse between the Parties (or the Parties' Alliance Managers) regarding any matter with respect to which a Party (or its Alliance Manager) has the right hereunder to withhold its (or their) consent, in such Party's sole discretion or judgment, or any matter that is otherwise committed to the sole discretion or judgment of a Party hereunder, shall not be subject to arbitration pursuant to Section 20.7. In the event of any such impasse described in clause (a) or (b), no action with respect to such matter shall be taken without the agreement or consent of a Party whose agreement or consent is required hereunder or to whose discretion such action is committed, and no action of one Party that has the right to conduct such action hereunder may be blocked by the other Party unless its agreement or consent thereto is required hereunder.

20.6.5.3 Expert Disputes . If the Dispute is designated in this Agreement or any Ancillary Agreement as an Expert Dispute, then the Parties shall refer the dispute to the applicable primary Expert selected pursuant to Section 20.6.3 or if unavailable, the applicable alternate Expert. Within five (5) Business Days after the applicable Expert is engaged with respect to such Expert Dispute, each Party shall provide such Expert and the other Party with a written summary of such Party's position with respect to the Expert Dispute, along with any relevant evidence in support thereof. The Expert shall make a final decision with respect to the Expert Dispute within five (5) Business Days following receipt of the Parties' written summaries. The decision by the Expert shall be final and binding, and not subject to appeal of any kind.

20.6.5.4 Patent Matters . To the extent the Dispute is a Patent Matter, then either Party may refer such Patent Matter for resolution pursuant to Section 20.8.2.

20.6.5.5 Arbitration Matters . To the extent the Dispute is an Arbitration Matter, then either Party may refer such Arbitration Matter to binding arbitration pursuant to Section 20.7.

20.6.6 Selection of Expert(s) . Within sixty (60) days after the Restatement Effective Date, the Parties shall agree upon a list of one or more mutually acceptable, disinterested, conflict-of-interest free individuals who have expertise relevant to, and knowledge of, matters related to potential Expert Disputes, which individual(s) (a) if agreed by the Parties, may be assigned to one or more categories of Expert Disputes, and (b) to the extent there is more than one of such individuals (if applicable, for any category of Expert Dispute), shall be designated as either a primary Expert or an alternate Expert (each such individual, an " **Expert** ").

20.6.7 Remedies . Nothing in this Section 20.6 is intended to, or shall limit or modify, either Party's rights under Section 15.6 or Section 20.7.8 to seek injunctive relief.

20.7 Arbitration .

20.7.1 Arbitration Matters shall be referred initially to the Executives as provided in Section 20.6. If such Arbitration Matter is not resolved as provided in Section 20.6, then, unless the Parties agree in writing to alternate provisions, such Arbitration Matter shall be

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resolved exclusively through binding arbitration administered by Judicial and Mediation Services " **JAMS** ") (or any successor entity thereto) and in accordance with the Comprehensive Arbitration Rules and Procedures then in effect, except where those rules conflict with these provisions, in which case these provisions control. The arbitration will be held in New York, New York.

20.7.2 The panel shall consist of three arbitrators appointed in accordance with Section 20.7.3 (unless the Parties agree on the selection of the arbitrators), each of whom shall be a lawyer with at least fifteen (15) years' experience with a law firm or corporate law department of over twenty-five (25) lawyers or who was a judge of a court of general jurisdiction. In the event the aggregate damages sought by the claimant are stated to be less than five million U.S. dollars ($5,000,000), and the aggregate damages sought by the counterclaimant are stated to be less than five million U.S. dollars ($5,000,000), and neither side seeks equitable relief, then a single arbitrator shall be chosen in accordance with Section 20.7.3, having the same qualifications and experience specified above. Each arbitrator shall be impartial and independent of the Parties and shall abide by the *Code of Ethics for Arbitrators in Commercial Disputes* (available at http://www.adr.org/EthicsAndStandards).

20.7.3 In the event the Parties cannot agree upon selection of the arbitrator(s), JAMS will select arbitrator(s) as follows: JAMS shall provide the Parties with a list of no less than twenty-five (25) proposed arbitrators (fifteen (15) if a single arbitrator is to be selected) having the credentials referenced above. Within fifteen (15) days of receiving such list, the Parties shall rank at least sixty-five percent (65%) of the proposed arbitrators on the initial JAMS list, after exercising cause challenges. The Parties may then jointly interview the five candidates (three if a single arbitrator is to be selected) with the highest combined rankings for no more than one hour each and, following the interviews, may exercise one peremptory challenge each. The panel will consist of the remaining three candidates (or one, if one arbitrator is to be selected) with the highest combined rankings. In the event these procedures fail to result in selection of the required number of arbitrators, JAMS shall select the appropriate number of arbitrators (having the credentials referenced above), allowing each side challenges for cause and one peremptory challenge each.

20.7.4 The Parties agree to cooperate (i) to attempt to select the arbitrator(s) by agreement within thirty (30) days of initiation of the arbitration, including jointly interviewing the final candidates, (ii) to meet with the arbitrator(s) within thirty (30) days of selection and (iii) to agree at that meeting or before upon procedures for discovery and as to the conduct of the hearing which will result in the hearing being concluded within no more than six (6) months after selection of the arbitrator(s) and in the award being rendered within sixty (60) days of the conclusion of the hearings, or of any post−hearing briefing, which briefing will be completed by both sides within thirty (30) days after the conclusion of the hearings.

20.7.5 In the event the Parties cannot agree upon procedures for discovery and conduct of the hearing that meet the schedule set forth in Section 20.7.4, then the arbitrator(s) shall set dates for the hearing, any post−hearing briefing, and the issuance of the award following the schedule set forth in Section 20.7.4 as closely as practical. The arbitrator(s) shall provide for

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discovery according to those time limits, giving recognition to the understanding of the Parties that they contemplate reasonable discovery, including document demands and depositions, but that such discovery will be limited so that the schedule set forth in Section 20.7.4 may be met without difficulty. In no event will the arbitrator(s), absent agreement of the Parties, allow more than ten (10) days for the hearing. Multiple hearing days will be scheduled consecutively to the greatest extent possible. The arbitrator(s) shall have power to exclude evidence on grounds of hearsay, prejudice beyond its probative value, redundancy, or irrelevance and no award shall be overturned by reason of any ruling on evidence. A transcript of the testimony adduced at the hearing shall be made and shall, upon request, be made available to either Party.

20.7.6 The arbitrator(s) are expressly empowered to decide dispositive motions in advance of any hearing, including but not limited to motions to dismiss and motions for summary judgment, and shall endeavor to decide such motions as would a federal district judge sitting in the State of New York.

20.7.7 The arbitrator(s) shall decide the issues presented in accordance with the governing law set forth in Section 20.5. The arbitrator(s) shall render a written opinion stating the reasons upon which the award is based. To the extent possible, the arbitration hearings and award will be maintained in confidence.

20.7.8 Nothing in this Agreement, including this Section 20.7, shall preclude either Party from seeking interim or provisional relief, including a temporary restraining order, preliminary injunction or other interim equitable relief concerning a Dispute with the other Party, either prior to or during the dispute resolution procedures set forth in this Section 20.7, if necessary to protect the interests of such Party.

20.7.9 EACH PARTY HERETO WAIVES ANY CLAIM OF DAMAGES TO THE EXTENT THAT SUCH DAMAGES ARE PRECLUDED PURSUANT TO SECTION 18.8.

20.7.10 EACH PARTY HERETO WAIVES ANY CLAIM FOR ATTORNEYS' FEES AND COSTS FROM THE OTHER (but for clarity, such waiver is not intended to limit a Party's right to indemnification for Proceedings and Losses under Article 18).

20.7.11 EACH PARTY HERETO WAIVES ITS RIGHT TO TRIAL OF ANY ISSUE BY JURY.

20.8 Consent to Jurisdiction .

20.8.1 Each Party, for the purpose of enforcing an award under Section 20.7 or for seeking interim or provisional relief as contemplated in Section 20.7.8 with respect to any breach of this Agreement or any Ancillary Agreement, (i) irrevocably submits to the exclusive (or in the case of such interim or provisional relief or the enforcement of judgments or court orders, non-exclusive) jurisdiction of the federal and state courts located in the City of New York, State of New York (the " **Court** "), and (ii) agrees not to raise any objection at any time to the laying or maintaining of the venue of any action, suit or proceeding for such purpose in any

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such Court, irrevocably waives any claim that such action, suit or other proceeding has been brought in an inconvenient forum, including any forum non conveniens argument, and further irrevocably waives the right to object, with respect to such action, suit or other proceeding, that such Court does not have any jurisdiction over such Party. Each Party further agrees that service of any process, summons, notice or document by U.S. registered mail to such Party's notice address provided for in this Agreement shall be effective service of process for any action, suit or proceeding in the Court with respect to any matters to which it has submitted to jurisdiction in this Section 20.8.1.

20.8.2 Notwithstanding anything in this Agreement to the contrary, any Patent Matter with respect to a given Patent shall be subject to adjudication in accordance with the laws of the country in which such Patent is pending or has been issued. The Parties agree that the venue of any such adjudication involving a Patent pending in or issued by the United States shall be a U.S. federal district court sitting in the City of New York, State of New York, and for a Patent pending in or issued by any other country, any competent court having jurisdiction over the subject of the Patent Matter sitting in the capital of such country (or if there is not any such competent court in the capital, a location reasonably proximate to the capital) and each Party irrevocably submits to the jurisdiction of such court. Each Party agrees not to raise any objection at any time to the laying or maintaining of the venue of any action, suit or proceeding for such purpose in any such court, irrevocably waives any claim that such action, suit or other proceeding has been brought in an inconvenient forum, including any forum non conveniens argument, and further irrevocably waives the right to object, with respect to such action, suit or other proceeding, that such court does not have any jurisdiction over such Party.

20.9 Waiver . A Party's failure to enforce, at any time or for any period of time, any provision of this Agreement, or to exercise any right or remedy, does not constitute a waiver of such provision, right or remedy, or prevent such Party thereafter from enforcing any or all provisions and exercising any or all rights and remedies. The exercise of any right or remedy does not constitute an election or prevent the exercise of any or all rights or remedies, all rights and remedies being cumulative.

20.10 Severability . If any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect, then, to the fullest extent permitted by Applicable Law, (a) all other provisions hereof shall remain in full force and effect and shall be liberally construed in order to carry out the intent of the Parties as nearly as may be possible, and (b) the Parties agree to use commercially reasonable efforts to negotiate a provision, in replacement of the provision held invalid, illegal or unenforceable, that is consistent with Applicable Law and accomplishes, as nearly as possible, the original intention of the Parties with respect thereto.

20.11 Counterparts . This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, and all of which, taken together, shall constitute one and the same instrument.

20.12 Construction . Except where the context otherwise requires, wherever used the singular shall include the plural, the plural the singular, and the use of any gender shall be applicable to all genders. The words "hereof" and "hereunder", and words of similar import,

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shall be construed to refer to this Agreement (including the Annexes hereto) as an entirety and not to any particular provision. The word "including" as used herein shall mean, including, without limiting the generality of any description preceding such term. Thus, e.g., "including" shall be interpreted as meaning "including without limitation" or "including but not limited to", regardless of whether the words "without limitation" or "but not limited to" actually follow the term "including". Similarly, the terms "such as", "for example", and "e.g." shall be understood as referring to non-limiting illustrations or examples. The word "or" is used in the inclusive sense (and/or). Any reference to a supranational, national, federal, state, local, or foreign statute or law shall be understood to refer to the applicable version of the law or statute then in force (as it may have been amended or superseded) as well as all rules and regulations promulgated thereunder, unless the context requires otherwise. All references to "dollars" or "$" shall mean United States dollars, and all references to "€" shall mean Euros. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. Any reference in this Agreement to a matter or action being subject to the "mutual agreement" or "mutual consultation" of the Parties, or words of similar import, shall not be construed as an agreement that the Parties shall agree to such matter or action. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party.

20.13 Status of the Parties . Neither Party shall have the right to enter into any agreements or take action on behalf of the other Party, nor shall it represent to any Person that it has any such right or authority. Nothing in this Agreement shall be construed as establishing a partnership or joint venture relationship between the Parties.

20.14 Entire Agreement .

20.14.1 Subject to Section 11.10, as of the Restatement Effective Date, this Agreement shall amend and restate in its entirety the Original Agreement; provided , however , that, except as provided in Section 20.17, such amendment and restatement shall not affect any rights or obligations of the Parties that accrued under the Original Agreement prior to the Restatement Effective Date. For clarity, (i) the provisions of this Agreement with respect to TAF, including any provisions of this Agreement with respect to the R/F/TAF Product, shall have no application to any period prior to the Restatement Effective Date and (ii) except as provided in Section 20.17, the provisions of this Agreement to the extent different from the provisions of the Original Agreement shall have no application to any period prior to the Restatement Effective Date.

20.14.2 Subject to Section 20.14.1, this Agreement (including the Annexes hereto), together with the Ancillary Agreements executed on or before the Restatement Effective Date by the Parties that remain in effect after the Restatement Effective Date, constitutes, on and as of the Restatement Effective Date, the entire agreement of the Parties with respect to the subject matter hereof, and all prior or contemporaneous understandings or agreements between Gilead, on the one hand, and Janssen, on the other hand, whether written or oral, with respect to such subject matter are hereby superseded in their entireties; provided , however , that (a) the

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CDA shall be superseded solely to the extent applicable to the subject matter of this Agreement and (b) certain other agreements and side letters shall terminate, remain in effect or be modified as separately mutually agreed by the Parties in a written instrument dated as of the date hereof. This Agreement shall not be amended in any respect whatsoever except by a further agreement, in writing, fully executed by Gilead and Janssen.

20.15 Third Parties . Except as set forth in Article 18 as to those Third Parties expressly referred to therein, the agreements, covenants, warranties and representations contained herein are for the benefit of the Parties only and are not for the benefit of any Third Parties.

20.16 Guarantee . Janssen shall cause Janssen Pharmaceutica NV to deliver to Gilead a letter in substantially the form of Annex U-1 , and Gilead Parent shall deliver to Janssen, a letter in substantially the form of Annex U-2 , in each case confirming that the guarantee agreement delivered by it under the Original Agreement covers this Agreement.

20.17 Prior Diligence . Janssen agrees not to assert any claim that Gilead failed to used Commercially Reasonable Efforts to conduct any activities that it was required to use Commercially Reasonable Efforts to conduct under the Original Agreement prior to the Restatement Effective Date.

[Signatures on following page]

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IN WITNESS WHEREOF, the Parties have caused this Amended & Restated Collaboration Agreement to be duly executed and delivered as of the date first above written.

JANSSEN R&D IRELAND

By: /s/ Margaret Dunlea
Name: Margaret Dunlea
Title: Managing Director

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IN WITNESS WHEREOF, the Parties have caused this Amended & Restated Collaboration Agreement to be duly executed and delivered as of the date first above written.

GILEAD SCIENCES, INC.

By: /s/ John F. Milligan
Name: John F. Milligan, Ph.D.
Title: President and Chief Operating Officer

GILEAD SCIENCES IRELAND UC

By: /s/ John F. Milligan
Name: John F. Milligan, Ph.D.
Title: Director

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ANNEXES

to

AMENDED AND RESTATED COLLABORATION AGREEMENT

(Complera and the R/F/TAF Product)

These annexes (these " **Annexes** ") are attached to and form part of the Amended and Restated Collaboration Agreement (Complera and the R/F/TAF Product) by and among Gilead Sciences, Inc., Gilead Sciences Ireland UC (formerly Gilead Sciences Limited) and Janssen R&D Ireland, dated as of December 23, 2014 as may be amended from time to time (the " **Collaboration Agreement** "). Capitalized terms used in these Annexes and not otherwise defined herein shall have the meanings ascribed thereto in the Collaboration Agreement. Unless otherwise specified, the term "Section" refers to the specified Section of the Collaboration Agreement.

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Annexes

Annex A-1	-	Gilead Licensed Trademarks
Annex A-2	-	Janssen Licensed Trademarks
Annex B-1	-	Gilead Patents
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Annex H	-	Calculation of Working Percentages
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Annex M-1	-	Financial Calculations for Post-Conversion Supply Price and Additional Supply Price
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Annex S-1	-	Gilead Restatement Effective Date Press Release
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Annex T	-	Compliance with Laws
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Annex CC	-	[Reserved]
Annex DD	-	[Reserved]

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Annex EE	-	Planned or Possible R/F/TAF Product Clinical Studies
Annex FF	-	Co-Detailing Countries
Annex GG-1	-	GS 7340; Tenofovir Alafenamide Fumarate
Annex GG-2	-	Tenofovir Disoproxil Fumarate
Annex GG-3	-	Emtricitabine
Annex GG-4	-	Rilpivirine
Annex GG-5	-	3TC
Annex GG-6	-	[Reserved]
Annex HH	-	Ongoing Edurant Studies
Annex II	-	Rights of Reference
Annex JJ	-	Registration Plan
Annex KK	-	Insurance Requirements

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Annex A-1: Gilead Licensed Trademarks

Janssen Countries

COUNTRY	VIREAD	EMTRIVA	TRUVADA
[*]	[*]	[*]	[*]
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[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
Hong Kong	Reg. No. 300139239	Reg. No. 300093140	Reg. No. 300265220
[*]	[*]	[*]	[*]
Israel	Reg. No. 169682	Reg. No. 167429	Reg. No. 174244
[*]	[*]	[*]	[*]
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[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
Mexico	Reg. No. 696914	Reg. No. 819568	Reg. No. 859177
Russia	Int'l Reg. No. 822747	Reg. No. 293835	Int'l Reg. No. 834700
[*]	[*]	[*]	[*]
Singapore	Int'l Reg. No. 822747	Reg. No. T03/16592G	Int'l Reg. No. 834700
South Korea	Int'l Reg. No. 822747	Reg. No. 606230	Int'l Reg. No. 834700
[*]	[*]	[*]	[*]
Taiwan	Reg. No. 1122967	Reg. No. 1105735	Reg. No. 1150544
[*]	[*]	[*]	[*]
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[*]

[*]	[*]	[*]	[*]
Australia	Reg. No. 859695	Reg. No. 974318	Int'l. Reg. No. 1028912 [*]
Canada	Reg. No. TMA577,635	Reg. No. TMA676,539	Reg. No. TMA677,907
Croatia	Reg. No. Z20040016	Reg. No. Z20031553A	Reg. No. Z20041286
Czech Republic	Unregistered	Reg. No. 264137	Unregistered
Estonia	Unregistered	Reg. No. 40344	Unregistered
European Union*	[*]	Reg. No. 3399466	Reg. No. 3965861
Hungary	Unregistered	Reg. No. 180771	Unregistered
Iceland	Int'l Reg. No. 822747	Reg. No. 951/2003	Int'l Reg. No. 834700
Ireland	Unregistered	Unregistered	Reg. No. 229350
Latvia	Unregistered	Reg. No. M53901	Unregistered
Lithuania	Unregistered	Reg. No. 49985	Unregistered
New Zealand	Reg. No. 706633	Reg. No. 702933	Reg. No. 716561
Norway	Reg. No. 209953	Reg. No. 24467	Int'l Reg. No. 834700
Poland	Unregistered	Reg. No. 177366	Unregistered
Romania	Int'l Reg. No. 822747	Reg. No. 57647	Int'l Reg. No. 834700
Slovak Republic	Unregistered	Reg. No. 207833	Unregistered
Slovenia	Unregistered	Reg. No. 200371487	Unregistered
Switzerland	Reg. No. 485710	Reg. No. 516574	Int'l Reg. No. 834700
Turkey	Int'l Reg. No. 822747	Reg. No. 2003/027845	Int'l Reg. No. 834700
United States	Reg. No. 2,586,295	Reg. No. 2,852,092	Reg. No. 2,915,213

**A European Union trademark registration is fully enforceable in all 28 member countries of the European Union, that is, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden and United Kingdom.*

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Annex A-2: Janssen Licensed Trademarks

Trademark	Country	Status	App or Reg No.
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
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Annex B-1: Gilead Patents

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[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]
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	[*]	[*]	[*]		
	[*]	[*]	[*]	[*]	[*]
	[*]	[*]	[*]		
	Singapore	9900229-7	[*]	61167	3/20/2001
	Taiwan	86110757	[*]	137852	11/27/2001
	Taiwan	89123708	[*]	148523	5/2/2002

[*]	[*]	[*]	[*]	[*]	[*]
[*]	Hong Kong	3102167	[*]	1051360	10/14/2005
	Hong Kong	3102166.1	[*]	1051373	4/7/2006
	Hong Kong	107207.4	[*]	1029793	6/20/2003
	[*]	[*]	[*]	[*]	[*]
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	[*]	[*]	[*]		
	Mexico	808	[*]	233118	12/19/2005
	Singapore	9905738-2	[*]	69439	3/25/2002
	Singapore	200200438-0	[*]	106656	9/29/2006
	Singapore	200200487-7	[*]	106657	12/29/2006
	Taiwan	87112168	[*]	I224103	11/21/2004
	[*]	[*]	[*]		
	Taiwan	93112403	7/24/1998	[*]	11/1/2005

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	[*]	[*]			
	Hong Kong	8112059.5	[*]		
	Hong Kong	6101818.2	[*]	1079122	8/29/2008
	Israel	169243	[*]		
	[*]	[*]	[*]	[*]	[*]
	[*]	[*]	[*]	[*]	[*]
	[*]	[*]	[*]		
	[*]	[*]	[*]		
	Mexico	PA/a/2005/007016	1/13/2004	[*]	[*]
	Mexico	MX/a/2008/015080	1/13/2004		
	Taiwan	93100813	1/13/2004	[*]	[*]
	[*]	[*]	[*]	[*]	[*]
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Annex B-2: Janssen Patents

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[*]	[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
[*]	Argentina		P020103034	[*]	[*]	[*]
JAB1713	ARIPO	[*]	AP/P/2004/002993	[*]	AP1610	8/05/2006
JAB1713	Armenia	[*]	200400304	[*]	6656	24/02/2006
JAB1713	Australia	[*]	2002329238	[*]	2002329238	[*]
JAB1713	Australia	[*]	2002329238	[*]	2002329238	[*]
[*]	[*]	[*]	[*]	[*]		
[*]	[*]	[*]	[*]	[*]		
[*]	[*]	[*]	[*]	[*]	[*]	[*]
JAB1713	Azerbaijan	[*]	200400304	[*]	6656	24/02/2006
JAB1713	Belarus	[*]	200400304	[*]	6656	24/02/2006
[*]	[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]		
[*]	[*]	[*]	[*]	[*]		
JAB1713	Botswana	[*]	AP/P/2004/002993	[*]	AP1610	8/05/2006
JAB1713	Brazil	[*]	PI0211909-9	[*]		
[*]	[*]	[*]	[*]	[*]		
[*]	[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]		
JAB1713	Canada	[*]	2452217	[*]	2452217	[*]
JAB1713	Chile		2002-1801	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
JAB1713	China	[*]	2815920.9	[*]	[*]	[*]
JAB1713	Croatia	[*]	P20040096A	[*]	[*]	[*]
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JAB1713	Eurasia	[*]	200400304	[*]	6656	24/02/2006
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JAB1713	Hong Kong	[*]	5102760.9	[*]	HK1070066	[*]
[*]	[*]	[*]	[*]	[*]		
JAB1713	Hungary	[*]	P0401346	[*]		
JAB1713	India	[*]	00265/DELNP/2004	[*]	222987	29/08/2008
JAB1713	India	[*]	715/DELNP/2008	[*]		
JAB1713	Indonesia	[*]	W00200400257	[*]	[*]	[*]
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[*]	[*]	[*]	[*]	[*]	[*]	[*]
JAB1713	Israel	[*]	160328	[*]	[*]	[*]
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[*]	[*]	[*]	[*]	[*]	[*]	[*]
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[*]	[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
JAB1713	Japan	[*]	521229/03	[*]		
JAB1713	Jordan		74/2002	[*]		
JAB1713	Kazakhstan	[*]	200400304	[*]	6656	24/02/2006
JAB1713	Kenya	[*]	AP/P/2004/002993	[*]	AP1610	8/05/2006
JAB1713	Korea S.	[*]	10-2007-7022611	[*]	[*]	[*]
JAB1713	Korea S.	[*]	10-2004-7000372	[*]	817453	21/03/2008
[*]	[*]	[*]	[*]	[*]	[*]	[*]
JAB1713	Kyrgyzstan	[*]	200400304	[*]	6656	24/02/2006
[*]	[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
JAB1713	Lebanon		6533	[*]	6533	[*]
JAB1713	Lesotho	[*]	AP/P/2004/002993	[*]	AP1610	8/05/2006
[*]	[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
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[*]	[*]		[*]	[*]		
[*]	[*]	[*]	[*]	[*]	[*]	[*]
JAB1713	Malawi	[*]	AP/P/2004/002993	[*]	AP1610	8/05/2006
JAB1713	Malaysia		PI20022969	[*]		
JAB1713	Malaysia	[*]	PI20071005	[*]		
JAB1713	Mexico	[*]	MX/a/2008/012940	[*]	[*]	[*]
JAB1713	Mexico	[*]	PA/A/2004/001401	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
JAB1713	Moldova	[*]	200400304	[*]	6656	24/02/2006
[*]	[*]	[*]	[*]	[*]	[*]	[*]
JAB1713	Mozambique	[*]	AP/P/2004/002993	[*]	AP1610	8/05/2006
[*]	[*]	[*]	[*]	[*]		
[*]	[*]	[*]	[*]	[*]		
[*]	[*]	[*]	[*]	[*]	[*]	[*]
JAB1713	New Zealand	[*]	530951	[*]	[*]	9/02/2006
[*]	[*]	[*]	[*]	[*]	[*]	[*]
JAB1713	Norway	[*]	20083770	[*]		
JAB1713	Norway	[*]	20040633	[*]	[*]	[*]

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[*]	[*]	[*]	[*]	[*]	[*]	[*]
JAB1713	OAPI	[*]	1200400047	[*]	12652	24/12/2004
JAB1713	Pakistan	[*]	0991/2006	[*]	[*]	[*]
JAB1713	Pakistan	[*]	0993/2006	[*]	[*]	[*]
JAB1713	Pakistan		0719/02	[*]	[*]	[*]
JAB1713	Panama		85529	[*]	85529	9/08/2005
[*]	[*]		[*]	[*]		
[*]	[*]	[*]	[*]	[*]		
JAB1713	Philippines	[*]	1-2004-500066	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]		
[*]	[*]	[*]	[*]	[*]		
JAB1713	Poland	[*]	P368270	[*]	[*]	[*]
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[*]	[*]	[*]	[*]	[*]	[*]	[*]
JAB1713	Russia	[*]	200400304	[*]	6656	[*]
JAB1713	Russia	[*]	200400304	[*]	6656	[*]
JAB1713	Sierra Leone	[*]	AP/P/2004/002993	[*]	AP1610	[*]
JAB1713	Singapore	[*]	200400698-7	[*]	102384	[*]
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[*]	[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
JAB1713	South Africa	[*]	2004/1159	[*]	2004/1159	27/07/2005
[*]	[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
JAB1713	Sri Lanka	[*]	13257	[*]	13257	29/04/2005
JAB1713	Sudan	[*]	AP/P/2004/002993	[*]	AP1610	8/05/2006
JAB1713	Swaziland	[*]	AP/P/2004/002993	[*]	AP1610	8/05/2006
[*]	[*]	[*]	[*]	[*]	[*]	[*]
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[*]	[*]	[*]	[*]	[*]	[*]	[*]
JAB1713	Taiwan	[*]	91118061	[*]		
JAB1713	Taiwan	[*]	95115978	[*]	[*]	[*]
JAB1713	Taiwan	[*]	95104654	[*]	[*]	[*]
JAB1713	Taiwan		91118061	[*]	[*]	11/02/2007
JAB1713	Tajikistan	[*]	200400304	[*]	6656	24/02/2006
JAB1713	Tanzania	[*]	AP/P/2004/002993	[*]	AP1610	8/05/2006
JAB1713	Thailand		75758	[*]		
JAB1713	Trinidad & Tobago	[*]	TT/A/2012/00023	[*]		
[*]	[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
JAB1713	Turkmenistan	[*]	200400304	[*]	6656	24/02/2006
JAB1713	Uganda	[*]	AP/P/2004/002993	[*]	AP1610	8/05/2006
JAB1713	Ukraine	[*]	2004031903	[*]	78221	15/03/2007
[*]	[*]	[*]	[*]	[*]		
[*]	[*]	[*]	[*]	[*]		
[*]	[*]	[*]	[*]	[*]	[*]	[*]
JAB1713	USA	[*]	12/168540	[*]	[*]	[*]
JAB1713	USA	[*]	11/474855	[*]	[*]	[*]
JAB1713	USA	[*]	11/219163	[*]	[*]	[*]
JAB1713	USA	[*]	10/485636	[*]	7125879	[*]
JAB1713	Venezuela		2002-001546	[*]		
JAB1713	Vietnam	[*]	1-2011-03318	[*]		
[*]	[*]	[*]	[*]	[*]	[*]	[*]
JAB1713	Zambia	[*]	AP/P/2004/002993	[*]	AP1610	8/05/2006
JAB1713	Zimbabwe	[*]	AP/P/2004/002993	[*]	AP1610	8/05/2006

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[*]	[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
PRD2428	ARIPO	[*]	AP/P/2007/003934	2/09/2005	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
PRD2428	Australia	[*]	2005279158	22/06/2012	[*]	[*]
PRD2428	Australia	[*]	2005279158	2/09/2005	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
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[*]	[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
PRD2428	Brazil	[*]	PI0514871-5	[*]		
[*]	[*]	[*]	[*]	[*]	[*]	[*]
PRD2428	Canada	[*]	2577288	[*]	[*]	[*]
PRD2428	China	[*]	200580038025.X	[*]		
PRD2428	Colombia	[*]	7023428	[*]		
PRD2428	Costa Rica	[*]	9031	[*]		
[*]	[*]	[*]	[*]	[*]	[*]	[*]
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[*]	[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
PRD2428	Ecuador	[*]	07-7288-PCT	[*]		
PRD2428	Egypt	[*]	PCT/215/2007	[*]		
PRD2428	EPO		5108086.9	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]		
[*]	[*]	[*]	[*]	[*]	[*]	[*]
PRD2428	Eurasia	[*]	200700536	[*]	[*]	[*]
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[*]	[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
PRD2428	Hong Kong		8103101.2	[*]		
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[*]	[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]

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[*]	[*]	[*]	[*]	[*]	[*]	[*]
PRD2428	India	[*]	1646/DELNP/2007	[*]		
PRD2428	Indonesia	[*]	W00200700682	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
PRD2428	Israel	[*]	181650	[*]		
[*]	[*]	[*]	[*]	[*]	[*]	[*]
PRD2428	Japan	[*]	528886/07	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
PRD2428	Korea S.	[*]	10-2007-7006837	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]		
[*]	[*]	[*]	[*]	[*]	[*]	[*]
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[*]	[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
PRD2428	Mexico	[*]	[*]	[*]	[*]	[*]
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[*]	[*]	[*]	[*]	[*]	[*]	[*]
PRD2428	New Zealand	[*]	553323	[*]	[*]	[*]
PRD2428	Nicaragua	[*]	2007-000068	[*]		
PRD2428	Norway	[*]	20071745	[*]		
PRD2428	OAPI	[*]	1200700088	[*]	[*]	[*]
[*]	[*]		[*]	[*]		
PRD2428	Philippines	[*]	1-2007-500460	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
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[*]	[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
PRD2428	Singapore	[*]	200701584-5	[*]	[*]	[*]
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[*]	[*]	[*]	[*]	[*]	[*]	[*]
PRD2428	South Africa	[*]	2007/01828	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
PRD2428	Sri Lanka	[*]	14407	[*]		
[*]	[*]	[*]	[*]	[*]	[*]	[*]
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[*]	[*]	[*]	[*]	[*]	[*]	[*]
PRD2428	Trinidad & Tobago	[*]	TT/A/2007/00047	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
PRD2428	Ukraine	[*]	a200701971	[*]	[*]	[*]
PRD2428	USA	[*]	11/219163	[*]	[*]	[*]
PRD2428	Vietnam	[*]	1-2007-00581	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]	[*]
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[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]
TIP0058	A.R.I.P.O.	AP/P/2006/003551	[*]	[*]	[*]
TIP0058	Argentina	P040103173	[*]		
TIP0058	Australia	2004268390	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]
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[*]	[*]	[*]	[*]	[*]	[*]
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TIP0058	Brazil	PI0414027-3	[*]		
[*]	[*]	[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]
TIP0058	Canada	2537095	[*]	[*]	[*]
[*]	[*]	[*]	[*]	[*]	[*]
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TIP0058	Chile	20042237	[*]		
[*]	[*]	[*]	[*]	[*]	[*]
TIP0058	China P.R.	200480025426.7	[*]	[*]	[*]
[*]	[*]	[*]	[*]		
TIP0058	Eurasia	200600522	[*]	[*]	[*]
TIP0058	EPO	4787096.9	[*]		
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TIP0058	Hong Kong	6113340.4	[*]		
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TIP0058	Israel	173438	[*]		
[*]	[*]	[*]	[*]		
TIP0058	India	687/DELNP/2006	[*]		

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[*]	[*]	[*]	[*]	[*]	[*]
TIP0058	Japan	525150/06	[*]	[*]	[*]
[*]	[*]	[*]	[*]		
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TIP0058	South Korea	10-2006-7003074	[*]		
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TIP0058	Mexico	PA/A/2006/002437	[*]	[*]	[*]
TIP0058	Malaysia	PI20043578	[*]		
[*]	[*]	[*]	[*]	[*]	[*]
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TIP0058	Norway	20061374	[*]	[*]	[*]
TIP0058	New Zealand	545306	[*]	[*]	[*]
TIP0058	O.A.P.I	1200600074	[*]	[*]	[*]
TIP0058	Philippines	1-2006-500349	[*]		
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TIP0058	Thailand	401003410	[*]		
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TIP0058	Taiwan	93126446	[*]	[*]	[*]
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TIP0058	United States	10/570228	[*]		
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[*]	[*]	[*]	[*]	[*]	[*]
TIP0058	South Africa	2006/01820	[*]	[*]	[*]
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Annex C: Alliance Managers as of the Restatement Effective Date

Gilead *Janssen*

Alliance Manager	**Alliance Manager**
[*]	[*]

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Annex D: [Reserved]

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Annex E: [Reserved]

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Annex F: Required Minimum Details

1. Minimum Details .

(a) Territory Complera . For each Detailing Major Market, for each applicable Detailing Year, through the Calendar Quarter that includes the last day of the applicable Complera Launch Period, Gilead shall perform the number of Details of Territory Complera in such Detailing Major Market as set forth below (which amounts shall be prorated for any partial Detailing Year) (" **Minimum Details** "):

i. United States [*]
ii. France [*]
iii. Germany [*]
iv. Italy [*]
v. Spain [*]
vi. United Kingdom [*]

For clarity, under the Original Agreement, the Minimum Details obligations set forth in this Section 1(a) for the following countries applied retroactively as follows: (a) for [*], the Minimum Details obligation of [*] shall apply retroactively beginning with the first Calendar Quarter of 2014; prior to that, a Minimum Details obligation of [*] applied retroactively beginning with the fourth Calendar Quarter of 2012; and (b) for [*], the Minimum Details obligation shall apply retroactively beginning with the first Calendar Quarter of 2012.

(b) Territory R/F/TAF Product . In the R/F/TAF Launch Period, Gilead shall perform [*] Details of the Territory R/F/TAF Product in [*].

(c) " **Detailing Major Market** " shall mean (i) with respect to Territory Complera, each Major Market other than [*] and (ii) with respect to the Territory R/F/TAF Product, [*].

2. Records and Reports . Gilead shall require its sales representatives who Detail Territory Complera or the Territory R/F/TAF Product, as applicable, to keep records of their Detailing efforts made during each Detailing Year (and during any period in which Gilead is making up for any shortfall in such efforts) in accordance with industry standards for each Detailing Major Market and sufficient to determine whether or not the required number of Details of Territory Complera or the Territory R/F/TAF Product, as applicable, are achieved and that the requirements of Section 6.2.2.3 are satisfied. Gilead shall, and shall cause its Affiliates and its and their sublicensees to, retain such records for two (2) years after the end of the applicable Detailing Year (or such shortfall make-up period, if applicable) to which such records pertain. Within thirty (30) days after the end of each Detailing Year, Gilead shall provide Janssen with a written report stating the number of Details of each such product for each applicable Detailing Major Market.

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3. Audit . With reasonable advance notice and not more often than once each Calendar Year for each Detailing Major Market and no later than two (2) years after the end of applicable Detailing Year (or such shortfall make-up period, if applicable), Janssen may audit Gilead's records in order to verify (a) the number of Details of Territory Complera and/or the Territory R/F/TAF Product in each Calendar Quarter of a Detailing Year made by Gilead in the applicable Detailing Major Market applicable to meeting the requirements of this Annex F and (b) whether or not the other requirements of Section 6.2.2.3 are satisfied. Any such audit shall be conducted during normal business hours at Gilead's facilities by a reputable independent Third Party selected by Janssen and reasonably acceptable to Gilead (the " **Auditor** "). Such Auditor shall sign a confidentiality agreement in a form reasonably satisfactory to Gilead, and shall not disclose to Janssen or any other person any information, except the number of Details of each such product made by Gilead per Detailing Major Market for each applicable Calendar Quarter of a Detailing Year determined by such audit, and the Auditor's findings as to whether or not the other requirements of Section 6.2.2.3 are satisfied. Such audit shall be at Janssen's expense, unless the Auditor determines (absent manifest error on the part of the Auditor) that Gilead incorrectly (i) over-reported the number of Details of Territory Complera and/or the Territory R/F/TAF Product made by Gilead for the applicable Detailing Major Market and Detailing Year and did not meet the applicable number of Details required for such product, Detailing Major Market and Detailing Year, and/or (ii) reported meeting the requirements of Section 6.2.2.3, in either of which cases Gilead shall be responsible for reimbursing Janssen for the fees and expenses charged by the Auditor in connection with such audit that are applicable to such product, Detailing Major Market and Detailing Year.

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Annex G: [Reserved]

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Annex H: Calculation of Working Percentages

1. Complera Working Percentage

For each Calendar Year, a working percentage for Complera for each Party shall be established for the Territory as a whole (each a "**Complera Working Percentage**") in accordance with this Annex H.

For each Calendar Year (commencing as of February 15th of such Calendar Year, and the prior Calendar Year's Working Percentages shall remain in effect until such date):

(a) the Complera Working Percentage of Janssen shall equal the Complera Actual Percentage of Janssen for the prior Calendar Year; and

(b) the Complera Working Percentage of Gilead shall equal the Complera Actual Percentage of Gilead for the prior Calendar Year.

Such Complera Working Percentages shall be calculated by Gilead and notified to Janssen no later than February 15th of such Calendar Year.

2. R/F/TAF Product Working Percentage

For each Calendar Year, a working percentage for the R/F/TAF Product for each Party shall be established for the Territory as a whole (each an "**R/F/TAF Product Working Percentage**") in accordance with this Annex H.

A. Prior to First Commercial Sale

For each Calendar Year up to and including the Calendar Year in which First Commercial Sale of the R/F/TAF Product in the Territory occurs:

(a) the R/F/TAF Product Working Percentage of Gilead shall equal one hundred percent minus the R/F/TAF Product Working Percentage of Janssen; and

(b) the R/F/TAF Product Working Percentage of Janssen shall equal [*].

Such R/F/TAF Product Working Percentages for a given Calendar Year shall be calculated by Gilead and notified to Janssen as promptly as practicable thereafter.

B. After First Commercial Sale

For each Calendar Year after the Calendar Year in which the First Commercial Sale of the R/F/TAF Product in the Territory occurs (commencing as of February 15th of such post-First Commercial Sale Calendar Year, and the prior Calendar Year's R/F/TAF Product Working Percentages shall remain in effect until such date):

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(a) the R/F/TAF Product Working Percentage of Janssen shall equal the R/F/TAF Product Actual Percentage of Janssen for the prior Calendar Year, and

(b) the R/F/TAF Product Working Percentage of Gilead shall equal the R/F/TAF Product Actual Percentage of Gilead for the prior Calendar Year.

Such R/F/TAF Product Working Percentages shall be calculated by Gilead and notified to Janssen no later than February 15 th of such Calendar Year.

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Annex I: Calculation of Actual Percentages

For each Calendar Year, an actual percentage for each Party shall be established for the Territory as a whole, for each Territory Combination Product (each an " **Actual Percentage** ") in accordance with this Annex I.

1. For each Calendar Year up to and including the Calendar Year prior to the Calendar Year in which First Commercial Sale of the applicable Territory Combination Product in the Territory occurs, the Actual Percentage of Gilead shall equal the Working Percentage of Gilead for such Calendar Year and the Actual Percentage of Janssen shall equal the Working Percentage of Janssen for such Calendar Year.

2. For each Calendar Year from and after the Calendar Year in which First Commercial Sale of the applicable Territory Combination Product in the Territory occurs:

(a) the Actual Percentage of Janssen for such Calendar Year shall equal [*]; and

(b) the Actual Percentage of Gilead for each Territory Combination Product shall equal one hundred percent (100%) less the Actual Percentage of Janssen for such Territory Combination Product for such Calendar Year, (i.e., 100% - Actual Percentage of Janssen for such Calendar Year).

Such Actual Percentages shall be calculated by Gilead and notified to Janssen no later than February 15 th of such Calendar Year.

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Annex J *:* [Reserved]

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Annex K: [Reserved]

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Annex L: [Reserved]

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Annex M-1

Financial Calculations for Post-Conversion Supply Price and Additional Supply Price

Capitalized terms not defined in this Annex M-1 shall have the meanings set forth in the Agreement or in Annex M-2 . The following terms and conditions of this Annex M-1 are subject to Annex M-2 . This Annex M-1 shall apply to Triggering Sales of each Territory Combination Product in Gilead Countries.

A. Post-Conversion Supply Price. [*].

B. [*].

C. [*].

D. [*].

E. [*].

F. [*].

G. Estimated Yield Rate and Annual Yield Rate.

Estimated Yield Rate

" **Estimated Yield Rate** " shall mean, with respect to Supplied RPV supplied for each Territory Combination Product, on a Territory Combination Product-by-Territory Combination Product basis, that number to be used in the calculation of the Post-Conversion Supply Price for such Supplied RPV for the First Calendar Year and each subsequent Calendar Year thereafter in which such Territory Combination Product is sold, to be established as set forth below, taking into account relevant factors, including [*]. The Estimated Yield Rate for Supplied RPV in the applicable Territory Combination Product for a First Calendar Year shall be mutually agreed by the Parties in writing, and thereafter established annually for each upcoming Calendar Year by mutual agreement of the Parties in writing. If the Parties do not agree on (i) an initial Estimated Yield Rate for such Supplied RPV for the applicable Territory Combination Product, by the First Commercial Sale of the applicable Territory Combination Product or (ii) any annual update to each such Estimated Yield Rate, no later than [*] the applicable Dispute shall be referred for resolution to the Manufacturing Executives. If the Manufacturing Executives do not reach agreement on such Estimated Yield Rate within ten (10) Business Days after such referral, then such Dispute shall constitute an Arbitration Matter and the arbitrator shall determine (in accordance with Section 20.7 of the Agreement) such Estimated Yield Rate for the First Calendar Year or other applicable Calendar Year based on the foregoing provisions. Any such Estimated Yield Rate determined by the arbitrator shall be binding on the Parties for such Calendar Year. An Estimated Yield Rate for a given Calendar Year shall be in effect for the applicable full Calendar Year (or the full First Calendar Year, as the case may be); provided , however , that at the reasonable request of Gilead or Janssen, and based on changes in the relevant factors affecting an

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Estimated Yield Rate (e.g.,[*]), the Parties shall update an Estimated Yield Rate for a given Calendar Year, which update shall apply for the remainder of the then-current Calendar Year, but only on a going forward basis for future Monthly Payments and shall not be applied retroactively. For clarity, no adjustments shall be made to a given Calendar Year's Estimated Yield Rate once established, except as provided in the prior sentence, and except as otherwise provided in this Annex M-1 no true-ups or adjustments shall be made to any Monthly Payments (but without limitation of any audit rights set forth herein).

" **First Calendar Year** " shall mean on a Territory Combination Product-by-Territory Combination Product basis, the Calendar Year or portion thereof commencing on the date of First Commercial Sale of such Territory Combination Product in a country of the Territory and ending on the last day of such Calendar Year plus the subsequent Calendar Year.

" **Manufacturing Executives** " shall mean (a) with respect to Janssen, a Senior Vice President of Pharmaceutical Manufacturing or any direct report designated by the foregoing and (b) with respect to Gilead, Gilead Parent's Vice President of Commercial Manufacturing or any direct report designated by the foregoing.

Annual Yield Rate .

" **Input Supplied RPV** " shall mean, with respect to any Calendar Year and with respect to Supplied RPV for the applicable Territory Combination Product, the total of (a) the quantity of such Supplied RPV in Gilead's inventory for such Territory Combination Product (including all work in process for which Manufacturing Completion has not occurred) at the beginning of such Calendar Year, plus (b) the quantity of such Supplied RPV delivered by Janssen (or its Affiliate) and accepted by Gilead during such Calendar Year, minus (c) the quantity of such Supplied RPV for such Territory Combination Product remaining in Gilead's inventory (including all work in process for which Manufacturing Completion has not occurred) at the end of such Calendar Year, minus (d) the quantity of such Supplied RPV that became Unusable Lost RPV during such Calendar Year.

"Manufacturing Completion " means completion of [*].

" **Lost Supplied RPV** " shall mean, with respect to any Calendar Year and with respect to Supplied RPV for the applicable Territory Combination Product,

a) Supplied RPV that becomes lost or destroyed or that otherwise becomes unusable during the storage and handling of such Supplied RPV by Gilead, its Affiliates or contract manufacturers, but, for clarity, excluding any Supplied RPV lost during the Manufacturing Process during such Calendar Year and excluding any Supplied RPV that is determined to have a non-conformity that arose prior to delivery to Gilead or its designee under the RPV Supply Agreement (" **Unusable Lost RPV** "),

b) Supplied RPV included in such Territory Combination Product that is [*].

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H. Adjustment Committee.

As expressly provided in this Annex M-1 , the Alliance Managers shall establish, on behalf of the Parties, an ad hoc committee pursuant to Section 2.4, which shall perform only such functions as are assigned to such committee hereunder. Such committee shall be comprised of the Alliance Manager from each Party, an attorney from each Party and any other representatives appointed by each Party; provided that the attorney representatives shall mutually approve the attendance of any such other representatives in advance of any meeting; provided further that any representatives of a Party's alliance management, finance or legal functions shall be treated as Necessary Personnel and in approving any other such representatives, the attorney representatives shall designate whether representatives should be subject to the rules in the Agreement applicable to Necessary Personnel or Additional Personnel, as applicable, or if such representatives should be subject to any alternate set of restrictions, and each Party shall comply with any such rules or restrictions so designated. Such representatives shall have skills reasonably appropriate to their responsibilities and functions as members of such committee. Each Party shall be responsible for the performance of its representatives on such committee and their compliance with the terms of this Section H of this Annex M-1 . Any issue regarding the functioning of such committee shall be reviewed jointly by the Parties' respective attorney

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representatives. Such committee may meet periodically (which meetings may be conducted by telephone or videoconference, so long as each attendee is able to hear the other attendees) as may be determined by members of such committee to determine such matters as are within the jurisdiction of such committee as set forth in this Annex M-1 . The decisions of such committee shall not be binding, unless the Parties mutually agree on such decisions in writing.

I. Other

1. [*].

2. " **Universal Calendar Month** " shall mean a month during the Term based on the universal calendar system used by Janssen and its Affiliates for internal business purposes; provided that the first Universal Calendar Month for the first Universal Calendar Year shall extend from the Original Effective Date to the end of the then-current Universal Calendar Month and the last Universal Calendar Month shall extend from the first day of such Universal Calendar Month until the effective date of the termination or expiration of the Agreement. For clarity, in no event shall Gilead be required to perform any calculations using Net Selling Price data for any Gilead Compound Product based on a Universal Calendar Month; rather, Gilead shall perform calculations based on the corresponding calendar month (i.e., the calendar month that has the greatest overlap with the applicable Universal Calendar Month).

3. " **Universal Calendar Quarter** " shall mean a quarter of a Universal Calendar Year during the Term based on the universal calendar system used by Janssen and its Affiliates for internal business purposes; provided that the first Universal Calendar Quarter for the first Universal Calendar Year shall extend from the Original Effective Date to the end of the then-current Universal Calendar Quarter and the last Universal Calendar Quarter shall extend from the first day of such Universal Calendar Quarter until the effective date of the termination or expiration of the Agreement. For clarity, in no event shall Gilead be required to perform any calculations using Net Selling Price data for any Gilead Compound Product based on a Universal Calendar Quarter; rather, Gilead shall perform calculations based on the corresponding calendar quarter (i.e., the Calendar Quarter that has the greatest overlap with the applicable Universal Calendar Quarter).

4. " **Universal Calendar Year** " shall mean a year during the Term, based on the universal calendar system used by Janssen and its Affiliates for internal business purposes; provided that the first Universal Calendar Year shall extend from the Original Effective Date to the end of the then-current Universal Calendar Year and the last Universal Calendar Year shall extend

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from the first day of such Universal Calendar Year until the effective date of the termination or expiration of the Agreement. For clarity, in no event shall Gilead be required to perform any calculations using Net Selling Price data for any Gilead Compound Product based on a Universal Calendar Year; rather, Gilead shall perform calculations based on the corresponding calendar year (i.e., the Calendar Year that has the greatest overlap with the applicable Universal Calendar Year).

An example of the calculation of the Post-Conversion Supply Price, the Additional Supply Price, and the Monthly Payment is included below for illustrative purposes only:

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Annex M-2

Post-Conversion Supply Price Reductions for Gilead Countries

The adjustments set forth in this Annex M-2 shall apply to the calculations of the Post-Conversion Supply Price and Additional Supply Price for the Gilead Countries. Capitalized terms not defined in this Annex M-2 are defined in the Agreement or in Annex M-1 .

[*].

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Annex M-3

Calculation of Manufacturing Fee Percentage

Capitalized terms not defined in this Annex M-3 shall have the meanings set forth in the Agreement.

No later than November 30 of the prior Calendar Year, a percentage of the Manufacturing Fee for each Party for the upcoming Calendar Year shall be established for the Territory as a whole (each a " **Manufacturing Fee Percentage** ") in accordance with this Annex M-3 .

[*].

For any Calendar Year prior to or in which the First Commercial Sale of a Territory R/F/TAF Product in the Territory occurs, the Manufacturing Fee Percentage of each Party shall equal the Manufacturing Fee Percentage of such Party with respect to the Territory Complera for such Calendar Year.

[*].

For each Calendar Year and for each Territory Combination Product, the Manufacturing Fee Percentage of Gilead shall equal one hundred percent (100%) minus the Manufacturing Fee Percentage of Janssen for such Calendar Year and such Territory Combination Product.

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Annex M-4

Manufacturing Fees

Capitalized terms not defined in this Annex M-4 shall have the meanings set forth in the Agreement. This Annex M-4 shall apply separately for each Territory Combination Product.

" **Manufacturing Fee** " shall mean [*].

1.1 **Payment of Manufacturing Fees** .

1.1.1 [*]. Janssen shall pay each such invoice within forty-five (45) days following its receipt by Janssen. For clarity, any amounts paid or payable pursuant to this Section 1.1.1 shall be subject to adjustment pursuant to Section 1.1.2 of this Annex M-4 .

1.1.2 Year-End Manufacturing Fee Adjustments . With respect to each Calendar Year, in the event that the aggregate amount invoiced to Janssen pursuant to Section 1.1.1 of this Annex M-4 for its portion of any Manufacturing Fees for a Territory Combination Product in such Calendar Year [*].

1.2 **Activities Covered by the Manufacturing Fee**
The Manufacturing Fee for a given Unit of Territory Combination Product shall include costs and expenses relating solely to the following activities performed by Gilead or a contract manufacturing organization of Gilead (a " **CMO** "), as applicable:

(a) All activities required to receive, store, handle and test Gilead's APIs and Supplied RPV used in the Manufacture of the applicable Territory Combination Product, from the time of delivery of such material to Gilead or, if delivered to a CMO, such CMO through the incorporation of such material into such Territory Combination Product.

(b) All activities required to Manufacture the applicable Territory Combination Product from Gilead's APIs and Supplied RPV through completion of Manufacture of the applicable primary container form (bottle, blister or other) of such Territory Combination Product, including shipment of such Territory Combination Product from a CMO to Gilead; but excluding any secondary packaging and labeling.

1.3 **Categories of Costs and Expenses**
The Manufacturing Fee for a given Unit of the applicable Territory Combination Product shall include costs and expenses in the following categories (but are not limited to such categories):

safety stock storage and handling, materials management, direct labor, maintenance, quality assurance, quality control, Chemistry Manufacturing & Controls, depreciation and site-specific overhead (including finance, information services, human resources, facilities and overall management), packaging materials [*], warehousing, contract administration, manufacturing administration, stability testing, and taking samples, in each case to the extent relating to the activities specified in Section 1.2 of this Annex M-4 .

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Gilead costs not directly allocable to the Manufacture and supply of the applicable Territory Combination Product shall not be included in Manufacturing Fees.

1.4 **Setting of Estimated Manufacturing Fee for a Calendar Year**

For each Territory Combination Product, at least thirty (30) days prior to the beginning of each Calendar Year, Gilead shall provide to Janssen an estimated Manufacturing Fee for such Calendar Year, together with reasonable documentation with respect thereto. Such estimated Manufacturing Fee shall constitute the Manufacturing Fee for purposes of invoicing of the Manufacturing Fee for [*] of the applicable Territory Combination Product for which Manufacturing Completion occurs during the applicable Calendar Year, subject to the true-up after the end of the Calendar Year as set forth in Section 1.1.2 of this Annex M-4 and any other adjustments expressly set forth in the Agreement or any Ancillary Agreement. To the extent that products or services covered by the Manufacturing Fee are expected to be sourced from multiple vendors in a given Calendar Year, the estimated Manufacturing Fee for such Calendar Year shall, to that extent, represent a weighted average standard based on expected sourcing.

1.5 **Annual Manufacturing Fee for a Calendar Year**

No later than January 31 after the end of each Calendar Year, Gilead shall calculate the Annual Manufacturing Fee with respect to such Calendar Year by multiplying (a) the actual Manufacturing Fee for such Calendar Year by (b) [*] of the applicable Territory Combination Product for which Janssen's portion of the Manufacturing Fee was invoiced to Janssen during such Calendar Year pursuant to Section 1.1.1 of this Annex M-4 (the product of (a) and (b), the " **Annual Manufacturing Fee** " for such Calendar Year). The Annual Manufacturing Fee shall be used for the purpose of making any year-end adjustments with respect to the applicable Calendar Year required pursuant to Section 1.1.2 of this Annex M-4 .

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Annex M-5

Payment Terms for Supplied RPV Invoices for Gilead Countries

Capitalized terms not defined in this Annex M-5 shall have the meanings set forth in the agreement to which this Annex M-5 is attached. The payment terms for the Pre-Conversion Invoices and Post-Conversion Invoices for the Gilead Countries are as follows:

[*].

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Annex M-6

Revaluation of API

Within fifteen (15) Business Days following December 31, 2014, Janssen shall provide Gilead with an invoice (or credit note) with respect to each Pre-Conversion Invoice (or portion thereof) for which a Triggering Sale for Territory Complera has not yet occurred with respect to the Supplied RPV Annual Revaluation for Calendar Year 2014 (such invoice, the " **Revaluation Pre-Conversion Invoice** ") as set forth below. For such purpose, such Triggering Sales shall be mapped to the earliest Pre-Conversion Invoices (or portion thereof) for Supplied RPV and for Territory Complera on a first-in, first-out basis so that the oldest outstanding invoices are paid first. The " **Supplied RPV Annual Revaluation** " due (or creditable) with respect to each Pre-Conversion Invoice shall be the amount in U.S. Dollars determined by multiplying the Revaluation RPV Supply Price by the kilograms of Supplied RPV sold to Gilead under the applicable invoice for which a Triggering Sale did not occur during Calendar Year 2014 or any previous Calendar Year. If the Supplied RPV Annual Revaluation amount is negative, then Janssen (or its applicable Affiliate) shall issue a credit note for such amount and if the Supplied RPV Annual Revaluation amount is positive, then Janssen shall invoice Gilead for such amount. Any credit note shall be issued to the entity (Gilead or the Gilead Affiliate) initially invoiced for the quantity of Supplied RPV in question and shall only be creditable against amounts owed by the entity (Gilead or the Gilead Affiliate) to which the credit note was issued.

" **Revaluation Supplied RPV Supply Price** " shall mean, [*].

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Annex M-7

Janssen Universal Calendar Year for 2015

2015 UNIVERSAL CALENDAR

	M	T	W	T	F	S	S
	29	30	31				
JAN				1	2	3	4
(4 Weeks)	5	6	7	8	9	10	11
	12	13	14	15	16	17	18
	19	20	21	22	23	24	25
	26	27	28	29	30	31	
FEB							1
(4 Weeks)	2	3	4	5	6	7	8
	9	10	11	12	13	14	15
	16	17	18	19	20	21	22
	23	24	25	26	27	28	
							1
MAR	2	3	4	5	6	7	8
(5 Weeks)	9	10	11	12	13	14	15
	16	17	18	19	20	21	22
	23	24	25	26	27	28	29
	30	31					
APR			1	2	3	4	5
(4 Weeks)	6	7	8	9	10	11	12
	13	14	15	16	17	18	19
	20	21	22	23	24	25	26
	27	28	29	30			
MAY					1	2	3
(4 Weeks)	4	5	6	7	8	9	10
	11	12	13	14	15	16	17
	18	19	20	21	22	23	24
	25	26	27	28	29	30	31
JUN	1	2	3	4	5	6	7
(5 Weeks)	8	9	10	11	12	13	14
	15	16	17	18	19	20	21
	22	23	24	25	26	27	28

	M	T	W	T	F	S	S
	29	30					
JUL			1	2	3	4	5
(4 Weeks)	6	7	8	9	10	11	12
	13	14	15	16	17	18	19
	20	21	22	23	24	25	26
	27	28	29	30	31		
AUG						1	2
(4 Weeks)	3	4	5	6	7	8	9
	10	11	12	13	14	15	16
	17	18	19	20	21	22	23
	24	25	26	27	28	29	30
	31						
SEP		1	2	3	4	5	6
(5 Weeks)	7	8	9	10	11	12	13
	14	15	16	17	18	19	20
	21	22	23	24	25	26	27
	28	29	30				
OCT				1	2	3	4
(4 Weeks)	5	6	7	8	9	10	11
	12	13	14	15	16	17	18
	19	20	21	22	23	24	25
	26	27	28	29	30	31	
NOV							1
(4 Weeks)	2	3	4	5	6	7	8
	9	10	11	12	13	14	15
	16	17	18	19	20	21	22
	23	24	25	26	27	28	29
	30						
DEC		1	2	3	4	5	6
(6 Weeks)	7	8	9	10	11	12	13
	14	15	16	17	18	19	20
	21	22	23	24	25	26	27
	28	29	30	31			
					1	2	3

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Annex N: Financial Reporting

Financial Reporting

Capitalized terms not defined in this Annex N shall have the meanings set forth in the Agreement or in Annex M-1 .

A. Provision of Territory Combination Product Sales Information required under In-License Agreements.

To enable each Party to comply with its obligations under any In-License Agreements, the other Party shall provide such first Party with any Territory Combination Product sales information that is required for such first Party to comply with the In-License Agreements, as specifically set forth in the In-License Requirements. Except as expressly provided hereunder, the receiving Party shall ensure that such Territory Combination Product sales information is made available only (x) to those persons in the receiving Party's Financial Reporting Committee and its Necessary Personnel and (y) as required to comply with the In-License Requirements (which Territory Combination Product sales information the receiving Party shall provide to its licensor only to the extent required to be provided under the applicable In-License Agreement and subject to confidentiality thereunder and Section 15.2.4 of the Agreement).

B. Provision of RPV NSP to Gilead.

Generally. For the avoidance of doubt, [*].

C. [*] **.**

D. [*] **.**

Forecasts Required Under In-License Agreements . Each Party shall also provide the other Party with any forecast requirements set forth in the In-License Requirements. Any such forecast requirements shall be for information purposes only, and shall not impose upon the providing Party an obligation to meet the sales in such forecast requirements.

[*] **.**

Forecasts Generally . Any forecasts provided pursuant to this Section D of this Annex N are, for clarity, the Confidential Information of the providing Party. Except as expressly provided hereunder, each Party shall ensure that such forecast(s) are made available only (x) to its Financial Reporting Committee representatives and Necessary Personnel and (y) as required to comply with the In-License Requirements (which forecasts the receiving Party shall provide to its licensor only to the extent required to be provided under the applicable In-License Agreement and subject to confidentiality thereunder and Section 15.2.4 of the Agreement). Neither Party shall be liable for any differences between its forecasted information and the actual corresponding sales realized by such Party.

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E. Right to Decline. Upon advance written notice to Gilead, Janssen may decline to receive any of the aforesaid data, information or forecasts (except to the extent that the information is required to be exchanged in order to perform the financial calculations required under the Agreement).

F. Changes to Accounting Standards. In the event there are any changes to Accounting Standards impacting financial reporting hereunder, the Parties shall mutually agree on any necessary amendments to this Annex N .

G. Provision of the Universal Calendar to Gilead. To enable the Parties to better coordinate with respect to the financial calculations and exchanges of financial information described in the Agreement, including under Articles 10 and 11, Annexes M-1 through M-6 and this Annex N , Janssen shall, at least six (6) Universal Calendar Months before the start of a given Universal Calendar Year, provide to Gilead a calendar detailing such Universal Calendar Year, including the calendar dates on which each Universal Calendar Month begins and ends. A copy of the universal calendar system used by Janssen and its Affiliates for internal business purposes for 2014 is set forth on Annex M-7 .

H. Provision of Exchange Rates to Janssen. For each month during the Term, Gilead shall include in the reports provided under Section C of this Annex N to Janssen the currency exchange rate(s) to be used for converting the local currency of each Post-Conversion Supply Price Country that is a Janssen Country in accordance with Section 10.7.

I. [*]

J. Inventory Reconciliation Reports. Each Calendar Year of the Term, Gilead shall provide to Janssen an inventory reconciliation report that contains an overview of the quantity of Supplied RPV that Gilead has in inventory either as API, WIP or finished product of a Territory Combination Product. Such report shall reflect the inventory situation at the end of the September calendar month and shall be provided no later than October 31 of such Calendar Year.

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Annex O: [Reserved]

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Annex P: [Reserved]

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Annex Q:[Reserved]

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Annex R: [Reserved]

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Annex S-1: Gilead Restatement Effective Date Press Release

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GILEAD
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CONTACTS:

Patrick O'Brien, Investors
(650) 522-1936

Ryan

McKeel, Media
(650) 377-3548

For Immediate Release

GILEAD ANNOUNCES AMENDED AGREEMENTS WITH JANSSEN TO DEVELOP AND COMMERCIALIZE TENOFOVIR ALAFENAMIDE-BASED SINGLE TABLET REGIMENS FOR HIV TREATMENT

Foster City, CA, December XX, 2014 – Gilead Sciences, Inc. (Nasdaq: GILD) today announced an expansion to its agreement with Janssen R&D Ireland for the development and commercialization of a new once-daily single tablet regimen containing Gilead's tenofovir alafenamide fumarate (TAF) and emtricitabine, and Janssen's rilpivirine. The original agreement was established in 2009 for the development and commercialization of Complera ®, marketed as Eviplera ® in the European Union, which combines tenofovir disoproxil fumarate, emtricitabine and rilpivirine in a once-daily tablet. Gilead will initiate Phase 3 studies of emtricitabine/rilpivirine/TAF in the coming months. Pending the product's approval, Gilead will be responsible for the manufacturing, registration, distribution and commercialization of the regimen in most countries, while Janssen will distribute in approximately 17 markets.

TAF is a novel nucleotide reverse transcriptase inhibitor that has demonstrated high antiviral efficacy at a dose 10 times lower than Gilead's Viread ® (tenofovir disoproxil fumarate), as well as an improved renal and bone safety profile.

"We believe that TAF's efficacy and safety advantages may make it a strong backbone of new fixed-dose combinations and single tablet regimens," said Norbert Bischofberger, PhD, Executive Vice President, Research and Development and Chief Scientific Officer, Gilead Sciences. "Gilead is pleased to continue its collaboration with Janssen to bring improved treatment options to patients living with HIV."

Gilead and Janssen also have amended a licensing agreement for the development and commercialization of a once-daily single tablet regimen for HIV containing Gilead's TAF, emtricitabine and cobicistat, and Janssen's darunavir. Under the amended agreement, Janssen will be responsible for further development of the regimen and, subject to regulatory approval, the manufacturing, registration, distribution and commercialization of the product worldwide.

Separate to the Janssen agreements, Gilead is advancing its own TAF-based single tablet regimen containing elvitegravir, cobicistat, emtricitabine and TAF. The company announced on November 6, 2014, it filed for regulatory approval in the United States.

TAF and TAF-based regimens are investigational products in the United States and have not yet been determined safe or efficacious in humans.

About Gilead Sciences

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Gilead Sciences is a biopharmaceutical company that discovers, develops and commercializes innovative therapeutics in areas of unmet medical need. The company's mission is to advance the care of patients suffering from life-threatening diseases. Gilead has operations in more than 30 countries worldwide, with headquarters in Foster City, California.

- more -

Forward-Looking Statement

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks, uncertainties and other factors, including risks related to whether ongoing clinical trials of TAF-based combinations will be successful and Gilead's ability to coformulate new single tablet regimens containing TAF, emtricitabine and rilpivirine, and TAF, emtricitabine, cobicistat and darunavir. In addition, Gilead and Janssen may make a strategic decision to discontinue development of the TAF combination products if, for example, the market for the products fails to materialize as expected. As a result, the agreements may terminate. Further, regulatory authorities may not approve TAF-based regimens, and marketing approvals, if granted, may have significant limitations on their use. As a result, TAF combination products may never be successfully commercialized. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. These and other risks are described in detail in Gilead's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, as filed with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to Gilead, and Gilead assumes no obligation to update any such forward-looking statements.

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For more information on Gilead Sciences, please visit the company's website at www.gilead.com, follow Gilead on Twitter (@GileadSciences) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.

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Annex S-2: Janssen Restatement Effective Date Press Release

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MEDIA CONTACT: **Ronan Collins**
+47 488 425 00
rcollin5@its.jnj.com

Daniel De Schryver
+49 173 768 9149
ddschryv@its.jnj.com

INVESTOR RELATIONS: Stan Panasewicz
+1 732 524 2524

Louise Mehrotra
+1 732 524 6491

JANSSEN ANNOUNCES COLLABORATION WITH GILEAD TO DEVELOP PREZISTA®-BASED SINGLE-TABLET REGIMEN FOR THE TREATMENT OF PEOPLE LIVING WITH HIV

-- TWO COMPANIES TO ALSO COLLABORATE ON THE FURTHER DEVELOPMENT OF COMPLERA®, MARKETED AS EVIPLERA® IN THE EUROPEAN UNION --

Cork, Ireland, [XX] December 2014 – Janssen R&D Ireland (Janssen) announced today an amendment to its existing agreement with Gilead Sciences, Inc. (Gilead), initially established in 2011, for the development of a once daily, darunavir-based, single-tablet regimen (STR) for the treatment of people living with HIV. This new STR contains a combination of darunavir (PREZISTA®), cobicistat (TYBOST®), emtricitabine and tenofovir alafenamide fumarate (TAF). A number of Phase 1 and 2 studies of the new STR have been completed. Under this amended agreement, Janssen will conduct all further clinical development of the regimen and, subject to regulatory approval, will be responsible for all manufacturing, registration, distribution and commercialization of the product worldwide.

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If successfully developed and approved by regulatory authorities, this treatment would represent the first protease inhibitor-based STR and thereby continue Janssen's commitment to providing its HIV products in more simplified dosing presentations.

"Janssen has vast experience in developing and making innovative HIV treatments available to patients and we have engaged in several successful collaborations with Gilead. We are proud to be extending our collaboration and leading the development of this darunavir-based single-tablet regimen," says Paul Stoffels, Chief Scientific Officer and Worldwide Chairman, Pharmaceuticals, Johnson & Johnson. "Our ultimate goal is to offer new treatment options for people living with HIV. If approved, this STR has the potential to provide additional choice in the form of another one pill, once a day, as a new and simplified regimen."

In addition to this collaboration, Janssen and Gilead have also expanded a separate agreement initiated in 2009 regarding the approved single-tablet regimen, COMPLERA®, marketed as EVIPLERA® in the European Union (EU) (rilpivirine, tenofovir disoproxil fumarate (TDF) and emtricitabine). This expanded agreement will allow for Gilead's investigational novel pro-drug tenofovir alafenamide fumarate (TAF) to replace TDF within COMPLERA®/ EVIPLERA®. TAF has been shown in clinical trials to have a better renal and bone safety profile than TDF. [1] Gilead will be responsible for the development and commercialization in most countries, while Janssen will lead the commercialization in select markets.

Since the beginning of the HIV epidemic, almost 75 million people have been infected with the HIV virus. [2] It is estimated that 35 million people are currently living with HIV globally, with 2.5 million people becoming newly infected each year. [2,3,4]

PREZISTA®
Indication
PREZISTA® (darunavir), coadministered with ritonavir (PREZISTA®/r), and with other antiretroviral agents (ARVs), is indicated for the treatment of human immunodeficiency virus (HIV-1) infection.

This indication is based on analyses of plasma HIV-1 RNA levels and CD4+ cell counts from 2 controlled Phase 3 trials of 48 weeks duration in ARV treatment-naïve and treatment-experienced patients and 2 controlled Phase 2 trials of 96 weeks duration in clinically advanced, treatment-experienced adult patients.

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In treatment-experienced adult patients, the following points should be considered when initiating therapy with PREZISTA®/r:

- Treatment history and, when available, genotypic or phenotypic testing should guide the use of PREZISTA®/r
- The use of other active agents with PREZISTA®/r is associated with a greater likelihood of treatment response

Important Safety Information

PREZISTA® (darunavir) is a prescription medicine. It is one treatment option in the class of HIV (human immunodeficiency virus) medicines known as protease inhibitors.

PREZISTA® is always taken with and at the same time as ritonavir (Norvir®), in combination with other HIV medicines for the treatment of HIV infection in adults. PREZISTA® should also be taken with food.

- The use of other medicines active against HIV in combination with PREZISTA®/ritonavir (Norvir®) may increase your ability to fight HIV. Your healthcare professional will work with you to find the right combination of HIV medicines
- It is important that you remain under the care of your healthcare professional during treatment with PREZISTA®

PREZISTA® does not cure HIV infection or AIDS and you may continue to experience illnesses associated with HIV-1 infection, including opportunistic infections. You should remain under the care of a doctor when using PREZISTA®.
Please read Important Safety Information below, and talk to your healthcare professional to learn if PREZISTA® is right for you.
Important Safety Information
What is the most important information I should know about PREZISTA®?

- **PREZISTA® can interact with other medicines and cause serious side effects. See "Who should not take PREZISTA®?"**
- **PREZISTA® may cause liver problems.** Some people taking PREZISTA®, together with Norvir® (ritonavir), have developed liver problems which may be life-threatening. Your healthcare professional should do blood tests before and during your combination treatment with PREZISTA®. If you have chronic hepatitis B or C infection, your healthcare professional should check your blood tests more often because you have an increased chance of developing liver problems
- Tell your healthcare professional if you have any of these signs and symptoms of liver problems: dark (tea-colored) urine, yellowing of your skin or whites of your eyes, pale colored stools (bowel movements), nausea, vomiting, pain or tenderness on your right side below your ribs, or loss of appetite
- **PREZISTA® may cause a severe or life-threatening skin reaction or rash.** Sometimes these skin reactions and skin rashes can become severe and require treatment in a hospital. You should call your healthcare professional immediately if you develop a rash. However, stop taking PREZISTA® and ritonavir combination treatment and call your

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healthcare professional immediately if you develop any skin changes with these symptoms: fever, tiredness, muscle or joint pain, blisters or skin lesions, mouth sores or ulcers, red or inflamed eyes, like “pink eye.” Rash occurred more often in patients taking PREZISTA® and raltegravir together than with either drug separately, but was generally mild

Who should not take PREZISTA®?

- **Do not take PREZISTA® if you are taking the following medicines:** alfuzosin (Uroxatral®), dihydroergotamine (D.H.E.45®, Embolex®, Migranal®), ergonovine, ergotamine (Cafergot®, Ergomar®), methylergonovine, cisapride (Propulsid®), pimozide (Orap®), oral midazolam, triazolam (Halcion®), the herbal supplement St. John's wort (Hypericum perforatum), lovastatin (Mevacor®, Altoprev®, Advicor®), simvastatin (Zocor®, Simcor®, Vytorin®), rifampin (Rifadin®, Rifater®, Rifamate®, Rimactane®), sildenafil (Revatio®) when used to treat pulmonary arterial hypertension, indinavir (Crixivan®), lopinavir/ritonavir (Kaletra®), saquinavir (Invirase®), boceprevir (Victrelis™), or telaprevir (Incivek™)
- Before taking PREZISTA®, tell your healthcare professional if you are taking sildenafil (Viagra®, Revatio®), vardenafil (Levitra®, Staxyn®), tadalafil (Cialis®, Adcirca®), atorvastatin (Lipitor®), rosuvastatin (Crestor®), pravastatin (Pravachol®), or colchicine (Colcrys®, Col-Probenecid®). Tell your healthcare professional if you are taking estrogen-based contraceptives (birth control). PREZISTA® might reduce the effectiveness of estrogen-based contraceptives. You must take additional precautions for birth control, such as condoms

This is not a complete list of medicines. Be sure to tell your healthcare professional about all the medicines you are taking or plan to take, including prescription and nonprescription medicines, vitamins, and herbal supplements.

What should I tell my doctor before I take PREZISTA®?

- Before taking PREZISTA®, tell your healthcare professional if you have any medical conditions, including liver problems (including hepatitis B or C), allergy to sulfa medicines, diabetes, or hemophilia
- Tell your healthcare professional if you are pregnant or planning to become pregnant, or are breastfeeding
  - The effects of PREZISTA® on pregnant women or their unborn babies are not known. You and your healthcare professional will need to decide if taking PREZISTA® is right for you
  - **Do not breastfeed** . It is not known if PREZISTA® can be passed to your baby in your breast milk and whether it could harm your baby. Also, mothers with HIV should not breastfeed because HIV can be passed to your baby in the breast milk

What are the possible side effects of PREZISTA®?

- High blood sugar, diabetes or worsening of diabetes, and increased bleeding in people with hemophilia have been reported in patients taking protease inhibitor medicines, including PREZISTA®

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- Changes in body fat have been seen in some patients taking HIV medicines, including PREZISTA®. The cause and long-term health effects of these conditions are not known at this time
- Changes in your immune system can happen when you start taking HIV medicines. Your immune system may get stronger and begin to fight infections that have been hidden
- The most common side effects related to taking PREZISTA® include diarrhea, nausea, rash, headache, stomach pain, and vomiting. This is not a complete list of all possible side effects. If you experience these or other side effects, talk to your healthcare professional. Do not stop taking PREZISTA® or any other medicines without first talking to your healthcare professional

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please refer to the ritonavir (Norvir®) Product Information (PI and PPI) for additional information on precautionary measures.

Please see full Product Information for more details:

http://www.prezista.com/sites/default/files/pdf/us_package_insert.pdf#zoom=100

About Janssen Pharmaceutical Companies of Johnson & Johnson

The Janssen Pharmaceutical Companies of Johnson & Johnson are dedicated to addressing and solving some of the most important unmet medical needs of our time in infectious diseases and vaccines, oncology, immunology, neuroscience, and cardiovascular and metabolic diseases. Driven by our commitment to patients, we develop innovative products, services and healthcare solutions to help people throughout the world.

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 including regarding product development. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen R&D Ireland and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges inherent in new product development, including obtaining regulatory approvals; competition, including technological advances, new products and patents attained by competitors; changes to regulations and domestic and foreign health care reforms; and general industry conditions, including trends toward health care cost containment. A further list and description of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 29, 2013, including in Exhibit 99 thereto, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies or Johnson & Johnson undertake to update any forward-looking statement as a result of new information or future events or developments.

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1. Sax P, Brar I, Elion R, et al. 48 Week study of tenofovir alafenamide (TAF) versus tenofovir disoproxil fumarate (TDF), each in a single tablet regimen with elvitegravir, cobicistat, and emtricitabine for initial HIV treatment. 53rd ICAAC. September 10-13, 2013. Denver. Abstract H1464d.

2. World Health Organization. Global summary of the AIDS epidemic. Available at: http://www.who.int/gho/hiv/en/ . Last accessed July 2014.

3. Hui Dy. Effects of HIV protease inhibitor therapy on lipid metabolism. *Prog Lipid Res* 2003; http://www.ncbi.nlm.nih.gov/pubmed/12547652 42(2):81-92.

4. World Health Organization. Global summary of the AIDS epidemic. Available at: http://www.who.int/hiv/data/2012_epi_core_en.png . Last accessed July 2014.

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Annex T: Compliance with Laws

1.1. Each Party acknowledges that the other Party aims to perform its activities, and to have parties such as a Party hereunder who enters into business arrangements with the other Party to perform their activities under such arrangements, in accordance with the highest ethical standards and best industry practices, including without limitation any voluntary codes of practice applicable in the industry. The Parties agree to use reasonable efforts to help ensure that the Parties do not fail to meet such aim with respect to activities hereunder through any violation of the U.S. Foreign Corrupt Practices Act (the " **FCPA** "), the U.S. False Claims Act (the " **FCA** "), the U.S. Anti-Kickback Law (the " **AKA** "), the United Kingdom Bribery Act (the " **UKBA** "), or any laws or regulations regarding governmental research grants (e.g., rules governing grants from the National Institutes of Health, or other governmental agencies.)

1.2. Each Party shall comply with all laws and regulations concerning its efforts in any country or jurisdiction where it is providing work hereunder or otherwise applying to any of its activities under this Agreement. Each Party shall use reasonable efforts to ensure that its personnel performing hereunder become reasonably familiar with the FCPA, the FCA, the UKBA and the AKA, and their prohibitions and purposes, and that they will not undertake any actions that would violate the FCPA, the FCA, the UKBA and the AKA. Accordingly, each Party hereby warrants that:

(i) neither it nor its agents or employees whose duties pertain to this Agreement are excluded from a federal health care program as outlined in Sections 1128 and 1156 of the Social Security Act (see the Office of Inspector General of the Department of Health and Human Services List of Excluded Individuals / Entities at http://www.oig.hhs.gov/FRAUD/exclusions/listofexcluded.html);

(ii) neither it nor its agents or employees whose duties pertain to this Agreement are debarred by the FDA under 21 U.S.C. 335a (see the FDA Office of Regulatory Affairs Debarment List at http://www.fda.gov/ora/compliance_ref/debar/);

(iii) neither it, nor its agents or employees are otherwise excluded from contracting with the federal government (see the Excluded Parties Listing System at http://epls.arnet.gov);

(iv) it, or its agents or employees, if required, are duly licensed and in good standing in accordance with applicable U.S., state or other applicable governmental licensing requirements;

(v) no payment or offer to pay, or the giving or offering to give, anything of value to an official or employee of any government or any department, agency or instrumentality thereof (including, but not limited to, any health or medical providers owned or controlled by the government), or to any political party or any candidate for political office, shall be made with the purpose of influencing any decisions favorable to either Party or its Affiliates and the business resulting therefrom in contravention of the FCPA or the laws of the country in which it is providing work;

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(vi) it has not paid, nor offered or agreed to pay, nor caused to be paid, directly or indirectly, any political contributions, fees or commissions to any governmental employee or representative (including, but not limited to, any employee of any health or medical provider owned or controlled by the government) that would appear to cause a violation of the FCPA; and

(vii) it will not, directly or indirectly offer, pay, promise to pay, or authorize the giving of money or anything of value to any governmental official or representative, to any political party or official thereof, or to any candidate for political office, or to any other person, for the purpose of:

a. inappropriately influencing any act or decisions of such person, official, political party, party official, or candidate in, if applicable, its official capacity, including a decision to fail to perform official functions, or

b. inducing such person, official, political party, party official, or candidate to use influence with the government, any instrumentality thereof, or any other entity to affect or influence any act or decision of such government or instrumentality, or entity, in order to assist Janssen or Gilead in obtaining or retaining business for or with, or directing business to, any Affiliate or Third Party.

Each Party further agrees that if subsequent developments cause the certifications and information reported herein to be no longer accurate or complete, it will immediately so advise the other Party in writing.

1.3 In the event of a claim or investigation, or an official request for a Party to cooperate with respect to any such claim or investigation, by a Regulatory Authority or other legal authority having jurisdiction over either Party, of an alleged violation of the FCPA arising from any activities conducted by the other Party relating specifically to this Agreement or to any Territory Combination Product, the other Party shall reasonably provide such Regulatory Authority or other legal authority having jurisdiction over the Party, with access to the other Party's facilities, records (financial and otherwise), and supporting documentation, as reasonably requested by the Party or its agents in order to cooperate in connection with such claim or investigation. Each Party acknowledges that the provisions of this Annex T granting the other Party certain audit rights shall in no way relieve the Party of any of its obligations under the Agreement, nor shall such provisions require the other Party to conduct any such audits.

1.4 During the Term, each Party shall maintain true, accurate and complete books and records, including, but not limited to, those: (i) documenting its interactions with any government or its officials or employees relating to its activities in connection with any Territory Combination Product; (ii) payments made to any officials or employees of any government or any department, agency or instrumentality thereof; and (iii) political contributions. Each Party shall also maintain a reasonable system of internal accounting controls sufficient to satisfy the FCPA.

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1.5 Each Party acknowledges and agrees that any breach of its obligations under this Annex T shall be a basis for notification of a material breach of this Agreement.

1.6 Notwithstanding anything to the contrary in this Agreement, a Party may disclose its terms and conditions (including any financial terms) to any governmental authorities in the U.S. or those in a country where it performs activities in connection with any Territory Combination Product that such Party determines in good faith has a legitimate need for access to such information for purposes of investigating or determining either Party's compliance with Applicable Law.

1.7 The Parties acknowledge that certain laws, now or in the future may require pharmaceutical, medical device and other companies to disclose information on compensation, gifts or other remuneration provided to physicians, institutions, and other health care professionals. Either Party may report information about remuneration provided under this Agreement. Once reported, such information may be publicly accessible.

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Cipla v. Gilead **IPR2025-00033** **Petitioner Exhibit 1030**

Annex U-1: Janssen Guarantee Acknowledgement

December 23, 2014

Gilead Sciences, Inc.
333 Lakeside Drive
Foster City, CA 94404

Gilead Sciences Ireland UC
Unit 13 Stillorgan Industrial Park
Blackrock, Co.
Dublin, Ireland

Re: Amended and Restated Collaboration Agreement (Complera and the R/F/TAF Product) dated as of December 23, 2014 by and among Gilead Sciences, Inc., Gilead Sciences Ireland UC (formerly Gilead Sciences Limited) and Janssen R&D Ireland (the " Amended and Restated Agreement ")

Ladies and Gentlemen:

Capitalized terms used but not defined in this letter have the meanings given to them in the Amended and Restated Agreement.

Janssen Pharmaceutica NV hereby confirms that the Amended and Restated Agreement is included within the definition of "Collaboration Agreement" for purposes of the guarantee agreement that was delivered by Janssen Pharmaceutica NV pursuant to Section 20.4 of the Original Agreement.

This letter shall in all respects be governed by and construed in accordance with the laws of the State of New York, without reference to the rules of conflict of laws thereof.

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JANSSEN PHARMACEUTICA NV

By: __
Name:
Title:

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Cipla v. Gilead **IPR2025-00033** **Petitioner Exhibit 1030**

Annex U-2: Gilead Guarantee Acknowledgement

December 23, 2014

Janssen R&D Ireland
Eastgate Village
Eastgate, Little Island
County Cork, Ireland

Re: Amended and Restated Collaboration Agreement (Complera and the R/F/TAF Product) dated as of December 23, 2014 by and among Gilead Sciences, Inc., Gilead Sciences Ireland UC (formerly Gilead Sciences Limited) and Janssen R&D Ireland (the " Amended and Restated Agreement ")

Ladies and Gentlemen:

Capitalized terms used but not defined in this letter have the meanings given to them in the Amended and Restated Agreement.

Gilead Parent hereby confirms that the Amended and Restated Agreement is included within the definition of "Collaboration Agreement" for purposes of the guarantee agreement that was delivered by Gilead Parent pursuant to Section 20.4 of the Original Agreement.

This letter shall in all respects be governed by and construed in accordance with the laws of the State of New York, without reference to the rules of conflict of laws thereof.

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GILEAD SCIENCES, INC.

By: __
Name:
Title:

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Annex V: [Reserved]

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Cipla v. Gilead **IPR2025-00033** **Petitioner Exhibit 1030**

Annex W: Existing RPV Licenses; Janssen In-License Requirements

[*]

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Cipla v. Gilead **IPR2025-00033** **Petitioner Exhibit 1030**

Annex X: [Reserved]

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Annex Y: Existing Gilead Licenses

[*]

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Annex Z: Janssen Distributor Agreement

Amended and Restated Janssen Distributor Agreement

THIS AMENDED AND RESTATED JANSSEN DISTRIBUTOR AGREEMENT (as the same may be amended, modified or supplemented from time to time, this " **JDA** ") is made as of December 23, 2014 (the " **Restatement Effective Date** "), by and among Gilead Sciences, Inc., a corporation organized and existing under the laws of the State of Delaware and having its principal place of business at 333 Lakeside Drive, Foster City, California 94404 (" **Gilead Parent** "), Gilead Sciences Ireland UC (formerly known as Gilead Sciences Limited), an unlimited liability company existing under the laws of Ireland and wholly-owned subsidiary of Gilead Parent having its principal place of business at IDA Business & Technology Park, Carrigtohill, Co. Cork, Ireland (" **Gilead Sub** " and, collectively with Gilead Parent, " **Gilead** ") and Janssen R&D Ireland, a company organized and existing under the laws of Ireland, having its principal place of business at Eastgate Village, Eastgate, Little Island, County Cork, Ireland (" **Janssen** ," formerly known as Tibotec Pharmaceuticals, " **Tibotec** "). Each of Gilead and Janssen is sometimes referred to individually herein as a " **Party** " and collectively as the " **Parties** ."

RECITALS

WHEREAS, the Parties have entered into that certain AMENDED & RESTATED COLLABORATION AGREEMENT (Complera and the R/F/TAF Product) dated as of December 23, 2014 (the " **Collaboration Agreement** ");

WHEREAS, the Parties have agreed pursuant to the Collaboration Agreement to enter into this JDA to set forth certain rights and obligations of each Party with respect to the Janssen Countries.

WHEREAS, the Parties previously entered into that certain Janssen Distributor Agreement provided in Annex Z of the Original Agreement (the " **Original JDA** "); and

WHEREAS, this JDA supersedes the Original JDA and the financial provisions set forth in Annex BB of the Original Agreement, except that the provisions in Exhibit B-1 , Exhibit B-2 , Exhibit B-3 and Exhibit C shall take effect January 1, 2015.

NOW, THEREFORE, in consideration of the mutual promises and covenants set forth below and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

SECTION 1
DEFINED TERMS

Capitalized terms used and not defined in this JDA shall have the respective meanings assigned to them in the Collaboration Agreement. Unless otherwise indicated, all section cross-references in this JDA are to the Sections of this JDA and not the Collaboration Agreement.

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1.1 " **Contract Manufacturer** " or " **CMO** " shall mean any Third Party contract manufacturer with which (a) Gilead or its Affiliates contracts for the Manufacture of Territory Combination Product, or any API contained therein, to fulfill its obligations under this JDA, or (b) Janssen or its Affiliates contracts for the labeling, packaging, handling or storage of Territory Combination Product.

1.2 " **Core Materials** " shall have the meaning set forth in Section 8.2.

1.3 " **Deficient Territory Combination Product** " shall have the meaning set forth in Section 2.2.

1.4 " **Delivery** " shall have the meaning set forth in Section 9.1. "Deliver" and "Delivered" shall have correlative meanings.

1.5 " **Election Notice** " shall have the meaning set forth in Section 13.2.

1.6 " **Failure to Supply** " shall have the meaning set forth in Section 6.3.

1.7 " **Firm Order** " shall have the meaning set forth in Section 3.4(a).

1.8 " **Forecast** " shall have the meaning set forth in Section 3.1.

1.9 " **Forecast Date** " shall have the meaning set forth in Section 3.1.

1.10 " **Gilead Manufacturer** " shall mean a Person that Manufactures Territory Combination Product supplied under this JDA, or any API contained therein, by or on behalf of Gilead and its Affiliates, whether it be Gilead, an Affiliate of Gilead or a Contract Manufacturer of Gilead (or an Affiliate of Gilead).

1.11 " **Initial Pre-Approval Order Agreement** " shall have the meaning set forth in Section 13.3(a).

1.12 " **Inspection** " shall have the meaning set forth in Section 12.1.

1.13 " **Janssen Destination** " shall have the meaning set forth in Section 9.1.

1.14 " **Janssen Packager** " shall mean a Person that packages or labels Territory Combination Product supplied under this JDA by or on behalf of Janssen and its Affiliates, whether it be Janssen, an Affiliate of Janssen or a Contract Manufacturer of Janssen (or an Affiliate of Janssen).

1.15 " **JPKK Quality Agreement** " shall have the meaning set forth in Section 11.4(d).

1.16 " **Lost Territory Combination Product** " shall mean, with respect to any Calendar Year and with respect to Territory Combination Product supplied to Janssen (or its Affiliate or Third Party Distributor) in accordance with this JDA: (i) any Territory Combination Product that [*].

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1.17 " **Major Market Complera** " shall mean any Territory Complera that is manufactured by Gilead in accordance with the applicable specifications set forth in this JDA, which specifications describe a product intended by the Parties to be sold or otherwise Distributed (or Manufactured for sale or other Distribution) in the Territory outside of Region B and Region C, which shall, for the avoidance of doubt, exclude any Branded Region B/C Complera.

1.18 " **Major Market R/F/TAF Product** " shall mean any R/F/TAF Product that is manufactured by Gilead in accordance with the applicable specifications set forth in this JDA, which specifications describe a product intended by the Parties to be sold or otherwise Distributed (or Manufactured for sale or other Distribution) in the Territory outside of Region B and Region C, which shall, for the avoidance of doubt, exclude any Branded Region B/C R/F/TAF Product.

1.19 " **Manufacturing-Related Change** " shall have the meaning set forth in Section 11.3.

1.20 " **Nonconforming** " shall have the meaning set forth in Section 5.1. "Nonconformity" shall have a correlative meaning.

1.21 " **Notice Period** " shall have the meaning set forth in Section 13.2.

1.22 " **Quality Agreement** " shall have the meaning set forth in Section 11.4(b).

1.23 " **Supply Committee** " shall have the meaning set forth in the RPV Supply Agreement.

1.24 " **Territory Combination Product Specifications** " shall mean the Territory Complera Specifications and the Territory R/F/TAF Product Specifications.

1.25 " **Territory Complera Specifications** " shall mean the following specifications for Major Market Complera and Branded Region B/C Complera, which, as of the Effective Date, have been provided to Janssen's members of the Supply Committee, as such specifications may be amended from time to time in accordance with this JDA and the Quality Agreement: G-SPEC-165-97.00 (Major Market Complera) and G-SPEC-165-96.00 (Branded Region B/C Complera).

1.26 " **Territory R/F/TAF Product Specifications** " shall mean the specifications for Major Market R/F/TAF Product and Branded Region B/C R/F/TAF Product, as applicable, and as provided by Gilead to Janssen in accordance with this JDA and the Quality Agreement, as applicable, as such specifications may be amended from time to time in accordance with this JDA and the Quality Agreement.

1.27 " **Unsalable Deficient Territory Combination Product** " shall have the meaning set forth in Section 2.2.

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SECTION 2
SUPPLY OF TERRITORY COMBINATION PRODUCT;
MINIMUM SHELF LIFE; PRODUCT EXPIRY

2.1 Generally . Subject to the terms and conditions of the Collaboration Agreement and this JDA, during the term of this JDA with respect to a country in the Janssen Countries, (a) Gilead shall sell to Janssen, and Janssen shall purchase exclusively from Gilead, pursuant to Firm Orders properly submitted to Gilead under this JDA, all of Janssen's requirements of Territory Combination Product for such country in unlabeled bottles of Major Market Complera, Branded Region B/C Complera, Major Market R/F/TAF Product or Branded Region B/C R/F/TAF Product, as applicable, for use solely as permitted under the Collaboration Agreement and this JDA, and (b) Janssen shall be Gilead's exclusive distributor of, and shall have the exclusive right to Distribute, Territory Combination Product in such country. The Supply Committee shall determine the commencement date for Manufacture and sale to Janssen under this JDA of Major Market R/F/TAF Product, Branded Region B/C Complera and Branded Region B/C R/F/TAF Product, including any required Manufacture of validation batches required by Applicable Law, provided that the Parties understand and agree that Gilead shall require at least five (5) months' advance notice to Manufacture any such required validation batches and commence Manufacture of Branded Region B/C Complera or Branded Region B/C R/F/TAF Product. In the event that the Supply Committee cannot reach agreement with respect to the commencement date for Manufacture and sale to Janssen under this JDA of Branded Region B/C Complera and Branded Region B/C R/F/TAF Product, then Gilead shall commence such Manufacture and sale on the date reasonably requested by Janssen and in no event earlier than the date on which Gilead is commencing commercial manufacture of the applicable Territory Combination Product for use by Gilead in the Gilead Countries.

2.2 Minimum Shelf Life . To ensure that minimum remaining shelf life requirements of Territory Combination Product in the Janssen Countries can be met by Janssen at the time of delivery in such Janssen Countries, [*] if Gilead Delivers any Territory Combination Product with less than the remaining shelf life specified in clause (i) above (" **Deficient Territory Combination Product** "), Janssen shall use Commercially Reasonable Efforts to sell (and to cause its Affiliates to sell) such Territory Combination Product [*]. For clarity, the percent remaining shelf life at the time of Delivery shall be calculated by the formula ((a-b)/a)*100, where "a" is the approved shelf life of the applicable Territory Combination Product (as described above), and "b" is the time elapsed between the date of completion of Manufacture (as defined by Applicable Law for purposes of establishing shelf life) and the date of Delivery. Prior to the Delivery of any Deficient Territory Combination Product, Gilead shall provide notice to the Supply Committee of its intent to Deliver such Deficient Territory Combination Product and the Supply Committee shall discuss whether such Deficient Territory Combination Product can reasonably be sold in any of the Janssen Countries by Janssen or its Affiliates. In addition, the Supply Committee shall coordinate regarding the Parties' rights and obligations under this Section 2.2 and any special needs of Janssen regarding shelf life for Territory Combination Product for particular jurisdictions. Provided that Janssen uses such efforts as described in clause (ii) above, Janssen shall notify Gilead in writing on an annual basis of any Deficient Territory Combination Product that it is unable to sell notwithstanding the exercise of

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Commercially Reasonable Efforts described in clause (ii) above (such Deficient Territory Combination Product, " **Unsalable Deficient Territory Combination Product** "), which notice shall specify the quantity of Unsalable Deficient Territory Combination Product. Such notification shall occur by January 31 of each Calendar Year with regards to Unsalable Territory Combination from the prior Calendar Year. Notwithstanding anything to the contrary in the Collaboration Agreement, this JDA or any other Ancillary Agreements, with respect to any quantity of Unsalable Deficient Territory Combination Product, [*].

2.3 Treatment of Expired or Unusable Product . Janssen shall arrange for the destruction, return to Gilead or other disposal, at Gilead's election, of any Territory Combination Product that is expired or otherwise rendered unusable (but not covered by Section 5), in accordance with Gilead's instructions and Applicable Law. The reasonable, direct, out-of-pocket costs and expenses of any such destruction, return or other disposal of Territory Combination Product by Janssen pursuant to this Section 2.3 shall be borne by [*].

SECTION 3
FORECASTS AND ORDERS

3.1 Generally . On or before the first day of each month (the " **Forecast Date** ") during the term of this JDA with respect to one or more countries, commencing as of the date specified in Section 3.2 or 3.3 of this JDA as applicable, Janssen shall submit to Gilead a forecast (which forecast shall be expressed in terms of Units) of the quantity of Major Market Complera, Branded Region B/C Complera, Major Market R/F/TAF Product and Branded Region B/C R/F/TAF Product that Janssen expects to order for each month during the twenty-four (24) month period following the applicable Forecast Date (each, a " **Forecast** "). Each Forecast shall be prepared in good faith consultation with Gilead. In addition, Janssen shall, prior to the end of each Calendar Year during the term of this JDA with respect to one or more countries, provide Gilead with Janssen's good faith estimate of its annual requirements for Major Market Complera, Branded Region B/C Complera, Major Market R/F/TAF Product and Branded Region B/C R/F/TAF Product for each of the third, fourth and fifth Calendar Years following the Calendar Year in which such estimate is given; provided , however , that, in the case of such third year, the estimate shall be broken down by Calendar Quarter. [*].

3.2 Territory Complera

(a) Major Market Complera . Janssen's obligation to submit Forecasts with respect to Major Market Complera shall commence nine (9) months before the anticipated First Commercial Sale of Territory Complera in the first (1 st) Janssen Country where Janssen will be selling Major Market Complera. The quantity of Major Market Complera set forth in a given Forecast for each of the first (1 st) through the fourth (4 th) months shall be binding. Except as provided in the foregoing sentence, Forecasts with respect to Major Market Complera shall be considered non-binding.

(b) Branded Region B/C Complera . Janssen's obligation to submit Forecasts with respect to Branded Region B/C Complera shall commence nine (9) months before the anticipated First Commercial Sale of Territory Complera in the first Janssen Country where

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Janssen will be selling Branded Region B/C Complera. The quantity of Branded Region B/C Complera set forth in a given Forecast for each of the first (1st) through the fifth (5th) months shall be binding. Except as provided in the foregoing sentence, Forecasts with respect to Branded Region B/C Complera shall be considered non-binding.

3.3 Territory R/F/TAF Product.

(a) Major Market R/F/TAF Product . Janssen's obligation to submit Forecasts with respect to Major Market R/F/TAF Product shall commence [*] before the anticipated First Commercial Sale of Territory R/F/TAF Product in the first (1st) Janssen Country where Janssen will be selling Major Market R/F/TAF Product. The quantity of Major Market R/F/TAF Product set forth in a given Forecast for [*] shall be binding. Except as provided in the foregoing sentence, Forecasts with respect to Major Market R/F/TAF Product shall be considered non-binding.

(b) Branded Region B/C R/F/TAF Product . Janssen's obligation to submit Forecasts with respect to Branded Region B/C R/F/TAF Product shall commence [*] before the anticipated First Commercial Sale of Territory R/F/TAF Product in the first (1st) Janssen Country where Janssen will be selling Branded Region B/C R/F/TAF Product. The quantity of Branded Region B/C R/F/TAF Product set forth in a given Forecast for [*] shall be binding. Except as provided in the foregoing sentence, Forecasts with respect to Branded Region B/C R/F/TAF Product shall be considered non-binding.

3.4 Orders and Non-Binding Period .

(a) Firm Orders . Janssen shall notify Gilead, in the form of a purchase order or other form agreed by the Parties (each a " **Firm Order** "), of the Units of each of Major Market Complera, Branded Region B/C Complera, Major Market R/F/TAF Product and Branded Region B/C R/F/TAF Product to be Delivered to satisfy Janssen's requirements at least four (4) months prior to the date on which such Territory Combination Product is to be Delivered. Each Firm Order shall (i) be consistent with the quantity set forth in the applicable binding portion of the Forecast; (ii) be denominated in Units, unless otherwise mutually agreed by the Parties; and (iii) specify the Delivery date and any reasonable delivery instructions set forth in the Firm Order;. Each Firm Order [*]. Janssen acknowledges and agrees that production yield rates for any whole batches ordered by Janssen may inherently vary and that, as a result, Delivered batch sizes may inherently vary from the estimated batch size and the Parties' obligations as to such inherent variation are detailed in Section 6.1.

(b) Non-Binding Forecasts During Initial Twelve (12) Months and by Supply Committee Determination . Notwithstanding Sections 3.2, 3.3 or 3.4(a), any Forecasts provided by Janssen prior to the end of the first twelve (12) months following (a) in the case of Major Market Complera for Delivery to Janssen Countries, the First Commercial Sale of Major Market Complera in a Janssen Country in Region A, (b) in the case of Branded Region B/C Complera for Delivery to Janssen Countries, the First Commercial Sale of Branded Region B/C Complera in a Janssen Country in Region B or Region C [*] shall be deemed non-binding and the quantities of such Territory Combination Product to be Delivered to Janssen and timing of any

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such Deliveries shall be determined by the Supply Committee and such determination of quantities and timing by the Supply Committee shall be binding on both Parties.

3.5 Japan . Janssen shall place separate Forecasts and Firm Orders for Major Market Complera and Major Market R/F/TAF Product that will be Distributed in Japan in accordance with each of Sections 3.1 through 3.4; provided , however , that such Forecasts shall be [*].

3.6 Acceptance of Firm Orders . Within five (5) Business Days of initial receipt of a Firm Order from Janssen, Gilead shall notify Janssen whether it accepts or rejects such Firm Order. Gilead shall accept any such Firm Order from Janssen to the extent that such Firm Order complies with the requirements above.

3.7 Supply Committee . The roles and responsibilities of the Supply Committee shall include the supply of Major Market Complera, Branded Region B/C Complera, Major Market R/F/TAF Product and Branded Region B/C R/F/TAF Product, including issues related to supply for Japan and those responsibilities that are assigned to the Supply Committee under the RPV Supply Agreement but as applied to Territory Combination Product rather than RPV.

3.8 Distribution Limitation . Janssen shall not Distribute (a) in Japan, any Territory Combination Product ordered and Delivered for a country other than Japan, or (b) outside of Japan, any Territory Combination Product ordered and Delivered for Japan.

SECTION 4
DEVIATIONS FROM FIRM ORDERS

4.1 Commercially Reasonable Efforts of Gilead . In the event Janssen desires to place a Firm Order for Major Market Complera, Branded Region B/C Complera, Major Market R/F/TAF Product or Branded Region B/C R/F/TAF Product in an amount that exceeds the prior binding Forecast, Gilead shall use Commercially Reasonable Efforts to supply such Territory Combination Product under this JDA to accommodate such excess and shall as soon as practicable notify Janssen of the quantities of Major Market Complera, Branded Region B/C Complera, Major Market R/F/TAF Product or Branded Region B/C R/F/TAF Product, as applicable, that Gilead expects to be able to Deliver by the Delivery date specified in the applicable Firm Order.

4.2 Reduced Order Quantity . In the event that Janssen places a Firm Order that is less than the binding Forecast for such period, Janssen shall reimburse Gilead for any non-recoverable costs and expenses reasonably incurred by Gilead, its Affiliates and its CMOs in connection with such reduction in quantity (including any costs and expenses incurred as a result of any Territory Combination Product being rendered unusable as a result of such reduction); provided , however , that Gilead shall use Commercially Reasonable Efforts to use the quantity of Territory Combination Product corresponding to such reduction in its own commercialization activities.

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SECTION 5
NON-CONFORMING PRODUCT

5.1 Notice of Nonconformity . Janssen shall notify Gilead in writing of any claim that any Territory Combination Product supplied under this JDA is not in conformance with the warranties set forth in Section 11.1 (" **Nonconforming** ") within thirty (30) days after Delivery thereof (or within thirty (30) days after discovery of any Nonconformity that could not reasonably have been detected by inspection on receipt at the applicable Janssen Destination). Janssen shall promptly provide Gilead with a sample of such Nonconforming Territory Combination Product, if available, and all relevant reports, data, and laboratory test results indicating that such Territory Combination Product is Nonconforming. Janssen shall have the option to require that Gilead use its Commercially Reasonable Efforts to replace such potentially Nonconforming Territory Combination Product as promptly as possible by placing a Firm Order therefor. Janssen shall be liable to pay for such Firm Order unless and until it shall have been determined by the independent testing laboratory described below, or by agreement of the Parties, that the Territory Combination Product in question was Nonconforming. If Gilead and Janssen disagree as to whether Units of Territory Combination Product are Nonconforming, Gilead and Janssen shall designate an independent testing laboratory reasonably acceptable to both Parties to make a determination, which determination shall be binding on the Parties, absent manifest error. Gilead shall bear the costs of such laboratory testing if such Territory Combination Product is determined to be Nonconforming (other than due to non-conforming Supplied RPV), and otherwise Janssen shall bear such costs. The Parties shall attempt to resolve any Nonconformity issue within ninety (90) days after Janssen notifies Gilead that any Territory Combination Product is Nonconforming.

5.2 Replacement of Nonconforming Territory Combination Product . If the independent testing laboratory (as set forth above) determines that any Territory Combination Product was Nonconforming or the Parties agree that any Territory Combination Product was Nonconforming, then Janssen shall have the option to:

(a) if not previously done (as set forth above), require that Gilead use its Commercially Reasonable Efforts to replace any Nonconforming Territory Combination Product as promptly as possible by placing a Firm Order therefor; or

(b) cancel the applicable Firm Order (or portion thereof) corresponding to the Nonconforming Territory Combination Product.

In the case of clause (a) (if notwithstanding such efforts, and for reasons other than a Force Majeure Event, Gilead does not so replace such Nonconforming Territory Combination Product) or clause (b), (i) the Parties shall make any necessary financial adjustments so that Janssen is not obligated to pay for such cancelled Territory Combination Product, and (ii) as Janssen's sole monetary remedy (but without limitation of Gilead's obligations under Article 18 of the Collaboration Agreement) in the case of Nonconforming Territory Combination Product, Gilead shall pay to Janssen any out-of-pocket, documented non-recoverable costs or expenses reasonably incurred by Janssen (or its Affiliates) as a result of any required rescheduling of the packaging and labeling by Janssen's or its Affiliates' Contract Manufacturers of any

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Nonconforming Territory Combination Product that Gilead failed to replace with conforming Territory Combination Product under this JDA within thirty (30) days after the Delivery date specified in the applicable Firm Order; provided , however , that Gilead shall not be liable for any such costs or expenses to the extent such Nonconforming Territory Combination Product was Nonconforming as a result of Supplied RPV from Janssen or its Affiliates; provided , further , that Janssen shall have notified Gilead of such Nonconformity within the thirty (30) day period described above. Janssen shall use Commercially Reasonable Efforts to minimize any such costs and expenses incurred by Janssen for such cancellation.

5.3 Destruction of Nonconforming Territory Combination Product . Janssen shall arrange for the destruction, return to Gilead or other disposal, at Gilead's election, of any Nonconforming Territory Combination Product in compliance with Gilead's instructions and Applicable Law. The reasonable, direct, out-of-pocket costs and expenses of any such destruction, return or other disposal of Nonconforming Territory Combination Product by Janssen pursuant to this Section 5.3 shall be borne by Gilead; provided , however , that Janssen shall bear all such costs to the extent such Territory Combination Product is Nonconforming due to Supplied RPV from Janssen or its Affiliates.

SECTION 6
TERRITORY COMBINATION PRODUCT SHORTAGE; FAILURE TO SUPPLY

6.1 Inadequate Delivered Quantity of Territory Combination Product . Janssen shall notify Gilead in writing of any (i) failure to Deliver Territory Combination Product or (ii) a shortage in quantity in any shipment of Territory Combination Product (as compared with the amount specified for Delivery in the applicable Firm Order given by Janssen (as set forth above)), in each case ((i) and (ii)), within thirty (30) days after Delivery (or scheduled Delivery) thereof. In the event Gilead disagrees with any claim of shortage by Janssen, each Party shall designate a representative to be present at the inventorying of the at-issue Territory Combination Product, as applicable, the results of which shall be binding on the Parties, absent manifest error (and Gilead shall invoice Janssen solely based on such binding results). Gilead shall Deliver any shortage amount (as agreed upon by the Parties or determined by the inventorying) of Territory Combination Product, as applicable, as promptly as reasonably possible. Further, as Janssen's sole monetary remedy in the case of a delayed Delivery of Territory Combination Product under this JDA, Gilead shall pay to Janssen any documented out-of-pocket, non-recoverable costs or expenses reasonably incurred by Janssen (or its Affiliates) as a result of any required rescheduling of the packaging and labeling by Janssen's or its Affiliates' Contract Manufacturers for any Territory Combination Product, as applicable, that Gilead fails to Deliver within thirty (30) days after the Delivery date specified in the applicable Firm Order, provided that Janssen shall have notified Gilead of such shortfall within such thirty (30) day period. [*].

6.2 Shortage of Territory Combination Product . If Gilead is unable to supply the full quantities of any Territory Combination Product set forth in the Firm Orders from Janssen and its Affiliates together with the amounts of Territory Combination Product needed by Gilead and its Affiliates, then Gilead shall allocate the available supply of the applicable Territory Combination

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Product to Janssen and Gilead and their respective Affiliates pro rata based on the worldwide sales of the applicable Territory Combination Product by each Party and its respective Affiliates in the last four (4) full Calendar Quarters immediately prior to the applicable Firm Order.

6.3 Notification and Cure . If Gilead fails to supply any Territory Combination Product for which it has received a Firm Order in accordance with this JDA, either (a) for a period of thirty (30) days or longer after the Delivery date set forth in such Firm Order due to its breach of this JDA, or (b) for any period after such Delivery date due to a Force Majeure Event that is reasonably anticipated to prevent Gilead from supplying Territory Combination Product (either such failure, a " **Failure to Supply** "), Janssen may provide written notice thereof to Gilead requesting a plan to fully restore the supply of Territory Combination Product. Within ten (10) Business Days after receipt of such notice, Gilead shall propose a plan to restore, within an additional ninety (90) calendar days, the supply of Territory Combination Product in accordance with this JDA by production at a facility (or facilities) of Gilead or its Affiliate and/or at a CMO engaged by Gilead (or its Affiliate). Upon either Party's request, the Parties shall meet, within ten (10) Business Days following Janssen's receipt of the proposed restoration plan, to discuss and attempt to agree on the restoration plan. If the Parties are unable to agree on the restoration plan, then the matter shall be referred to the Executives for resolution pursuant to Section 20.6.1 of the Collaboration Agreement.

6.4 Other Remedies . Subject to the express limitations set forth herein and the Collaboration Agreement, the remedies set forth in this SECTION 6 for a material breach by Gilead shall be in addition to any other remedies Janssen may have under the Collaboration Agreement and this JDA.

SECTION 7
LABELING AND PACKAGING OF SUPPLIED TERRITORY COMBINATION PRODUCT

7.1 Form of Supply . All Territory Combination Product supplied by Gilead to Janssen under this JDA shall be supplied as Units of unlabeled bottles.

7.2 Packaging . Each shipment of Territory Combination Product supplied by Gilead to Janssen under this JDA shall be packed, sealed, and shipped in accordance with Gilead's customary packaging practices and GMP. In the event that specific packaging practices are required by Janssen for any particular Janssen Destination (including with regard to temperature control), the Parties shall cooperate in good faith through the Supply Committee to agree on the manner for implementing such practices.

SECTION 8
PACKAGING, LABELING AND STORAGE TECHNOLOGY TRANSFER; PACKAGING AND LABELING REQUIREMENTS

8.1 Procedures . Gilead shall assist Janssen in establishing proper procedures with respect to packaging, labeling and storage of Territory Combination Product.

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8.2 Secondary Packaging . Gilead shall provide Janssen with the core secondary packaging and packaging insert artwork with respect to each Territory Combination Product (" **Core Materials** ") for use by Janssen in packaging and labeling such Territory Combination Product. Janssen shall use the Core Materials to package and label the Territory Combination Product, but shall modify the Core Materials as required by Applicable Law and shall provide any necessary translations. Gilead shall have the right, but not the obligation, to review and approve in advance the Core Materials, as so modified, for any Janssen Country.

SECTION 9
TERRITORY COMBINATION PRODUCT DELIVERY

9.1 Delivery . Delivery of Territory Combination Product under this JDA shall be [*].

9.2 Shipments . Each shipment of Territory Combination Product under this JDA shall be labeled with a traceable batch number, and for each shipment the bill of lading shall list the gross weight and net weight of such shipment. Concurrent with each shipment of Territory Combination Product under this JDA, Gilead shall provide Janssen with an electronic copy of the certificate of analysis confirming that such batch meets the applicable Territory Combination Product Specifications. In addition, upon Delivery of any shipment of Territory Combination Product under this JDA to Janssen's carrier, Gilead shall provide Janssen with notice that such shipment has been Delivered, including the quantity of Territory Combination Product Delivered. If Janssen requests, Gilead shall provide a written certificate of compliance for a batch or batches of Territory Combination Product Delivered to Janssen under this JDA [*].

SECTION 10
SAFETY STOCK

[*].

SECTION 11
QUALITY CONTROL

11.1 Warranty on Territory Combination Product . Gilead represents and warrants that, at the time of Delivery, the Territory Combination Product supplied under this JDA, other than as a result of any defect or condition of the Supplied RPV included therein, including any breach of any warranty with respect to the Supplied RPV made by Janssen in the RPV Supply Agreement, (a) shall have been Manufactured in accordance with GMP and Applicable Law, and (b) shall conform to the applicable Territory Combination Product Specifications for Major Market Complera, Branded Region B/C Complera, Major Market R/F/TAF Product or Branded Region B/C R/F/TAF Product, as applicable, and the applicable certificate of analysis.

11.2 Changes to Territory Combination Product Specifications .

(a) Promptly following Marketing Approval of the Territory R/F/TAF Product in the United States or by the European Commission, whichever occurs first, Gilead shall establish and provide the proposed Territory R/F/TAF Product Specifications for each of Major

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Market R/F/TAF Product and Branded Region B/C R/F/TAF Product to Janssen. In the event any Regulatory Authority requests or requires any modifications to such specifications for the Janssen Countries, any such modifications shall be mutually agreed by the Parties and set forth in the Quality Agreement. Upon request of Gilead, Janssen shall [*].

(b) Changes to Territory Combination Product Specifications that are an Additional Requirement shall be governed by Section 8.4 of the Collaboration Agreement. All other changes to the Territory Combination Product Specifications for Major Market Complera, Branded Region B/C Complera, Major Market R/F/TAF Product or Branded Region B/C R/F/TAF Product shall be subject to the provisions of this JDA.

(c) If Gilead wishes to amend any of the Territory Combination Product Specifications, Gilead shall provide written notice thereof to Janssen. The Parties, through the Supply Committee, shall negotiate in good faith to develop a plan for the implementation of such amendment, which plan shall cover the Parties' respective obligations in connection with implementing such amendment, the timing for such amendment and any related regulatory filings, and the allocation of costs and expenses in connection with performing such obligations, taking into account the benefit that each Party is anticipated to obtain as a result of such change on a worldwide basis. Janssen shall make any regulatory filings required to allow for the use of such amended specifications for the Territory Combination Product for distribution in the Janssen Countries as promptly as reasonably practicable in light of anticipated timelines for any such specification changes.

(d) As of the Restatement Effective Date, Gilead has established and provided to Janssen the specifications for bottle size and shape with respect to the supplied Territory Complera (to the extent not provided in the Territory Complera Specifications). Prior to the first Delivery of Territory R/F/TAF Product to Janssen pursuant to this JDA and solely to the extent not provided in the Territory R/F/TAF Product Specifications, Gilead shall establish and provide to Janssen the specifications for bottle size and shape with respect to the supplied Territory R/F/TAF Product. Any changes to such bottle size and shape specifications (for either Territory Complera or Territory R/F/TAF Product) shall be treated in accordance with the process for changing Territory Combination Product Specifications.

11.3 Territory Combination Product Manufacturing-Related Changes . Manufacturing-related changes that are an Additional Requirement shall be governed by Section 8.4 of the Collaboration Agreement. Subject to the requirements of Section 11.2, other manufacturing-related changes with respect to a Territory Combination Product, including changes to the manufacturing location, materials, equipment, Manufacturing process, and procedures (" **Manufacturing-Related Change** ") may be made at the discretion of Gilead; provided , however , that if such Manufacturing-Related Change will require (a) customer notification under Applicable Law or (b) approval by a Regulatory Authority in the Territory, then Gilead shall notify Janssen and shall reasonably confer and coordinate with Janssen regarding such Manufacturing-Related Change as it relates to customer notification or required Regulatory Approval, as applicable. Any Manufacturing-Related Changes made with respect to Territory Combination Product shall, in each case, comply with GMP and Applicable Law. In the event of

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any such Manufacturing-Related Change, Gilead shall (i) be responsible for ensuring that all Territory Combination Product Manufactured under the changed Manufacturing process by or on behalf of Gilead or its Affiliates meets the applicable Territory Combination Product Specifications, and (ii) provide Janssen in a timely manner with all information reasonably needed to make corresponding amendments to the applicable regulatory filings in the Territory maintained by Janssen with respect to the Territory Combination Product (including amending Marketing Approvals in the Territory), to the extent necessary. Janssen shall make such regulatory filings as promptly as reasonably practicable in light of anticipated timelines for any Manufacturing-Related Changes. For each Territory Combination Product and APIs contained therein (other than Supplied RPV), a list of Manufacturing locations is provided as Schedule 11.3 of this JDA. Such list shall be updated from time to time by the Supply Committee to reflect any applicable Manufacturing-Related Changes with regard to such Manufacturing locations and the anticipated timelines for obtaining the applicable Regulatory Approvals. Territory Combination Product supplied hereunder shall only be Manufactured at the Manufacturing locations specified in Schedule 11.3 , and from API Manufactured at the locations specified in Schedule 11.3 , as such list of locations is updated from time to time in accordance with this Section 11.3.

11.4 Quality Agreements .

(a) Between Gilead and its CMOs . During the term of this JDA with respect to one or more countries, Gilead shall have quality agreements in place with each of its Contract Manufacturers that Manufacture Territory Combination Product for supply under this JDA, and those that Manufacture the API (other than Supplied RPV) contained therein. Such quality agreements shall, at a minimum, have terms governing GMP compliance as are customary in the pharmaceutical industry.

(b) Between Gilead and Janssen . The Parties (or their Affiliates) have entered into that certain Quality Agreement for the Manufacture and Supply of Commercial Products (Britestock) for Tibotec Territories, dated on or around March 20, 2012, with respect to the operational and quality assurance activities and regulatory compliance objectives contemplated under this JDA with respect to the Territory Complera and the subsequent labeling, packaging and storage of such Territory Complera by Janssen (as amended from time to time, the " **Quality Agreement** "). Any amendment to the Quality Agreement shall require the written agreement of the Parties. Within one hundred twenty (120) days of the Effective Date, the Parties shall negotiate in good faith and execute an amendment to the Quality Agreement so that the subject matter of such agreement extends to the Territory R/F/TAF Product, where applicable.

(c) Between Janssen and its CMOs . During the term of this JDA with respect to one or more countries, Janssen shall have quality agreements in place with each of its CMOs that package, label or handle Territory Combination Product purchased under this JDA. Such quality agreements shall, at a minimum, have terms governing GMP compliance as are customary in the pharmaceutical industry.

(d) Among Janssen, Gilead and its CMO . The Parties or their Affiliates have entered into that certain Quality Agreement for the Manufacture and Supply of Commercial Products (Britestock) for Japan, dated on or around October 17, 2014, with respect to the

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operational and quality assurance activities and regulatory compliance objectives contemplated under this JDA with respect to the Territory Complera to be sold in Japan and the subsequent labeling, packaging and storage of such Territory Complera by Janssen or its Affiliates (the " **JPKK Quality Agreement** "). Any amendment to this JPKK Quality Agreement shall require the written agreement of the parties thereto. Within one hundred twenty (120) days of the Effective Date, the Parties shall negotiate in good faith and execute an amendment to the JPKK Quality Agreement so that the subject matter of such agreement extends to the Territory R/F/TAF Product, where applicable.

SECTION 12
COMBINATION PRODUCT INSPECTIONS

12.1 Annual Inspections . During the term of this JDA with respect to one or more countries and no more than once during any twelve (12) month period, upon reasonable prior written request:

(a) Janssen and/or its agents may inspect, during regular business hours, those portions of the facilities of a Gilead Manufacturer where Territory Combination Product or API contained therein is being Manufactured, to ascertain compliance with GMP, Applicable Law, the Territory Combination Product Specifications and the terms of this JDA in the Manufacture, handling and shipping of Territory Combination Product; and

(b) Gilead and/or its agents may inspect, during regular business hours, those portions of the facilities of a Janssen Packager where Territory Combination Product is being packaged, labeled and/or stored, to ascertain compliance with GMP, Applicable Law, the Territory Combination Product Specifications and the terms of this JDA.

Any such inspection of a Gilead Manufacturer or a Janssen Packager shall be coordinated with inspections thereof conducted by or on behalf of the other Party or its Affiliates, and may be conditioned on the execution of a customary confidentiality agreement between the inspecting Party (or its agent) and such Gilead Manufacturer or Janssen Packager. As part of any inspection conducted pursuant to this Section 12.1, the inspecting Party and/or its agents may inspect, as applicable, (i) the raw materials and API used in the Manufacture of the Territory Combination Product, (ii) the holding facilities for such API, raw materials and/or the Territory Combination Product, (iii) the equipment used in the Manufacture (including packaging and labeling) of the Territory Combination Product, (iv) the facilities where Territory Combination Product is being stored and handled and (v) any related Manufacturing (including packaging and labeling) and storage records (such activities, an " **Inspection** ").

12.2 " For Cause" Inspection .

(a) Janssen may conduct an Inspection of the relevant facilities of any Gilead Manufacturer, if such an Inspection is a reasonable response to an audit notice or inquiry from a Regulatory Authority in a Janssen Country regarding any Territory Combination Product, an unresolved deviation in the Manufacture of the Territory Combination Product, or customer complaints or adverse events regarding the Territory Combination Product. Janssen and Gilead

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shall coordinate in good faith as to the timing of any Inspection of a Contract Manufacturer conducted pursuant to this Section 12.2(a) and Gilead or its designee shall be present at any such Inspection.

(b) Gilead may conduct an Inspection of the relevant facilities of any Janssen Packager, if such an Inspection is a reasonable response to an audit notice or inquiry from a Regulatory Authority in a Janssen Country regarding any Territory Combination Product, an unresolved deviation in the packaging, labeling or storage of the Territory Combination Product, or customer complaints or adverse events regarding the Territory Combination Product. Janssen and Gilead shall coordinate in good faith as to the timing of any Inspection of a Contract Manufacturer conducted pursuant to this Section 12.2(b) and Janssen or its designee shall be present at any such Inspection.

12.3 Remedial Efforts . Following any Inspection conducted (as described above), the Parties shall meet to discuss the inspecting Party's findings, and the other Party shall use Commercially Reasonable Efforts to implement (or cause its Contract Manufacturers to implement) corrective action within the period of time set forth in the Quality Agreement. If such implementation cannot reasonably be completed within such time period, the implementing Party shall commence such implementation or cause its Contract Manufacturers to commence such implementation, within such time period, and shall diligently continue such implementation thereafter.

SECTION 13
COMMERCIALIZATION

13.1 Distribution Activities . Subject to the terms and conditions of the Collaboration Agreement and this JDA, the Parties hereby acknowledge and agree that Janssen (or its Affiliate or Third Party Distributor) shall have the right to Distribute each Territory Combination Product in each Janssen Country. Janssen (or such other Person) shall have the sole responsibility and right to fill orders with respect to such Territory Combination Product in each Janssen Country and shall have the sole responsibility and right to distribute (or right to cause such other Person to distribute) such Territory Combination Product and to perform Distribution Activities with respect thereto. Janssen shall not (a) grant rights to conduct any Distribution Activities with respect to a Territory Combination Product in any of the Janssen Countries to any Person other than its Affiliates, Distribution Subcontractors or (subject to Section 13.2) Third Party Distributors, (b) sell or permit its Affiliates or Third Party Distributors to sell any Territory Combination Product in a country outside of the European Union if Janssen (or such Affiliate or Third Party Distributor) has reason to believe that such Territory Combination Product will be exported from such country to any Gilead Country, or (c) export or have exported, or permit its Affiliates or Third Party Distributors to export, any Territory Combination Product from any country outside of the European Union if Janssen (or such Affiliate or Third Party Distributor) has reason to believe that such Territory Combination Product will be Distributed (by Janssen, its Affiliates or any other Person) in or to any Gilead Country without the written consent of Gilead, unless refusing to so export the Territory Combination Product would violate Applicable Law. Janssen shall perform (or cause to be performed) the Distribution Activities with respect to the

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Territory Combination Products in the Janssen Countries consistent with Applicable Law. Gilead shall promptly forward (or cause its Affiliates to forward) to Janssen (or its designee) any order(s) for the purchase of a Territory Combination Product in the Janssen Countries that are received by Gilead or any of its Affiliates, provided that Gilead's failure to forward any such order to Janssen (or its designee) shall not constitute a breach of this JDA unless such failure constitutes willful misconduct.

13.2 Third Party Distributors . [*].

13.3 Pre-Approval Order Fulfillment in Janssen Countries .

(a) [*].

(b) [*].

13.4 Use of Trademarks .

(a) Janssen shall refrain from, and shall cause its Affiliates and Third Party Distributors to refrain from, using, directly or indirectly, any Product Trademarks other than the Combination Product Trademarks, the Gilead Licensed Trademarks and the Janssen Licensed Trademarks in connection with the Exploitation of Territory Combination Products for sale or distribution in the Janssen Countries; provided , however , that, the foregoing shall not be construed to preclude Janssen or its Affiliates or its Third Party Distributors from using any Trademark in connection with the Exploitation of a Territory Combination Product for sale or distribution in the Janssen Countries to the extent that Applicable Law requires such Trademark to be so used.

(b) [*].

(c) All Branded Region B/C Complera and Branded Region B/C R/F/TAF Product shall have a different tablet color and tablet design and packaging than the Major Market Complera or Major Market R/F/TAF Product, respectively. Without limitation of Section 6.8 of the Collaboration Agreement, Gilead shall designate such tablet color and design and shall design the packaging for the Branded Region B/C Complera and Branded Region B/C R/F/TAF Product, which packaging (and only such packaging) shall be used by Janssen and its Affiliates and Third Party Distributors; provided , however , that Janssen shall modify such packaging as required to comply with local Applicable Law and shall translate such packaging to the local language as necessary. Janssen shall notify Gilead and obtain Gilead's prior written approval of any such packaging modifications with respect to the Branded Region B/C Complera and Branded Region B/C R/F/TAF Product, except to the extent such modifications are required to comply with local Applicable Law.

13.5 Lost Territory Combination Product . Janssen shall notify Gilead in writing on an annual basis of any Territory Combination Product supplied by Gilead to Janssen under the Collaboration Agreement or this JDA that becomes Lost Territory Combination Product in any Calendar Year, which notice shall specify the quantity of such Lost Territory Combination

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Product. Such notification shall occur by January 31 of each Calendar Year with regards to Lost Territory Combination Product from the prior Calendar Year. Notwithstanding anything to the contrary in the Collaboration Agreement, this JDA or any other Ancillary Agreements, with respect to any quantity of Lost Territory Combination Product, [*].

13.6 If Janssen breaches its obligations under Section 13.1(b), Section 13.1(c) or Section 13.4(b) with respect to one or more Janssen Countries, Gilead shall have the right to give Janssen notice specifying the nature of such breach. Janssen shall have a period of [*] after receipt of such notice to cure such breach in a manner reasonably acceptable to Gilead. In the event that Janssen has not cured such breach with respect to such country(ies) in such [*] period, [*]. This Section 13.6 is without limitation of Gilead's termination rights under Section 19.4 of the Collaboration Agreement.

SECTION 14PAYMENTS

14.1 Territory Combination Product . Subject to the terms and conditions of the Collaboration Agreement and this JDA, for Territory Combination Product Delivered by Gilead to Janssen under this JDA, Gilead shall issue to Janssen an invoice upon shipment of such Territory Combination Product as provided in Exhibit B of this JDA. Each such invoice shall state the quantity of Major Market Complera, Branded Region B/C Complera, Major Market R/F/TAF Product or Branded Region B/C R/F/TAF Product, as applicable, covered by such invoice and specify all amounts due in United States Dollars. Subject to the terms and conditions of this JDA and the Collaboration Agreement, Janssen shall pay each such invoice in accordance with the payment terms set forth in Exhibit B of this JDA.

14.2 Reporting; Audit Rights .

(a) Each Party shall provide reports to the other Party in accordance with Exhibit C of this JDA.

(b) Section 10.8.1 of the Collaboration Agreement shall apply *mutatis mutandis* for the purpose of verifying the accuracy of the reports provided under Section 14.2(a).

14.3 Expenses . Unless otherwise agreed by the Parties (including in Exhibit B of this JDA or Article 10 of the Collaboration Agreement), (a) each Party promptly shall invoice the other Party for any amounts due under this JDA and (b) each Party shall pay any invoice provided by the other Party pursuant to this JDA within forty-five (45) days after receipt of such invoice.

SECTION 15
JANSSEN REPRESENTATIONS, WARRANTIES AND COVENANTS

15.1 Warranty on Distributed Territory Combination Product . Janssen represents and warrants that, at the time of distribution or sale by Janssen or its Affiliates to Third Parties of any Territory Combination Product supplied under this JDA, such Territory Combination Product

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shall not be expired or otherwise unfit for sale as a result of Janssen's packaging, labeling, handling or storage of such Territory Combination Product and such Territory Combination Product shall be in conformance with the applicable Territory Combination Product Specifications and Applicable Law with respect to packaging and labeling.

15.2 Permits . Janssen shall obtain and maintain all necessary permits for the packaging, labeling, receipt, storage, handling and distribution of Territory Combination Product at the facility(ies) where Territory Combination Product supplied under this JDA is packaged, labeled and/or stored by or on behalf of Janssen or its Affiliates.

15.3 Manufacturing and Storage Records . Janssen shall maintain complete and accurate records relating to the receipt, handling, storage, use, packaging, labeling and disposal by or on behalf of Janssen or its Affiliates of the Territory Combination Product supplied under this JDA and standard operating procedures for the foregoing in accordance with Applicable Law and GMP and shall provide a written account of any discrepancies. Gilead shall have the right to review such records upon the reasonable request of Gilead.

15.4 Packaging and Labeling Specifications . Janssen shall label and package the Territory Combination Product in accordance with GMP and Applicable Law for the country or region in which such Territory Combination Product will be sold, released or distributed. If any Territory Combination Product intended for release, sale or distribution by Janssen fails to comply with the labeling and packaging requirements in accordance with the Territory Combination Product Specifications or Applicable Law for the country or region in which such Territory Combination Product will be sold, released or distributed, then Janssen shall not release, sell or distribute such Territory Combination Product.

15.5 Janssen Packagers . Janssen shall, or shall cause the Janssen Packagers to, maintain the facilities, equipment and machinery used in connection with the labeling and packaging of Territory Combination Product in a state of repair and operating efficiency that enables it to meet the applicable Territory Combination Product Specifications. Janssen shall, or shall cause such Janssen Packagers to, validate the equipment and the labeling and packaging process and any other appropriate steps performed at such facilities and validate/calibrate all instruments used in testing such equipment and machinery, in each case to the extent used in connection with the labeling or packaging of Territory Combination Product and as required by GMP and Applicable Law.

15.6 Handling and Storage . Janssen shall at all times handle, store and transport Territory Combination Product in accordance with Applicable Law, GMP and GDP and in a manner and with a level of care consistent with Janssen's handling, storage and transport of similar pharmaceutical products.

SECTION 16
TERMINATION; CONSEQUENCES OF TERMINATION

16.1 Termination .

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(a) At any time, Janssen may terminate this JDA in its entirety or with respect to any Janssen Country upon [*] written notice to Gilead. In the event of any such termination, Gilead may elect to convert any terminated Janssen Country to a Gilead Country by providing written notice of such election to Janssen within [*] after delivery of Janssen's termination notice with respect to such Janssen Country and such terminated Janssen Country shall be deemed to be a Gilead Take-Over Country upon Janssen's receipt of such election notice.

(b) If Gilead elects to (i) convert a Janssen Diligence Country to a Gilead Country pursuant to [*] or (ii) convert a Janssen Country to a Gilead Country pursuant to [*] Section 16.1(a), then as of the effectiveness of such election as specified in [*], this JDA shall be deemed terminated with respect to such country and such country shall be deemed a Gilead Take-Over Country.

(c) For clarity, this JDA shall automatically terminate with respect to a Territory Combination Product (i) with respect to a country, upon any termination of the Collaboration Agreement with respect to such Territory Combination Product with respect to such country, and (ii) with respect to all countries, upon any termination of the Collaboration Agreement with respect to such Territory Combination Product with respect to all countries.

(d) In the event that a Janssen Country becomes a Gilead Take-Over Country [*].

16.2 Consequences of Termination .

(a) If this JDA is terminated with respect to a country for any reason and such country is a Gilead Take-Over Country, then:

(1) Janssen, upon receiving any necessary or appropriate approval from the applicable Regulatory Authority (ies), shall cease selling (and cause its Affiliates and Third Party Distributors, as applicable, to cease selling) [*] in such Gilead Take-Over Country, but shall not conduct any withdrawal or recall with respect to the [*] in such Gilead Take-Over Country;

(2) if Janssen (or its Affiliate or Third Party Distributor) holds any Drug Approval Application or Marketing Approval with respect to any Territory Combination Product with respect to such Gilead Take-Over Country, Janssen shall, as promptly as reasonably practicable after the effective date of such termination (or, if later, the date on which Gilead makes such election to convert the country to a Gilead Take-Over Country), transfer (or cause to be transferred) to Gilead (or its designated Affiliate, Sublicensee or Third Party Distributor) such Drug Approval Application(s) or Marketing Approval(s) and the Parties shall coordinate in good faith to effect such transfer (and, for clarity, until such time as such transfer has been completed, as between the Parties, Janssen shall remain responsible for performing all activities required to be performed by the holder of such Drug Approval Application(s) or Marketing Approval(s) in accordance with Applicable Law), and Janssen shall be responsible for the costs of such transfer, unless such Gilead Take-Over Country was converted to a Gilead Take-Over Country pursuant to [*], in which case, Gilead shall be responsible for the costs of such transfer;

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(3) Janssen shall remain responsible for the performance of its obligations hereunder and under the Collaboration Agreement with respect to such Gilead Take-Over Country as a Janssen Country for the period during which it was a Janssen Country, including with respect to indemnification with respect to any acts or omissions occurring during such period; and

(4) Gilead shall not have any diligence obligations whatsoever with respect to the Exploitation of any Territory Combination Product with respect to such Gilead Take-Over Country; provided , however , that if such Gilead Take-Over Country was a Janssen Diligence Country that was converted to a Gilead Take-Over Country pursuant to [*], the obligations of Janssen set forth in [*] with respect to Territory Combination Products in such country shall thereafter apply to Gilead.

(b) If this JDA is terminated with respect to a country for any reason and such country is not a Gilead Take-Over Country (and Gilead no longer has the right to convert such country to a Gilead Take-Over Country), then:

(1) Janssen, upon receiving any necessary or appropriate approval from the applicable Regulatory Authority (ies), shall cease selling (and cause its Affiliates and Third Party Distributors, as applicable, to cease selling) [*] in such country;

(2) if Janssen (or its Affiliate or Third Party Distributor) holds any Drug Approval Application or Marketing Approval with respect to any Territory Combination Product with respect to such country, Janssen shall, [*], as promptly as practicable after the effective date of such termination (or, if later, the expiration of such time period in which Gilead could have made such election to convert the country to a Gilead Take-Over Country), withdraw such Drug Approval Application(s) or Marketing Approval(s) (and recall such Territory Combination Product in connection therewith, if required by Applicable Law, at its own cost) (and, for clarity, until such time as such withdrawal(s) (and recalls, if applicable) have been completed, as between the Parties, Janssen shall remain responsible for performing all activities required to be performed by the holder of such Drug Approval Application(s) or Marketing Approval(s) in accordance with Applicable Law);

(3) if Gilead (or its Affiliate) holds any Drug Approval Application or Marketing Approval with respect to any Territory Combination Product with respect to such country, Gilead shall, [*], as promptly as practicable after the effective date of such termination (or, if later, the expiration of such time period in which Gilead could have made such election to convert the country to a Gilead Take-Over Country), withdraw such Drug Approval Application(s) or Marketing Approval(s) (and recall such Territory Combination Product in connection therewith, if required by Applicable Law, [*]);

(4) from and after the date on which the withdrawal(s) (and recall(s), if applicable) described in clause (1) or (2) above have been completed with respect to such country, such country shall be deemed a Gilead Country and for clarity, Gilead shall not have any diligence obligations whatsoever with respect to the development or commercialization of any Territory Combination Product with respect to such country.

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(c) Supply Wind-Down . Without limiting Section 16.2(a), in the event of any termination of this JDA in its entirety or with respect to a country, the Parties shall coordinate in good faith to wind down matters relating to the Manufacture and supply of the Territory Combination Product(s) under this JDA (if applicable, with respect to the terminated country), including the appropriate disposition of any quantities of such Territory Combination Product(s) then in Janssen's (or its Affiliates') inventory to the extent not otherwise usable by Janssen for commercialization of such Territory Combination Product(s) under this JDA; provided , however , that [*].

SECTION 17
SURVIVAL

17.1 Termination of this JDA, in whole or in part, shall be without prejudice to any liabilities that shall have accrued prior to such termination or any remedies to which either Party may be entitled. Such termination shall not relieve a Party from obligations that are expressly indicated to survive such termination of this JDA.

17.2 Without limiting anything contained in SECTION 16 to the contrary, in the event of any termination of this JDA for any reason, the following sections shall survive such termination: SECTION 14 (in the case of Sections 14.1 and 14.2, to the extent related to Triggering Sales made prior to termination of this JDA), 15.3 (to the extent such records are required for a period of three (3) years following termination of this JDA), 16.1 (with respect to any post-termination rights or obligations set forth therein, as applicable), 16.2, 17, 18.2 and 19, and any definitions of capitalized terms or other provisions (including any Exhibits) required to give effect to the foregoing provisions.

SECTION 18
SUBCONTRACTING

18.1 Subject to the terms and conditions of this JDA, Gilead may subcontract the Manufacture of Territory Combination Product to one or more Contract Manufacturers. Gilead shall have the right to select such Contract Manufacturers in its sole discretion. In the event that Gilead delegates any of its obligations under this JDA to a subcontractor, Gilead shall remain primarily (and not secondarily or derivatively) liable for the full and timely performance by such subcontractor of all its obligations under this JDA. Notwithstanding anything to the contrary contained herein, if Gilead engages a subcontractor to fulfill any of Gilead's obligations under this JDA, Gilead shall cause such subcontractor to comply with the provisions of this JDA.

18.2 For clarity, Janssen shall not be considered a subcontractor of Gilead for any purpose under the Collaboration Agreement or this JDA.

SECTION 19
MISCELLANEOUS

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19.1 This JDA is subject to the terms of the Collaboration Agreement. If there is any inconsistency between the provisions of this JDA and the provisions of the Collaboration Agreement, the provisions of the Collaboration Agreement shall control. If there is any inconsistency between the provisions of this JDA and the Quality Agreement, or any purchase order, confirmation, or other document passing between the Parties relating to supply of Territory Combination Product by Gilead to Janssen or the subsequent packaging, handling or storage of the Territory Combination Product by Janssen under this JDA, the provisions of this JDA shall control except that the Quality Agreement shall control with respect to procedures for verifying compliance with quality requirements.

19.2 Subject to Section 20.14.1 of the Original Agreement and to Section 19.1 above, this JDA (including the Exhibits hereto), constitutes, on and as of the Restatement Effective Date, the entire agreement of the Parties with respect to the subject matter hereof, and all prior or contemporaneous understandings or agreements between Gilead, on the one hand, and Janssen, on the other hand, whether written or oral, with respect to such subject matter are hereby superseded in their entireties; provided , however , that (a) the CDA shall be superseded solely to the extent applicable to the subject matter of this Agreement, (b) certain other agreements and side letters shall terminate, remain in effect or be modified as separately mutually agreed by the Parties in writing; and (c) this JDA shall supersede the Original JDA, except the provisions in Exhibit B-1 , Exhibit B-2 , Exhibit B-3 and Exhibit C shall take effect January 1, 2015. This Agreement shall not be amended in any respect whatsoever except by a further agreement, in writing, fully executed by Gilead and Janssen.

19.3 Sections 20.1, 20.2, 20.3, 20.4, 20.5, 20.6, 20.7, 20.8, 20.9, 20.10, 20.11, 20.12, 20.13 and 20.15 of the Collaboration Agreement shall apply *mutatis mutandis* .

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Cipla v. Gilead **IPR2025-00033** **Petitioner Exhibit 1030**

IN WITNESS WHEREOF, the Parties have caused this JDA to be duly executed and delivered as of the date first above written.

JANSSEN R&D IRELAND

By: _____
Name: Margaret Dunlea
Title: Managing Director

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IN WITNESS WHEREOF, the Parties have caused this JDA to be duly executed and delivered as of the date first above written.

GILEAD SCIENCES, INC.

By: _____
Name: John F. Milligan, Ph.D.
Title: President and Chief Operating Officer

GILEAD SCIENCES IRELAND UC

By: _____
Name: John F. Milligan, Ph.D.
Title: Director

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SCHEDULE LIST :

Schedule 11.3 : Approved Manufacturing Sites

EXHIBIT LIST :

Exhibit B-0 : Invoicing and Payment Terms for Janssen Countries
Exhibit B-1 : Financial Calculations for Territory Combination Product in Janssen Countries
Exhibit B-2 : TCP Actual Supply Price Reductions for Janssen Countries
Exhibit B-3 : Payment Terms for TCP Invoices for Janssen Countries
Exhibit C : Financial Reporting

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CONFIDENTIAL TREATMENT REQUESTED
UNDER 17 C.F.R. §§ 200.80(b)(4) AND 240.24B-2

Schedule 11.3

Approved Manufacturing Sites

CURRENT AS OF DECEMBER 15, 2014

[*]

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Exhibit B-0

Invoicing and Payment Terms for Janssen Countries

1 PAYMENTS

1.1 Payments .

1.1.1 Payment of TCP Interim Supply Price . Gilead shall submit an invoice to Janssen at the TCP Interim Supply Price for any Units of Territory Combination Product used or intended to be used for commercial purposes at the time of Delivery to Janssen of such Territory Combination Product or promptly thereafter. Payments with respect to each such invoice shall be payable and due in accordance with the terms of this JDA, including Section 1.4 and Section 1.5.1 of this Exhibit B-0 . For clarity, for each Territory Combination Product, the TCP Interim Supply Price shall be invoiced collectively for the Janssen Countries in Region A, Region B and Region C.

1.1.2 Monthly Payments . Subject to Exhibit B-1 , for each Territory Combination Product, Janssen shall make a Monthly Payment with respect to all Janssen Countries that are Janssen Post-Conversion Supply Price Countries in Region A, Region B and Region C (in a single amount for all such Janssen Post-Conversion Supply Price Countries), subject to any adjustments specified hereunder, which payment shall be payable and due in accordance with the terms of this JDA, including Sections 1.4, 1.5.2 and 1.5.3 of this Exhibit B-0 .

1.2 TCP Actual Supply Price and Additional Supply Price Reductions . The TCP Actual Supply Price or Additional Supply Price, as applicable, for each Territory Combination Product in each Janssen Post-Conversion Supply Price Country shall be adjusted as set forth in Exhibit B-2 (provided that, with respect to Section A of Exhibit B-2 , such adjustments shall apply only with respect to [*].

1.3 Monthly Payment Term . For each Territory Combination Product, the Monthly Payment shall be made for the Janssen Post-Conversion Supply Price Countries in Region A, Region B and Region C, until the expiration of the last to expire Monthly Payment Term in the Janssen Post-Conversion Supply Price Countries in Region A, Region B and Region C (and the calculations in Exhibit B-1 shall take account of the exclusion of countries for which the Monthly Payment Term has expired following the end of the applicable Monthly Payment Term). " **Janssen Post-Conversion Supply Price Country(ies)** " shall mean any Janssen Countries in the Territory for which a Monthly Payment Term is in effect.

1.4 Mode of Payment . All payments to Gilead hereunder shall be made by wire transfer of U.S. Dollars in the requisite amount to the account designated by Gilead; provided , however , that any notice by Gilead of a change in such account shall not be effective [*].

1.5 Reports & Payments .

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1.5.1 TCP Interim Supply Price Payments . TCP Interim Supply Invoices shall be due and payable by Janssen or its designated Affiliate in accordance with Exhibit B-3 .

1.5.2 Monthly Payments . For each Territory Combination Product, Janssen or its designated Affiliate shall make the Monthly Payments collectively for Region A, Region B and Region C, for each Universal Calendar Month during the Term in accordance with Exhibit B-3 , subject to prior receipt of an invoice from Gilead for such amount.

1.5.3 Monthly Payment Calculation . For each Territory Combination Product, the calculation of a Monthly Payment shall be based on the total number of Units of such Territory Combination Product sold by Janssen and its Affiliates to Third Parties during such Universal Calendar Month (adjusted on a pro rata basis in the event that the applicable Monthly Payment Term has expired during such Universal Calendar Month) in Janssen Countries that are Janssen Post-Conversion Supply Price Countries where the Monthly Payment Term has not yet expired, as provided in Exhibit B-1 .

1.5.4 Monthly Reports . Janssen shall provide to Gilead the Post-Launch NSP Information and monthly reports described in Exhibit C on a product-by-product and country-by-country basis setting forth the Units of each Territory Combination Product sold. Such Post-Launch NSP Information and monthly reports shall be due no later than five (5) Business Days after the end of each Universal Calendar Month. All other reports described on Exhibit C shall be provided by the applicable Party to the other Party within the time periods set forth in Exhibit C . Gilead shall be responsible for making the calculations set forth in Exhibit B-1 .

1.5.5 Other Payments . For all other payments due hereunder, the invoicing Party shall submit an invoice to the paying Party and such invoices shall be due and payable within [*] after receipt unless otherwise provided in this JDA or the Collaboration Agreement.

1.5.6 Communication of Non-Public Pricing Information . The Parties shall communicate all non-public Net Selling Price information necessary to perform the financial calculations required by this JDA solely through their respective representatives on the Financial Reporting Committee or as otherwise approved by such committee.

1.5.7 Other Reports . Without limitation of the foregoing, each Party shall also provide such other financial-related reports as are set forth on Exhibit C and otherwise comply with the requirements of Exhibit C .

1.6 [Reserved] .

1.7 Currency Conversion . The Party responsible for making any currency conversions hereunder shall, in a manner consistent with Gilead's then-current standard worldwide currency conversion methodology, convert the applicable amounts incurred or sold, as the case may be, into the applicable currency. Gilead's standard worldwide currency conversion methodology on the Restatement Effective Date is based on a monthly rate that is within the day's trading range during NYC trading hours in Bloomberg Professional service application on the third (3rd) to last Business Day of the prior month. Gilead shall inform

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Janssen of any changes to its standard worldwide currency conversion methodology prior to any such changes becoming effective. For clarity, all currency conversions required under this Section 1.7 shall use the exchange rate for the applicable month then used by Gilead in accordance with the foregoing.

1.8 Audits . Section 10.8.1, Section 10.8.2 (except Section 10.8.2.1), Section 10.8.3 and Section 10.8.4 of the Collaboration Agreement shall apply *mutatis mutandis* to the Janssen Countries.

1.9 Interest Due . In case of any delay in payment by a Party to the other Party hereunder, interest on the overdue payment shall accrue at an annual interest rate equal to the lower of (a) the sum of (i) the prime rate of interest in force on the date the payment is due as published in The Wall Street Journal (Eastern United States Edition) and (ii) [*] and (b) the maximum rate of interest permissible by Applicable Law. The foregoing interest shall be due from the paying Party without any special notice.

1.10 Tax Withholding . Section 10.10 of the Collaboration Agreement shall apply *mutatis mutandis* to payments under this JDA.

1.11 [Reserved] .

1.12 [Reserved] .

1.13 [Reserved] .

1.14 [Reserved] .

1.15 [Reserved] .

2 FINANCIAL CALCULATIONS AND ADJUSTMENTS

2.1 Calculations . Section 11.1 of the Collaboration Agreement shall apply *mutatis mutandis* to calculations hereunder.

2.2 [Reserved] .

2.3 [Reserved] .

2.4 [Reserved] .

2.5 [Reserved] .

2.6 [Reserved] .

2.7 [Reserved] .

2.8 [Reserved] .

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2.9 [Reserved] .

2.10 Application of Original Agreement . Notwithstanding anything to the contrary in the Collaboration Agreement, this JDA or any other Ancillary Agreement, the provisions related to pricing, revenue sharing, payment, financial reporting and audit and committees related to the foregoing (including the Discount Committee (as defined in the Original Agreement) and the Launch Coordination Committee (as defined in the Original Agreement)) of the Original Agreement and not the provisions related to pricing, revenue sharing, payment, financial reporting, audit and committees of the Collaboration Agreement or this JDA shall govern any applicable activities conducted by the Parties (including any Triggering Sales (as defined in the Original Agreement)) with respect to Territory Complera on or before December 31, 2014, as well as any audits hereunder with respect to such period.

2.11 Japan . [*].

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Exhibit B-1

Financial Calculations for Territory Combination Product in Janssen Countries

Capitalized terms not defined in this Exhibit B-1 shall have the meanings set forth in the Collaboration Agreement or in Exhibit B-2 . The following terms and conditions of this Exhibit B-1 are subject to Exhibit B-2 . This Exhibit B-1 shall apply to Triggering Sales of each Territory Combination Product in Janssen Countries other than Japan.

A. TCP Actual Supply Price, TCP Interim Supply Price, Unit Pre-Conversion Supply Price.

1. [*].

2. [*].

3. [*].

4. [*].

B. [*]

1. [*].

2. [*].

3. [*].

4. [*].

5. [*].

6. [*].

7. [*].

8. [*].

9. [*].

C. [*]

1. [*]

(a) [*]

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(b) [*].

2. [*].

3. [*].

(a) [*]

(b) [*].

D. [*].

1. [*]

2. [*].

3. [*]

4. [*].

E. [*].

F. Other

1. " **Triggering Sale** " shall have the meaning set forth in Paragraph 1 of Section I of Annex M-1 of the Collaboration Agreement.

2. " **Universal Calendar Month** " shall have the meaning set forth in Paragraph 2 of Section I of Annex M-1 of the Collaboration Agreement.

3. " **Universal Calendar Quarter** " shall have the meaning set forth in Paragraph 3 of Section I of Annex M-1 of the Collaboration Agreement.

4. " **Universal Calendar Year** " shall have the meaning set forth in Paragraph 4 of Section I of Annex M-1 of the Collaboration Agreement.

An example of the calculation of the TCP Actual Supply Price and the Monthly Payment is included below for illustrative purposes only:

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Region A Janssen Countries

[*]

Regions B and C Janssen Countries

[*]

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Exhibit B-2

TCP Actual Supply Price Reductions for Janssen Countries

[*].

A. [*].

B. [*].

C. [*].

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Exhibit B-3

Payment Terms for TCP Invoices for Janssen Countries

Capitalized terms not defined in this Exhibit B-3 shall have the meanings set forth in the Collaboration Agreement. The payment terms for the Interim TCP Invoices and Final TCP Invoices for the Janssen Countries are as follows:

Within fifteen (15) Business Days after the end of each calendar month, with respect to any Triggering Sales of each Territory Combination Product in Janssen Countries occurring in the corresponding Universal Calendar Month, (a) Gilead shall notify Janssen of the date by which any Interim TCP Invoice (or portion thereof) with respect to such Triggering Sales of each applicable Territory Combination Product is due and payable and (b) Gilead shall calculate the TCP Actual Supply Price (if applicable) for Units of each applicable Territory Combination Product for which Triggering Sales occurred in such Universal Calendar Month in accordance with Exhibit B-1 , and shall notify Janssen of the amount of such TCP Actual Supply Price for such Units of Territory Combination Product.

The due date for all Interim TCP Invoices and Final TCP Invoices (the " **Janssen Payment Term** ") initially shall be [*].

For each Interim TCP Invoice (or portion thereof) for which a due date is set based on Triggering Sales during the Monthly Payment Term in a given Universal Calendar Month, Janssen shall notify Gilead (or its applicable Affiliate) that Gilead should issue a corresponding invoice for the Additional Supply Price corresponding to the Units of Territory Combination Product that are the subject of such Interim TCP Invoice (or portion thereof) (such invoice, the " **Final TCP Invoice** "), which invoice shall have the same due date as the corresponding Interim TCP Invoice (or portion thereof).

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Exhibit B-4

Revaluation of Territory Combination Product

Within fifteen (15) Business Days following December 31, 2014, Gilead shall provide Janssen with a credit note with respect to each outstanding invoice for Territory Complera purchased by Janssen on or before December 31, 2014 for Territory Complera for which a Triggering Sale has not occurred on or before December 31, 2014 to reflect the amount in U.S. Dollars that equals the difference between the amount charged on the original invoice and the Interim TCP Invoice. Any credit note shall be issued to the entity (Janssen or the Janssen Affiliate) initially invoiced for the quantity of Territory Complera in question and shall only be creditable against amounts owed by the entity (Janssen or the Janssen Affiliate) to which the credit note was issued.

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Exhibit C

Financial Reporting

Capitalized terms not defined in this Exhibit C shall have the meanings set forth in the Collaboration Agreement or in Exhibit B-1 , Exhibit B-2 or Exhibit B-3 .

A. [Reserved].

B. [*].

C. [*].

D. [*].

(i) [*]

(ii) [*].

Forecasts Generally . Any forecasts provided pursuant to this Section D of this Exhibit C are, for clarity, the Confidential Information of the providing Party. Except as expressly provided hereunder, each Party shall ensure that such forecast(s) are made available only (x) to its Financial Reporting Committee representatives and Necessary Personnel and (y) as required to comply with the In-License Requirements (which forecasts the receiving Party shall provide to its licensor only to the extent required to be provided under the applicable In-License Agreement and subject to confidentiality thereunder and Section 15.2.4 of the Collaboration Agreement). Neither Party shall be liable for any differences between its forecasted information and the actual corresponding sales realized by such Party.

E. Right to Decline. Upon advance written notice to Janssen, Gilead may decline to receive any of the aforesaid data, information or forecasts (including any data, information or forecasts provided under Annex N of the Collaboration Agreement) (except to the extent that the information is required to be exchanged in order to perform the financial calculations required under the JDA).

F. [*].

G. [*].

H. [*].

I. [Reserved].

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Annex AA-1: Regions

Regions

For clarity, the applicable region shall automatically include any country that is derived from the territory of a country listed below.

[*]

[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]

[*]

[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	

Region B

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Algeria	Iran	Paraguay
Azerbaijan	Iraq	Peru
Belarus	Jordan	Philippines
Cayman Islands	Libya	Sint Maarten
Curacao	Morocco	Tunisia
China (Mainland)	Panama	Ukraine
Egypt		

Region C

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Afghanistan	Georgia	Guatemala
Angola	Ghana	Guinea
Anguilla	Grenada	Rwanda
Antigua and Barbuda	Guinea-Bissau	Saint Kitts and Nevis
Armenia	Guyana	Saint Lucia
Aruba	Haiti	Saint Vincent and the Grenadines
Bahamas	Honduras	Samoa
Bangladesh	India	Sao Tome and Principe
Barbados	Indonesia	Senegal
Belize	Jamaica	Seychelles
Benin	Kazakhstan	Sierra Leone
Bhutan	Kenya	Solomon Islands
Bolivia	Kiribati	Somalia
Botswana	Korea, Dem. People's Rep of	South Africa
British Virgin Islands	Kyrgyzstan	South Sudan
Burkina Faso	Lao, People's Dem. Rep.	Sri Lanka
Burundi	Lesotho	Sudan
Cambodia	Liberia	Suriname
Cameroon	Madagascar	Swaziland
Cape Verde	Malawi	Syria
Central African Republic	Maldives	Tajikistan
Chad	Mali	Tanzania, U. Rep. of
Comoros	Mauritania	Thailand
Congo	Mauritius	Timor-Leste
Congo, Dem. Rep. of the	Moldova, Rep. of	Togo
Cote d'Ivoire	Mongolia	Tonga
Cuba	Montserrat	Trinidad and Tobago
Djibouti	Mozambique	Turkmenistan
Dominica	Myanmar	Turks and Caicos
Dominican Republic	Namibia	Tuvalu
Ecuador	Nauru	Uganda
El Salvador	Nepal	Uzbekistan
Equatorial Guinea	Nicaragua	Vanuatu
Eritrea	Niger	Vietnam
Ethiopia	Nigeria	Yemen
Fiji	Pakistan	Zambia
Gabon	Palau	Zimbabwe
Gambia	Papua New Guinea	

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Annex AA-2: Janssen Countries

The Janssen Countries as of the Restatement Effective Date are listed below.

Region A

Country	Gilead Marketing Approval (if any) that is required in order for Janssen to Obtain or Maintain a Marketing Approval in the applicable Janssen Country	
	For Janssen Obtaining Marketing Approval	Certificate of Pharmaceutical Product (import license) For Janssen Maintaining Marketing Approval
Hong Kong*	[*]	[*]
Israel	[*]	[*]
Japan	[*]	[*]
Mexico	[*]	[*]
Russia	[*]	[*]
Singapore	[*]	[*]
South Korea	[*]	[*]
Taiwan	[*]	[*]

*The Marketing Approval for Macau is dependent on the Marketing Approval for Hong Kong.

Region B

Country	Referenced Gilead Marketing Approval (if any) that is required in order for Janssen to Obtain or Maintain a Marketing Approval in the applicable Janssen Country	
	For Janssen Obtaining Marketing Approval	Certificate of Pharmaceutical Product (import license) For Janssen Maintaining Marketing Approval
Azerbaijan	[*]	[*]
Belarus	[*]	[*]
China (Mainland)	[*]	[*]
Ukraine	[*]	[*]

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Region C

Country	**Referenced Gilead Marketing Approval (if any) that is required in order for Janssen to Obtain or Maintain a Marketing Approval in the applicable Janssen Country**	
	For Janssen Obtaining Marketing Approval	**Certificate of Pharmaceutical Product (import license) For Janssen Maintaining Marketing Approval**
Armenia	[*]	[*]
Kazakhstan	[*]	[*]
Kyrgyzstan	[*]	[*]
Tajikistan	[*]	[*]
Uzbekistan	[*]	[*]

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Annex BB: [Reserved]

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Annex CC: [Reserved]

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Annex DD: [Reserved]

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Annex EE: Planned or Possible R/F/TAF Product Clinical Studies

	Study	Description	Comments
1	[*]	[*]	[*]
2	Phase 3b Study GS-US-366-1216	Complera → R/F/TAF 48-week Switch Study	[*] Dosing Q1 2015
3	Phase 3b Study GS-US-366-1160	Atripla® → R/F/TAF 48-week Switch Study	[*] Dosing Q1 2015
4	[*]	[*]	[*]
5	[*]	[*]	[*]
6	[*]	[*]	[*]
7	[*]	[*]	[*]
8	[*]	[*]	[*]
9	[*]	[*]	[*]
10	[*]	[*]	[*]
11	[*]	[*]	[*]

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Annex FF: Co-Detailing Countries

1. Australia
2. Austria
3. Belgium
4. Canada
5. Croatia
6. Czech Republic
7. Denmark
8. Estonia
9. Finland
10. France
11. Germany
12. Greece
13. Hungary
14. Iceland
15. Ireland
16. Italy
17. Latvia
18. Lithuania
19. Luxembourg
20. Netherlands
21. New Zealand
22. Norway
23. Poland
24. Portugal
25. Romania
26. Slovak Republic
27. Slovenia
28. Spain
29. Sweden
30. Switzerland
31. Turkey
32. United Kingdom
33. United States

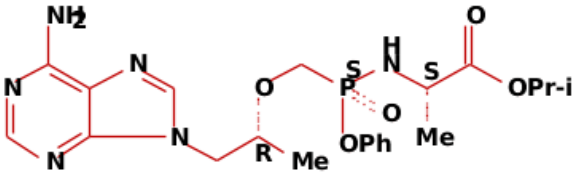
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Annex GG-1: GS 7340; Tenofovir Alafenamide Fumarate

Registry Number: 379270-37-8

Absolute stereochemistry



Formula: C21 H29 N6 O5 P

CA Index Name: L-Alanine, N-[(S)-[[(1R)-2-(6-amino-9H-purin-9-yl)-1-methylethoxy]methyl]phenoxyphosphinyl]-, 1-methylethyl ester

Other Names: GS 7340; Tenofovir alafenamide fumarate

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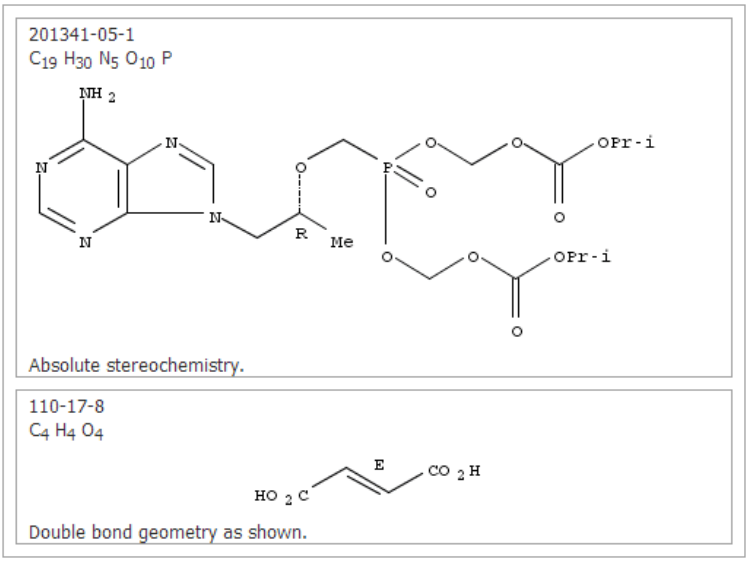
Annex GG-2: Tenofovir Disoproxil Fumarate

CAS Registry Number: 202138-50-9

$C_{19}H_{30}N_5O_{10}P.C_4H_4O_4$

2,4,6,8-Tetraoxa-5-phosphanonanedioic acid, 5-[[(1 *R*)-2-(6-amino-9 *H* -purin-9-yl)-1-methylethoxy]methyl]-, 1,9-bis(1-methylethyl) ester, 5-oxide, (2 *E*)-2-butenedioate (1:1)

2,4,6,8-Tetraoxa-5-phosphanonanedioic acid, 5-[[(1R)-2-(6-amino-9H-purin-9-yl)-1-methylethoxy]methyl]-, bis(1-methylethyl) ester, 5-oxide, (2E)-2-butenedioate (1:1) (9CI); 2,4,6,8-Tetraoxa-5-phosphanonanedioic acid, 5-[[2-(6-amino-9H-purin-9-yl)-1-methylethoxy]methyl]-, bis(1-methylethyl) ester, 5-oxide, (R)-, (E)-2-butenedioate (1:1); GS 4331-05; PMPA Prodrug; Tenofovir DF; Tenofovir disoproxil fumarate; Virea;Viread

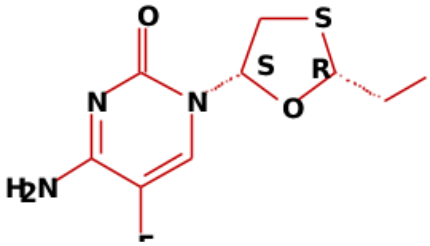


[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

Annex GG-3: Emtricitabine

Registry Number: 143491-57-0

Absolute stereochemistry. Rotation (-)



Formula: C8 H10 F N3 O3 S

CA Index Name: 2(1H)-Pyrimidinone, 4-amino-5-fluoro-1-[(2R,5S)-2-(hydroxymethyl)-1,3-oxathiolan-5-yl]-

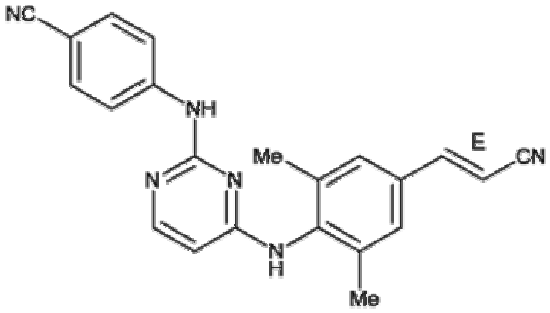
Other Names: 2(1H)-Pyrimidinone, 4-amino-5-fluoro-1-[2-(hydroxymethyl)-1,3-oxathiolan-5-yl]-, (2R-cis)-; 1,3-Oxathiolane, 2(1H)-pyrimidinone deriv.; (-)-2',3'-Dideoxy-5-fluoro-3'-thiacytidine; (-)-2'-Deoxy-5-fluoro-3'-thiacytidine; (-)-FTC; 524W91; BW 1592; BW 524W91; Coviracil; Emtricitabine; Emtriva; FTC, (-)-

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Annex GG-4: Rilpivirine

Registry Number: 500287-72-9

Absolute stereochemistry



Formula : $C_{22}H_{18}N_6$

CA Index Name: Benzonitrile, 4-[[4-[[4-[(*1E*)-2-cyanoethenyl]-2,6-dimethylphenyl]amino]-2-pyrimidinyl]amino]

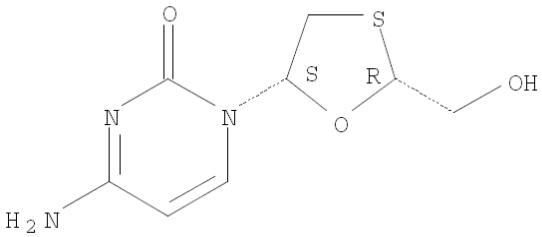
Other names: (E)-4-((4-((4-(2-cyanovinyl)-2,6-dimethylphenyl)amino)pyrimidin-2-yl)amino)benzonitrile; Rilpivirine; Edurant; R 278474; TMC 278

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Annex GG-5: 3TC

Registry Number: 134678-17-4

Absolute stereochemistry. Rotation (-)



Formula: C8 H11 N3 O3 S

CA Index Name: 2(1H)-Pyrimidinone, 4-amino-1-[(2R,5S)-2-(hydroxymethyl)-1,3-oxathiolan-5-yl]-

Other Names: 2(1H)-Pyrimidinone, 4-amino-1-[2-(hydroxymethyl)-1,3-oxathiolan-5-yl]-, (2R-cis)-; 1,3-Oxathiolane, 2(1H)-pyrimidinone deriv.; (-)-2'-Deoxy-3'-thiacytidine; (-)-BCH 189; 2-Hydroxymethyl-5-(cytosin-1-yl)-1,3-oxathiolane; 3TC; BCH 189, (-)-; Epivir; Epivir HBV; GR 109714X; Hepitec; Heptodin; Heptovir; L-SddC; Lamivir; Lamivudine; Virolam; Zeffix; Zefix; cis(-)-2-Hydroxymethyl-5-(cytosin-1-yl)-1,3-oxathiolane; β-L-2',3'-Dideoxy-3'-thiacytidine; β-L-3'-Thia-2',3'-dideoxycytidine

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Annex GG-6: [Reserved]

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Annex HH: Ongoing Edurant Studies

1. **TMC278-TiDP38-C213** : A Phase 2, open label, single arm study to evaluate the pharmacokinetics, safety, tolerability, and antiviral activity of RPV in antiretroviral naïve HIV-1 infected adolescents aged 12 to <18 years.

2. **TMC114HIV3015** : A single arm, open label study to assess the pharmacokinetics of darunavir/ritonavir and/or etravirine and RPV in HIV-1 infected pregnant women.

3. **TMC278-TiDP38-C220** (= IMPAACT P1111 trial): A Phase 2, open label, single arm study to evaluate the pharmacokinetics, safety, tolerability, and antiviral activity of RPV in antiretroviral naïve HIV-1 infected adolescents aged <12 years.

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Cipla v. Gilead **IPR2025-00033** **Petitioner Exhibit 1030**

Annex II: Rights of Reference

Rights of Reference to Gilead for Territory Complera:

[*]

Rights of Reference to Gilead for Territory R/F/TAF Product:

[*]

Rights of Reference to Janssen for Territory Complera:

[*]

Rights of Reference to Janssen for Territory R/F/TAF Product:

[*]

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

Annex JJ: Registration Plan

R/F/TAF Fixed Dose Combination Tablet (STR)

Country	Planned Submission Date**	Anticipated Approval Date
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]

[*]

Current initial target indications ([*])
[*]

[*] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

Annex KK: Insurance Requirements

I. Gilead:

Gilead shall maintain, at its sole cost and expense, the following minimum amounts of insurance coverage:

(A) Clinical Trials Liability Insurance: Insuring against claims for bodily injury arising out of Gilead's (or its Affiliates' or Sublicensees') sponsored clinical trials. Coverage and limits shall, at a minimum, comply with statutory/country requirements where the trials will be performed.

(B) General and Products Liability: Insuring against claims, including bodily injury, property damage and advertising liability, with minimum limits of not less than $50,000,000 U.S., covering claims brought and suits served anywhere in the world.

II. Janssen:

Janssen shall maintain, at its sole cost and expense, the following minimum amounts of insurance coverage:

(A) Clinical Trials Liability Insurance: Insuring against claims for bodily injury arising out of Janssen's (or its Affiliates' or Sublicensees') sponsored clinical trials. Coverage and limits shall, at a minimum, comply with statutory/country requirements where the trials will be performed.

(B) General and Products Liability: Insuring against claims, including bodily injury, property damage and advertising liability, with minimum limits of not less than $50,000,000 U.S., covering claims brought and suits served anywhere in the world.

III. General Terms:

(A) In the event that any of the required policies of insurance are written on a claims-made basis, then such policies shall be maintained during the Term and for a period of not less than five (5) years following the termination or expiration of the Agreement.

(B) Each Party may elect to self-insure its respective risks. For the avoidance of doubt, nothing contained in this Annex KK is intended, or shall be construed, to limit a Party's indemnity obligations pursuant to Article 18 of the Agreement.

(C) Each Party shall provide written evidence of insurance upon written request upon execution of this Agreement and upon written request annually thereafter, evidencing the policies above, and shall provide that the foregoing policies shall not be cancelled, terminated or materially altered without thirty (30) days' prior written notice to the other Party.

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Cipla v. Gilead **IPR2025-00033** **Petitioner Exhibit 1030**

Exhibit 21.1

SUBSIDIARIES OF GILEAD SCIENCES, INC.

Name of Subsidiary	Country of Incorporation
Bristol-Myers Squibb and Gilead Sciences Limited	Ireland
Bristol-Myers Squibb & Gilead Sciences, LLC	United States
Cytopia Pty. Ltd.	Australia
Gilead Alberta ULC	Canada
Gilead Alberta, LLC	United States
Gilead Biologics, Inc.	United States
Gilead Biopharmaceutics Ireland UC	Ireland
Gilead Calistoga, LLC	United States
Gilead Colorado, Inc.	United States
Gilead Connecticut, Inc.	United States
Gilead Holdings, LLC	United States
Gilead Ireland Research UC	Ireland
Gilead Oncology Ireland UC	Ireland
Gilead Pharmasset LLC	United States
Gilead Sciences (NZ)	New Zealand
Gilead Sciences (Shanghai) Consulting Co., Ltd.	China
Gilead Sciences Americas S. de R.L.	Panama
Gilead Sciences Argentina S.R.L.	Argentina
Gilead Sciences Belgium BVBA	Belgium
Gilead Sciences Canada, Inc.	Canada
Gilead Sciences Denmark ApS	Denmark
Gilead Sciences Europe Ltd.	United Kingdom
Gilead Sciences Farmacêutica do Brasil Ltda	Brazil
Gilead Sciences Finland Oy	Finland
Gilead Sciences GesmbH.	Austria
Gilead Sciences GmbH	Germany
Gilead Sciences Hellas EPE	Greece
Gilead Sciences Holding, LLC	United States
Gilead Sciences Hong Kong Limited	Hong Kong
Gilead Sciences International Ltd.	United Kingdom
Gilead Sciences KK	Japan
Gilead Sciences Korea Limited	South Korea
Gilead Sciences Lda.	Portugal
Gilead Sciences Limited	Ireland
Gilead Sciences llac Ticaret Limited Sireketi	Turkey
Gilead Sciences Ltd.	United Kingdom
Gilead Sciences Luxembourg S.a.r.l.	Luxembourg
Gilead Sciences Mexico S. de R.L. de C.V.	Mexico
Gilead Sciences Netherlands BV	Netherlands
Gilead Sciences Norway AS	Norway
Gilead Sciences Poland Sp. z o.o.	Poland

SUBSIDIARIES OF GILEAD SCIENCES, INC. (Continued)

Name of Subsidiary	Country of Incorporation
Gilead Sciences Pty Limited	Australia
Gilead Sciences Russia LLC	Russia
Gilead Sciences S.L.	Spain
Gilead Sciences S.r.l.	Italy
Gilead Sciences s.r.o.	Czech Republic
Gilead Sciences SAS	France
Gilead Sciences Singapore Pte. Ltd.	Singapore
Gilead Sciences Slovakia s.r.o.	Slovakia
Gilead Sciences South Africa (Pty) Ltd	South Africa
Gilead Sciences Sweden AB	Sweden
Gilead Sciences Switzerland Sarl	Switzerland
Gilead YM Australia Pty Ltd	Australia
Gilead YM ULC	Canada
GSI Pharma Private Limited	India
Tri-Supply Limited	Ireland
YM BioSciences Australia Pty Ltd.	Australia
YM BioSciences USA Inc.	United States

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-08083, 333-08085, 333-58893, 333-84719, 333-84713, 333-47520, 333-64628, 333-102911, 333-102912, 333-117480, 333-126012, 333-135412, 333-136814, 333-138985, 333-143920, 333-151624, 333-158638, 333-161069, 333-163871 and 333-171983) pertaining to the 1991 Stock Option Plan, the Employee Stock Purchase Plan, the International Employee Stock Purchase Plan, the 1995 Non-Employee Directors' Stock Option Plan, the 2004 Equity Incentive Plan of Gilead Sciences, Inc., the NeXstar Pharmaceuticals, Inc. 1993 Incentive Stock Plan, the NeXstar Pharmaceuticals, Inc. 1995 Director Option Plan, the Vestar, Inc. 1988 Stock Option Plan, the Triangle Pharmaceuticals, Inc. 1996 Stock Incentive Plan, Option Agreement, dated August 5, 2002, between Triangle Pharmaceuticals, Inc. and Daniel G. Welch, the Corus Pharma, Inc. 2001 Stock Plan, the Myogen, Inc. 2003 Equity Incentive Plan, the CV Therapeutics, Inc. 1994 Equity Incentive Plan, the CV Therapeutics, Inc. 2000 Equity Incentive Plan, the CV Therapeutics, Inc. 2000 Nonstatutory Incentive Plan, the CV Therapeutics, Inc. 2004 Employment Commencement Incentive Plan, the CV Therapeutics, Inc. Non-Employee Directors' Stock Option Plan, the Arresto Biosciences, Inc. 2007 Equity Incentive Plan and the Registration Statements on Form S-3 (Nos. 333-87167, 333-54350, 333-103871, 333-111451, 333-138979, 333-173006, and 333-194298) of Gilead Sciences, Inc. and in the related Prospectuses, as applicable, of our reports dated February 25, 2015 , with respect to the consolidated financial statements and schedule of Gilead Sciences, Inc., and the effectiveness of internal control over financial reporting of Gilead Sciences, Inc., included in this Annual Report (Form 10-K) for the year ended December 31, 2014 .

/s/ E RNST & Y OUNG LLP

Redwood City, California
February 25, 2015

Exhibit 31.1

CERTIFICATION

I, John C. Martin, Ph.D., certify that:

1. I have reviewed this annual report on Form 10-K of Gilead Sciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 25, 2015

/s/ JOHN C. MARTIN

John C. Martin, Ph.D.
Chairman and Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, Robin L. Washington, certify that:

1. I have reviewed this annual report on Form 10-K of Gilead Sciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 25, 2015

/s/ Robin L. Washington

Robin L. Washington
Executive Vice President and Chief Financial Officer

Exhibit 32.1

CERTIFICATIONS
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Gilead Sciences, Inc. (the Company) on Form 10-K for the annual period ended December 31, 2014 as filed with the Securities and Exchange Commission on the date hereof (the Annual Report) and pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. § 1350, as adopted), John C. Martin, Ph.D., the Chairman and Chief Executive Officer of the Company, and Robin L. Washington, the Executive Vice President and Chief Financial Officer of the Company, each hereby certifies that, to the best of his or her knowledge:

1. The Company's Annual Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition of the Company at the end of the periods covered by the Annual Report and results of operations of the Company for the periods covered by the Annual Report.

Dated: February 25, 2015

/s/ JOHN C. MARTIN

John C. Martin, Ph.D.
Chairman and Chief Executive Officer

/s/ ROBIN L. WASHINGTON

Robin L. Washington
Executive Vice President and Chief Financial Officer

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the SEC and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.