GILEAD SCIENCES INC
Form 10-Q
November 04, 2015

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

FORM 10-Q

ý QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2015

or

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

Commission File No. 0-19731

GILEAD SCIENCES, INC.

(Exact Name of Registrant as Specified in Its Charter)

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

650-574-3000
Registrant's Telephone Number, Including Area Code

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 ý 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 ý No ¨
Indicate by check mark whether the 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.
Large accelerated filer ý 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 ý

Number of shares outstanding of the issuer’s common stock, par value $0.001 per share, as of October 30, 2015: 1,441,180,186

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

PART I. FINANCIAL INFORMATION

Item I. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

GILEAD SCIENCES, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(unaudited)

(in millions, except per share amounts)

	September 30, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$13,965	$10,027
Short-term marketable securities	1,749	101
Accounts receivable, net	6,105	4,635
Inventories	1,988	1,386
Deferred tax assets	894	508
Prepaid and other current assets	1,209	1,057
Total current assets	25,910	17,714
Property, plant and equipment, net	2,143	1,674
Long-term portion of prepaid royalties	409	466
Long-term deferred tax assets	291	236
Long-term marketable securities	9,400	1,598
Intangible assets, net	10,454	11,073
Goodwill	1,172	1,172
Other long-term assets	858	731
Total assets	$50,637	$34,664
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$1,239	$955
Accrued government and other rebates	4,713	2,316
Other accrued liabilities	2,721	1,873
Deferred revenues	356	134
Current portion of long-term debt and other obligations, net	331	483
Total current liabilities	9,360	5,761
Long-term debt, net	21,894	11,921
Long-term income taxes payable	1,027	562
Long-term deferred tax liabilities	30	51
Other long-term obligations	378	535
Commitments and contingencies (Note 9)		
Equity component of currently redeemable convertible notes	4	15
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 September 30, 2015 and December 31, 2014; shares issued and outstanding of 1,449 at September 30, 2015 and 1,499 at December 31, 2014	1	2
Additional paid-in capital	285	2,391
Accumulated other comprehensive income	167	301
Retained earnings	16,961	12,732
Total Gilead stockholders' equity	17,414	15,426
Noncontrolling interest	530	393

Total stockholders' equity	17,944	15,819
Total liabilities and stockholders' equity	$50,637	$34,664

See accompanying notes.

GILEAD SCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF INCOME
(unaudited)
(in millions, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenues:				
Product sales	$8,211	$5,968	$23,742	$17,252
Royalty, contract and other revenues	84	74	391	324
Total revenues	8,295	6,042	24,133	17,576
Costs and expenses:				
Cost of goods sold	1,064	987	2,944	2,725
Research and development expenses	743	630	2,257	1,809
Selling, general and administrative expenses	903	945	2,360	2,107
Total costs and expenses	2,710	2,562	7,561	6,641
Income from operations	5,585	3,480	16,572	10,935
Interest expense	(165)	(104)	(458)	(282)
Other income (expense), net	52	(5)	108	(27)
Income before provision for income taxes	5,472	3,371	16,222	10,626
Provision for income taxes	880	647	2,801	2,029
Net income	4,592	2,724	13,421	8,597
Net loss attributable to noncontrolling interest	(8)	(7)	(4)	(17)
Net income attributable to Gilead	$4,600	$2,731	$13,425	$8,614
Net income per share attributable to Gilead common stockholders - basic	$3.14	$1.80	$9.11	$5.64
Shares used in per share calculation - basic	1,463	1,514	1,474	1,528
Net income per share attributable to Gilead common stockholders - diluted	$3.06	$1.67	$8.73	$5.18
Shares used in per share calculation - diluted	1,503	1,637	1,538	1,662
Cash dividends declared per share	$0.43	$—	$0.86	$—

See accompanying notes.

GILEAD SCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(unaudited)
(in millions)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Net income	$4,592	$2,724	$13,421	$8,597
Other comprehensive income (loss):				
Net foreign currency translation gains (losses), net of tax	3	(10)	(4)	(3)
Available-for-sale securities:				
Net unrealized gains, net of tax impact of $0, $0, $2 and $1	—	—	3	1
Net change	—	—	3	1
Cash flow hedges:				
Net unrealized gains, net of tax impact of $11, $6, $14 and $6	49	224	322	257
Reclassifications to net income, net of tax impact of $(5), $(1), $(14) and $(3)	(132)	2	(455)	44
Net change	(83)	226	(133)	301
Other comprehensive income (loss)	(80)	216	(134)	299
Comprehensive income	4,512	2,940	13,287	8,896
Comprehensive loss attributable to noncontrolling interest	(8)	(7)	(4)	(17)
Comprehensive income attributable to Gilead	$4,520	$2,947	$13,291	$8,913

See accompanying notes.

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GILEAD SCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)
(in millions)

	Nine Months Ended September 30,	
	2015	2014
Operating Activities:		
Net income	$13,421	$8,597
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation expense	116	94
Amortization expense	704	681
Stock-based compensation expense	285	265
Excess tax benefits from stock-based compensation	(498)	(358)
Tax benefits from exercise and vesting of stock-based awards	499	360
Deferred income taxes	(442)	(67)
Other	34	51
Changes in operating assets and liabilities:		
Accounts receivable, net	(1,610)	(827)
Inventories	(659)	101
Prepaid expenses and other assets	(167)	(429)
Accounts payable	288	(75)
Income taxes payable	523	136
Accrued liabilities	2,617	1,256
Deferred revenues	344	12
Net cash provided by operating activities	15,455	9,797
Investing Activities:		
Purchases of marketable securities	(12,291)	(1,532)
Proceeds from sales of marketable securities	2,464	477
Proceeds from maturities of marketable securities	371	27
Capital expenditures	(581)	(390)
Net cash used in investing activities	(10,037)	(1,418)
Financing Activities:		
Proceeds from debt financing, net of issuance costs	9,902	3,965
Proceeds from convertible note hedges	600	1,629
Purchases of convertible note hedges	—	(26)
Repayments of debt and other obligations	(763)	(2,860)
Payment of contingent consideration	(2)	(98)
Payments to settle warrants	(3,865)	(4,093)
Proceeds from issuances of common stock	281	275
Repurchases of common stock	(6,951)	(3,348)
Payments of dividends	(1,260)	—
Excess tax benefits from stock-based compensation	498	358
Contributions from (distributions to) noncontrolling interest	141	(61)
Net cash used in financing activities	(1,419)	(4,259)
Effect of exchange rate changes on cash and cash equivalents	(61)	(24)
Net change in cash and cash equivalents	3,938	4,096

Cash and cash equivalents at beginning of period	10,027	2,113
Cash and cash equivalents at end of period	$13,965	$6,209

See accompanying notes.

GILEAD SCIENCES, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared in accordance with U.S. generally accepted accounting principles for interim financial information. The financial statements include all adjustments (consisting only of normal recurring adjustments) that the management of Gilead Sciences, Inc. (Gilead, we or us) believes are necessary for a fair presentation of the periods presented. These interim financial results are not necessarily indicative of results expected for the full fiscal year or for any subsequent interim period.

The accompanying Condensed 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 Condensed 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 Condensed Consolidated Financial Statements include the results of companies acquired by us from the date of each acquisition for the applicable reporting periods.

The accompanying Condensed Consolidated Financial Statements and related Notes to Condensed Consolidated Financial Statements should be read in conjunction with the audited Consolidated Financial Statements and the related notes thereto for the year ended December 31, 2014, included in our Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission.

Significant Accounting Policies, Estimates and Judgments

The preparation of these Condensed 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.

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 September 30, 2015, our accounts receivable in Southern Europe, specifically Greece, Italy, Portugal and Spain, totaled approximately $1.8 billion, of which $198 million were greater than 120 days past due, including $27 million 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 September 30, 2015.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB), 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 August 2015, the FASB issued an accounting standard update which defers the effective date of the new standard by one year.

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The standard will become effective for us beginning in the first quarter of 2018. Early application is permitted in 2017. Entities have the option of using either a full retrospective or a modified retrospective approach to adopt this new guidance. We are currently evaluating the impact of our pending adoption of this standard on our Condensed Consolidated Financial Statements.

In April 2015, the FASB issued an accounting standard update which requires presentation of debt issuance costs as a direct deduction from the carrying amount of a recognized debt liability on the balance sheet. The update does not change the guidance on the recognition and measurement of debt issuance costs. This guidance will become effective for us for annual periods beginning after December 15, 2015, and interim periods thereafter. At the time of adoption, we will reclassify debt issuance costs to a liability as a direct deduction from the carrying value of the debt, consistent with the presentation of a debt discount. We do not expect that the adoption of this update will have a material impact on our Condensed 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. Our Level 3 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 Condensed Consolidated Balance Sheets. Short-term and long-term debt are reported at their amortized cost on our Condensed Consolidated Balance Sheets. The remaining financial instruments are reported on our Condensed Consolidated Balance Sheets at amounts that approximate current fair values. There were no transfers between Level 1, Level 2 and Level 3 in the periods presented.

The following table summarizes the assets and liabilities measured at fair value on a recurring basis, by level, within the fair value hierarchy (in millions):

	September 30, 2015				December 31, 2014			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Assets:								
Money market funds	$12,029	$—	$—	$12,029	$7,926	$—	$—	$7,926
Corporate debt securities	—	4,824	—	4,824	—	938	—	938
U.S. treasury securities	3,378	—	—	3,378	363	—	—	363
Residential mortgage and asset-backed securities	—	1,306	—	1,306	—	269	—	269
U.S. government agencies securities	—	864	—	864	—	113	—	113
Certificates of deposit	—	489	—	489	—	—	—	—
Non-U.S. government securities	—	301	—	301	—	—	—	—
Foreign currency derivative contracts	—	267	—	267	—	349	—	349
Municipal debt securities	—	29	—	29	—	16	—	16
Deferred compensation plan	61	—	—	61	54	—	—	54
	$15,468	$8,080	$—	$23,548	$8,343	$1,685	$—	$10,028
Liabilities:								
Contingent consideration	$—	$—	$127	$127	$—	$—	$133	$133
Deferred compensation plan	61	—	—	61	54	—	—	54
Foreign currency derivative contracts	—	35	—	35	—	—	—	—
	$61	$35	$127	$223	$54	$—	$133	$187

Level 2 Inputs

We estimate the fair values of our corporate debt securities, residential mortgage and asset-backed securities, government related securities and certificates of deposit 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 derivative 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 our convertible senior notes and senior unsecured notes (in millions):

		September 30, 2015		December 31, 2014	
Type of Borrowing	Description	Carrying Value	Fair Value	Carrying Value	Fair Value
Convertible Senior	May 2016 Notes	$331	$1,434	$483	$2,097
Senior Unsecured	April 2021 Notes	995	1,090	995	1,108
Senior Unsecured	December 2016 Notes	700	717	700	727
Senior Unsecured	December 2021 Notes	1,248	1,356	1,248	1,377
Senior Unsecured	December 2041 Notes	998	1,145	998	1,229
Senior Unsecured	April 2019 Notes	499	503	499	500
Senior Unsecured	April 2024 Notes	1,748	1,798	1,747	1,836
Senior Unsecured	April 2044 Notes	1,747	1,767	1,747	1,954
Senior Unsecured	February 2020 Notes	499	504	499	504
Senior Unsecured	February 2025 Notes	1,748	1,766	1,748	1,797
Senior Unsecured	February 2045 Notes	1,740	1,693	1,740	1,872
Senior Unsecured	September 2018 Notes	1,000	1,008	—	—
Senior Unsecured	September 2020 Notes	1,996	2,014	—	—
Senior Unsecured	September 2022 Notes	999	1,011	—	—
Senior Unsecured	March 2026 Notes	2,739	2,767	—	—
Senior Unsecured	September 2035 Notes	997	1,007	—	—
Senior Unsecured	March 2046 Notes	2,241	2,263	—	—

Level 3 Inputs

As of September 30, 2015 and December 31, 2014, the only assets or liabilities that were measured using Level 3 inputs were contingent consideration liabilities of $127 million and $133 million, respectively. 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.

The contingent consideration liabilities primarily included the potential future contingent consideration payments resulting from the acquisition of Arresto Biosciences, Inc. for royalty obligations on future sales once specified sales-based milestones are achieved, and the acquisitions of CGI Pharmaceuticals, Inc. and Calistoga Pharmaceuticals, Inc. upon achievement of development or regulatory approval-based milestones.

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 Condensed Consolidated Balance Sheets (in millions):

	September 30, 2015				December 31, 2014			
	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	$12,029	$ —	$ —	$12,029	$7,926	$ —	$ —	$7,926
Corporate debt securities	4,832	5	(13)	4,824	941	—	(3)	938
U.S. treasury securities	3,370	8	—	3,378	363	—	—	363
Residential mortgage and asset-backed securities	1,305	2	(1)	1,306	269	—	—	269
Certificates of deposit	489	—	—	489	—	—	—	—
U.S. government agencies securities	863	1	—	864	113	—	—	113

Non-U.S. government securities	301	—	—	301	—	—	—	—
Municipal debt securities	29	—	—	29	16	—	—	16
Total	$23,218	$ 16	$ (14)	$23,220	$9,628	$ —	$ (3)	$9,625

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

	September 30, 2015	December 31, 2014
Cash and cash equivalents	$12,071	$7,926
Short-term marketable securities	1,749	101
Long-term marketable securities	9,400	1,598
Total	$23,220	$9,625

Cash and cash equivalents in the table above exclude cash of $1.9 billion as of September 30, 2015 and $2.1 billion as of December 31, 2014.

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

	September 30, 2015	
	Amortized Cost	Fair Value
Less than one year	$13,821	$13,820
Greater than one year but less than five years	9,254	9,257
Greater than five years but less than ten years	118	118
Greater than ten years	25	25
Total	$23,218	$23,220

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
September 30, 2015						
Corporate debt securities	$(13)	$2,343	$—	$58	$(13)	$2,401
Residential mortgage and asset-backed securities	(1)	527	—	17	(1)	544
Non-U.S. government securities	—	188	—	—	—	188
U.S. government agencies securities	—	52	—	—	—	52
U.S. treasury securities	—	42	—	—	—	42
Municipal debt securities	—	5	—	—	—	5
Total	$(14)	$3,157	$—	$75	$(14)	$3,232
December 31, 2014						
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

We held a total of 1,165 positions as of September 30, 2015 and 468 positions as of December 31, 2014 that were in an unrealized loss position. The unrealized losses were immaterial both individually and in aggregate. We did not record any other-than-temporary impairments on these securities as of September 30, 2015, because we do not intend to sell these securities nor do we believe that we will be required to sell them before they recover their amortized costs at maturity. Gross realized gains and gross realized losses were immaterial for the three and nine months ended September 30, 2015 and 2014.

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4. DERIVATIVE FINANCIAL INSTRUMENTS

Our operations in foreign countries expose 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 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 entities 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 Condensed 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 regression analysis which calculates the change in cash flow as a result of the hedge instrument. On a quarterly 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 September 30, 2015 are expected to be reclassified to product sales within 12 months.

The cash flow effects of our derivative contracts for the nine months ended September 30, 2015 and 2014 are included within net cash provided by operating activities in the Condensed Consolidated Statements of Cash Flows.

We had notional amounts on foreign currency exchange contracts outstanding of $7.9 billion at September 30, 2015 and $6.4 billion at December 31, 2014.

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 Condensed Consolidated Balance Sheets (in millions):

	September 30, 2015			
	Asset Derivatives		Liability Derivatives	
	Classification	Fair Value	Classification	Fair Value
Derivatives designated as hedges:				
Foreign currency exchange contracts	Other current assets	$258	Other accrued liabilities	$(29)
Foreign currency exchange contracts	Other long-term assets	9	Other long-term obligations	(6)
Total derivatives		$267		$(35)

	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		$—

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Derivatives designated as hedges:				
Gains recognized in accumulated OCI (effective portion)	$60	$230	$336	$263
Gains (losses) reclassified from accumulated OCI into product sales (effective portion)	$137	$(1)	$469	$(41)
Gains (losses) recognized in other income (expense), net (ineffective portion and amounts excluded from effectiveness testing)	$4	$(3)	$11	$(7)
Derivatives not designated as hedges:				
Gains recognized in other income (expense), net	$21	$73	$89	$83

From time to time, we may discontinue cash flow hedges and as a result, record related amounts in other income (expense), net on our Condensed Consolidated Statements of Income. There were no material amounts recorded in other income (expense), net for the three and nine months ended September 30, 2015 and 2014 as a result of the discontinuance of cash flow hedges.

As of September 30, 2015 and December 31, 2014, 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 Condensed Consolidated Balance Sheets (in millions):

As of September 30, 2015

Offsetting of Derivative Assets/Liabilities

				Gross Amounts Not Offset in the Condensed Consolidated Balance Sheet		
Description	Gross Amounts of Recognized Assets/Liabilities	Gross Amounts Offset in the Condensed Consolidated Balance Sheet	Amounts of Assets/Liabilities Presented in the Condensed Consolidated Balance Sheet	Derivative Financial Instruments	Cash Collateral Received/Pledged	Net Amount (Legal Offset)
Derivative assets	$ 267	$—	$267	$(35)	$ —	$232
Derivative liabilities	(35)	—	(35)	35	—	—

As of December 31, 2014

Offsetting of Derivative Assets/Liabilities

				Gross Amounts Not Offset in the Condensed Consolidated Balance Sheet		
Description	Gross Amounts of Recognized	Gross Amounts Offset in the	Amounts of Assets/Liabilities	Derivative Financial	Cash Collateral Received/Pledged	Net Amount

	Assets/Liabilities	Condensed Consolidated Balance Sheet	Presented in the Condensed Consolidated Balance Sheet	Instruments		(Legal Offset)
Derivative assets	$ 349	$—	$349	$—	$ —	$349
Derivative liabilities	—	—	—	—	—	—

5. SUPPLEMENTAL FINANCIAL INFORMATION

Inventories

Inventories are summarized as follows (in millions):

	September 30, 2015	December 31, 2014
Raw materials	$1,198	$909
Work in process	622	500
Finished goods	744	466
Total	$2,564	$1,875
Reported as:		
Inventories	$1,988	$1,386
Other long-term assets	576	489
Total	$2,564	$1,875

Amounts reported as other long-term assets primarily consisted of raw materials as of September 30, 2015 and December 31, 2014.

The joint venture formed by Gilead Sciences, LLC and Bristol-Myers Squibb Company (BMS) (See Note 7, Collaborative Arrangements), which is included in our Condensed 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 $1.3 billion as of September 30, 2015 and $806 million as of December 31, 2014.

Prepaid and other current assets

The components of prepaid and other current assets are summarized as follows (in millions):

	September 30, 2015	December 31, 2014
Prepaid taxes	$479	$391
Prepaid expenses	240	194
Other current assets	490	472
Total prepaid and other current assets	$1,209	$1,057

Other accrued liabilities

The components of other accrued liabilities are summarized as follows (in millions):

	September 30, 2015	December 31, 2014
Income taxes payable	$159	$105
Compensation and employee benefits	288	316
Branded Prescription Drug Fee	651	186
Other accrued expenses	1,623	1,266
Total other accrued liabilities	$2,721	$1,873

6. INTANGIBLE ASSETS

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

	September 30, 2015	December 31, 2014
Finite-lived intangible assets	$10,022	$10,641
Indefinite-lived intangible assets	432	432
Total intangible assets	$10,454	$11,073

Finite-Lived Intangible Assets

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

	September 30, 2015		December 31, 2014	
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Intangible asset - sofosbuvir	$10,720	$1,281	$10,720	$757
Intangible asset - Ranexa	688	341	688	277
Other	455	219	455	188
Total	$11,863	$1,841	$11,863	$1,222

Amortization expense related to finite-lived intangible assets included primarily in cost of goods sold on our Condensed Consolidated Statements of Income totaled $206 million and $619 million for the three and nine months ended September 30, 2015 and $202 million and $601 million for the three and nine months ended September 30, 2014. As of September 30, 2015, the estimated future amortization expense associated with our finite-lived intangible assets for the remaining three months of 2015 and each of the five succeeding fiscal years is as follows (in millions):

Fiscal Year	Amount
2015 (remaining three months)	$206
2016	832
2017	846
2018	853
2019	741
2020	713
Total	$4,191

Indefinite-Lived Intangible Assets

The following table summarizes our indefinite-lived intangible assets as of September 30, 2015 and December 31, 2014 (in millions):

	Amount
Indefinite-lived intangible asset - momelotinib (formerly CYT387)	$315
Indefinite-lived intangible assets - Other	117
Total	$432

7. 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 variable interest entity (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 September 30, 2015, 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

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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 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 September 30, 2015 and December 31, 2014, 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 were primarily included in inventories on our Condensed Consolidated Balance Sheets.

Selected financial information for the joint venture was as follows (in millions):

	September 30, 2015	December 31, 2014
Total assets	$2,796	$2,138
Cash and cash equivalents	257	250
Accounts receivable, net	294	297
Inventories	2,244	1,590
Total liabilities	1,503	1,157
Accounts payable	1,045	749
Other accrued liabilities	457	408

These asset and liability amounts do not reflect the impact of intercompany eliminations that are included in our Condensed 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, 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 (EU), 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 September 30, 2015 and December 31, 2014, efavirenz purchased from BMS at BMS's estimated net selling price of efavirenz in the European Territory is included in inventories on our Condensed 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.

8. DEBT AND CREDIT FACILITY

Financing Arrangements

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

Type of Borrowing	Description	Issue Date	Due Date	Interest Rate	September 30, 2015	December 31, 2014
Convertible Senior	May 2016 Notes	July 2010	May 2016	1.625%	$ 331	$ 483
Senior Unsecured	April 2021 Notes	March 2011	April 2021	4.50%	995	995
Senior Unsecured	December 2016 Notes	December 2011	December 2016	3.05%	700	700
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	499
Senior Unsecured	April 2024 Notes	March 2014	April 2024	3.70%	1,748	1,747
Senior Unsecured	April 2044 Notes	March 2014	April 2044	4.80%	1,747	1,747
Senior Unsecured	February 2020 Notes	November 2014	February 2020	2.35%	499	499
Senior Unsecured	February 2025 Notes	November 2014	February 2025	3.50%	1,748	1,748
Senior Unsecured	February 2045 Notes	November 2014	February 2045	4.50%	1,740	1,740
Senior Unsecured	September 2018 Notes	September 2015	September 2018	1.85%	1,000	—
Senior Unsecured	September 2020 Notes	September 2015	September 2020	2.55%	1,996	—
Senior Unsecured	September 2022 Notes	September 2015	September 2022	3.25%	999	—
Senior Unsecured	March 2026 Notes	September 2015	March 2026	3.65%	2,739	—
Senior Unsecured	September 2035 Notes	September 2015	September 2035	4.60%	997	—
Senior Unsecured	March 2046 Notes	September 2015	March 2046	4.75%	2,241	—
Total debt, net					22,225	12,404
Less current portion					331	483
Total long-term debt, net					$ 21,894	$ 11,921

Convertible Senior Notes

During the nine months ended September 30, 2015, a portion of our convertible senior notes due in May 2016 (the May 2016 Notes) was settled and we repaid $163 million of principal balance related to these notes. We also paid

$600 million in cash related to the conversion spread of the May 2016 Notes, which represents the conversion value in excess of the principal amount, and received $600 million in cash from the convertible note hedges related to the May 2016 Notes. The initial conversion rate for the May 2016 Notes was 44.0428 shares per $1,000 principal amount (which represented an initial conversion price of approximately $22.71 per share). The conversion rate for the May 2016 Notes is adjusted in connection with our quarterly cash dividend. As of September 30, 2015, the conversion rate was 44.3764 (which represented a conversion price of approximately $22.53 per share).

As of September 30, 2015 and 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 $4 million and $15 million, as of September 30, 2015 and December 31, 2014, respectively, were classified as equity component of currently redeemable convertible notes on our Condensed Consolidated Balance Sheets.

As of December 31, 2014, there were 55 million shares of our common stock underlying our warrants expiring in 2016 (the 2016 Warrants). Under the terms of the original agreements, the 2016 Warrants had a strike price of $30.05 per share and were due to expire during the 40 trading-day period commencing August 1, 2016.

During the second quarter of 2015, we entered into modified agreements with our warrant counterparties which changed the timing of the expiration for 46 million of our 2016 Warrants. The modified agreements allowed us to settle the 46 million warrants at our option, in cash or shares. According to the terms of the modified agreements, these warrants expired during a 32 trading-day period which commenced on May 11, 2015 and ended on June 24, 2015. We exercised our option to settle in cash, and as a result, paid $3.9 billion as the market value of our common stock at the time of the exercise of the warrants exceeded their strike prices. Because these warrants could have been settled at our option, in cash or shares of common stock, under both the original and the modified agreements and these contracts met all of the applicable criteria for equity classification, the settlement payments were recorded as a reduction to additional paid-in capital on our Condensed Consolidated Balance Sheet. As additional paid-in capital was reduced to zero as of June 30, 2015, the remainder of the warrants settlement was recorded as a reduction in retained earnings.

As of September 30, 2015, 9 million of the 2016 Warrants remained outstanding and have a strike price of $29.19 per share and are due to expire during the 40 trading-day period commencing August 1, 2016. The strike price of the 2016 Warrants is adjusted in connection with our quarterly cash dividend. There were no other changes in terms for the remaining 9 million 2016 Warrants.

September 2015 Issuance of Senior Unsecured Notes

We issued $10.0 billion aggregate principal amount of senior unsecured notes in September 2015 (collectively, the "2015 Notes"), in six tranches with maturities ranging from 2018 to 2046, the terms of which are summarized in the table above. Debt issuance costs incurred in connection with the issuance of the 2015 Notes totaled approximately $70 million and are being amortized to interest expense over the contractual term of each of the respective notes.

The 2015 Notes may be redeemed at our option 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 value 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 for the notes due in September 2018, 15 basis points for the notes due in September 2020, 20 basis points for the notes due in September 2022, 25 basis points for the notes due in March 2026, 25 basis points for the notes due in September 2035 and 30 basis points for the notes due in March 2046. The 2015 Notes maturing from September 2022 through March 2046 also have a call feature, exercisable at our option, to redeem the notes at par in whole or in part two to six months immediately preceding maturity. In each case, accrued and unpaid interest is also required to be redeemed to the date of redemption.

In the event of the occurrence of a change in control and a downgrade in the rating of the 2015 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 intend to use the net proceeds for general corporate purposes, which may include the repayment of debt, working capital, payment of dividends and the repurchase of our outstanding common stock pursuant to our authorized share repurchase program.

Credit Facility

There were no amounts outstanding under the revolving credit facility credit agreement as of September 30, 2015. We are required to comply with certain covenants under the credit agreement and note indentures and as of September 30, 2015, we were not in violation of any covenants.

9. COMMITMENTS AND CONTINGENCIES

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, Inc. (Pharmasset). Through the acquisition, we acquired sofosbuvir, a nucleotide analog that acts to inhibit the replication of the hepatitis C virus (HCV). In December 2013, we received U.S. Food

and Drug Administration (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. While we have carefully considered these claims both prior to and following the acquisition and believe they are without merit, we cannot predict the ultimate outcome of such claims or range of loss.

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 Harvoni or Sovaldi. For example, we are aware of patents and patent applications owned by other parties that have been or may in the future be alleged by such parties to cover the use of Harvoni and Sovaldi. We cannot predict the ultimate outcome of intellectual property claims related to Harvoni or Sovaldi. We have spent, and will continue to spend, significant resources defending against these claims.

If third parties successfully obtain valid and enforceable patents, and successfully prove infringement of those patents by Harvoni and/or Sovaldi, 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. On January 29, 2014, the USPTO Patent Trial and Appeal Board (PTAB) determined that Pharmasset and not Idenix was the first to invent the compounds in dispute and accordingly Gilead prevailed in the First Idenix Interference. Idenix has appealed the PTAB’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 Idenix’s U.S. Patent No. 7,608,600 (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 purpose of the Second Idenix Interference was to determine who was first to invent the claimed methods of treating HCV with compounds similar to those which were involved in the First Idenix Interference. On March 23, 2015, the PTAB determined that Pharmasset and not Idenix was the first to invent the claimed methods of treating HCV. Idenix appealed this decision in both the U.S. District Court for the District of Delaware and the U.S. Court of Appeal for the Federal Circuit (CAFC). We have filed a motion to dismiss the appeal in Delaware and will respond to the appeal filed in the CAFC.

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 was held in January and February 2015, and on November 2, 2015, the Federal Court of Canada rendered its public decision holding that Idenix's patent is invalid and that Gilead's patent is valid.

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. The appeal hearing from the March 2014 decision is scheduled for 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 its Australian patent corresponding to the ’600 patent. A month-long trial on these issues was completed in October 2015 in Sydney, and we are currently awaiting a decision.

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 was granted, we filed an opposition with the EPO seeking to revoke the ’489 patent. The EPO has sent an opposition hearing for February 2016. Also on that day, Idenix initiated

infringement proceedings against Gilead in the United Kingdom (UK), Germany and France alleging that the commercialization of Sovaldi would infringe the UK, German and French counterparts of the ’489 patent. A trial was held in the UK 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 challenged claims of the ’489 patent on multiple grounds. The UK Court has granted Idenix permission to appeal the December 1, 2014 judgment. The appeal of the UK Court's decision is scheduled for July 2016. On March 12, 2015, the German court in Düsseldorf determined that the Idenix patent was highly likely to be invalid and stayed the infringement proceedings pending the outcome of the opposition filed in the EPO. Idenix has not appealed this decision of the German court staying the proceedings. Upon Idenix's request, the French proceedings have been stayed.

Idenix has not been awarded patents corresponding to the ’600 patent in Japan or China. In the event such patents are issued, 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 transferred the Massachusetts litigation to the U.S. District Court for the District of Delaware. The district court has set trial dates in October 2016 and December 2016 for resolution of these issues. A decision by the district court may be appealed by either party to the 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. 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. 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 may 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 fixed dose combination of ledipasvir and sofosbuvir (LDV/SOF), now known commercially as Harvoni for the treatment of HCV. Gilead is aware that AbbVie has pending patent applications in the United States and granted and pending 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 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 LDV/SOF. In February and March 2014, AbbVie responded to our lawsuit by also filing two lawsuits in the U.S. District Court for the District of Delaware alleging that our fixed-dose combination of LDV/SOF will infringe its patents. All of those lawsuits have been consolidated into a single action. In the United States, either party may 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, Canada, or Europe. We do not expect any other foreign patents to block or

delay the commercialization around the world. The court has set a trial date of September 12, 2016 for this lawsuit. Additionally, AbbVie has obtained U.S. Patent No. 9,034,832 which purports to cover a solid oral dosage form containing ledipasvir. Accordingly, in May 2015, we filed a lawsuit in the U.S. District Court for the District of Delaware seeking declaratory judgment that AbbVie's patent is invalid, as well as other relief. We do not expect AbbVie's patent to block the commercialization of our combination product. The court has set a trial date of July 31, 2017.

In August 2015, we brought an impeachment action seeking a declaration that AbbVie's Canadian Patent No. 2,811,250 ('250 Patent), which purports to cover the use of a combination of LDV/SOF (or Harvoni) for the treatment of HCV, is invalid. On the same day, AbbVie brought an infringement action which asserts that commercialization of Harvoni in Canada will infringe its '250 Patent. The impeachment action has been stayed and we have counterclaimed for invalidity in the infringement proceeding. A trial date has not been set.

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.

European Patent Claims

In February 2015, several parties filed oppositions in the EPO requesting revocation of our granted European patent covering sofosbuvir that expires in 2028. While we are confident in the strength of our sofosbuvir patent, we cannot predict the ultimate outcome of these oppositions. If we are unsuccessful in defending these oppositions, some or all of our patent claims may be narrowed or revoked and the patent protection for sofosbuvir in Europe could be substantially shortened or eliminated entirely. If the sofosbuvir patent is revoked, and no other European patents are granted covering sofosbuvir, our exclusivity will be based entirely on regulatory exclusivity granted by the European Medicines Agency (EMA). Sovaldi has been granted regulatory exclusivity that will prevent generic sofosbuvir from entering the EU for 10 years following approval of Sovaldi, or January 2024. If we lose exclusivity for Sovaldi prior to 2028, our expected revenues and results of operation could be negatively impacted for the years including and succeeding the year in which such exclusivity is lost.

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 these 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

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 submitted petitions for Inter Partes Review (IPR) to the PTAB 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. In January 2015, Mylan requested a rehearing on the basis that it believes the PTAB decision is wrong. In August 2015, the PTAB denied Mylan's request for a rehearing on the three patents covering the tenofovir disoproxil prodrug.

In July 2015, we received notice that Mylan submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Complera. In the notice, Mylan alleges that our patents associated with emtricitabine and the fixed-dose combination of emtricitabine with tenofovir disoproxil fumarate, in addition to patents associated with rilpivirine, are invalid, unenforceable and/or will not be infringed by Mylan's manufacture, use or sale of a generic version of Complera. In August 2015, Gilead and Janssen filed suit in the U.S. District Court for the District of Delaware, and in September 2015, filed suit in the U.S. District Court for the Northern District of West Virginia and asserted patents associated with rilpivirine. In August 2015, we also filed suit separately in the U.S. District Court

for the Northern District of West Virginia asserting patents associated with emtricitabine and the fixed-dose combination of emtricitabine with tenofovir disoproxil fumarate. In October 2015, we reached an agreement with Mylan to settle the lawsuit in the U.S. District Court for the Northern District of West Virginia relating to the patents associated with emtricitabine and the fixed-dose combination of emtricitabine with tenofovir disoproxil fumarate. The terms of the settlement agreement are confidential. The settlement agreement has been filed with the Federal Trade Commission and Department of Justice as required by law.

Apotex

In June 2014, we received notice that Apotex Corp. (Apotex) submitted an abbreviated new drug submission (ANDS) to Health Canada 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

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 Health Canada (for Teva's generic versions of Viread, Truvada, and Atripla) took place. 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 appealed the decision of the court prohibiting Health Canada 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 Health Canada should be prohibited from issuing the Notices of Compliance for Teva's products. The appeal will be heard by the Canadian Federal Court of Appeal after the trial in the Impeachment Action. Separately, the court will determine the validity of the patents in the pending Impeachment Action. A trial in the Impeachment Action is scheduled for November 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. In April 2015, we filed a lawsuit against Watson in the U.S. District Court for the District of New Jersey.

SigmaPharm

In June 2015, we received notice that SigmaPharm Laboratories, LLC (SigmaPharm) submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Letairis. In the notice, SigmaPharm alleges that one of the patents associated with ambrisentan tablets is invalid, unenforceable and/or will not be infringed by SigmaPharm's manufacture, use or sale of a generic version of Letairis. In June 2015, we filed a lawsuit against SigmaPharm in the U.S. District Court for the District of New Jersey.

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 U.S. 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 plaintiffs filed a Second Amended Complaint. We moved to dismiss the Second Amended Complaint and in June 2015, the federal district court issued an order granting our motion to dismiss the Second Amended Complaint. In July 2015, the plaintiffs filed a notice of appeal in the U.S. Court of Appeals for Ninth Circuit.

Other Matters

We are a party to various legal actions that arise 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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10. STOCKHOLDERS' EQUITY

The following table summarizes the changes in 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, 2014	1,499	$ 2	$ 2,391	$ 301	$ 12,732	$ 393	$ 15,819
Net income	—	—	—	—	13,425	(4)	13,421
Other comprehensive loss, net of tax	—	—	—	(134)	—	—	(134)
Change in noncontrolling interest	—	—	—	—	—	141	141
Issuances under employee stock purchase plan	1	—	86	—	—	—	86
Issuances under equity incentive plans	18	—	195	—	—	—	195
Stock-based compensation	—	—	285	—	—	—	285
Tax benefits from employee stock plans	—	—	499	—	—	—	499
Repurchases of common stock	(69)	(1)	(152)	—	(7,092)	—	(7,245)
Convertible notes settlement	—	—	(599)	—	—	—	(599)
Convertible notes hedge settlement	—	—	600	—	—	—	600
Dividends declared	—	—	—	—	(1,270)	—	(1,270)
Warrants settlement	—	—	(3,031)	—	(834)	—	(3,865)
Reclassification to equity component of currently redeemable convertible notes	—	—	11	—	—	—	11
Balance at September 30, 2015	1,449	$ 1	$ 285	$ 167	$ 16,961	$ 530	$ 17,944

Accumulated Other Comprehensive Income (Loss)

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, 2014	$(54)	$ 12	$ 343	$ 301
Other comprehensive income (loss) before reclassifications	(4)	3	322	321
Amounts reclassified from accumulated other comprehensive income (loss)	—	—	(455)	(455)
Net current period other comprehensive income (loss)	(4)	3	(133)	(134)
Balance at September 30, 2015	$(58)	$ 15	$ 210	$ 167

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

Repurchases of Common Stock

We completed our $5.0 billion stock repurchase program authorized in May 2014 and repurchased and retired a total of $3.0 billion or 30 million shares of common stock under the program in the first quarter of 2015. During the second quarter of 2015, we began repurchases under our $15.0 billion stock repurchase program authorized in January 2015 (2015 Program). As of September 30, 2015, we repurchased and retired a total of $4.0 billion or 36 million shares of common stock under the 2015 Program. In addition to repurchases from our stock repurchase programs, we repurchased shares of common stock withheld by us from employee restricted stock awards to satisfy our applicable tax withholding obligations.

Dividends

During the second quarter of 2015, we declared a quarterly cash dividend of $0.43 per share, or a total of $639 million to all stockholders of record as of the close of business on June 16, 2015. This was the first quarterly dividend declared under our dividend program previously announced in February 2015.

During the third quarter of 2015, we declared a quarterly cash dividend of $0.43 per share, or a total of $631 million to all stockholders of record as of the close of business on September 16, 2015.

On October 27, 2015, we announced that our Board of Directors declared a quarterly cash dividend of $0.43 per share of our common stock, with a payment date of December 30, 2015 to all stockholders of record as of the close of business on December 16, 2015.

11. STOCK-BASED COMPENSATION

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Cost of goods sold	$3	$3	$9	$8
Research and development expenses	44	40	128	111
Selling, general and administrative expenses	50	57	148	146
Stock-based compensation expenses included in total costs and expenses	97	100	285	265
Income tax effect	(53)	(18)	(101)	(48)
Stock-based compensation expenses, net of tax	$44	$82	$184	$217

12. 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, performance shares and the assumed exercise of warrants relating to our convertible senior notes, including the convertible senior notes that were due in May 2014 (the May 2014 Notes) and the May 2016 Notes (collectively, the May Notes) were determined under the treasury stock method.

Because the principal amount of the May Notes has been or will be settled in cash, only the conversion spread relating to the May Notes is included in our calculation of diluted net income per share attributable to Gilead common stockholders. Our 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 2014 Notes had a dilutive effect when the average market price of our common stock during the period exceeded the conversion price of $22.54 for the May 2014 Notes. Our common stock resulting from the assumed settlement of the conversion spread of the May 2016 Notes has a dilutive effect when the average market price of our common stock during the period exceeds the conversion price for the May 2016 Notes. See Note 8, Debt and Credit Facility for additional information.

Warrants related to our May 2014 Notes and a portion of the 2016 Warrants were settled and as a result, we have only included their impact for the periods they were outstanding on our net income per share calculations. Warrants relating to the May 2014 Notes had a dilutive effect when the average market price of our common stock during the period exceeded the warrants' exercise price of $28.38. Warrants relating to the May 2016 Notes had a dilutive effect when the average market price of our common stock during the period exceeded the warrants' exercise price. See Note 8, Debt and Credit Facility for additional information.

We have excluded stock options to purchase approximately 1 million weighted-average shares of our common stock that were outstanding for both of the three and nine months ended September 30, 2015 and 2014 from 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):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Net income attributable to Gilead	$4,600	$2,731	$13,425	$8,614
Shares used in per share calculation - basic	1,463	1,514	1,474	1,528
Effect of dilutive securities:				
Stock options and equivalents	21	32	24	34
Conversion spread related to the May Notes	12	27	14	32
Warrants related to the May Notes	7	64	26	68
Shares used in per share calculation - diluted	1,503	1,637	1,538	1,662

13. SEGMENT INFORMATION

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. Total product sales on an individual product basis are summarized in the following table (in millions):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Antiviral products:				
Harvoni	$3,332	$20	$10,519	$20
Sovaldi	1,466	2,796	3,729	8,551
Truvada	903	877	2,523	2,443
Atripla	818	895	2,334	2,545
Stribild	511	327	1,314	812
Complera/Eviplera	360	330	1,047	880
Viread	297	275	802	747
Other antiviral	15	24	53	67
Total antiviral products	7,702	5,544	22,321	16,065
Other products:				
Letairis	181	146	508	414
Ranexa	161	132	419	366
AmBisome	88	98	276	284
Zydelig	36	6	92	6
Other	43	42	126	117
Total product sales	$8,211	$5,968	$23,742	$17,252

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):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
McKesson Corp.	28 %	24 %	26 %	24 %
AmerisourceBergen Corp.	19 %	23 %	20 %	25 %
Cardinal Health, Inc.	14 %	15 %	15 %	13 %

14. INCOME TAXES

Our income tax rate of 16.1% and 17.3% for the three and nine months ended September 30, 2015, 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 Branded Prescription Drug Fee, also known as the pharmaceutical excise tax, 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.

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 Internal Revenue Service (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 record liabilities related to uncertain tax positions in accordance with the income tax guidance which 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. Resolution of one or more of these uncertain tax positions in any period may have a material impact on the results of operations for that period.

Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Quarterly Report on Form 10-Q 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, and the Securities Exchange Act of 1934, as amended. The forward-looking statements are contained principally in this section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Risk Factors." Words such as "expect," "anticipate," "target," "goal," "project," "hope," "intend," "plan," "believe," "seek," "estimate," "continue," "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." 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, 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.

In evaluating our business, you should carefully consider the risks described in the section entitled "Risk Factors" under Part II, Item 1A below, in addition to the other information in this Quarterly Report on Form 10-Q. Any of the risks contained herein could materially and adversely affect our business, results of operations and financial condition.

You should read the following management's discussion and analysis of our financial condition and results of operations in conjunction with our audited Consolidated Financial Statements and related notes thereto included as part of our Annual Report on Form 10-K for the year ended December 31, 2014 and our unaudited Condensed Consolidated Financial Statements for the three and nine months ended September 30, 2015 and other disclosures (including the disclosures under Part II, Item 1A, "Risk Factors") included in this Quarterly Report on Form 10-Q.

Our Condensed 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 liver diseases such as chronic hepatitis C virus (HCV) infection and chronic hepatitis B virus (HBV) infection, human immunodeficiency virus (HIV), serious cardiovascular and respiratory conditions, and oncology and inflammation. 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 Harvoni®, Sovaldi®, Truvada®, Atripla®, Stribild®, Complera®/Eviplera®, Viread®, Letairis®, Ranexa®, AmBisome®, Zydelig®, Emtriva®, Tybost®, Hepsera®, Vitekta®, Cayston®, 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 the third quarter of 2015, 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. Recent key announcements include:

Antiviral Program

- Announced positive topline results from four Phase 3 clinical studies (ASTRAL-1, ASTRAL-2, ASTRAL-3 and ASTRAL-4) evaluating a once-daily, fixed-dose combination of sofosbuvir with velpatasvir (SOF/VEL), an investigational pangenotypic NS5A inhibitor, for the treatment of genotype 1-6 chronic HCV infection.
- Announced that our marketing authorization application (MAA) for an investigational, once-daily single tablet regimen that combines emtricitabine 200 mg, tenofovir alafenamide 25 mg and rilpivirine 25 mg (R/F/TAF) was fully validated

and under evaluation by the European Medicines Agency (EMA). The data included in the application support the use of R/F/TAF for the treatment of HIV-1 infection in adults and pediatric patients 12 years and older.

- Announced that the Committee for Medicinal Products for Human Use, the scientific committee of the EMA, adopted a positive opinion on our MAA for an investigational, once-daily single tablet regimen containing elvitegravir 150 mg, cobicistat 150 mg, emtricitabine 200 mg and tenofovir alafenamide 10 mg (E/C/F/TAF).
- Announced that a Phase 3 study of F/TAF for the treatment of HIV-1 infection met its primary objective. The ongoing study was designed to explore the efficacy and safety of an investigational, fixed-dose combination of emtricitabine 200 mg and tenofovir alafenamide 25 or 10 mg (F/TAF) based regimens among virologically suppressed adult patients switching from HIV treatment regimens containing emtricitabine/tenofovir disoproxil fumarate.
- Announced positive results from a Phase 3 study of E/C/F/TAF among virologically suppressed adult patients switching from tenofovir-containing regimens. The study met its primary endpoint by demonstrating non-inferiority of E/C/F/TAF to the tenofovir-based regimens at week 48. The study also demonstrated statistical superiority among patients with HIV-1 RNA levels less than 50 copies/mL at week 48 and statistically significant improvements in bone and renal laboratory parameters.
- Announced 96-week results from two Phase 3 studies evaluating our investigational once-daily single tablet regimen of E/C/F/TAF, for the treatment of HIV-1 infection in treatment-naïve adults.
- Announced that a new drug application was submitted to the U.S. Food and Drug Administration (FDA) for an investigational, once-daily fixed-dose combination of SOF/VEL for the treatment of chronic 1-6 C virus HCV infection.

Cardiovascular Program

- Announced that the FDA has approved the use of Letairis (ambrisentan) in combination with tadalafil for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to reduce the risks of disease progression and hospitalization for worsening PAH, and to improve exercise ability.

Financial Highlights

During the third quarter of 2015, total revenues increased to $8.3 billion, compared to $6.0 billion in the third quarter of 2014 primarily due to sales of our HCV products, Harvoni and Sovaldi. Sales of HCV products totaled $4.8 billion for the third quarter of 2015, compared to $2.8 billion for the third quarter of 2014.

Research and development (R&D) expenses for the third quarter of 2015 increased to $743 million, compared to $630 million in the third quarter of 2014. Selling, general and administrative (SG&A) expenses for the third quarter of 2015 decreased to $903 million, compared to $945 million in the third quarter of 2014.

Net income attributable to Gilead for the third quarter of 2015 increased to $4.6 billion or $3.06 per diluted share, compared to $2.7 billion or $1.67 per diluted share during the same period in 2014.

As of September 30, 2015, our cash, cash equivalents and marketable securities totaled $25.1 billion. During the third quarter of 2015, we issued senior unsecured notes for a total aggregate principal balance of $10.0 billion (2015 Notes) and generated $4.1 billion in operating cash flows. Also during the third quarter of 2015, we utilized $3.1 billion to repurchase 28 million shares of our common stock under the $15.0 billion repurchase plan approved in January 2015 and paid a cash dividend of $627 million, or $0.43 per share.

Results of Operations

Total Revenues

The following table summarizes our product sales, and royalty, contract and other revenues:

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In millions)	2015	2014	Change	2015	2014	Change
Revenues:						
Product sales	$8,211	$5,968	38 %	$23,742	$17,252	38 %
Royalty, contract and other revenues	84	74	14 %	391	324	21 %
Total revenues	$8,295	$6,042	37 %	$24,133	$17,576	37 %

Product Sales

Total product sales were $8.2 billion for the three months ended September 30, 2015 and $6.0 billion for the three months ended September 30, 2014. Total product sales were $23.7 billion for the nine months ended September 30, 2015 and $17.3 billion for the nine months ended September 30, 2014. Product sales for both periods increased primarily due to our HCV products, Harvoni and Sovaldi. Increased sales from the launch of Harvoni across various geographies were partially offset by a year-over-year decline in Sovaldi sales, with patients in the United States being prescribed Harvoni instead of Sovaldi. HIV products also contributed to the year-over-year sales increases primarily due to increased sales of our newer HIV single-tablet regimens, Stribild and Complera/Eviplera, partially offset by declines in Atripla sales volumes as doctors prescribed newer treatments such as Stribild and Complera/Eviplera.

Product sales generated outside of the United States were 32% during the three months ended September 30, 2015 and 31% during the nine months ended September 30, 2015. As a result, we face exposure to movements in foreign currency exchange rates, primarily in the Euro. We use foreign currency exchange contracts to hedge a percentage of our foreign currency exposure. Foreign currency exchange, net of hedges, had unfavorable impacts on our product sales of $195 million for the three months ended September 30, 2015 and $559 million for the nine months ended September 30, 2015, compared to the same periods in 2014.

Product sales in the United States were $5.6 billion for the three months ended September 30, 2015 and $4.2 billion for the three months ended September 30, 2014, an increase of 33% primarily due to sales of Harvoni, partially offset by a decrease in sales of Sovaldi. Product sales during the three months ended September 30, 2015 benefited from strong Veteran's Administration purchases following allocation by Congress of $500 million in additional funds for HCV treatment. Product sales in the United States were $16.4 billion for the nine months ended September 30, 2015 and $12.7 billion for the nine months ended September 30, 2014, an increase of 29% primarily due to sales of Harvoni, partially offset by a decrease in sales of Sovaldi.

Product sales in Europe were $1.7 billion for the three months ended September 30, 2015 and $1.4 billion for the three months ended September 30, 2014, an increase of 17% primarily due to sales of Harvoni, partially offset by a decrease in sales of Sovaldi. Product sales in Europe were $5.5 billion for the nine months ended September 30, 2015 and $3.8 billion for the nine months ended September 30, 2014, an increase of 46% primarily due to sales of Harvoni and Sovaldi. Foreign currency exchange, net of hedges, had unfavorable impacts on our product sales in Europe of $156 million for the three months ended September 30, 2015 and $469 million for the nine months ended September 30, 2015, compared to the same periods in 2014.

Product sales in other international locations were $958 million for the three months ended September 30, 2015 and $327 million for the three months ended September 30, 2014, an increase of 193%. Product sales in other international locations were $1.9 billion for the nine months ended September 30, 2015 and $838 million for the nine months ended September 30, 2014, an increase of 127%. The increases in both periods were primarily due to the approval of Sovaldi and Harvoni in Japan, in March 2015 and July 2015, respectively.

Since our HCV products, Harvoni and Sovaldi were only recently launched, future sales are difficult to predict as historical sales may not be indicative of future sales. The number of HCV new patient starts in the United States has diminished since the first quarter of 2015, and we anticipate that the rate at which new patients start treatment at the end of 2015 may be more indicative of the pace of new patient starts in 2016.

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

(In millions, except percentages)	Three Months Ended September 30, 2015	2014	Change	Nine Months Ended September 30, 2015	2014	Change
Antiviral products:						
Harvoni	$3,332	$20	*	$10,519	$20	*
Sovaldi	1,466	2,796	(48)%	3,729	8,551	(56)%
Truvada	903	877	3 %	2,523	2,443	3 %
Atripla	818	895	(9)%	2,334	2,545	(8)%
Stribild	511	327	56 %	1,314	812	62 %
Complera/Eviplera	360	330	9 %	1,047	880	19 %
Viread	297	275	8 %	802	747	7 %
Other antiviral	15	24	(38)%	53	67	(21)%
Total antiviral products	7,702	5,544	39 %	22,321	16,065	39 %
Other products:						
Letairis	181	146	24 %	508	414	23 %
Ranexa	161	132	22 %	419	366	14 %
AmBisome	88	98	(10)%	276	284	(3)%
Zydelig	36	6	*	92	6	*
Other	43	42	2 %	126	117	8 %
Total product sales	$8,211	$5,968	38 %	$23,742	$17,252	38 %

* Percentage not meaningful

Following is additional discussion related to the key period over period changes in net product sales:

•Harvoni

Net product sales of Harvoni for the three and nine months ended September 30, 2015 accounted for 43% and 47%, respectively, of our total antiviral product sales. Harvoni was approved by the FDA in October 2014 and by the European Commission in November 2014. In Japan, Harvoni was approved in July 2015 as the first once-daily single tablet regimen for the treatment of chronic HCV genotype 1 infection in adults with or without compensated cirrhosis. During the three months ended September 30, 2015, net product sales of Harvoni were $2.5 billion in the United States, $532 million in Europe and $259 million in other international locations. During the nine months ended September 30, 2015, net product sales of Harvoni were $8.4 billion in the United States, $1.6 billion in Europe, and $504 million in other international locations.

•Sovaldi

Net product sales of Sovaldi for the three and nine months ended September 30, 2015 accounted for 19% and 17%, respectively, of our total antiviral product sales. In Japan, Sovaldi was approved in March 2015 for the suppression of viremia in patients with genotype 2 chronic HCV infection with or without compensated cirrhosis.

During the three months ended September 30, 2015, net product sales of Sovaldi were $692 million in the United States, $337 million in Europe and $437 million in other international locations, compared to $2.2 billion in the United States, $523 million in Europe and $73 million in other international locations for the same period in 2014. The quarter over prior year quarter decline in sales of Sovaldi was primarily due to volume declines with patients being prescribed Harvoni instead of Sovaldi, partially offset by increased sales following the launch in Japan.

During the nine months ended September 30, 2015, net product sales of Sovaldi were $1.7 billion in the United States, $1.3 billion in Europe and $659 million in other international locations, compared to $7.3 billion in the United States, $1.1 billion in Europe and $135 million in other international locations for the same period in 2014. The year-over-year decline in sales of Sovaldi in the United States was primarily due to volume declines in the United States with patients being prescribed Harvoni instead of Sovaldi, partially offset by volume increases in Europe and Japan as we continue to launch Sovaldi in various geographies.

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- Atripla

Net product sales of Atripla for the three and nine months ended September 30, 2015 accounted for 11% and 10% of our total antiviral product sales, respectively.

During the three months ended September 30, 2015, net product sales of Atripla were $597 million in the United States and $161 million in Europe, compared to $621 million in the United States and $223 million in Europe for the same period in 2014. During the nine months ended September 30, 2015, net product sales of Atripla were $1.6 billion in the United States and $533 million in Europe, compared to $1.7 billion in the United States, and $694 million in Europe for the same period in 2014. The year-over-year decline in sales of Atripla was due primarily to declines in volume as doctors prescribed newer treatments such as Stribild and Complera/Eviplera.

The efavirenz component of Atripla sales, which has a gross margin of zero, comprised $307 million and $865 million, of our Atripla sales for the three and nine months ended September 30, 2015, respectively. For the three and nine months ended September 30, 2014, the efavirenz component of Atripla sales comprised $329 million and $930 million of our Atripla sales, respectively.

- Stribild

Net product sales of Stribild for the three and nine months ended September 30, 2015 accounted for 7% and 6% of our total antiviral product sales, respectively.

During the three months ended September 30, 2015, net product sales of Stribild were $422 million in the United States and $73 million in Europe, compared to $278 million in the United States and $38 million in Europe for the same period in 2014. During the nine months ended September 30, 2015, net product sales of Stribild were $1.1 billion in the United States and $199 million in Europe, compared to $695 million in the United States and $93 million in Europe for the same period in 2014. The increases in sales of Stribild in both periods were driven primarily by higher sales volume.

- Complera/Eviplera

Net product sales of Complera/Eviplera accounted for 5% of our total antiviral product sales for both the three and nine months ended September 30, 2015, respectively.

During the three months ended September 30, 2015, net product sales of Complera/Eviplera were $210 million in the United States and $137 million in Europe, compared to $183 million in the United States and $134 million in Europe for the same period in 2014. Net product sales of Complera/Eviplera for the nine months ended September 30, 2015 were $580 million in the United States and $427 million in Europe, compared to $467 million in the United States and $375 million in Europe for the same period in 2014. The increases in sales of Complera/Eviplera in both periods were driven primarily by higher sales volume.

Cost of Goods Sold and Product Gross Margin

The following table summarizes our cost of goods sold and product gross margin:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In millions, except percentages)	2015	2014	2015	2014
Cost of goods sold	$1,064	$987	$2,944	$2,725
Product gross margin	87 %	83 %	88 %	84 %

Product gross margin was 87% and 88% for the three and nine months ended September 30, 2015 respectively, compared to 83% and 84% for the same periods in 2014. The margin change in the three and nine months ended September 30, 2015 compared to the same periods in 2014 was due to changes in product mix, as Atripla sales declined and HCV sales increased as a percentage of product sales.

Operating Expenses

The following table summarizes the period over period changes in our R&D expenses and SG&A expenses:

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In millions, except percentages)	2015	2014	Change	2015	2014	Change
Research and development expenses	$743	$630	18 %	$2,257	$1,809	25 %
Selling, general and administrative expenses	$903	$945	(4)%	$2,360	$2,107	12 %

Research and Development Expenses

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.

R&D expenses for the three months ended September 30, 2015 increased by $113 million or 18%, compared to the same period in 2014. This increase was primarily due to $77 million related to clinical study activity, particularly due to the continued progression of our clinical studies in our HIV TAF-based programs.

R&D expenses for the nine months ended September 30, 2015 increased by $448 million or 25%, compared to the same period in 2014. This increase was primarily due to $212 million related to clinical study activity, an increase of $147 million related to personnel and infrastructure expenses to support our ongoing clinical activity and geographic expansion and $66 million for acquisition-related expenses.

Selling, General and Administrative Expenses

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.

SG&A expenses for the three months ended September 30, 2015 decreased by $42 million or 4%, compared to the same period in 2014. A decrease of $197 million in the non-tax deductible Branded Prescription Drug (BPD) fee, also known as the pharmaceutical excise tax was partially offset by an increase of $174 million in headcount-related and other expenses to support the growth of our business, including our commercial expansion to support our HCV products. SG&A expenses for the three months ended September 30, 2014 included a cumulative catch-up of $337 million related to the BPD fee. In July 2014, the Internal Revenue Service (IRS) issued final regulations related to the BPD fee that indicate that an entity's obligation to pay its portion of the fee in any given calendar year is triggered by the qualifying sales in the previous year, instead of the first qualifying sales in the current calendar year.

SG&A expenses for the nine months ended September 30, 2015 increased by $253 million or 12%, compared to the same period in 2014, primarily due to an increase of $373 million in headcount-related and other expenses to support the growth of our business, partially offset by a decrease of $139 million in the BPD fee. The 2014 period included the $337 million cumulative catch-up of the BPD fee accrual.

Interest Expense

Interest expense for the three months ended September 30, 2015 was $165 million, an increase of 59%, compared to the same period in 2014. The increase was primarily due to issuances of senior unsecured notes in November 2014 and September 2015. Interest expense for the nine months ended September 30, 2015 was $458 million, an increase of 62% compared to the same period in 2014. The increase was primarily due to issuances of senior unsecured notes in March 2014, November 2014 and September 2015. See Note 8, Debt and Credit Facility of the Notes to Condensed Consolidated Financial Statements in this quarterly report.

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Provision for Income Taxes

Our provision for income taxes was $880 million and $2.8 billion for the three and nine months ended September 30, 2015, respectively, compared to $647 million and $2.0 billion for the same periods in 2014. Our effective tax rates were 16.1% and 17.3% for the three and nine months ended September 30, 2015, respectively, compared to 19.2% and 19.1% for the same periods in 2014. The effective tax rates for the three and nine months ended September 30, 2015 were lower than the effective tax rates for the same periods in 2014 primarily due to higher earnings from non-U.S. subsidiaries that are considered indefinitely reinvested.

The effective tax rates for the three and nine months ended September 30, 2015 and September 30, 2014 differed from the U.S. federal statutory rate of 35% primarily due 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.

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. The following table summarizes our cash, cash equivalents and marketable securities and working capital:

(In millions)	September 30, 2015	December 31, 2014
Cash, cash equivalents and marketable securities	$25,114	$11,726
Working capital	$16,550	$11,953

Cash, Cash Equivalents and Marketable Securities

As of September 30, 2015, cash, cash equivalents and marketable securities totaled $25.1 billion, an increase of $13.4 billion from December 31, 2014. During the nine months ended September 30, 2015, we generated $15.5 billion in cash flows from operations, received $9.9 billion in net proceeds from the issuance of our 2015 Notes and repurchased $7.0 billion of common stock. Additionally, we utilized $3.9 billion to settle 46 million warrants related to the May 2016 Notes and paid cash dividends of $1.3 billion.

Of the total cash, cash equivalents and marketable securities at September 30, 2015, approximately $12.4 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 $16.6 billion as of September 30, 2015. The increase of $4.6 billion in working capital from December 31, 2014 was driven primarily by the increase in cash, cash equivalents and short-term marketable securities and an increase in accounts receivable, partially offset by increases in accrued government and other rebates.

Cash Flows

The following table summarizes our cash flow activities:

	Nine months ended September 30,	
(In millions)	2015	2014
Cash provided by (used in):		
Operating activities	$15,455	$9,797
Investing activities	$(10,037)	$(1,418)
Financing activities	$(1,419)	$(4,259)

Cash Provided by Operating Activities

Cash provided by operating activities was $15.5 billion for the nine months ended September 30, 2015 and consisted primarily of net income of $13.4 billion, adjusted for non-cash items of $698 million and $1.3 billion related to

changes in

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operating assets and liabilities. Cash flows from operations may decrease in the future as we continue to make cash payments related to accrued government and other rebates.

Cash provided by operating activities was $9.8 billion for the nine months ended September 30, 2014 and consisted primarily of net income of $8.6 billion, adjusted for non-cash items of $1.0 billion and $174 million related to changes in operating assets and liabilities.

Cash Used in Investing Activities

Cash used in investing activities for the nine months ended September 30, 2015 was $10.0 billion, consisting of $9.5 billion in net purchases of marketable securities and $581 million in capital expenditures related to the expansion of our business.

Cash used in investing activities for the nine months ended September 30, 2014 was $1.4 billion, consisting primarily of $1.0 billion in net purchases of marketable securities and $390 million in capital expenditures related to the expansion of our business.

Cash Used in Financing Activities

Cash used in financing activities for the nine months ended September 30, 2015 was $1.4 billion, consisting primarily of $7.0 billion used to repurchase common stock under our stock repurchase programs, $3.9 billion used to settle the warrants related to the May 2016 Notes (the 2016 Warrants), and $1.3 billion used to pay dividends. These payments were primarily offset by $9.9 billion in net proceeds from the issuance of our 2015 Notes.

Cash used in financing activities for the nine months ended September 30, 2014 was $4.3 billion, consisting primarily of $1.3 billion used to repay debt, net of amounts received from convertible note hedges, $3.3 billion used to repurchase common stock under our stock repurchase programs, and $4.1 billion to settle the warrants related to our convertible senior notes that were retired in May 2014. These payments were primarily offset by $4.0 billion in net proceeds from the March 2014 issuance of senior unsecured notes (March 2014 Notes).

Long-Term Obligations

The following is a summary of our borrowing under various financing arrangements for the period ended September 30, 2015 (in millions):

Type of Borrowing	Description	Issue Date	Due Date	Interest Rate	September 30, 2015	December 31, 2014
Convertible Senior	May 2016 Notes	July 2010	May 2016	1.625%	$ 331	$ 483
Senior Unsecured	April 2021 Notes	March 2011	April 2021	4.50%	995	995
Senior Unsecured	December 2016 Notes	December 2011	December 2016	3.05%	700	700
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	499
Senior Unsecured	April 2024 Notes	March 2014	April 2024	3.70%	1,748	1,747
Senior Unsecured	April 2044 Notes	March 2014	April 2044	4.80%	1,747	1,747
Senior Unsecured	February 2020 Notes	November 2014	February 2020	2.35%	499	499
Senior Unsecured	February 2025 Notes	November 2014	February 2025	3.50%	1,748	1,748
Senior Unsecured	February 2045 Notes	November 2014	February 2045	4.50%	1,740	1,740
Senior Unsecured	September 2018 Notes	September 2015	September 2018	1.85%	1,000	—
Senior Unsecured	September 2020 Notes	September 2015	September 2020	2.55%	1,996	—
Senior Unsecured	September 2022 Notes	September 2015	September 2022	3.25%	999	—
Senior Unsecured	March 2026 Notes	September 2015	March 2026	3.65%	2,739	—

Senior Unsecured	September 2035 Notes	September 2015	September 2035	4.60%	997	—
Senior Unsecured	March 2046 Notes	September 2015	March 2046	4.75%	2,241	—
Total debt, net					22,225	12,404
Less current portion					331	483
Total long-term debt, net					$ 21,894	$ 11,921

Debt Financing

In September 2015, we issued the 2015 Notes in a registered offering for a total aggregate principal amount of $10.0 billion. We intend to use the net proceeds for general corporate purposes, which may include the repayment of debt, working capital, payment of dividends and the repurchase of our outstanding common stock pursuant to our authorized share repurchase program. The notes may be redeemed before their maturity dates, in whole or in part, based on terms and circumstances as described in Note 8, Debt and Credit Facility of the Notes to Condensed Consolidated Financial Statements in this quarterly report.

Convertible Senior Notes

During the nine months ended September 30, 2015, a portion of the May 2016 Notes was settled and we repaid $163 million of principal balance related to these notes. We also paid $600 million in cash related to the conversion spread of the May 2016 Notes, which represents the conversion value in excess of the principal amount, and received $600 million in cash from the convertible note hedges related to the May 2016 Notes.

As of September 30, 2015, the carrying value of the May 2016 Notes was $331 million and the conversion rate was 44.3764 (which represented a conversion price of approximately $22.53 per share).

During the second quarter of 2015, we entered into modified agreements with our warrant counterparties which changed the timing of the expiration for 46 million of the 2016 Warrants. The agreements allowed us to settle the 46 million warrants at our option, in cash or shares. According to the terms of the agreements, these warrants expired during a 32 trading-day period which commenced on May 11, 2015 and ended on June 24, 2015. We exercised our option to settle in cash, and as a result, paid $3.9 billion as the market value of our common stock at the time of the exercise of the warrants exceeded their strike prices.

As of September 30, 2015, 9 million of the 2016 Warrants remained outstanding and have a strike price of $29.19 per share and are due to expire during the 40 trading-day period commencing August 1, 2016.

Credit Facility

There were no amounts outstanding under the revolving credit facility credit agreement as of September 30, 2015. We are required to comply with certain covenants under the credit agreement and note indentures and as of September 30, 2015, we were not in violation of any covenants.

Repurchases of Common Stock

During the third quarter of 2015, we repurchased 28 million shares of common stock for $3.1 billion. During the nine months ended September 30, 2015, we repurchased 66 million shares of common stock for $7.0 billion. As of September 30, 2015, we have $11.1 billion remaining under our $15.0 billion stock repurchase program authorized in January 2015 (2015 Program). We completed our $5.0 billion stock repurchase program authorized in May 2014 in the first quarter of 2015.

Dividends

During the nine months ended September 30, 2015, we paid cash dividends of $1.3 billion or $0.86 per share. On October 27, 2015, we announced that our Board of Directors declared a quarterly cash dividend of $0.43 per share of our common stock, with a payment date of December 30, 2015 to all stockholders of record as of the close of business on December 16, 2015.

Critical Accounting Policies, Estimates and Judgments

The preparation of our Condensed Consolidated Financial Statements requires us to make estimates and judgments that affect the reported amounts in the financial statements 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. A summary of our critical accounting policies is presented in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2014. There have been no material changes to our critical accounting policies during the nine months ended September 30, 2015.

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.

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Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB), 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 August 2015, the FASB issued an accounting standard update which defers the effective date of the new standard by one year. The standard will become effective for us beginning in the first quarter of 2018. Early application is permitted in 2017. Entities have the option of using either a full retrospective or a modified retrospective approach to adopt this new guidance. We are currently evaluating the impact of our pending adoption of this standard on our Condensed Consolidated Financial Statements.

In April 2015, the FASB issued an accounting standard update which requires presentation of debt issuance costs as a direct deduction from the carrying amount of a recognized debt liability on the balance sheet. The update does not change the guidance on the recognition and measurement of debt issuance costs. This guidance will become effective for us for annual periods beginning after December 15, 2015, and interim periods thereafter. At the time of adoption, we will reclassify debt issuance costs to a liability as a direct deduction from the carrying value of the debt, consistent with the presentation of a debt discount. We do not expect that the adoption of this update will have a material impact on our Condensed Consolidated Financial Statements.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There have been no material changes in our market risk during the nine months ended September 30, 2015 compared to the disclosures in Part II, Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2014.

As of September 30, 2015, our accounts receivable in Southern Europe, specifically Greece, Italy, Portugal and Spain, totaled approximately $1.8 billion, of which $198 million were greater than 120 days past due, including $27 million 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 September 30, 2015. However, we will continue to monitor the European economic environment for collectability issues related to our outstanding receivables.

Item 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

An evaluation as of September 30, 2015 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 September 30, 2015.

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 September 30, 2015, 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.

Limitations on the Effectiveness of Controls

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met and, as set forth above, our Chief Executive Officer and Chief

Financial Officer have concluded, based on their evaluation as of the end of the period covered by this report, that our disclosure controls and procedures were effective to provide reasonable assurance that the objectives of our disclosure control system were met.

PART II. OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

Litigation Related to 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 hepatitis C virus (HCV). In December 2013, we received U.S. Food and Drug Administration (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 (LDV/SOF), now known commercially as Harvoni. We have received a number of contractual and intellectual property claims regarding sofosbuvir. While we have carefully considered these claims both prior to and following the acquisition and believe they are without merit, we cannot predict the ultimate outcome of such claims or range of loss.

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 have been or may in the future 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. We have spent, and will continue to spend, significant resources defending against these claims.

If third 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. On January 29, 2014, the USPTO Patent Trial and Appeal Board (PTAB) determined that Pharmasset and not Idenix was the first to invent the compounds in dispute and accordingly Gilead prevailed in the First Idenix Interference. Idenix has appealed the PTAB’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 Idenix’s U.S. Patent No. 7,608,600 (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 purpose of the Second Idenix Interference was to determine who was first to invent the claimed methods of treating HCV with compounds similar to those which were involved in the First Idenix Interference. On March 23, 2015, the PTAB determined that Pharmasset and not Idenix was the first to invent the claimed methods of treating HCV. Idenix appealed this decision in both the U.S. District Court for the District of Delaware and the U.S. Court of Appeal for the Federal Circuit (CAFC). We have filed a motion to dismiss the appeal in Delaware and will respond to the appeal filed in the CAFC.

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 was held in January and February 2015, and on November 2, 2015, the Federal Court of Canada rendered its public decision holding that Idenix's patent is invalid and that Gilead's patent is valid.

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. The appeal hearing from the March 2014 decision is scheduled for 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 its Australian patent corresponding to the '600 patent. A month-long trial was completed in October 2015 in Sydney, and we are currently awaiting a decision.

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 was granted, we filed an opposition with the EPO seeking to revoke the '489 patent. The EPO has set an opposition hearing for February 2016. Also on that day, Idenix initiated infringement proceedings against Gilead in the United Kingdom (UK), Germany and France alleging that the commercialization of Sovaldi would infringe the UK, German and French counterparts of the '489 patent. A trial was held in the UK 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 challenged claims of the '489 patent on multiple grounds. The UK Court has granted Idenix permission to appeal the December 1, 2014 judgment. The appeal of the UK Court's decision is scheduled for July 2016. On March 12, 2015, the German court in Düsseldorf determined that the Idenix patent was highly likely to be invalid and stayed the infringement proceedings pending the outcome of the opposition filed in the EPO. Idenix has not appealed this decision of the German court staying the proceedings. Upon Idenix's request, the French proceedings have been stayed.

Idenix has not been awarded patents corresponding to the '600 patent in Japan or China. In the event such patents are issued, 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 transferred the Massachusetts litigation to the U.S. District Court for the District of Delaware. The district court has set trial dates in October 2016 and December 2016 for resolution of these issues. A decision by the district court may be appealed by either party to the 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. 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. 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 may 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 LDV/SOF (or Harvoni) for the treatment of HCV. Gilead is aware that AbbVie has pending patent applications in the United States and granted and pending 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 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 LDV/SOF. In February and March 2014, AbbVie responded to our lawsuit by also filing two lawsuits in the U.S. District Court for the District of Delaware alleging that our fixed-dose combination of LDV/SOF will infringe its patents. All of those lawsuits have been consolidated into a single action. In the United States, either party may 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, Canada, or Europe. We do not expect any other foreign patents to block or delay the commercialization around the world. The court has set a trial date of September 12, 2016 for this lawsuit.

Additionally, AbbVie has obtained U.S. Patent No. 9,034,832 which purports to cover a solid oral dosage form containing ledipasvir. Accordingly, in May 2015, we filed a lawsuit in the U.S. District Court for the District of Delaware seeking declaratory judgment that AbbVie's patent is invalid, as well as other relief. We do not expect AbbVie's patent to block the commercialization of our combination product. The court has set a trial date of July 31, 2017.

In August 2015, we brought an impeachment action seeking a declaration that AbbVie's Canadian Patent No. 2,811,250 ('250 Patent), which purports to cover the use of a combination of LDV/SOF (or Harvoni) for the treatment of HCV, is invalid. On the same day, AbbVie brought an infringement action which asserts that commercialization of Harvoni in Canada will infringe its '250 Patent. The impeachment action has been stayed and we have counterclaimed for invalidity in the infringement proceeding. A trial date has not been set.

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.

European Patent Claims

In February 2015, several parties filed oppositions in the European Patent Office requesting revocation of our granted European patent covering sofosbuvir that expires in 2028. While we are confident in the strength of our sofosbuvir patent, we cannot predict the ultimate outcome of these oppositions. If we are unsuccessful in defending these oppositions, some or all of our patent claims may be narrowed or revoked and the patent protection for sofosbuvir in Europe could be substantially shortened or eliminated entirely. If the sofosbuvir patent is revoked, and no other European patents are granted covering sofosbuvir, our exclusivity will be based entirely on regulatory exclusivity granted by the European Medicines Agency (EMA). Sovaldi has been granted regulatory exclusivity that will prevent generic sofosbuvir from entering the European Union for 10 years following approval of Sovaldi, or January 2024. If we lose exclusivity for Sovaldi prior to 2028, our expected revenues and results of operation could be negatively impacted for the years including and succeeding the year in which such exclusivity is lost, which may cause our stock price to decline.

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.

HIV Products

In November 2011, we received notice that Teva 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. 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 an 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. The appeal will be heard by the Canadian Federal Court of Appeal after the trial in the Impeachment Action. The court will determine the validity of the patents in the pending Impeachment Action. A trial in the Impeachment Action is scheduled for November 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 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. The court has set a trial date of May 16, 2016 for this lawsuit. In October 2015, we reached an agreement with Mylan to settle the lawsuit. The terms of the settlement agreement are confidential. The settlement agreement has been filed with the Federal Trade Commission and Department of Justice as required by law.

In June 2014, we received notice that Mylan submitted petitions for Inter Partes Review (IPR) to the PTAB 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. In January 2015, Mylan requested rehearing on the basis that it believes the PTAB decision is wrong. In August 2015, the PTAB denied Mylan's request for a rehearing on the three patents covering the tenofovir disoproxil prodrug.

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.

In July 2015, we received notice that Mylan submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Complera. In the notice, Mylan alleges that our patents associated with emtricitabine and the fixed-dose combination of emtricitabine with tenofovir disoproxil fumarate, in addition to patents associated with rilpivirine, are invalid, unenforceable and/or will not be infringed by Mylan's manufacture, use or sale of a generic version of Complera. In August 2015, Gilead and Janssen filed suit in the U.S. District Court for the District of Delaware, and in September 2015, filed suit in the U.S. District Court for the Northern District of West Virginia and asserted patents associated with rilpivirine. In August 2015, Gilead also filed suit separately in the U.S. District Court for the Northern District of West Virginia asserting patents associated with emtricitabine and the fixed-dose combination of emtricitabine with tenofovir disoproxil fumarate. In October 2015, we reached an agreement with Mylan to settle the lawsuit in the U.S. District Court for the Northern District of West Virginia relating to the patents associated with emtricitabine and the fixed-dose combination of emtricitabine with tenofovir disoproxil fumarate. The terms of the settlement agreement are confidential. The settlement agreement has been filed with the Federal Trade Commission and Department of Justice as required by law.

Letairis

In August 2014, Natco Pharma Ltd. (Natco) filed a complaint with the U.S. District Court for the District of Minnesota against Gilead and Express Scripts Holding Co. (Express Scripts), 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 October 2015, the U.S. District Court granted Gilead's and Express Scripts' Motion to Dismiss Natco's claims.

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. In April 2015, we filed a lawsuit against Watson in the U.S. District Court for the District of New Jersey.

In June 2015, we received notice that SigmaPharm Laboratories, LLC (SigmaPharm) submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Letairis. In the notice, SigmaPharm alleges that one of the patents associated with ambrisentan tablets is invalid, unenforceable and/or will not be infringed by SigmaPharm’s manufacture, use or sale of a generic version of Letairis. In June 2015, we filed a lawsuit against SigmaPharm in the U.S. District Court for the District of New Jersey.

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 our products could be substantially shortened. Further, if all of the patents covering one or more products are invalidated, the FDA or Health Canada 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 U.S. 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 plaintiffs filed a Second Amended Complaint. We moved to dismiss the Second Amended Complaint and in June 2015, the federal district court issued an order granting our motion to dismiss the Second Amended Complaint. In July 2015, the plaintiffs filed a notice of appeal in the U.S. Court of Appeals for Ninth Circuit.

Other Matters

We are a party to various legal actions that arise 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.

Item 1A. RISK FACTORS

In evaluating our business, you should carefully consider the following risks in addition to the other information in this Quarterly Report on Form 10-Q. 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 nine months ended September 30, 2015, sales of Harvoni and Sovaldi for the treatment of HCV, accounted for approximately 60% of our total product sales. Since Harvoni and Sovaldi were only recently launched, we cannot be certain if 2014 and the first half of 2015 sales of our HCV products are indicative of future sales. The number of warehoused HCV patients has diminished since the first quarter of 2015, and we anticipate that the rate at which new patients start treatment at the end of 2015 may be more indicative of the pace of new patient starts in 2016. With the approval and entry of a competitor’s HCV product in December 2014 and the potential entry of a competitor's HCV product in early 2016, 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. 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. Many of the commercial arrangements for our HCV products were entered into during the first two quarters of 2015, and as a result, the full impact of the discounts or rebates is expected to affect the second half of 2015.

In addition, future sales of Harvoni and Sovaldi 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 (EU), several governments have announced or implemented measures to manage healthcare expenditures. We continue to experience global pricing pressure which often results in increases in the amount of discounts required on our products or delayed reimbursement, which could negatively impact our future product sales and results of operations. Also, private and public payers can choose to exclude Harvoni or Sovaldi from their formulary coverage lists or limit the types of patients for whom coverage will be provided, which would negatively impact the demand for, and revenues of, Harvoni and Sovaldi. 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 expected future sales levels of HCV products or obtain approval or reimbursement for additional 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, Stribild, Complera/Eviplera and Atripla. During the nine months ended September 30, 2015, sales of our HIV products accounted for approximately 34% 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 Stribild, Complera/Eviplera and Atripla, 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.
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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 new or generic HIV products are introduced into major markets, our ability to maintain pricing and market share may be affected.

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 the fourth quarter of 2014, we filed our new drug application (NDA) and marketing authorization application (MAA) for approval of the single tablet regimen of elvitegravir, cobicistat, emtricitabine and tenofovir alafenamide (TAF) for the treatment of HIV-1 infection in adults in the United States and European Union. In the second quarter of 2015, we filed our NDA and MAA for the approval of two doses of a fixed-dose combination of emtricitabine and TAF for the treatment of HIV-1 infection in adults and pediatric patients age 12 years and older, in combination with other HIV antiretroviral agents, in the United States and European Union. Also in the second quarter of 2015, we filed our NDA for approval of the single tablet regimen of rilpivirine, emtricitabine and TAF in the United States. 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, Harvoni and Sovaldi, 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 Harvoni and Sovaldi will depend 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 Harvoni or Sovaldi from their formulary coverage lists or limit the types of patients for whom coverage will be provided, which would negatively impact the demand for and revenues of Harvoni and Sovaldi. 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. We have experienced, and may continue to experience, 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 nine months ended September 30, 2015, approximately 90% 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 2014, 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 2015. 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 funds, may cause purchasing patterns to not reflect patient demand of our products. For example, in the first quarters of certain prior years, we observed large non-retail purchases of our HIV products by a number 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 an industry fee (also known as the Branded Prescription Drug (BPD) fee), of $3.0 billion for 2015 calculated based on select government sales during the 2013 calendar year as a percentage of total industry government sales.

The amount of the annual BPD fee imposed on the pharmaceutical industry as a whole is $3.0 billion in 2014 through 2016, which will 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. 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 Harvoni, Sovaldi or other sofosbuvir containing products and/or reduce coverage of Harvoni, Sovaldi 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 31% 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 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. Foreign currency exchange, net of hedges, had an unfavorable impact of

$195 million and $559 million on our product sales for the three and nine months ended September 30, 2015, respectively, compared to the same periods in 2014.

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, Harvoni and Sovaldi, compete with a product marketed by AbbVie Inc. (AbbVie) and Janssen R&D Ireland (Janssen).

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 Stribild, Complera/Eviplera, Atripla and Truvada. For Tybost, we compete with ritonavir marketed by AbbVie. In addition, two products marketed by ViiV, Tivicay (dolutegravir), an integrase inhibitor, and Triumeq, a single-tablet triple-combination antiretroviral regimen, could adversely impact sales of our HIV products.

We also face competition from generic HIV products. Generic versions of lamivudine and Combivir (lamivudine and zidovudine) are available in the United States and certain other countries. 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 (BMS) 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.

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 U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA) and comparable regulatory agencies in other countries. We are continuing clinical trials for Harvoni, Sovaldi, Stribild, Complera/Eviplera, Atripla, Truvada, 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, safety reporting 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. 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 idelalisib for the treatment of relapsed refractory indolent non-Hodgkin lymphoma and

frontline and relapsed refractory chronic lymphocytic leukemia; momelotinib for the treatment of myelofibrosis and pancreatic cancer; eleclazine (formerly GS-6615) for the treatment of long QT-3 syndrome; and TAF as a standalone agent for the treatment of HBV, 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 Janssen for Complera/Eviplera; 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.

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 our Letairis Education and Access Program (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.

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 36 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 53.

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 Part II, Item 1, "Legal Proceedings" and the risk factor entitled "If any party is successful in establishing exclusive rights to Harvoni and/or Sovaldi, our expected revenues and earnings from the sale of Harvoni and/or Sovaldi could be adversely affected" beginning on page 49.

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 Harvoni and/or Sovaldi, our expected revenues and earnings from the sale of Harvoni and/or Sovaldi 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 Harvoni or Sovaldi. 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 Harvoni and Sovaldi. We cannot predict the ultimate outcome of intellectual property claims related to Harvoni or Sovaldi, 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 Harvoni and/or Sovaldi, 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.

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. On January 29, 2014, the USPTO Patent Trial and Appeal Board (PTAB) determined that Pharmasset and not Idenix was the first to invent the compounds in dispute and accordingly

Gilead prevailed in the First Idenix Interference. Idenix has appealed the PTAB'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 Idenix's U.S. Patent No. 7,608,600 (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 purpose of the Second Idenix Interference was to determine who was first to invent the claimed methods of treating HCV with compounds similar to those which were involved in the First Idenix Interference. On March 23, 2015, the PTAB determined that Pharmasset and not Idenix was the first to invent the claimed methods of treating HCV. Idenix appealed this decision in both the U.S. District Court for the District of Delaware and the U.S. Court of Appeal for the Federal Circuit (CAFC). We have filed a motion to dismiss the appeal in Delaware and will respond to the appeal filed in the CAFC.

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 was held in January and February 2015, and on November 2, 2015, the Federal Court of Canada rendered its public decision holding that Idenix's patent is invalid and that Gilead's patent is valid.

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. The appeal hearing from the March 2014 decision is scheduled for 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 its Australian patent corresponding to the '600 patent. A month-long trial on these issues was completed in October 2015 in Sydney and we are currently awaiting a decision.

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 was granted, we filed an opposition with the EPO seeking to revoke the '489 patent. The EPO has set an opposition hearing for February 2016. Also on that day, Idenix initiated infringement proceedings against Gilead in the United Kingdom (UK), Germany and France alleging that the commercialization of Sovaldi would infringe the UK, German and French counterparts of the '489 patent. A trial was held in the UK 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 challenged claims of the '489 patent on multiple grounds. The UK Court has granted Idenix permission to appeal the December 1, 2014 judgment. The appeal of the UK Court's decision is scheduled for July 2016. On March 12, 2015, the German court in Düsseldorf determined that the Idenix patent was highly likely to be invalid and stayed the infringement proceedings pending the outcome of the opposition filed in the EPO. Idenix has not appealed this decision of the German court staying the proceedings. Upon Idenix's request, the French proceedings have been stayed.

Idenix has not been awarded patents corresponding to the '600 patent in Japan or China. In the event such patents are issued, 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 transferred the Massachusetts litigation to the U.S. District Court for the District of Delaware. The district court has set trial dates in October 2016 and December 2016 for resolution of these issues. A decision by the district court may be appealed by either party to the 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. 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. 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 may 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

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 LDV/SOF (or Harvoni) for the treatment of HCV. Gilead is aware that AbbVie has pending patent applications in the United States and granted and pending 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 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 LDV/SOF. In February and March 2014, AbbVie responded to our lawsuit by also filing two lawsuits in the U.S. District Court for the District of Delaware alleging that our fixed-dose combination of LDV/SOF will infringe its patents. All of those lawsuits have been consolidated into a single action. In the United States, either party may 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, Canada, or Europe. We do not expect any other foreign patents to block or delay the commercialization around the world. The court has set a trial date of September 12, 2016 for this lawsuit.

Additionally, AbbVie has obtained U.S. Patent No. 9,034,832 which purports to cover a solid oral dosage form containing ledipasvir. Accordingly, in May, 2015 we filed a lawsuit in the U.S. District Court for the District of Delaware seeking declaratory judgment that AbbVie's patent is invalid, as well as other relief. We do not expect AbbVie's patent to block the commercialization of our combination product. The court has set a trial date of July 31, 2017.

In August 2015, we brought an impeachment action seeking a declaration that AbbVie's Canadian Patent No. 2,811,250 ('250 Patent), which purports to cover the use of a combination of LDV/SOF (or Harvoni) for the treatment of HCV, is invalid. On the same day, AbbVie brought an infringement action which asserts that commercialization of Harvoni in Canada will infringe its '250 Patent. The impeachment action has been stayed and we have counterclaimed for invalidity in the infringement proceeding. A trial date has not been set.

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.

European Patent Claims

In February 2015, several parties filed oppositions in the European Patent Office requesting revocation of our granted European patent covering sofosbuvir that expires in 2028. While we are confident in the strength of our sofosbuvir patent, we cannot predict the ultimate outcome of these actions. If we are unsuccessful in defending these oppositions, some or all of our patent claims may be narrowed or revoked and the patent protection for sofosbuvir in Europe could be substantially shortened or eliminated entirely. If the sofosbuvir patent is revoked, and no other European patents are granted covering sofosbuvir, our exclusivity will be based entirely on regulatory exclusivity granted by the EMA.

Sovaldi has been granted regulatory exclusivity that will prevent generic sofosbuvir from entering the EU for 10 years following approval of Sovaldi, or January 2024. If we lose exclusivity for Sovaldi prior to 2028, our expected revenues and results of operation could be negatively impacted for the years including and succeeding the year in which such exclusivity is lost, which may cause our stock price to decline.

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. 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. To the extent these risks materialize and affect their performance obligations to us, our financial results may be adversely affected.

Our manufacturing operations are subject to routine inspections by regulatory agencies. For example, in 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. 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 completed and filed our responses to these observations with the FDA. If we are unable to remedy the deficiencies cited by the FDA or to the extent there are additional deficiencies cited by the FDA in future 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.

Suppliers of key components and materials must be named in the NDA or MAA 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 (Harvoni, Sovaldi, Stribild, Complera/Eviplera, Atripla, Truvada, 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 submitted petitions for Inter Partes Review (IPR) to the PTAB 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. In January 2015, Mylan requested a rehearing on the basis that it believes the PTAB decision is wrong. In August 2015, the PTAB denied Mylan's request for a rehearing on the three patents covering the tenofovir disoproxil prodrug.

In July 2015, we received notice that Mylan submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Complera. In the notice, Mylan alleges that our patents associated with emtricitabine and the fixed-dose combination of emtricitabine with tenofovir disoproxil fumarate, in addition to patents associated with rilpivirine, are invalid, unenforceable and/or will not be infringed by Mylan's manufacture, use or sale of a generic version of Complera. In August 2015, Gilead and Janssen filed suit in the U.S. District Court for the District of Delaware, and in September 2015, filed suit in the U.S. District Court for the Northern District of West Virginia and asserted patents associated with rilpivirine. In August 2015, we also filed suit separately in the U.S. District Court for the Northern District of West Virginia asserting patents associated with emtricitabine and the fixed-dose combination of emtricitabine with tenofovir disoproxil fumarate. In October 2015, we reached an agreement with Mylan to settle the lawsuit in the U.S. District Court for the Northern District of West Virginia relating to the patents associated with emtricitabine and the fixed-dose combination of emtricitabine with tenofovir disoproxil fumarate. The terms of the settlement agreement are confidential. The settlement agreement has been filed with the Federal Trade Commission and Department of Justice as required by law.

Apotex

In June 2014, we received notice that Apotex Inc. (Apotex) submitted an abbreviated new drug submission (ANDS) to Health Canada 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

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 Health Canada (for Teva's generic versions of Viread, Truvada, and Atripla) took place. 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 appealed the decision of the court prohibiting Health Canada 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 Health Canada 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. In April 2015, we filed a lawsuit against Watson in the U.S. District Court for the District of New Jersey.

SigmaPharm

In June 2015, we received notice that SigmaPharm Laboratories, LLC (SigmaPharm) submitted an ANDA to the FDA requesting permission to manufacture and market a generic version of Letairis. In the notice, SigmaPharm alleges that one of the patents associated with ambrisentan tablets is invalid, unenforceable and/or will not be infringed by SigmaPharm's manufacture, use or sale of a generic version of Letairis. In June 2015, we filed a lawsuit against SigmaPharm in the U.S. District Court for the District of New Jersey.

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 Letairis 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 Health Canada 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 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 September 30, 2015, our accounts receivable in these countries totaled approximately $1.8 billion, of which $198 million were greater than 120 days past due, including $27 million greater than 365 days past due.

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.

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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 and TAF, contingent on U.S. regulatory approval, 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. Starting 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 101 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 developing world 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 Related to Sofosbuvir and Litigation with Generic Manufacturers in "Legal Proceedings" beginning on page 36. 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 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 Harvoni, Sovaldi, 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 La Verne, 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.

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 annual BPD fee, 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, 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. Any future declarations, amount and timing of any 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 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Issuer Purchases of Equity Securities

In January 2015, our Board of Directors authorized a $15.0 billion five-year share repurchase program (2015 Program). The table below summarizes our stock repurchase activity under the 2015 Program for the three months ended September 30, 2015:

	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)	Maximum Fair Value of Shares that May Yet Be Purchased Under the Program (in millions)
July 1 - July 31, 2015	6,058	$ 115.95	5,909	$13,415
August 1 - August 31, 2015	10,495	$ 112.84	10,148	$12,271
September 1 - September 30, 2015	11,542	$ 106.07	11,513	$11,050
Total	28,095 [1]	$ 110.73	27,570 [1]	

(1) 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.

Item 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

Item 5. OTHER INFORMATION

Not applicable.

Item 6. EXHIBITS

Exhibit Footnote	Exhibit Number	Description of Document
(1)	1.1	Underwriting Agreement, dated September 9, 2015, 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
	4.1	Reference is made to Exhibit 3.1 and Exhibit 3.2
(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)
(8)	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)
(9)	4.7	Fourth Supplemental Indenture related to Senior Notes, dated as of November 17, 2014, between Registrant and Wells Fargo, National Association, as Trustee (including Form of 2020 Note, Form of 2025 Note, Form of 2045 Note)
(1)	4.8	Fifth Supplemental Indenture, dated as of September 14, 2015, between Registrant and Wells Fargo Bank, National Association, as Trustee (including Form of 2018 Note, Form of 2020 Note, Form of 2022 Note, Form of 2026 Note, Form of 2035 Note and Form of 2046 Note)
(10)	10.1	Confirmation of OTC Convertible Note Hedge related to 2016 Notes, dated July 26, 2010, between Registrant and Goldman, Sachs & Co.
(10)	10.2	Confirmation of OTC Convertible Note Hedge related to 2016 Notes, dated July 26, 2010, between Registrant and JPMorgan Chase Bank, National Association
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		Confirmation of OTC Warrant Transaction, dated July 26, 2010, between Registrant and Goldman, Sachs & Co. for warrants expiring in 2016
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(11)	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
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(12)	10.13	Amendment to Base Warrants (2016), dated May 8, 2015, between Registrant and Goldman, Sachs & Co.
(12)	10.14	Amendment to Base Warrants (2016), dated May 8, 2015, between Registrant and JPMorgan Chase Bank, National Association
(13)	10.15	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
(13)	10.16	Parent Guaranty Agreement (5-Year Revolving Credit Facility), dated as of January 12, 2012, by Registrant
*(3)	10.17	Gilead Sciences, Inc. 2004 Equity Incentive Plan, as amended through May 8, 2013

*(14)	10.18	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants prior to February 2008)
*(15)	10.19	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants made February 2008 through April 2009)
*(16)	10.20	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants commencing in May 2009)
*(17)	10.21	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants commencing in February 2010)
*(18)	10.22	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for 2011 and subsequent year grants)
*(15)	10.23	Form of non-employee director stock option agreement used under 2004 Equity Incentive Plan (for grants prior to 2008)
*(15)	10.24	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for initial grants made in 2008)
*(15)	10.25	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for annual grants made in May 2008 and through May 2012)
*(16)	10.26	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for annual grants commencing in May 2009 and through May 2012)
*(19)	10.27	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for annual grants made in May 2013)
*(19)	10.28	Form of non-employee director option agreement (non-U.S.) used under 2004 Equity Incentive Plan (for annual grants made in May 2013)
*(20)	10.29	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for annual grants made in and after May 2014)
*(21)	10.30	Form of restricted stock unit issuance agreement used under 2004 Equity Incentive Plan (for annual grants to non-employee directors in May 2012)
*(16)	10.31	Form of restricted stock award agreement used under 2004 Equity Incentive Plan (for annual grants to certain non-employee directors prior to May 2012)
*(19)	10.32	Form of restricted stock unit issuance agreement used under 2004 Equity Incentive Plan (for annual grants to non-employee directors commencing in May 2013)
*(20)	10.33	Form of restricted stock unit issuance agreement used under 2004 Equity Incentive Plan (for annual grants to non-employee directors commencing in and after May 2014)
*(19)	10.34	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)

*(16)	10.35	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for grants to certain executive officers made in 2009)
*(17)	10.36	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for grants to certain executive officers made in 2010)
*(18)	10.37	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for grants to certain executive officers made in 2011)
*(19)	10.38	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for grants to certain executive officers made in 2012)
*(22)	10.39	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for TSR Goals in 2013 and 2014)
*(23)	10.40	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for Revenue Goals in 2013 and 2014)
*(24)	10.41	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for TSR Goals - Non-US in 2015)
*(24)	10.42	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for Revenue Goals - Non-US in 2015)
*(25)	10.43	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)
*(16)	10.44	Form of restricted stock unit issuance agreement used under the 2004 Equity Incentive Plan (for grants to certain executive officers commencing in May 2009)
*(26)	10.45	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)
*(18)	10.46	Form of restricted stock unit issuance agreement used under the 2004 Equity Incentive Plan (service-based vesting for certain executive officers commencing in 2011)
*(27)	10.47	Gilead Sciences, Inc. Employee Stock Purchase Plan, restated on January 22, 2015
*(28)	10.48	Gilead Sciences, Inc. Deferred Compensation Plan-Basic Plan Document
*(26)	10.49	Gilead Sciences, Inc. Deferred Compensation Plan-Adoption Agreement
*(28)	10.50	Addendum to the Gilead Sciences, Inc. Deferred Compensation Plan
*(29)	10.51	Gilead Sciences, Inc. 2005 Deferred Compensation Plan, as amended and restated on October 23, 2008
*(22)	10.52	Gilead Sciences, Inc. Severance Plan, as amended on January 26, 2012

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*(14)	10.53	Gilead Sciences, Inc. Corporate Bonus Plan
*(30)	10.54	Amended and Restated Gilead Sciences, Inc. Code Section 162(m) Bonus Plan
*(31)	10.55	2015 Base Salaries for the Named Executive Officers
*(32)	10.56	Offer Letter dated April 16, 2008 between Registrant and Robin Washington
*(33)	10.57	Form of Indemnity Agreement entered into between Registrant and its directors and executive officers
*(34)	10.58	Form of Employee Proprietary Information and Invention Agreement entered into between Registrant and certain of its officers and key employees
*(17)	10.59	Form of Employee Proprietary Information and Invention Agreement entered into between Registrant and certain of its officers and key employees (revised in September 2006)
+ (35)	10.60	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
+ (15)	10.61	Commercialization Agreement by and between Gilead Sciences Ireland UC (formerly Gilead Sciences Limited) and Bristol-Myers Squibb Company, dated December 10, 2007
+ (36)	10.62	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)
+ (37)	10.63	Amendment Agreement between Registrant and IOCB/REGA, dated December 27, 2000 amending the 1991 License Agreement and the December 1992 License Agreement
+ (35)	10.64	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
+ (38)	10.65	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
+ (39)	10.66	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
+ (40)	10.67	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

+ (40)	10.68	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
+ (41)	10.69	License Agreement between Japan Tobacco Inc. and Registrant, dated March 22, 2005
+ (42)	10.70	First Amendment to License Agreement between Japan Tobacco Inc. and Registrant, dated May 19, 2005
+ (42)	10.71	Second Amendment to License Agreement between Japan Tobacco Inc. and Registrant, dated May 17, 2010
+(12)	10.72	Third Amendment (Revised) to License Agreement between Japan Tobacco Inc. and Registrant, dated June 10, 2015
+ (42)	10.73	Fourth Amendment to License Agreement between Japan Tobacco Inc. and Registrant, dated July 5, 2011
+(43)	10.74	Amendment to License Agreement between Japan Tobacco Inc. and Registrant, dated October 10, 2013
+(44)	10.75	Fifth Amendment to License Agreement between Japan Tobacco Inc. and Registrant, dated September 29, 2014
+(45)	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
+(46)	10.77	Master Clinical and Commercial Supply Agreement between Gilead World Markets, Limited, Registrant and Patheon Inc., dated January 1, 2003
+(47)	10.78	Restated and Amended Toll Manufacturing Agreement between Gilead Sciences Ireland UC (formerly Gilead Sciences Limited), Registrant and Takeda GmbH (formerly Nycomed GmbH and Altana Pharma Oranienburg GmbH), dated November 7, 2005
	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
	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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, formatted in Extensible Business Reporting Language (XBRL) includes: (i) Condensed Consolidated Balance Sheets (unaudited), (ii) Condensed Consolidated Statements of Income (unaudited), (iii) Condensed Consolidated Statements of Comprehensive Income (unaudited), (iv) Condensed Consolidated Statements of Cash Flows (unaudited) and (v) Notes to

Condensed Consolidated Financial Statements (unaudited).

(1) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on September 14, 2015, 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 8, 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 Current Report on Form 8-K filed on March 7, 2014, and incorporated herein by reference.

(9) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on November 17, 2014, and incorporated herein by reference.

(10) 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.

(11) 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.

(12) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, and incorporated herein by reference.

(13) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on January 17, 2012, and incorporated herein by reference.

(14) Filed as an exhibit to Registrant's Current Report on Form 8-K/A filed on February 22, 2006, and incorporated herein by reference.

(15) 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.

(16) 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.

(17) 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.

(18) 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.

(19) 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

(20) 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.

(21) 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.

(22) 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.

(23) 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.

(24) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, and incorporated herein by reference.

(25) Filed as an exhibit to Registrant's Current Report on Form 8-K first filed on December 19, 2007, and incorporated herein by reference.

(26) 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.

(27) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on May 8, 2015, and incorporated herein by reference.

(28) 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.

(29) 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.

(30) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on May 13, 2013, and incorporated herein by reference.

(31) Information is included in Registrant's Current Report on Form 8-K filed on January 28, 2015, and incorporated herein by reference.

(32) 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.

(33) Filed as an exhibit to Registrant's Registration Statement on Form S-1 (No. 33-55680), as amended, and incorporated herein by reference.

(34) 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.

(35) 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.

(36) 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.

(37) 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.

(38) 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.

(39) 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.

(40) 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.

(41) 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.

(42) 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.

(43) 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.

(44) 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.

(45) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2014, and incorporated herein by reference.

(46) 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.

(47) 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-Q 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-Q), 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.

SIGNATURES

Pursuant to the requirements 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. (Registrant)
Date: November 4, 2015	/s/ JOHN C. MARTIN John C. Martin, Ph.D. Chairman and Chief Executive Officer (Principal Executive Officer)
Date: November 4, 2015	/s/ ROBIN L. WASHINGTON Robin L. Washington Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)

Exhibit Index

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(1)	1.1	Underwriting Agreement, dated September 9, 2015, 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
	4.1	Reference is made to Exhibit 3.1 and Exhibit 3.2
(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)
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(12)	10.13	Amendment to Base Warrants (2016), dated May 8, 2015, between Registrant and Goldman, Sachs & Co.
(12)	10.14	Amendment to Base Warrants (2016), dated May 8, 2015, between Registrant and JPMorgan Chase Bank, National Association
(13)	10.15	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
(13)	10.16	Parent Guaranty Agreement (5-Year Revolving Credit Facility), dated as of January 12, 2012, by Registrant
*(3)	10.17	Gilead Sciences, Inc. 2004 Equity Incentive Plan, as amended through May 8, 2013

*(14)	10.18	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants prior to February 2008)
*(15)	10.19	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants made February 2008 through April 2009)
*(16)	10.20	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants commencing in May 2009)
*(17)	10.21	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants commencing in February 2010)
*(18)	10.22	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for 2011 and subsequent year grants)
*(15)	10.23	Form of non-employee director stock option agreement used under 2004 Equity Incentive Plan (for grants prior to 2008)
*(15)	10.24	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for initial grants made in 2008)
*(15)	10.25	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for annual grants made in May 2008 and through May 2012)
*(16)	10.26	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for annual grants commencing in May 2009 and through May 2012)
*(19)	10.27	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for annual grants made in May 2013)
*(19)	10.28	Form of non-employee director option agreement (non-U.S.) used under 2004 Equity Incentive Plan (for annual grants made in May 2013)
*(20)	10.29	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for annual grants made in and after May 2014)
*(21)	10.30	Form of restricted stock unit issuance agreement used under 2004 Equity Incentive Plan (for annual grants to non-employee directors in May 2012)
*(16)	10.31	Form of restricted stock award agreement used under 2004 Equity Incentive Plan (for annual grants to certain non-employee directors prior to May 2012)
*(19)	10.32	Form of restricted stock unit issuance agreement used under 2004 Equity Incentive Plan (for annual grants to non-employee directors commencing in May 2013)
*(20)	10.33	Form of restricted stock unit issuance agreement used under 2004 Equity Incentive Plan (for annual grants to non-employee directors commencing in and after May 2014)
*(19)	10.34	

		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)
*(16)	10.35	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for grants to certain executive officers made in 2009)
*(17)	10.36	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for grants to certain executive officers made in 2010)
*(18)	10.37	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for grants to certain executive officers made in 2011)
*(19)	10.38	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for grants to certain executive officers made in 2012)
*(22)	10.39	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for TSR Goals in 2013 and 2014)
*(23)	10.40	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for Revenue Goals in 2013 and 2014)
*(24)	10.41	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for TSR Goals - Non-US in 2015)
*(24)	10.42	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for Revenue Goals - Non-US in 2015)
*(25)	10.43	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)
*(16)	10.44	Form of restricted stock unit issuance agreement used under the 2004 Equity Incentive Plan (for grants to certain executive officers commencing in May 2009)
*(26)	10.45	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)
*(18)	10.46	Form of restricted stock unit issuance agreement used under the 2004 Equity Incentive Plan (service-based vesting for certain executive officers commencing in 2011)
*(27)	10.47	Gilead Sciences, Inc. Employee Stock Purchase Plan, restated on January 22, 2015
*(28)	10.48	Gilead Sciences, Inc. Deferred Compensation Plan-Basic Plan Document
*(26)	10.49	Gilead Sciences, Inc. Deferred Compensation Plan-Adoption Agreement
*(28)	10.50	Addendum to the Gilead Sciences, Inc. Deferred Compensation Plan
*(29)	10.51	Gilead Sciences, Inc. 2005 Deferred Compensation Plan, as amended and restated on October 23, 2008
*(22)	10.52	Gilead Sciences, Inc. Severance Plan, as amended on January 26, 2012

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*(14)	10.53	Gilead Sciences, Inc. Corporate Bonus Plan
*(30)	10.54	Amended and Restated Gilead Sciences, Inc. Code Section 162(m) Bonus Plan
*(31)	10.55	2015 Base Salaries for the Named Executive Officers
*(32)	10.56	Offer Letter dated April 16, 2008 between Registrant and Robin Washington
*(33)	10.57	Form of Indemnity Agreement entered into between Registrant and its directors and executive officers
*(34)	10.58	Form of Employee Proprietary Information and Invention Agreement entered into between Registrant and certain of its officers and key employees
*(17)	10.59	Form of Employee Proprietary Information and Invention Agreement entered into between Registrant and certain of its officers and key employees (revised in September 2006)
+ (35)	10.60	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
+ (15)	10.61	Commercialization Agreement by and between Gilead Sciences Ireland UC (formerly Gilead Sciences Limited) and Bristol-Myers Squibb Company, dated December 10, 2007
+ (36)	10.62	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)
+ (37)	10.63	Amendment Agreement between Registrant and IOCB/REGA, dated December 27, 2000 amending the 1991 License Agreement and the December 1992 License Agreement
+ (35)	10.64	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
+ (38)	10.65	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
+ (39)	10.66	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
+ (40)	10.67	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
+ (40)	10.68	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
+ (41)	10.69	License Agreement between Japan Tobacco Inc. and Registrant, dated March 22, 2005
+ (42)	10.70	First Amendment to License Agreement between Japan Tobacco Inc. and Registrant, dated May 19, 2005
+ (42)	10.71	Second Amendment to License Agreement between Japan Tobacco Inc. and Registrant, dated May 17, 2010
+(12)	10.72	Third Amendment (Revised) to License Agreement between Japan Tobacco Inc. and Registrant, dated June 10, 2015
+ (42)	10.73	Fourth Amendment to License Agreement between Japan Tobacco Inc. and Registrant, dated July 5, 2011
+(43)	10.74	Amendment to License Agreement between Japan Tobacco Inc. and Registrant, dated October 10, 2013
+(44)	10.75	Fifth Amendment to License Agreement between Japan Tobacco Inc. and Registrant, dated September 29, 2014
+(45)	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
+(46)	10.77	Master Clinical and Commercial Supply Agreement between Gilead World Markets, Limited, Registrant and Patheon Inc., dated January 1, 2003
+(47)	10.78	Restated and Amended Toll Manufacturing Agreement between Gilead Sciences Ireland UC (formerly Gilead Sciences Limited), Registrant and Takeda GmbH (formerly Nycomed GmbH and Altana Pharma Oranienburg GmbH), dated November 7, 2005
	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
	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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, formatted in Extensible Business Reporting Language (XBRL) includes: (i) Condensed Consolidated Balance Sheets (unaudited), (ii) Condensed Consolidated Statements of Income (unaudited), (iii) Condensed Consolidated Statements of Comprehensive Income

(unaudited), (iv) Condensed Consolidated Statements of Cash Flows (unaudited) and (v) Notes to Condensed Consolidated Financial Statements (unaudited).

(1) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on September 14, 2015, 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 8, 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 Current Report on Form 8-K filed on March 7, 2014, and incorporated herein by reference.

(9) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on November 17, 2014, and incorporated herein by reference.

(10) 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.

(11) 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.

(12) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, and incorporated herein by reference.

(13) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on January 17, 2012, and incorporated herein by reference.

(14) Filed as an exhibit to Registrant's Current Report on Form 8-K/A filed on February 22, 2006, and incorporated herein by reference.

(15) 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.

(16) 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.

(17) 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.

(18) 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.

(19) 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

(20) 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.

(21) 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.

(22) 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.

(23) 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.

(24) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, and incorporated herein by reference.

(25) Filed as an exhibit to Registrant's Current Report on Form 8-K first filed on December 19, 2007, and incorporated herein by reference.

(26) 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.

(27) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on May 8, 2015, and incorporated herein by reference.

(28)

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.

(29) 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.

(30) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on May 13, 2013, and incorporated herein by reference.

(31) Information is included in Registrant's Current Report on Form 8-K filed on January 28, 2015, and incorporated herein by reference.

(32) 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.

(33) Filed as an exhibit to Registrant's Registration Statement on Form S-1 (No. 33-55680), as amended, and incorporated herein by reference.

(34) 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.

(35) 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.

(36) 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.

(37) 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.

(38) 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.

(39) 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.

(40) 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.

(41) 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.

(42) 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.

(43) 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.

(44) 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.

(45) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2014, and incorporated herein by reference.

(46) 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.

(47) 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-Q 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-Q), 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.