GILEAD SCIENCES INC Form 10-Q August 05, 2016

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

FORM 10-Q

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

For the quarterly period ended June 30, 2016

or

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

For the transition period from \_\_\_\_\_\_ to \_\_\_\_\_
Commission File No. 0-19731

GILEAD SCIENCES, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware 94-3047598
(State or Other Jurisdiction of Incorporation or Organization) 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  $\acute{y}$ 

Number of shares outstanding of the issuer's common stock, par value \$0.001 per share, as of July 31, 2016: 1,319,658,489

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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®, AMBISOME®, CAYSTON®, COMPLERA®, DESCOVY®, EMTRIVA®, EPCLUSA®, EVIPLERA®, GENVOYA®, HARVONI®, HEPSERA®, LETAIRIS®, ODEFSEY®, RANEXA®, RAPISCAN®, SOVALDI®, STRIBILD®, TRUVADA®, TYBOST®, VIREAD®, VITEKTA®, VOLIBRIS® and ZYDELIG®. 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 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

GILEAD SCIENCES, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(unaudited)

(in millions, except per share amounts)

(in millions, except per share amounts)		
	June 30, 2016	December 31, 2015
Assets	2010	2013
Current assets:		
Cash and cash equivalents	\$6,485	\$ 12,851
Short-term marketable securities	2,267	1,756
Accounts receivable, net of allowances of \$1,435 at June 30, 2016 and \$1,032 at December		
31, 2015	5,752	5,854
Inventories	1,862	1,955
Deferred tax assets	835	828
Prepaid and other current assets	1,152	1,518
Total current assets	18,353	24,762
Property, plant and equipment, net	2,599	2,276
Long-term portion of prepaid royalties	365	400
Long-term deferred tax assets	433	324
Long-term marketable securities	15,864	11,601
Intangible assets, net	9,713	10,247
Goodwill	1,172	1,172
Other long-term assets	1,481	934
Total assets	\$49,980	
Liabilities and Stockholders' Equity	. ,	,
Current liabilities:		
Accounts payable	\$1,122	\$ 1,178
Accrued government and other rebates	5,447	4,118
Other accrued liabilities	2,830	3,172
Deferred revenues	345	440
Current portion of long-term debt and other obligations, net	700	982
Total current liabilities	10,444	9,890
Long-term debt, net	21,427	21,073
Long-term income taxes payable	1,527	1,243
Other long-term obligations	467	395
Commitments and contingencies (Note 10)		
Equity component of currently redeemable convertible notes		2
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 June 30, 2016 and		
December 31, 2015; shares issued and outstanding of 1,331 at June 30, 2016 and 1,422 at	1	1
December 31, 2015		
Additional paid-in capital	632	444
Accumulated other comprehensive income (loss)	` ,	88
Retained earnings	14,949	18,001
Total Gilead stockholders' equity	15,536	18,534
Noncontrolling interest	579	579
Total stockholders' equity	16,115	19,113

Total liabilities and stockholders' equity

\$49,980 \$ 51,716

See accompanying notes.

# GILEAD SCIENCES, INC. CONDENSED CONSOLIDATED STATEMENTS OF INCOME (unaudited)

(in millions, except per share amounts)

	Ended		Six Months Ended	
			June 30,	
	2016	2015	2016	2015
Revenues:				
Product sales	\$7,651	\$8,126	\$15,332	\$15,531
Royalty, contract and other revenues	125	118	238	307
Total revenues	7,776	8,244	15,570	15,838
Costs and expenses:				
Cost of goods sold	864	998	2,057	1,880
Research and development expenses	1,484	818	2,749	1,514
Selling, general and administrative expenses	890	812	1,575	1,457
Total costs and expenses	3,238	2,628	6,381	4,851
Income from operations	4,538	5,616	9,189	10,987
Interest expense	(227)	(140)	(457)	(293)
Other income (expense), net	88	35	169	56
Income before provision for income taxes	4,399	5,511	8,901	10,750
Provision for income taxes	902	1,014	1,837	1,921
Net income	3,497	4,497	7,064	8,829
Net income attributable to noncontrolling interest		5	1	4
Net income attributable to Gilead	\$3,497	\$4,492	\$7,063	\$8,825
Net income per share attributable to Gilead common stockholders - basic	\$2.62	\$3.05	\$5.20	\$5.96
Shares used in per share calculation - basic	1,335	1,472	1,359	1,480
Net income per share attributable to Gilead common stockholders - diluted	\$2.58	\$2.92	\$5.11	\$5.68
Shares used in per share calculation - diluted	1,355	1,540	1,383	1,555
Cash dividends declared per share	\$0.47	\$0.43	\$0.90	\$0.43

See accompanying notes.

# GILEAD SCIENCES, INC.

# CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (unaudited)

(in millions)

Net income	Three M Ended June 30 2016 \$3,497		Six Mo Ended June 30 2016 \$7,064	), 2015
Other comprehensive income (loss): Net foreign currency translation gains (losses), net of tax	9	3	11	(7)
Available-for-sale securities:		3	11	(1)
Net unrealized gains (losses), net of tax impact of \$(12), \$(1), \$18 and \$2, respectively	154	(3)	130	3
Reclassifications to net income, net of tax	(2	) —	(2	) —
Net change	152	(3)	128	3
Cash flow hedges:				
Net unrealized gains (losses), net of tax impact of \$(1), \$(3), \$(11) and \$3, respectively	(54	(110)	(204	) 273
Reclassifications to net income, net of tax impact of \$(1), \$(5), \$(7), and \$(9), respectively	11	(182)	(69	) (323 )
Net change	(43	(292)	(273	) (50 )
Other comprehensive income (loss)	118	(292)	(134	) (54 )
Comprehensive income	3,615	4,205	6,930	8,775
Comprehensive income attributable to noncontrolling interest		5	1	4
Comprehensive income attributable to Gilead	\$3,615	\$4,200	\$6,929	\$8,771

See accompanying notes.

# GILEAD SCIENCES, INC.

# CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited) (in millions)

	Six Mor Ended June 30, 2016	
Operating Activities: Net income	\$7,064	\$8,829
Adjustments to reconcile net income to net cash provided by operating activities:	\$ 7,004	\$0,029
Depreciation expense	85	75
Amortization expense	482	467
Stock-based compensation expense	183	188
Excess tax benefits from stock-based compensation		(326)
Tax benefits from exercise and vesting of stock-based awards	125	326
Deferred income taxes	(116)	(260)
In-process research and development impairment	114	
Other	(7)	27
Changes in operating assets and liabilities:		
Accounts receivable, net	190	(810)
Inventories	(97)	(634)
Prepaid expenses and other		(127)
Accounts payable		620
Income taxes payable	645	574
Accrued liabilities	876	2,045
Deferred revenues	(162)	
Net cash provided by operating activities	8,853	11,359
Investing Activities:		
Purchases of marketable securities	(12,022)	(6,847)
Proceeds from sales of marketable securities	6,583	1,143
Proceeds from maturities of marketable securities	784	148
Other investments	(357)	
Capital expenditures	(381)	
Net cash used in investing activities	(5,393)	(5,851)
Financing Activities:		
Proceeds from debt financing, net of issuance costs	349	_
Proceeds from convertible note hedges	956	508
Proceeds from issuances of common stock	120	202
Repurchases of common stock		(3,901)
Repayments of debt and other obligations	(1,246)	` ,
Payments to settle warrants		(3,865)
Payments of dividends	(1,213)	
Excess tax benefits from stock-based compensation	127	326
Payment of contingent consideration	,	<u> </u>
Contributions from noncontrolling interest		(50)
Net cash used in financing activities	(9,912)	(8,063)

Effect of exchange rate changes on cash and cash equivalents	86 (55 )
Net change in cash and cash equivalents	(6,366) (2,610)
Cash and cash equivalents at beginning of period	12,851 10,027
Cash and cash equivalents at end of period	\$6,485 \$7,417

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 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. All intercompany transactions have been eliminated. For consolidated entities where we own or are exposed to less than 100% of the economics, we record Net income (loss) attributable to noncontrolling interest 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.

We assess whether we are the primary beneficiary of a variable interest entity (VIE) at the inception of the arrangement and at each reporting date. This assessment is 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 of June 30, 2016, the only material VIE was our joint venture with Bristol-Myers Squibb Company (BMS) which is described in Note 8, Collaborative Arrangements.

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, 2015, 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, we evaluate our 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. Estimates are assessed each period and updated to reflect current information. Actual results may differ significantly from these estimates.

Concentrations of Risk

We are subject to credit risk from our portfolio of cash, 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, Europe and Japan.

As of June 30, 2016, our accounts receivable in Southern Europe, specifically Greece, Italy, Portugal and Spain, totaled approximately \$630 million, of which \$171 million were greater than 120 days past due, including \$36 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 June 30, 2016. Recent Accounting Pronouncements

In May 2014, the FASB issued Accounting Standard Update No. 2014-09 (ASU 2014-09) "Revenue 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. The standard will become effective for us beginning in the first quarter of 2018. Early adoption is permitted in 2017. Entities have the option of using either a full retrospective or a modified retrospective approach to adopt this new guidance. The FASB issued supplemental adoption guidance and clarification to ASU 2014-09 in March 2016, April 2016 and May 2016

within ASU 2016-08 (ASU 2016-08) "Revenue From Contracts With Customers: Principal vs. Agent Considerations," ASU 2016-10 (ASU 2016-10) "Revenue From Contracts with Customers: Identifying Performance Obligations and Licensing," and ASU 2016-12 (ASU 2016-12) "Revenue from Contracts with Customers: Narrow-Scope Improvements and Practical Expedients," respectively. We are evaluating the impact of the adoption of these standards on our Condensed Consolidated Financial Statements.

In November 2015, the FASB issued Accounting Standard Update No. 2015-17 (ASU 2015-17) "Balance Sheet Classification of Deferred Taxes." ASU 2015-17 requires that deferred tax liabilities and assets be classified as noncurrent on the balance sheet. Previous guidance required deferred tax liabilities and assets to be separated into current and noncurrent amounts on the balance sheet. The guidance will become effective for us beginning in the first quarter of 2017 and may be applied either prospectively or retrospectively. Early adoption is permitted. At the time of adoption, we will reclassify current deferred tax amounts on our Consolidated Balance Sheets as noncurrent. We are evaluating the impact of the method of adoption of this standard on our Condensed Consolidated Financial Statements.

In January 2016, the FASB issued Accounting Standard Update No. 2016-01(ASU 2016-01) "Recognition and Measurement of Financial Assets and Financial Liabilities." ASU 2016-01 changes accounting for equity investments, financial liabilities under the fair value option and the presentation and disclosure requirements for financial instruments. In addition, it clarified guidance related to the valuation allowance assessment when recognizing deferred tax assets resulting from unrealized losses on available-for-sale debt securities. The guidance will become effective for us beginning in the first quarter of 2018 and must be adopted using a modified retrospective approach, with certain exceptions. Early adoption is permitted for certain provisions. We are evaluating the impact of the adoption of this standard on our Condensed Consolidated Financial Statements.

In February 2016, the FASB issued Accounting Standard Update No. 2016-02 (ASU 2016-02) "Leases." ASU 2016-02 amends a number of aspects of lease accounting, including requiring lessees to recognize almost all leases with a term greater than one year as a right-of-use asset and corresponding liability, measured at the present value of the lease payments. The guidance will become effective for us beginning in the first quarter of 2019 and is required to be adopted using a modified retrospective approach. Early adoption is permitted. We are evaluating the impact of the adoption of this standard on our Condensed Consolidated Financial Statements, however, we anticipate recognition of additional assets and corresponding liabilities related to leases on our Condensed Consolidated Balance Sheets. In March 2016, the FASB issued Accounting Standard Update No. 2016-09 (ASU 2016-09) "Improvements to Employee Share-Based Payment Accounting." ASU 2016-09 simplifies several aspects of employee share-based payment accounting, including the income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. This guidance will become effective for us beginning in the first quarter of 2017. Early adoption is permitted. We are evaluating the impact of the adoption of this standard on our Condensed Consolidated Financial Statements.

In June 2016, the FASB issued Accounting Standard Update No. 2016-13 (ASU 2016-13) "Measurement of Credit Losses on Financial Instruments." ASU 2016-13 requires measurement and recognition of expected credit losses for financial assets held. This guidance will become effective for us beginning in the first quarter of 2020 and must be adopted using a modified retrospective approach, with certain exceptions. Early adoption is permitted beginning in the first quarter of 2019. We are evaluating the impact of the adoption of this standard 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 primarily of cash and cash equivalents, marketable securities, accounts receivable, foreign currency exchange contracts, equity securities, accounts payable and short-term and long-term debt. Cash and cash equivalents, marketable securities, foreign currency exchange contracts and equity securities are reported at their respective fair values in our Condensed Consolidated Balance Sheets. Short-term and long-term debt are reported at their amortized cost in our Condensed Consolidated Balance Sheets. The remaining financial instruments are reported in 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 types of assets and liabilities measured at fair value on a recurring basis, by level, within the fair value hierarchy (in millions):

	June 30, 2016			December 31, 2015				
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level	Total
Assets:								
Money market funds	\$4,486	<b>\$</b> —	\$ —	\$4,486	\$10,161	\$—	\$ —	\$10,161
Corporate debt securities	_	8,700		8,700	_	5,773	_	5,773
U.S. treasury securities	5,169	_	_	5,169	4,389	_	_	4,389
Residential mortgage and asset-backed securities		2,566		2,566		1,695		1,695
U.S. government agencies securities		924		924		707		707
Non-U.S. government securities		507		507		313		313
Certificates of deposit		231		231		448		448
Municipal debt securities		34		34		34		34
Equity securities	370		_	370			_	
Foreign currency derivative contracts		91		91		210	_	210
Deferred compensation plan	76		_	76	66		_	66
	\$10,101	\$13,053	\$ —	\$23,154	\$14,616	\$9,180	\$ —	\$23,796
Liabilities:								
Contingent consideration	<b>\$</b> —	<b>\$</b> —	\$ 31	\$31	<b>\$</b> —	<b>\$</b> —	\$ 59	\$59
Deferred compensation plan	76		_	76	66		_	66
Foreign currency derivative contracts		193	_	193	_	41	_	41
	\$76	\$193	\$ 31	\$300	\$66	\$41	\$ 59	\$166

# Level 2 Inputs

We estimate the fair values of Level 2 instruments 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 within an 18 months 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 total estimated fair values of our short term and long term debt, determined using Level 2 inputs based on their quoted market values, were approximately \$24.4 billion at June 30, 2016 and \$23.7 billion at December 31, 2015, and the carrying values were \$22.1 billion at June 30, 2016 and \$22.1 billion at December 31, 2015.

#### Level 3 Inputs

As of June 30, 2016 and December 31, 2015, the only assets or liabilities that were measured using Level 3 inputs were our contingent consideration liabilities, which were immaterial. 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.

#### 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 our available-for-sale securities (in millions):

	June 30,	2016				Decemb	er 31, 201	15		
	Amortiz	Gross	Gross		Estimated	Amortiz	Gross	Gross		Estimated
	Cost	Unrealize	edUnreal	ize	e <b>d</b> Fair	Cost	Unrealiz	e <b>U</b> nreal	ize	edFair
	Cost	Gains	Losses	5	Value	Cost	Gains	Losses		Value
Money market funds	\$4,486	\$ —	\$ —		\$4,486	\$10,161	\$ —	\$ —		\$10,161
Corporate debt securities	8,651	51	(2	)	8,700	5,795	1	(23	)	5,773
U.S. treasury securities	5,146	23			5,169	4,407		(18	)	4,389
Residential mortgage and asset-backed securities	2,559	8	(1	)	2,566	1,701	_	(6	)	1,695
U.S. government agencies securities	921	3			924	709	_	(2	)	707
Non-U.S. government securities	505	2			507	315		(2	)	313
Certificates of deposit	231	_			231	448		_		448
Municipal debt securities	34	_			34	34		_		34
Equity securities	357	13			370	_	_			_
Total	\$22,890	\$ 100	\$ (3	)	\$22,987	\$23,570	\$ 1	\$ (51	)	\$23,520

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

	June 30,	December 31,
	2016	2015
Cash and cash equivalents	\$4,486	\$ 10,163
Short-term marketable securities	2,267	1,756
Long-term marketable securities	15,864	11,601
Other long-term assets	370	_
Total	\$22,987	\$ 23,520

Cash and cash equivalents in the table above exclude cash of \$2.0 billion as of June 30, 2016 and \$2.7 billion as of December 31, 2015.

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

	June 30, 2016		
	Amortize	Fair ed Cost Value	
Less than one year	\$6,751	\$6,753	
Greater than one year but less than five years	15,442	15,524	
Greater than five years but less than ten years	213	212	
Greater than ten years	127	128	
Total	\$22,533	\$22,617	

The following table summarizes our available-for-sale 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 Estimated	Gross	Gross Estimated
	Gross Estimated Unreal Fait Losses Value	Unrealized	Unreal izacid
	LossesValue	Losses	Losses Value
June 30, 2016			
Corporate debt securities	\$(2) \$833	\$ -\$ 124	\$(2) \$957
U.S. treasury securities	<b>—</b> 16	<del></del>	<b>—</b> 16
Residential mortgage and asset-backed securities	(1) 478	— 12	(1) 490
U.S. government agencies securities	— 90	<del></del>	— 90
Non-U.S. government securities	<b>—</b> 31	<b>—</b> 7	<del></del>
Total	\$(3) \$1,448	\$ -\$ 143	\$(3) \$1,591
December 31, 2015			
Corporate debt securities	\$(23) \$4,891	\$ -\$ 43	\$(23) \$4,934
U.S. treasury securities	(18 ) 4,342		(18 ) 4,342
Residential mortgage and asset-backed securities	(6 ) 1,626	<b>—</b> 20	(6 ) 1,646
U.S. government agencies securities	(2) 707		(2) 707
Non-U.S. government securities	(2) 313	<del></del>	(2) 313
Municipal debt securities	<u> </u>		21
Total	\$(51) \$11,900	\$ -\$ 63	\$(51) \$11,963

We held a total of 513 positions as of June 30, 2016 and 2,742 positions as of December 31, 2015 related to our debt securities that were in an unrealized loss position.

Based on our review of our available-for-sale securities, we believe we had no other-than-temporary impairments on these securities as of June 30, 2016 and December 31, 2015, because we do not intend to sell these securities nor do we believe that we will be required to sell these securities before the recovery of their amortized cost basis. Gross realized gains and gross realized losses were immaterial for the three and six months ended June 30, 2016 and 2015.

## 4. DERIVATIVE FINANCIAL INSTRUMENTS

### Foreign Currency Exposure

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

We hedge our exposure to foreign currency exchange rate fluctuations for certain monetary assets and liabilities of our 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, in 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 (loss) (AOCI) 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 AOCI at June 30, 2016 are expected to be reclassified to product sales within 12 months.

The cash flow effects of our derivative contracts for the six months ended June 30, 2016 and 2015 are included within Net cash provided by operating activities in our Condensed Consolidated Statements of Cash Flows.

We had notional amounts on foreign currency exchange contracts outstanding of \$9.7 billion at June 30, 2016 and \$9.1 billion at December 31, 2015.

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 in our Condensed Consolidated Balance Sheets (in millions):

	June 30, 2016				
	Asset Derivatives		Liability Derivatives		
	Classification	Fair Value	Classification	Fair Valu	
Derivatives designated as hedges:					
Foreign currency exchange contracts	Other current assets	\$ 76	Other accrued liabilities	\$(18	31)
Foreign currency exchange contracts	Other long-term assets	14	Other long-term obligations	(12	)
Total derivatives designated as hedges		90		(193	)
Derivatives not designated as hedges:					
Foreign currency exchange contracts	Other current assets	1	Other accrued liabilities	_	
Total derivatives not designated as hedges		1		_	
Total derivatives		\$ 91		\$(19	93)
	December 31, 2015				
	Asset Derivatives		Liability Derivatives		
	Classification	Fair Value	Classification	Fair Value	e
Derivatives designated as hedges:					
Foreign currency exchange contracts	Other current assets	\$ 200	Other accrued liabilities	\$(32	)
Foreign currency exchange contracts	Other long-term assets	9	Other long-term obligations	(8	)
Total derivatives designated as hedges		209		(40	)
Derivatives not designated as hedges:					
Foreign currency exchange contracts	Other current assets	1	Other accrued liabilities	(1	)
Total derivatives not designated as hedges		1		(1	)
Total derivatives		\$ 210		\$(41	)
Total derivatives not designated as hedges	Other current assets	1	oner accract natimics	(1	)

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Derivatives designated as hedges:				
Gains (losses) recognized in AOCI (effective portion)	\$(55)	\$(113)	\$(215)	\$276
Gains (losses) reclassified from AOCI into product sales (effective portion)	\$(10)	\$187	\$76	\$332
Gains (losses) recognized in Other income (expense), net (ineffective portion and amounts excluded from effectiveness testing)	\$13	\$6	\$27	\$7
Derivatives not designated as hedges:				
Gains (losses) recognized in Other income (expense), net	\$(115)	\$(40)	\$(266)	\$68

From time to time, we may discontinue cash flow hedges and as a result, record related amounts in Other income (expense), net in our Condensed Consolidated Statements of Income. There were no material amounts recorded in Other income (expense), net for the three and six months ended June 30, 2016 and 2015 as a result of the discontinuance of cash flow hedges.

As of June 30, 2016 and December 31, 2015, 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 in our Condensed Consolidated Balance Sheets (in millions):

Gross Amounts Not Offset in the Condensed Consolidated Balance Sheet

					Consolidated Dalance Sheet	*
Description	Gross Amour of Recognize Assets/Liabil	d	Gross Amounts Offset in the Condensed Consolidated Balance Sheet	Amounts of Assets/Liabilities Presented in the Condensed Consolidated Balance Sheet	Cash Collateral	Net Amount d (Legal Offset)
As of June 30, 2016						
Derivative assets	\$ 91		\$	-\$ 91	\$ (87 ) \$ -	- \$ 4
Derivative liabilities	(193	)		(193)	87 —	(106)
As of December 31, 2015						
Derivative assets	\$ 210		\$	-\$ 210	\$ (38 ) \$ -	<b>-</b> \$ 172
Derivative liabilities	(41	)	_	(41)	38 —	(3)

May 2016 Convertible Senior Notes and Convertible Note Hedges

In March 2016, we exercised our option to elect cash for the settlement of the conversion value in excess of the principal amount (the conversion spread) of our remaining convertible senior notes due in May 2016 (the Convertible Notes) and for the related convertible note hedges. Until our cash settlement election, the conversion spread of the Convertible Notes and the convertible note hedges met the applicable criteria for equity classification and were therefore recorded in stockholders' equity in our Condensed Consolidated Balance Sheets. Upon our cash settlement election, we reclassified \$733 million of the fair value of the conversion spread from Stockholders' equity to Current portion of long-term debt and other obligations, net, and reclassified \$733 million of the fair value of the convertible note hedges from Stockholders' equity to Prepaid and other current assets in our Condensed Consolidated Balance Sheets. At March 31, 2016, we revalued both the conversion spread and the convertible note hedges at \$792 million, respectively, and recorded a loss of \$59 million on the conversion spread and a gain of \$59 million on the convertible note hedges in our Condensed Consolidated Statements of Income.

During the second quarter of 2016, we settled both the conversion spread and the convertible note hedges associated with the Convertible Notes. Upon settlement, we revalued both the conversion spread and the convertible note hedges at \$861 million, respectively, and recorded a loss of \$69 million on the conversion spread and a gain of \$69 million on the convertible note hedges in our Condensed Consolidated Statements of Income.

#### 5. OTHER FINANCIAL INFORMATION

**Inventories** 

Inventories are summarized as follows (in millions):

June 30, December 31, 2016 2015

2016 2015
Raw materials \$1,277 \$ 1,332
Work in process 530 542
Finished goods 996 852
Total \$2,803 \$ 2,726

Reported as:

Inventories \$1,862 \$ 1,955
Other long-term assets 941 771
Total \$2,803 \$ 2,726

Amounts reported as Other long-term assets primarily consisted of raw materials as of June 30, 2016 and December 31, 2015.

The joint ventures formed by Gilead Sciences, LLC and BMS, which are 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 \$1.2 billion as of June 30, 2016 and \$1.3 billion as of December 31, 2015. See Note 8, Collaborative Arrangements for further information.

Prepaid and other current assets

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

June 30, December 31,

Prepaid taxes 2016 2015

Prepaid taxes \$330 \$773

Other prepaid expenses 305 240

Other current assets 517 505

Total prepaid and other current assets \$1,152 \$1,518

Other accrued liabilities

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

June 30, December 31,

Branded Prescription Drug fee \$513 \$649
Output tax payable 368 376
Compensation and employee benefits 292 380
Other accrued expenses 1,657 1,767
Total other accrued liabilities \$2,830 \$3,172

## 6. INTANGIBLE ASSETS

The following table summarizes the carrying amounts of our Intangible assets, net (in millions):

June 30, December 31,

2016 2015

Finite-lived intangible assets \$9,395 \$ 9,815 Indefinite-lived intangible assets 318 432 Total intangible assets \$9,713 \$ 10,247

#### Finite-Lived Intangible Assets

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

	June 30, 2016		December 31, 2015		
	Gross Carkyingmulated		Gross Carkyingnulated		
	Amount	Amortization	Amount	Amortization	
Intangible asset - sofosbuvir	\$10,720	\$ 1,806	\$10,720	\$ 1,456	
Intangible asset - Ranexa	688	413	688	363	
Other	455	249	455	229	
Total	\$11,863	\$ 2,468	\$11,863	\$ 2,048	

Amortization expense related to finite-lived intangible assets included primarily in Cost of goods sold in our Condensed Consolidated Statements of Income totaled \$210 million and \$420 million for the three and six months ended June 30, 2016 and \$207 million and \$413 million for the three and six months ended June 30, 2015, respectively. As of June 30, 2016, the estimated future amortization expense associated with our finite-lived intangible assets for the remaining six months of 2016 and each of the five succeeding fiscal years and thereafter is as follows (in millions):

Fiscal Year	Amount
2016 (remaining six months)	\$419
2017	844
2018	849
2019	741
2020	713
2021 and thereafter	5,829
Total	\$9,395

Indefinite-Lived Intangible Assets

The following table summarizes our indefinite-lived intangible assets (in-process research and development) (in millions):

	June 30,	December 31 2015
	2016	2013
Indefinite-lived intangible asset - momelotinib	\$201	\$ 315
Indefinite-lived intangible assets - Other	117	117
Total	\$318	\$ 432

In the first quarter of 2016, the estimated fair value of the intangible asset related to momelotinib declined to \$201 million due to changes in its planned clinical development, and as a result, we recorded an impairment charge of \$114 million within Research and development expenses in our Condensed Consolidated Statements of Income.

#### 7. ACQUISITION

In May 2016, we acquired Nimbus Apollo, Inc., a privately held company, and its Acetyl-CoA Carboxylase inhibitor program, which is being evaluated in Phase 1 trials for the potential treatment of non-alcoholic steatohepatitis, hepatocellular carcinoma and other diseases.

The consideration included a payment of \$400 million and contingent development and regulatory milestone-based payments of up to \$800 million. The transaction did not meet the requirements to be accounted for as a business combination under ASC 805 - Business Combinations and therefore was accounted for as an asset acquisition. As a result, the payment of \$400 million was recorded within Research and development expenses in our Condensed Consolidated Statements of Income.

#### 8. COLLABORATIVE ARRANGEMENTS

We enter into collaborative 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 exposed to significant risks and rewards depending on the commercial success of the activities. Selected information related to our collaborative arrangements follows.

Bristol-Myers Squibb Company

North America

In 2004, we entered into a collaboration arrangement with BMS to develop and commercialize a single-tablet regimen containing our Truvada and BMS's Sustiva (efavirenz) in the United States. This combination was approved for use in the United States in 2006 and is sold under the brand name Atripla. We and BMS structured this collaboration as a joint venture that operates as a limited liability company named Bristol-Myers Squibb & Gilead Sciences, LLC, which we consolidate. We and BMS granted royalty free sublicenses to the joint venture for the use of our respective company owned technologies and, in return, were granted a license by the joint venture to use any intellectual property that results from the collaboration. In 2006, we and BMS amended the joint venture's collaboration agreement to allow the joint venture to sell Atripla in Canada. The economic interests of the joint venture held by us and BMS (including a share of revenues and out-of-pocket expenses) are based on the portion of the net selling price of Atripla attributable to efavirenz and Truvada. Since the net selling price for Truvada may change over time relative to the net selling price of efavirenz, both our and BMS's respective economic interests in the joint venture may vary annually. We and BMS shared marketing and sales efforts. Starting in the second quarter of 2011, except for a limited number of activities that are 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 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 June 30, 2016 and December 31, 2015, 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 in our Condensed Consolidated Balance Sheets.

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

	June 30, 2016	December 31, 2015
Total assets	\$2,197	\$ 2,464
Cash and cash equivalents	128	166
Accounts receivable, net	287	269
Inventories	1,780	2,027
Total liabilities	803	1,055
Accounts payable	390	606
Other accrued liabilities	413	449

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 UC, 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, 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 are jointly managed, the parties no longer coordinate detailing and promotional activities in the European Territory. We are responsible for accounting, financial reporting and tax reporting for the collaboration. As of June 30, 2016 and December 31, 2015, efavirenz purchased from BMS at BMS's estimated net selling price of efavirenz in the European Territory is included in Inventories in our Condensed Consolidated Balance Sheets.

The parties also formed a limited liability company to hold the marketing authorization for Atripla in European Territory. 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.

## Galapagos NV

During the first quarter of 2016, we closed on a license and collaboration agreement with Galapagos NV (Galapagos), a clinical-stage biotechnology company based in Belgium, for the development and commercialization of filgotinib, a JAK1-selective inhibitor being evaluated in Phase 2 trials for inflammatory disease indications.

Upon closing of the license and collaboration agreement, we made an up-front license fee payment of \$300 million and a \$425 million equity investment in Galapagos by subscribing for new shares at a price of €58 per share, including issuance premium. As a result, we received 6.8 million new shares of Galapagos, representing 14.75% of their outstanding share capital. The license fee payment of \$300 million and the issuance premium on the equity investment of \$68 million were recorded within Research and development expenses in our Condensed Consolidated Statements of Income. The equity investment, net of issuance premium, of \$357 million was recorded as an available-for-sale security in Other long-term assets in our Condensed Consolidated Balance Sheets. Galapagos is eligible to receive development and regulatory milestone-based payments of up to \$755 million, sales-based milestone payments of up to \$600 million, plus tiered royalties on global sales starting at 20%, with the exception of certain co-promotion territories where profits would be shared equally.

Under the terms of the agreement, we have an exclusive, worldwide, royalty-bearing, sublicensable license for filgotinib and products containing filgotinib. We are primarily responsible for development and seeking regulatory approval related to filgotinib. We are responsible for 80% and Galapagos is responsible for 20% of the development costs incurred. We are also responsible for the manufacturing and commercialization activities. Galapagos has the option to co-promote filgotinib in certain territories, in which case, we and Galapagos will share profits equally.

#### 9. DEBT AND CREDIT FACILITY

#### Financing Arrangements

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

Type of Borrowing	Issue Date	Due Date	Interest Rate	June 30, 2016	December 31, 2015 (1)
Convertible Notes	July 2010	May 2016	1.625%	<b>\$</b> —	\$ 283
Senior Unsecured	December 2011	December 2016	3.05%	700	699
Senior Unsecured	September 2015	September 2018	1.85%	997	997
Senior Unsecured	March 2014	April 2019	2.05%	498	498
Senior Unsecured	November 2014	February 2020	2.35%	497	497
Senior Unsecured	September 2015	September 2020	2.55%	1,990	1,989
Senior Unsecured	March 2011	April 2021	4.50%	993	992
Senior Unsecured	December 2011	December 2021	4.40%	1,245	1,244
Senior Unsecured	September 2015	September 2022	3.25%	995	995
Senior Unsecured	March 2014	April 2024	3.70%	1,741	1,740
Senior Unsecured	November 2014	February 2025	3.50%	1,743	1,742
Senior Unsecured	September 2015	March 2026	3.65%	2,725	2,724
Senior Unsecured	September 2015	September 2035	4.60%	988	988
Senior Unsecured	December 2011	December 2041	5.65%	995	995
Senior Unsecured	March 2014	April 2044	4.80%	1,732	1,732
Senior Unsecured	November 2014	February 2045	4.50%	1,729	1,728
Senior Unsecured	September 2015	March 2046	4.75%	2,213	2,212
Floating-rate Borrowings	May 2016	May 2019	Variable	346	
Total debt, net				\$22,127	\$ 22,055
Less current portion				700	982
Total long-term debt, net				\$21,427	\$ 21,073

In connection with our adoption of the ASU relating to the presentation of debt issuance costs during the first quarter of 2016, debt balances at December 31, 2015 have been retrospectively adjusted by \$123 million to include

#### Convertible Notes

During the six months ended June 30, 2016, our Convertible Notes matured and we repaid \$285 million of principal balance related to the Convertible Notes. We also paid \$956 million in cash related to the conversion spread of the Convertible Notes, which represents the conversion value in excess of the principal amount, and received \$956 million in cash from the convertible note hedges related to the Convertible Notes.

As of June 30, 2016, there were 9 million shares of our common stock underlying our warrants associated with our Convertible Notes (the 2016 Warrants). The 2016 Warrants have a strike price of \$27.86 per share and expire during the 40 trading-day period commencing on August 1, 2016 and ending on September 26, 2016. On July 27, 2016, we exercised our option to settle the warrants in cash.

#### Credit Facility

In May 2016, we terminated our existing revolving credit facility and entered into a new \$2.5 billion, five-year revolving credit facility maturing in May 2021. The facility can be used for working capital requirements and for general corporate purposes, including, without limitation, acquisitions. As of June 30, 2016, there were no amounts outstanding under the revolving credit facility.

We are required to comply with certain covenants under the credit agreements and note indentures governing our senior notes. As of June 30, 2016, we were not in violation of any covenants.

<sup>(1)</sup> unamortized debt issuance costs. Prior to our adoption of the ASU, these unamortized debt issuance costs were included in Prepaid and other current assets and Other long-term assets in our Condensed Consolidated Balance Sheets.

#### 10. 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 (LDV/SOF), now known commercially as Harvoni. In June 2016, we received approval of the fixed-dose combination of sofosbuvir and velpatasvir (SOF/VEL), now known commercially as Epclusa. 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 combinations of ledipasvir and sofosbuvir (Harvoni) and sofosbuvir and velpatasvir (Epclusa). 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, Harvoni or Epclusa. 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, Harvoni and Epclusa. We cannot predict the ultimate outcome of intellectual property claims related to Sovaldi, Harvoni or Epclusa. 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, Harvoni and/or Epclusa, 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 a proceeding before the USPTO designed to determine who was the first to invent the subject matter claimed by both parties. In January 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 we 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 is related to the Idenix patent application at issue in the First Idenix Interference and includes claims directed to methods of treating HCV with nucleoside compounds. 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. In March 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 have responded to the appeal filed in the CAFC. The CAFC has not yet set a hearing date for this appeal. The Delaware court has stayed the appeal relating to the Second Idenix Interference.

We believe that the Idenix claims involved in the First and Second Idenix Interferences, and similar U.S. and foreign patents claiming the same compounds, metabolites and uses thereof, are invalid. As a result, we filed an Impeachment Action in the Federal Court of Canada to invalidate Idenix Canadian Patent No. 2,490,191 (the '191 patent), which is the Canadian patent that corresponds to the '600 patent. Idenix 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. In November 2015, the Canadian court held that Idenix's patent is

invalid and that Gilead's patent is valid. Idenix appealed the decision to the Canadian Federal Court of Appeal in November 2015.

We filed a similar legal action in Norway in the Oslo District Court seeking to invalidate Idenix's Norwegian patent corresponding to the '600 patent. In September 2013, Idenix filed an invalidation action in the Norwegian proceedings against our Norwegian Patent No. 333700 patent, which corresponds to the '572 patent. In March 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. Idenix

appealed the decision to the Norwegian Court of Appeal. In April 2016, the Court of Appeal issued its decision invalidating the Idenix patent and upholding the Gilead patent. Idenix has not filed a further appeal. 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 infringes its Australian patent corresponding to the '600 patent. In March 2016, the Australia court revoked Idenix's Australian patent. Idenix has appealed this decision. The appeal hearing is scheduled for November 2016. In March 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. An opposition hearing was held in February 2016, and the EPO ruled in our favor and revoked the '489 patent. In March 2014, Idenix also initiated infringement proceedings against us 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. Idenix appealed. The appeal hearing was held in July 2016. In March 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 hearing held by the EPO in February 2016. Idenix has not appealed this decision of the German court staying the proceedings. Upon Idenix's request, the French proceedings have been stayed; however, in March 2016, Idenix requested that the French litigation be reactivated.

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

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. In June 2014, the court transferred the Massachusetts litigation to the U.S. District Court for the District of Delaware. The Delaware 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 & Co. Inc. (Merck) in August 2014, and Merck continues to pursue the Idenix claims described herein.

#### 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 No. 7,105,499 (the '499 patent) and U.S. Patent No. 8,481,712 (the '712 patent), which it co-owns with Isis Pharmaceuticals, Inc. The '499 and '712 patents cover compounds which do not include, but may relate to, sofosbuvir. We filed a lawsuit in August 2013 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. During patent prosecution, Merck amended its patent application in an attempt to cover compounds related to sofosbuvir. Initially, in March 2016, a jury determined that we had not established that Merck's patents are invalid for lack of written description or lack of enablement and awarded Merck \$200 million in damages. However, in June 2016, the court ruled in Gilead's favor on our defense of unclean hands. As a result, the court determined that Merck may not recover any damages from us for the '499 and '712 patents. We have filed a motion seeking recovery of certain fees and have requested judgment that the jury's earlier verdict be vacated. As a result, during the second quarter of 2016, we reversed the \$200 million litigation reserve that was recorded in Cost of goods sold in our Condensed Consolidated Statements of Income during the first quarter of 2016.

Once the court has heard and ruled on Gilead's motions, the case will be ready for appeal. Merck has filed a notice of appeal to the Court of Appeals for the Federal Circuit regarding the court's decision on our defense of unclean hands. If the decision on our defense of unclean hands is reversed on appeal, we may be required to pay damages and a royalty on sales of sofosbuvir-containing products following the appeal. In that event, the judge has indicated that she

will determine the amount of the royalty, if necessary, at the conclusion of any appeal in this case.

## 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 (the AbbVie Patents) which purport to cover the use of a combination of LDV/SOF (or Harvoni) for the treatment of HCV. We are 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 LDV/SOF. 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 products 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. The AbbVie Patents have not blocked the commercialization of our combination products. The court has set a trial date of July 31, 2017 for this lawsuit.

In August 2015, we filed an impeachment action against AbbVie seeking a declaration that AbbVie's Canadian Patent No. 2,811,250 (the '250 patent), which purports to cover the use of a combination of LDV/SOF for the treatment of HCV, is invalid. On the same day, AbbVie filed an infringement action against us asserting that commercialization of Harvoni in Canada will infringe the '250 patent. The impeachment action has been stayed and we have counterclaimed for invalidity in the infringement proceeding. The court has set a trial date of April 11, 2018 for this impeachment action.

Additionally, AbbVie has obtained Canadian Patent No. 2,857,339 (the '339 patent) which purports to cover a solid composition that contains ledipasvir. In November 2015, AbbVie filed an infringement action against us asserting that commercialization of Harvoni in Canada infringes the '339 patent. We have filed a counterclaim asserting the invalidity of AbbVie's patent. The court has set a trial date of October 15, 2018 for this impeachment action. In November 2015, AbbVie filed a lawsuit against us in the Regional Court Düsseldorf for infringement of two quasi-patents, known as "utility models." Utility models are unexamined IP rights and are not the same as standard patents. One utility model, DE 20 2012 013 117, purports to cover the use of a combination of direct-acting antivirals which includes at least an HCV polymerase inhibitor and an HCV NS5A inhibitor in the treatment of HCV; the other utility model, DE 21 2012 000 197, purports to cover a solid dispersion that includes ledipasvir. The court has set a trial date of March 23, 2017 for this lawsuit.

# **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. In January 2016, several parties filed oppositions in the EPO requesting revocation of our granted European patent covering tenofovir alafenamide (TAF) that expires in 2021. In March 2016, three parties filed oppositions in the EPO requesting revocation of our granted European patent covering cobicistat that expires in 2027. While we are confident in the strength of our patents, 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, TAF and cobicistat in Europe could be substantially shortened or eliminated entirely. If our patents are revoked, and no other European patents are granted covering these compounds, our exclusivity may be based entirely on regulatory exclusivity granted by the European Medicines Agency. 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, FDA granted us a New Chemical Entity (NCE) exclusivity period during which other manufacturers' applications for approval of generic versions of our product will not be approved. Generic manufacturers may challenge the patents protecting products that have been granted NCE exclusivity one year prior to the end of the NCE exclusivity period. Generic manufacturers have sought and may continue to seek FDA approval for a similar or identical

drug through an abbreviated new drug application (ANDA), the application form typically used by manufacturers seeking approval of a generic drug. The sale of generic versions of our products earlier than their patent expiration would have a significant negative effect on our revenues and results of operations.

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

## **HIV Products**

In November 2011, December 2011 and August 2012, we received notices that Teva Pharmaceuticals (Teva) submitted an abbreviated new drug submission (ANDS) to the Canadian Minister of Health requesting permission to manufacture and market generic versions of Truvada, Atripla and Viread. In the notices, Teva alleges that the patents associated with Truvada, Atripla and Viread are invalid, unenforceable and/or will not be infringed by Teva's manufacture, use or sale of generic versions of those products. We filed lawsuits against Teva in the Federal Court of Canada seeking an order of prohibition against approval of these applications.

In December 2013, the court issued an order prohibiting the Canadian Minister of Health from approving Teva's generic versions of our Viread, Truvada and Atripla products until expiry of our patents in July 2017. Teva has appealed that decision. The court's decision did not rule on the validity of the patents and accordingly the only issue on appeal is whether the Canadian Minister of Health should be prohibited from approving Teva's products. The appeal will be heard by the Canadian Federal Court of Appeal after the trial in the Impeachment Action filed by Teva in August 2012 seeking invalidation of one of our Canadian patents associated with Viread. The court will determine the validity of the patent in the pending Impeachment Action. A trial in the Impeachment Action is scheduled for November 2016. If Teva is successful in invalidating the patent, Teva may be able to launch generic versions of our Viread, Truvada and Atripla products in Canada prior to the expiry of our patent.

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 version of Truvada 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 lawsuits against Apotex in the Federal Court of Canada seeking orders of prohibition against approval of these ANDSs. A hearing in those cases was held in April 2016. In July 2016, the court issued an order prohibiting the Canadian Minister of Health from approving Apotex's generic version of our Viread product until the expiry of our patents in July 2017. The court declined to prohibit approval of Apotex's generic version of our Truvada product. The court's decision did not rule on the validity of the patents. The launch of Apotex's generic version of our Truvada product would be at risk of infringement of our patents, including patents that we were unable to assert in the present lawsuit, and liability for our damages. Apotex may elect to appeal the decision.

In February 2016, we received notice that Mylan Pharmaceuticals, Inc. (Mylan) submitted an ANDA to FDA requesting permission to manufacture and market a generic version of Tybost (cobicistat). In the notice, Mylan alleges that the patent covering cobicistat is invalid as obvious and that Mylan's generic product cannot infringe an invalid claim. In March 2016, we filed lawsuits against Mylan in the U.S. District Court for the District of Delaware and U.S. District Court for the Northern District of West Virginia. The trial in Delaware is scheduled for January 2018. The patent in suit that covers Tybost is also listed in the Orange Book for Stribild and Genvoya.

In May 2016, we received notices that Aurobindo Pharma (Aurobindo) submitted ANDAs to FDA requesting permission to manufacture and market generic versions of Emtriva and Truvada. In the notices, Aurobindo alleges that two of the patents associated with our emtricitabine tablets and four of the patents associated with our emtricitabine and tenofovir disoproxil fumarate fixed dose combination tablets are invalid, unenforceable and/or will not be infringed by Aurobindo's manufacture, use or sale of generic versions of Emtriva and Truvada, respectively. In June 2016 and July 2016, we filed lawsuits against Aurobindo in the U.S. District Court for the District of New Jersey for infringement of the patents associated with Emtriva and Truvada.

## Letairis

In February 2015, we received notice that Watson Laboratories, Inc. (Watson) submitted an ANDA to 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 for infringement of our patents.

In June 2015, we received notice that SigmaPharm Laboratories, LLC (SigmaPharm) submitted an ANDA to 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 for infringement of our patents.

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, FDA or the Canadian Minister of Health could approve the requests to manufacture a generic version of such products in the United States or Canada, respectively, prior to the expiration date of those patents. The sale of generic versions of these products earlier than their patent expiration would have a significant negative effect on our revenues and results of operations.

## **TAF Litigation**

In January 2016, AIDS Healthcare Foundation, Inc. (AHF) filed a complaint with the U.S. District Court for the Northern District of California against Gilead, Japan Tobacco, Inc., Japan Tobacco International, U.S.A. (together, Japan Tobacco), and Emory University (Emory). In April 2016, AHF amended its complaint to add Janssen Sciences Ireland UC (Janssen) and Johnson & Johnson Inc. (J&J) as defendants. AHF claims that U.S. Patent Nos. 7,390,791; 7,800,788; 8,754,065; 8,148,374; and 8,633,219 are invalid. In addition, AHF claims that Gilead, independently and together with Japan Tobacco, Akros, Janssen and J&J, is violating federal and state antitrust and unfair competition laws in the market for sales of TAF by offering TAF as part of a fixed-dose combination product with elvitegravir, cobicistat and emtricitabine (Genvoya), a fixed-dose combination product with elvitegravir and rilpivirine (Odefsey) and in a fixed-dosed combination product with elvitegravir (Descovy). AHF seeks a declaratory judgment of invalidity against each of the patents as well as monetary damages. In May 2016, we, Japan Tobacco, Janssen, and J&J filed motions to dismiss all of AHF's claims, which AHF opposed. In June 2016, a hearing was held on the motions to dismiss. In July 2016, the judge granted our and the other defendants' motions and dismissed all of AHF's claims. AHF may elect to appeal this decision.

## Department of Justice Investigations

In June 2011, we received a subpoena from the U.S. Attorney's Office for the Northern District of California requesting documents related to the manufacture, and related quality and distribution practices, of Complera, Atripla, Truvada, Viread, Emtriva, Hepsera and Letairis. We cooperated with the government's inquiry. In April 2014, the United States Department of Justice informed us that, following an investigation, it declined to intervene in a False Claims Act lawsuit filed by two former employees. In April 2014, the former employees served a First Amended Complaint. In January 2015, the federal district court issued an order granting in its entirety, without prejudice, our motion to dismiss the First Amended Complaint. In February 2015, the plaintiffs filed a 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. In February 2016, we received a subpoena from the U.S. Attorney's Office for the District of Massachusetts requesting documents related to our support of 501(c)(3) organizations that provide financial assistance to patients, and for our HCV products, documents concerning our provision of financial assistance to patients. Other companies have disclosed similar inquiries. We are cooperating with this inquiry.

# Massachusetts Attorney General Investigation

In January 2016, we received a letter from the Massachusetts Attorney General that their office is considering whether our pricing of Sovaldi and Harvoni may constitute an unfair trade practice in violation of Massachusetts law. In February 2016, the Massachusetts Attorney General's office served us with a Civil Investigative Demand (CID) requesting that we produce documents related to our HCV products. In July 2016, the Massachusetts Attorney General's office notified us of their decision to suspend Gilead's obligations under the CID until further notice. Other Matters

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

## 11. STOCKHOLDERS' EQUITY

The following table summarizes the changes in stockholders' equity (in millions):

	Gilead	Stockl	nolders' E	quity				
	Comm	on		Accumulate	ed		Total	
	Stock		Addition		Retained	Noncontrol Interest	Total	dama'
			Paid-In	Compreher	siye	Interest	Stockholo	uers
	Shares	Amou	ınCapital	Income	Earnings		Equity	
			-	(Loss)				
Balance at December 31, 2015	1,422	\$ 1	\$ 444	\$ 88	\$18,001	\$ 579	\$ 19,113	
Net income				_	7,063	1	7,064	
Other comprehensive loss, net of tax				(134)		_	(134	)
Change in noncontrolling interest				_		(1)	(1	)
Issuances under employee stock purchase	1		10				10	
plan	1		48	_	_	_	48	
Issuances under equity incentive plans	8		69				69	
Stock-based compensation			183	_	_	_	183	
Tax benefits from employee stock plans			125				125	
Repurchases of common stock	(100)		(239)	<del></del>	(8,897)	<del></del>	(9,136	)
Convertible Notes settlement			(95)	<del></del>	_	_	(95	)
Convertible note hedges settlement			95	_	_	_	95	
Dividends declared			_	_	(1,218)	<del></del>	(1,218	)
Reclassification of conversion spread of			(733)				(733	`
Convertible Notes	_	_	(133 )	<del></del>	_	<del></del>	(733	,
Reclassification of convertible note hedges	_		733		_		733	
Reclassification to equity component of			2				2	
currently redeemable Convertible Notes	_	_	<i>L</i>	<del></del>	_	<del></del>	<i>L</i>	
Balance at June 30, 2016	1,331	\$ 1	\$ 632	\$ (46 )	\$14,949	\$ 579	\$ 16,115	
Accumulated Other Comprehensive Income	(Lose)							

Accumulated Other Comprehensive Income (Loss)

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

	Foreign Currency Items	Unrealized Gains and Losses on Available-for-Sale Securities	Unrealized Gains and Losses on Total Cash Flow Hedges
Balance at December 31, 2015	\$ (45 )	\$ (16)	\$ 149 \$88
Other comprehensive income (loss) before reclassifications	11	130	(204 ) (63 )
Amounts reclassified from AOCI	_	(2)	(69 ) (71 )
Net current period other comprehensive income (loss)	11	128	(273 ) (134)
Balance at June 30, 2016	\$ (34 )	\$ 112	\$ (124 ) \$(46)

Amounts reclassified for gains (losses) on cash flow hedges are recorded as part of Product sales in 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 in our Condensed Consolidated Statements of Income.

## Stock Repurchase Programs

In February 2016, we entered into an accelerated stock repurchase program (ASR) to repurchase \$5.0 billion of our common stock under the \$15.0 billion stock repurchase program announced in January 2015 (2015 Program). We made an upfront payment of \$5.0 billion and received 46 million shares of our common stock. The 46 million shares represented approximately 80% of the total shares calculated based on our common stock closing price of \$86.68 per share on the date we entered into the ASR. In April 2016, the ASR settled and we received an additional 8 million shares of our common stock based on the average price of our common stock during the ASR purchase period less a

predetermined discount. As a result, the average purchase price of our common stock from the ASR was \$92.09 per share.

We accounted for the ASR as two separate transactions: (a) as shares of common stock acquired in a treasury stock transaction recorded on the transaction date and (b) as a forward contract indexed to our own common stock. As such, the up-front payment of \$5.0 billion was accounted for as a reduction to Stockholders' equity in our Condensed Consolidated Balance Sheets in the period the payment was made. The ASR met all of the applicable criteria for equity classification, and therefore was not accounted for as a derivative instrument. The shares received under the ASR were retired in the periods they were received.

During the first quarter of 2016, we also repurchased and retired 34 million shares of our common stock for an aggregate purchase price of \$3.0 billion through open market transactions under the 2015 Program.

In February 2016, our Board of Directors authorized a \$12.0 billion stock repurchase program (2016 Program) under which repurchases may be made in the open market or in privately negotiated transactions. We started repurchases under our 2016 Program in April 2016, upon completion of the 2015 program.

During the second quarter of 2016, we repurchased a total of 10 million shares of our common stock for an aggregate purchase price of \$1.0 billion through open market transactions.

## 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 and equivalents, the assumed conversion of our outstanding Convertible Notes and the assumed exercise of the 2016 Warrants were determined under the treasury stock method.

In March 2016, we exercised our option to elect cash settlement for the conversion spread of the remaining Convertible Notes. Prior to our cash settlement election, our common stock resulting from the assumed settlement of the conversion spread of the Convertible Notes had a dilutive effect when the average market price of our common stock during the period exceeded the conversion price for the Convertible Notes. As a result, we included their dilutive impact in our net income per share calculations. Additionally, the 2016 Warrants have a dilutive effect when the average market price of our common stock during the period exceeded the warrants' exercise price. See Note 9, Debt and Credit Facility for additional information.

Our ASR was reflected as repurchases of our common stock upon the receipt of shares and as forward contracts indexed to our common stock. We excluded the forward contracts from the computation of diluted net income per share attributable to Gilead common stockholders because their effect was antidilutive.

For the three and six months ended June 30, 2016 and 2015, the number of anti-dilutive stock options and equivalents excluded from the computation of diluted net income per share attributable to Gilead common stockholders was not significant.

The following table shows the calculation of basic and diluted net income per share attributable to Gilead common stockholders (in millions except for per share amounts):

	Timee IV	vionuis	SIX MIO	nuis
	Ended June 30,		Ended	
			June 30	,
	2016	2015	2016	2015
Net income attributable to Gilead	\$3,497	\$4,492	\$7,063	\$8,825
Shares used in per share calculation - basic	1,335	1,472	1,359	1,480
Effect of dilutive securities:				
Stock options and equivalents	14	23	15	25
Conversion spread related to the Convertible Notes		14	3	15
Warrants related to the Convertible Notes	6	31	6	35
Shares used in per share calculation - diluted	1,355	1,540	1,383	1,555
Net income per share attributable to Gilead common stockholders - basic	\$2.62	\$3.05	\$5.20	\$5.96
Net income per share attributable to Gilead common stockholders - diluted	\$2.58	\$2.92	\$5.11	\$5.68

Three Months Six Months

## 13. SEGMENT INFORMATION

We have one operating segment, which primarily focuses on the discovery, development and commercialization of innovative medicines in areas of unmet medical need. Therefore, our results of operations are reported on a consolidated basis consistent with internal management reporting reviewed by our chief operating decision maker, our chief executive officer. Total product sales on an individual product basis are summarized in the following table (in millions):

	Three N	<b>Months</b>	Six Months			
	Ended		Ended			
	June 30	),	June 30,			
	2016	2015	2016	2015		
Antiviral products:						
Harvoni	\$2,564	\$3,608	\$5,581	\$7,187		
Sovaldi	1,358	1,291	2,635	2,263		
Truvada	942	849	1,840	1,620		
Atripla	673	782	1,348	1,516		
Stribild	429	447	906	803		
Complera/Eviplera	368	367	749	687		
Genvoya	302	_	460	_		
Viread	287	271	559	505		
Epclusa	64	_	64	_		
Descovy	61	_	61	_		
Odefsey	58	_	69	_		
Other antiviral	20	16	37	38		
Total antiviral products	7,126	7,631	14,309	14,619		
Other products:						
Letairis	203	176	378	327		
Ranexa	153	141	297	258		
AmBisome	85	103	171	188		
Zydelig	41	30	90	56		
Other	43	45	87	83		
Total product sales	\$7,651	\$8,126	\$15,332	\$15,53		

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	Six
	Months	Months
	Ended	Ended
	June 30,	June 30,
	2016 2015	2016 2015
McKesson Corp.	$23\%\ 24\%$	22% 25%
AmerisourceBergen Corp.	18% 20%	17% 20%
Cardinal Health, Inc.	16% 15%	16% 16%
4.4. TO LOGO NET TO LA TERM		

## 14. INCOME TAXES

Our income tax rate of 20.5% and 20.6% for the three and six months ended June 30, 2016, 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 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 and California 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.

Our income tax returns are subject to audit 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. 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.

# $_{\mbox{\scriptsize Item}}$ 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, 2015 and our unaudited Condensed Consolidated Financial Statements for the three and six months ended June 30, 2016 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 human immunodeficiency virus (HIV), liver diseases such as chronic hepatitis C virus (HCV) infection and chronic hepatitis B virus (HBV) infection, cardiovascular, hematology/oncology and inflammation/respiratory. 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 AmBisome®, Atripla®, Cayston®, Complera®/Eviplera®, Descovy®, Emtriva®, Epclusa®, Genvoya®, Harvoni®, Hepsera®, Letairis®, Odefsey®, Ranexa®, Sovaldi®, Stribild®, Tamiflu®, Truvada®, Tybost®, Viread®, Vitekta®, and Zydelig®. 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 second quarter of 2016, 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:

U.S. Food and Drug Administration (FDA) and European Commission approved Epclusa (sofosbuvir 400 mg/velpatasvir 100 mg; SOF/VEL), the first all-oral, pan-genotypic, single-tablet regimen (STR) for the treatment of adults with genotype 1-6 HCV infection. Epclusa is also the first STR approved for the treatment of patients with HCV genotype 2 and 3, without the need for ribavirin (RBV). Epclusa for 12 weeks was approved in patients without cirrhosis or with compensated cirrhosis (Child-Pugh A), and in combination with RBV for patients with decompensated cirrhosis (Child-Pugh B or C).

FDA granted Epclusa a Priority Review and Breakthrough Therapy designation, which is given to investigational medicines that may offer major advances in treatment over existing options.

The European Commission granted marketing authorization for the once-daily STR Odefsey (emtricitabine 200 mg/rilpivirine 25 mg/tenofovir alafenamide 25 mg) for the treatment of HIV-1 infection. Odefsey combines our emtricitabine and tenofovir alafenamide (marketed as Descovy) with rilpivirine, marketed by Janssen Sciences Ireland UC, one of the Janssen Pharmaceutical Companies of Johnson & Johnson. Odefsey is our second STR based on the Descovy backbone to receive marketing authorization in the European Union and is currently the smallest STR for the treatment of HIV.

Presented at the American Society of Microbiology Microbe 2016 conference positive data from four pre-clinical and Phase 1 studies evaluating bictegravir (GS-9883), a novel, unboosted, investigational once-daily integrase strand transfer inhibitor. The studies examined the antiviral potency, resistance profile, pharmacokinetics and safety of bictegravir.

Presented data at the 51st Annual Meeting of the European Association for the Study of the Liver, which included the announcement of:

Positive results from the open-label, Phase 3 ASTRAL-5 study evaluating once-daily SOF/VEL for 12 weeks among patients with HCV genotype 1-6 who are co-infected with HIV demonstrated that SOF/VEL was well-tolerated and resulted in high sustained virologic response rates at 12 weeks after treatment (SVR12).

Positive results from three Phase 2 trials evaluating SOF/VEL plus voxilaprevir (VOX), a pan-genotypic protease inhibitor (Studies1168 and1169 and TRILOGY-3). Studies 1168 and 1169 evaluated 6 weeks of SOF/VEL plus VOX among treatment-naïve patients, 8 weeks of SOF/VEL plus VOX, with or without RBV, among treatment-naïve patients, and 12 weeks of SOF/VEL plus VOX among patients who failed prior treatment including those previously exposed to a direct acting antiviral (DAA) regimen. Study 1168 evaluated genotype 1 patients and Study 1169 evaluated genotype 2-6 patients. TRILOGY-3 featured data from the Phase 2 trial evaluating 12 weeks of a fixed-dose combination of SOF/VEL/VOX, with or without RBV, among genotype 1, DAA-experienced, HCV-infected patients, including patients with cirrhosis.

The European Commission granted marketing authorization for two doses of Descovy (200/10 mg and 200/25 mg), a fixed-dose combination for the treatment of HIV-1 infection. Descovy is our second tenofovir alafenamide (TAF)-based therapy to receive marketing authorization in the European Union. Descovy was approved by FDA and is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients 12 years of age and older.

Purchased Nimbus Apollo, Inc. (Nimbus), a wholly-owned subsidiary of Nimbus Therapeutics, and its Acetyl-CoA Carboxylase (ACC) inhibitor program. The Nimbus program includes the lead candidate NDI-010976, an ACC inhibitor, and other pre-clinical ACC inhibitors for the potential treatment of non-alcoholic steatohepatitis, hepatocellular carcinoma and other diseases. NDI-010976 was granted Fast Track designation by FDA in February 2016. In connection with the purchase, we made a payment of \$400 million during the second quarter of 2016. Financial Highlights

Total revenues were \$7.8 billion for the second quarter of 2016, compared to \$8.2 billion in the second quarter of 2015, primarily due to lower product sales, which were \$7.7 billion compared to \$8.1 billion in the same quarter of 2015.

Cost of goods sold was \$864 million for the second quarter of 2016, compared to \$998 million in the second quarter of 2015, primarily due to the reversal of the \$200 million litigation reserve recorded in the first quarter of 2016 following a favorable court decision.

Research and development (R&D) expenses were \$1.5 billion for the second quarter of 2016, compared to \$818 million in the second quarter of 2015, primarily driven by our purchase of Nimbus, purchase of a FDA priority review voucher and the overall progression of our clinical studies.

Selling, general and administrative (SG&A) expenses were \$890 million for the second quarter of 2016, compared to \$812 million in the second quarter of 2015, primarily driven by costs to support our new product launches and geographic expansion of our business.

Net income attributable to Gilead was \$3.5 billion or \$2.58 per diluted share for the second quarter of 2016, compared to \$4.5 billion or \$2.92 per diluted share for the second quarter of 2015, primarily due to increases in R&D and SG&A expenses and a decrease in product sales. Year over year earnings per share were favorably impacted by our share repurchase activities in the first half of 2016 and the second half of 2015. During the first half of 2016, we repurchased a total of 98 million shares for \$9 billion, of which 54 million shares or \$5 billion were repurchased under an accelerated stock repurchase program. During the second half of 2015, we repurchased a total of 56 million shares for \$6.1 billion.

As of June 30, 2016, we had \$24.6 billion of cash, cash equivalents and marketable securities, compared to \$21.3 billion as of March 31, 2016. During the second quarter of 2016, cash flow from operating activities was \$4.9 billion. Results of Operations

**Total Revenues** 

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

	Three Months			Six Mon	Six Months			
	Ended			Ended				
	June 30	),		June 30,				
(In millions, except percentages)	2016	2015	Chang	e 2016	2015	Change		
Revenues:								
Product sales	\$7,651	\$8,126	(6)%	\$15,332	\$15,531	(1)%		
Royalty, contract and other revenues	125	118	6 %	238	307	(22)%		
Total revenues	\$7,776	\$8,244	(6)%	\$15,570	\$15,838	(2)%		
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Product sales for the three months ended June 30, 2016

Total product sales were \$7.7 billion for the three months ended June 30, 2016, compared to \$8.1 billion for the same period in 2015, primarily due to a decrease in antiviral product sales.

Antiviral product sales, which include sales of our HIV and other antiviral products and HCV products, were \$7.1 billion for the three months ended June 30, 2016, compared to \$7.6 billion for the same period in 2015. HIV and other antiviral product sales were \$3.1 billion for the three months ended June 30, 2016, compared to \$2.7 billion for the same period in 2015 primarily due to sales of our tenofovir alafenamide (TAF)-based products, Genvoya, Descovy and Odefsey. HCV product sales, which consist of Harvoni, Sovaldi and Epclusa, were \$4.0 billion for the three months ended June 30, 2016, compared to \$4.9 billion for the same period in 2015 primarily due to a decline in sales of Harvoni.

Other product sales, which include sales of Ranexa, Letairis and AmBisome, were \$525 million for the three months ended June 30, 2016, compared to \$495 million for the same period in 2015.

Foreign currency exchange, net of hedges, had an unfavorable impact on our product sales of \$115 million for the three months ended June 30, 2016, compared to the same period in 2015. Of our total product sales, 36% were generated outside of the United States (U.S.) during the three months ended June 30, 2016. We faced 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.

Product sales in the U.S. were \$4.9 billion for the three months ended June 30, 2016, compared to \$5.6 billion for the same period in 2015. A decline in sales of Harvoni was partially offset by sales of our TAF-based products, Genvoya, Odefsey and Descovy, and an increase in sales of Truvada.

Product sales in Europe were \$1.6 billion for the three months ended June 30, 2016, compared to \$2.0 billion for the same period in 2015. The decrease was primarily due to lower Sovaldi and Harvoni sales volume and a higher proportion of sales in countries with lower Sovaldi and Harvoni average net selling prices. In addition, foreign currency exchange rates, net of hedges, had an unfavorable impact of \$104 million on our product sales for the three months ended June 30, 2016, compared to the same period in 2015.

Product sales in Japan, which consist of Sovaldi and Harvoni, were \$619 million for the three months ended June 30, 2016, compared to \$62 million for the same period in 2015. Sovaldi and Harvoni were launched in Japan in May and September 2015, respectively.

Product sales in other international locations were \$531 million for the three months ended June 30, 2016, compared to \$515 million for the same period in 2015, primarily due to continued launches of our HCV products.

Product sales for the six months ended June 30, 2016

Total product sales were \$15.3 billion for the six months ended June 30, 2016, compared to \$15.5 billion for the same period in 2015, primarily due to a decrease in antiviral product sales.

Antiviral product sales were \$14.3 billion for the six months ended June 30, 2016, compared to \$14.6 billion for the same period in 2015. HIV and other antiviral product sales were \$6.0 billion for the six months ended June 30, 2016, compared to \$5.2 billion for the same period in 2015 primarily due to sales of our TAF-based products, Genvoya, Descovy, and Odefsey. HCV product sales were \$8.3 billion for the six months ended June 30, 2016, compared to \$9.4 billion for the same period in 2015 primarily due to a decline in sales of Harvoni.

Other product sales, which include sales of Ranexa, Letairis and AmBisome, were \$1.0 billion for the six months ended June 30, 2016, compared to \$912 million for the same period in 2015.

Foreign currency exchange, net of hedges, had an unfavorable impact on our product sales of \$300 million for the six months ended June 30, 2016, compared to the same period in 2015. Of our total product sales, 40% were generated outside of the U.S. during the six months ended June 30, 2016. We faced 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.

Product sales in the U.S. were \$9.3 billion for the six months ended June 30, 2016, compared to \$10.8 billion for the same period in 2015. A decline in sales of Harvoni was partially offset by an increase in sales of Sovaldi, sales of Genvoya, which was launched in the U.S. in November 2015, and an increase in sales of Truvada where we have seen an increase in the use of Truvada as a preventive treatment for HIV.

Product sales in Europe were \$3.2 billion for the six months ended June 30, 2016, compared to \$3.8 billion for the same period in 2015. The decrease was primarily due to lower HCV products average net selling prices and lower Sovaldi sales volume. In addition, foreign currency exchange rates, net of hedges, had an unfavorable impact of \$245 million on our product sales for the six months ended June 30, 2016, compared to the same period in 2015. Product sales in Japan, which consist of Sovaldi and Harvoni, were \$1.7 billion for the six months ended June 30, 2016, compared to \$62 million for the same period in 2015. Sovaldi and Harvoni were launched in Japan in May and September 2015, respectively. During the six months ended June 30, 2016, sales volume declined from early launch levels reached during the second half of 2015 and pricing for Sovaldi and Harvoni was adjusted to reflect a mandatory price reduction of 32% that was effective April 1, 2016.

Product sales in other international locations were \$1.1 billion for the six months ended June 30, 2016, compared to \$879 million for the same period in 2015, primarily due to continued launches of our HCV products.

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

	Three N	Three Months			Six Months				
	Ended				Ended				
	June 30,			June 30,					
(In millions, except percentages)	2016	2015	Cha	nge	2016	2015	Cha	ange	
Antiviral products:									
Harvoni	\$2,564	\$3,608	(29	)%	\$5,581	\$7,187	(22	)%	
Sovaldi	1,358	1,291	5	%	2,635	2,263	16	%	
Truvada	942	849	11	%	1,840	1,620	14	%	
Atripla	673	782	(14	)%	1,348	1,516	(11	)%	
Stribild	429	447	(4	)%	906	803	13	%	
Complera/Eviplera	368	367		%	749	687	9	%	
Genvoya	302		*		460	_	*		
Viread	287	271	6	%	559	505	11	%	
Epclusa	64		*		64		*		
Descovy	61		*		61		*		
Odefsey	58		*		69		*		
Other antiviral	20	16	25	%	37	38	(3	)%	
Total antiviral products	7,126	7,631	(7	)%	14,309	14,619	(2	)%	
Other products:									
Letairis	203	176	15	%	378	327	16	%	
Ranexa	153	141	9	%	297	258	15	%	
AmBisome	85	103	(17	)%	171	188	(9	)%	
Zydelig	41	30	37	%	90	56	61	%	
Other	43	45	(4	)%	87	83	5	%	
Total product sales	\$7,651	\$8,126	(6	)%	\$15,332	\$15,531	(1	)%	

<sup>\*</sup> Percentage not meaningful

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

Net product sales of Harvoni for the three and six months ended June 30, 2016 accounted for 36% and 39% of our total antiviral product sales, respectively.

For the three months ended June 30, 2016, net product sales of Harvoni were \$1.5 billion in the U.S., \$512 million in Europe, \$448 million in Japan, and \$130 million in other international locations, compared to \$2.8 billion in the U.S., \$623 million in Europe and \$159 million in other international locations for the same period in 2015. In the U.S., the decrease was primarily due to lower average net selling price and lower sales volume compared to Harvoni's early launch levels during the prior year. The number of patients that started treatment with Harvoni in the U.S. peaked in the first half of 2015 indicative of the rapid initiation of treatment for many warehoused patients. Harvoni was launched in the U.S. in October 2014. During the second quarter, we also had a favorable revision to our Harvoni sales return reserve of \$181 million. In Europe, the decrease was primarily due to lower sales volume and a higher proportion of sales from countries that have lower average net selling prices. Additionally, we have seen a slight decline in average treatment duration, as countries are treating more patients with lower fibrosis scores who qualify for an eight-week treatment duration. In Japan, we launched Harvoni in September 2015. In other international locations, the decrease was primarily due to higher sales from countries that have lower average net selling prices. For the six months ended June 30, 2016, net product sales of Harvoni were \$2.9 billion in the U.S., \$1.1 billion in Europe, \$1.3 billion in Japan, and \$298 million in other international locations, compared to \$5.8 billion in the U.S., \$1.1 billion in Europe and \$245 million in other international locations for the same period in 2015. In the U.S., the decrease was primarily due to lower sales volume and lower average net selling price. The number of patients that started treatment with Harvoni in the U.S. peaked in the first half of 2015 indicative of the rapid initiation of treatment

for many warehoused patients. In Europe, higher sales volume were offset by a higher proportion of sales from countries that have lower average net selling prices and unfavorable foreign exchange currency rates, net of hedges. In Japan, the increase was driven by the launch of Harvoni in September 2015. In other international locations, the increase was driven by the continued launches of Harvoni.

#### Sovaldi

Net product sales of Sovaldi for the three and six months ended June 30, 2016 accounted for 19% and 18% of our total antiviral product sales, respectively.

For the three months ended June 30, 2016, net product sales of Sovaldi were \$775 million in the U.S., \$263 million in Europe, \$171 million in Japan, and \$149 million in other international locations, compared to \$615 million in the U.S., \$522 million in Europe, \$62 million in Japan and \$92 million in other international locations for the same period in 2015. In the U.S., the increase includes a favorable revision to our Sovaldi sales return reserve of \$98 million and higher sales volume, partially offset by lower average net selling price. In Europe, the decrease was primarily due to lower sales volume and lower average net selling price. In Japan, the increase is reflective of the launch of Sovaldi in May 2015. In other international locations, the increase was primarily driven by the continued launches of Sovaldi. For the six months ended June 30, 2016, net product sales of Sovaldi were \$1.4 billion in the U.S., \$543 million in Europe, \$373 million in Japan, and \$299 million in other international locations, compared to \$1.0 billion in the U.S., \$1.0 billion in Europe, \$62 million in Japan and \$160 million in other international locations for the same period in 2015. In the U.S., the increase was primarily driven by higher sales volume. In Europe, the decrease was primarily due to lower sales volume and lower average net selling price. In Japan, the increase was primarily driven by the launch of Sovaldi in May 2015. In other international locations, the increase was primarily driven by the continued launches of Sovaldi.

## •Truvada

Net product sales of Truvada for both the three and six months ended June 30, 2016 accounted for 13% of our antiviral product sales.

For the three months ended June 30, 2016, net product sales of Truvada were \$631 million in the U.S., \$245 million in Europe and \$66 million in other international locations, compared to \$500 million in the U.S., \$277 million in Europe and \$72 million in other international locations for the same period in 2015. The increase was primarily driven by higher average net selling price and higher sales volume primarily driven by increased usage of Truvada for pre-exposure prophylaxis or PrEP.

For the six months ended June 30, 2016, net product sales of Truvada were \$1.2 billion in the U.S., \$496 million in Europe and \$137 million in other international locations, compared to \$909 million in the U.S., \$578 million in Europe and \$133 million in other international locations for the same period in 2015. The increase was primarily driven by higher average net selling price and higher sales volume primarily driven by increased usage of Truvada for PrEP.

# Atripla

Net product sales of Atripla for both the three and six months ended June 30, 2016 accounted for 9% of our total antiviral product sales.

For the three months ended June 30, 2016, net product sales of Atripla were \$479 million in the U.S. and \$140 million in Europe, compared to \$549 million in the U.S. and \$178 million in Europe for the same period in 2015. The decrease was primarily due to declines in sales volume as doctors prescribed newer regimens, including tenofovir disoproxil fumarate (TDF) and TAF-based regimens. The efavirenz component of Atripla sales, which has a gross margin of zero, comprised \$246 million of our Atripla sales for the three months ended June 30, 2016, compared to \$290 million for the same period in 2015.

For the six months ended June 30, 2016, net product sales of Atripla were \$968 million in the U.S. and \$283 million in Europe, compared to \$1.0 billion in the U.S. and \$372 million in Europe for the same period in 2015. The decrease was primarily due to declines in sales volume as doctors prescribed newer regimens, including TDF and TAF-based regimens. The efavirenz component of Atripla sales, which has a gross margin of zero, comprised \$494 million of our Atripla sales for the six months ended June 30, 2016, compared to \$558 million for the same period of 2015.

## Stribild

Net product sales of Stribild for both the three and six months ended June 30, 2016 accounted for 6% of our total antiviral product sales.

For the three months ended June 30, 2016, net product sales of Stribild were \$326 million in the U.S. and \$84 million in Europe, compared to \$364 million in the U.S. and \$65 million in Europe for the same period in 2015. The decrease was primarily due to the launch of our new TAF-based product, Genvoya.

For the six months ended June 30, 2016, net product sales of Stribild were \$702 million in the U.S. and \$165 million in Europe, compared to \$646 million in the U.S. and \$126 million in Europe for the same period in 2015. The increase was primarily driven by higher sales volume.

•TAF-based regimens - Genvoya, Descovy, and Odefsey

Net product sales of our recently launched TAF-based regimens for the three and six months ended June 30, 2016 accounted for 6% and 4% of our total antiviral product sales, respectively. Genvoya was launched in the U.S. and Europe in November 2015. Descovy was launched in the U.S. and Europe in April 2016. Odefsey was launched in the U.S. in March 2016 and approved by European Commission in June 2016.

For the three months ended June 30, 2016, net product sales of Genvoya were \$302 million, primarily driven by sales in the U.S. of \$268 million.

For the six months ended June 30, 2016, net product sales of Genvoya were \$460 million, primarily driven by sales in the U.S. of \$409 million.

While we have seen continued strength in our HIV and other product sales, there has been a slowing of HCV patient treatments in the U.S. and earlier launch markets in Europe since the first half of 2015 when Harvoni had been recently launched, indicative of the rapid initiation of treatment for many warehoused patients. In addition, we have seen lower average net selling prices for our HCV products primarily as a result of a mix shift towards payer segments in the U.S. that receive significantly higher rebates and discounts and towards countries with lower average net selling prices in Europe. We expect a continued gradual trend toward shorter duration of HCV treatments and could experience a decline in market share due to increased competition in the future. We anticipate that total net product sales for the full year 2016 will be lower than net product sales for 2015.

Cost of Goods Sold and Product Gross Margin

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

	Three M Ended	Ionths	Six Mont	hs Ended		
	June 30	,	June 30,			
(In millions, except percentages)	2016	2015	2016	2015		
Cost of goods sold	\$864	\$998	\$2,057	\$1,880		
Product gross margin	89 %	88 %	87 %	88 %		

The product gross margin change in the three months ended June 30, 2016 compared to the same period in 2015 was primarily due to the reversal of the \$200 million litigation reserve recorded in the first quarter of 2016 following a favorable court decision.

**Operating Expenses** 

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

	Three Months Ended June 30,			Six Months Ended June 30,			
(In millions, except percentages)	2016	2015	Chang	e 2016	2015	Cha	inge
Research and development expenses	\$1,484	\$818	81 %	\$2,749	\$1,514	82	%
Selling, general and administrative expenses	\$890	\$812	10 %	\$1,575	\$1,457	8	%
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, up-front and 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 June 30, 2016 increased by \$666 million or 81%, compared to the same period in 2015, primarily due to \$624 million related to our purchase of Nimbus and a FDA priority review voucher, and the overall progression of clinical studies.

R&D expenses for the six months ended June 30, 2016 increased by \$1.2 billion or 82%, compared to the same period in 2015, primarily due to \$1.0 billion related to our collaboration and acquisition related expenses, including our purchase of Nimbus, our license and collaboration agreement with Galapagos NV, the purchase of a FDA priority review voucher, and the overall progression of clinical studies. In addition, during the first quarter of 2016, we recorded a \$114 million in-process R&D impairment charge related to momelotinib.

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 June 30, 2016 increased by \$78 million or 10%, compared to the same period in 2015, primarily due to expenses to support new product launches and geographic expansion.

SG&A expenses for the six months ended June 30, 2016 increased by \$118 million or 8%, compared to the same period in 2015, primarily due to expenses to support new product launches and geographic expansion. These increases were partially offset by a net decrease of \$103 million in Branded Prescription Drug (BPD) fee expenses. The first quarter of 2016 and 2015 were favorably impacted by a credit to the BPD fee of \$191 million and \$100 million, respectively, based on receipt of the Internal Revenue Service (IRS) invoices. The BPD fee is calculated based on select government sales during each calendar year as a percentage of total industry government sales.

# Interest Expense

Interest expense for the three months ended June 30, 2016 was \$227 million, compared to \$140 million for the same period in 2015. Interest expense for the six months ended June 30, 2016 was \$457 million, compared to \$293 million for the same period in 2015. The increases in both periods were primarily due to interest expense incurred related to the issuances of senior unsecured notes in September 2015. For more information see Note 9, Debt and Credit Facility of the Notes to Condensed Consolidated Financial Statements in this quarterly report.

## Provision for Income Taxes

Provision for income taxes for the three months ended June 30, 2016 was \$902 million, compared to \$1.0 billion for the same period in 2015. Our effective tax rate was 20.5% for the three months ended June 30, 2016, compared to 18.4% for the same period in 2015.

Provision for income taxes for the six months ended June 30, 2016 was \$1.8 billion, compared to \$1.9 billion for the same period in 2015. Our effective tax rate was 20.6% for the six months ended June 30, 2016, compared to 17.9% for the same period in 2015.

The effective tax rates for the three and six months ended June 30, 2016 were higher than the effective tax rates for the same periods in 2015 primarily due to changes in the geographic mix of earnings.

The effective tax rates for the three and six months ended June 30, 2016 and 2015 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:

2015

June 30, December 31, (In millions) 2016

Cash, cash equivalents and marketable securities \$24,616 \$ 26,208 Working capital \$7,909 \$ 14,872

Cash, Cash Equivalents and Marketable Securities

Cash, cash equivalents and marketable securities totaled \$24.6 billion at June 30, 2016, a decrease of \$1.6 billion when compared to \$26.2 billion at December 31, 2015. A discussion of the key drivers of our cash flows follows

Of the total cash, cash equivalents and marketable securities at June 30, 2016, approximately \$23.4 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 \$7.9 billion at June 30, 2016, compared to \$14.9 billion at December 31, 2015. The decrease of \$7.0 billion was primarily due to a decline in cash and cash equivalents as described below.

Cash Flows

The following table summarizes our cash flow activities:

Six months ended

June 30.

(In millions) 2016 2015

Cash provided by (used in):

Operating activities \$8,853 \$11,359 Investing activities \$(5,393) \$(5,851) Financing activities \$(9,912) \$(8,063)

Cash Provided by Operating Activities

Cash provided by operating activities was \$8.9 billion for the six months ended June 30, 2016. Cash flows from operating activities represent the cash receipts and disbursements related to all of our activities other than investing and financing activities. Operating cash flow is derived by adjusting our net income of \$7.1 billion for non-cash items of \$739 million and changes in operating assets and liabilities of \$1.1 billion. The changes in operating assets and liabilities were primarily due to an increase in accrued government and other rebates resulting from timing of payments. We expect our cash flow from operations to decrease in the future as we continue to make cash payments related to accrued government and other rebates as well as milestone payments.

For the six months ended June 30, 2016, compared to the same period in 2015, the decrease in cash provided by operating activities was primarily due to lower net income and a decrease in the change of accrued liabilities resulting from timing of payments.

Cash Used in Investing Activities

Cash used in investing activities for the six months ended June 30, 2016 was \$5.4 billion, consisting of \$4.7 billion net purchases of marketable securities, \$357 million of other investments related to our agreement with Galapagos and \$381 million in capital expenditures related to the expansion of our business.

Cash used in investing activities for the six months ended June 30, 2015 was \$5.9 billion, consisting of \$5.6 billion in net purchases of marketable securities and \$295 million in capital expenditures related to the expansion of our business.

## Cash Used in Financing Activities

Cash used in financing activities for the six months ended June 30, 2016 was \$9.9 billion, consisting primarily of \$9.0 billion utilized to repurchase our common stock under our stock repurchase programs and \$1.2 billion used to pay cash dividends. Of our \$9.0 billion common stock repurchases, \$5.0 billion and \$4.0 billion were through an accelerated stock repurchase program and open market transactions, respectively. We anticipate stock repurchases in the second half of 2016 to be lower than the first half of 2016.

In February 2016, our Board of Directors authorized a \$12.0 billion share repurchase program (2016 Program) under which repurchases may be made in the open market or in privately negotiated transactions. We started repurchases under our 2016 Program in April 2016.

Cash used in financing activities for the six months ended June 30, 2015 was \$8.1 billion, consisting primarily of \$3.9 billion used to repurchase our common stock under our stock repurchase programs and \$3.9 billion for our warrant settlements.

# Debt and Credit Facility

In May 2016, we terminated our existing revolving credit facility and entered into a new \$2.5 billion, five-year revolving credit facility maturing in May 2021. The facility can be used for working capital requirements and for general corporate purposes, including, without limitation, acquisitions. As of June 30, 2016, there were no amounts outstanding under the revolving credit facility.

As of June 30, 2016, there were 9 million shares of our common stock underlying our warrants associated with our May 2016 Convertible Senior Notes (the 2016 Warrants). The 2016 Warrants have a strike price of \$27.86 per share and expire during the 40 trading-day period commencing on August 1, 2016 and ending on September 26, 2016. On July 27, 2016, we exercised our option to settle the warrants in cash.

The summary of our borrowings under various financing arrangements is included in Item 1, Note 9 Debt and Credit Facility of our Notes to Condensed Consolidated Financial Statements of this Form 10-Q. There were no other material changes to our debt and credit facility during the first six months of 2016.

## 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 and estimates is presented in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2015. There were no material changes to our critical accounting policies and estimates during the six months ended June 30, 2016

## **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. Recent Accounting Pronouncements

See Item 1, Note 1 Summary of Significant Accounting Policies of our Notes to 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 six months ended June 30, 2016 compared to the disclosures in Part II, Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2015. As of June 30, 2016, our accounts receivable in Southern Europe, specifically Greece, Italy, Portugal and Spain, totaled approximately \$630 million, of which \$171 million were greater than 120 days past due, including \$36 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 June 30, 2016. 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 June 30, 2016 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 June 30, 2016.

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 June 30, 2016, 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

For a description of our significant pending legal proceedings, please see Item 1, Note 10 Commitments and Contingencies of our Notes to Condensed Consolidated Financial Statements.

## 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 six months ended June 30, 2016, sales of Harvoni, Sovaldi and Epclusa for the treatment of HCV accounted for approximately 54% of our total product sales. We cannot be certain if prior year sales of our HCV products are indicative of future sales. Sales of our HCV products peaked in the first quarter of 2015 as warehoused patients started treatment in large numbers. Since then, the number of new patient starts has diminished. In the second quarter of 2016, we saw slowing of patient starts in the U.S. commercial segment and some of the earlier launch markets of Europe. We expect the revenue per patient to decline as a result of payers opening coverage to patients with lower fibrosis scores in exchange for additional discounts, a shift in our payer mix toward more deeply discounted government payer segments in the United States and countries with a lower average net selling price in Europe, competition and a decrease in the average duration of treatment as fewer patients are treated for 24 weeks and more patients are treated for 8 weeks. We also could experience a decline in market share due to increased competition.

In addition, future sales of Harvoni, Sovaldi and Epclusa are difficult to estimate because demand depends, in part, on the extent of reimbursement of our HCV products by private and government payers. In light of continued fiscal and debt crises experienced by several countries in the European Union and Japan, governments have announced or implemented measures to manage healthcare expenditures. We may continue to experience global pricing pressure which could result in larger discounts or rebates on our products or delayed reimbursement, which negatively impacts our product sales and results of operations. Also, private and public payers can choose to exclude Harvoni, Sovaldi or Epclusa 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, Sovaldi and Epclusa. 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. For example, the government of Japan implemented mandatory price reductions on Harvoni and Sovaldi effective as of April 1, 2016. If we are unable to achieve our forecasted HCV sales, our HCV product revenues and results of operations could be negatively affected, and our stock price could experience significant volatility.

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, Genvoya, Odefsey, Stribild, Complera/Eviplera and Atripla. During the six months ended June 30, 2016, sales of our HIV products accounted for approximately 39% of our total product sales. Most of our HIV products contain tenofovir alafenamide (TAF), tenofovir disoproxil fumarate and/or emtricitabine, which belong to the nucleoside class of antiviral therapeutics. In addition, if the treatment paradigm for HIV changes, causing nucleoside-based therapeutics to fall out of favor, or if we are unable to maintain or increase 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 be unable to sustain or increase sales of our HCV or HIV products for any number of reasons including, but not limited to, the following:

As our HCV and HIV products are used over a longer period of time in many patients and in combination with other products, and additional studies are conducted, new issues with respect to safety, resistance and interactions with

other drugs may arise, which could cause us to provide additional warnings or contraindications on our labels, narrow our approved indications or halt sales of a product, each of which could reduce our revenues.

As our 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.

If physicians do not see the benefit of our HCV or HIV products, the sales of our HCV or HIV products will be limited.

As new or generic products are introduced into major markets, our ability to maintain pricing and market share may be affected. For example, tenofovir disoproxil fumarate, one of the active pharmaceutical ingredients in Stribild,

Complera/Eviplera, Atripla and Truvada, is expected to face generic competition in the United States and European Union in 2017, which may have an impact on our business and results of operations.

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 or increase sales of our existing products, we will not be able to increase or maintain our total revenues nor continue to expand our research and development efforts. Drug development is inherently risky and many product candidates fail during the drug development process. For example, in January 2016 we announced that we terminated our Phase 2 study of simtuzumab for the treatment of idiopathic pulmonary fibrosis. In the first quarter of 2016, we filed our NDA and MAA in the United States and European Union for the approval of TAF for the treatment of chronic hepatitis B virus (HBV) infection. 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, uptake of new products or fluctuations in customer inventories makes it difficult for us to accurately forecast sales and may cause our forecasted 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, Sovaldi and Epclusa, represent a significant change in the treatment paradigm for HCV-infected patients due to the shortened duration of treatment and the elimination of pegylated interferon injection and ribavirin in most patient populations. Because these products represent a cure and competitors' HCV products have entered the market, revenues from our HCV products in 2016 and beyond are difficult for us and investors to estimate. Demand for Harvoni, Sovaldi and Epclusa will depend on the availability of HCV patients and the extent of reimbursement of our HCV products by private and public payers in the United States and other countries. In addition, private and public payers can choose to exclude Harvoni, Sovaldi or Epclusa 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, Sovaldi and Epclusa. We have experienced, and we may continue to experience, pricing pressure in the United States, European Union, Japan and other countries. 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. In addition, because rebate claims for product discounts are made by payers one or two quarters in arrears, we estimate the rebates we will be required to pay in connection with sales during a particular quarter based on claims data from prior quarters. In the first quarter of 2016, we received higher than expected prior quarter rebate claims. This had the effect of lowering our revenue for the quarter. 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 six months ended June 30, 2016, approximately 92% 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 2015, 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 2016. 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), Veterans Administration (VA), 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. Additionally, during the second half of 2015, we experienced fluctuations in VA new HCV patient starts and purchasing patterns due to VA funding. 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 the United States, 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), calculated based on select government sales during the 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 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. Our BPD fee expenses were \$414 million in 2015, \$590 million in 2014 and \$110 million in 2013. We expect our portion of the BPD fee to increase as the total annual industry-wide fee increases through 2017 and drug patents expire on major drugs of other companies. The BPD fee is not tax deductible. In addition, 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. Further, certain states have proposed legislation that seeks to regulate pharmaceutical drug pricing. If such proposed legislation is passed, we may experience additional pricing pressures on our products. 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 in the markets where we sell our products. Government health authorities, private health insurers and other organizations generally provide reimbursement. In the United States, the European Union, Japan 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. A significant portion of our sales of the majority of our products are subject to significant discounts from list price. 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."

Pricing for pharmaceutical products has come under increasing scrutiny by governments, legislative bodies and enforcement agencies. These activities may result in actions that have the effect of reducing prices or harming our business or reputation.

In July 2014, we received a letter from the U.S. Senate Committee on Finance (Senate Committee) 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. In December 2015, the Senate Committee released the results of the investigation, which alleged that we engaged in a revenue-driven pricing strategy in setting Sovaldi's price. Gilead disagrees with many of the conclusions in the report. In January 2016, we received a letter from the Massachusetts Attorney General advising that their office is considering whether our pricing of Sovaldi and Harvoni may constitute an unfair trade practice in violation of Massachusetts law. In February 2016, the Massachusetts Attorney General's office served us with a Civil Investigative Demand (CID) requesting that we produce documents related to our HCV products. In July 2016, the Massachusetts Attorney General's office notified us of their decision to suspend Gilead's

obligations under the CID until further notice. In February 2016, we received a subpoena from the U.S. Attorney's Office for the District of Massachusetts requesting documents related to our support of 501(c)(3) organizations that provide financial assistance to patients, and for our HCV products, documents concerning our provision of financial assistance to patients. Other companies have disclosed similar inquiries. We are cooperating with this inquiry. It is possible that the results of the Senate Committee investigation and any actions taken by the U.S. Department of Justice, the Massachusetts Attorney General or other state governments could result in civil penalties or injunctive relief, negative publicity or other negative actions that could harm our reputation, reduce demand for Harvoni, Sovaldi, Epclusa or other sofosbuvir containing products and/or reduce coverage of Harvoni, Sovaldi, Epclusa or other sofosbuvir containing products, including by federal health care programs such as Medicare

and Medicaid and state health care programs. If any or all of these events occur, our business and stock price could be materially and adversely affected.

Approximately 40% 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 and Yen, 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.

We use foreign currency exchange forward and option contracts to hedge a percentage of our forecasted international sales, primarily those denominated in the Euro and Yen. 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 \$115 million and \$300 million on our product sales for the three and six months ended June 30, 2016, respectively, compared to the same periods in 2015.

We cannot predict future fluctuations in the foreign currency exchange rates 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, Sovaldi and Epclusa, compete with Viekira Pak (ombitasvir, paritaprevir and ritonavir tablets co-packaged with dasabuvir tablets) and Viekira XR (dasabuvir, ombitasvir, paritaprevir and ritonavir) marketed by AbbVie Inc. (AbbVie), Zepatier (elbasvir and grazoprevir) marketed by Merck & Co. Inc. (Merck), Daklinza (daclastavir) marketed by BMS and Olysio (simeprevir) marketed by Janssen Therapeutics.

Our HIV products compete primarily with products from ViiV Healthcare (ViiV), which markets fixed-dose combination products that compete with Descovy, Odefsey, Genvoya, Stribild, Complera/Eviplera, Atripla and Truvada. For example, 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. In addition, lamivudine, marketed by ViiV, competes with emtricitabine, the active pharmaceutical ingredient of Emtriva and a component of Genvoya, Stribild, Complera/Eviplera, Atripla and Truvada. For Tybost, we compete with ritonavir marketed by AbbVie.

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 in the United States in December 2017. We have observed some pricing pressure related to the Sustiva component of our Atripla sales.

Our HBV products, Viread and Hepsera, face competition from Baraclude (entecavir) marketed by BMS as well as generic entecavir. Our HBV products also compete with Tyzeka/Sebivo (telbivudine) marketed by Novartis Pharmaceuticals Corporation (Novartis).

Zydelig competes with Imbruvica (ibrutinib) marketed by Pharmacyclics LLC (an AbbVie company), Gazyva (obinutuzumab) marketed by Genentech (a member of the Roche Group) and Treanda (bendamustine hydrochloride) marketed by Cephalon, Inc.

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

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

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

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

AmBisome competes with Vfend (voriconazole) marketed 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. 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.

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.

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, Epclusa, Truvada, Atripla, Stribild, Complera/Eviplera, Viread, Genvoya, Descovy, Odefsey, Emtriva, Tybost, Vitekta, Letairis, Ranexa, Cayston, Zydelig and Hepsera 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, how we manufacture and sell our products is 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 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 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. For example, in January 2016, we announced that we terminated our Phase 2 trial of simtuzumab for the treatment of idiopathic pulmonary fibrosis after results showed a lack of treatment benefit. 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 the single-tablet regimen of bictegravir (formerly GS-9883), emtricitabine and TAF, the single-tablet regimen of sofosbuvir, velpatasvir and voxilaprevir (formerly GS-9857) for the treatment of chronic HCV, idelalisib for the treatment of relapsed refractory chronic lymphocytic leukemia; momelotinib for the treatment of myelofibrosis; eleclazine for the treatment of long QT-3 syndrome; and GS-5745 for the treatment of ulcerative colitis and gastric cancer, 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 Odefsey and 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 eease 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 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 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.

Tenofovir disoproxil fumarate, one of the active pharmaceutical ingredients in Stribild, Complera/Eviplera, Atripla and Truvada, is expected to face generic competition in the United States and European Union in 2017, which may have an impact on our business and results of operations. In addition, patents do not cover the ranolazine compound, the active ingredient of Ranexa. Instead, when it was discovered that only a sustained-release formulation of ranolazine would achieve therapeutic plasma levels, patents were obtained on those formulations and the characteristic plasma levels they achieve. Patents do not cover the active ingredients in AmBisome.

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

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 Note 10 Commitments and Contingencies of the Notes to Condensed Consolidated Financial Statements included in this Quarterly Report on Form 10-Q 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 49.

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 Note 10 Commitments and Contingencies of the Notes to Condensed Consolidated Financial Statements included in this Quarterly Report on Form 10-Q and the risk factor entitled "If any party is successful in establishing exclusive rights to Harvoni, Sovaldi and/or Epclusa, our expected revenues and earnings from the sale of Harvoni, Sovaldi and/or Epclusa could be adversely affected" beginning on page 45. Furthermore, we also rely on unpatented trade secrets and improvements, unpatented internal know-how and technological innovation. 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, Sovaldi and/or Epclusa, our expected revenues and earnings from the sale of Harvoni, Sovaldi and/or Epclusa 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 combinations of ledipasvir and sofosbuvir (Harvoni) and sofosbuvir and velpatasvir (Epclusa). 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, Sovaldi or Epclusa. 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, Sovaldi and Epclusa. We cannot predict the ultimate outcome of intellectual property claims related to Harvoni, Sovaldi or Epclusa, 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, Sovaldi and/or Epclusa, 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 a proceeding before the USPTO designed to determine who was the first to invent the subject matter claimed by both parties. In January 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 we 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 is related to the Idenix patent application at issue in the First Idenix Interference and includes claims directed to methods of treating HCV with nucleoside compounds. 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. In March 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 have responded to the appeal filed in the CAFC. The CAFC has not yet set a hearing date for this appeal. The Delaware court has stayed the appeal relating to the Second Idenix Interference.

We believe that the Idenix claims involved in the First and Second Idenix Interferences, and similar U.S. and foreign patents claiming the same compounds, metabolites and uses thereof, are invalid. As a result, we filed an Impeachment Action in the Federal Court of Canada to invalidate Idenix Canadian Patent No. 2,490,191 (the '191 patent), which is the Canadian patent that corresponds to the '600 patent. Idenix 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. In November 2015, the Canadian court held that Idenix's patent is invalid and that Gilead's patent is valid. Idenix appealed the decision to the Canadian Federal Court of Appeal in November 2015.

We filed a similar legal action in Norway in the Oslo District Court seeking to invalidate Idenix's Norwegian patent corresponding to the '600 patent. In September 2013, Idenix filed an invalidation action in the Norwegian proceedings against our Norwegian Patent No. 333700 patent, which corresponds to the '572 patent. In March 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. Idenix appealed the decision to the Norwegian Court of Appeal. In April 2016, the Court of Appeal issued its decision invalidating the Idenix patent and upholding the Gilead patent. Idenix has not filed a further appeal.

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 infringes its Australian patent corresponding to the '600 patent. In March 2016, the Australia court revoked Idenix's patent. Idenix has appealed this decision. The appeal hearing is scheduled for November 2016. In March 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. An opposition hearing was held in February 2016, and the EPO ruled in our favor and revoked the '489 patent. In March 2014, Idenix also initiated infringement proceedings against us 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. Idenix appealed. The appeal hearing was held in July 2016. In March 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 hearing held by the EPO in February 2016. Idenix has not appealed this decision of the German court staying the proceedings. Upon Idenix's request, the French proceedings have been stayed; however, in March 2016, Idenix requested that the French litigation be reactivated.

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. In June 2014, the court transferred the Massachusetts litigation to the U.S. District Court for the District of Delaware. The Delaware 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 & Co. Inc. (Merck) in August 2014, and Merck continues to pursue the Idenix claims described herein.

#### 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 No. 7,105,499 (the '499 patent) and U.S. Patent No. 8,481,712 (the '712 patent), which it co-owns with Isis Pharmaceuticals, Inc. The '499 and '712 patents cover compounds which do not include, but may relate to, sofosbuvir. We filed a lawsuit in August 2013 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. During patent prosecution, Merck amended its patent application in an attempt to cover compounds related to sofosbuvir. Initially, in March 2016, a jury determined that we had not established that Merck's patents are invalid for lack of written description or lack of enablement and awarded Merck \$200 million in damages. However, in June 2016, the court ruled in our favor on our defense of unclean hands. As a result, the court determined that Merck may not recover any damages from us for the '499 and '712 patents. We have filed a motion seeking recovery of certain fees and have requested judgment that the jury's earlier verdict should be vacated. Once the court has heard and ruled on our motions, the case will be ready for appeal. Merck has filed a notice of appeal to the Court of Appeals for the Federal Circuit regarding the court's decision on our defense of unclean hands.

If the decision on our defense of unclean hands is reversed on appeal, we may be required to pay damages and a royalty on sales of sofosbuvir-containing products following the appeal. In that event, the judge has indicated that she will determine the amount of the royalty, if necessary, at the conclusion of any appeal in this case. 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 (the AbbVie Patents) which purport to cover the use of a combination of LDV/SOF (or Harvoni) for the treatment of HCV. We are 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 LDV/SOF. 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 products 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. The AbbVie Patents have not blocked the commercialization of our combination products. The court has set a trial date of July 31, 2017 for this lawsuit.

In August 2015, we filed an impeachment action against AbbVie seeking a declaration that AbbVie's Canadian Patent No. 2,811,250 (the '250 patent), which purports to cover the use of a combination of LDV/SOF for the treatment of

HCV, is invalid. On the same day, AbbVie filed an infringement action against us asserting that commercialization of Harvoni in Canada will infringe the '250 patent. The impeachment action has been stayed and we have counterclaimed for invalidity in the infringement proceeding. The court has set a trial date of April 11, 2018 for this impeachment action.

Additionally, AbbVie has obtained Canadian Patent No. 2,857,339 (the '339 patent) which purports to cover a solid composition that contains ledipasvir. In November 2015, AbbVie filed an infringement action against us asserting that

commercialization of Harvoni in Canada infringes the '339 patent. We have filed a counterclaim asserting the invalidity of AbbVie's patent. The court has set a trial date of October 15, 2018 for this impeachment action. In November 2015, AbbVie filed a lawsuit against us in the Regional Court Düsseldorf for infringement of two quasi-patents, known as "utility models." Utility models are unexamined IP rights and are not the same as standard patents. One utility model, DE 20 2012 013 117, purports to cover the use of a combination of direct-acting antivirals which includes at least an HCV polymerase inhibitor and an HCV NS5A inhibitor in the treatment of HCV; the other utility model, DE 21 2012 000 197, purports to cover a solid dispersion that includes ledipasvir. The court has set a trial date of March 23, 2017 for this lawsuit.

#### **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. In January 2016, several parties filed oppositions in the EPO requesting revocation of our granted European patent covering TAF that expires in 2021. In March 2016, three parties filed oppositions in the EPO requesting revocation of our granted European patent covering cobicistat that expires in 2027. While we are confident in the strength of our patents, 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, TAF and cobicistat in Europe could be substantially shortened or eliminated entirely. If our patents are revoked, and no other European patents are granted covering these compounds, our exclusivity may be based entirely on regulatory exclusivity granted by the 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.

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 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. If we are unable to remedy any deficiencies cited by FDA in these inspections, our currently marketed products and the timing of regulatory approval of products in development could be adversely affected. Further, there is risk that regulatory agencies in other countries where marketing applications are pending will undertake similar additional reviews or apply a heightened standard of review, which could delay the regulatory approvals for products in those countries. If approval of any of our product candidates were delayed or if production of our marketed products was interrupted, our

anticipated revenues and our stock price would be adversely affected.

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

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

Suppliers of key components and materials must be named in the NDA or MAA filed with 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 amphotericin B, the active pharmaceutical ingredient of AmBisome, and high-quality cholesterol in the manufacture of AmBisome. We also rely on a single source for the active pharmaceutical ingredients found in Letairis and Cayston. 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 (including Harvoni, Sovaldi, Epclusa, Truvada, Atripla, Stribild, Complera/Eviplera, Viread, Genvoya, Descovy, Odefsey and Emtriva) 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, 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:

#### **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 version of Truvada 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 lawsuits against Apotex in the Federal Court of Canada seeking orders of prohibition against approval of these ANDSs. A hearing in those cases was held in April 2016. In July 2016, the court issued an order prohibiting the Canadian Minister of Health from approving Apotex's generic version of our Viread product until the expiry of our patents in July 2017. The court declined to prohibit approval of Apotex's generic version of our Truvada product. The court's decision did not rule on the validity of the patents. The launch of Apotex's generic version of our Truvada product would be at risk of infringement of our patents, including patents that we were unable to assert in the present lawsuit, and liability for our damages. Apotex may elect to appeal the decision.

In November 2011, December 2011 and August 2012, we received notices that Teva Pharmaceuticals (Teva) submitted an abbreviated new drug submission (ANDS) to the Canadian Minister of Health requesting permission to manufacture and market generic versions of Truvada, Atripla and Viread. In the notices, Teva alleges that the patents associated with Truvada, Atripla and Viread are invalid, unenforceable and/or will not be infringed by Teva's manufacture, use or sale of generic versions of those products. We filed lawsuits against Teva in the Federal Court of Canada seeking an order of prohibition against approval of these applications.

In December 2013, the court issued an order prohibiting the Canadian Minister of Health from approving Teva's generic versions of our Viread, Truvada and Atripla products until expiry of our patent in July 2017. Teva has appealed that decision. The court's decision did not rule on the validity of the patents and accordingly the only issue on appeal is whether the Canadian Minister of Health should be prohibited from approving Teva's products. The appeal will be heard by the Canadian Federal Court of Appeal after the trial in the Impeachment Action filed by Teva in August 2012 seeking invalidation of one of our Canadian patents associated with Viread. The court will determine the validity of the patent in the pending Impeachment Action. A trial in the Impeachment Action is scheduled for November 2016. If Teva is successful in invalidating the patent, 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 February 2016, we received notice that Mylan Pharmaceuticals, Inc. (Mylan) submitted an ANDA to FDA requesting permission to manufacture and market a generic version of Tybost (cobicistat). In the notice, Mylan alleges that the patent covering cobicistat is invalid as obvious and that Mylan's generic product cannot infringe an invalid claim. In March 2016, we filed lawsuits against Mylan in the U.S. District Court for the District of Delaware and U.S. District Court for the Northern District of West Virginia. The trial in Delaware is scheduled for January 2018. The patent in suit that covers Tybost is also listed in the Orange Book for Stribild and Genvoya. Aurobindo

In May 2016, we received notices that Aurobindo Pharma (Aurobindo) submitted ANDAs to FDA requesting permission to manufacture and market generic versions of Emtriva and Truvada. In the notices, Aurobindo alleges that two of the patents associated with our emtricitabine tablets and four of the patents associated with our emtricitabine and tenofovir disoproxil fumarate fixed dose combination tablets are invalid, unenforceable and/or will not be infringed by Aurobindo's manufacture, use or sale of generic versions of Emtriva and Truvada, respectively. In June 2016 and July 2016, we filed lawsuits against Aurobindo in the U.S. District Court for the District of New Jersey for infringement of the patents associated with Emtriva and Truvada.

## Watson

In February 2015, we received notice that Watson Laboratories, Inc. (Watson) submitted an ANDA to 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 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, FDA or the Canadian Minister of Health could approve the requests to manufacture a generic version of such products in the United States or Canada, respectively, prior to the expiration date of those patents. The sale of generic versions of these products earlier than their patent expiration would have a significant negative effect on our revenues and results of operations. We face credit risks from our Emerging Market and Southern European customers that may adversely affect our results of operations.

We have exposure to customer credit risks in emerging markets and Southern Europe. Southern European product sales to government-owned or supported customers in Southern Europe, specifically Spain, Italy, Portugal and Greece have historically been 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 June 30, 2016, our accounts receivable in Southern Europe, specifically Greece, Italy, Portugal and Spain, totaled approximately \$630 million, of which \$171 million were greater than 120 days past due, including \$36 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.

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 LDV/SOF 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, investigation and other dispute-related matters in Note 10 Commitments and Contingencies of the Notes to Condensed Consolidated Financial Statements included in this Quarterly Report on Form 10-Q. The outcome of such lawsuits or any other lawsuits that may be brought against us, the investigations 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. 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 may not carry adequate 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, 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 subject to audit by federal, state and foreign tax authorities. We are currently under examination by the IRS for the 2010, 2011 and 2012 tax years and by various state and foreign jurisdictions. There are differing interpretations of tax laws and regulations, and as a result, significant disputes may arise with these tax authorities involving issues of the timing and amount of deductions and allocations of income among various tax jurisdictions. 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.

Our Board of Directors authorized a dividend program under which we intend to pay quarterly dividends of \$0.47 per share, subject to quarterly declarations by our Board of Directors. Our Board of Directors also approved the repurchase of up to an additional \$12.0 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 April 2016, we completed the \$15.0 billion share repurchase program authorized in January 2015 (2015 Program). In February 2016, our Board of Directors authorized a \$12.0 billion share repurchase program (2016 Program) under which repurchases may be made in the open market or in privately negotiated transactions.

During the second quarter of 2016, we repurchased approximately 10 million shares of our common stock for an aggregate purchase price of \$1.0 billion through open market transactions.

The table below summarizes our stock repurchase activity under both 2015 and 2016 Programs for the three months ended June 30, 2016:

Total

	Total Number of Shares Purchased (in thousands)		P po (i	verage rice Paid er Share n ollars)		Number of Shares Purchased as Part of Publicly Announced Program (in thousands)		the Pu	aximum Fair alue of Shares at May Yet Be archased Under e Program n millions)
2015 Program April 1 - April 30, 2016 2016 Program	8,149	(2)	\$	92.09	(2)	8,149	(2)	\$	_
April 1 - April 30, 2016	8,490		\$	97.82		8,466		\$	11,172
May 1 - May 31, 2016	1,214		\$	85.52		1,178		\$	11,071
June 1 - June 30, 2016	867		\$	84.22		844		\$	11,000
Total	18,720	(1)	\$	93.90		18,637	(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

In February 2016, we entered into an accelerated stock repurchase program (ASR) to purchase \$5.0 billion of our common stock under our 2015 Program. We made an upfront payment of \$5.0 billion and received 46 million

<sup>(2)</sup> shares of our common stock under the ASR program. In April 2016, at the end of the purchase period, the ASR was settled and an additional 8 million shares were received and retired. In total, 54 million shares were received under this ASR at an average repurchase price of \$92.09 per share.