GILEAD SCIENCES INC
Form 10-Q
November 07, 2016

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

FORM 10-Q

ý QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2016
or
o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____
Commission File No. 0-19731

GILEAD SCIENCES, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	94-3047598
(State or Other Jurisdiction of Incorporation or Organization)	(IRS Employer Identification No.)

333 Lakeside Drive, Foster City, California	94404
(Address of principal executive offices)	(Zip Code)

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ý No ¨
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ý No ¨
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.
Large accelerated filer ý Accelerated filer ¨ Non-accelerated filer ¨ Smaller reporting company ¨
(Do not check if a smaller reporting company)

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

Number of shares outstanding of the issuer's common stock, par value $0.001 per share, as of October 31, 2016: 1,317,456,071

GILEAD SCIENCES, INC.
INDEX

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)

	September 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 9,809	$ 12,851
Short-term marketable securities	2,457	1,756
Accounts receivable, net of allowances of $935 at September 30, 2016 and $1,032 at December 31, 2015	5,075	5,854
Inventories	1,900	1,955
Deferred tax assets	762	828
Prepaid and other current assets	1,422	1,518
Total current assets	21,425	24,762
Property, plant and equipment, net	2,714	2,276
Long-term portion of prepaid royalties	439	400
Long-term deferred tax assets	481	324
Long-term marketable securities	19,345	11,601
Intangible assets, net	9,386	10,247
Goodwill	1,172	1,172
Other long-term assets	1,647	934
Total assets	$ 56,609	$ 51,716
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,052	$ 1,178
Accrued government and other rebates	5,482	4,118
Other accrued liabilities	3,478	3,172
Deferred revenues	361	440
Current portion of long-term debt and other obligations, net	700	982
Total current liabilities	11,073	9,890
Long-term debt, net	26,371	21,073
Long-term income taxes payable	1,621	1,243
Other long-term obligations	184	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 September 30, 2016 and December 31, 2015; shares issued and outstanding of 1,322 at September 30, 2016 and 1,422 at December 31, 2015	1	1
Additional paid-in capital	321	444
Accumulated other comprehensive income (loss)	(108)	88
Retained earnings	16,654	18,001
Total Gilead stockholders' equity	16,868	18,534
Noncontrolling interest	492	579
Total stockholders' equity	17,360	19,113

Total liabilities and stockholders' equity	$ 56,609	$ 51,716

See accompanying notes.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenues:				
Product sales	$7,405	$8,211	$22,737	$23,742
Royalty, contract and other revenues	95	84	333	391
Total revenues	7,500	8,295	23,070	24,133
Costs and expenses:				
Cost of goods sold	1,129	1,064	3,186	2,944
Research and development expenses	1,141	743	3,890	2,257
Selling, general and administrative expenses	831	903	2,406	2,360
Total costs and expenses	3,101	2,710	9,482	7,561
Income from operations	4,399	5,585	13,588	16,572
Interest expense	(242)	(165)	(699)	(458)
Other income (expense), net	119	52	288	108
Income before provision for income taxes	4,276	5,472	13,177	16,222
Provision for income taxes	951	880	2,788	2,801
Net income	3,325	4,592	10,389	13,421
Net loss attributable to noncontrolling interest	(5)	(8)	(4)	(4)
Net income attributable to Gilead	$3,330	$4,600	$10,393	$13,425
Net income per share attributable to Gilead common stockholders - basic	$2.52	$3.14	$7.72	$9.11
Shares used in per share calculation - basic	1,322	1,463	1,347	1,474
Net income per share attributable to Gilead common stockholders - diluted	$2.49	$3.06	$7.59	$8.73
Shares used in per share calculation - diluted	1,339	1,503	1,369	1,538
Cash dividends declared per share	$0.47	$0.43	$1.37	$0.86

See accompanying notes.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Net income	$3,325	$4,592	$10,389	$13,421
Other comprehensive income (loss):				
Net foreign currency translation gains (losses), net of tax	(50)	3	(39)	(4)
Available-for-sale securities:				
Net unrealized gains, net of tax impact of $1, $0, $19 and $2, respectively	29	—	159	3
Reclassifications to net income, net of tax	(6)	—	(8)	—
Net change	23	—	151	3
Cash flow hedges:				
Net unrealized gains (losses), net of tax impact of $2, $11, $(9) and $14, respectively	(45)	49	(249)	322
Reclassifications to net income, net of tax impact of $(1), $(5), $(8) and $(14), respectively	10	(132)	(59)	(455)
Net change	(35)	(83)	(308)	(133)
Other comprehensive loss	(62)	(80)	(196)	(134)
Comprehensive income	3,263	4,512	10,193	13,287
Comprehensive loss attributable to noncontrolling interest	(5)	(8)	(4)	(4)
Comprehensive income attributable to Gilead	$3,268	$4,520	$10,197	$13,291

See accompanying notes.

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

	Nine Months Ended September 30,	
	2016	2015
Operating Activities:		
Net income	$10,389	$13,421
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation expense	129	116
Amortization expense	737	704
Stock-based compensation expense	278	285
Excess tax benefits from stock-based compensation	(162)	(498)
Tax benefits from exercise and vesting of stock-based awards	157	499
Deferred income taxes	(95)	(442)
In-process research and development impairment	231	—
Other	(15)	34
Changes in operating assets and liabilities:		
Accounts receivable, net	770	(1,610)
Inventories	(274)	(659)
Prepaid expenses and other	(785)	(167)
Accounts payable	(115)	288
Income taxes payable	1,029	523
Accrued liabilities	1,057	2,617
Deferred revenues	(148)	344
Net cash provided by operating activities	13,183	15,455
Investing Activities:		
Purchases of marketable securities	(19,881)	(12,291)
Proceeds from sales of marketable securities	10,376	2,464
Proceeds from maturities of marketable securities	1,131	371
Other investments	(357)	—
Capital expenditures	(579)	(581)
Net cash used in investing activities	(9,310)	(10,037)
Financing Activities:		
Proceeds from debt financing, net of issuance costs	5,293	9,902
Proceeds from convertible note hedges	956	600
Proceeds from issuances of common stock	180	281
Repurchases of common stock	(10,001)	(6,951)
Repayments of debt and other obligations	(1,251)	(763)
Payments to settle warrants	(469)	(3,865)
Payments of dividends	(1,836)	(1,260)
Excess tax benefits from stock-based compensation	162	498
Payment of contingent consideration	(3)	(2)
Contributions from (distributions to) noncontrolling interest	(83)	141
Net cash used in financing activities	(7,052)	(1,419)

Effect of exchange rate changes on cash and cash equivalents	137	(61)
Net change in cash and cash equivalents	(3,042)	3,938
Cash and cash equivalents at beginning of period	12,851	10,027
Cash and cash equivalents at end of period	$9,809	$13,965

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 or 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 September 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 September 30, 2016, our accounts receivable in Southern Europe, specifically Greece, Italy, Portugal and Spain, totaled approximately $566 million, of which $132 million were greater than 120 days past due, including $62 million greater than 365 days past due. To date, we have not experienced significant losses with respect to the collection of our accounts receivable. We believe that our allowance for doubtful accounts was adequate at September 30, 2016.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (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 “Revenue from Contracts with Customers: Principal vs. Agent Considerations,” ASU 2016-10 “Revenue from Contracts with Customers: Identifying Performance Obligations and Licensing” and 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. We plan to adopt the guidance in the first quarter of 2017 on a retrospective basis and will reclassify current deferred tax amounts on our Condensed Consolidated Balance Sheets as noncurrent.

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 plan to adopt the guidance in the first quarter of 2017. 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 costs 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):

	September 30, 2016				December 31, 2015			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Assets:								
Money market funds	$7,362	$—	$ —	$7,362	$10,161	$—	$ —	$10,161
Corporate debt securities	—	11,180	—	11,180	—	5,773	—	5,773
U.S. treasury securities	5,176	—	—	5,176	4,389	—	—	4,389
Residential mortgage and asset-backed securities	—	3,359	—	3,359	—	1,695	—	1,695
U.S. government agencies securities	—	1,234	—	1,234	—	707	—	707
Non-U.S. government securities	—	609	—	609	—	313	—	313
Certificates of deposit	—	244	—	244	—	448	—	448
Municipal debt securities	—	30	—	30	—	34	—	34
Equity securities	432	—		432	—	—	—	—
Foreign currency derivative contracts	—	65	—	65	—	210	—	210
Deferred compensation plan	82	—	—	82	66	—	—	66
	$13,052	$16,721	$ —	$29,773	$14,616	$9,180	$ —	$23,796
Liabilities:								
Contingent consideration	$—	$—	$ 25	$25	$—	$—	$ 59	$59
Deferred compensation plan	82	—	—	82	66	—	—	66
Foreign currency derivative contracts	—	162	—	162	—	41	—	41
	$82	$162	$ 25	$269	$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 Ratings Services, 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 exchange 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 $29.3 billion at September 30, 2016 and $23.7 billion at December 31, 2015, and the carrying values were $27.1 billion at September 30, 2016 and $22.1 billion at December 31, 2015.

8

Level 3 Inputs

As of September 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):

	September 30, 2016				December 31, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds	$7,362	$ —	$ —	$7,362	$10,161	$ —	$ —	$10,161
Corporate debt securities	11,152	35	(7)	11,180	5,795	1	(23)	5,773
U.S. treasury securities	5,172	6	(2)	5,176	4,407	—	(18)	4,389
Residential mortgage and asset-backed securities	3,349	11	(1)	3,359	1,701	—	(6)	1,695
U.S. government agencies securities	1,234	1	(1)	1,234	709	—	(2)	707
Non-U.S. government securities	609	1	(1)	609	315	—	(2)	313
Certificates of deposit	244	—	—	244	448	—	—	448
Municipal debt securities	30	—	—	30	34	—	—	34
Equity securities	357	75	—	432	—	—	—	—
Total	$29,509	$ 129	$ (12)	$29,626	$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):

	September 30, 2016	December 31, 2015
Cash and cash equivalents	$ 7,392	$ 10,163
Short-term marketable securities	2,457	1,756
Long-term marketable securities	19,345	11,601
Other long-term assets	432	—
Total	$ 29,626	$ 23,520

Cash and cash equivalents in the table above exclude cash of $2.4 billion as of September 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):

	September 30, 2016	
	Amortized Cost	Fair Value
Less than one year	$9,848	$9,849
Greater than one year but less than five years	18,620	18,661
Greater than five years but less than ten years	531	531
Greater than ten years	153	153
Total	$29,152	$29,194

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 Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value
September 30, 2016						
Corporate debt securities	$(6)	$ 3,565	$—	$ 166	$(6)	$ 3,731
U.S. treasury securities	(2)	1,810	—	—	(2)	1,810
Residential mortgage and asset-backed securities	(1)	389	(1)	35	(2)	424
U.S. government agencies securities	(1)	553	—	—	(1)	553
Non-U.S. government securities	(1)	299	—	11	(1)	310
Total	$(11)	$ 6,616	$(1)	$ 212	$(12)	$ 6,828
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	—	20	(6)	1,646
U.S. government agencies securities	(2)	707	—	—	(2)	707
Non-U.S. government securities	(2)	313	—	—	(2)	313
Municipal debt securities	—	21	—	—	—	21
Total	$(51)	$ 11,900	$—	$ 63	$(51)	$ 11,963

We held a total of 1,058 positions as of September 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 September 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 nine months ended September 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 and the gains or losses are reclassified into product sales when the hedged transactions affect earnings. The majority of gains and losses related to the hedged forecasted transactions reported in AOCI at September 30, 2016 are expected to be reclassified to product sales within 12 months.

The cash flow effects of our derivative contracts for the nine months ended September 30, 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 $8.8 billion at September 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):

	September 30, 2016			
	Asset Derivatives		Liability Derivatives	
	Classification	Fair Value	Classification	Fair Value
Derivatives designated as hedges:				
Foreign currency exchange contracts	Other current assets	$ 57	Other accrued liabilities	$(156)
Foreign currency exchange contracts	Other long-term assets	7	Other long-term obligations	(5)
Total derivatives designated as hedges		64		(161)
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		$ 65		$(162)

	December 31, 2015			
	Asset Derivatives		Liability Derivatives	
	Classification	Fair Value	Classification	Fair Value
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)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Derivatives designated as hedges:				
Gains (losses) recognized in AOCI (effective portion)	$(43)	$60	$(258)	$336

Gains (losses) reclassified from AOCI into product sales (effective portion)	$(9)	$137	$67	$469
Gains recognized in Other income (expense), net (ineffective portion and amounts excluded from effectiveness testing)	$11	$4	$38	$11
Derivatives not designated as hedges:				
Gains (losses) recognized in Other income (expense), net	$(62)	$21	$(328)	$89

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 nine months ended September 30, 2016 and 2015 as a result of the discontinuance of cash flow hedges.

As of September 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):

Description	Gross Amounts of Recognized Assets/Liabilities	Gross Amounts Offset in the Condensed Consolidated Balance Sheet	Amounts of Assets/Liabilities Presented in the Condensed Consolidated Balance Sheet	Gross Amounts Not Offset in the Condensed Consolidated Balance Sheet		Net Amount (Legal Offset)
				Derivative Financial Instruments	Cash Collateral Received/Pledged	
As of September 30, 2016						
Derivative assets	$ 65	$ —	$ 65	$ (65)	$ —	$ —
Derivative liabilities	(162)	—	(162)	65	—	(97)
As of December 31, 2015						
Derivative assets	$ 210	$ —	$ 210	$ (38)	$ —	$ 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):

	September 30, 2016	December 31, 2015
Raw materials	$ 1,522	$ 1,332
Work in process	553	542
Finished goods	891	852
Total	$ 2,966	$ 2,726

Reported as:		
Inventories	$ 1,900	$ 1,955
Other long-term assets	1,066	771
Total	$ 2,966	$ 2,726

Amounts reported as Other long-term assets primarily consisted of raw materials as of September 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 September 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):

	September 30, 2016	December 31, 2015
Prepaid taxes	$ 322	$ 773
Other prepaid expenses	280	240
Other current assets	820	505
Total prepaid and other current assets	$ 1,422	$ 1,518

Other accrued liabilities

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

	September 30, 2016	December 31, 2015
Output tax payable	$ 599	$ 376
Branded prescription drug fee	405	649
Income taxes payable	390	65
Other accrued expenses	2,084	2,082
Total other accrued liabilities	$ 3,478	$ 3,172

6. INTANGIBLE ASSETS

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

	September 30, 2016	December 31, 2015
Finite-lived intangible assets	$ 9,185	$ 9,815
Indefinite-lived intangible assets	201	432
Total intangible assets	$ 9,386	$ 10,247

Finite-Lived Intangible Assets

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

	September 30, 2016		December 31, 2015	
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Intangible asset - sofosbuvir	$10,720	$ 1,981	$10,720	$ 1,456
Intangible asset - Ranexa	688	437	688	363
Other	455	260	455	229
Total	$11,863	$ 2,678	$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 $630 million for the three and nine months ended September 30, 2016 and $206 million and $619 million for the three and nine months ended September 30, 2015, respectively. As of September 30, 2016, the estimated future amortization expense associated with our finite-lived intangible assets for the remaining three months of 2016 and each of the five succeeding fiscal years and thereafter is as follows (in millions):

Fiscal Year	Amount
2016 (remaining three months)	$ 209
2017	844
2018	849
2019	741
2020	713
2021 and thereafter	5,829
Total	$ 9,185

Indefinite-Lived Intangible Assets

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

	September 30, 2016	December 31, 2015
Indefinite-lived intangible asset - momelotinib	$ 201	$ 315
Indefinite-lived intangible asset - Other	—	117
Total	$ 201	$ 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. In the third quarter of 2016, the estimated fair value of our Indefinite-lived intangible asset - Other, related to simtuzumab, declined to zero due to changes in clinical development plans, and as a result, we recorded an impairment charge of $117 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. During the third quarter of 2016, based on the achievement of certain clinical development milestones, we recorded a $200 million expense 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 September 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):

	September 30, 2016	December 31, 2015
Total assets	$ 2,117	$ 2,464
Cash and cash equivalents	126	166
Accounts receivable, net	260	269
Inventories	1,721	2,027
Total liabilities	936	1,055
Accounts payable	519	606
Other accrued liabilities	417	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 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 September 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 the 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	September 30, 2016	December 31, 2015 [1]
Convertible Notes	July 2010	May 2016	1.625%	$ —	$ 283
Senior Unsecured	December 2011	December 2016	3.05%	700	699
Senior Unsecured	September 2015	September 2018	1.85%	998	997
Senior Unsecured	March 2014	April 2019	2.05%	498	498
Senior Unsecured	November 2014	February 2020	2.35%	498	497
Senior Unsecured	September 2015	September 2020	2.55%	1,991	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 2016	March 2022	1.95%	497	—
Senior Unsecured	September 2015	September 2022	3.25%	995	995
Senior Unsecured	September 2016	September 2023	2.50%	744	—
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 2016	March 2027	2.95%	1,243	—
Senior Unsecured	September 2015	September 2035	4.60%	989	988
Senior Unsecured	September 2016	September 2036	4.00%	739	—
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
Senior Unsecured	September 2016	March 2047	4.15%	1,722	—
Floating-rate Borrowings	May 2016	May 2019	Variable	341	—
Total debt, net				$ 27,071	$ 22,055
Less current portion				700	982
Total long-term debt, net				$ 26,371	$ 21,073

[1] 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 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.

Convertible Notes

During the nine months ended September 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.

Warrants associated with our Convertible Notes (the 2016 Warrants) expired 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, and as a result, we paid $469 million as the market value of our common stock at the time of the settlement of the warrants exceeded their strike price. There were 9 million shares of our common stock underlying the 2016 Warrants, which had a strike price of $27.86 per share at the time of our exercise. Because the warrants could have been settled at our option, in cash or shares of our common stock, and the related contracts met

all of the applicable criteria for equity classification, the settlement was recorded as a reduction of Additional paid-in capital in our Condensed Consolidated Balance Sheet.

September 2016 Issuance of Senior Unsecured Notes

We issued $5.0 billion aggregate principal amount of senior unsecured notes in September 2016 (collectively, the 2016 Senior Notes), in five tranches with maturities ranging from 2022 to 2047, the terms of which are summarized in the table above.

The 2016 Senior Notes may be redeemed at our option at a redemption price equal to the greater of (i) 100% of the principal amount of the notes to be redeemed and (ii) the sum, as determined by an independent investment banker, of the present value of the remaining scheduled payments of principal and interest on the notes to be redeemed (exclusive of interest accrued to the date of redemption) discounted to the redemption date on a semiannual basis at the Treasury Rate plus 12.5 basis points for the notes due in March 2022, 15 basis points for the notes due in September 2023, 20 basis points for the notes due in March 2027, 25 basis points for the notes due in September 2036 and 25 basis points for the notes due in March 2047. The 2016 Senior Notes also have a call feature, exercisable at our option, to redeem the notes at par in whole or in part one to six months immediately preceding maturity. In each case, accrued and unpaid interest is also required to be redeemed to the date of redemption.

In the event of the occurrence of a change in control and a downgrade in the rating of the 2016 Senior Notes below investment grade by Standard & Poor's Ratings Services and Moody's Investors Service, Inc., the holders may require us to purchase all or a portion of their notes at a price equal to 101% of the aggregate principal amount of the notes repurchased, plus accrued and unpaid interest to the date of repurchase.

We intend to use the net proceeds for general corporate purposes, which may include the repayment of debt, working capital, payment of cash dividends, the repurchase of our outstanding common stock pursuant to our authorized share repurchase program and future acquisitions.

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 September 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 September 30, 2016, we were not in violation of any covenants.

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 to determine who was the first to invent certain nucleoside compounds. In January 2014, the USPTO Patent Trial and Appeal Board (PTAB) determined that Pharmasset and not Idenix was the first to invent the compounds. Idenix has appealed the PTAB’s decisions to the U.S. District Court for the District of Delaware.

In December 2013, after receiving our request to do so, the USPTO declared Interference No. 105,981 (Second Idenix Interference) between our pending U.S. Patent Application No. 11/854,218 and Idenix’s U.S. Patent No. 7,608,600 (the ’600 patent). The ’600 patent includes claims directed to methods of treating HCV with nucleoside compounds. 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). The CAFC heard oral arguments in September 2016, and we are awaiting its decision. We filed a motion to dismiss the appeal in Delaware, and the 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 our ’572 patent, is invalid. In November 2015, the Canadian court held that Idenix’s patent is invalid and that our 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 our 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 our 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 Australian 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. Idenix has appealed. 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. 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. Idenix has not been awarded patents corresponding to the ’600 patent in Japan or China.

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 for 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 and determined that Merck may not recover any damages from us for the ’499 and ’712 patents. 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. The judge has determined that Merck is required to pay our attorneys’ fees due to the exceptional nature of this case. The amount of fees owed to us by Merck is yet to be determined by the court.

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. We appealed the issue relating to the invalidity of Merck’s patent. If the decision on our defense of unclean hands is reversed on appeal and Merck’s patent is upheld, 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 the University of Minnesota

The University of Minnesota (the University) has obtained Patent No. 8,815,830 (the ’830 patent), which purports to broadly cover nucleosides with antiviral and anticancer activity. In August 2016, the University filed a lawsuit against us in the U.S. District Court for the District of Minnesota, alleging that the commercialization of sofosbuvir-containing products infringes the ’830 patent. We believe that the ’830 patent is invalid and will not be infringed by the continued commercialization of sofosbuvir.

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 granted, 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.

Since December 2013, several lawsuits were filed in the United States and several foreign jurisdictions, including Canada, Australia, Sweden, Switzerland, Germany and others by both Gilead and AbbVie regarding the AbbVie Patents. The AbbVie Patents have not blocked or delayed the commercialization of our combination products in the United States or any other country.

In August 2016, we and AbbVie entered into a settlement agreement to resolve the ongoing contested proceedings concerning the AbbVie Patents. Terms of the settlement are confidential.

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 October 2016, the EPO upheld the validity of certain claims of our sofosbuvir patent. We anticipate that the challengers will appeal this decision in favor of our patent. The appeal process may take several years.

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 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 has appealed the court's 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. In September 2016, we and Aurobindo reached agreement to settle those lawsuits. Terms of the settlement are confidential.

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 sought 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 has appealed the court's decision dismissing the challenge to the validity of our TAF patents.

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.

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 Stockholders' Equity						
	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Retained Earnings	Noncontrolling Interest	Total Stockholders' Equity
	Shares	Amount					
Balance at December 31, 2015	1,422	$ 1	$ 444	$ 88	$18,001	$ 579	$ 19,113
Net income	—	—	—	—	10,393	(4)	10,389
Other comprehensive loss, net of tax	—	—	—	(196)	—	—	(196)
Change in noncontrolling interest	—	—	—	—	—	(83)	(83)
Issuances under employee stock purchase plan	1	—	84	—	—	—	84
Issuances under equity incentive plans	11	—	93	—	—	—	93
Stock-based compensation	—	—	278	—	—	—	278
Tax benefits from employee stock plans	—	—	157	—	—	—	157
Repurchases of common stock	(112)	—	(268)	—	(9,897)	—	(10,165)
Convertible Notes settlement	—	—	(95)	—	—	—	(95)
Convertible note hedges settlement	—	—	95	—	—	—	95
Dividends declared	—	—	—	—	(1,843)	—	(1,843)
Reclassification of conversion spread of Convertible Notes	—	—	(733)	—	—	—	(733)
Reclassification of convertible note hedges	—	—	733	—	—	—	733
Warrants settlement	—	—	(469)	—	—	—	(469)
Reclassification to equity component of currently redeemable Convertible Notes	—	—	2	—	—	—	2
Balance at September 30, 2016	1,322	$ 1	$ 321	$ (108)	$16,654	$ 492	$ 17,360

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 Cash Flow Hedges	Total
Balance at December 31, 2015	$ (45)	$ (16)	$ 149	$88
Other comprehensive income (loss) before reclassifications	(39)	159	(249)	(129)
Amounts reclassified from AOCI	—	(8)	(59)	(67)
Net current period other comprehensive income (loss)	(39)	151	(308)	(196)
Balance at September 30, 2016	$ (84)	$ 135	$ (159)	$(108)

Amounts reclassified for gains or losses on cash flow hedges are recorded as part of Product sales in our Condensed Consolidated Statements of Income. Amounts reclassified for gains or 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 and third quarter of 2016, we repurchased and retired 10 million and 12 million shares of our common stock for $1.0 billion and $1.0 billion, through open market transactions, respectively.

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, during the third quarter of 2016, our 2016 Warrants expired, and we exercised our option to settle the warrants in cash. Prior to the settlement, our common stock resulting from the assumed settlement of the 2016 Warrants had a dilutive effect when the average market price of our common stock during the period exceeded the warrants' exercise price. As a result, we included their dilutive impact in our net income per share calculations. 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 nine months ended September 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):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Net income attributable to Gilead	$3,330	$4,600	$10,393	$13,425
Shares used in per share calculation - basic	1,322	1,463	1,347	1,474
Effect of dilutive securities:				
Stock options and equivalents	13	21	15	24
Conversion spread related to the Convertible Notes	—	12	2	14
Warrants related to the Convertible Notes	4	7	5	26
Shares used in per share calculation - diluted	1,339	1,503	1,369	1,538

Net income per share attributable to Gilead common stockholders - basic	$2.52	$3.14	$7.72	$9.11
Net income per share attributable to Gilead common stockholders - diluted	$2.49	$3.06	$7.59	$8.73

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 Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Antiviral products:				
Harvoni	$1,860	$3,332	$7,441	$10,519
Truvada	858	903	2,698	2,523
Sovaldi	825	1,466	3,460	3,729
Atripla	650	818	1,998	2,334
Epclusa	640	—	704	—
Stribild	621	511	1,527	1,314
Genvoya	461	—	921	—
Complera/Eviplera	411	360	1,160	1,047
Viread	303	297	862	802
Odefsey	105	—	174	—
Descovy	88	—	149	—
Other antiviral	19	15	56	53
Total antiviral products	6,841	7,702	21,150	22,321
Other products:				
Letairis	215	181	593	508
Ranexa	170	161	467	419
AmBisome	91	88	262	276
Zydelig	39	36	129	92
Other	49	43	136	126
Total product sales	$7,405	$8,211	$22,737	$23,742

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
McKesson Corp.	23%	28%	22%	26%
AmerisourceBergen Corp.	18%	19%	18%	20%
Cardinal Health, Inc.	16%	14%	16%	15%

14. INCOME TAXES

Our income tax rate of 22.2% and 21.2% for the three and nine months ended September 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.

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 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 nine months ended September 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 third 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:

- Announced positive results from four international Phase 3 clinical studies (POLARIS-1, POLARIS-2, POLARIS-3 and POLARIS-4) evaluating an investigational, once-daily, fixed-dose combination of sofosbuvir, velpatasvir and voxilaprevir, a pangenotypic NS3/4A protease inhibitor, for the treatment of genotype 1-6 chronic HCV infection. The primary endpoint for all these studies was sustained virologic response rates at 12 weeks after treatment (SVR12).
- Announced positive results from Phase 2 clinical study of GS-4997 (selonsertib), an investigational inhibitor of apoptosis signal-regulating kinase 1 (ASK1), in nonalcoholic steatohepatitis (NASH). GS-4997 demonstrated anti-fibrotic activity in an open-label Phase 2 clinical trial that included 72 patients with NASH and moderate to severe (F2-F3) liver fibrosis, who received treatment with GS-4997 alone or in combination with simtuzumab.

- The European Commission granted marketing authorization for once-daily Truvada (emtricitabine 200 mg/tenofovir disoproxil 245 mg) in combination with safer-sex practices to reduce the risk of sexually acquired HIV-1 infection among uninfected adults at high risk, a strategy known as pre-exposure prophylaxis, or PrEP. Truvada was approved by the European Medicines Agency in 2005 for use in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults aged 18 years and over, and is currently the most prescribed antiretroviral medicine in Europe as part of combination therapy.
- The European Commission granted marketing authorization for Epclusa (sofosbuvir 400 mg/velpatasvir 100 mg), the first pan-genotypic, single-tablet regimen for the treatment of adults with genotype 1-6 chronic HCV infection. Epclusa for 12 weeks was authorized for use in patients without cirrhosis or with compensated cirrhosis (Child-Pugh A), and in combination with ribavirin (RBV) for patients with decompensated cirrhosis (Child-Pugh B or C). Epclusa is also the first single-tablet regimen approved for the treatment of patients with HCV genotype 2 and 3, without the need for RBV. Physicians also have the flexibility to consider the addition of RBV for genotype 3 infected patients with compensated cirrhosis. The marketing authorization followed an accelerated review procedure by the European Medicines Agency, reserved for medicinal products expected to be of major public health interest.

Financial Highlights

Total revenues were $7.5 billion for the third quarter of 2016, compared to $8.3 billion in the third quarter of 2015, primarily due to lower product sales, which were $7.4 billion compared to $8.2 billion in the same quarter of 2015.

Research and development (R&D) expenses were $1.1 billion for the third quarter of 2016, compared to $743 million in the third quarter of 2015, primarily due to the overall progression of our clinical studies, including a $200 million milestone expense associated with our purchase of Nimbus Apollo, Inc. (Nimbus).

Selling, general and administrative (SG&A) expenses were $831 million for the third quarter of 2016, compared to $903 million in the third quarter of 2015, primarily due to lower branded prescription drug (BPD) fee expense.

Net income attributable to Gilead was $3.3 billion or $2.49 per diluted share for the third quarter of 2016, compared to $4.6 billion or $3.06 per diluted share for the third quarter of 2015, primarily due to lower product sales and higher R&D expenses, partially offset by lower SG&A expenses. Year-over-year earnings per share were favorably impacted by our share repurchase activities. During the first nine months of 2016, we repurchased a total of 110 million shares for $10.0 billion, of which 54 million shares or $5.0 billion were repurchased under an accelerated stock repurchase program.

As of September 30, 2016, we had $31.6 billion of cash, cash equivalents and marketable securities, compared to $24.6 billion as of June 30, 2016. During the third quarter of 2016, cash flow from operating activities was $4.3 billion.

Results of Operations

Total Revenues

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In millions, except percentages)	2016	2015	Change	2016	2015	Change
Revenues:						
Product sales	$7,405	$8,211	(10)%	$22,737	$23,742	(4)%
Royalty, contract and other revenues	95	84	13 %	333	391	(15)%
Total revenues	$7,500	$8,295	(10)%	$23,070	$24,133	(4)%

Product sales for the three months ended September 30, 2016

Total product sales were $7.4 billion for the three months ended September 30, 2016, compared to $8.2 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 $6.8 billion for the three months ended September 30, 2016, compared to $7.7 billion for the same period in 2015. HIV and other antiviral product sales were $3.5 billion for the three months ended September 30, 2016, compared to $2.9 billion for the same period in 2015. This increase was primarily driven by the continued uptake of our tenofovir

alafenamide (TAF)-based products, Genvoya, Descovy and Odefsey. HCV product sales, which consist of Harvoni, Sovaldi and Epclusa, were $3.3 billion for the three months ended September 30, 2016, compared to $4.8 billion for the same period in 2015. The decline was due to lower sales of Harvoni and Sovaldi, partially offset by sales of Epclusa, which was launched in the United States and Europe in June and July 2016, respectively.

Other product sales, which include sales of Letairis, Ranexa and AmBisome, were $564 million for the three months ended September 30, 2016, compared to $509 million for the same period in 2015.

Foreign currency exchange, net of hedges, had an unfavorable impact on our product sales of $108 million for the three months ended September 30, 2016, compared to the same period in 2015. Of our total product sales, 32% were generated outside the United States during the three months ended September 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 United States were $5.1 billion for the three months ended September 30, 2016, compared to $5.6 billion for the same period in 2015. Declines in sales of our HCV products were partially offset by increases in sales of our HIV and other antiviral products. The increases in the sales of our HIV and other antiviral products were primarily driven by sales of our newly launched TAF-based products and a favorable revision to our rebate reserves of $332 million, primarily related to our tenofovir disoproxil fumarate (TDF)-based products.

Product sales in Europe were $1.4 billion for the three months ended September 30, 2016, compared to $1.7 billion for the same period in 2015. The decrease was primarily due to lower Sovaldi and Harvoni sales volume. In addition, foreign currency exchange, net of hedges, had an unfavorable impact of $140 million on our product sales for the three months ended September 30, 2016, compared to the same period in 2015.

Product sales in Japan, which consist of Sovaldi and Harvoni, were $452 million for the three months ended September 30, 2016, compared to $454 million for the same period in 2015. Harvoni was launched in Japan in September 2015. Sales volume for Sovaldi declined, 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 $479 million for the three months ended September 30, 2016, compared to $504 million for the same period in 2015, primarily due to a lower average net selling price.

Product sales for the nine months ended September 30, 2016

Total product sales were $22.7 billion for the nine months ended September 30, 2016, compared to $23.7 billion for the same period in 2015, primarily due to a decrease in antiviral product sales.

Antiviral product sales were $21.2 billion for the nine months ended September 30, 2016, compared to $22.3 billion for the same period in 2015. HIV and other antiviral product sales were $9.5 billion for the nine months ended September 30, 2016, compared to $8.1 billion for the same period in 2015. The increase was primarily driven by the continued uptake of our TAF-based products, Genvoya, Descovy and Odefsey. HCV product sales were $11.6 billion for the nine months ended September 30, 2016, compared to $14.2 billion for the same period in 2015. The decrease was primarily due to lower sales of Harvoni and Sovaldi, partially offset by sales of Epclusa.

Other product sales, which include sales of Letairis, Ranexa and AmBisome, were $1.6 billion for the nine months ended September 30, 2016, compared to $1.4 billion for the same period in 2015.

Foreign currency exchange, net of hedges, had an unfavorable impact on our product sales of $392 million for the nine months ended September 30, 2016, compared to the same period in 2015. Of our total product sales, 37% were generated outside the United States during the nine months ended September 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 United States were $14.3 billion for the nine months ended September 30, 2016, compared to $16.4 billion for the same period in 2015. Declines in sales of our HCV products were partially offset by increases in sales of our HIV and other antiviral products. The increases in the sales of our HIV and other antiviral products were primarily driven by sales of our newly launched TAF- based products and a favorable revision to our rebate reserves of $332 million, primarily related to our TDF-based products.

Product sales in Europe were $4.7 billion for the nine months ended September 30, 2016, compared to $5.5 billion for the same period in 2015. The decrease was primarily due to lower Sovaldi sales volume and lower average net selling prices of our HCV products. In addition, foreign currency exchange, net of hedges, had an unfavorable impact of $386 million on our product sales for the nine months ended September 30, 2016, compared to the same period in 2015.

Product sales in Japan, which consist of Sovaldi and Harvoni, were $2.2 billion for the nine months ended September 30, 2016, compared to $516 million for the same period in 2015. The increase was primarily driven by higher sales

volume as Sovaldi and Harvoni were launched in Japan in May and September 2015, respectively. The increase was partially offset by a mandatory price reduction of 32% that was effective April 1, 2016.

Product sales in other international locations were $1.6 billion for the nine months ended September 30, 2016, compared to $1.4 billion for the same period in 2015, primarily driven by continued launches of our HCV products.

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

(In millions, except percentages)	Three Months Ended September 30, 2016	2015	Change	Nine Months Ended September 30, 2016	2015	Change
Antiviral products:						
Harvoni	$1,860	$3,332	(44)%	$7,441	$10,519	(29)%
Truvada	858	903	(5)%	2,698	2,523	7 %
Sovaldi	825	1,466	(44)%	3,460	3,729	(7)%
Atripla	650	818	(21)%	1,998	2,334	(14)%
Epclusa	640	—	*	704	—	*
Stribild	621	511	22 %	1,527	1,314	16 %
Genvoya	461	—	*	921	—	*
Complera/Eviplera	411	360	14 %	1,160	1,047	11 %
Viread	303	297	2 %	862	802	7 %
Odefsey	105	—	*	174	—	*
Descovy	88	—	*	149	—	*
Other antiviral	19	15	27 %	56	53	6 %
Total antiviral products	6,841	7,702	(11)%	21,150	22,321	(5)%
Other products:						
Letairis	215	181	19 %	593	508	17 %
Ranexa	170	161	6 %	467	419	11 %
AmBisome	91	88	3 %	262	276	(5)%
Zydelig	39	36	8 %	129	92	40 %
Other	49	43	14 %	136	126	8 %
Total product sales	$7,405	$8,211	(10)%	$22,737	$23,742	(4)%

* 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 nine months ended September 30, 2016 accounted for 27% and 35% of our total antiviral product sales, respectively.

For the three months ended September 30, 2016, net product sales of Harvoni were $1.1 billion in the United States, $380 million in Europe, $309 million in Japan and $87 million in other international locations, compared to $2.5 billion in the United States, $532 million in Europe, $111 million in Japan and $148 million in other international locations for the same period in 2015. In the United States, the decrease was primarily due to lower sales volume compared to Harvoni's early launch levels during the prior year and a lower average net selling price. The number of patients that started treatment with Harvoni in the United States peaked in the first half of 2015, as many warehoused patients initiated treatment after the product launch. In Europe, the decrease was primarily due to lower sales volume. Additionally, we have seen a slight decline in average treatment duration, as European 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. The increase was driven by higher sales volume, partially offset by a mandatory price reduction of 32% that was effective April 1, 2016. In other international locations, the decrease was primarily due to lower sales volume.

For the nine months ended September 30, 2016, net product sales of Harvoni were $4.0 billion in the United States, $1.4 billion in Europe, $1.6 billion in Japan and $385 million in other international locations, compared to $8.4 billion in the United States, $1.6 billion in Europe, $111 million in Japan and $393 million in other international locations for the same period in 2015. In the United States, the decrease was primarily due to lower sales volume and a lower average net selling price, which was partially offset by a favorable revision to our Harvoni sales return reserve of $181

million recorded during the second quarter of 2016. The number of patients that started treatment with Harvoni in the United States peaked in the first half of 2015, as many warehoused patients initiated treatment after the product launch.

In Europe, the decrease was primarily due to unfavorable foreign currency exchange, net of hedges, and a lower average net selling price. In Japan, the increase was driven by higher sales volume, partially offset by a mandatory price reduction of 32% that was effective April 1, 2016. In other international locations, the decrease was primarily due to a lower average net selling price, partially offset by the continued launches of Harvoni.

•Truvada

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

For the three months ended September 30, 2016, net product sales of Truvada were $573 million in the United States, $217 million in Europe and $68 million in other international locations, compared to $561 million in the United States, $268 million in Europe and $74 million in other international locations for the same period in 2015. The overall decrease was primarily due to lower sales volume.

For the nine months ended September 30, 2016, net product sales of Truvada were $1.8 billion in the United States, $713 million in Europe and $205 million in other international locations, compared to $1.5 billion in the United States, $846 million in Europe and $207 million in other international locations for the same period in 2015. The overall increase was primarily driven by a higher average net selling price and higher sales volume, primarily driven by increased usage of Truvada for PrEP.

•Sovaldi

Net product sales of Sovaldi for the three and nine months ended September 30, 2016 accounted for 12% and 16% of our total antiviral product sales, respectively.

For the three months ended September 30, 2016, net product sales of Sovaldi were $363 million in the United States, $184 million in Europe, $143 million in Japan and $135 million in other international locations, compared to $692 million in the United States, $337 million in Europe, $343 million in Japan and $94 million in other international locations for the same period in 2015. In the United States and Europe, the decrease was primarily due to lower sales volume. In Japan, the decrease was primarily due to lower sales volume and a mandatory price reduction of 32% that was effective April 1, 2016. In other international locations, the increase was primarily driven by the continued launches of Sovaldi.

For the nine months ended September 30, 2016, net product sales of Sovaldi were $1.8 billion in the United States, $727 million in Europe, $516 million in Japan and $434 million in other international locations, compared to $1.7 billion in the United States, $1.3 billion in Europe, $405 million in Japan and $254 million in other international locations for the same period in 2015. In the United States, the increase was primarily driven by higher sales volume and a favorable revision to our Sovaldi sales return reserve of $98 million recorded during the second quarter of 2016. In Europe, the decrease was primarily due to lower sales volume and a lower average net selling price. In Japan, the increase was primarily driven by higher sales volume due to the launch of Sovaldi in May 2015, partially offset by a mandatory price reduction of 32% that was effective April 1, 2016. In other international locations, the increase was primarily driven by the continued launches of Sovaldi.

•Atripla

Net product sales of Atripla for the three and nine months ended September 30, 2016 accounted for 10% and 9% of our total antiviral product sales, respectively.

For the three months ended September 30, 2016, net product sales of Atripla were $486 million in the United States and $129 million in Europe, compared to $597 million in the United States and $161 million in Europe for the same period in 2015. The decrease was primarily due to a decline 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 $242 million of our Atripla sales for the three months ended September 30, 2016, compared to $307 million for the same period in 2015.

For the nine months ended September 30, 2016, net product sales of Atripla were $1.5 billion in the United States and $412 million in Europe, compared to $1.6 billion in the United States and $533 million in Europe for the same period in 2015. The decrease was primarily due to a decline 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 $736 million of our Atripla sales for the nine months ended September 30, 2016, compared to $865 million

for the same period of 2015.

•Epclusa

Net product sales of Epclusa for the three and nine months ended September 30, 2016 accounted for 9% and 3% of

our total antiviral product sales, respectively. Epclusa was launched in the United States and Europe in June and July 2016, respectively.

During the three and nine months ended September 30, 2016, net product sales of Epclusa were $640 million and $704 million, respectively, primarily driven by sales in the United States.

- Stribild

Net product sales of Stribild for the three and nine months ended September 30, 2016 accounted for 9% and 7% of our total antiviral product sales, respectively.

For the three months ended September 30, 2016, net product sales of Stribild were $525 million in the United States and $78 million in Europe, compared to $422 million in the United States and $73 million in Europe for the same period in 2015. The increase was primarily due to a favorable revision to our rebate reserves of $223 million, partially offset by lower sales volume as a result of the continued launch of our new TAF-based product, Genvoya.

For the nine months ended September 30, 2016, net product sales of Stribild were $1.2 billion in the United States and $243 million in Europe, compared to $1.1 billion in the United States and $199 million in Europe for the same period in 2015. The increase was primarily due to a favorable revision to our rebate reserves of $223 million during the third quarter of 2016, partially offset by lower sales volume as a result of the continued launch of our new TAF-based product, Genvoya.

- TAF-based regimens - Genvoya, Descovy and Odefsey

Net product sales of our recently launched TAF-based regimens for the three and nine months ended September 30, 2016 accounted for 10% and 6% of our total antiviral product sales, respectively. Genvoya was launched in the United States and Europe in November 2015. Descovy was launched in the United States and Europe in April 2016. Odefsey was launched in the United States in March 2016 and launched in Europe in July 2016.

For the three months ended September 30, 2016, net product sales of Genvoya were $461 million, primarily driven by sales in the United States of $407 million.

For the nine months ended September 30, 2016, net product sales of Genvoya were $921 million, primarily driven by sales in the United States of $816 million.

- Complera/Eviplera:

Net product sales of Complera/Eviplera for the three and nine months ended September 30, 2016, accounted for 6% and 5% of our total antiviral product sales, respectively.

For the three months ended September 30, 2016, net product sales of Complera/Eviplera were $254 million in the United States and $143 million in Europe, compared to $210 million in the United States and $137 million in Europe for the same period in 2015. The increase was primarily due to a favorable revision to our rebate reserves of $89 million, partially offset by lower sales volume as a result of the continued launch of our new TAF-based products.

For the nine months ended September 30, 2016, net product sales of Complera/Eviplera were $675 million in the United States and $445 million in Europe, compared to $580 million in the United States and $427 million in Europe for the same period in 2015. The increase was primarily due to a favorable revision to our rebate reserves of $89 million during the third quarter of 2016.

While we have seen continued strength in our HIV and other product sales, there has been a slowing of HCV patient treatments in the United States, Europe and Japan, since the time when Harvoni was launched in these markets, 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 United States 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 Months Ended September 30,		Nine Months Ended September 30,	
(In millions, except percentages)	2016	2015	2016	2015
Cost of goods sold	$1,129	$1,064	$3,186	$2,944
Product gross margin	85 %	87 %	86 %	88 %

The product gross margin changes in the three and nine months ended September 30, 2016 compared to the same periods in 2015 were primarily due to changes in product mix.

Operating Expenses

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In millions, except percentages)	2016	2015	Change	2016	2015	Change
Research and development expenses	$1,141	$743	54 %	$3,890	$2,257	72 %
Selling, general and administrative expenses	$831	$903	(8)%	$2,406	$2,360	2 %

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 payments under collaboration arrangements, milestone payments, personnel costs, including salaries and benefits, stock-based compensation and overhead allocations consisting of various support and facilities-related costs.

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

R&D expenses for the three months ended September 30, 2016 increased by $398 million or 54%, compared to the same period in 2015, primarily due to the overall progression of our clinical studies, including a $200 million milestone expense associated with our purchase of Nimbus, and an impairment charge of $117 million related to simtuzumab.

R&D expenses for the nine months ended September 30, 2016 increased by $1.6 billion or 72%, compared to the same period in 2015, primarily due to our collaboration and acquisition related expenses, including our purchase of Nimbus and our license and collaboration agreement with Galapagos, the purchase of a U.S. Food and Drug Administration priority review voucher, R&D impairment charges related to momelotinib and simtuzumab, and the overall progression of clinical studies.

Selling, General and Administrative Expenses

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

SG&A expenses for the three months ended September 30, 2016 decreased by $72 million or 8%, compared to the same period in 2015, primarily due to lower BPD fee expense.

SG&A expenses for the nine months ended September 30, 2016 increased by $46 million or 2%, 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 lower BPD fee expense of $151 million. 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 September 30, 2016 was $242 million, compared to $165 million for the same period in 2015. Interest expense for the nine months ended September 30, 2016 was $699 million, compared to $458 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 and 2016. For more information see Note 9 Debt and Credit Facility of the Notes to Condensed Consolidated Financial Statements included in this Quarterly Report on Form 10-Q.

Provision for Income Taxes

Provision for income taxes for the three months ended September 30, 2016 was $951 million, compared to $880 million for the same period in 2015. Our effective tax rate was 22.2% for the three months ended September 30, 2016, compared to 16.1% for the same period in 2015.

Provision for income taxes for the nine months ended September 30, 2016 and 2015 was $2.8 billion. Our effective tax rate was 21.2% for the nine months ended September 30, 2016, compared to 17.3% for the same period in 2015. The effective tax rates for the three and nine months ended September 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 nine months ended September 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:

(In millions)	September 30, 2016	December 31, 2015
Cash, cash equivalents and marketable securities	$ 31,611	$ 26,208
Working capital	$ 10,352	$ 14,872

Cash, Cash Equivalents and Marketable Securities

Cash, cash equivalents and marketable securities totaled $31.6 billion at September 30, 2016, an increase of $5.4 billion when compared to $26.2 billion at December 31, 2015. A discussion of the key drivers of our cash flows follows below.

Of the total cash, cash equivalents and marketable securities at September 30, 2016, approximately $25.2 billion was generated from operations in foreign jurisdictions and is intended for use in our foreign operations. We do not rely on unrepatriated earnings as a source of funds for our domestic business as we expect to have sufficient cash flow and borrowing capacity in the United States to fund our domestic operational and strategic needs.

Working Capital

Working capital was $10.4 billion at September 30, 2016, compared to $14.9 billion at December 31, 2015. The decrease of $4.5 billion was primarily due to a decline in cash and cash equivalents.

Cash Flows

The following table summarizes our cash flow activities:

	Nine months ended September 30,	
(In millions)	2016	2015
Cash provided by (used in):		
Operating activities	$13,183	$15,455
Investing activities	$(9,310)	$(10,037)

Financing activities	$(7,052)	$(1,419)

Cash Provided by Operating Activities

Cash provided by operating activities was $13.2 billion for the nine months ended September 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 $10.4 billion for non-cash items of $1.3 billion and changes in operating assets and liabilities of $1.5 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 associated with our R&D pipeline progression.

For the nine months ended September 30, 2016, compared to the same period in 2015, the decrease in cash provided by operating activities was primarily due to lower net income.

Cash Used in Investing Activities

Cash used in investing activities for the nine months ended September 30, 2016 was $9.3 billion, consisting of $8.4 billion net purchases of marketable securities, $357 million of other investments related to our agreement with Galapagos and $579 million in capital expenditures related to the expansion of our business.

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

Cash Used in Financing Activities

Cash used in financing activities for the nine months ended September 30, 2016 was $7.1 billion, consisting primarily of $10.0 billion used to repurchase our common stock under our stock repurchase programs, $1.8 billion used to pay cash dividends, and $469 million used to settle the remaining warrants associated with our convertible senior notes due in May 2016 (the 2016 Warrants). These payments were primarily offset by $5.3 billion net proceeds from our debt issuances. Of our $10.0 billion common stock repurchases, $5.0 billion was through an accelerated stock repurchase program and $5.0 billion was through open market transactions.

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 nine months ended September 30, 2015 was $1.4 billion, consisting primarily of $7.0 billion used to repurchase our common stock under our stock repurchase programs, $3.9 billion used to settle a portion of the 2016 Warrants and $1.3 billion used to pay cash dividends. These payments were primarily offset by $9.9 billion in net proceeds from the issuance of our 2015 Notes.

Debt and Credit Facility

Debt Financing

In September 2016, we issued $5.0 billion aggregate principal amount of senior unsecured notes (collectively, the 2016 Senior Notes). We intend to use the net proceeds for general corporate purposes, which may include the repayment of debt, working capital, payment of cash dividends, the repurchase of our outstanding common stock pursuant to our authorized share repurchase program and future acquisitions. The 2016 Senior Notes may be redeemed before their maturity dates, in whole or in part, based on terms and circumstances as described in Note 9 Debt and Credit Facility of the Notes to Condensed Consolidated Financial Statements included in this Quarterly Report on Form 10-Q.

Convertible Notes

During the nine months ended September 30, 2016, our remaining convertible senior notes due in May 2016 (the 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.

The 2016 Warrants expired 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, and as a result, we paid

$469 million as the market value of our common stock at the time of the settlement of the warrants exceeded their strike price. There were 9 million shares of our common stock underlying the 2016 Warrants, which had a strike price of $27.86 per share at the time of our exercise. Because the warrants could have been settled at our option, in cash or shares of our common stock, and the related contracts met all of the applicable criteria for equity classification, the settlement was recorded as a reduction of Additional paid-in capital in our Condensed Consolidated Balance Sheet.

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 September 30, 2016, there were no amounts outstanding under the revolving credit facility.

The summary of our borrowings under various financing arrangements is included Note 9 Debt and Credit Facility of the Notes to Condensed Consolidated Financial Statements included in this Quarterly Report on Form 10-Q. There were no other material changes to our debt and credit facility during the first nine 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 nine months ended September 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 Note 1 Summary of Significant Accounting Policies of the Notes to Condensed Consolidated Financial Statements included in this Quarterly Report on Form 10-Q.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There have been no material changes in our market risk during the nine months ended September 30, 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 September 30, 2016, our accounts receivable in Southern Europe, specifically Greece, Italy, Portugal and Spain, totaled approximately $566 million, of which $132 million were greater than 120 days past due, including $62 million greater than 365 days past due. To date, we have not experienced significant losses with respect to the collection of our accounts receivable. We believe that our allowance for doubtful accounts was adequate at September 30, 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 September 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 September 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 September 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 Note 10 Commitments and Contingencies of the Notes to Condensed Consolidated Financial Statements included in this Quarterly Report on Form 10-Q.

Item 1A. RISK FACTORS

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

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

During the nine months ended September 30, 2016, sales of Harvoni, Sovaldi and Epclusa for the treatment of HCV accounted for approximately 51% 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 second quarter of 2015 as warehoused patients started treatment in large numbers. Since then, the number of new patient starts has diminished, and we have seen the slowing of patient starts in the United States, Europe and Japan. 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, which include Descovy, Odefsey, Genvoya, Truvada, Stribild, Complera/Eviplera and Atripla. During the nine months ended September 30, 2016, sales of our HIV products accounted for approximately 42% of our total product sales. Most of our HIV products contain tenofovir alafenamide (TAF), tenofovir disoproxil fumarate (TDF) 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, TDF, 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, during 2016 we announced that we terminated our Phase 2 and 2b studies of simtuzumab for the treatment of idiopathic pulmonary fibrosis, nonalcoholic steatohepatitis and primary sclerosing cholangitis, our Phase 2 and 2/3 studies of GS-5745 for the treatment of Crohn's Disease and ulcerative colitis, our Phase 2 studies of GS-4997 for the treatment of pulmonary arterial hypertension and diabetic kidney disease, and our Phase 2 study of eleclazine for the treatment of ventricular tachycardia/ventricular fibrillation.

In the first quarter of 2016, we filed our new drug application (NDA) and marketing authorization application (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 nine months ended September 30, 2016, approximately 89% 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. We disagree with many of the conclusions in the report. 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 or 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 37% 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 $108 million and $392 million on our product sales for the three and nine months ended September 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, during 2016 we announced that we terminated our Phase 2 and 2b studies of simtuzumab for the treatment of idiopathic pulmonary fibrosis, nonalcoholic steatohepatitis and primary sclerosing cholangitis, our Phase 2 and 2/3 studies of GS-5745 for the treatment of Crohn's Disease and ulcerative colitis, our Phase 2 studies of GS-4997 for the treatment of pulmonary arterial hypertension and diabetic kidney disease, and our Phase 2 study of eleclazine for the treatment of ventricular tachycardia/ventricular fibrillation, after determining that study data showed insufficient evidence 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, emtricitabine and TAF, the single-tablet regimen of sofosbuvir, velpatasvir and voxilaprevir 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 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
- cease operations.

We also rely on a third party to administer our Letairis Education and Access Program (LEAP), the restricted distribution program designed to support Letairis. This third party provides information and education to prescribers and patients on the risks of Letairis, confirms insurance coverage and investigates alternative sources of reimbursement or assistance, ensures fulfillment of the risk management requirements mandated for Letairis by 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. We are also aware of U.S. Patent No. 9044509 assigned to the U.S. Department of Health and Human Services that purports to claim a process of protecting a primate host from infection by an immunodeficiency retrovirus by administering a combination of emtricitabine and tenofovir or tenofovir disoproxil fumarate prior to exposure of the host to the immunodeficiency retrovirus. See also 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 to determine who was the first to invent certain nucleoside compounds. In January 2014, the USPTO Patent Trial and Appeal Board (PTAB) determined that Pharmasset and not Idenix was the first to invent the compounds. Idenix has appealed the PTAB’s decisions to the U.S. District Court for the District of Delaware.

In December 2013, after receiving our request to do so, the USPTO declared Interference No. 105,981 (Second Idenix Interference) between our pending U.S. Patent Application No. 11/854,218 and Idenix’s U.S. Patent No. 7,608,600 (the ’600 patent). The ’600 patent includes claims directed to methods of treating HCV with nucleoside compounds. 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). The CAFC heard oral arguments in September 2016, and we are awaiting its decision. We filed a motion to dismiss the appeal in Delaware, and the 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 our ’572 patent, is invalid. In November 2015, the Canadian court held that Idenix’s patent is invalid and that our 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 our 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 our 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 Australian 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. Idenix has appealed. 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. 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. Idenix has not been awarded patents corresponding to the '600 patent in Japan or China. 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 for 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 and determined that Merck may not recover any damages from us for the ’499 and ’712 patents. The judge has determined that Merck is required to pay our attorneys’ fees due to the exceptional nature of this case. The amount of fees owed to us by Merck is yet to be determined by the court.

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. We appealed the issue relating to the invalidity of Merck’s patent. If the decision on our defense of unclean hands is reversed on appeal and Merck’s patent is upheld, 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 the University of Minnesota

The University of Minnesota (the University) has obtained Patent No. 8,815,830 (’830 patent), which purports to broadly cover nucleosides with antiviral and anticancer activity. In August 2016, the University filed a lawsuit against us in the U.S. District Court for the District of Minnesota, alleging that the commercialization of sofosbuvir-containing products infringes the ’830 patent. We believe that the ’830 patent is invalid and will not be infringed by the continued commercialization of sofosbuvir.

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 granted, 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.

Since December 2013, several lawsuits were filed in the United States and several foreign jurisdictions, including Canada, Australia, Sweden, Switzerland, Germany and others, by both Gilead and AbbVie regarding the AbbVie Patents. The AbbVie Patents have not blocked or delayed the commercialization of our combination products in the United States or any other country.

In August 2016, we and AbbVie entered into a settlement agreement to resolve the ongoing contested proceedings concerning the AbbVie Patents. Terms of the settlement are confidential.

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 October 2016, the EPO upheld the validity of certain claims of our sofosbuvir patent. We anticipate that the challengers will appeal this decision in favor of our patent. The appeal process may take several years.

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 has appealed the court's decision.

Teva

In November 2011, December 2011 and August 2012, we received notices that Teva Pharmaceuticals (Teva) submitted an 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.

Mylan

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. In September 2016, we and Aurobindo reached agreement to settle those lawsuits. Terms of the settlement are confidential.

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 September 30, 2016, our accounts receivable in Southern Europe, specifically Greece, Italy, Portugal and Spain, totaled approximately $566 million, of which $132 million were greater than 120 days past due, including $62 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 versions of our HCV products to 101 developing countries. If generic versions of our HIV and HCV products 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. We also make our HCV products available in low- and middle-income countries at significantly discounted prices. If the discounted HCV products are re-exported from these low- and middle-income 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 $12.0 billion of our common stock, of which $10 billion is available for repurchase as of September 30, 2016. 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 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.

During the third quarter of 2016, we repurchased approximately 12 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 the 2016 Program for the three months ended September 30, 2016:

	Total Number of Shares Purchased (in thousands)	Average Price Paid per Share (in dollars)	Total Number of Shares Purchased as Part of Publicly Announced Program (in thousands)	Maximum Fair Value of Shares that May Yet Be Purchased Under the Program (in millions)
July 1 - July 31, 2016	11,837	$ 85.08	11,749	$ 10,000
August 1 - August 31, 2016	252	$ 78.90	—	$ 10,000
September 1 - September 30, 2016	21	$ 78.05	—	$ 10,000
Total	12,110 [(1)]	$ 84.94	11,749 [(1)]	

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

Item 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

Item 5. OTHER INFORMATION

Not applicable.

Item 6. EXHIBITS

Reference is made to the Exhibit Index included herein.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

GILEAD SCIENCES, INC.
(Registrant)

Date: November 7, 2016 /s/ JOHN F. MILLIGAN
John F. Milligan, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 7, 2016 /s/ ROBIN L. WASHINGTON
Robin L. Washington
Executive Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit Index

Exhibit Footnote	Exhibit Number	Description of Document
(1)	1.1	Underwriting Agreement, dated September 15, 2016, among Registrant and Merrill Lynch, Pierce, Fenner & Smith Incorporated and J.P. Morgan Securities LLC, as representatives of the several underwriters listed in Schedule 1 thereto
†(2)	2.1	Agreement and Plan of Merger among Registrant, Merger Sub and Pharmasset, Inc., dated as of November 21, 2011
(3)	3.1	Restated Certificate of Incorporation of Registrant
(4)	3.2	Amended and Restated Bylaws of Registrant
	4.1	Reference is made to Exhibit 3.1 and Exhibit 3.2
(5)	4.2	Indenture related to Senior Notes, dated as of March 30, 2011, between Registrant and Wells Fargo, National Association, as Trustee
(5)	4.3	First Supplemental Indenture related to Senior Notes, dated as of March 30, 2011, between Registrant and Wells Fargo, National Association, as Trustee (including form of Senior Notes)
(6)	4.4	Second Supplemental Indenture related to Senior Notes, dated as of December 13, 2011, between Registrant and Wells Fargo, National Association, as Trustee (including Form of 2014 Note, Form of 2016 Note, Form of 2021 Note, Form of 2041 Note)
(7)	4.5	Third Supplemental Indenture related to Senior Notes, dated as of March 7, 2014, between Registrant and Wells Fargo, National Association, as Trustee (including Form of 2019 Note, Form of 2024 Note, Form of 2044 Note)
(8)	4.6	Fourth Supplemental Indenture related to Senior Notes, dated as of November 17, 2014, between Registrant and Wells Fargo, National Association, as Trustee (including Form of 2020 Note, Form of 2025 Note, Form of 2045 Note)
(9)	4.7	Fifth Supplemental Indenture, dated as of September 14, 2015, between Registrant and Wells Fargo Bank, National Association, as Trustee (including Form of 2018 Note, Form of 2020 Note, Form of 2022 Note, Form of 2026 Note, Form of 2035 Note and Form of 2046 Note)
(1)	4.8	Sixth Supplemental Indenture, dated as of September 20, 2016, between Registrant and Wells Fargo Bank, National Association, as Trustee (including Form of 2022 Note, Form of 2023 Note, Form of 2027 Note, Form of 2036 Note and Form of 2047 Note)
(10)	10.1	Confirmation of OTC Warrant Transaction, dated July 26, 2010, between Registrant and Goldman, Sachs & Co. for warrants expiring in 2016
(10)	10.2	Confirmation of OTC Warrant Transaction, dated July 26, 2010, between Registrant and JPMorgan Chase Bank, National Association for warrants expiring in 2016
(11)	10.3	

		Confirmation of OTC Additional Warrant Transaction, dated August 5, 2010, between Registrant and Goldman, Sachs & Co. for warrants expiring in 2016
(11)	10.4	Confirmation of OTC Additional Warrant Transaction, dated August 5, 2010, between Registrant and JPMorgan Chase Bank, National Association for warrants expiring in 2016
(12)	10.5	Amendment to Base Warrants (2016), dated May 8, 2015, between Registrant and Goldman, Sachs & Co.
(12)	10.6	Amendment to Base Warrants (2016), dated May 8, 2015, between Registrant and JPMorgan Chase Bank, National Association
*(3)	10.7	Gilead Sciences, Inc. 2004 Equity Incentive Plan, as amended through May 8, 2013
*(13)	10.8	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants prior to February 2008)
*(14)	10.9	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants made February 2008 through April 2009)
*(15)	10.10	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants commencing in May 2009)
*(16)	10.11	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants commencing in February 2010)
*(17)	10.12	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for 2011 and subsequent year grants)
*(14)	10.13	Form of non-employee director stock option agreement used under 2004 Equity Incentive Plan (for grants prior to 2008)
*(14)	10.14	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for initial grants made in 2008)
*(14)	10.15	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for annual grants made in May 2008 and through May 2012)
*(15)	10.16	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for annual grants commencing in May 2009 and through May 2012)
*(18)	10.17	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for annual grants made in May 2013)
*(18)	10.18	Form of non-employee director option agreement (non-U.S.) used under 2004 Equity Incentive Plan (for annual grants made in May 2013)
*(19)	10.19	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for annual grants made in and after May 2014)
*(20)	10.20	

		Form of restricted stock unit issuance agreement used under 2004 Equity Incentive Plan (for annual grants to non-employee directors in May 2012)
*(15)	10.21	Form of restricted stock award agreement used under 2004 Equity Incentive Plan (for annual grants to certain non-employee directors prior to May 2012)
*(18)	10.22	Form of restricted stock unit issuance agreement used under 2004 Equity Incentive Plan (for annual grants to non-employee directors commencing in May 2013)
*(19)	10.23	Form of restricted stock unit issuance agreement used under 2004 Equity Incentive Plan (for annual grants to non-employee directors commencing in and after May 2014)
*(18)	10.24	Form of restricted stock unit issuance agreement (non-U.S.) used under 2004 Equity Incentive Plan (for annual grants to non-employee directors commencing in May 2013)
*(15)	10.25	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for grants to certain executive officers made in 2009)
*(16)	10.26	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for grants to certain executive officers made in 2010)
*(17)	10.27	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for grants to certain executive officers made in 2011)
*(18)	10.28	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for grants to certain executive officers made in 2012)
*(21)	10.29	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for TSR Goals in 2013 and 2014)
*(22)	10.30	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for TSR Goals (US) in 2016)
*(22)	10.31	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for TSR Goals (US) with Director Retirement Provisions in 2016)
*(23)	10.32	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for Revenue Goals in 2013 and 2014)
*(22)	10.33	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for Revenue Goals (US) in 2016)
*(22)	10.34	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for Revenue Goals (US) with Director Retirement Provisions in 2016)
*(24)	10.35	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for TSR Goals - Non-US in 2015)
*(22)	10.36	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for TSR Goals -Non-US in 2016)

*(24)	10.37	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for Revenue Goals - Non-US in 2015)
*(22)	10.38	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for Revenue Goals - Non-US in 2016)
*(25)	10.39	Form of restricted stock unit issuance agreement used under the 2004 Equity Incentive Plan (for grants to certain executive officers made prior to May 2009)
*(15)	10.40	Form of restricted stock unit issuance agreement used under the 2004 Equity Incentive Plan (for grants to certain executive officers commencing in May 2009)
*(26)	10.41	Form of restricted stock unit issuance agreement used under the 2004 Equity Incentive Plan (service-based vesting for certain executive officers commencing in November 2009)
*(17)	10.42	Form of restricted stock unit issuance agreement used under the 2004 Equity Incentive Plan (service-based vesting for certain executive officers commencing in 2011)
*(27)	10.43	Gilead Sciences, Inc. Employee Stock Purchase Plan, restated on January 22, 2015
*(28)	10.44	Gilead Sciences, Inc. Deferred Compensation Plan-Basic Plan Document
*(26)	10.45	Gilead Sciences, Inc. Deferred Compensation Plan-Adoption Agreement
*(28)	10.46	Addendum to the Gilead Sciences, Inc. Deferred Compensation Plan
*(29)	10.47	Gilead Sciences, Inc. 2005 Deferred Compensation Plan, as amended and restated on October 23, 2008
*(30)	10.48	Gilead Sciences, Inc. Severance Plan, as amended on March 8, 2016
*(31)	10.49	Gilead Sciences, Inc. Corporate Bonus Plan, amended on November 4, 2015
*(32)	10.50	Amended and Restated Gilead Sciences, Inc. Code Section 162(m) Bonus Plan
*(33)	10.51	2016 Base Salaries for the Named Executive Officers
*(34)	10.52	Offer Letter dated April 16, 2008 between Registrant and Robin Washington
*(35)	10.53	Offer Letter dated May 20, 2016 between Registrant and Kevin Young
*(36)	10.54	Form of Indemnity Agreement entered into between Registrant and its directors and executive officers
*(37)	10.55	Form of Employee Proprietary Information and Invention Agreement entered into between Registrant and certain of its officers and key employees
*(16)	10.56	Form of Employee Proprietary Information and Invention Agreement entered into between Registrant and certain of its officers and key employees (revised in September 2006)
+(38)	10.57	

		Amendment Agreement, dated October 25, 1993, between Registrant, the Institute of Organic Chemistry and Biochemistry (IOCB) and Rega Stichting v.z.w. (REGA), together with the following exhibits: the License Agreement, dated December 15, 1991, between Registrant, IOCB and REGA (the 1991 License Agreement), the License Agreement, dated October 15, 1992, between Registrant, IOCB and REGA (the October 1992 License Agreement) and the License Agreement, dated December 1, 1992, between Registrant, IOCB and REGA (the December 1992 License Agreement)
+ (39)	10.58	Amendment Agreement between Registrant and IOCB/REGA, dated December 27, 2000 amending the 1991 License Agreement and the December 1992 License Agreement
+(40)	10.59	Sixth Amendment Agreement to the License Agreement, between IOCB/REGA and Registrant, dated August 18, 2006 amending the October 1992 License Agreement and the December 1992 License Agreement
+(41)	10.60	Seventh Amendment Agreement to the License Agreement, between IOCB/REGA and Registrant dated July 1, 2013 amending the October 1992 License Agreement and the December 1992 License Agreement
+(42)	10.61	Exclusive License Agreement between Registrant (as successor to Triangle Pharmaceuticals, Inc.), Glaxo Group Limited, The Wellcome Foundation Limited, Glaxo Wellcome Inc. and Emory University, dated May 6, 1999
+(43)	10.62	Royalty Sale Agreement by and among Registrant, Emory University and Investors Trust & Custodial Services (Ireland) Limited, solely in its capacity as Trustee of Royalty Pharma, dated July 18, 2005
+(43)	10.63	Amended and Restated License Agreement between Registrant, Emory University and Investors Trust & Custodial Services (Ireland) Limited, solely in its capacity as Trustee of Royalty Pharma, dated July 21, 2005
+(44)	10.64	License Agreement between Japan Tobacco Inc. and Registrant, dated March 22, 2005
+(45)	10.65	First Amendment to License Agreement between Japan Tobacco Inc. and Registrant, dated May 19, 2005
+(45)	10.66	Second Amendment to License Agreement between Japan Tobacco Inc. and Registrant, dated May 17, 2010
+(12)	10.67	Third Amendment (Revised) to License Agreement between Japan Tobacco Inc. and Registrant, dated June 10, 2015
+(45)	10.68	Fourth Amendment to License Agreement between Japan Tobacco Inc. and Registrant, dated July 5, 2011
+(46)	10.69	Amendment to License Agreement between Japan Tobacco Inc. and Registrant, dated October 10, 2013
+(47)	10.70	Fifth Amendment to License Agreement between Japan Tobacco Inc. and Registrant, dated September 29, 2014

+(48)	10.71	Amended and Restated Collaboration Agreement by and among Registrant, Gilead Sciences Ireland UC (formerly Gilead Sciences Limited) and Janssen R&D Ireland, dated December 23, 2014
+(49)	10.72	Restated and Amended Toll Manufacturing Agreement between Gilead Sciences Ireland UC (formerly Gilead Sciences Limited), Registrant and Takeda GmbH (formerly Nycomed GmbH and Altana Pharma Oranienburg GmbH), dated November 7, 2005
	31.1	Certification of Chief Executive Officer, as required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended
	31.2	Certification of Chief Financial Officer, as required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended
	32.1**	Certifications of Chief Executive Officer and Chief Financial Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350)
	101***	The following materials from Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, formatted in Extensible Business Reporting Language (XBRL) includes: (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Income, (iii) Condensed Consolidated Statements of Comprehensive Income, (iv) Condensed Consolidated Statements of Cash Flows and (v) Notes to Condensed Consolidated Financial Statements.

(1) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on September 20, 2016, and incorporated herein by reference
(2) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on November 25, 2011, and incorporated herein by reference.
(3) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on May 8, 2013, and incorporated herein by reference.
(4) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on December 23, 2015, and incorporated herein by reference.
(5) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on April 1, 2011, and incorporated herein by reference.
(6) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on December 13, 2011, and incorporated herein by reference.
(7) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on March 7, 2014, and incorporated herein by reference.
(8) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on November 17, 2014, and incorporated herein by reference
(9) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on September 14, 2015, and incorporated herein by reference
(10) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2010, and incorporated herein by reference.
(11) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2010, and incorporated herein by reference.
(12) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, and incorporated herein by reference.
(13) Filed as an exhibit to Registrant's Current Report on Form 8-K/A filed on February 22, 2006, and incorporated herein by reference.

(14) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2007, and incorporated herein by reference.
(15) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2009, and incorporated herein by reference.
(16) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2009, and incorporated herein by reference.
(17) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2011, and incorporated herein by reference.
(18) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, and incorporated herein by reference
(19) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2014, and incorporated herein by reference.
(20) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2012, and incorporated herein by reference.
(21) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2012, and incorporated herein by reference.
(22) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, and incorporated herein by reference.
(23) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2013, and incorporated herein by reference.
(24) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, and incorporated herein by reference.
(25) Filed as an exhibit to Registrant's Current Report on Form 8-K first filed on December 19, 2007, and incorporated herein by reference.
(26) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2010, and incorporated herein by reference.
(27) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on May 8, 2015, and incorporated herein by reference.
(28) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2001, and incorporated herein by reference.
(29) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2008, and incorporated herein by reference.
(30) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on March 8, 2016, and incorporated herein by reference.
(31) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2015, and incorporated herein by reference.
(32) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on May 17, 2016, and incorporated herein by reference.
(33) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on February 3, 2016, and incorporated herein by reference.
(34) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008, and incorporated herein by reference.
(35) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, and incorporated herein by reference.
(36) Filed as an exhibit to Registrant's Registration Statement on Form S-1 (No. 33-55680), as amended, and incorporated herein by reference.
(37) Filed as an exhibit to Registrant's Registration Statement on Form S-8 (No. 333-102912) filed on January 31, 2003, and incorporated herein by reference.
(38) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended March 31, 1994, and incorporated herein by reference.

(39) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2000, and incorporated herein by reference.
(40) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2006, and incorporated herein by reference.
(41) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2013, and incorporated herein by reference.
(42) Filed as an exhibit to Triangle Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q/A filed on November 3, 1999, and incorporated herein by reference.
(43) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2005, and incorporated herein by reference.
(44) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2005, and incorporated herein by reference.
(45) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2011, and incorporated herein by reference.
(46) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2013, and incorporated herein by reference.
(47) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, and incorporated herein by reference.
(48) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2014, and incorporated herein by reference.
(49) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2005, and incorporated herein by reference.

† The Agreement and Plan of Merger (the Pharmasset Merger Agreement) contains representations and warranties of Registrant, Merger Sub and Pharmasset, Inc. made solely to each other as of specific dates. Those representations and warranties were made solely for purposes of the Pharmasset Merger Agreement and may be subject to important qualifications and limitations agreed to by Registrant, Merger Sub and Pharmasset, Inc. Moreover, some of those representations and warranties may not be accurate or complete as of any specified date, may be subject to a standard of materiality provided for in the Pharmasset Merger Agreement and have been used for the purpose of allocating risk among Registrant, Merger Sub and Pharmasset, Inc. rather than establishing matters as facts.

* Management contract or compensatory plan or arrangement.

** This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

*** XBRL information is filed herewith.

+ Certain confidential portions of this Exhibit were omitted by means of marking such portions with an asterisk (the Mark). This Exhibit has been filed separately with the Secretary of the Securities and Exchange Commission without the Mark pursuant to Registrant's Application Requesting Confidential Treatment under Rule 24b-2 under the Securities Exchange Act of 1934, as amended.