GILEAD SCIENCES INC
Form 10-Q
November 06, 2018

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, 2018
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 every Interactive Data File required to be submitted 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 such files). Yes ý No ¨
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer" "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.
Large accelerated filer ý Accelerated filer ¨ Non-accelerated filer ¨
Smaller reporting company ¨ Emerging growth company ¨
If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the

Exchange Act. ¨

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

Number of shares outstanding of the issuer's common stock, par value $0.001 per share, as of October 30, 2018:
1,293,619,612

GILEAD SCIENCES, INC.
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We own or have rights to various trademarks, copyrights and trade names used in our business, including the following: GILEAD®, GILEAD SCIENCES®, AMBISOME®, ATRIPLA®, AXI-CEL™, BIKTARVY®,

CAYSTON®, COMPLERA®, DESCOVY®, EMTRIVA®, EPCLUSA®, EVIPLERA®, GENVOYA®, GILEAD COMPASS INITIATIVE™, HARVONI®, HEPSERA®, LETAIRIS®, ODEFSEY®, RANEXA®, SOVALDI®, STRIBILD®, SYNNOTCH™, THROTTLE™, TRUVADA®, TYBOST®, VEMLIDY®, VIREAD®, VOLIBRIS®, VOSEVI®, YESCARTA® and ZYDELIG®. LEXISCAN® is a registered trademark of Astellas U.S. LLC. MACUGEN® is a registered trademark of Eyetech, Inc. SYMTUZA® is a registered trademark of Janssen Sciences Ireland UC (Janssen). TAMIFLU® is a registered trademark of 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, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 14,569	$ 7,588
Short-term marketable securities	13,897	17,922
Accounts receivable, net of allowances of $514 and $455, respectively	3,465	3,851
Inventories	816	801
Prepaid and other current assets	2,171	1,661
Total current assets	34,918	31,823
Property, plant and equipment, net	3,791	3,295
Long-term marketable securities	2,378	11,184
Intangible assets, net	16,314	17,100
Goodwill	4,117	4,159
Other long-term assets	2,787	2,722
Total assets	$ 64,305	$ 70,283
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 580	$ 814
Accrued government and other rebates	4,456	4,704
Other accrued liabilities	2,333	3,370
Current portion of long-term debt and other obligations, net	2,747	2,747
Total current liabilities	10,116	11,635
Long-term debt, net	24,570	30,795
Long-term income taxes payable	6,018	6,794
Other long-term obligations	594	558
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, par value $0.001 per share; 5 shares authorized; none outstanding	—	—
Common stock, par value $0.001 per share; 5,600 shares authorized; 1,294 and 1,308 shares issued and outstanding, respectively	1	1
Additional paid-in capital	2,118	1,264
Accumulated other comprehensive income	36	165
Retained earnings	20,706	19,012
Total Gilead stockholders' equity	22,861	20,442
Noncontrolling interest	146	59
Total stockholders' equity	23,007	20,501
Total liabilities and stockholders' equity	$ 64,305	$ 70,283

See accompanying notes.

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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,	
	2018	2017	2018	2017
Revenues:				
Product sales	$5,455	$6,402	$15,996	$19,825
Royalty, contract and other revenues	141	110	336	333
Total revenues	5,596	6,512	16,332	20,158
Costs and expenses:				
Cost of goods sold	1,086	1,032	3,283	3,115
Research and development expenses	939	789	3,068	2,584
Selling, general and administrative expenses	948	879	2,925	2,626
Total costs and expenses	2,973	2,700	9,276	8,325
Income from operations	2,623	3,812	7,056	11,833
Interest expense	(264)	(291)	(820)	(821)
Other income (expense), net	305	150	547	391
Income before provision for income taxes	2,664	3,671	6,783	11,403
Provision for income taxes	565	959	1,326	2,923
Net income	2,099	2,712	5,457	8,480
Net income (loss) attributable to noncontrolling interest	2	(6)	5	(13)
Net income attributable to Gilead	$2,097	$2,718	$5,452	$8,493
Net income per share attributable to Gilead common stockholders - basic	$1.62	$2.08	$4.19	$6.50
Shares used in per share calculation - basic	1,296	1,306	1,302	1,307
Net income per share attributable to Gilead common stockholders - diluted	$1.60	$2.06	$4.15	$6.44
Shares used in per share calculation - diluted	1,307	1,319	1,313	1,319
Cash dividends declared per share	$0.57	$0.52	$1.71	$1.56

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,	
	2018	2017	2018	2017
Net income	$2,099	$2,712	$5,457	$8,480
Other comprehensive income (loss):				
Net foreign currency translation gain (loss), net of tax	1	(4)	(17)	(51)
Available-for-sale securities:				
Net unrealized gain, net of tax impact of $0, $1, $0 and $4, respectively	31	185	25	311
Reclassifications to net income, net of tax impact of $0, $0, $0 and $(8), respectively	—	(1)	4	(7)
Net change	31	184	29	304
Cash flow hedges:				
Net unrealized gain (loss), net of tax impact of $0, $(2), $1 and $(11), respectively	(6)	(76)	51	(278)
Reclassifications to net income, net of tax impact of $0, $1, $0 and $0, respectively	8	25	101	(4)
Net change	2	(51)	152	(282)
Other comprehensive income (loss)	34	129	164	(29)
Comprehensive income	2,133	2,841	5,621	8,451
Comprehensive income (loss) attributable to noncontrolling interest	2	(6)	5	(13)
Comprehensive income attributable to Gilead	$2,131	$2,847	$5,616	$8,464

See accompanying notes.

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

	Nine Months Ended September 30,	
	2018	2017
Operating Activities:		
Net income	$5,457	$8,480
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation expense	169	155
Amortization expense	902	734
Stock-based compensation expense	670	304
Deferred income taxes	10	127
Other	14	227
Changes in operating assets and liabilities:		
Accounts receivable, net	367	473
Inventories	(191)	(79)
Prepaid expenses and other	749	311
Accounts payable	(217)	(515)
Income taxes payable	(1,551)	(48)
Accrued liabilities	(324)	(1,024)
Net cash provided by operating activities	6,055	9,145
Investing Activities:		
Purchases of marketable securities	(5,786)	(18,813)
Proceeds from sales of marketable securities	1,201	8,966
Proceeds from maturities of marketable securities	17,021	4,164
Capital expenditures	(676)	(370)
Other	(140)	—
Net cash provided by (used in) investing activities	11,620	(6,053)
Financing Activities:		
Proceeds from issuances of common stock	239	183
Proceeds from debt financing, net of issuance costs	—	2,991
Repurchases of common stock	(1,938)	(848)
Repayments of debt and other obligations	(6,250)	(90)
Payments of dividends	(2,235)	(2,049)
Other	(464)	(141)
Net cash provided by (used in) financing activities	(10,648)	46
Effect of exchange rate changes on cash and cash equivalents	(46)	141
Net change in cash and cash equivalents	6,981	3,279
Cash and cash equivalents at beginning of period	7,588	8,229
Cash and cash equivalents at end of period	$14,569	$11,508

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, our or us) believes are necessary for a fair presentation of the periods presented. These interim financial results are not necessarily indicative of results expected for the full fiscal year or for any subsequent interim period.

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

We assess whether we are the primary beneficiary of a variable interest entity (VIE) at the inception of the arrangement and at each reporting date. This assessment is based on our power to direct the activities of the VIE that most significantly impact the VIE's economic performance and our obligation to absorb losses or the right to receive benefits from the VIE that could potentially be significant to the VIE. As of September 30, 2018, we did not have any material VIEs.

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, 2017, included in our Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (SEC).

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

We are also subject to credit risk from our accounts receivable related to our product sales. The majority of our trade accounts receivable arises from product sales in the United States and Europe. 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 as of September 30, 2018.

Recently Adopted Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update No. 2014-09 "Revenue from Contracts with Customers" (Topic 606). Topic 606 supersedes the revenue recognition requirements in Topic 605 "Revenue Recognition" (Topic 605) and requires entities to recognize revenue in an amount that reflects the consideration to which the entity expects to be entitled when promised goods or services are transferred to a customer.

Entities adopting Topic 606 had the option of using either a full retrospective or a modified retrospective approach. On January 1, 2018, we adopted Topic 606 using the modified retrospective method applied to those contracts which were not completed as of January 1, 2018. As such, results for reporting periods beginning after January 1, 2018 are presented under Topic 606, while prior period amounts are not adjusted and continue to be reported in accordance with our historical accounting under Topic 605.

As discussed further in Note 2, Revenues, our product sales are recognized when control of the product transfers, generally upon shipment or delivery to the customer. Certain product sales that were deferred under the sell-through or cash basis methods of accounting because fees were not fixed or determinable prior to the adoption of Topic 606 are now recognized upon transfer of control. Royalty revenue is recognized in the period in which the corresponding sales by our corporate partners occur. Prior to the adoption of Topic 606, royalty revenue was generally recognized in the quarter following the quarter in which the corresponding sales by our corporate partners occurred.

The cumulative effect of the changes made to our Condensed Consolidated Balance Sheets as of January 1, 2018 for the adoption of Topic 606 was as follows (in millions):

	December 31, 2017	Adjustments Due to Topic 606	January 1, 2018
Prepaid and other current assets	$ 1,661	$ 96	$ 1,757
Other long-term assets	$ 2,722	$ 10	$ 2,732
Other accrued liabilities	$ 3,370	$ (115)	$ 3,255
Other long-term obligations	$ 558	$ 31	$ 589
Retained earnings	$ 19,012	$ 190	$ 19,202

For the three and nine months ended September 30, 2018, the impact to our Condensed Consolidated Financial Statements as a result of applying Topic 606 in place of Topic 605 was not material.

In January 2016, the FASB issued Accounting Standards Update No. 2016-01 “Financial Instruments - Overall: Recognition and Measurement of Financial Assets and Financial Liabilities” (ASU 2016-01). ASU 2016-01 changes accounting for equity investments, financial liabilities under the fair value option and the presentation and disclosure requirements for financial instruments. Additionally, ASU 2016-01 clarifies guidance related to the valuation allowance assessment when recognizing deferred tax assets resulting from unrealized losses on available-for-sale debt securities. On January 1, 2018, we adopted this standard using a modified retrospective approach. The standard requires that equity investments with readily determinable fair values be measured at fair value with any changes in fair value recognized in earnings. As a result of the adoption, we reclassified $293 million of unrealized net gain from accumulated other comprehensive income (AOCI) to retained earnings on January 1, 2018, which primarily consisted of $278 million unrealized gain from our equity investment in Galapagos NV.

In August 2017, the FASB issued Accounting Standards Update No. 2017-12 “Derivatives and Hedging: Targeted Improvements to Accounting for Hedging Activities” (ASU 2017-12). The amendments in ASU 2017-12 more closely align the results of hedge accounting with risk management activities. ASU 2017-12 also amends the presentation and disclosure requirements and eases documentation and effectiveness assessment requirements. Pursuant to the provisions of ASU 2017-12, we are no longer required to separately measure and recognize hedge ineffectiveness for highly effective hedges. On January 1, 2018, we early adopted this standard on a prospective basis. Upon adoption of ASU 2017-12, we no longer recognize hedge ineffectiveness in our Condensed Consolidated Statements of Income, but we instead recognize the entire change in the fair value of the hedge contract in AOCI. The adoption did not have a material impact on our Condensed Consolidated Financial Statements. The primary impact of adoption was required disclosure changes. See Note 5, Derivative Financial Instruments, for additional information.

In March 2018, the FASB issued Accounting Standards Update No. 2018-05 “Income Taxes (Topic 740): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118” (ASU 2018-05). ASU 2018-05 amends Topic 740 by incorporating the SEC Staff Accounting Bulletin No. 118 (SAB 118) issued on December 22, 2017. SAB 118 provides guidance on accounting for the effects of the Tax Cuts and Jobs Act (Tax Reform) and allows a company to record provisional amounts during a measurement period not to extend beyond one year from the enactment date. See Note 14, Income Taxes, for additional information.

Recently Issued Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued Accounting Standards Update No. 2016-02 “Leases” (Topic 842). Topic 842 amends a number of aspects of lease accounting, including requiring lessees to recognize 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. In July 2018, the FASB issued supplemental adoption guidance and clarification to Topic 842 within ASU 2018-10

“Codification Improvements to Topic 842, Leases” and ASU 2018-11 “Leases (Topic 842): Targeted Improvements.” The guidance will become effective for us beginning in the first quarter of 2019 and early adoption is permitted. We plan to adopt these standards on the effective date by recording a cumulative effect adjustment to the opening balance of retained earnings on January 1, 2019.

As we continue to evaluate the impact of the adoption of these standards, we anticipate recognition of additional assets and corresponding liabilities related to leases on our Condensed Consolidated Balance Sheets with no material impact to our Condensed Consolidated Statements of Income. We plan to elect the practical expedients upon transition that will retain the lease classification

and initial direct costs for any leases that existed prior to the adoption of these standards. We will not reassess whether any contracts entered into prior to the adoption are leases. We are in the process of implementing a new lease accounting system and updating our controls and procedures for maintaining and accounting for our lease portfolio under the new guidance.

In June 2016, the FASB issued Accounting Standards Update No. 2016-13 “Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments” (ASU 2016-13). ASU 2016-13 requires measurement and recognition of expected credit losses for financial assets. 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. REVENUES

On January 1, 2018, we adopted Topic 606 using the modified retrospective method. As a result, we have changed our accounting policies for revenue recognition as detailed below.

Product Sales

We recognize revenue from product sales when control of the product transfers, generally upon shipment or delivery, to the customer. Upon recognition of revenue from product sales, provisions are made for various forms of variable consideration, which include government and other rebates such as Medicaid reimbursements, customer incentives such as cash discounts for prompt payment, distributor fees and expected returns of expired products, as appropriate. Our payment terms to customers generally range from 30 to 90 days.

Royalty, Contract and Other Revenues

Royalty revenue is recognized in the period in which the obligation is satisfied and the corresponding sales by our corporate partners occur.

Policy Elections and Practical Expedients Taken

- We account for shipping and handling activities that are performed after a customer has obtained control of a good as fulfillment costs rather than as separate performance obligations; and
- If we expect, at contract inception, that the period between the transfer of control and corresponding payment from the customer will be one year or less, we do not adjust the amount of consideration for the effects of a significant financing component.

Variable Consideration

Rebates and Chargebacks

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

Cash Discounts

We estimate cash discounts based on contractual terms, historical customer payment patterns and our expectations regarding future customer payment patterns.

Distributor Fees

Under our inventory management agreements with our significant U.S. wholesalers, we pay the wholesalers a fee primarily for compliance with certain contractually determined covenants such as the maintenance of agreed upon

inventory levels. These distributor fees are based on a contractually determined fixed percentage of sales.

Product Returns

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

Revenues Recognized from Performance Obligations Satisfied in Prior Periods

During the three and nine months ended September 30, 2018, revenues recognized from performance obligations satisfied in prior years related to royalties for licenses of our intellectual property were $167 million and $395 million, respectively. Changes in estimates for variable consideration related to sales made in prior years were not material during the three and nine months ended September 30, 2018.

Contract Assets

Our contract assets, which consist of unbilled amounts primarily from arrangements where the licensing of intellectual property is the only or predominant performance obligation, totaled $117 million and $132 million as of September 30, 2018 and January 1, 2018, respectively.

Disaggregation of Revenues

The following table disaggregates our product sales by product and geographic region and disaggregates our royalty, contract and other revenues by geographic region for the three and nine months ended September 30, 2018 and 2017. The information for the three and nine months ended September 30, 2017 has not been adjusted in accordance with our modified retrospective adoption of Topic 606 and continues to be reported in accordance with our historical accounting under Topic 605.

	Three Months Ended September 30, 2018				Three Months Ended September 30, 2017			
(In millions)	U.S.	Europe	Other International	Total	U.S.	Europe	Other International	Total
Product sales:								
Atripla	$221	$ 29	$ 8	$258	$324	$79	$ 36	$439
Biktarvy	375	11	—	386	—	—	—	—
Complera/Eviplera	61	67	11	139	91	133	13	237
Descovy	310	81	15	406	241	65	10	316
Genvoya	921	203	52	1,176	810	146	32	988
Odefsey	323	95	5	423	255	37	4	296
Stribild	111	20	15	146	181	40	8	229
Truvada	665	62	30	757	604	154	53	811
Other HIV[1]	10	2	2	14	13	2	—	15
Revenue share - Symtuza[2]	8	14	—	22	—	—	—	—
AmBisome	9	59	34	102	9	51	32	92
Epclusa	225	136	116	477	543	263	76	882
Harvoni	185	38	88	311	718	110	145	973
Letairis	241	—	—	241	213	—	—	213
Ranexa	178	—	—	178	164	—	—	164
Vemlidy	66	2	19	87	34	2	1	37
Viread	17	10	43	70	137	55	82	274
Vosevi	78	21	4	103	117	5	1	123
Yescarta	75	—	—	75	—	—	—	—
Zydelig	15	4	1	20	18	22	—	40
Other[3]	37	19	8	64	70	33	170	273

Total product sales	4,131	873	451	5,455	4,542	1,197	663	6,402
Royalty, contract and other revenues	20	102	19	141	21	74	15	110
Total revenues	$4,151	$ 975	$ 470	$5,596	$4,563	$1,271	$ 678	$6,512

	Nine Months Ended September 30, 2018				Nine Months Ended September 30, 2017			
(In millions)	U.S.	Europe	Other International	Total	U.S.	Europe	Other International	Total
Product Sales:								
Atripla	$723	$119	$ 79	$921	$974	$259	$ 133	$1,366
Biktarvy	593	13	—	606	—	—	—	—
Complera/Eviplera	210	279	39	528	315	385	44	744
Descovy	895	234	41	1,170	682	149	22	853
Genvoya	2,678	596	144	3,418	2,189	358	67	2,614
Odefsey	905	230	15	1,150	688	87	6	781
Stribild	388	83	36	507	632	161	38	831
Truvada	1,821	245	108	2,174	1,635	527	175	2,337
Other HIV[1]	30	6	10	46	34	5	2	41
Revenue share - Symtuza[2]	8	34	—	42	—	—	—	—
AmBisome	40	170	102	312	26	153	97	276
Epclusa	733	502	278	1,513	2,142	649	154	2,945
Harvoni	649	116	225	990	2,628	583	515	3,726
Letairis	689	—	—	689	654	—	—	654
Ranexa	581	—	—	581	517	—	—	517
Vemlidy	172	8	41	221	66	3	1	70
Viread	40	72	137	249	395	202	237	834
Vosevi	250	57	12	319	117	5	1	123
Yescarta	183	—	—	183	—	—	—	—
Zydelig	46	44	2	92	52	57	1	110
Other[3]	93	75	117	285	228	279	496	1,003
Total product sales	11,727	2,883	1,386	15,996	13,974	3,862	1,989	19,825
Royalty, contract and other revenues	54	233	49	336	62	226	45	333
Total revenues	$11,781	$3,116	$ 1,435	$16,332	$14,036	$4,088	$ 2,034	$20,158

[1] Includes Emtriva and Tybost

[2] Represents Gilead's revenue from cobicistat (C), emtricitabine (FTC) and tenofovir alafenamide (TAF) in Symtuza (darunavir/C/FTC/TAF), a fixed dose combination product commercialized by Janssen

[3] Includes Cayston, Hepsera and Sovaldi

3. 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 include quoted prices in active markets for identical assets or liabilities;
- Level 2 inputs 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 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 assets and liabilities include those whose fair value measurements are determined using pricing models, discounted cash flow methodologies or similar valuation

techniques and significant management judgment or estimation.

Our financial instruments consist 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 debt and equity securities, and foreign currency exchange contracts are reported at their respective fair values on our Condensed Consolidated Balance Sheets. Short-term and long-term debt are reported at their amortized costs on 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, 2018				December 31, 2017			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Assets:								
Available-for-sale debt securities:								
U.S. treasury securities	$3,075	$—	$ —	$3,075	$4,061	$—	$ —	$4,061
Certificates of deposit	—	4,392	—	4,392	—	5,131	—	5,131
U.S. government agencies securities	—	932	—	932	—	926	—	926
Non-U.S. government securities	—	260	—	260	—	664	—	664
Corporate debt securities	—	12,757	—	12,757	—	14,747	—	14,747
Residential mortgage and asset-backed securities	—	2,037	—	2,037	—	4,058	—	4,058
Marketable equity securities:								
Money market funds	5,138	—	—	5,138	4,714	—	—	4,714
Equity securities	825	—	—	825	635	—	—	635
Deferred compensation plan	139	—	—	139	116	—	—	116
Foreign currency derivative contracts	—	42	—	42	—	13	—	13
Total	$9,177	$20,420	$ —	$29,597	$9,526	$25,539	$ —	$35,065
Liabilities:								
Deferred compensation plan	$139	$—	$ —	$139	$116	$—	$ —	$116
Foreign currency derivative contracts	—	6	—	6	—	93	—	93
Total	$139	$6	$ —	$145	$116	$93	$ —	$209

For the three and nine months ended September 30, 2018, changes in the fair value of marketable equity securities resulted in unrealized gains of $168 million and $149 million, respectively, which were included in Other income (expense), net, on our Condensed Consolidated Statements of Income.

Our available-for-sale debt securities are classified as cash equivalents, short-term marketable securities and long-term marketable securities. See Note 4, Available-for-Sale Debt Securities, for additional information.

The following table summarizes the classification of our marketable equity securities in our Condensed Consolidated Balance Sheets (in millions):

	September 30, 2018	December 31, 2017
Cash and cash equivalents	$ 5,138	$ 4,714
Prepaid and other current assets	829	637
Other long-term assets	135	114
Total	$ 6,102	$ 5,465

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-based and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include

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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-month time horizon and all are with counterparties that have a minimum credit rating of A- or equivalent by S&P Global Ratings, Moody's Investors Service, Inc. or Fitch Ratings, 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 observable 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 $27.5 billion and $35.5 billion as of September 30, 2018 and December 31, 2017, respectively, and the carrying values were $27.3 billion and $33.5 billion as of September 30, 2018 and December 31, 2017, respectively.

4. AVAILABLE-FOR-SALE DEBT SECURITIES

The following table summarizes our available-for-sale debt securities (in millions):

	September 30, 2018				December 31, 2017			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. treasury securities	$3,090	$ —	$ (15)	$3,075	$4,090	$ —	$ (29)	$4,061
Certificates of deposit	4,392	—	—	4,392	5,131	—	—	5,131
U.S. government agencies securities	938	—	(6)	932	934	—	(8)	926
Non-U.S. government securities	262	—	(2)	260	668	—	(4)	664
Corporate debt securities	12,792	2	(37)	12,757	14,790	3	(46)	14,747
Residential mortgage and asset-backed securities	2,049	—	(12)	2,037	4,072	1	(15)	4,058
Total	$23,523	$ 2	$ (72)	$23,453	$29,685	$ 4	$ (102)	$29,587

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

	September 30, 2018	December 31, 2017
Cash and cash equivalents	$ 7,178	$ 481
Short-term marketable securities	13,897	17,922
Long-term marketable securities	2,378	11,184
Total	$ 23,453	$ 29,587

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

	September 30, 2018	
	Amortized Cost	Fair Value
Within one year	$21,130	$21,075
After one year through five years	2,313	2,299
After five years through ten years	58	57
After ten years	22	22
Total	$23,523	$23,453

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

	Less Than 12 Months		12 Months or Greater		Total	
	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value
September 30, 2018						
U.S. treasury securities	$(1)	$ 1,339	$(14)	$ 1,613	$(15)	$ 2,952
U.S. government agencies securities	—	285	(6)	612	(6)	897
Non-U.S. government securities	—	—	(2)	234	(2)	234
Corporate debt securities	(6)	2,636	(31)	3,602	(37)	6,238
Residential mortgage and asset-backed securities	(1)	409	(11)	1,300	(12)	1,709
Total	$(8)	$ 4,669	$(64)	$ 7,361	$(72)	$ 12,030
December 31, 2017						
U.S. treasury securities	$(2)	$ 821	$(27)	$ 3,240	$(29)	$ 4,061
U.S. government agencies securities	(1)	206	(7)	700	(8)	906
Non-U.S. government securities	(1)	203	(3)	461	(4)	664
Corporate debt securities	(14)	7,674	(32)	3,561	(46)	11,235
Residential mortgage and asset-backed securities	(4)	2,245	(11)	1,206	(15)	3,451
Total	$(22)	$ 11,149	$(80)	$ 9,168	$(102)	$ 20,317

We held a total of 1,523 and 2,957 positions, which were in an unrealized loss position, as of September 30, 2018 and December 31, 2017, respectively.

Based on our review of these securities, we believe we had no other-than-temporary impairments as of September 30, 2018 and December 31, 2017, 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 not material for the three and nine months ended September 30, 2018 and 2017.

5. DERIVATIVE FINANCIAL INSTRUMENTS

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

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

We hedge our exposure to foreign currency exchange rate fluctuations for forecasted product sales that are denominated in a non-functional currency. The derivative instruments we use to hedge this exposure are designated as cash flow hedges and have maturities of 18 months or less. Upon executing a hedging contract and quarterly thereafter, we assess hedge effectiveness using regression analysis. Prior to January 2018, we excluded time value from our effectiveness testing and recognized changes in the time value of the hedge in Other income (expense), net,

on our Condensed Consolidated Statements of Income. Starting in January 2018, we include time value in our effectiveness testing and the entire change in the value of hedge contracts is recorded as unrealized gains or losses in AOCI within Stockholders' equity on our Condensed Consolidated Balance Sheets. The unrealized gains or losses in AOCI are reclassified into product sales when the respective hedged transactions affect earnings. As of September 30, 2018, the amount of unrealized gains and losses related to the hedged forecasted transactions reported in AOCI that is expected to be reclassified into product sales within the next 12 months was not material.

The cash flow effects of our derivative contracts for the nine months ended September 30, 2018 and 2017 are included within Net cash provided by operating activities on our Condensed Consolidated Statements of Cash Flows.

We had notional amounts on foreign currency exchange contracts outstanding of $2.5 billion and $2.8 billion as of September 30, 2018 and December 31, 2017, respectively.

While all of our derivative contracts allow us the right to offset assets and liabilities, we have presented amounts on a gross basis. The following table summarizes the classification and fair values of derivative instruments in our Condensed Consolidated Balance Sheets (in millions):

	September 30, 2018			
	Asset Derivatives		Liability Derivatives	
	Classification	Fair Value	Classification	Fair Value
Derivatives designated as hedges:				
Foreign currency exchange contracts	Other current assets	$ 40	Other accrued liabilities	$ (5)
Foreign currency exchange contracts	Other long-term assets	2	Other long-term obligations	(1)
Total derivatives designated as hedges		42		(6)
Derivatives not designated as hedges:				
Foreign currency exchange contracts	Other current assets	—	Other accrued liabilities	—
Total derivatives not designated as hedges		—		—
Total derivatives		$ 42		$ (6)

	December 31, 2017			
	Asset Derivatives		Liability Derivatives	
	Classification	Fair Value	Classification	Fair Value
Derivatives designated as hedges:				
Foreign currency exchange contracts	Other current assets	$ 2	Other accrued liabilities	$ (89)
Foreign currency exchange contracts	Other long-term assets	1	Other long-term obligations	(3)
Total derivatives designated as hedges		3		(92)
Derivatives not designated as hedges:				
Foreign currency exchange contracts	Other current assets	10	Other accrued liabilities	(1)
Total derivatives not designated as hedges		10		(1)
Total derivatives		$ 13		$ (93)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Derivatives designated as hedges:				
Gains (losses) recognized in AOCI	$(6)	$(78)	$52	$(289)
Gains (losses) reclassified from AOCI into product sales	$(8)	$(26)	$(101)	$4
Gains recognized in Other income (expense), net	$—	$10	$—	$32
Derivatives not designated as hedges:				
Gains (losses) recognized in Other income (expense), net	$15	$(2)	$11	$(112)

From time to time, we may discontinue cash flow hedges and, as a result, record related amounts in Other income (expense), net, on our Condensed Consolidated Statements of Income. There were no material amounts recorded in Other income (expense), net, on our Condensed Consolidated Statements of Income for the three and nine months ended September 30, 2018 and 2017 as a result of the discontinuance of cash flow hedges.

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As of September 30, 2018 and December 31, 2017, we held one type of financial instrument, which was derivative contracts related to foreign currency exchange contracts. The following table summarizes the potential effect of offsetting derivatives by type of financial instrument on our Condensed Consolidated Balance Sheets (in millions):

Description	Gross Amounts of Recognized Assets/Liabilities	Gross Amounts Offset on our Condensed Consolidated Balance Sheets	Amounts of Assets/Liabilities Presented on our Condensed Consolidated Balance Sheets	Gross Amounts Not Offset on our Condensed Consolidated Balance Sheets		
				Derivative Financial Instruments	Cash Collateral Received/ Pledged	Net Amount (Legal Offset)
As of September 30, 2018						
Derivative assets	$ 42	$ —	$ 42	$ (6)	$ —	$ 36
Derivative liabilities	$ (6)	$ —	$ (6)	$ 6	$ —	$ —
As of December 31, 2017						
Derivative assets	$ 13	$ —	$ 13	$ (8)	$ —	$ 5
Derivative liabilities	$ (93)	$ —	$ (93)	$ 8	$ —	$ (85)

6. ACQUISITION, COLLABORATIONS AND OTHER ARRANGEMENTS

Acquisition

On October 3, 2017 (the Kite acquisition date), we completed a tender offer for all of the outstanding common stock of Kite Pharma, Inc. (Kite) for $180 per share in cash. As a result, Kite became our wholly-owned subsidiary. The acquisition of Kite helps establish our foundation for improving the treatment of hematological malignancies and solid tumors.

The consideration transferred for the acquisition of Kite was $11,155 million, consisting of $10,420 million in cash to the outstanding Kite common stockholders, $645 million cash payment to vested equity award holders, $15 million to warrant holders and $75 million representing the portion of the replaced stock-based awards attributable to the pre-combination period. In addition, $733 million was excluded from the consideration transferred, representing the portion of the replaced stock-based awards attributable to the post combination period, which is expected to be recognized through 2021.

The acquisition of Kite was accounted for as a business combination using the acquisition method of accounting. This method requires, among other things, that assets acquired and liabilities assumed be recognized at fair value as of the Kite acquisition date. The determination of estimated fair value requires us to make significant estimates and assumptions. During the nine months ended September 30, 2018, we recorded a $42 million reduction to goodwill primarily due to revision of deferred income taxes as a result of finalization of Kite’s pre-acquisition federal income tax return. The fair value estimates for the assets acquired and liabilities assumed in the acquisition have been completed.

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

Cash and cash equivalents	$652
Identifiable intangible assets:	
Indefinite-lived intangible assets - in-process research and development (IPR&D)	8,950
Outlicense acquired	91
Deferred income taxes	(1,564)
Other assets acquired (liabilities assumed), net	81

Total identifiable net assets	8,210
Goodwill	2,945
Total consideration transferred	$11,155

Collaborations and Other Arrangements

We enter into collaborations and other arrangements with third parties for the research and development of certain products and product candidates. These arrangements may include non-refundable up-front payments, payments by us for options to acquire certain rights, contingent obligations by us for potential development and regulatory milestone payments and/or sales-based milestone payments, royalty payments, revenue or profit sharing arrangements, cost sharing arrangements and equity investments. While we do not consider any collaborations and other arrangements entered into during 2018 to be individually material, notable

terms of these arrangements are described below. Amounts related to collaborations entered into during 2018 that are not specifically presented are included in the aggregate as Other Collaboration Arrangements.

Gadeta B.V. (Gadeta):

In July 2018, we entered into a collaboration arrangement with Gadeta, a privately-held company based in Utrecht, the Netherlands, to develop gamma delta T cell receptor therapies for various cancers. Under the financial terms, we will provide research and development (R&D) funding for the collaboration and Gadeta will be eligible to receive future payments upon achievement of certain regulatory milestones. In addition, we made an upfront purchase of equity in Gadeta from Gadeta's shareholders upon entering into the collaboration arrangement and may acquire additional equity in Gadeta upon achievement of certain R&D milestones. We also have the exclusive option to acquire the remaining equity in Gadeta for €300 million, adjusted for closing cash, transaction expenses and closing indebtedness. The option is exercisable at our discretion.

Gadeta is a VIE, and we are its primary beneficiary because we have the power to direct the activities of Gadeta that most significantly impact its economic performance and as a result of the financial terms described above. Upon the initial consolidation of Gadeta we recorded $82 million to noncontrolling interest, primarily reflecting acquired intangible assets related to IPR&D with a fair value of $117 million. Gadeta does not meet the definition of a business as defined in ASC 805 - Business Combinations, and as a result, no goodwill was recognized.

Other Collaboration Arrangements:

For the nine months ended September 30, 2018, we entered into several other collaboration arrangements that resulted in cash payments of $333 million, of which $160 million was recorded as up-front collaboration expense within Research and development expenses on our Condensed Consolidated Statements of Income and the remaining amounts were recorded in current and other long-term assets on our Condensed Consolidated Balance Sheets.

Under the financial terms of these arrangements, we may be required to make payments upon achievement of various developmental, regulatory and commercial milestones, which could be significant. In addition, we may be required to pay significant royalties on future sales if products related to these arrangements are commercialized. The payment of these amounts, however, is contingent upon the occurrence of various future events, which have a high degree of uncertainty of occurrence.

7. OTHER FINANCIAL INFORMATION

Inventories

Inventories are summarized as follows (in millions):

	September 30, 2018	December 31, 2017
Raw materials	$ 2,144	$ 1,880
Work in process	241	352
Finished goods	574	670
Total	$ 2,959	$ 2,902
Reported as:		
Inventories	$ 816	$ 801
Other long-term assets	2,143	2,101
Total	$ 2,959	$ 2,902

Amounts reported as other long-term assets primarily consisted of raw materials as of September 30, 2018 and December 31, 2017.

Other Accrued Liabilities

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

	September 30, 2018	December 31, 2017
Compensation and employee benefits	$ 436	$ 455
Branded prescription drug fee	62	284
Income taxes payable	17	713

Other accrued expenses	1,818	1,918
Total	$ 2,333	$ 3,370

Supplemental Disclosure of Cash Flow Information - Non-Cash Investing Activity

As of September 30, 2018, Prepaid and other current assets on our Condensed Consolidated Balance Sheets included $470 million of available-for-sale debt securities that were matured but unsettled. These available-for-sale debt securities were settled in October 2018 and will be reflected as cash from investing activities in the fourth quarter of 2018. As of December 31, 2017, available-for-sale debt securities that were matured but unsettled were not material.

8. INTANGIBLE ASSETS

The following table summarizes our intangible assets, net (in millions):

	September 30, 2018				December 31, 2017		
	Gross Carrying Amount	Accumulated Amortization	Foreign Currency Translation Adjustment	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Finite-lived intangible assets:							
Intangible asset - sofosbuvir	$10,720	$ (3,379)	$ —	$7,341	$10,720	$ (2,855)	$7,865
Intangible asset - axicabtagene ciloleucel (DLBCL)	6,200	(330)	—	5,870	6,200	(72)	6,128
Intangible asset - Ranexa	688	(650)	—	38	688	(566)	122
Other	546	(347)	(1)	198	546	(311)	235
Total finite-lived intangible assets	18,154	(4,706)	(1)	13,447	18,154	(3,804)	14,350
Indefinite-lived intangible assets - IPR&D	2,867	—	—	2,867	2,750	—	2,750
Total intangible assets	$21,021	$ (4,706)	$ (1)	$16,314	$20,904	$ (3,804)	$17,100

Amortization expense related to finite-lived intangible assets is included in Cost of goods sold on our Condensed Consolidated Statements of Income and totaled $301 million and $902 million for the three and nine months ended September 30, 2018, respectively, and $209 million and $629 million for the three and nine months ended September 30, 2017, respectively.

As of September 30, 2018, the estimated future amortization expense associated with our finite-lived intangible assets is as follows (in millions):

Fiscal Year	Amount
2018 (remaining three months)	$301
2019	1,088
2020	1,064
2021	1,064
2022	1,064
Thereafter	8,866
Total	$13,447

9. DEBT AND CREDIT FACILITIES

The following table summarizes our borrowings under various financing arrangements (in millions):

Type of Borrowing	Issue Date	Due Date	Interest Rate	Carrying Amount	
				September 30, 2018	December 31, 2017
Senior Unsecured	September 2015	September 2018	1.85%	$—	$ 999
Senior Unsecured	September 2017	September 2018	3-month LIBOR + 0.17%	—	749
Term Loan	October 2017	October 2018	Variable	—	999
Senior Unsecured	September 2017	March 2019	3-month LIBOR + 0.22%	749	748
Senior Unsecured	March 2014	April 2019	2.05%	500	499
Senior Unsecured	September 2017	September 2019	1.85%	998	997
Senior Unsecured	September 2017	September 2019	3-month LIBOR + 0.25%	499	499
Senior Unsecured	November 2014	February 2020	2.35%	499	499
Senior Unsecured	September 2015	September 2020	2.55%	1,995	1,994
Term Loan	October 2017	October 2020	Variable	—	998
Senior Unsecured	March 2011	April 2021	4.50%	996	995
Senior Unsecured	December 2011	December 2021	4.40%	1,247	1,246
Senior Unsecured	September 2016	March 2022	1.95%	498	497
Senior Unsecured	September 2015	September 2022	3.25%	997	996
Term Loan	October 2017	October 2022	Variable	—	2,497
Senior Unsecured	September 2016	September 2023	2.50%	745	745
Senior Unsecured	March 2014	April 2024	3.70%	1,743	1,742
Senior Unsecured	November 2014	February 2025	3.50%	1,745	1,744
Senior Unsecured	September 2015	March 2026	3.65%	2,731	2,729
Senior Unsecured	September 2016	March 2027	2.95%	1,245	1,244
Senior Unsecured	September 2015	September 2035	4.60%	990	990
Senior Unsecured	September 2016	September 2036	4.00%	740	740
Senior Unsecured	December 2011	December 2041	5.65%	995	995
Senior Unsecured	March 2014	April 2044	4.80%	1,734	1,733
Senior Unsecured	November 2014	February 2045	4.50%	1,730	1,730
Senior Unsecured	September 2015	March 2046	4.75%	2,216	2,215
Senior Unsecured	September 2016	March 2047	4.15%	1,724	1,723
Total debt, net				27,316	33,542
Less current portion				2,746	2,747
Total long-term debt, net				$24,570	$ 30,795

In September 2018, we repaid $1.0 billion of our senior unsecured notes upon maturity that were issued in September 2015 and $750 million of senior unsecured notes upon maturity that were issued in September 2017.

In March 2018, we fully repaid the $4.5 billion outstanding debt under our term loan facility credit agreement, at which time the term loan facility credit agreement terminated.

We are required to comply with certain covenants under our credit agreement and note indentures governing our senior notes. As of September 30, 2018, we were not in violation of any covenants. Additionally, as of September 30, 2018, there were no amounts outstanding under our revolving credit facility.

10. COMMITMENTS AND CONTINGENCIES

We are a party to various legal actions. The most significant of these are described below. We recognize accruals for such actions to the extent that we conclude that a loss is both probable and reasonably estimable. We accrue for the best estimate of a

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loss within a range; however, if no estimate in the range is better than any other, then we accrue the minimum amount in the range. If we determine that a loss is reasonably possible and the loss or range of loss can be estimated, we disclose the possible loss. Unless otherwise noted, 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.

We did not recognize any accruals for the actions described below in our Condensed Consolidated Balance Sheets as of September 30, 2018 and December 31, 2017, as we did not believe losses were probable.

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 approval from U.S. Food and Drug Administration (FDA) for sofosbuvir, now known commercially as Sovaldi. Sofosbuvir is also included in all of our marketed HCV products. 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 are aware of patents and patent applications owned by third parties that have been or may in the future be alleged by such parties to cover the use of our HCV products. If third parties obtain valid and enforceable patents, and successfully prove infringement of those patents by our HCV products, we could be required to pay significant monetary damages. We cannot predict the ultimate outcome of intellectual property claims related to our HCV products. We have spent, and will continue to spend, significant resources defending against these claims.

Interference Proceedings and Litigation with Idenix Pharmaceuticals, Inc. (Idenix), Universita Degli Studi di Cagliari (UDSG), Centre National de la Recherche Scientifique and L'Universite Montpellier II

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 was acquired by Merck & Co. Inc. (Merck) in August 2014. Idenix appealed the PTAB's decisions to the U.S. District Court for the District of Delaware, and in September 2018, the District Court dismissed the First Idenix Interference with prejudice.

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 Appeals for the Federal Circuit (CAFC). The CAFC heard oral arguments in September 2016 and affirmed the PTAB decision in June 2017. Idenix filed a Petition for Writ of Certiorari to the Supreme Court of the United States (U.S. Supreme Court) in March 2018. In April 2018, the U.S. Supreme Court denied certiorari; accordingly, the decision finding that Idenix is not entitled to the '600 patent is now final. All pending actions concerning the '600 patent have been dismissed.

We believe that 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. In July 2017, the Canadian Federal Appeal Court affirmed the lower court's decision in our favor. In September 2017, Idenix appealed the decision to the Supreme Court of Canada. In April 2018, the Supreme Court of Canada refused to hear Idenix's appeal. The decision invalidating Idenix's Canadian patent is now final.

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 appealed this decision, and in December 2017, the Federal Court of Australia dismissed Idenix’s appeal. In January 2018, Idenix applied for Special Leave to Appeal to the High Court of Australia and, in April 2018, the High Court of Australia refused to hear Idenix’s appeal. The decision revoking Idenix’s Australian patent is now final.

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. In November 2016, the appeals court affirmed the UK Court’s decision invalidating Idenix’s patent, and in April 2017, the UK Supreme Court refused Idenix’s application for permission to appeal. 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.

In December 2013, Idenix, 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 (the ‘054 patent) and 7,608,597 (the ‘597 patent). In June 2014, the court transferred the Massachusetts litigation to the U.S. District Court for the District of Delaware.

Prior to trial in December 2016, Idenix committed to give us a covenant not to sue with respect to any claims arising out of the ‘054 patent related to sofosbuvir and withdrew that patent from the trial. In addition, Idenix declined to litigate the ‘600 patent infringement action at trial in light of the appeal then pending at the CAFC. Since the U.S. Supreme Court denied Idenix’s petition for certiorari in the Second Idenix Interference, all pending actions concerning the ‘600 patent have been dismissed. A jury trial was held in December 2016 on the ‘597 patent. In December 2016, the jury found that we willfully infringed the asserted claims of the ‘597 patent and awarded Idenix $2.54 billion in past damages. In February 2018, the judge invalidated Idenix’s ‘597 patent and vacated the jury’s award of $2.54 billion in past damages. Idenix has appealed this decision to the CAFC. We believe the Delaware court’s decision correctly found that, as a matter of law, the ‘597 patent is invalid, and we remain confident in the merits of our case on appeal. We believe that the possibility of a material adverse outcome on this matter is remote.

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 Ionis 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. 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 attorney’s fees due to the exceptional nature of this case. In July 2017, the court issued a decision setting the amount of attorney fees awarded to us.

Merck filed notices of appeal to the CAFC regarding the court’s decision on our defense of unclean hands and its award of attorney’s fees. In April 2018, the CAFC affirmed the court’s decision on unclean hands. Merck has filed a petition for review by the U.S. Supreme Court. If the decision on our defense of unclean hands is reversed subsequently 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 the ‘830 patent is invalid and will not be infringed by the continued commercialization of sofosbuvir. In October 2017, the court granted our motion to transfer the case

to California. We have also filed four petitions for inter partes review with the PTAB alleging that all asserted claims are invalid for anticipation and obviousness. In March 2018, the District Court stayed the litigation until after the PTAB rules on our petitions for inter partes review.

Petitions for Inter Partes Review filed by Initiative for Medicines, Access & Knowledge

In October 2017, we received notice that Initiative for Medicines, Access & Knowledge (I-MAK) submitted multiple petitions requesting inter partes review to the PTAB alleging that certain patents associated with sofosbuvir are invalid as either not novel or obvious. We strongly believe I-MAK's petitions are without merit and that sofosbuvir, the only approved HCV drug of its kind, is both novel and not obvious. Accordingly, we defended against these allegations, and the PTAB declined to institute all ten of I-MAK's petitions for inter partes review and denied I-MAK's petitions for rehearing.

European Patent Claims

In February 2015, several parties filed oppositions in the EPO requesting revocation of one of our granted European patents covering sofosbuvir that expires in 2028. In October 2016, the EPO upheld the validity of certain claims of our sofosbuvir patent. We have appealed this decision, seeking to restore all of the original claims, and several of the original opposing parties have also appealed, requesting full revocation. The appeal process may take several years.

In April 2017, several parties filed oppositions in the EPO requesting revocation of our granted European patent relating to sofosbuvir that expires in 2024. The EPO conducted an oral hearing for this opposition in September 2018 and upheld the claims. The decision may be appealed.

In January 2016, several parties filed oppositions in the EPO requesting revocation of our granted European patent covering TAF that expires in 2021. In July 2017, the EPO upheld the validity of the claims of our TAF patent. Three parties have appealed this decision. The appeal process may take several years.

In July 2017, several parties filed oppositions in the EPO requesting revocation of our granted European patent relating to TAF hemifumarate that expires in 2032. We have responded to these oppositions. The EPO has not yet set a date for the oral hearing regarding this opposition.

In March 2016, three parties filed oppositions in the EPO requesting revocation of our granted European patent covering cobicistat that expires in 2027. In December 2017, the EPO upheld the validity of the claims of our cobicistat patent. The parties that filed the oppositions may appeal this decision. The appeal process may take several years.

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 the European Union 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 patent protection for sofosbuvir prior to 2028, our revenues and results of operations 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 Related to Axicabtagene Ciloleucel

In October 2017, we acquired Kite, which is now our wholly-owned subsidiary. Through the acquisition, we acquired axicabtagene ciloleucel, a chimeric antigen receptor (CAR) T cell therapy. In October 2017, we received approval from FDA for axicabtagene ciloleucel, now known commercially as Yescarta.

We own patents and patent applications that claim axicabtagene ciloleucel chimeric DNA segments. Third parties may have, or may obtain rights to, patents that allegedly could be used to prevent or attempt to prevent us from commercializing axicabtagene ciloleucel or to require us to obtain a license in order to commercialize axicabtagene ciloleucel. For example, we are aware that Juno Therapeutics, Inc. (Juno) has exclusively licensed Patent No. 7,446,190 (the ‘190 patent), which was issued to Sloan Kettering Cancer Center. In September 2017, Juno and Sloan Kettering Cancer Center filed a lawsuit against Kite in the U.S. District Court for the Central District of California, alleging that the commercialization of axicabtagene ciloleucel infringes the ‘190 patent. In October 2017, following FDA approval for Yescarta, Juno filed a second complaint alleging that axicabtagene ciloleucel infringes the ‘190 patent. Juno subsequently moved to dismiss the September 2017 complaint and has maintained the October 2017 complaint. The court has set a trial date of October 2019 for this lawsuit.

In August 2015, Kite filed a petition for inter partes review in the USPTO alleging that the asserted claims of the ‘190 patent are invalid as obvious. In December 2016, the PTAB determined that the claims of the ‘190 patent are not invalid due to obviousness. In February 2017, Kite filed a Notice of Appeal to the CAFC. In June 2018, the CAFC affirmed the PTAB’s determination that the ‘190 patent claims are not invalid due to obviousness.

We cannot predict the ultimate outcome of intellectual property claims related to axicabtagene ciloleucel. If Juno’s patent is upheld as valid and Juno successfully proves infringement of that patent by axicabtagene ciloleucel, we could be required to pay significant monetary damages or we could be prevented from selling Yescarta unless we were able to obtain a license to this patent. Such a license may not be available on commercially reasonable terms or at all.

Litigation Related to Bictegravir

In February 2018, ViiV Healthcare Company (ViiV) filed a lawsuit against us in the U.S. District Court of Delaware, alleging that the commercialization of bictegravir, now known commercially as Biktarvy, infringes ViiV's U.S. Patent No. 8,129,385 (the '385 patent), which was issued to Shionogi & Co. Ltd. & GlaxoSmithKline LLC. The '385 patent is the compound patent covering ViiV's dolutegravir. Bictegravir is structurally different from dolutegravir, and we believe that bictegravir does not infringe the

claims of the ‘385 patent. To the extent that ViiV’s patent claims are interpreted to cover bictegravir, we believe those claims are invalid. The USPTO has granted us patents covering bictegravir. The court has set a trial date of September 2020 for this lawsuit.

In February 2018, ViiV also filed a lawsuit against us in the Federal Court of Canada, alleging that our activities relating to our bictegravir product have infringed ViiV’s Canadian Patent No. 2,606,282 (the ‘282 patent), which was issued to Shionogi & Co. Ltd. and ViiV. The ‘282 patent is the compound patent covering ViiV’s dolutegravir. We believe that bictegravir does not infringe the claims of the ‘282 patent. To the extent that ViiV’s patent claims are interpreted to cover bictegravir, we believe those claims are invalid.

We cannot predict the ultimate outcome of intellectual property claims related to bictegravir. If ViiV’s patents are upheld as valid and ViiV successfully proves infringement of those patents by bictegravir, we could be required to pay significant monetary damages.

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. To seek approval for a generic version of a product having NCE status, a generic company may submit its ANDA to FDA four years after the branded product’s approval.

Current legal proceedings of significance with generic manufacturers include:

HIV Products

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 parties have agreed to dismiss the action in West Virginia, and the trial in Delaware was stayed. The patent in suit that covers Tybost is also listed in the Orange Book for Stribild and Genvoya. In November 2017, we received notice that Mylan submitted an ANDA to FDA requesting permission to manufacture and market a generic version of Evotaz (atazanavir/cobicistat) and challenging the validity of our cobicistat compound patent, citing the arguments it has made in the ongoing litigation involving Tybost. In December 2017, we filed a lawsuit against Mylan in the U.S. District Court for the Northern District of West Virginia. In July 2018, we reached an agreement with Mylan to resolve all pending lawsuits. The settlement agreement has been filed with the Federal Trade Commission and Department of Justice as required by law.

In April and May 2018, we received notices that Aurobindo Pharma USA Inc. (Aurobindo) submitted an ANDA to FDA requesting permission to manufacture and market generic versions of Truvada at low dosage strengths. In the May notice, Aurobindo alleges that two patents associated with emtricitabine are invalid, unenforceable and/or will not be infringed by Aurobindo’s manufacture, use or sale of generic versions of Truvada at low dosage strengths. In May 2018, we filed a lawsuit against Aurobindo in the U.S. District Court for the District of Delaware for infringement of our patents. In October 2018, we reached an agreement with Aurobindo to resolve the lawsuit. The settlement agreement has been filed with the Federal Trade Commission and Department of Justice as required by law.

In May 2018, we received notice that Strides Pharma Inc. (Strides) submitted an ANDA to FDA requesting permission to manufacture and market a generic version of Truvada. In the notice, Strides alleges that two patents associated with emtricitabine and four patents associated with the emtricitabine and tenofovir disoproxil fumarate fixed-dose combination are invalid, unenforceable and/or will not be infringed by Strides’ manufacture, use or sale of a generic version of Truvada. In June 2018, we filed a lawsuit against Strides in the U.S. District Court for the District of New Jersey for infringement of our patents.

HCV Products

In February 2018, we received notices from Natco Pharma Limited (Natco) and Teva Pharmaceuticals (Teva) that they have each submitted an ANDA to FDA requesting permission to manufacture and market a generic version of Sovaldi. In Teva's notice, it alleges that nine patents associated with sofosbuvir are invalid, unenforceable and/or will not be infringed by Teva's manufacture, use or sale of generic versions of Sovaldi. In March 2018, we filed lawsuits against Teva in the U.S. District Court for the District of New Jersey and the U.S. District Court for the District of Delaware for infringement of these patents. In Natco's notice, it alleges that two patents associated with sofosbuvir are invalid, unenforceable and/or will not be infringed by Natco's manufacture, use or sale of generic versions of Sovaldi. Natco did not challenge all patents listed on the Orange Book for Sovaldi. In March 2018,

we filed lawsuits against Natco in the U.S. District Court for the District of New Jersey and the U.S. District Court for the District of Delaware for infringement of these patents.

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. and Japan Tobacco International, U.S.A. (together, JT), and Emory University. In April 2016, AHF amended its complaint to add 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 JT, 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 emtricitabine and rilpivirine (Odefsey) and in a fixed-dosed combination product with emtricitabine (Descovy). AHF sought a declaratory judgment of invalidity against each of the patents as well as monetary damages. In May 2016, we, JT, 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 subsequently appealed the court's decision dismissing the challenge to the validity of our TAF patents. In May 2018, the Federal Circuit affirmed the lower court's decision dismissing AHF's claims. In August 2018, AHF filed a petition for review by the U.S. Supreme Court and, in October 2018, the U.S. Supreme Court denied AHF's petition.

Government Investigations and Related Litigation

In June 2011, we received a subpoena from the U.S. Attorney's Office for the Northern District of California requesting documents related to the manufacture, and related quality and distribution practices, of Complera, Atripla, Truvada, Viread, Emtriva, Hepsera and Letairis. We cooperated with the government's inquiry. In April 2014, the U.S. Department of Justice informed us that, following an investigation, it declined to intervene in a False Claims Act lawsuit filed by two former employees. In April 2014, the former employees served a First Amended Complaint. In January 2015, the U.S. District Court for the Northern District of California 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 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 the Ninth Circuit. In July 2017, a three-judge panel of the Ninth Circuit reversed and remanded the case back to the District Court. In October 2017, the Ninth Circuit granted our motion to stay the case pending an appeal to the U.S. Supreme Court. In December 2017, we filed a Petition for a Writ of Certiorari to the U.S. Supreme Court. We expect the U.S. Supreme Court to decide whether it will hear the case later this year.

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 documents concerning our provision of financial assistance to patients for our HCV products. We are cooperating with this inquiry. In October 2017, we received a subpoena from the U.S. Attorney's Office for the District of Massachusetts requesting documents related to our copay coupon program and Medicaid price reporting methodology. We are cooperating with this inquiry.

In September 2017, we received a voluntary request for information from the U.S. Attorney's Office for the Eastern District of Pennsylvania requesting information related to our reimbursement support offerings, clinical education programs and interactions with specialty pharmacies for Sovaldi and Harvoni. In June 2018, we received another voluntary request for information related to our speaker programs and advisory boards for our HCV and hepatitis B virus (HBV) products. We are cooperating with these voluntary requests.

In October 2017, we received a subpoena from the California Department of Insurance and the Alameda County District Attorney's Office requesting documents related to our marketing activities, reimbursement support offerings, clinical education programs and interactions with specialty pharmacies. We are cooperating with this inquiry.

In November 2017, Health Choice Advocates LLC served us with a complaint in the United States District Court for the Eastern District of Texas alleging violations of the False Claims Act and similar state statutes through our marketing activities, reimbursement support offerings and clinical education programs for Sovaldi and Harvoni. The

lawsuit was unsealed after the United States and 31 plaintiff-states declined to intervene in the action. In February 2018, we filed two motions to dismiss the complaint. In July 2018, the District Court entered an order dismissing the matter without prejudice as to all claims.

In November 2017, we received a subpoena from the U.S. Department of Health and Human Services requesting documents related to our Frontlines of Communities in the United States (FOCUS) program. We are cooperating with this inquiry.

In November 2017, we also received a subpoena from the U.S. Attorney's Office for the Southern District of New York requesting documents related to our promotional speaker programs for HIV. 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, 2017	1,308	$ 1	$ 1,264	$ 165	$ 19,012	$ 59	$ 20,501
Change in noncontrolling interest	—	—	—	—	—	82	82
Net income	—	—	—	—	5,452	5	5,457
Other comprehensive income, net of tax	—	—	—	164	—	—	164
Issuances under employee stock purchase plan	1	—	91	—	—	—	91
Issuances under equity incentive plans	12	—	167	—	—	—	167
Stock-based compensation	—	—	667	—	—	—	667
Repurchases of common stock	(27)	—	(71)	—	(1,996)	—	(2,067)
Dividends declared	—	—	—	—	(2,245)	—	(2,245)
Cumulative effect from the adoption of new accounting standards	—	—	—	(293)	483	—	190
Balance at September 30, 2018	1,294	$ 1	$ 2,118	$ 36	$ 20,706	$ 146	$ 23,007

Accumulated Other Comprehensive Income (Loss)

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

	Foreign Currency Translation	Unrealized Gains and Losses on Available-for-Sale Securities	Unrealized Gains and Losses on Cash Flow Hedges	Total
Balance at December 31, 2017	$ 85	$ 194	$ (114)	$ 165
Reclassifications to retained earnings as a result of the adoption of new accounting standards	—	(293)	—	(293)
Balance at January 1, 2018	85	(99)	(114)	(128)
Net unrealized gain (loss)	(17)	25	51	59
Reclassifications to net income	—	4	101	105
Net current period other comprehensive income (loss)	(17)	29	152	164
Balance at September 30, 2018	$ 68	$ (70)	$ 38	$ 36

The amounts reclassified to net income for gains and losses on cash flow hedges are recorded as part of Product sales on our Condensed Consolidated Statements of Income. See Note 5, Derivative Financial Instruments, for additional information. The amounts reclassified to net income for gains and losses on available-for-sale debt securities are recorded as part of Other income (expense), net, on our Condensed Consolidated Statements of Income.

Stock Repurchase Program

In the first quarter of 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 the 2016 Program in April 2016.

During the three and nine months ended September 30, 2018, we repurchased and retired 6 million and 26 million shares of our common stock for $449 million and $1.9 billion, respectively, through open market transactions under the 2016 Program. As of September 30, 2018, the remaining authorized repurchase amount under the 2016 Program was $6.1 billion.

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 potentially dilutive shares of our common stock resulting from the assumed exercise of outstanding stock options and equivalents were determined under the treasury stock method.

We have excluded stock options and equivalents of 12 million and 13 million for the three and nine months ended September 30, 2018, respectively, and 9 million for both the three and nine months ended September 30, 2017 from the computation of diluted net income per share attributable to Gilead common stockholders because their effect was antidilutive.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net income attributable to Gilead	$2,097	$2,718	$5,452	$8,493
Shares used in per share calculation - basic	1,296	1,306	1,302	1,307
Dilutive effect of stock options and equivalents	11	13	11	12
Shares used in per share calculation - diluted	1,307	1,319	1,313	1,319
Net income per share attributable to Gilead common stockholders - basic	$1.62	$2.08	$4.19	$6.50
Net income per share attributable to Gilead common stockholders - diluted	$1.60	$2.06	$4.15	$6.44

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, who is our chief executive officer.

See Note 2, Revenues, for a summary of disaggregated revenues by product and geographic region.

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,	
	2018	2017	2018	2017
AmerisourceBergen Corp.	20%	21%	20%	20%
Cardinal Health, Inc.	20%	19%	20%	18%
McKesson Corp.	22%	25%	21%	23%

14. INCOME TAXES

On December 22, 2017, Tax Reform was signed into law making significant changes to the Internal Revenue Code of 1986, as amended. Changes include, but are not limited to, a corporate tax rate decrease from 35% to 21% effective for tax years beginning after December 31, 2017, implementation of a modified territorial tax system and a repatriation tax on deemed repatriated earnings of foreign subsidiaries. We included a provisional estimate of the impact from Tax Reform in our 2017 income tax provision in accordance with our interpretation of Tax Reform and SAB 118.

We may refine our provisional estimates as further guidance is issued from the U.S. Treasury, the SEC and the FASB. Additionally, we are continuing to evaluate the accounting policy election required with regard to the tax on Global

Intangible Low-Taxed Income (the Global Minimum Tax). The FASB allows companies to adopt a policy election to account for the Global Minimum Tax under one of two methods: (i) account for the Global Minimum Tax as a component of tax expense in the period in which a company is subject to the rules (the period cost method), or (ii) account for the Global Minimum Tax in a company's measurement of deferred taxes (the deferred method). We have not elected a method and will only do so after our completion of the analysis of the Global Minimum Tax provisions. Our election method will depend, in part, on analyzing expected future U.S. taxable income inclusions related to Global Minimum Tax under both methodologies in order to determine the most appropriate method. Should we decide to elect the deferred method of accounting for the Global Minimum Tax, it is possible that our provisional

estimate for re-measuring our deferred taxes may materially change. We will finalize the analysis for the accounting policy election during the fourth quarter of 2018.

During the three and nine months ended September 30, 2018, we repatriated $500 million and $29.7 billion, respectively, of cash, cash equivalents and marketable securities to our parent company headquartered in the United States. Prior to the enactment of Tax Reform, these earnings were considered indefinitely reinvested and no U.S. taxes had been provided. In 2017, U.S. taxes were provided on these earnings through the accrual of the Tax Reform transition tax.

Our effective income tax rate of 21.2% for the three months ended September 30, 2018 differed from the U.S. federal statutory rate of 21% primarily due to the Global Minimum Tax and state taxes, partially offset by earnings from non-U.S. subsidiaries that operate in jurisdictions with lower tax rates than the United States.

Our effective income tax rate of 19.5% for the nine months ended September 30, 2018 differed from the U.S. federal statutory rate of 21% primarily due to a $202 million tax benefit related to settlement of a tax examination for an acquired entity and earnings from non-U.S. subsidiaries that operate in jurisdictions with lower tax rates than the United States, partially offset by the Global Minimum Tax and state taxes.

We file federal, state and foreign income tax returns in the United States and in many foreign jurisdictions. 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 IRS for the tax years from 2013 to 2015 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.

Our unrecognized tax benefits decreased by $736 million during the nine months ended September 30, 2018 primarily due to a $706 million decrease for settlement of a tax examination. As of September 30, 2018, we believe that it is reasonably possible that our unrecognized tax benefits will decrease by approximately $100 million in the next 12 months due to potential settlements with taxing authorities.

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 (SEC), we do not undertake and specifically decline any obligation to update any of these statements or to publicly announce the results of any revisions to any forward-looking statements after the distribution of this report, whether as a result of new information, future events, changes in assumptions or otherwise. 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, 2017 and our unaudited Condensed Consolidated Financial Statements for the three and nine months ended September 30, 2018 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, our 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. We strive to transform and simplify care for people with life-threatening illnesses around the world. We have operations in more than 35 countries worldwide, with headquarters in Foster City, California. Gilead's primary areas of focus include HIV/AIDS, liver diseases, hematology/oncology and inflammation/respiratory diseases. We seek to add to our existing portfolio of products through our internal discovery and clinical development programs and through product acquisition and in-licensing strategies.

Our portfolio of marketed products includes AmBisome®, Atripla®, Biktarvy®, Cayston®, Complera®/Eviplera®, Descovy®, Emtriva®, Epclusa®, Genvoya®, Harvoni®, Hepsera®, Letairis®, Odefsey®, Ranexa®, Sovaldi®, Stribild®, Truvada®, Tybost®, Vemlidy®, Viread®, Vosevi®, Yescarta® and Zydelig®. We have U.S. and international commercial sales operations, with marketing subsidiaries in over 35 countries. We also sell and distribute certain products through our corporate partners under royalty-paying collaborative agreements.

Business Highlights

During the third quarter of 2018, 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 need. Recent key announcements include:

HIV and Liver Diseases Programs

- The Hong Kong Department of Health approved Biktarvy for the treatment of HIV-1 infection in adults. Hong Kong is the first market in Asia to approve Biktarvy.
- We announced 96-week results from two Phase 3, randomized, double-blinded studies evaluating the safety and efficacy of Biktarvy for the treatment of HIV-1 infection in treatment-naive adults. In the ongoing studies, Biktarvy was found to be statistically non-inferior to a regimen of dolutegravir and emtricitabine/tenofovir alafenamide (50 mg) (DTG+FTC/TAF) and a regimen of abacavir/DTG/lamivudine (600/50/300mg) through 96 weeks of therapy.
- We announced plans to launch authorized generic versions of Epclusa and Harvoni in the United States through a newly created subsidiary, Asegua Therapeutics LLC.
- We entered into a strategic collaboration with Precision BioSciences (Precision) to develop therapies targeting the in vivo elimination of hepatitis B virus (HBV) with Precision's proprietary genome editing platform, ARCUS.
- The China National Drug Administration approved Genvoya for the treatment of HIV-1 infection.

Oncology and Cell Therapy Programs

- We announced a global strategic collaboration with Tango Therapeutics, Inc. (Tango) to discover, develop and commercialize a pipeline of targeted immuno-oncology treatments for patients with cancer. Under the multi-year collaboration, Tango will perform target discovery and validation and we will have options to worldwide rights on up to five targets emerging from Tango's proprietary functional genomics-based discovery platform.
- We entered into a research collaboration and license agreement with HiFiBiO Therapeutics to develop technology supporting the discovery of neoantigen-reactive T cell receptors for the potential treatment of various cancers, including solid tumors.
- We entered into a license agreement with Trianni, Inc. (Trianni) that grants us the use of the Trianni transgenic human monoclonal antibody discovery platform to support our drug discovery efforts.
- European Commission granted Marketing Authorization for Yescarta as a treatment for adult patients with relapsed or refractory diffuse large B-cell lymphoma and primary mediastinal large B-cell lymphoma, after two or more lines of systemic therapy.

Inflammation Programs

- We announced that detailed results from two clinical trials (EQUATOR and TORTUGA) evaluating filgotinib, an investigational, selective JAK 1 inhibitor, for the treatment of psoriatic arthritis and ankylosing spondylitis (AS) were both published in The Lancet. The results of the EQUATOR and TORTUGA studies demonstrate that filgotinib improved

the signs and symptoms of patients with psoriatic arthritis whose disease had not responded to prior therapies and independently, for those with AS.

- We announced detailed results from the Phase 3 FINCH 2 clinical trial of filgotinib, an investigational, selective JAK1 inhibitor, in adults with moderately-to-severely active rheumatoid arthritis and prior inadequate response or intolerance to biologic agents. The data, which are being presented as a late-breaking poster at the 2018 American College of Rheumatology/Association of Rheumatology Health Professionals Annual Meeting in Chicago, suggest filgotinib has a potential role in addressing important unmet needs in the treatment of rheumatoid arthritis. FINCH 2 achieved its primary endpoint in the proportion of patients achieving an American College of Rheumatology 20 percent response at week 12.
- We announced that the randomized, placebo-controlled Phase 2 TORTUGA study of filgotinib achieved its primary efficacy endpoint in adults with moderately to severely active AS. In the study, patients treated with filgotinib achieved significantly greater improvements in AS Disease Activity Score, the primary endpoint, at week 12, with a mean change from baseline of -1.5 versus -0.6 for those treated with placebo ($p<0.0001$).

Financial Highlights

Total revenues decreased to $5.6 billion for the third quarter of 2018, compared to $6.5 billion for the third quarter of 2017, primarily due to lower product sales, which were $5.5 billion compared to $6.4 billion for the same period in 2017.

Research and development (R&D) expenses increased to $939 million for the third quarter of 2018, compared to $789 million for the third quarter of 2017. Selling, general and administrative (SG&A) expenses increased to $948 million for the third quarter of 2018, compared to $879 million for the third quarter of 2017. The increases in both R&D and SG&A expenses were primarily due to higher costs to support the growth of our business following the acquisition of Kite Pharma, Inc. (Kite) and stock-based compensation expenses associated with our acquisition of Kite.

As of September 30, 2018, we had $30.8 billion of cash, cash equivalents and marketable securities, compared to $31.7 billion as of June 30, 2018. During the third quarter of 2018, we generated $2.2 billion in operating cash flow, repaid $1.8 billion of our senior unsecured notes due in September 2018, paid cash dividends of $742 million and repurchased 6 million shares of our common stock for $449 million through open market transactions.

Results of Operations

Total Revenues

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In millions, except percentages)	2018	2017	Change	2018	2017	Change
Revenues:						
Product sales	$5,455	$6,402	(15)%	$15,996	$19,825	(19)%
Royalty, contract and other revenues	141	110	28 %	336	333	1 %
Total revenues	$5,596	$6,512	(14)%	$16,332	$20,158	(19)%

On January 1, 2018, we adopted Accounting Standards Update No. 2014-09 (Topic 606) using the modified retrospective method applied to those contracts which were not completed as of January 1, 2018. As such, results for the three and nine months ended September 30, 2018 are presented under Topic 606, while the information for the three and nine months ended September 30, 2017 has not been adjusted and continues to be reported in accordance with our historical accounting under Topic 605 “Revenue Recognition” (Topic 605). See Note 1, Summary of Significant Accounting Policies, and Note 2, Revenues, of the Notes to Condensed Consolidated Financial Statements included in Item 1 of this Quarterly Report on Form 10-Q for further information.

Product sales for the three months ended September 30, 2018

Total product sales decreased by 15% to $5.5 billion for the three months ended September 30, 2018, compared to $6.4 billion for the same period in 2017, primarily due to lower sales of our HCV products, partially offset by increased sales of our HIV products.

HIV product sales increased by 12% to $3.7 billion for the three months ended September 30, 2018, compared to $3.3 billion for the same period in 2017, primarily due to the continued uptake of Descovy, Genvoya and Odefsey and our launch of Biktarvy in 2018. Biktarvy was approved by FDA in February 2018 and the European Commission in June 2018.

HCV product sales, which consist of Epclusa, Harvoni, Vosevi and Sovaldi, decreased by 59% to $902 million for the three months ended September 30, 2018, compared to $2.2 billion for the same period in 2017. The decline was primarily due to lower sales of Harvoni, Epclusa and Sovaldi across all major markets as a result of increased competition.

In HCV, we expect a continued decline in product sales in the fourth quarter of 2018, compared to the same period in 2017, in major markets as a result of increased competition. HCV revenues are driven by four variables: patient starts, net pricing, market share and treatment duration. Treatment duration has stabilized as a variable and pricing has largely stabilized. We will continue to compete for market share across market segments and geographies. We anticipate patient starts to be more predictable with a continued slight decline moving forward.

Yescarta, which was launched in the United States in October 2017, generated $75 million in sales during the three months ended September 30, 2018.

Other product sales, which include products from our HBV, cardiovascular, oncology and other categories inclusive of Vemlidy, Viread, Letairis, Ranexa, Zydelig and AmBisome, decreased by 14% to $751 million for the three months ended September 30, 2018, compared to $874 million for the same period in 2017. Sales of Viread, which is primarily used for treatment of chronic HBV, decreased due to the availability of generic versions of the product. Letairis is expected to face generic competition in the United States because the U.S. patent for ambrisentan, the active pharmaceutical ingredient in Letairis, expired in July 2018. Ranexa is expected to face generic competition in the United States starting in the first quarter of 2019. We expect a decline in our Letairis and Ranexa sales in the United States after the generic entries.

Of our total product sales, 24% were generated outside the United States during the three months ended September 30, 2018. We faced exposure to movements in foreign currency exchange rates, primarily in the Euro. We used foreign currency exchange contracts to hedge a percentage of our foreign currency exposure. Foreign currency exchange, net of hedges, had an immaterial impact on our product sales for the three months ended September 30, 2018, compared to the same period in 2017.

Product sales in the United States decreased by 9% to $4.1 billion for the three months ended September 30, 2018, compared to $4.5 billion for the same period in 2017. The decrease was primarily due to lower sales of our HCV products, partially offset by higher sales of our HIV products. The decrease in sales of our HCV products was primarily due to lower average net selling price and lower sales volume as a result of increased competition. The increase in sales of our HIV products was primarily driven by increased demand for our Descovy (FTC/TAF))-based products and to a lesser extent, higher average net selling price, partially offset by the decrease in sales volume of our Truvada (FTC and tenofovir disoproxil fumarate (TDF))-based products, which include Atripla, Complera/Eviplera and Stribild.

Product sales in Europe decreased by 27% to $873 million for the three months ended September 30, 2018, compared to $1.2 billion for the same period in 2017. The decrease was primarily due to lower sales of our HCV products and the availability of generic versions of Truvada, Atripla and Viread. The decrease in sales of our HCV products was primarily due to lower average net selling price and lower sales volume as a result of increased competition. The decrease was partially offset by the continued uptake of our Descovy (FTC/TAF)-based products. Foreign currency exchange, net of hedges, had an immaterial impact on our product sales for the three months ended September 30, 2018, compared to the same period in 2017.

Product sales in other locations decreased by 32% to $451 million for the three months ended September 30, 2018, compared to $663 million for the same period in 2017, primarily due to lower sales in Japan. Sales of our HCV products in Japan decreased to $45 million for the three months ended September 30, 2018, compared to $170 million for the same period in 2017, primarily due to lower market share as a result of increased competition.

Product sales for the nine months ended September 30, 2018

Total product sales decreased by 19% to $16.0 billion for the nine months ended September 30, 2018, compared to $19.8 billion for the same period in 2017, primarily due to lower sales of our HCV products, partially offset by increased sales of our HIV products.

HIV product sales increased by 10% to $10.6 billion for the nine months ended September 30, 2018, compared to $9.6 billion for the same period in 2017, primarily due to the continued uptake of Descovy, Genvoya and Odefsey and our launch of Biktarvy in 2018.

HCV product sales decreased by 61% to $2.9 billion for the nine months ended September 30, 2018, compared to $7.6 billion for the same period in 2017, primarily due to lower sales of Harvoni, Epclusa and Sovaldi across all major markets as a result of increased competition.

Yescarta generated $183 million in sales during the nine months ended September 30, 2018.

Other product sales, which include products from our HBV, cardiovascular, oncology and other categories inclusive of Vemlidy, Viread, Letairis, Ranexa, Zydelig and AmBisome, decreased by 12% to $2.3 billion for the nine months ended September 30, 2018, compared to $2.6 billion for the same period in 2017. Sales of Viread decreased due to the availability of generic versions of the product.

Of our total product sales, 27% were generated outside the United States during the nine months ended September 30, 2018. We faced exposure to movements in foreign currency exchange rates, primarily in the Euro. We used foreign currency exchange

contracts to hedge a percentage of our foreign currency exposure. Foreign currency exchange, net of hedges, had a favorable impact on our product sales of $89 million for the nine months ended September 30, 2018, compared to the same period in 2017.

Product sales in the United States decreased by 16% to $11.7 billion for the nine months ended September 30, 2018, compared to $14.0 billion for the same period in 2017. The decrease was primarily due to lower sales of our HCV products, partially offset by higher sales of our HIV products. The decrease in sales of our HCV products was primarily due to lower average net selling price and lower sales volume as a result of increased competition. The increase in the sales of our HIV products was primarily driven by higher demand for our Descovy (FTC/TAF)-based products and to a lesser extent, higher average net selling price, partially offset by the decrease in sales volume of our Truvada (FTC/TDF)-based products.

Product sales in Europe decreased by 25% to $2.9 billion for the nine months ended September 30, 2018, compared to $3.9 billion for the same period in 2017. The decrease was primarily due to lower sales of our HCV products and the availability of generic versions of Truvada, Atripla and Viread. The decrease in sales of our HCV products was primarily due to lower sales volume and average net selling price as a result of increased competition. The decrease was partially offset by the continued uptake of our Descovy (FTC/TAF)-based products. Foreign currency exchange, net of hedges, had a favorable impact on our product sales of $62 million for the nine months ended September 30, 2018, compared to the same period in 2017.

Product sales in other locations decreased by 30% to $1.4 billion for the nine months ended September 30, 2018, compared to $2.0 billion for the same period in 2017, primarily due to lower sales in Japan. Sales of our HCV products in Japan decreased to $124 million for the nine months ended September 30, 2018, compared to $556 million for the same period in 2017, primarily due to lower market share as a result of increased competition.

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In millions, except percentages)	2018	2017	Change	2018	2017	Change
Atripla	$258	$439	(41)%	$921	$1,366	(33)%
Biktarvy	386	—	*	606	—	*
Complera/Eviplera	139	237	(41)%	528	744	(29)%
Descovy	406	316	28 %	1,170	853	37 %
Genvoya	1,176	988	19 %	3,418	2,614	31 %
Odefsey	423	296	43 %	1,150	781	47 %
Stribild	146	229	(36)%	507	831	(39)%
Truvada	757	811	(7)%	2,174	2,337	(7)%
Other HIV[1]	14	15	(7)%	46	41	12 %
Revenue share - Symtuza[2]	22	—	*	42	—	*
AmBisome	102	92	11 %	312	276	13 %
Epclusa	477	882	(46)%	1,513	2,945	(49)%
Harvoni	311	973	(68)%	990	3,726	(73)%
Letairis	241	213	13 %	689	654	5 %
Ranexa	178	164	9 %	581	517	12 %
Vemlidy	87	37	*	221	70	*
Viread	70	274	(74)%	249	834	(70)%
Vosevi	103	123	(16)%	319	123	*
Yescarta	75	—	*	183	—	*
Zydelig	20	40	(50)%	92	110	(16)%
Other[3]	64	273	(77)%	285	1,003	(72)%
Total product sales	$5,455	$6,402	(15)%	$15,996	$19,825	(19)%

* Percentage not meaningful
(1) Includes Emtriva and Tybost
(2) Represents Gilead's revenue from cobicistat (C), FTC and TAF in Symtuza® (darunavir/C/FTC/TAF), a fixed dose combination product commercialized by Janssen
(3) Includes Cayston, Hepsera and Sovaldi

The following is additional discussion of our results by product:

- Descovy (FTC/TAF)-based products - Biktarvy, Descovy, Genvoya and Odefsey

Product sales of our Descovy (FTC/TAF)-based products were $2.4 billion and $6.3 billion, and accounted for 44% and 40% of our total product sales for the three and nine months ended September 30, 2018, respectively. Product sales of our Descovy (FTC/TAF)-based products were $1.6 billion and $4.2 billion, and accounted for 25% and 21% of our total product sales for the three and nine months ended September 30, 2017, respectively.

For the three months ended September 30, 2018, sales of our Descovy (FTC/TAF)-based products were $1.9 billion in the United States and $390 million in Europe, compared to $1.3 billion in the United States and $248 million in Europe for the same period in 2017. The increases in all major markets were primarily driven by higher sales volume reflecting the increased demand for Descovy, Genvoya and Odefsey and our launch of Biktarvy in 2018.

For the nine months ended September 30, 2018, sales of our Descovy (FTC/TAF)-based products were $5.1 billion in the United States and $1.1 billion in Europe, compared to $3.6 billion in the United States and $594 million in Europe for the same period in 2017. The increases in all major markets were primarily driven by higher sales volume reflecting the increased demand for Descovy, Genvoya and Odefsey and our launch of Biktarvy in 2018.

- Truvada (FTC/TDF)-based products - Atripla, Complera/Eviplera, Stribild and Truvada

Product sales of our Truvada (FTC/TDF)-based products were $1.3 billion and $4.1 billion, and accounted for 24% and 26% of our total product sales for the three and nine months ended September 30, 2018, respectively. Product sales of our Truvada (FTC/TDF)-based products were $1.7 billion and $5.3 billion, and accounted for 27% of our total product sales for both the three and nine months ended September 30, 2017, respectively.

For the three months ended September 30, 2018, sales of our Truvada (FTC/TDF)-based products were $1.1 billion in the United States, $178 million in Europe and $64 million in other locations, compared to $1.2 billion in the United States, $406 million in Europe and $110 million in other locations for the same period in 2017. In the United States, the decrease was primarily due to lower sales volume as a result of the continued uptake of our Descovy (FTC/TAF)-based products, partially offset by the increased usage of Truvada for PrEP and higher average net selling price. In Europe, the decrease was primarily due to lower sales volume as a result of the availability of generic versions of Truvada and Atripla and the continued uptake of our Descovy (FTC/TAF)-based products.

For the nine months ended September 30, 2018, sales of our Truvada (FTC/TDF)-based products were $3.1 billion in the United States, $726 million in Europe and $262 million in other locations, compared to $3.6 billion in the United States, $1.3 billion in Europe and $390 million in other locations for the same period in 2017. In the United States, the decrease was primarily due to lower sales volume as a result of the continued uptake of our Descovy (FTC/TAF)-based products, partially offset by the increased usage of Truvada for PrEP and higher average net selling price. In Europe, the decrease was primarily due to lower sales volume as a result of the availability of generic versions of Truvada and Atripla and the continued uptake of our Descovy (FTC/TAF)-based products.

- Epclusa

Epclusa sales accounted for 9% of our total product sales for both the three and nine months ended September 30, 2018, respectively, and 14% and 15% of our total product sales for the three and nine months ended September 30, 2017, respectively.

For the three months ended September 30, 2018, Epclusa product sales were $225 million in the United States and $136 million in Europe, compared to $543 million in the United States and $263 million in Europe for the same period in 2017. Sales of Epclusa decreased across all major markets primarily due to lower average net selling price as a result of increased competition.

For the nine months ended September 30, 2018, Epclusa product sales were $733 million in the United States and $502 million in Europe, compared to $2.1 billion in the United States and $649 million in Europe for the same period in 2017. Sales of Epclusa decreased across all major markets primarily due to lower average net selling price as a result of increased competition.

- Harvoni

Harvoni sales accounted for 6% of our total product sales for both the three and nine months ended September 30, 2018, and 15% and 19% of our total product sales for the three and nine months ended September 30, 2017, respectively.

For the three months ended September 30, 2018, Harvoni product sales were $185 million in the United States, $38 million in Europe and $88 million in other locations, compared to $718 million in the United States, $110 million in

Europe and $145 million in other locations for the same period in 2017. The decreases in all major markets were primarily due to lower sales volume as a result of increased competition.

For the nine months ended September 30, 2018, Harvoni product sales were $649 million in the United States, $116 million in Europe and $225 million in other locations, compared to $2.6 billion in the United States, $583 million in Europe and $515 million in other locations for the same period in 2017. The decreases in all major markets were primarily due to lower sales volume as a result of increased competition.

- Other Products - Cayston, Hepsera and Sovaldi

Other product sales accounted for 1% and 2% of our total product sales for the three and nine months ended September 30, 2018 and 4% and 5% of our total product sales for the three and nine months ended September 30, 2017, respectively.

For the three months ended September 30, 2018, other product sales decreased to $64 million, compared to $273 million for the same period in 2017, primarily due to lower Sovaldi sales. Sales of Sovaldi decreased to $11 million for the three months ended September 30, 2018, compared to $219 million for the same period in 2017, primarily due to lower sales volume driven by a shift in the market from Sovaldi to Epclusa.

For the nine months ended September 30, 2018, other product sales decreased to $285 million, compared to $1.0 billion for the same period in 2017, primarily due to lower Sovaldi sales. Sales of Sovaldi decreased to $126 million for the nine months ended September 30, 2018, compared to $847 million for the same period in 2017, primarily due to lower sales volume driven by a shift in the market from Sovaldi to Epclusa.

Cost of Goods Sold and Product Gross Margin

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
(In millions, except percentages)	2018	2017	Change	2018	2017	Change
Total product sales	$5,455	$6,402	(15)%	$15,996	$19,825	(19)%
Cost of goods sold	$1,086	$1,032	5 %	$3,283	$3,115	5 %
Product gross margin	80 %	84 %	(4)%	79 %	84 %	(5)%

Our cost of goods sold for the three and nine months ended September 30, 2018 increased by $54 million and $168 million, respectively, compared to the same periods in 2017, primarily due to $87 million and $263 million, respectively, in amortization expense related to the intangible assets acquired in connection with our acquisition of Kite. The increases were partially offset by lower costs of efavirenz, a component of Atripla, as a result of the termination of a collaboration arrangement with Bristol-Myers Squibb Company on December 31, 2017.

Our product gross margin for the three and nine months ended September 30, 2018 decreased by 4% and 5%, respectively, compared to the same periods in 2017, primarily due to changes in our product mix and factors noted above.

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)	2018	2017	Change	2018	2017	Change
Research and development expenses	$939	$789	19 %	$3,068	$2,584	19 %
Selling, general and administrative expenses	$948	$879	8 %	$2,925	$2,626	11 %

Research and Development Expenses

R&D expenses consist primarily of clinical studies performed by contract research organizations, materials and supplies, licenses and fees, up-front payments under collaboration agreements, milestone payments, in-process research and development (IPR&D) impairment charges, personnel costs, including salaries, benefits and stock-based

compensation and overhead allocations consisting of various support and facilities-related costs. IPR&D assets capitalized in connection with acquisitions are tested for impairment in the fourth quarter of each year, or earlier if impairment indicators exist. No impairment charges were recorded for the three and nine months ended September 30, 2018 and 2017. For more information, refer to our critical accounting policies and estimates on valuation of intangible assets presented in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2017.

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, 2018 increased by $150 million or 19%, compared to the same period in 2017, primarily due to higher costs to support the growth of our business following the acquisition of Kite and stock-based compensation expenses associated with our acquisition of Kite.

R&D expenses for the nine months ended September 30, 2018 increased by $484 million or 19%, compared to the same period in 2017, primarily due to higher costs to support the growth of our business following the acquisition of Kite, stock-based compensation expenses associated with our acquisition of Kite and up-front collaboration payments related to our collaboration agreement with Sangamo Therapeutics, Inc.

Selling, General and Administrative Expenses

SG&A expenses relate to sales and marketing, finance, human resources, legal and other administrative activities. Expenses consist primarily of personnel costs, facilities and overhead costs, outside marketing, advertising and legal expenses, and other general and administrative costs. SG&A expenses also include the branded prescription drug (BPD) fee. In the United States, we, along with other pharmaceutical manufacturers of branded drug products, are required to pay a portion of the BPD fee, which is estimated based on select government sales during the prior year as a percentage of total industry government sales and is trued-up upon receipt of invoices from the Internal Revenue Service.

SG&A expenses for the three and nine months ended September 30, 2018, increased by $69 million or 8%, and $299 million or 11%, respectively, compared to the same periods in 2017, primarily due to increased expenses to support the growth of our business following the acquisition of Kite and stock-based compensation expenses associated with our acquisition of Kite, partially offset by lower BPD fees.

Other Income (Expense), Net

Other income (expense), net, increased to $305 million and $547 million for the three and nine months ended September 30, 2018, respectively, compared to $150 million and $391 million, respectively, for the same periods in 2017. The increases were primarily due to unrealized gains from changes in the fair value of our marketable equity securities. Starting in January 2018, we recorded unrealized gains (losses) from changes in the fair value of our marketable equity securities in Other income (expense), net on our Condensed Consolidated Statements of Income as a result of the adoption of Accounting Standards Update No. 2016-01 “Financial Instruments-Overall: Recognition and Measurement of Financial Assets and Financial Liabilities”. See Note 1, Summary of Significant Accounting Policies, of the Notes to Condensed Consolidated Financial Statements included in Item 1 of this Quarterly Report on Form 10-Q for further information.

Provision for Income Taxes

Our provision for income taxes was $565 million and $959 million for the three months ended September 30, 2018 and 2017, respectively. Our effective tax rate decreased to 21.2% for the three months ended September 30, 2018 compared to 26.1% for same period in 2017, primarily due to a reduction of the U.S. corporate tax rate as a result of the enactment of the Tax Cuts and Jobs Act (Tax Reform) in December 2017, partially offset by changes to the geographic mix of earnings and the Global Intangible Low-Taxed Income (the Global Minimum Tax).

Our provision for income taxes was $1.3 billion and $2.9 billion for the nine months ended September 30, 2018 and 2017, respectively. Our effective tax rate decreased to 19.5% for the nine months ended September 30, 2018 compared to 25.6% for the same period in 2017, primarily due to a reduction of the U.S. corporate tax rate as a result of the enactment of Tax Reform in December 2017 and a tax benefit related to settlement of a tax examination for an acquired entity in the three months ended June 30, 2018, partially offset by changes to the geographic mix of earnings and the Global Minimum Tax.

We calculated a provisional estimate of the impact from Tax Reform in our 2017 income tax provision in accordance with our interpretation of Tax Reform and the SEC Staff Accounting Bulletin 118. We expect to finalize the

provisional estimate during the fourth quarter of 2018.

We are evaluating certain changes to our legal entity structure in response to guidelines and requirements in various international tax jurisdictions where we conduct business. These changes may take multiple reporting periods to implement and may result in certain material, but non-recurring, adjustments to our deferred tax assets and/or liabilities, which will cause an offsetting increase or decrease to our tax provision. Estimates of these adjustments cannot be reasonably determined at this time.

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, 2018	December 31, 2017
Cash, cash equivalents and marketable securities	$ 30,844	$ 36,694
Working capital	$ 24,802	$ 20,188

Cash, Cash Equivalents and Marketable Securities

Cash, cash equivalents and marketable securities totaled $30.8 billion as of September 30, 2018, a decrease of $5.9 billion compared to $36.7 billion as of December 31, 2017. During the nine months ended September 30, 2018, we generated $6.1 billion in operating cash flow. We repaid $1.8 billion of our senior unsecured notes due in September 2018, repaid $4.5 billion of term loans borrowed in connection with our acquisition of Kite, paid cash dividends of $2.2 billion and utilized $1.9 billion on stock repurchases.

Working Capital

Working capital was $24.8 billion as of September 30, 2018, compared to $20.2 billion as of December 31, 2017. The increase of $4.6 billion was primarily driven by a shift in the duration of our marketable securities portfolio to reduce interest rate risk.

Cash Flows

The following table summarizes our cash flow activities:

	Nine Months Ended September 30,	
(In millions)	2018	2017
Cash provided by (used in):		
Operating activities	$6,055	$9,145
Investing activities	$11,620	$(6,053)
Financing activities	$(10,648)	$46

Cash Provided by Operating Activities

Cash provided by operating activities represents 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 for non-cash items and changes in operating assets and liabilities. Cash provided by operating activities decreased by $3.1 billion to $6.1 billion for the nine months ended September 30, 2018, when compared to the same period in 2017, primarily due to lower product sales and higher tax payments. The tax payments included a $500 million payment related to the first annual installment of the Tax Reform transition tax during the first quarter of 2018, a $700 million deemed early payment of the Tax Reform transition tax and a $514 million settlement of a tax examination in the second quarter of 2018.

Cash Provided by (Used in) Investing Activities

Cash provided by (used in) investing activities primarily consists of purchases, sales and maturities of our marketable securities, our capital expenditures and other investments. Cash provided by investing activities was $11.6 billion for the nine months ended September 30, 2018, compared to cash used in investing activities of $6.1 billion for the same period in 2017. The change in cash provided by (used in) investing activities was primarily due to lower purchases of marketable securities and higher proceeds from maturities of our marketable securities, partially offset by lower proceeds from sales of our marketable securities.

Cash Provided by (Used in) Financing Activities

Cash used in financing activities was $10.6 billion for the nine months ended September 30, 2018, compared to cash provided by financing activities of $46 million for the same period in 2017. The change in cash provided by (used in) financing activities was primarily due to the $1.8 billion repayment of our senior unsecured notes upon maturity, $4.5 billion repayment of term loans borrowed in connection with our acquisition of Kite and higher repurchases of our common stock. In addition, we had $3.0 billion net proceeds from debt issuances during the nine months ended

September 30, 2017. No debt was issued during the nine months ended September 30, 2018.

Debt and Credit Facilities

The summary of our borrowings under various financing arrangements is included in Note 9, Debt and Credit Facilities, of the Notes to Condensed Consolidated Financial Statements included in Item 1 of this Quarterly Report on Form 10-Q.

In September 2018, we repaid $1.8 billion of our senior unsecured notes upon maturity.

In March 2018, we fully repaid the $4.5 billion outstanding debt under our term loan facility credit agreement, at which time the term loan facility credit agreement terminated.

Other than the aforementioned repayments, there were no material changes to our debt and our credit facilities during the three and nine months ended September 30, 2018. As of September 30, 2018, no amounts were outstanding under our revolving credit facility.

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, 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. 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, 2017. Other than the adoption of Topic 606, as described below, there were no material changes to our critical accounting policies and estimates during the nine months ended September 30, 2018.

Revenue Recognition

Adoption of ASC Topic 606, “Revenue from Contracts with Customers”

On January 1, 2018, we adopted Topic 606 using the modified retrospective method whereby results for reporting periods beginning after January 1, 2018 are presented under Topic 606, while prior period amounts are not adjusted and continue to be reported in accordance with our historical accounting under Topic 605. Under Topic 606, an entity recognizes revenue when it transfers control of 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. We recorded the cumulative effect of applying the new revenue standard as a net increase of $190 million to the opening balance of retained earnings. The impact as a result of applying Topic 606 in place of Topic 605 was not material for the three and nine months ended September 30, 2018.

Product Sales

We recognize revenues from product sales when control of the product transfers, generally upon shipment or delivery to the customer, in an amount that reflects the consideration we expect to receive for those products. We record product sales net of estimated mandatory and supplemental discounts to government and private payers, in addition to discounts to private payers, and other related charges. These are generally referred to as variable consideration and are recorded in the same period the related sales occur. Government and other rebates and chargebacks represent the majority of our variable consideration and require complex and significant judgment by management. Estimates are assessed each period and updated to reflect current information.

Government and Other Rebates and Chargebacks

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

For qualified programs that can purchase our products through wholesalers or other distributors at a lower contractual price, the wholesalers or distributors charge back to us the difference between their acquisition cost and the lower contractual price. Our consolidated allowances for government and other chargebacks that are payable to our direct customers are classified as reductions of Accounts receivable on our Condensed Consolidated Balance Sheets.

Our consolidated allowance for government and other rebates that will be paid to parties other than our direct customers are recorded in Accrued government and other rebates on our Condensed Consolidated Balance Sheets. Our allowances for government and other rebates and chargebacks are estimated based on products sold, historical payer mix, pertinent third-party industry information, estimated patient population, known market events or trends, channel inventory data and/or other market data. We also consider new information regarding changes in programs' regulations and guidelines that would impact the amount of the actual rebates and/or our expectations regarding future payer mix for these programs. We believe the methodology that we use to estimate our government and other rebates and chargebacks is reasonable and appropriate given

the current facts and circumstances. However, actual results may differ significantly from our estimates. Historically, our actual government rebates and chargebacks claimed for prior periods have varied by less than 5% from our estimates.

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 Item 1 of this Quarterly Report on Form 10-Q for additional information.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There have been no material changes in our market risk during the three and nine months ended September 30, 2018 compared to the disclosures in Part II, Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2017.

Item 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

An evaluation as of September 30, 2018 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 our management, including our 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 as of September 30, 2018.

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, 2018, 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 Part I, Item I of 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 HIV and HCV. If we are unable to increase HIV sales or if HCV sales decrease more than anticipated, then our results of operations may be adversely affected.

We receive a substantial portion of our revenue from sales of our products for the treatment of HIV infection, which include Genvoya, Truvada, Odefsey, Descovy, Biktarvy, Atripla, Stribild and Complera/Eviplera. During the nine months ended September 30, 2018, sales of our HIV products accounted for approximately 66% of our total product sales, and we expect our HIV products to account for a higher percentage of our total product sales in 2018 than in 2017. 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. 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.

During the nine months ended September 30, 2018, sales of Epclusa, Harvoni, Vosevi and Sovaldi for the treatment of HCV accounted for approximately 18% of our total product sales. Our HCV revenues have declined and we expect a further decline in product sales in 2018, compared to 2017, in major markets as a result of increased competition. However, we believe that the overall HCV market and our HCV revenues have begun to stabilize in 2018. The drivers of our HCV product revenues are patient starts, net pricing, market share and treatment duration. With treatment duration stabilizing and pricing largely stabilizing in 2018, we expect to continue to compete for market share across market segments and geographies. While the number of new patient starts has diminished, we anticipate patient starts to be more predictable with a continued slight decline moving forward. Any unexpected and adverse changes to these drivers, including any larger than anticipated shifts, may adversely impact our HCV product revenues.

In addition, future sales of our HIV and HCV products depends, in part, on the extent of reimbursement of our products by private and public payers. 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 our products 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, our products. Any change in the formulary coverage, reimbursement levels or discounts or rebates offered on our products to payers may impact our anticipated revenues. If we are unable to achieve our forecasted HIV and HCV sales, our stock price could be adversely impacted.

We may be unable to sustain or increase sales of our HIV or HCV products for any number of reasons including, but not limited to, the reasons discussed above and the following:

- As our 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 HIV or HCV products, the sales of our HIV or HCV products will be limited.
- As new branded 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 Truvada, Atripla, Complera/Eviplera and Stribild, faces generic competition in the European Union, the United States and certain other countries. In addition, because emtricitabine, the other active pharmaceutical ingredient of Truvada, faces generic competition in the European Union, Truvada faces generic competition in the European Union and certain other countries outside

of the United States. This has had, and is expected to continue to have, a negative 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 R&D efforts. Drug development is inherently risky and many product candidates fail during the drug development process. For example, during 2018, we terminated our Phase 3 study of andecaliximab for the treatment of gastric cancer. We may decide to terminate product development after expending significant resources and effort. In addition, if we are unable to obtain regulatory approval for product candidates from our recent acquisition of Kite Pharma, Inc. (Kite) and effectively commercialize Kite's product candidates, we may not be able to realize the anticipated benefits from our acquisition of Kite, including any expected future revenues from Kite's product candidates.

Further, any future marketing applications we file may not be approved by the regulatory authorities on a timely basis, or at all. Even if marketing approval is granted, there may be significant limitations on their use.

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, the non-retail sector in the United States, which includes government institutions, including state AIDS Drug Assistance Programs (ADAPs), the U.S. Department of Veterans Affairs, 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, 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 2018 and certain prior years, we observed large non-retail purchases of our HIV products by a number of state ADAPs that exceeded patient demand. We believe such purchases were driven by the grant cycle for federal ADAP funds. We expect to continue to experience fluctuations in the purchasing patterns of our non-retail customers which may result in fluctuations in our product sales, revenues and earnings in the future. In light of the 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.

During the nine months ended September 30, 2018, approximately 86% of our product sales in the United States were to three wholesalers, AmerisourceBergen Corp., Cardinal Health, Inc. and McKesson Corp. 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, increased competition 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 2017, strong wholesaler and sub-wholesaler purchases of our products resulted in inventory draw-down by wholesalers and sub-wholesalers in the first quarter of 2018. 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.

Further, because our HCV products represent a cure and competitors' HCV products have entered the market, revenues from our HCV products are difficult for us and investors to estimate. See a discussion of the primary drivers of our HCV product revenues and the factors that can negatively impact such revenues in the risk factor entitled "A

substantial portion of our revenues is derived from sales of products to treat HIV and HCV. If we are unable to increase HIV sales or if HCV sales decrease more than anticipated, then our results of operations may be adversely affected" starting on page 37. In addition, 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 United States, actual rebate claims are typically made by payers one to three quarters in arrears. Actual claims may vary significantly from our estimates which can cause an adjustment to our product revenues. Because HCV product revenues are difficult to predict, investors may have widely varying expectations that may be materially higher or lower than our actual or anticipated revenues. To the extent our actual or anticipated HCV product revenues exceed or fall short of these expectations, our stock price could be adversely impacted.

Yescarta, a chimeric antigen receptor (CAR) T cell therapy, represents a novel approach to cancer treatment that creates significant challenges for us.

Yescarta, a CAR T cell therapy, involves (i) harvesting T cells from the patient's blood, (ii) engineering T cells to express cancer-specific receptors, (iii) increasing the number of engineered T cells and (iv) infusing the functional cancer-specific T cells back into the patient. Advancing this novel and personalized therapy creates significant challenges, including:

- educating and certifying medical personnel regarding the procedures and the potential side effect profile of our therapy, such as the potential adverse side effects related to cytokine release syndrome and neurologic toxicities, in compliance with the Risk Evaluation and Mitigation Strategy (REMS) program required by FDA for Yescarta;
- using medicines to manage adverse side effects of our therapy, such as tocilizumab and corticosteroids, which may not be available in sufficient quantities, may not adequately control the side effects and/or may have a detrimental impact on the efficacy of the treatment;
- sourcing clinical and commercial supplies for the materials used to manufacture and process Yescarta;
- developing a robust and reliable process, while limiting contamination risks, for engineering a patient's T cells ex vivo and infusing the engineered T cells back into the patient; and
- conditioning patients with chemotherapy in advance of administering our therapy, which may increase the risk of adverse side effects.

The use of engineered T cells as a potential cancer treatment is a recent development and may not be broadly accepted by physicians, patients, hospitals, cancer treatment centers, payers and others in the medical community. We may not be able to establish or demonstrate in the medical community or commercial or governmental payers the safety and efficacy of Yescarta and the potential advantages and side effects compared to existing and future therapeutics. If we fail to overcome these significant challenges, our sales of Yescarta, results of operations and stock price could be adversely affected.

We face significant competition.

We face significant competition from global pharmaceutical and biotechnology companies, specialized pharmaceutical firms and generic drug manufacturers. Our products compete with other available products based primarily on efficacy, safety, tolerability, acceptance by doctors, ease of patient compliance, ease of use, price, insurance and other reimbursement coverage, distribution and marketing.

Our HIV products compete primarily with products from ViiV Healthcare Company (ViiV), which markets fixed-dose combination products that compete with Genvoya, Truvada, Descovy, Odefsey, Atripla, Complera/Eviplera, Stribild and Biktarvy. For example, products marketed by ViiV, including Tivicay (dolutegravir), Triumeq (abacavir/dolutegravir/lamivudine) and Juluca (dolutegravir/rilpivirine), compete with our HIV products. For Tybost, we compete with ritonavir marketed by AbbVie Inc. (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 efavirenz, a component of Atripla, are available in the United States, Canada and Europe. We have observed some pricing pressure related to the efavirenz component of our Atripla sales. TDF, one of the active pharmaceutical ingredients in Truvada, Atripla, Complera/Eviplera and Stribild, faces generic competition in the European Union, the United States and certain other countries. In addition, because emtricitabine, the other active pharmaceutical ingredient of Truvada, faces generic competition in the European Union, Truvada also faces generic competition in the European Union and certain other countries outside of the United States.

Our HCV products, Epclusa, Harvoni, Sovaldi and Vosevi, compete primarily with Mavyret (glecaprevir/pibrentasvir) marketed by AbbVie and Zepatier (elbasvir and grazoprevir) marketed by Merck.

Our HBV products, Viread, Vemlidy and Hepsera, face competition from existing therapies for treating patients with HBV. Our HBV products face competition from generic versions of TDF. Our HBV products also compete with Baraclude (entecavir), an oral nucleoside analog marketed by Bristol-Myers Squibb Company, as well as generic entecavir, and Tyzeka/Sebivo (telbivudine), an oral nucleoside analog marketed by Novartis Pharmaceuticals Corporation (Novartis).

Yescarta competes with Kymriah, a CAR T cell therapy for the treatment of relapsed or refractory diffuse large B-cell lymphoma, marketed by Novartis, and is expected to compete with products from other companies developing advanced T cell therapies.

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. Because the U.S. patent for ambrisentan, the active pharmaceutical ingredient in Letairis, expired in July 2018, Letairis is expected to face generic competition in the United States.

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. Ranexa is expected to face generic competition in the United States starting in the first quarter of 2019.

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 as a result of new technologies, commercialization strategies or otherwise, it could adversely affect our results of operations and stock price.

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 prior 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 $4.1 billion in 2018 and $2.8 billion in 2019 and thereafter. Our BPD fee expenses were $385 million in 2017, $270 million in 2016 and $414 million in 2015. The BPD fee is not tax deductible.

Since the November 2016 U.S. election, President Trump and the U.S. Congress have made numerous efforts to repeal or amend the Affordable Care Act in whole or in part. In May 2017, the U.S. House of Representatives voted to pass the American Health Care Act (the AHCA), which would repeal many provisions of the Affordable Care Act. Although the U.S. Senate considered but failed to pass the AHCA and other comparable measures, the U.S. Congress may consider further legislation to repeal or replace elements of the Affordable Care Act. In addition, the Tax Cuts and Jobs Act, which President Trump signed into law in December 2017, repeals the Affordable Care Act's individual health insurance mandate, which is considered a key component of the Affordable Care Act. The future stability of the Affordable Care Act and the resulting impact on our business is thus uncertain and could be material.

In addition, many states have proposed legislation that seeks to indirectly or directly regulate pharmaceutical drug pricing by requiring biopharmaceutical manufacturers to publicly report proprietary pricing information or to place a maximum price ceiling on pharmaceutical products purchased by state agencies. If such proposed legislation is passed, we may experience additional pricing pressures on our products. For example, in October 2017, California's governor signed a prescription drug price transparency state bill into law, requiring prescription drug manufacturers to provide advance notice and explanation for price increases of certain drugs that exceed a specified threshold. Similar bills have been previously introduced at the federal level, and the Trump administration has focused attention on proposed efforts to curb prescription drug prices. In May 2018, President Trump and the Health and Human Services (HHS) Secretary released the American Patients First blueprint, which included measures to increase generic drug and biosimilar competition, the ability of the Medicare program to negotiate drug prices, public transparency regarding drug prices and information available to beneficiaries regarding ways to lower out-of-pocket costs. The Trump Administration has begun implementing many of these measures, and in October 2018, President Trump proposed a demonstration project to establish an "international pricing index" that would be used as a benchmark in deciding how much to pay for Medicare Part B drugs. The potential effect of health insurance market destabilization during ongoing repeal and replace discussions, as well as the impact of potential changes to the way the Medicaid program is financed, will likely affect patients' sources of insurance and resultant drug coverage. In addition to the Trump Administration's proposals, discussions continue at the federal level regarding policies that would require manufacturers to pay higher rebates in Medicare Part D, give states more flexibility on drugs that are covered under the Medicaid program, permit the re-importation of prescription medications from Canada or other countries and other policy proposals that could impact reimbursement for our products. It is difficult to predict the impact, if any, of any such legislation, executive actions or Medicaid flexibility on the use and reimbursement of our products in the United States, including the potential for the importation of generic versions of 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 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. In addition, standard reimbursement structures may not adequately reimburse for innovative therapies. For example, Yescarta is typically administered on an in-patient basis. Reimbursement through federal programs like Medicare and Medicaid is challenging and may be insufficient to cover the complete cost associated with the therapy. For example, effective October 1, 2018, the Centers for Medicare and Medicaid Services (CMS) established inpatient reimbursement for patients receiving Yescarta. The reimbursement includes payment for a severity adjusted diagnosis related group (DRG) 016, a new technology add-on payment (NTAP) for Yescarta that at most will cover one half the cost of Yescarta and may cover less than that, and, in some cases, an outlier payment. Taken together, the total payment may not be sufficient to reimburse hospitals for their cost of care for patients receiving Yescarta. Furthermore, this payment methodology is likely to be in effect until at least September 2020. Limited payments such as this could impact the willingness of some hospitals to offer the therapy and doctors to recommend the therapy and could lessen the attractiveness of our therapy to patients, which could have an adverse effect on sales of Yescarta and our results of operations. CMS has also opened a National Coverage Analysis on CAR T cells and may impose coverage limitations on that therapy. These coverage limitations would apply to the entire Medicare program and could include, among other things, a requirement for patients to be enrolled in a clinical trial or registry in order for the hospital and physician to be paid for CAR T cell therapy. Further, commercial payers may follow Medicare coverage policies and could impose similar limitations. Lastly, in the European Union, there could be barriers to reimbursement in individual countries that could limit the uptake of Yescarta.

Laws and regulations applicable to the health care industry could impose new obligations on us, require us to change our business practices and restrict our operations in the future.

The health care industry is subject to various federal, state and international laws and regulations pertaining to drug reimbursement, rebates, price reporting, health care fraud and abuse, and data privacy and security. In the United States, these laws include anti-kickback and false claims laws, laws and regulations relating to the Medicare and Medicaid programs and other federal and state programs, the Medicaid Rebate Statute, individual state laws relating to pricing and sales and marketing practices, the Health Insurance Portability and Accountability Act (HIPAA) and other federal and state laws relating to the privacy and security of health information. In addition, while not specific to the health care industry, we may be subject to additional data privacy and security laws, such as the California Consumer Privacy Act of 2018.

Violations of these laws or any related regulations may be punishable by criminal and/or civil sanctions, including, in some instances, substantial fines, civil monetary penalties, exclusion from participation in federal and state health care programs, including Medicare, Medicaid, Veterans Administration health programs, and federal employee health benefit programs, actions against executives overseeing our business and burdensome remediation measures. In addition, these laws and regulations are broad in scope and they are subject to change and evolving interpretations, which could require us to incur substantial costs associated with compliance or to alter one or more of our sales or marketing practices. Violations of these laws, or allegations of such violations, could also result in negative publicity or other consequences that could harm our reputation, disrupt our business or adversely affect our results of operations. If any or all of these events occur, our business and stock price could be materially and adversely affected.

Recently, there has been enhanced scrutiny of company-sponsored patient assistance programs, including insurance premium and co-pay assistance programs and donations to third-party charities that provide such assistance. There has also been enhanced scrutiny by governments on reimbursement support offerings, clinical education programs and promotional speaker programs. If we, or our agents, vendors or donation recipients, are deemed to have failed to comply with laws, regulations or government guidance in any of these areas, we could be subject to criminal or civil sanctions. Any similar violations by our competitors could also negatively impact our industry reputation and increase scrutiny over our business and our products.

See a description of our government investigations and related litigation in Note 10, Commitments and Contingencies of the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

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We have engaged in, and may in the future engage in, business acquisitions, licensing arrangements, strategic collaborations or disposal of our assets, which could cause us to incur significant expenses and could adversely affect our financial condition and results of operations.

We have engaged in, and may in the future engage in, business acquisitions, licensing arrangements, strategic collaborations or disposal of our assets, as part of our business strategy. We may not identify suitable transactions in the future and, if we do, we may not complete such transactions in a timely manner, on a cost-effective basis, or at all, and may not realize the expected benefits. If we are successful in making an acquisition, the products and technologies that are acquired may not be successful or may require significantly greater resources and investments than originally anticipated. We may not be able to integrate acquisitions successfully into our existing business and could incur or assume significant debt and unknown or contingent liabilities. We also conduct annual impairment testing of our goodwill and other indefinite lived intangible assets in the fourth quarter, or earlier if impairment indicators exist, as required under U.S. generally accepted accounting principles. If we fail to overcome these risks, it could cause us to incur significant expenses and negatively affect profitability, which could have an adverse effect on our results of operations. We could also experience negative effects on our reported results of operations from acquisition or disposition-related charges, amortization of expenses related to intangibles and charges for impairment of long-term assets.

Approximately 27% of our product sales occur outside the United States, and currency fluctuations and hedging expenses may cause our earnings to fluctuate, which could adversely affect our stock price.

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

We use foreign currency exchange forward and option contracts to hedge a percentage of our forecasted international sales, primarily those denominated in the Euro. We also hedge certain monetary assets and liabilities denominated in foreign currencies, which reduces but does not eliminate our exposure to currency fluctuations between the date a transaction is recorded and the date cash is collected or paid. Foreign currency exchange, net of hedges, had a favorable impact on our product sales of $89 million for the nine months ended September 30, 2018, compared to the same period in 2017.

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.

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, such as 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.

For Yescarta, a novel CAR T cell therapy, treatment-related adverse effects may not be appropriately recognized and managed by the treating medical staff, as toxicities resulting from personalized T cell therapy are not typically encountered in the general patient population and by medical personnel. Common medicines that may be used at academic medical centers and hospitals to help manage adverse side effects of Yescarta, such as tocilizumab and corticosteroids, may not be available in sufficient quantities, may not adequately control such adverse side effects and/or may have a detrimental impact on the efficacy of the treatment. We have trained and expect to continue to train medical personnel to understand the side effect profile of Yescarta in compliance with the REMS program required by FDA for Yescarta, although we can give no assurances on the efficacy of our training efforts.

Inadequate training in recognizing or managing the potential adverse effects of Yescarta, or the disregard or modification of our training by medical staff, could result in more severe or prolonged toxicities or even patient deaths.

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 FDA, the European Medicines Agency (EMA) and comparable regulatory agencies in other countries. We are continuing clinical trials for many of our products 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 REMS 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 imposed 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 2018, we terminated our Phase 3 study of andecaliximab for the treatment of gastric cancer, 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 Descovy for pre-exposure prophylaxis (PrEP); selonsertib for the treatment of nonalcoholic steatohepatitis (NASH); axicabtagene ciloleucel for the treatment of second line diffuse large B-cell lymphoma; and filgotinib for the treatment of rheumatoid arthritis, Crohn’s disease and ulcerative colitis, 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, patient enrollment, ongoing monitoring, site 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, technology, development, logistics 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 collaborative relationships with major pharmaceutical companies for our sales and marketing performance in certain territories. For example, we have collaboration arrangements with Janssen Sciences Ireland UC for Odefsey, Complera/Eviplera and Symtuza. In some countries, we rely on international distributors for sales of certain of our products. 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.

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.

Yescarta is available only through a REMS program, which is required by FDA to mitigate the potential risks of the product. Only hospitals and their associated clinics certified in the REMS program are permitted to dispense Yescarta. All relevant staff involved in the prescribing, dispensing or administering of Yescarta must be trained on the REMS program requirements and must successfully complete a REMS program knowledge assessment. Failure of hospitals and clinics to enroll in the Yescarta REMS program or to successfully complete and comply with the program requirements may result in regulatory action from FDA or decreased sales of Yescarta, which could harm our business and our reputation.

For Yescarta, we rely on technology partners to assist in the development and maintenance of the Kite Konnect platform. This platform is critical to ensure positive prescriber and patient experience, as well as chain of identity and chain of custody of Yescarta. If the technology platform is incomplete, insufficiently maintained or develops technological issues, we may experience a disruption to the sales and logistics of our Yescarta business, which could extend for a significant period of time, and we may need to expend considerable resources and time to repair or improve the platform in cooperation with our partners. In addition, we rely on sites to collect patient white blood cells, known as apheresis centers, shippers, couriers, and hospitals for the logistical collection of patient's white blood cells and ultimate delivery of Yescarta to patients. Any disruption or difficulties incurred by any of these vendors could result in product loss and regulatory action and harm our Yescarta business and our reputation.

In addition, to ensure that any apheresis center is prepared to ship cells to our manufacturing facilities, we plan to conduct quality certifications of each apheresis center. However, apheresis centers may choose not to participate in the certification process or we may be unable to complete certification in a timely manner or at all, which could delay or restrain our manufacturing and commercialization efforts. As a result, our sales of Yescarta may be limited which could harm our results of operations.

Our success depends 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 depends to a significant degree on our ability to:

- obtain patents and licenses to patent rights;
- preserve trade secrets and internal know-how;

- 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 or validity of any patent granted. Litigation, interference or other proceedings are unpredictable and expensive, and could divert management attention from other operations, such that, even if we are ultimately successful, our results of operations may be adversely affected by such events.

For example, TDF, one of the active pharmaceutical ingredients in Truvada, Atripla, Complera/Eviplera and Stribild, and the main active pharmaceutical ingredient in Viread, faces generic competition in the European Union, the United States and certain other countries. In addition, because emtricitabine, the other active pharmaceutical ingredient of Truvada, faces generic competition in the European Union, Truvada also faces generic competition in the European Union and certain other countries outside of the United States. Because the U.S. patent for ambrisentan, the active pharmaceutical ingredient in Letairis, expired in July 2018, Letairis is expected to face generic competition in the United States. Further, Ranexa is also expected to face generic competition in the United States starting in the first quarter of 2019. The entry of these generic products may lead to market share and price erosion and have a negative impact on our business and results of operations. In addition, we do not own any patents covering ranolazine, the active ingredient of Ranexa. Instead, when it was discovered that only a sustained-release formulation of ranolazine would achieve therapeutic plasma levels, we obtained patents on those formulations and the characteristic plasma levels they achieve. For Yescarta, the composition of matter patent has expired in the European Union. In the European Union and the United States, patent applications are pending related to Kite’s proprietary manufacturing processes. We own a granted patent in the United States and pending applications in the United States and European Union relating to Kite’s proprietary pre-conditioning methods.

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 Part I, Item 1 of 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 required to pay significant monetary damages or 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 commercially 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 and patent applications owned by third parties that such parties may claim cover the use of sofosbuvir, axicabtagene ciloleucel and bictegravir. See also a description of our litigation regarding sofosbuvir, axicabtagene ciloleucel and bictegravir in Note 10, Commitments and Contingencies of the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q and the risk factors entitled "If any of our HCV products is proven to infringe the patents of any third party, we may be required to pay significant monetary damages, which could adversely affect our financial results" beginning on page 46 and "If any party is successful in establishing exclusive rights to axicabtagene ciloleucel, our anticipated revenues and earnings from the sale of that product could be adversely affected" beginning on page 47. We are also aware of U.S. Patent Nos. 9,044,509, 9,579,333 and 9,937,191 assigned to the U.S. Department of Health and Human Services that purport to claim a process of protecting a primate host from infection by an immunodeficiency retrovirus by administering a

combination of emtricitabine and tenofovir or TDF prior to exposure of the host to the immunodeficiency retrovirus. We have been in contact with the U.S. Department of Health and Human Services about the scope and relevance of the patents and have explained that we do not believe that these patents are valid because the patent office was not given the most relevant prior art and because physicians and patients were using the claimed methods years before the Centers for Disease Control and Prevention filed the applications for the patents.

Furthermore, we also rely on unpatented trade secrets and improvements, unpatented internal know-how and technological innovation. For example, a great deal of our liposomal manufacturing expertise, which is a key component of our liposomal technology, is not covered by patents but is instead protected as a trade secret. We protect these rights mainly through confidentiality agreements with our corporate partners, employees, consultants and vendors. These agreements provide that all confidential information developed or made known to an individual during the course of their relationship with us will be kept confidential and will not be used or disclosed to third parties except in specified circumstances. In the case of employees, the agreements provide that all inventions made by an individual while employed by us will be our exclusive property. We cannot be certain that these parties will comply with these confidentiality agreements, that we have adequate remedies for any breach or that our trade secrets, internal know-how or technological innovation 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, internal know-how, technological innovation 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 of our HCV products is proven to infringe the patents of any third party, we may be required to pay significant monetary damages, which could adversely affect our financial results.

We own patents and patent applications that claim sofosbuvir (Sovaldi) as a chemical entity and its metabolites and the fixed-dose combinations of sofosbuvir and velpatasvir (Epclusa), ledipasvir and sofosbuvir (Harvoni) and sofosbuvir, velpatasvir and voxilaprevir (Vosevi). We are aware of patents and patent applications owned by third parties that have been or may in the future be alleged by such parties to cover the use of our HCV products. If third parties obtain valid and enforceable patents, and successfully prove infringement of those patents by our HCV products, we could be required to pay significant monetary damages.

Current legal proceedings of significance related to sofosbuvir include:

Litigation with Idenix Pharmaceuticals, Inc. (Idenix)

See the risk factor entitled “We may be required to pay material damages to Merck if the court’s decision invalidating a patent owned by Merck’s Idenix subsidiary is overturned on appeal” beginning on page 47. See also a description of our Idenix litigation in Note 10, Commitments and Contingencies of the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Litigation with Merck & Co., Inc. (Merck)

In August 2013, Merck contacted us requesting that we pay royalties on the sales of sofosbuvir and obtain a license to U.S. Patent No. 7,105,499 (the ‘499 patent) and U.S. Patent No. 8,481,712 (the ‘712 patent), which it co-owns with Ionis 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. 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 attorney’s fees due to the exceptional nature of this case. In July 2017, the court issued a decision setting the amount of attorney fees awarded to us.

Merck filed notices of appeal to the CAFC regarding the court’s decision on our defense of unclean hands and its award of attorney’s fees. In April 2018, the CAFC affirmed the court’s decision on unclean hands. Merck has filed a petition for review by the U.S. Supreme Court. If the decision on our defense of unclean hands is reversed

subsequently 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 the ‘830 patent is invalid and will not be infringed by the continued commercialization of sofosbuvir. In October 2017, the court granted our motion to transfer the case to California. We have also filed four petitions for inter partes review with the U.S. Patent and Trademark Office (USPTO) Patent Trial and Appeal Board (PTAB) alleging that all asserted claims are invalid for anticipation and obviousness. In March 2018, the District Court stayed the litigation until after the PTAB rules on our petitions for inter partes review.

Petitions for Inter Partes Review filed by Initiative for Medicines, Access & Knowledge

In October 2017, we received notice that Initiative for Medicines, Access & Knowledge (I-MAK) submitted multiple petitions requesting inter partes review to the USPTO PTAB alleging that certain patents associated with sofosbuvir are invalid as either not novel or obvious. We strongly believe I-MAK’s petitions are without merit and that sofosbuvir, the only approved HCV drug of its kind, is both novel and not obvious. Accordingly, we defended against these allegations, and the PTAB declined to institute all ten of I-MAK’s petitions for inter partes review as well as all of I-MAK’s petitions for rehearing.

European Patent Claims

In February 2015, several parties filed oppositions in the EPO requesting revocation of one of our granted European patents covering sofosbuvir that expires in 2028. In October 2016, the EPO upheld the validity of certain claims of our sofosbuvir patent. We have appealed this decision, seeking to restore all of the original claims, and several of the original opposing parties have also appealed, requesting full revocation. The appeal process may take several years.

In April 2017, several parties filed oppositions in the EPO requesting revocation of our granted European patent relating to sofosbuvir that expires in 2024. The EPO conducted an oral hearing for this opposition in September 2018 and upheld the claims. The decision may be appealed.

We cannot predict the ultimate outcome of intellectual property claims related to our HCV products, and we have spent, and will continue to spend, significant resources defending against these claims. If we are unsuccessful in all or some of these lawsuits, we could be required to pay significant monetary damages, which could have a significant negative effect on our financial results.

We may be required to pay material damages to Merck if the court’s decision invalidating a patent owned by Merck’s Idenix subsidiary is overturned on appeal.

In December 2013, Idenix, 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 Universita Degli Studi di Cagliari 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 (the ‘054 patent) and 7,608,597 (the ‘597 patent). In June 2014, the court transferred the Massachusetts litigation to the U.S. District Court for the District of Delaware. Idenix was acquired by Merck in August 2014.

Prior to trial in December 2016, Idenix committed to give us a covenant not to sue with respect to any claims arising out of the ‘054 patent related to sofosbuvir and withdrew that patent from the trial. In addition, Idenix declined to litigate the ‘600 patent infringement action at trial in light of the appeal then pending at the U.S. Court of Appeals for the Federal Circuit (CAFC). Since the U.S. Supreme Court denied Idenix’s petition for certiorari in the appeal of the interference decision on the ‘600 patent, all pending actions concerning the ‘600 patent have been dismissed. A jury trial was held in December 2016 on the ‘597 patent. In December 2016, the jury found that we willfully infringed the asserted claims of the ‘597 patent and awarded Idenix $2.54 billion in past damages. In February 2018, the judge invalidated Idenix’s ‘597 patent and vacated the jury’s award of $2.54 billion in past damages. Idenix has appealed this decision to the CAFC. We believe the Delaware court’s decision correctly found that, as a matter of law, the ‘597 patent is invalid, and we remain confident in the merits of our case on appeal.

If the court’s decision invalidating Idenix’s patent is overturned on appeal, the amount we could be required to pay could be material. The timing and magnitude of the amount of any such payment could have a material adverse impact on our results of operations and stock price.

If any party is successful in establishing exclusive rights to axicabtagene ciloleucel, our anticipated revenues and earnings from the sale of that product could be adversely affected.

In October 2017, we acquired Kite, which is now our wholly-owned subsidiary. Through the acquisition, we acquired axicabtagene ciloleucel, a CAR T cell therapy. In October 2017, we received approval from FDA for axicabtagene ciloleucel, now known commercially as Yescarta.

We own patents and patent applications that claim axicabtagene ciloleucel chimeric DNA segments. Third parties may have, or may obtain rights to, patents that allegedly could be used to prevent or attempt to prevent us from commercializing axicabtagene ciloleucel or to require us to obtain a license in order to commercialize axicabtagene ciloleucel. For example, we are aware that

Juno Therapeutics, Inc. (Juno) has exclusively licensed Patent No. 7,446,190 (the ‘190 patent) which was issued to Sloan Kettering Cancer Center. In September 2017, Juno and Sloan Kettering Cancer Center filed a lawsuit against Kite in the U.S. District Court for the Central District of California, alleging that the commercialization of axicabtagene ciloleucel infringes the ‘190 patent. In October 2017, following FDA approval for Yescarta, Juno filed a second complaint alleging that axicabtagene ciloleucel infringes the ‘190 patent. Juno subsequently moved to dismiss the September 2017 complaint and has maintained the October 2017 complaint. The court has set a trial date of October 2019 for this lawsuit.

In August 2015, Kite filed a petition for inter partes review in the USPTO alleging that the asserted claims of the ‘190 patent are invalid as obvious. In December 2016, the PTAB determined that the claims of the ‘190 patent are not invalid due to obviousness. In February 2017, Kite filed a Notice of Appeal to the CAFC. In June 2018, the CAFC affirmed the PTAB’s determination that the ‘190 patent claims are not invalid due to obviousness.

We cannot predict the ultimate outcome of intellectual property claims related to axicabtagene ciloleucel. If Juno’s patent is upheld as valid and Juno successfully proves infringement of that patent by axicabtagene ciloleucel, we could be required to pay significant monetary damages or we could be prevented from selling Yescarta unless we were able to obtain a license to this patent. Such a license may not be available on commercially reasonable terms or at all, which could adversely impact our business and results of operations.

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. 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 EMA. Similar regulations are in effect in other jurisdictions.

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, and we may not be able to locate additional or replacement facilities on a reasonable basis or at all. Our sales of such products could also be adversely impacted by our reliance on such limited number of facilities. 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 have limited experience managing the T cell engineering process, and our processes may be more difficult or more expensive than the approaches taken by our current and future competitors. We cannot be sure that the manufacturing processes employed by us will result in engineered T cells that will be safe and effective. In addition, we may encounter difficulties in production, particularly in scaling up and validating initial production to meet patient demand and ensuring the absence of contamination. These problems could include difficulties with production costs

and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Further, if contaminants are discovered in our supply of Yescarta or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could require substantial resources and management attention. We cannot assure you that any stability or other issues relating to the manufacture of Yescarta will not occur in the future or that any such issues may be remedied on a timely basis or at all. In addition, we may fail to manage the logistics of collecting and shipping patient material to the manufacturing site and shipping Yescarta back to the patient. Logistical and shipment delays and problems caused by us, our vendors or other factors not in our control, such as weather and natural disasters, could prevent or delay the delivery of our products and product candidates to patients. Additionally, we are required to maintain a complex chain of identity and custody with respect to patient

material as such material moves to the manufacturing facilities, through the manufacturing process, and back to the patient. Failure to maintain chain of identity and custody could result in patient death, loss of product or regulatory action, which could have an adverse effect on us, our reputation and our stock price.

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 new drug application 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, which we may not able to replace in a timely manner and on commercially reasonable terms, or at all. Problems with any of the single suppliers we depend on, including in the event of a disaster, such as an earthquake, equipment failure or other difficulty, may negatively impact our development and commercialization efforts.

A significant portion of the raw materials and intermediates used to manufacture our antiviral products are supplied by third-party manufacturers and corporate partners outside of the United States. As a result, any political or economic factors in a specific country or region, including any changes in or interpretations of trade regulations, compliance requirements or tax legislation, that would limit or prevent third parties outside of the United States 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.

If we were to encounter any of these difficulties, our ability to provide our products and product candidates to patients would be jeopardized.

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. To seek approval for a generic version of a product having NCE status, a generic manufacturer may submit its ANDA to FDA four years after the branded product's approval.

Current legal proceedings of significance with generic manufacturers include:

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 parties have agreed to dismiss the action in West Virginia, and the trial in Delaware was stayed. The patent in suit that covers Tybost is also listed in the Orange Book for Stribild and Genvoya. In November 2017, we received notice that Mylan submitted an ANDA to FDA requesting permission to manufacture and market a generic version of Evotaz (atazanavir/cobicistat) and challenging the validity of our cobicistat compound patent, citing the arguments it has made in the ongoing litigation involving Tybost. In December 2017, we filed a lawsuit against Mylan in the U.S. District Court for the Northern District of West Virginia.

In July 2018, we reached an agreement with Mylan to resolve all pending lawsuits. The settlement agreement has been filed with the Federal Trade Commission and Department of Justice as required by law.

Aurobindo

In April and May 2018, we received notices that Aurobindo Pharma USA Inc. (Aurobindo) submitted an ANDA to FDA requesting permission to manufacture and market generic versions of Truvada at low dosage strengths. In the May notice, Aurobindo alleges that two patents associated with emtricitabine are invalid, unenforceable and/or will not be infringed by Aurobindo's manufacture, use or sale of generic versions of Truvada at low dosage strengths. In May 2018, we filed a lawsuit against Aurobindo in the U.S. District Court for the District of Delaware for infringement of our patents. In October 2018, we reached an agreement with Aurobindo to resolve the lawsuit. The settlement agreement has been filed with the Federal Trade Commission and Department of Justice as required by law.

Strides

In May 2018, we received notice that Strides Pharma Inc. (Strides) submitted an ANDA to FDA requesting permission to manufacture and market a generic version of Truvada. In the notice, Strides alleges that two patents associated with emtricitabine and four patents associated with the emtricitabine and tenofovir disoproxil fumarate (TDF) fixed-dose combination are invalid, unenforceable and/or will not be infringed by Strides' manufacture, use or sale of a generic version of Truvada. In June 2018, we filed a lawsuit against Strides in the U.S. District Court for the District of New Jersey for infringement of our patents.

Natco and Teva

In February 2018, we received notices from Natco Pharma Limited (Natco) and Teva Pharmaceuticals (Teva) that they have each submitted an ANDA to FDA requesting permission to manufacture and market a generic version of Sovaldi. In Teva's notice, it alleges that nine patents associated with sofosbuvir are invalid, unenforceable and/or will not be infringed by Teva's manufacture, use or sale of generic versions of Sovaldi. In March 2018, we filed lawsuits against Teva in the U.S. District Court for the District of New Jersey and the U.S. District Court for the District of Delaware for infringement of these patents. In Natco's notice, it alleges that two patents associated with sofosbuvir are invalid, unenforceable and/or will not be infringed by Natco's manufacture, use or sale of generic versions of Sovaldi. Natco did not challenge all patents listed on the Orange Book for Sovaldi. In March 2018, we filed lawsuits against Natco in the U.S. District Court for the District of New Jersey and the U.S. District Court for the District of Delaware for infringement of these patents.

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 these products could be substantially shortened. Further, if all of the patents covering one or more products are invalidated, FDA could approve the requests to manufacture a generic version of such products in the United States 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.

Imports from countries where our products are available at lower prices and unapproved generic or counterfeit versions of our products could have a negative impact on our reputation and business.

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. If our HIV, HBV and HCV products, which we have agreed to make available at substantially reduced prices to certain low- and middle-income countries participating in our Gilead Access Program, are re-exported from these low- and middle-income countries into the United States, Europe or other higher price markets, our revenues would be adversely affected. In addition, we have entered into voluntary licensing agreements with generic drug companies in India, South Africa and China, as well as a licensing agreement with the Medicines Patent Pool, a United Nations-backed public health organization, which allows generic drug companies to manufacture generic versions of HIV and HBV products incorporating our licensed compounds, TAF, cobicistat, elvitegravir and bictegravir, for distribution in certain low- and middle-income countries. We have also entered into licensing agreements with generic manufacturers in India, Egypt and Pakistan to produce and distribute generic

versions of our HCV products in certain low- and middle-income countries. If generic versions of our HIV, HBV and HCV products under these licenses are then re-exported to the United States, Europe or other markets outside of these low- and middle-income countries, our revenues would 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.

We are also aware of the existence of various "Buyers Clubs" around the world that promote the personal importation of generic versions of our HCV products that have not been approved for use in the countries into which they are imported. As a result, patients may be at risk of taking unapproved medications which may not be what they purport to be, may not have the potency they claim to have or may contain harmful substances. To the extent patients take unapproved generic versions of one or more of our medications and are injured or not cured by these products, our brand or the commercial or scientific reputation of our HCV products could be harmed.

Further, third parties may illegally distribute and sell counterfeit versions of our products, which do not meet the rigorous quality standards of our manufacturing and supply chain. For example, in 2017 and 2018, there were reports that a product labeled as Epclusa was available in multiple countries, which we determined was not authentic product based on sample analysis and the lot number. We have cooperated and continue to cooperate with regulatory authorities to investigate this matter. We actively take actions to discourage counterfeits of our products around the world, including working with local regulatory and legal authorities to enforce laws against counterfeit drugs. Counterfeit drugs pose a serious risk to patient health and safety. Our reputation and business could suffer as a result of counterfeit drugs sold under our brand name.

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 and require significant management attention. 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 Part I, Item 1 of this Quarterly Report on Form 10-Q. The outcome of such legal proceedings or any other legal proceedings that may be brought against us, the investigations or any other investigations that may be initiated and any other dispute-related matters, 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, governments may 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 HIV or HCV infection available at low cost. Alternatively, governments in those developing countries could issue compulsory licenses or government use 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 other means including compulsory licenses. The government of Malaysia has exercised Government Rights under Section 84 of the Malaysian Patents Act to practice the patented invention of sofosbuvir for a period of three years for use only in government hospitals and clinics. 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. If compulsory licenses permit generic manufacturing to override our product patents for our HIV, HCV or other products, or if compulsory licenses or government use licenses are issued 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, or permit our patents to issue, and third-party manufacturers are able to sell generic versions of our products in those countries. For example, in 2017, the Brazilian Health Regulatory Agency rejected our patent applications related to sofosbuvir and our HCV products. We successfully appealed those decisions, and those applications are now under examination at the Brazilian Patent and Trademark Office. 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 and such liability 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 have limited insurance for product liabilities that may arise. If we do not maintain adequate coverage or if claims exceed our coverage, our financial condition 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.

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. In July 2018, we announced that John F. Milligan will step down as our President and Chief Executive Officer after a 28-year career with the company. While our Board of Directors conducts a search to identify a successor, Dr. Milligan will remain in his current position through the end of the year, or if earlier, when his successor is named and commences in the role. 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. Additionally, changes to U.S. immigration and work authorization laws and regulations could make it more difficult for employees to work in or transfer to jurisdictions in which we have operations and could impair our ability to attract and retain qualified personnel. If we are unsuccessful in our recruitment and retention efforts, our business may be harmed. Further, if there are delays with the selection of a new Chief Executive Officer or if we do not successfully manage the transition, our business may be negatively impacted.

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 uninsured or inadequately insured. Our corporate headquarters in Foster City and our Santa Monica location, which together house a majority of our R&D activities, and our San Dimas, La Verne, Oceanside and El Segundo 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. In addition, our Yescarta business is also reliant on our ability to manage the logistics of collecting and shipping patient material to our manufacturing facilities and shipping Yescarta back to the patient. Any logistical and shipment delays caused by such natural or man-made disasters could prevent or delay the delivery of our products to patients and could harm our Yescarta business.

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

We are dependent upon information technology systems, infrastructure and data, including our new Kite Konnect platform. 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 and technology 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, or the efforts of our partners and vendors, 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.

Regulators globally are also imposing greater monetary fines for privacy violations. For example, in 2016, the European Union adopted a new law governing data practices and privacy called the General Data Protection Regulation (GDPR), which became effective in May 2018. The law established new requirements regarding the handling of personal data, and non-compliance with the GDPR may result in monetary penalties of up to 4% of worldwide revenue. In addition, we may be subject to additional data privacy and security laws, such as the California Consumer Privacy Act of 2018. The GDPR and other changes in laws or regulations associated with the enhanced

protection of certain types of sensitive data, such as healthcare data or other personal information, could greatly increase our cost of providing our products and services or even prevent us from offering certain services in jurisdictions that we operate.

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

We are subject to income taxes in the United States and various foreign jurisdictions including Ireland. Due to economic and political conditions, various countries are actively considering and have made 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. For example, the United States recently enacted significant tax reform, and certain provisions of the new law will significantly affect us. The accounting for these changes is currently considered provisional and may change materially during the measurement period due to the issuance of anticipated guidance and finalization of certain accounting method elections. See Note 14, Income Taxes, of the

Notes to Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for additional details.

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 Internal Revenue Service for the tax years from 2013 to 2015 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.

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 $0.57 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 $6.1 billion is available for repurchase as of September 30, 2018. 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 the first quarter of 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 the 2016 Program in April 2016.

During the third quarter of 2018, we repurchased and retired 6 million shares of our common stock for $449 million through open market transactions under the 2016 Program. The table below summarizes our stock repurchase activity under the 2016 Program for the three months ended September 30, 2018:

	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, 2018	870	$ 75.35	653	$ 6,508

August 1 - August 31, 2018	3,292		$ 75.80	3,026	$ 6,279
September 1 - September 30, 2018	2,328		$ 73.96	2,300	$ 6,109
Total	6,490	(1)	$ 75.08	5,979	(1)

(1) The difference between the total number of shares purchased and the total number of shares purchased as part of publicly announced program 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.

Exhibit Index

Exhibit Footnote	Exhibit Number	Description of Document
(1)	3.1	Restated Certificate of Incorporation of Registrant
(2)	3.2	Amended and Restated Bylaws of Registrant
	4.1	Reference is made to Exhibit 3.1 and Exhibit 3.2
(3)	4.2	Indenture related to Senior Notes, dated as of March 30, 2011, between Registrant and Wells Fargo, National Association, as Trustee
(3)	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)
(4)	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)
(5)	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)
(6)	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)
(7)	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)
(8)	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)
(9)	4.9	Seventh Supplemental Indenture, dated as of September 21, 2017, between Registrant and Wells Fargo Bank, National Association, as Trustee (including Form of Fixed Rate Note, Form of Form of September 2018 Note, Form of March 2019 Note and Form of September 2019 Note)
*(10)	10.1	Gilead Sciences, Inc. 2004 Equity Incentive Plan, as amended and restated May 10, 2017
*(11)	10.2	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants made February 2008 through April 2009)
*(12)	10.3	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants commencing in May 2009)
*(13)	10.4	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for grants commencing in February 2010)

*(14)	10.5	Form of employee stock option agreement used under 2004 Equity Incentive Plan (for 2011 and subsequent year grants)
*(12)	10.6	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for annual grants commencing in May 2009 and through May 2012)
*(15)	10.7	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for annual grants made in May 2013)
*(15)	10.8	Form of non-employee director option agreement (non-U.S.) used under 2004 Equity Incentive Plan (for annual grants made in May 2013)
*(16)	10.9	Form of non-employee director option agreement used under 2004 Equity Incentive Plan (for annual grants made in and after May 2014)
*(15)	10.10	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)
*(17)	10.11	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for TSR Goals (US) in 2016)
*(17)	10.12	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for TSR Goals (US) with Director Retirement Provisions in 2016)
*(17)	10.13	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for Revenue Goals (US) in 2016)
*(17)	10.14	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for Revenue Goals (US) with Director Retirement Provisions in 2016)
*(18)	10.15	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for TSR Goals - Non-US in 2015)
*(17)	10.16	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for TSR Goals -Non-US in 2016)
*(18)	10.17	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for Revenue Goals - Non-US in 2015)
*(17)	10.18	Form of performance share award agreement used under the 2004 Equity Incentive Plan (for Revenue Goals - Non-US in 2016)
*(14)	10.19	Form of restricted stock unit issuance agreement used under the 2004 Equity Incentive Plan (service-based vesting for certain executive officers commencing in 2011)
*(19)	10.20	Gilead Sciences, Inc. Employee Stock Purchase Plan, restated on January 22, 2015
*(20)	10.21	Gilead Sciences, Inc. Deferred Compensation Plan-Basic Plan Document
*(20)	10.22	Gilead Sciences, Inc. Deferred Compensation Plan-Adoption Agreement

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*(20)	10.23	Addendum to the Gilead Sciences, Inc. Deferred Compensation Plan
*(21)	10.24	Gilead Sciences, Inc. 2005 Deferred Compensation Plan, as amended and restated on October 23, 2008
*(22)	10.25	Gilead Sciences, Inc. Severance Plan, as amended on March 8, 2016
*(23)	10.26	Gilead Sciences, Inc. Corporate Bonus Plan, as amended and restated on January 1, 2019
*(24)	10.27	Amended and Restated Gilead Sciences, Inc. Code Section 162(m) Bonus Plan
*	10.28	Gilead Sciences, Inc. Retention Program for Executive Officers
*(25)	10.29	2018 Base Salaries for the Named Executive Officers
*(26)	10.30	Offer Letter dated April 16, 2008 between Registrant and Robin Washington
*(27)	10.31	Separation Agreement and Release dated August 6, 2018 between Registrant and John F. Milligan, Ph.D.
*(28)	10.32	Form of Indemnity Agreement entered into between Registrant and its directors and executive officers
*(28)	10.33	Form of Employee Proprietary Information and Invention Agreement entered into between Registrant and certain of its officers and key employees
*(29)	10.34	Form of Employee Proprietary Information and Invention Agreement entered into between Registrant and certain of its officers and key employees (revised in September 2006)
+(30)	10.35	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)
+(31)	10.36	Amendment Agreement between Registrant and IOCB/REGA, dated December 27, 2000 amending the 1991 License Agreement and the December 1992 License Agreement
+(32)	10.37	Sixth Amendment Agreement to the License Agreement, between IOCB/REGA and Registrant, dated August 18, 2006 amending the October 1992 License Agreement and the December 1992 License Agreement
+(33)	10.38	Seventh Amendment Agreement to the License Agreement, between IOCB/REGA and Registrant dated July 1, 2013 amending the October 1992 License Agreement and the December 1992 License Agreement
+(34)	10.39	Exclusive License Agreement between Registrant (as successor to Triangle Pharmaceuticals, Inc.), Glaxo Group Limited, The Wellcome Foundation Limited, Glaxo Wellcome Inc. and Emory

		University, dated May 6, 1999
+(35)	10.40	Royalty Sale Agreement by and among Registrant, Emory University and Investors Trust & Custodial Services (Ireland) Limited, solely in its capacity as Trustee of Royalty Pharma, dated July 18, 2005
+(35)	10.41	Amended and Restated License Agreement between Registrant, Emory University and Investors Trust & Custodial Services (Ireland) Limited, solely in its capacity as Trustee of Royalty Pharma, dated July 21, 2005
+(36)	10.42	License Agreement between Japan Tobacco Inc. and Registrant, dated March 22, 2005
+(37)	10.43	First Amendment to License Agreement between Japan Tobacco Inc. and Registrant, dated May 19, 2005
+(37)	10.44	Second Amendment to License Agreement between Japan Tobacco Inc. and Registrant, dated May 17, 2010
+(38)	10.45	Third Amendment (Revised) to License Agreement between Japan Tobacco Inc. and Registrant, dated June 10, 2015
+(37)	10.46	Fourth Amendment to License Agreement between Japan Tobacco Inc. and Registrant, dated July 5, 2011
+(39)	10.47	Amendment to License Agreement between Japan Tobacco Inc. and Registrant, dated October 10, 2013
+(40)	10.48	Fifth Amendment to License Agreement between Japan Tobacco Inc. and Registrant, dated September 29, 2014
+(41)	10.49	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
+(42)	10.50	License Agreement by and among Kite Pharma, Inc., Cabaret Biotech Ltd. and Dr. Zelig Eshhar, dated December 12, 2013
	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.INS***	XBRL Instance Document
	101.SCH***	XBRL Taxonomy Extension Schema Document

101.CAL*** XBRL Taxonomy Extension Calculation Linkbase Document

101.DEF*** XBRL Taxonomy Extension Definition Linkbase Document

101.LAB*** XBRL Taxonomy Extension Label Linkbase Document

101.PRE*** XBRL Taxonomy Extension Presentation Linkbase Document

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

(2) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on December 23, 2015, and incorporated herein by reference.

(3) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on April 1, 2011, and incorporated herein by reference.

(4) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on December 13, 2011, and incorporated herein by reference.

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

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

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

(8) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on September 20, 2016, and incorporated herein by reference.

(9) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on September 21, 2017, and incorporated herein by reference.

(10) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on May 12, 2017, and incorporated herein by reference.

(11) 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.

(12) 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.

(13) 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.

(14) 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.

(15) 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

(16) 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.

(17) 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.

(18) 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.

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

(20) 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.

(21) 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.

(22) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on March 11, 2016, and incorporated herein by reference.

(23) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, and incorporated herein by reference.

(24) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on May 17, 2016, and incorporated herein by reference.

(25) Filed on Registrant's Current Report on Form 8-K filed on February 5, 2018, and incorporated herein by reference.

(26) 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.

(27) Filed as an exhibit to Registrant's Current Report on Form 8-K filed on August 7, 2018, and incorporated herein by reference.

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

(29) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2006, and incorporated herein by reference.

(30) 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.

(31) 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.

(32) 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.

(33) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2013, and incorporated herein by reference.

(34) Filed as an exhibit to Triangle Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q/A filed on November 3, 1999, and incorporated herein by reference.

(35) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2005, and incorporated herein by reference.

(36) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2005, and incorporated herein by reference.

(37) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2011, and incorporated herein by reference.

(38) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, 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, 2013, 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, 2014, and incorporated herein by reference.

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

(42) Filed as an exhibit to Kite Pharma, Inc.'s Registration Statement on Form S-1/A (No. 333-196081) filed on June 17, 2014, and incorporated herein by reference.

* Management contract or compensatory plan or arrangement.

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

*** XBRL information is filed herewith.

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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, 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 6, 2018 /s/ JOHN F. MILLIGAN
John F. Milligan, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 6, 2018 /s/ ROBIN L. WASHINGTON
Robin L. Washington
Executive Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)