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

FORM 10-Q

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

For the quarterly period ended March 31, 2019

or

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

For the transition period from _____ to _____

Commission File No. 0-19731

GILEAD SCIENCES, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**94-3047598**
(State or Other Jurisdiction of Incorporation or Organization)	**(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

Title of each class	**Securities registered pursuant to Section 12(b) of the Act: Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value, $0.001 per share	**GILD**	**The Nasdaq Global Select Market**

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

Indicate by check mark whether the registrant has submitted electronically 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 ☒ 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 ☒ 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 ☒

Number of shares outstanding of the issuer's common stock, par value $0.001 per share, as of April 30, 2019: 1,271,554,672

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®, BIKTARVY®, CAYSTON®, COMPLERA®, DESCOVY®, EMTRIVA®, EPCLUSA®, EVIPLERA®, GENVOYA®, HARVONI®, HEPSERA®, LETAIRIS®, ODEFSEY®, RANEXA®, SOVALDI®, STRIBILD®, TRUVADA®, TRUVADAFORPREP®, TYBOST®, VEMLIDY®, VIREAD®, 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. 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)

	March 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 16,927	$ 17,940
Short-term marketable securities	10,977	12,149
Accounts receivable, net of allowances of $669 and $583, respectively	3,283	3,327
Inventories	898	814
Prepaid and other current assets	1,939	1,606
Total current assets	34,024	35,836
Property, plant and equipment, net	4,116	4,006
Long-term marketable securities	2,221	1,423
Intangible assets, net	15,438	15,738
Goodwill	4,117	4,117
Other long-term assets	2,921	2,555
Total assets	$ 62,837	$ 63,675
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 577	$ 790
Accrued government and other rebates	3,974	3,928
Other accrued liabilities	2,348	3,139
Current portion of long-term debt and other obligations, net	2,498	2,748
Total current liabilities	9,397	10,605
Long-term debt, net	24,080	24,574
Long-term income taxes payable	5,809	5,922
Other long-term obligations	1,460	1,040
Commitments and contingencies (Note 11)		
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; 1,274 and 1,282 shares issued and outstanding, respectively	1	1
Additional paid-in capital	2,494	2,282
Accumulated other comprehensive income	130	80
Retained earnings	19,326	19,024
Total Gilead stockholders' equity	21,951	21,387
Noncontrolling interest	140	147
Total stockholders' equity	22,091	21,534
Total liabilities and stockholders' equity	$ 62,837	$ 63,675

See accompanying notes.

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

	Three Months Ended March 31,	
	2019	2018
Revenues:		
Product sales	$ 5,200	$ 5,001
Royalty, contract and other revenues	81	87
Total revenues	5,281	5,088
Costs and expenses:		
Cost of goods sold	957	1,001
Research and development expenses	1,057	937
Selling, general and administrative expenses	1,030	997
Total costs and expenses	3,044	2,935
Income from operations	2,237	2,153
Interest expense	(254)	(290)
Other income (expense), net	367	170
Income before provision for income taxes	2,350	2,033
Provision for income taxes	382	494
Net income	1,968	1,539
Net income (loss) attributable to noncontrolling interest	(7)	1
Net income attributable to Gilead	$ 1,975	$ 1,538
Net income per share attributable to Gilead common stockholders - basic	$ 1.55	$ 1.18
Shares used in per share calculation - basic	1,276	1,307
Net income per share attributable to Gilead common stockholders - diluted	$ 1.54	$ 1.17
Shares used in per share calculation - diluted	1,283	1,320

See accompanying notes.

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

	Three Months Ended March 31,	
	2019	2018
Net income	$ 1,968	$ 1,539
Other comprehensive income (loss):		
Net foreign currency translation gain, net of tax	21	7
Available-for-sale debt securities:		
Net unrealized gain (loss), net of tax	30	(36)
Reclassifications to net income, net of tax	—	—
Net change	30	(36)
Cash flow hedges:		
Net unrealized gain (loss), net of tax	28	(61)
Reclassifications to net income, net of tax	(29)	48
Net change	(1)	(13)
Other comprehensive income (loss)	50	(42)
Comprehensive income	2,018	1,497
Comprehensive income (loss) attributable to noncontrolling interest	(7)	1
Comprehensive income attributable to Gilead	$ 2,025	$ 1,496

See accompanying notes.

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

	Three Months Ended March 31, 2019						
	Gilead Stockholders' Equity						
	Common Stock						
	Shares	Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Retained Earnings	Noncontrolling Interest	Total Stockholders' Equity
Balance at December 31, 2018	1,282	$ 1	$ 2,282	$ 80	$ 19,024	$ 147	$ 21,534
Net income (loss)	—	—	—	—	1,975	(7)	1,968
Other comprehensive income, net of tax	—	—	—	50	—	—	50
Issuances under employee stock purchase plan	1	—	63	—	—	—	63
Issuances under equity incentive plans	4	—	41	—	—	—	41
Stock-based compensation	—	—	144	—	—	—	144
Repurchases of common stock	(13)	—	(36)	—	(867)	—	(903)
Dividends declared ($0.63 per share)	—	—	—	—	(814)	—	(814)
Cumulative effect from the adoption of new leases standard (Note 1)	—	—	—	—	8	—	8
Balance at March 31, 2019	1,274	$ 1	$ 2,494	$ 130	$ 19,326	$ 140	$ 22,091

	Three Months Ended March 31, 2018						
	Gilead Stockholders' Equity						
	Common Stock						
	Shares	Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Retained Earnings	Noncontrolling Interest	Total Stockholders' Equity
Balance at December 31, 2017	1,308	$ 1	$ 1,264	$ 165	$ 19,012	$ 59	$ 20,501
Net income	—	—	—	—	1,538	1	1,539
Other comprehensive loss, net of tax	—	—	—	(42)	—	—	(42)
Issuances under employee stock purchase plan	1	—	48	—	—	—	48
Issuances under equity incentive plans	5	—	64	—	—	—	64
Stock-based compensation	—	—	224	—	—	—	224
Repurchases of common stock	(14)	—	(36)	—	(1,085)	—	(1,121)
Dividends declared ($0.57 per share)	—	—	—	—	(752)	—	(752)
Cumulative effect from the adoption of new accounting standards	—	—	—	(293)	483	—	190
Balance at March 31, 2018	1,300	$ 1	$ 1,564	$ (170)	$ 19,196	$ 60	$ 20,651

See accompanying notes.

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

	Three Months Ended March 31,	
	2019	2018
Operating Activities:		
Net income	$ 1,968	$ 1,539
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation expense	60	56
Amortization expense	299	301
Stock-based compensation expense	143	220
Deferred income taxes	24	35
Other	(157)	49
Changes in operating assets and liabilities:		
Accounts receivable, net	32	101
Inventories	(15)	(14)
Prepaid expenses and other	(43)	529
Accounts payable	(201)	(92)
Income taxes payable	(249)	(618)
Accrued liabilities and other	(417)	164
Net cash provided by operating activities	1,444	2,270
Investing Activities:		
Purchases of marketable debt securities	(6,722)	(397)
Proceeds from sales of marketable debt securities	575	221
Proceeds from maturities of marketable debt securities	6,511	4,762
Capital expenditures	(237)	(212)
Other	(238)	(20)
Net cash provided by (used in) investing activities	(111)	4,354
Financing Activities:		
Proceeds from issuances of common stock	103	111
Repurchases of common stock	(834)	(1,039)
Repayments of debt and other obligations	(750)	(4,500)
Payments of dividends	(817)	(753)
Other	(68)	(414)
Net cash used in financing activities	(2,366)	(6,595)
Effect of exchange rate changes on cash and cash equivalents	20	26
Net change in cash and cash equivalents	(1,013)	55
Cash and cash equivalents at beginning of period	17,940	7,588
Cash and cash equivalents at end of period	$ 16,927	$ 7,643

See accompanying notes.

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 March 31, 2019, 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, 2018, 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 March 31, 2019.

Recently Adopted Accounting Standards

In February 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update No. 2016-02 "Leases" (ASU 2016-02) and subsequently issued supplemental adoption guidance and clarification (collectively, Topic 842). Topic 842 amends a number of aspects of lease accounting, including requiring lessees to recognize right-of-use assets and lease liabilities for operating leases with a lease term greater than one year. Topic 842 supersedes Topic 840 "Leases."

On January 1, 2019, we adopted Topic 842 using the modified retrospective approach. Results for reporting periods beginning after January 1, 2019 are presented under Topic 842, while prior period amounts are not adjusted and continue to be reported in accordance with our historical accounting under Topic 840. We elected the package of practical expedients permitted under the transition guidance within Topic 842, which allowed us to carry forward the historical lease classification, retain the initial direct costs for any leases that existed prior to the adoption of the standard and not reassess whether any contracts entered into prior to the adoption are leases. We also elected to account for lease and nonlease components in our lease agreements as a single lease component in determining lease assets and liabilities. In addition, we elected not to recognize the right-of-use assets and liabilities for leases with lease terms of one year or less.

Upon adoption of Topic 842, we recorded $441 million of right-of-use assets within Other long-term assets and $490 million of operating lease liabilities, classified primarily within Other long-term obligations on our Condensed Consolidated Balance Sheet, as of January 1, 2019. The adoption did not have a material impact on our Condensed Consolidated Statements of Income or Condensed Consolidated Statements of Cash Flows. See Note 10. Leases for additional information.

Recently Issued Accounting Standards Not Yet Adopted

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. In April 2019, the FASB issued clarification to ASU 2016-13 within ASU 2019-04 "Codification Improvements to Topic 326, Financial Instruments-Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments." The 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 these standards but we currently do not expect a material impact on our Condensed Consolidated Financial Statements.

In November 2018, the FASB issued Accounting Standards Update No. 2018-18 "Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606" (ASU 2018-18). ASU 2018-18 clarifies that certain transactions between participants in a collaborative arrangement should be accounted for under ASC 606 when the counterparty is a customer. In addition, the update precludes an entity from presenting consideration from a transaction in a collaborative arrangement as revenue if the counterparty is not a customer for that transaction. This guidance will become effective for us beginning in the first quarter of 2020 and will be applied retrospectively to January 1, 2018 when we initially adopted Topic 606. Early adoption is permitted. We are evaluating the impact of the adoption of this standard but we currently do not expect a material impact on our revenue.

2. REVENUES

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 (in millions):

	Three Months Ended March 31, 2019				Three Months Ended March 31, 2018			
	U.S.	Europe	Other International	Total	U.S.	Europe	Other International	Total
Product sales:								
Atripla	$ 133	$ 16	$ 22	$ 171	$ 228	$ 51	$ 35	$ 314
Biktarvy	739	48	6	793	35	—	—	35
Complera/Eviplera	44	62	9	115	67	109	14	190
Descovy	233	68	41	342	274	75	12	361
Genvoya	728	193	94	1,015	853	186	43	1,082
Odefsey	282	106	9	397	279	58	5	342
Stribild	67	18	11	96	133	29	12	174
Truvada	551	33	22	606	507	97	48	652
Other HIV[1]	11	1	5	17	9	1	3	13
Revenue share – Symtuza[2]	42	24	—	66	—	7	—	7
AmBisome	8	57	28	93	17	56	34	107
Ledipasvir/Sofosbuvir[3]	117	27	81	225	234	56	58	348
Letairis	197	—	—	197	204	—	—	204
Ranexa	155	—	—	155	195	—	—	195
Sofosbuvir/Velpatasvir[4]	230	154	107	491	269	198	69	536
Vemlidy	65	4	32	101	47	3	8	58
Viread	12	14	46	72	7	30	60	97
Vosevi	45	16	2	63	86	16	5	107
Yescarta	90	6	—	96	40	—	—	40
Zydelig	11	15	1	27	14	18	1	33
Other[5]	36	20	6	62	29	15	62	106
Total product sales	3,796	882	522	5,200	3,527	1,005	469	5,001
Royalty, contract and other revenues	22	56	3	81	20	52	15	87
Total revenues	$ 3,818	$ 938	$ 525	$ 5,281	$ 3,547	$ 1,057	$ 484	$ 5,088

Notes:

(1) Includes Emtriva and Tybost

(2) Represents our revenue from cobicistat (C), emtricitabine (FTC) and tenofovir alafenamide (TAF) in Symtuza (darunavir/C/FTC/TAF), a fixed dose combination product commercialized by Janssen Sciences Ireland UC (Janssen)

(3) Amounts consist of sales of Harvoni and the authorized generic version of Harvoni sold by our separate subsidiary, Asegua Therapeutics LLC

(4) Amounts consist of sales of Epclusa and the authorized generic version of Epclusa sold by our separate subsidiary, Asegua Therapeutics LLC

(5) Includes Cayston, Hepsera and Sovaldi

Revenues Recognized from Performance Obligations Satisfied in Prior Periods

During the three months ended March 31, 2019 and 2018, revenues recognized from performance obligations satisfied in prior years related to royalties for licenses of our intellectual property were $155 million and $97 million, respectively. Changes in estimates for variable consideration related to sales made in prior years resulted in a $107 million increase and $87 million decrease in revenues during the three months ended March 31, 2019 and 2018, respectively.

Contract Balances

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 $140 million and $125 million as of March 31, 2019 and December 31, 2018, respectively.

Contract liabilities were not material as of March 31, 2019 and December 31, 2018.

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 debt securities, accounts receivable, foreign currency exchange contracts, equity securities, accounts payable and short-term and long-term debt. Cash and cash equivalents, marketable debt securities, certain equity securities and foreign currency exchange contracts are reported at their respective fair values on our Condensed Consolidated Balance Sheets. Equity securities with no readily determinable fair values are recorded using the measurement alternative of cost less impairment, if any, adjusted for observable price changes in orderly transactions for identical or similar investments of the same issuer. 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):

	March 31, 2019				December 31, 2018			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Assets:								
Available-for-sale debt securities:								
U.S. treasury securities	$ 4,782	$ —	$ —	$ 4,782	$ 3,969	$ —	$ —	$ 3,969
Certificates of deposit	—	4,211	—	4,211	—	4,361	—	4,361
U.S. government agencies securities	—	1,444	—	1,444	—	938	—	938
Municipal debt securities	—	25	—	25	—	—	—	—
Non-U.S. government securities	—	452	—	452	—	305	—	305
Corporate debt securities	—	12,565	—	12,565	—	13,067	—	13,067
Residential mortgage and asset-backed securities	—	1,036	—	1,036	—	1,524	—	1,524
Equity securities:								
Money market funds	3,778	—	—	3,778	5,305	—	—	5,305
Publicly traded equity securities	1,099	18	—	1,117	881	—	—	881
Deferred compensation plan	150		—	150	124	—	—	124
Foreign currency derivative contracts	—	77	—	77	—	78	—	78
Total	$ 9,809	$ 19,828	$ —	$ 29,637	$ 10,279	$ 20,273	$ —	$ 30,552
Liabilities:								
Deferred compensation plan	$ 150	$ —	$ —	$ 150	$ 124	$ —	$ —	$ 124
Foreign currency derivative contracts	—	2	—	2	—	1	—	1
Total	$ 150	$ 2	$ —	$ 152	$ 124	$ 1	$ —	$ 125

For the three months ended March 31, 2019 and 2018, changes in the fair value of equity securities resulted in net unrealized gains of $197 million and $45 million, respectively, which were included in Other income (expense), net on our Condensed

Consolidated Statements of Income. Investments in equity securities without readily determinable fair values were not material for the periods presented.

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

	March 31, 2019	December 31, 2018
Cash and cash equivalents	$ 3,778	$ 5,305
Prepaid and other current assets	1,105	863
Other long-term assets	162	142
Total	$ 5,045	$ 6,310

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

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 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 $27.3 billion and $27.1 billion as of March 31, 2019 and December 31, 2018, respectively, and the carrying values were $26.6 billion and $27.3 billion as of March 31, 2019 and December 31, 2018, respectively.

4. AVAILABLE-FOR-SALE DEBT SECURITIES

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

	March 31, 2019				December 31, 2018			
	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	$ 4,786	$ —	$ (4)	$ 4,782	$ 3,978	$ —	$ (9)	$ 3,969
Certificates of deposit	4,211	—	—	4,211	4,361	—	—	4,361
U.S. government agencies securities	1,446	—	(2)	1,444	943	—	(5)	938
Municipal debt securities	25	—	—	25	—	—	—	—
Non-U.S. government securities	453	—	(1)	452	307	—	(2)	305
Corporate debt securities	12,576	1	(12)	12,565	13,095	1	(29)	13,067
Residential mortgage and asset-backed securities	1,040	—	(4)	1,036	1,532	—	(8)	1,524
Total	$ 24,537	$ 1	$ (23)	$ 24,515	$ 24,216	$ 1	$ (53)	$ 24,164

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

	March 31, 2019	December 31, 2018
Cash and cash equivalents	$ 11,317	$ 10,592
Short-term marketable securities	10,977	12,149
Long-term marketable securities	2,221	1,423
Total	$ 24,515	$ 24,164

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

	March 31, 2019	
	Amortized Cost	Fair Value
Within one year	$ 22,313	$ 22,294
After one year through five years	2,175	2,172
After five years through ten years	31	31
After ten years	18	18
Total	$ 24,537	$ 24,515

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
March 31, 2019						
U.S. treasury securities	$ —	$ 2,971	$ (4)	$ 917	$ (4)	$ 3,888
U.S. government agencies securities	—	483	(2)	458	(2)	941
Non-U.S. government securities	—	100	(1)	160	(1)	260
Corporate debt securities	(1)	1,049	(11)	2,938	(12)	3,987
Residential mortgage and asset-backed securities	—	85	(4)	817	(4)	902
Total	$ (1)	$ 4,688	$ (22)	$ 5,290	$ (23)	$ 9,978
December 31, 2018						
U.S. treasury securities	$ —	$ 896	$ (9)	$ 1,383	$ (9)	$ 2,279
U.S. government agencies securities	—	30	(5)	553	(5)	583
Non-U.S. government securities	—	86	(2)	192	(2)	278
Corporate debt securities	(1)	1,600	(28)	4,204	(29)	5,804
Residential mortgage and asset-backed securities	—	192	(8)	1,186	(8)	1,378
Total	$ (1)	$ 2,804	$ (52)	$ 7,518	$ (53)	$ 10,322

We held a total of 915 and 1,348 positions, which were in an unrealized loss position, as of March 31, 2019 and December 31, 2018, respectively.

Based on our review of these securities, we believe we had no other-than-temporary impairments as of March 31, 2019 and December 31, 2018, 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 months ended March 31, 2019 and 2018.

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. 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. The unrealized gains or losses in Accumulated other comprehensive income (AOCI) are reclassified into product sales when the respective hedged transactions affect earnings. The majority of gains and losses related to the hedged forecasted transactions reported in AOCI at March 31, 2019 are expected to be reclassified to product sales within 12 months.

The cash flow effects of our derivative contracts for the three months ended March 31, 2019 and 2018 were 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 $2.2 billion at March 31, 2019 and December 31, 2018, respectively.

While all 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):

	March 31, 2019			
	Asset Derivatives		Liability Derivatives	
	Classification	Fair Value	Classification	Fair Value
Derivatives designated as hedges:				
Foreign currency exchange contracts	Other current assets	$ 74	Other accrued liabilities	$ (1)
Foreign currency exchange contracts	Other long-term assets	3	Other long-term obligations	—
Total derivatives designated as hedges		77		(1)
Derivatives not designated as hedges:				
Foreign currency exchange contracts	Other current assets	—	Other accrued liabilities	(1)
Total derivatives not designated as hedges		—		(1)
Total derivatives		$ 77		$ (2)

	December 31, 2018			
	Asset Derivatives		Liability Derivatives	
	Classification	Fair Value	Classification	Fair Value
Derivatives designated as hedges:				
Foreign currency exchange contracts	Other current assets	$ 73	Other accrued liabilities	$ (1)
Foreign currency exchange contracts	Other long-term assets	5	Other long-term obligations	—
Total derivatives designated as hedges		78		(1)
Derivatives not designated as hedges:				
Foreign currency exchange contracts	Other current assets	—	Other accrued liabilities	—
Total derivatives not designated as hedges		—		—
Total derivatives		$ 78		$ (1)

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

	Three Months Ended March 31,	
	2019	2018
Derivatives designated as hedges:		
Gains (losses) recognized in AOCI	$ 28	$ (61)
Gains (losses) reclassified from AOCI into product sales	29	(48)
Derivatives not designated as hedges:		
Losses recognized in Other income (expense), net	$ (6)	$ (14)

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 months ended March 31, 2019 and 2018 as a result of the discontinuance of cash flow hedges.

As of March 31, 2019 and December 31, 2018, we only held 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):

				Gross Amounts Not Offset on our Condensed Consolidated Balance Sheets		
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	Derivative Financial Instruments	Cash Collateral Received/ Pledged	Net Amount (Legal Offset)
As of March 31, 2019						
Derivative assets	$ 77	$ —	$ 77	$ (2)	$ —	$ 75
Derivative liabilities	(2)	—	(2)	2	—	—
As of December 31, 2018						
Derivative assets	$ 78	$ —	$ 78	$ (1)	$ —	$ 77
Derivative liabilities	(1)	—	(1)	1	—	—

6. COLLABORATIVE ARRANGEMENTS

We enter into collaborative arrangements with third parties for the development and commercialization of certain products and product candidates. These arrangements involve two or more parties who are active participants in the operating activities of the collaboration and are exposed to significant risks and rewards depending on the commercial success of the activities. 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, equity investments, or a combination of these terms.

During the three months ended March 31, 2019, we entered into collaboration arrangements that resulted in cash payments of $165 million, of which $126 million was recorded as up-front collaboration expense within Research and development expenses on our Condensed Consolidated Statements of Income and the remaining balance was recorded in Prepaid and other current assets on our Condensed Consolidated Balance Sheets. During the three months ended March 31, 2018, the initial cash consideration related to collaborations and other arrangements was not material. We do not consider any of these collaboration arrangements to be individually material.

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. Future milestone payments and royalties, if any, will be reflected on our Condensed Consolidated Statements of Income when the corresponding events become probable.

7. OTHER FINANCIAL INFORMATION

Inventories

The following table summarizes our inventories (in millions):

	March 31, 2019	December 31, 2018
Raw materials	$ 1,860	$ 1,888
Work in process	267	235
Finished goods	501	507
Total	$ 2,628	$ 2,630
Reported as:		
Inventories	$ 898	$ 814
Other long-term assets	1,730	1,816
Total	$ 2,628	$ 2,630

Amounts reported as other long-term assets primarily consisted of raw materials as of March 31, 2019 and December 31, 2018.

Other Accrued Liabilities

The following table summarizes the components of other accrued liabilities (in millions):

	March 31, 2019	December 31, 2018
Compensation and employee benefits	$ 325	$ 555
Accrued payment for marketing-related rights acquired from Japan Tobacco Inc.	185	365
Other accrued expenses	1,838	2,219
Total	$ 2,348	$ 3,139

8. INTANGIBLE ASSETS

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

	March 31, 2019				December 31, 2018			
	Gross Carrying Amount	Accumulated Amortization	Foreign Currency Translation Adjustment	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Foreign Currency Translation Adjustment	Net Carrying Amount
Finite-lived assets:								
Intangible asset - sofosbuvir	$ 10,720	$ (3,729)	$ —	$ 6,991	$ 10,720	$ (3,554)	$ —	$ 7,166
Intangible asset - axicabtagene ciloleucel (DLBCL)	6,200	(502)	—	5,698	6,200	(416)	—	5,784
Intangible asset - Ranexa	688	(688)	—	—	688	(678)	—	10
Other	1,098	(387)	(4)	707	1,096	(359)	(3)	734
Total finite-lived assets	18,706	(5,306)	(4)	13,396	18,704	(5,007)	(3)	13,694
Indefinite-lived assets - In Process Research & Development	2,047	—	(5)	2,042	2,047	—	(3)	2,044
Total intangible assets	$ 20,753	$ (5,306)	$ (9)	$ 15,438	$ 20,751	$ (5,007)	$ (6)	$ 15,738

Aggregate amortization expense related to finite-lived intangible assets was $299 million and $301 million for the three months ended March 31, 2019 and 2018, respectively, and was primarily included in Cost of goods sold on our Condensed Consolidated Statements of Income.

The following table summarizes the estimated future amortization expense associated with our finite-lived intangible assets as of March 31, 2019 (in millions):

Fiscal Year	Amount
2019 (remaining nine months)	$ 851
2020	1,125
2021	1,125
2022	1,125
2023	1,125
Thereafter	8,045
Total	$ 13,396

9. DEBT AND CREDIT FACILITIES

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

				Carrying Amount	
Type of Borrowing	Issue Date	Due Date	Interest Rate	March 31, 2019	December 31, 2018
Senior Unsecured	September 2017	March 2019	3-month LIBOR + 0.22%	$ —	$ 750
Senior Unsecured	March 2014	April 2019	2.05%	500	500
Senior Unsecured	September 2017	September 2019	1.85%	999	999
Senior Unsecured	September 2017	September 2019	3-month LIBOR + 0.25%	500	499
Senior Unsecured	November 2014	February 2020	2.35%	499	499
Senior Unsecured	September 2015	September 2020	2.55%	1,997	1,996
Senior Unsecured	March 2011	April 2021	4.50%	997	997
Senior Unsecured	December 2011	December 2021	4.40%	1,247	1,247
Senior Unsecured	September 2016	March 2022	1.95%	498	498
Senior Unsecured	September 2015	September 2022	3.25%	997	997
Senior Unsecured	September 2016	September 2023	2.50%	746	746
Senior Unsecured	March 2014	April 2024	3.70%	1,744	1,744
Senior Unsecured	November 2014	February 2025	3.50%	1,745	1,745
Senior Unsecured	September 2015	March 2026	3.65%	2,732	2,731
Senior Unsecured	September 2016	March 2027	2.95%	1,245	1,245
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	1,734
Senior Unsecured	November 2014	February 2045	4.50%	1,731	1,730
Senior Unsecured	September 2015	March 2046	4.75%	2,217	2,216
Senior Unsecured	September 2016	March 2047	4.15%	1,725	1,724
Total debt, net				26,578	27,322
Less current portion				2,498	2,748
Total long-term debt, net				$ 24,080	$ 24,574

In March 2019, we repaid $750 million of our senior unsecured notes upon maturity that were issued in September 2017.

We are required to comply with certain covenants under our credit agreement and note indentures governing our senior notes. As of March 31, 2019, we were not in violation of any covenants. Additionally, as of March 31, 2019 and December 31, 2018, there were no amounts outstanding under our $2.5 billion five-year revolving credit facility agreement maturing in May 2021.

In April 2019, we repaid $500 million of our senior unsecured notes upon maturity that were issued in March 2014.

10. LEASES

We lease facilities and equipment primarily related to administrative, research and development, and sales and marketing activities under various non-cancelable operating leases in the United States and international markets. We determine if an arrangement contains a lease at inception. Right-of-use assets and lease liabilities are recognized at the commencement date based on the present value of the lease payments over the lease term, which is the non-cancelable period stated in the contract adjusted for any options to extend or terminate when it is reasonably certain that we will exercise that option. Some of our leases include options to extend the terms for up to 15 years and some include options to terminate the lease within one year after the lease commencement date. Right-of-use assets include any prepaid lease payments, and exclude lease incentives and initial direct costs incurred.

As of March 31, 2019, we do not have material finance leases. As most of our operating leases do not provide an implicit interest rate, we use a portfolio approach to determine a collateralized incremental borrowing rate based on the information available at the commencement date to determine the lease liability. Operating lease expense is recognized on a straight-line basis over the lease term. Operating lease expense was $36 million for the three months ended March 31, 2019.

The following table summarizes balance sheet and other information related to our operating leases as of March 31, 2019 (in millions, except weighted average data):

	Classification	Amount
Right-of-use assets, net	Other long-term assets	$ 455
Lease liabilities - current	Other accrued liabilities	$ 75
Lease liabilities - noncurrent	Other long-term obligations	$ 429
Weighted average remaining lease term		9.5 years
Weighted average discount rate		3.61%

The following table summarizes other supplemental information related to our operating leases (in millions):

	Three Months Ended March 31, 2019
Cash paid for amounts included in the measurement of lease liabilities	$ 18
Right-of-use assets obtained in exchange for lease liabilities	$ 30

The following table summarizes a maturity analysis of our operating lease liabilities showing the aggregate lease payments as of March 31, 2019 (in millions):

Fiscal Year	Amount
2019 (remaining nine months)	$ 69
2020	84
2021	72
2022	65
2023	57
Thereafter	257
Total undiscounted lease payments	604
Less: imputed interest	(100)
Total discounted lease payments	$ 504

The following table summarizes the aggregate undiscounted non-cancelable future minimum lease payments for operating leases under the prior leases standard as of December 31, 2018 (in millions):

Fiscal Year	Amount
2019	$ 89
2020	78
2021	66
2022	60
2023	52
Thereafter	229
Total minimum lease payments	$ 574

11. 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 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 March 31, 2019 and December 31, 2018, 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 litigation 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.

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

In 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 infringes U.S. Patent No. 7,608,600 (the '600 patent). Also in 2013, Idenix and UDSG sued us in the U.S. District Court for the District of Massachusetts alleging that the commercialization of sofosbuvir infringes U.S. Patent Nos. 6,914,054 (the '054 patent) and 7,608,597 (the '597 patent). In 2014, the court transferred the Massachusetts litigation to the U.S. District Court for the District of Delaware.

Prior to trial in 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. A jury trial was held in 2016 on the '597 patent, and the jury found that we willfully infringed the asserted claims of the '597 patent and awarded Idenix $2.54 billion in past damages. In 2018, the judge invalidated Idenix's '597 patent and vacated the jury's award of $2.54 billion in past damages. Idenix appealed this decision to the U.S. Court of Appeals for the Federal Circuit (CAFC), and briefing is now complete. 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.

In 2014, the European Patent Office (EPO) granted Idenix's 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 2016, and the EPO ruled in our favor and revoked the '489 patent. Idenix has appealed. In 2014, Idenix also initiated infringement proceedings against us in Germany and France alleging that the

commercialization of Sovaldi would infringe the German and French counterparts of the ‘489 patent. In 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 2016. Idenix has not appealed this decision of the German court staying the proceedings. Upon Idenix’s request, the French proceedings have been stayed.

Litigation with Merck & Co. Inc. (Merck)

In 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 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 2016, a jury determined that we had not established that Merck’s patents are invalid and awarded Merck $200 million in damages. However, in 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.

In 2018, the CAFC affirmed the court’s decision on unclean hands. In January 2019, the U.S. Supreme Court denied Merck’s petition for review. In March 2019, the parties executed an agreement concerning the total amount that Merck should reimburse us for the court’s award of attorney’s fees, appellate fees and interest, and Merck paid us the agreed upon amount. Accordingly, this matter is now closed.

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 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 2017, the court granted our motion to transfer the case to California. We have also filed four petitions for inter partes review with the USPTO Patent Trial and Appeal Board (PTAB) alleging that all asserted claims are invalid for anticipation and obviousness. In 2018, the District Court stayed the litigation until after the PTAB rules on our petitions for inter partes review.

Litigation Related to Axicabtagene Ciloleucel

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 December 2019 for this lawsuit.

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 2018, ViiV Healthcare Company (ViiV) filed a lawsuit against us in the U.S. District Court of Delaware, alleging that the commercialization of bictegravir, sold commercially in combination with tenofovir alafenamide and emtricitabine as Biktarvy, infringes ViiV’s U.S. Patent No. 8,129,385 (the ‘385 patent), which was issued to Shionogi & Co. Ltd. and 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 U.S. Patent and Trademark Office (USPTO) has granted us patents covering bictegravir. The court has set a trial date of September 2020 for this lawsuit.

In 2018, ViiV also filed a lawsuit against us in the Federal Court of Canada, alleging that our activities relating to our bictegravir compound 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 2018, we received notice that Zydus Pharmaceuticals (USA) Inc. (Zydus) submitted an ANDA to FDA requesting permission to manufacture and market generic versions of Truvada at various dosage strengths. In the notice, Zydus 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 Zydus' manufacture, use or sale of generic versions of Truvada at various dosage strengths. In response, we filed a lawsuit against Zydus in the U.S. District Court for the District of New Jersey for infringement of our patents.

In 2018, we received notice that Mylan Pharmaceuticals Inc. (Mylan) submitted an ANDA to FDA requesting permission to manufacture and market a generic version of Stribild. In the notice, Mylan alleges that one patent owned by Japan Tobacco Inc. (JT) and associated with elvitegravir is invalid, unenforceable and/or will not be infringed by Mylan's manufacture, use or sale of a generic version of Stribild. In 2019, JT filed a lawsuit against Mylan in the U.S. District Court for the Northern District of West Virginia for infringement of its patent.

HCV Products

In 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 response, 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. We also 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. In 2018, we reached an agreement with Teva to resolve the lawsuit, which has been dismissed. The settlement agreement has been filed with the Federal Trade Commission and Department of Justice as required by law.

European Patent Claims

In 2015, several parties filed oppositions in the EPO requesting revocation of one of our granted European patents covering sofosbuvir that expires in 2028. In 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 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 2018 and upheld the claims. Two of the original opposing parties have appealed, requesting full revocation. The appeal process may take several years.

In 2016, several parties filed oppositions in the EPO requesting revocation of our granted European patent covering TAF that expires in 2021. In 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 2017, several parties filed oppositions in the EPO requesting revocation of our granted European patent relating to TAF hemifumarate that expires in 2032. We responded to these oppositions, and a hearing was held in February 2019. The patent was upheld at this hearing. The opposing parties may choose to appeal this decision, which could take several years to conclude.

In 2016, three parties filed oppositions in the EPO requesting revocation of our granted European patent covering cobicistat that expires in 2027. In 2017, the EPO upheld the validity of the claims of our cobicistat patent. One of the original opposing parties has appealed 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. If we lose patent protection for any of these compounds, 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.

Government Investigations and Related Litigation

In 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 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. Also in 2014, the former employees served a First Amended Complaint, and 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 2015, the plaintiffs filed a Second Amended Complaint, and the District Court issued an order granting our motion to dismiss the Second Amended Complaint. The plaintiffs then filed a notice of appeal in the U.S. Court of Appeals for the Ninth Circuit. In 2017, the Ninth Circuit granted our motion to stay the case pending an appeal to the U.S. Supreme Court, and we filed a Petition for a Writ of Certiorari to the U.S. Supreme Court. In 2018, the Solicitor General submitted a brief for the United States to the Supreme Court stating its intention to file a motion to dismiss under the federal False Claims Act. In January 2019, the Supreme Court denied the Petition and the case has been remanded to the District Court. In March 2019, the Department of Justice filed a motion to dismiss the Second Amended Complaint, which the District Court is expected to rule upon later this year.

In 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 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 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 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 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 for Harvoni and Sovaldi. We are cooperating with this inquiry.

In 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 cooperated with the inquiry, and in February 2019, the government informed us that it declined to intervene in the False Claims Act qui tam lawsuit related to the inquiry. In March 2019, the relator filed a voluntary dismissal of the qui tam lawsuit without prejudice as to all claims.

In 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.

Product Liability

We have been named as a defendant in one class action lawsuit filed in 2018 and various product liability lawsuits related to Viread, Truvada, Atripla, Complera and Stribild. Plaintiffs allege that Viread, Truvada, Atripla, Complera and/or Stribild caused them to suffer kidney and/or bone injuries. The lawsuits, all of which are pending in state or federal court in California, involve hundreds of plaintiffs. Plaintiffs in these cases seek damages and other relief on various grounds for alleged personal injury and economic loss. We intend to vigorously defend ourselves in these actions. While we believe these cases are without merit, we cannot predict the ultimate outcome. If plaintiffs are successful in their claims, we could be required to pay significant monetary damages.

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.

12. STOCKHOLDERS' EQUITY

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 months ended March 31, 2019 and 2018, we repurchased and retired 12 million and 13 million shares of our common stock for $834 million and $1.0 billion, respectively, through open market transactions under the 2016 Program. As of March 31, 2019, the remaining authorized repurchase amount under the 2016 Program was $4.3 billion.

Accumulated Other Comprehensive Income (Loss)

The following table summarizes the changes in AOCI by component, net of tax during the three months ended March 31, 2019 and 2018 (in millions):

	Foreign Currency Translation	Unrealized Gains and Losses on Available-for-Sale Debt Securities	Unrealized Gains and Losses on Cash Flow Hedges	Total
Balance at December 31, 2018	$ 47	$ (52)	$ 85	$ 80
Net unrealized gain	21	30	28	79
Reclassifications to net income	—	—	(29)	(29)
Net current period other comprehensive income (loss)	21	30	(1)	50
Balance at March 31, 2019	$ 68	$ (22)	$ 84	$ 130

	Foreign Currency Translation	Unrealized Gains and Losses on Available-for-Sale Debt 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)	7	(36)	(61)	(90)
Reclassifications to net income	—	—	48	48
Net current period other comprehensive income (loss)	7	(36)	(13)	(42)
Balance at March 31, 2018	$ 92	$ (135)	$ (127)	$ (170)

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. The income tax impact allocated to each component of other comprehensive income was not material for any period presented.

13. 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 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.

Potential shares of common stock excluded from the computation of diluted net income per share attributable to Gilead common stockholders because their effect would have been antidilutive were 16 million and 12 million shares for the three months ended March 31, 2019 and 2018, respectively.

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 March 31,	
	2019	2018
Net income attributable to Gilead	$ 1,975	$ 1,538
Shares used in per share calculation - basic	1,276	1,307
Dilutive effect of stock options and equivalents	7	13
Shares used in per share calculation - diluted	1,283	1,320
Net income per share attributable to Gilead common stockholders - basic	$ 1.55	$ 1.18
Net income per share attributable to Gilead common stockholders - diluted	$ 1.54	$ 1.17

14. 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 March 31,	
	2019	2018
AmerisourceBergen Corp.	21%	21%
Cardinal Health, Inc.	20%	21%
McKesson Corp.	20%	20%

15. INCOME TAXES

Our effective tax rate of 16.3% for the three months ended March 31, 2019 differed from the U.S. federal statutory rate of 21% primarily due to a $119 million tax benefit related to settlements with taxing authorities and earnings from non-U.S. subsidiaries that operate in jurisdictions with lower tax rates than the United States, partially offset by the tax on Global Intangible Low-Taxed Income, state taxes and our portion of the non-tax deductible branded prescription drug fee.

Our effective tax rate of 24.3% for the three months ended March 31, 2018 differed from the U.S. federal statutory rate of 21% primarily due to a $49 million tax expense related to a settlement of a foreign tax examination, state taxes and our portion of the non-tax deductible branded prescription drug fee, partially offset by earnings from non-U.S. subsidiaries that operate in jurisdictions with lower tax rates than the United States.

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 2013 and 2010 onwards, respectively. 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 regularly 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 $119 million during the three months ended March 31, 2019 due to settlements with taxing authorities. As of March 31, 2019, we do not believe that it is reasonably possible that our unrecognized tax benefits will materially increase or decrease in the next 12 months.

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," "may," "could," "should," "might," variations of such words and similar expressions are intended to identify such forward-looking statements. In addition, any statements other than statements of historical fact are forward-looking statements, including statements regarding overall trends, operating cost and revenue trends, liquidity and capital needs and other statements of expectations, beliefs, future plans and strategies, anticipated events or trends and similar expressions. We have based these forward-looking statements on our current expectations about future events. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Our actual results may differ materially from those suggested by these forward-looking statements for various reasons, including those identified below under "Risk Factors." 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, 2018 and our unaudited Condensed Consolidated Financial Statements for the three months ended March 31, 2019 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. With each new discovery and investigational drug candidate, 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, product acquisition, in-licensing and strategic collaborations.

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 sell and distribute authorized generic versions of Epclusa and Harvoni in the United States through our separate subsidiary, Asegua Therapeutics LLC. In addition, we sell and distribute certain products through our corporate partners under collaborative agreements.

Business Highlights

During the first quarter of 2019, 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

- We announced that STELLAR-3, a Phase 3 study evaluating the safety and efficacy of selonsertib, an investigational, once daily, oral inhibitor of apoptosis signal-regulating kinase 1 (ASK1), for patients with bridging fibrosis (F3) due to nonalcoholic steatohepatitis (NASH), did not meet the pre-specified week 48 primary endpoint of a ≥ 1-stage histologic improvement in fibrosis without worsening of NASH.
- We entered into a strategic collaboration with Insitro, Inc. to discover and develop therapies for patients with NASH.

- We announced the intent to collaborate with Novo Nordisk A/S (Novo Nordisk) on a clinical trial combining compounds from our respective pipelines in NASH. The intended clinical trial will be a proof of concept study combining Novo Nordisk's semaglutide and our cilofexor and firsocostat for the treatment of patients with NASH.
- We submitted a supplemental new drug application to FDA for Descovy for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection among individuals who are HIV-negative and at risk for HIV. A priority review voucher was submitted with the filing, leading to an anticipated review time of six months.
- Japan's Ministry of Health, Labour and Welfare (MHLW) approved Biktarvy for the treatment of HIV-1 infection.
- Japan's MHLW approved Epclusa for adults with chronic HCV infection with decompensated cirrhosis and for patients with chronic HCV infection without cirrhosis or with compensated cirrhosis who have had prior treatment with a direct-acting antiviral therapy.
- We entered into a licensing and collaboration agreement with Yuhan Corporation to co-develop novel therapeutic candidates for the treatment of advanced fibrosis due to NASH.

Oncology and Cell Therapy Programs

- We announced plans for a new facility in Maryland to expand cell therapy production capabilities.

Inflammation Programs

- We announced week 24 results of FINCH 1, an ongoing, randomized, double-blind, placebo- and active-controlled Phase 3 study of filgotinib, an investigational, oral, selective JAK1 inhibitor, in adults with moderately-to-severely active rheumatoid arthritis (RA). FINCH 1 evaluated filgotinib versus adalimumab or placebo, on a stable background dose of methotrexate (MTX) in patients with prior inadequate response to MTX. The study achieved its primary endpoint for both doses of filgotinib in the proportion of patients achieving an American College of Rheumatology 20% response (ACR20) compared to placebo at week 12.
- We announced week 24 results of FINCH 3, an ongoing, randomized, double-blind, active-controlled Phase 3 study of filgotinib in adults with moderately-to-severely active RA. FINCH 3 evaluated filgotinib in combination with MTX and as monotherapy in MTX-naïve patients. The study achieved its primary endpoint in the proportion of patients achieving an ACR20 response at week 24. The proportion of patients achieving the primary endpoint of ACR20 response at week 24 was significantly higher for filgotinib 200 mg plus MTX and filgotinib 100 mg plus MTX compared with MTX alone.
- We announced interim safety information from four studies of filgotinib for the treatment of RA. The data include 24 week results of the ongoing Phase 3 FINCH 1, 2 and 3 trials and updated week 156 safety data from the Phase 2b DARWIN 3 long-term extension study in patients with RA.

Financial Highlights

Total revenues increased by 4% to $5.3 billion for the first quarter of 2019, compared to $5.1 billion for the same period in 2018, primarily due to higher product sales, which were $5.2 billion compared to $5.0 billion for the same period in 2018.

Research and development (R&D) expenses increased by 13% to $1.1 billion for the first quarter of 2019, compared to $937 million for the same period in 2018, primarily due to up-front collaboration expenses and higher investments to support our cell therapy programs partially offset by lower stock-based compensation expense. Stock-based compensation expense was higher for the first quarter of 2018 following the acquisition of Kite Pharma, Inc. (Kite).

Selling, general and administrative (SG&A) expenses increased by 3% to $1,030 million for the first quarter of 2019, compared to $997 million for the same period in 2018, primarily due to higher promotional expenses in the United States and expenses associated with the expansion of our products in Europe and Japan, partially offset by lower stock-based compensation expense. Stock-based compensation expense was higher for the first quarter of 2018 following the acquisition of Kite.

Net income attributable to Gilead was $2.0 billion or $1.54 per diluted share for the first quarter of 2019, compared to $1.5 billion or $1.17 per diluted share for the same period in 2018, primarily due to higher product sales and higher net unrealized gains from changes in the fair value of our equity securities.

As of March 31, 2019, we had $30.1 billion of cash, cash equivalents and marketable debt securities compared to $31.5 billion as of December 31, 2018. During the first quarter of 2019, we generated $1.4 billion in operating cash flow, repaid $750 million of debt, paid cash dividends of $817 million and repurchased 12 million shares of our common stock for $834 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:

(In millions, except percentages)	Three Months Ended March 31, 2019	2018	Change
Revenues:			
Product sales	$ 5,200	$ 5,001	4 %
Royalty, contract and other revenues	81	87	(7)%
Total revenues	$ 5,281	$ 5,088	4 %

Product sales for the three months ended March 31, 2019

Total product sales increased by 4% to $5.2 billion for the three months ended March 31, 2019, compared to $5.0 billion for the same period in 2018, primarily due to higher HIV product sales, partially offset by lower HCV product sales.

HIV product sales increased by 14% to $3.6 billion for the three months ended March 31, 2019, compared to $3.2 billion for the same period in 2018, driven by higher sales volume as a result of the continued uptake of Biktarvy, partially offset by lower average net selling prices and decreases in sales volume of our Truvada (emtricitabine (FTC) and tenofovir disoproxil fumarate (TDF))-based products.

HCV product sales decreased by 24% to $790 million for the three months ended March 31, 2019, compared to $1.0 billion for the same period in 2018, primarily due to lower patient starts and competitive dynamics, including a decline in average net selling price in U.S. Medicare in 2019.

Yescarta, which was approved in the United States in October 2017 and in Europe in August 2018, generated $96 million in sales during the three months ended March 31, 2019, compared to $40 million for the same period in 2018. The increase was driven by an increase in the number of therapies provided to patients.

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 7% to $696 million for the three months ended March 31, 2019, compared to $745 million for the same period in 2018. The decrease was primarily due to the expected decline in Ranexa sales after the entry of generic versions of Ranexa in the United States in the first quarter of 2019. Letairis is expected to face competition from generic versions of Letairis in the United States starting in the second quarter of 2019. We expect a decline in our Letairis sales in the United States after the entry of generic versions.

Of our total product sales, 27% and 29% were generated outside the United States during the three months ended March 31, 2019 and 2018, respectively. We faced exposure to movements in foreign currency exchange rates, primarily in the Euro. We used foreign currency exchange contracts to hedge a portion of our foreign currency exposure. Foreign currency exchange, net of hedges, had an immaterial impact on our product sales for the three months ended March 31, 2019, based on a comparison using foreign currency exchange rates from the three months ended March 31, 2018.

Product sales in the United States increased by 8% to $3.8 billion for the three months ended March 31, 2019, compared to $3.5 billion for the same period in 2018. The increase was primarily due to higher sales of our HIV products, partially offset by lower sales of HCV products. The increase in sales of our HIV products was primarily due to the continued uptake of Biktarvy and increased usage of Truvada for PrEP, partially offset by lower average net selling price and decreases in sales volume of Genvoya, Atripla, Stribild, Descovy and Complera. The decrease in sales of our HCV products was due to lower average net selling price, including a decline in average net selling price in U.S. Medicare in 2019, and lower sales volume as a result of fewer patient starts.

Product sales in Europe decreased by 12% to $882 million for the three months ended March 31, 2019, compared to $1.0 billion for the same period in 2018. The decrease was primarily due to lower sales of our HCV products and the broader 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 as a result of increased competition and lower patient starts. The decrease was partially offset by the continued uptake of Biktarvy and Odefsey. Foreign currency exchange, net of hedges, had an immaterial impact on our product sales in Europe for the three months ended March 31, 2019.

Product sales in other locations increased by 11% to $522 million for the three months ended March 31, 2019, compared to $469 million for the same period in 2018, primarily due to higher HIV product sales in Japan as a result of acquiring the rights to certain products in our HIV portfolio in Japan effective January 1, 2019.

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

(In millions, except percentages)	Three Months Ended March 31, 2019	2018	Change
Atripla	$ 171	$ 314	(46)%
Biktarvy	793	35	*
Complera/Eviplera	115	190	(39)%
Descovy	342	361	(5)%
Genvoya	1,015	1,082	(6)%
Odefsey	397	342	16 %
Stribild	96	174	(45)%
Truvada	606	652	(7)%
Other HIV[1]	17	13	31 %
Revenue share - Symtuza[2]	66	7	*
Total HIV	3,618	3,170	14 %
AmBisome	93	107	(13)%
Ledipasvir/Sofosbuvir[3]	225	348	(35)%
Letairis	197	204	(3)%
Ranexa	155	195	(21)%
Sofosbuvir/Velpatasvir[4]	491	536	(8)%
Vemlidy	101	58	74 %
Viread	72	97	(26)%
Vosevi	63	107	(41)%
Yescarta	96	40	*
Zydelig	27	33	(18)%
Other[5]	62	106	(42)%
Total product sales	$ 5,200	$ 5,001	4 %

* Percentage is greater than 100%

(1) Includes Emtriva and Tybost

(2) Represents our revenue from cobicistat (C), FTC and tenofovir alafenamide (TAF) in Symtuza (darunavir/C/FTC/TAF), a fixed dose combination product commercialized by Janssen Sciences Ireland UC

(3) Amounts consist of sales of Harvoni and the authorized generic version of Harvoni sold by our separate subsidiary, Asegua Therapeutics LLC

(4) Amounts consist of sales of Epclusa and the authorized generic version of Epclusa sold by our separate subsidiary, Asegua Therapeutics LLC

(5) Includes Cayston, Hepsera and Sovaldi

The following is additional discussion of our results on certain products:

- *Descovy (FTC/TAF)-based products - Biktarvy, Descovy, Genvoya, Odefsey and Revenue Share - Symtuza*

  Product sales of our Descovy (FTC/TAF)-based products were $2.6 billion and $1.8 billion and were 50% and 37% of our total product sales and were 72% and 58% of total HIV product sales for the three months ended March 31, 2019 and 2018, respectively.

  For the three months ended March 31, 2019, sales of our Descovy (FTC/TAF)-based products were $2.0 billion in the United States, $439 million in Europe and $150 million in other locations, compared to $1.4 billion in the United States, $326 million in Europe and $60 million in other locations for the same period in 2018. In the United States, the increase was primarily due to higher sales volume as a result of the continued uptake of Biktarvy, partially offset by lower average net selling prices. In Europe, the increase was primarily due to higher sales volume as a result of the continued uptake of Odefsey and Biktarvy.

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

  Product sales of our Truvada (FTC/TDF)-based products were $988 million and $1.3 billion and were 19% and 27% of our total product sales for the three months ended March 31, 2019 and 2018, respectively.

  For the three months ended March 31, 2019, sales of our Truvada (FTC/TDF)-based products were $795 million in the United States, $129 million in Europe and $64 million in other locations, compared to $935 million in the United States, $286 million in Europe and $109 million in other locations for the same period in 2018. In the United States, the decrease was primarily due to lower sales volume as a result of patients switching to newer regimens containing TAF, partially offset by the increased usage of Truvada for PrEP. In Europe, the decrease was primarily due to lower sales volume as a result of the broader availability of generic versions of Truvada and Atripla and patients switching to newer regimens containing TAF.

- *HCV products - Epclusa, Harvoni, Sovaldi, Vosevi and Authorized Generics of Epclusa and Harvoni*

  HCV product sales were $790 million and $1.0 billion, and were 15% and 21% of our total product sales for the three months ended March 31, 2019 and 2018, respectively.

  For the three months ended March 31, 2019, sales of our HCV products were $393 million in the United States, $203 million in Europe and $194 million in other locations. For the three months ended March 31, 2018, sales of our HCV products were $584 million in the United States, $271 million in Europe and $191 million in other locations.

  In the United States, the decrease was due to lower average net selling price, including a decline in average net selling price in U.S. Medicare in 2019, and lower sales volume as a result of a decrease in market share and fewer patient starts. In Europe, the decrease was primarily due to lower average net selling price as a result of increased competition and lower patient starts.

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 March 31,		
(In millions, except percentages)	**2019**	**2018**	**Change**
Total product sales	$ 5,200	$ 5,001	4 %
Cost of goods sold	$ 957	$ 1,001	(4)%
Product gross margin	82%	80%	2 %

The decrease in cost of goods sold was primarily due to lower fees paid to Bristol-Myers Squibb Company (BMS) for the net sales of Atripla.

The increase in product gross margin was primarily due to Biktarvy growth, overall HIV product mix and the factor noted above.

Research and Development Expenses

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

	Three Months Ended March 31,		
(In millions, except percentages)	**2019**	**2018**	**Change**
Research and development expenses	$ 1,057	$ 937	13%

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

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

R&D expenses for the three months ended March 31, 2019 increased by $120 million, or 13%, compared to the same period in 2018, primarily due to $126 million of up-front collaboration expenses and higher investments to support our cell therapy

programs, partially offset by lower stock-based compensation expense. Stock-based compensation expense was $42 million higher for the three months ended March 31, 2018 following the acquisition of Kite.

Selling, General and Administrative Expenses

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

	Three Months Ended March 31,		
(In millions, except percentages)	**2019**	**2018**	**Change**
Selling, general and administrative expenses	$ 1,030	$ 997	3%

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 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 (IRS).

SG&A expenses for the three months ended March 31, 2019 increased by $33 million, or 3%, compared to the same period in 2018, primarily due to higher promotional expenses in the United States and expenses associated with the expansion of our products in Europe and Japan, partially offset by lower stock-based compensation expense. Stock-based compensation expense was $36 million higher for the three months ended March 31, 2018 following the acquisition of Kite. BPD fee expense for the three months ended March 31, 2019 increased to $99 million compared to $79 million for the same period in 2018, primarily due to net adjustments based on IRS invoices.

Other Income (Expense), Net

Other income (expense), net for the three months ended March 31, 2019 increased to $367 million compared to $170 million for the same period in 2018, primarily due to $152 million higher net unrealized gains from changes in the fair value of our equity securities recorded in the three months ended March 31, 2019 compared to the same period in 2018.

Provision for Income Taxes

Our provision for income taxes was $382 million and $494 million for the three months ended March 31, 2019 and 2018, respectively. Our effective tax rate was 16.3% and 24.3% for the three months ended March 31, 2019 and 2018, respectively.

The decrease in the effective tax rate for the three months ended March 31, 2019 compared to the same period in 2018 was primarily due to $119 million of favorable settlements with taxing authorities in the three months ended March 31, 2019 and a $49 million unfavorable settlement of a foreign tax examination in the three months ended March 31, 2018.

We continue to evaluate 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 and are dependent on the changes actually implemented.

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 debt securities and working capital:

(In millions)	**March 31, 2019**	**December 31, 2018**
Cash, cash equivalents and marketable debt securities	$ 30,125	$ 31,512
Working capital	$ 24,627	$ 25,231

Cash, Cash Equivalents and Marketable Debt Securities

Cash, cash equivalents and marketable debt securities decreased by $1.4 billion, or 4%, compared to December 31, 2018. During the three months ended March 31, 2019, we generated $1.4 billion in operating cash flow, repaid $750 million principal amount of debt, paid cash dividends of $817 million and repurchased 12 million shares of our common stock for $834 million through open market transactions.

Working Capital

Working capital decreased by $604 million, or 2%, compared to December 31, 2018, primarily due to a decrease in cash, cash equivalents and short-term marketable debt securities.

Cash Flows

The following table summarizes our cash flow activities:

	Three Months Ended March 31,	
(In millions)	**2019**	**2018**
Cash provided by (used in):		
Operating activities	$ 1,444	$ 2,270
Investing activities	$ (111)	$ 4,354
Financing activities	$ (2,366)	$ (6,595)

Cash Provided by Operating Activities

Cash provided by operating activities represents the cash receipts and disbursements related to all 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 $826 million to $1.4 billion for the three months ended March 31, 2019 compared to the same period in 2018. The decrease was primarily due to changes in operating assets and liabilities, including a decrease in accrued government and other rebates and the collection of a receivable from BMS during the three months ended March 31, 2018 following the termination of the collaboration pursuant to the terms of the existing agreements. The decrease was partially offset by lower tax payments during the three months ended March 31, 2019.

Cash Provided by (Used in) Investing Activities

Cash provided by (used in) investing activities primarily consists of purchases, sales and maturities of our marketable debt securities, our capital expenditures and other investments. Cash used in investing activities was $111 million for the three months ended March 31, 2019, compared to cash provided by investing activities of $4.4 billion for the same period in 2018. The change in cash provided by (used in) investing activities was primarily due to higher purchases of marketable debt securities, partially offset by higher proceeds from maturities of our marketable debt securities and a $180 million payment to Japan Tobacco Inc. during the three months ended March 31, 2019 in connection with acquiring the rights to market and distribute certain HIV products in Japan.

Cash Used in Financing Activities

Cash used in financing activities was $2.4 billion for the three months ended March 31, 2019, compared to cash used in financing activities of $6.6 billion for the same period in 2018. The decrease in cash used in financing activities was primarily due to lower repayments of debt and lower repurchases of common stock during the three months ended March 31, 2019.

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 Part 1, Item 1 of this Quarterly Report on Form 10-Q.

In March 2019, we repaid $750 million of our senior unsecured notes upon maturity that were issued in September 2017. Other than the aforementioned repayment, there were no material changes to our debt or our credit facility during the three months ended March 31, 2019. As of March 31, 2019, no amounts were outstanding under our $2.5 billion five-year revolving credit facility agreement maturing in May 2021.

In April 2019, we repaid $500 million of our senior unsecured notes upon maturity that were issued in March 2014.

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, 2018. There were no material changes to our critical accounting policies and estimates during the three months ended March 31, 2019.

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 Part 1, 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 months ended March 31, 2019 compared to the disclosures in Part II, Item 7A of our Annual Report on Form 10-K for the year ended December 31, 2018.

Item 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

An evaluation as of March 31, 2019 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 March 31, 2019.

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 March 31, 2019, 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 11. 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. During the three months ended March 31, 2019, sales of our HIV products accounted for approximately 70% of our total product sales, and we expect our HIV products to account for a higher percentage of our total product sales in 2019 than in 2018. 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 future drug development and spending on research and development (R&D) efforts.

During the three months ended March 31, 2019, sales of our products for the treatment of chronic hepatitis C virus (HCV) infection accounted for approximately 15% of our total product sales. Our HCV revenues have declined, and we expect a further decline in product sales in 2019, compared to 2018, in major markets. 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, we expect to continue to compete for market share across market segments and geographies. We anticipate patient starts to continue to steadily decline and be more predictable. 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 depend, in part, on the extent of reimbursement of our products by private and public payers. We may continue to experience global pricing pressure that 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.

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

The success of our business depends on our ability to introduce new products as well as expand the indications for our existing products to address areas of unmet medical need. The launch of commercially successful products is necessary to cover our substantial research and development expenses and to offset revenue losses when our existing products lose market share due to various factors such as competition and loss of patent exclusivity, as well as to provide for the growth of our business. There are

many difficulties and uncertainties inherent in drug development and the introduction of new products. The product development cycle is characterized by significant investments of resources, long lead times and unpredictable outcomes due to the nature of developing medicines for human use. We expend significant time and resources on our product pipeline without any assurance that we will recoup our investments or that our efforts will be commercially successful. A high rate of failure is inherent in the discovery and development of new products, and failure can occur at any point in the process, including late in the process after substantial investment. For example, see "We face risks in our clinical trials, including the potential for unfavorable results, delays in anticipated timelines and disruption, which may adversely affect our prospects for future revenue growth and our results of operations." We cannot state with certainty when or whether any of our product candidates under development will be approved or launched; whether we will be able to develop, license or acquire additional product candidates or products; or whether any products, once launched, will be commercially successful. Failure to launch commercially successful new products or new indications for existing products could have a material adverse effect on our future revenues, results of operations and long-term success.

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 stock price.

We may be unable to accurately predict demand for our products, including the uptake of new products, as demand depends 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 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. 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.

We sell and distribute most of our products in the United States exclusively through the wholesale channel. During the three months ended March 31, 2019, 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. In addition, we have observed that strong wholesaler and sub-wholesaler purchases of our products in the fourth quarter typically results in inventory draw-down by wholesalers and sub-wholesalers in the subsequent first quarter. As inventory in the distribution channel fluctuates from quarter to quarter, we may continue to see fluctuations in our earnings and a mismatch between prescription demand for our products and our revenues.

In addition, 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. To the extent our actual or anticipated product revenues exceed or fall short of investors' 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, which may impact our ability to increase sales of Yescarta.

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 program required by U.S. Food and Drug Administration (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;
- 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 to the medical community or commercial or governmental payers the safety and efficacy of Yescarta and the potential advantages 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 TAF-containing HIV products compete primarily with products from ViiV Healthcare Company (ViiV). We also face competition from generic HIV products. 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. Pursuant to a settlement agreement relating to patents that protect Truvada and Atripla, Teva Pharmaceuticals will be able to launch generic fixed-dose combinations of emtricitabine and TDF and generic fixed-dose combinations of emtricitabine, TDF and efavirenz in the United States on September 30, 2020.

Our HCV products compete primarily with products marketed by AbbVie and Merck.

Our HBV products face competition from existing therapies for treating patients with HBV as well as generic versions of TDF. Our HBV products also compete with products marketed by Bristol-Myers Squibb Company and Novartis Pharmaceuticals Corporation (Novartis).

Yescarta competes with a CAR T cell therapy marketed by Novartis and is expected to compete with products from other companies developing advanced T cell therapies.

Letairis competes with products marketed by Actelion Pharmaceuticals US, Inc., 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 competition from manufacturers of generic versions of Letairis in the United States starting in the second quarter of 2019.

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 also faces competition from manufacturers of generic versions of Ranexa in the United States.

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 legislative and regulatory actions.

Legislative and regulatory actions affecting government prescription drug procurement and reimbursement programs occur relatively frequently. In the United States, the Affordable Care Act (the ACA) was enacted in 2010 to expand healthcare coverage. Since then, numerous efforts have been made to repeal, amend or administratively limit the ACA in whole or in part. For example, the Tax Cuts and Jobs Act, signed into law by President Trump in 2017, repealed the individual health insurance mandate, which is considered a key component of the ACA. In December 2018, a Texas federal district court struck down the ACA on the grounds

that the individual health insurance mandate is unconstitutional, although this ruling has been stayed pending appeal. The ongoing challenges to the ACA and new legislative proposals have resulted in uncertainty regarding the ACA's future viability and destabilization of the health insurance market. The resulting impact on our business is uncertain and could be material.

Efforts to control prescription drug prices could also have a material adverse effect on our business. For example, in 2018, President Trump and the Secretary of the U.S. Department of Health and Human Services (HHS) released the "American Patients First Blueprint" and have begun implementing certain portions. The initiative includes proposals to increase generic drug and biosimilar competition, enable the Medicare program to negotiate drug prices more directly and improve transparency regarding drug prices and ways to lower consumers' out-of-pocket costs. The Trump administration also proposed to establish an “international pricing index” that would be used as a benchmark to determine the costs and potentially limit the reimbursement of drugs under Medicare Part B. In addition, many states have proposed or enacted legislation that seeks to indirectly or directly regulate pharmaceutical drug pricing, such as by requiring biopharmaceutical manufacturers to publicly report proprietary pricing information or to place a maximum price ceiling on pharmaceutical products purchased by state agencies. For example, in 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. Both Congress and state legislatures are considering various bills that would reform drug purchasing and price negotiations, allow greater use of utilization management tools to limit Medicare Part D coverage, facilitate the import of lower-priced drugs from outside the United States and encourage the use of generic drugs. Such initiatives and legislation may cause added pricing pressures on our products.

Changes to the Medicaid program at the federal or state level could also have a material adverse effect on our business. Proposals that could impact coverage and reimbursement of our products, including giving states more flexibility to manage drugs covered under the Medicaid program and permitting the re-importation of prescription medications from Canada or other countries, could have a material adverse effect by limiting our products’ use and coverage. Furthermore, state Medicaid programs could request additional supplemental rebates on our products as a result of an increase in the federal base Medicaid rebate. To the extent that private insurers or managed care programs follow Medicaid coverage and payment developments, they could use the enactment of these increased rebates to exert pricing pressure on our products, and the adverse effects may be magnified by their adoption of lower payment schedules.

Other proposed regulatory actions affecting manufacturers could have a material adverse effect on our business. For example, in December 2018, HHS proposed a rule that would modify the Medicare Part D protected class policy to provide Part D Plan Sponsors broader authority to impose step therapy, prior authorization and other utilization management controls on products in the Part D protected classes, including our HIV products. In January 2019, HHS also proposed a rule that would remove regulatory protection under the Discount Safe Harbor to the Federal Anti-Kickback Statute for manufacturer rebates paid to Part D Plan Sponsors, Medicaid managed care organizations and pharmacy benefit managers under contract with them, and would create new safe harbors for arrangements with these entities. It is difficult to predict the impact, if any, of any such proposed legislative and regulatory actions or resulting state actions on the use and reimbursement of our products in the United States, but our results of operations may be adversely affected.

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 substantial portion of sales of our products is subject to significant discounts from list price. In addition, standard reimbursement structures may not adequately reimburse for innovative therapies.

For example, effective October 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. 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 of 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 on our results of operations. CMS has also proposed a National Coverage Decision on CAR T cell therapy and would impose certain coverage limitations on that therapy. These coverage limitations would apply to the entire Medicare program and includes, 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. Additionally, in the European Union, there are 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.

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.

For a description of our government investigations and related litigation, see Note 11. 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.

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 portion 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 an immaterial impact on our product sales for the three months ended March 31, 2019, compared to the same period in 2018.

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 reputation may be harmed and our future sales may be reduced, which could 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 patients with underlying health problems or other medicines, we expect to continue finding new issues related to safety, resistance or drug interactions. Any such issues may require changes to our product labels, such as additional warnings, contraindications or even narrowed indications. If any of these were to occur, it could reduce the market acceptance and sales of our 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.

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 could 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. In certain circumstances, we may be required to implement a Risk Evaluation and Mitigation Strategy program for our products, which could include a medication guide, patient package insert, a communication plan to healthcare providers, restrictions on distribution or use of a product and other elements FDA deems necessary to assure safe use of the drug. 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.

We face risks in our clinical trials, including the potential for unfavorable results, delays in anticipated timelines and disruption, which may adversely affect our prospects for future revenue growth and our results of operations.

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, we recently announced that our KITE-585 program, an anti-B cell maturation antigen being evaluated for the treatment of multiple myeloma, will not be moving forward. We also recently announced that STELLAR-3 and STELLAR-4, Phase 3 studies evaluating the safety and efficacy of selonsertib for the treatment of nonalcoholic steatohepatitis (NASH), did not meet the pre-specified week 48 primary endpoints. 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 and our results of operations may 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 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. For example, FDA has requested that we conduct a safety study of filgotinib in men with ulcerative colitis (MANTA study), and enrollment in this MANTA study will likely be the rate limiting factor to filing an NDA for filgotinib in the United States. 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 and our results of operations 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 adversely affect our results of operations and harm our business.

In addition, 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 may be adversely affected.

We depend on relationships with third parties for sales and marketing performance, technology, development, logistics and commercialization of products. Failure to maintain these relationships, poor performance by these companies or disputes with these third parties could negatively impact our business.

We rely on a number of collaborative relationships with third parties 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.

In addition, we rely on third-party sites to collect patients' white blood cells, known as apheresis centers, shippers, couriers, and hospitals for the logistical collection of patients' 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. 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.

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 of our patents and efforts to invalidate them; 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.

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. In addition, if competitors file patent applications covering our technology, we may have to participate in litigation, post-grant proceedings before the U.S. Patent and Trademark Office or other proceedings to determine the right to a patent or validity of any patent granted. Litigation, post-grant proceedings before the U.S. Patent and Trademark Office 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.

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 process typically used by manufacturers seeking approval of a generic drug. For a description of our ANDA litigation, see Note 11. 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 entry of generic versions of our products may lead to market share and price erosion and have a negative impact on our business and results of operations.

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 11, 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. 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. 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.

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 subject to their own unique operational and financial risks that 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 could 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 may be adversely affected.

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

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

Suppliers of key components and materials must be named in the new drug application or marketing authorization application filed with the 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 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 could in turn decrease our revenues and harm our business. In addition, if deliveries of materials 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 product candidates in development for clinical trials. In addition, some of our products and the materials that we utilize in our operations are manufactured at only one facility, which we may not be 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 could 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 conduct clinical trials on product candidates and to manufacture and sell our products could be impaired, which could have an adverse effect on our business.

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 could 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 agreements with generic manufacturers in India, Egypt and Pakistan allowing them to produce and/or distribute generic versions of our HCV products in certain low- and middle-income countries. If generic versions of our HIV, HBV and HCV products produced and/or distributed under these agreements are then re-exported to the United States, Europe or other markets outside of these low- and middle-income countries, our revenues could be adversely affected. In addition, purchases of our products in countries where our selling prices are relatively low for resale in countries in which our selling prices are relatively high may adversely impact our revenues and gross margin and may cause our sales to fluctuate from quarter to quarter. Additionally, use of these diverted products could occur in countries where they have not been approved and patients could source the product outside the legitimate supply chain. Therefore, the products may be handled, shipped and stored inappropriately, which may affect the efficacy of the product and could harm patients, our brands or the commercial or scientific reputation of our products.

In the European Union, we are required to permit products purchased in one EU member state to be sold in another EU member state. 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 and HIV 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 by these generic products, our brands or the commercial or scientific reputation of our HCV and HIV 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 an 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 the distribution and sale of counterfeits of our products around the world, including working with local regulatory and legal authorities to enforce laws against counterfeit drugs, raising public awareness of the dangers of counterfeit drugs and promoting public policies to hinder the sale and availability of counterfeit drugs. Counterfeit drugs pose a serious risk to patient health and safety and may raise the risk of product recalls. Our reputation and business could suffer as a result of counterfeit drugs sold under our brand names.

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. For a description of our litigation, investigations and other dispute-related matters, see Note 11. 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 and reputation.

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 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. For a description of our product liability matters, see Note 11. 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.

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

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

In April 2019, we announced that Robin L. Washington plans to retire from her position as our Executive Vice President and Chief Financial Officer, effective March 1, 2020, or if earlier, when a successor is named and commences in the role. Should a successor be named and commences in the role prior to March 1, 2020, Ms. Washington has agreed to remain in an advisory capacity through the completion of our reporting of 2019 financial results. If there are delays with the selection of a new Chief Financial 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 adversely affect our revenues and materially reduce our earnings.

Our worldwide operations, third-party manufacturers or corporate partners could be subject to business interruptions stemming from natural or man-made disasters, including those related to climate change, for which we or they 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.

We are dependent on information technology systems, infrastructure and data, which may be subject to cyberattacks and security breaches.

We are dependent upon information technology systems, infrastructure and data, including our Kite Konnect platform, which is critical to ensure chain of identity and chain of custody of Yescarta. 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 pose a risk that sensitive data, including our intellectual property or trade secrets or the 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. Such interruptions or breaches could adversely affect our business and operations and/or cause the loss of critical or sensitive information, which could result in financial, legal, business or reputational harm to us. In addition, our insurance may not be sufficient in type or amount to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems.

Regulators globally are also imposing new data security requirements, including greater monetary fines for privacy violations. For example, the General Data Protection Regulation (GDPR) that became effective in Europe in 2018 established new regulations regarding the handling of personal data, and non-compliance with the GDPR may result in monetary penalties of up to four percent 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, including 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 in which 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 and regulatory changes that could have a material adverse impact on our results of operations. For example, the United States enacted significant tax reform, and certain provisions of the new law are complex and will continue to significantly affect us.

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 branded prescription drug 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, resolution of federal, state and foreign income tax audits, and potential changes to our legal entity structure. 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 $0.63 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 $4.3 billion is available for repurchase as of March 31, 2019. 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 three months ended March 31, 2019, we repurchased and retired 12 million shares of our common stock for $834 million through open market transactions under the 2016 Program. The table below summarizes our stock repurchase activity for the three months ended March 31, 2019:

	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)
January 1 - January 31, 2019	8,999		$ 68.00	8,973		$ 4,537
February 1 - February 28, 2019	2,334		$ 67.06	1,670		$ 4,425
March 1 - March 31, 2019	2,084		$ 64.28	1,730		$ 4,313
Total	13,417	(1)	$ 67.26	12,373	(1)	

(1) The difference between the total number of shares purchased and the total number of shares purchased as part of a 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

*(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
*(25)	10.28	Gilead Sciences, Inc. Retention Program for Executive Officers
*(26)	10.29	Offer Letter dated April 16, 2008 between Registrant and Robin Washington
*(27)	10.30	Separation Agreement and Release dated August 6, 2018 between Registrant and John F. Milligan, Ph.D.
*(28)	10.31	Offer Letter dated November 30, 2018 between Registrant and Daniel O'Day
*(29)	10.32	Form of Indemnity Agreement entered into between Registrant and its directors and executive officers
*(29)	10.33	Form of Employee Proprietary Information and Invention Agreement entered into between Registrant and certain of its officers and key employees
*(30)	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)
+(31)	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)
+(32)	10.36	Amendment Agreement between Registrant and IOCB/REGA, dated December 27, 2000 amending the 1991 License Agreement and the December 1992 License Agreement
+(33)	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
+(34)	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
+(35)	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
+(36)	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
+(36)	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
++(37)	10.42	Amended and Restated EVG License Agreement between Japan Tobacco Inc., and Registrant, dated November 29, 2018
++(37)	10.43	Master Agreement by and between Registrant, Gilead Sciences K.K. and Japan Tobacco Inc., dated November 29, 2018
+(38)	10.44	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
+(39)	10.45	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 as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 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 Current Report on Form 8-K filed on December 10, 2018, and incorporated herein by reference.
(29) Filed as an exhibit to Registrant's Registration Statement on Form S-1 (No. 33-55680), as amended, and incorporated herein by reference.
(30) 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.
(31) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended March 31, 1994, and incorporated herein by reference.
(32) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2000, and incorporated herein by reference.
(33) Filed as an exhibit to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2006, and incorporated herein by reference.
(34) 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.
(35) 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.
(36) 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.
(37) Filed as an exhibit to Registrant's Amendment No. 1 to Annual Report on Form 10-K/A filed on April 18, 2019, and incorporated herein by reference.
(38) Filed as an exhibit to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2014, and incorporated herein by reference.
(39) 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.
** Furnished herewith.
*** 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.
++ Certain confidential portions of this Exhibit were omitted by means of marking such portions with the Mark because the identified confidential portions are (i) not material and (ii) would be competitively harmful if publicly disclosed.

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: May 7, 2019

/s/ DANIEL P. O'DAY

Daniel P. O'Day
Chairman and Chief Executive Officer
(Principal Executive Officer)

Date: May 7, 2019

/s/ ROBIN L. WASHINGTON

Robin L. Washington
Executive Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION

I, Daniel P. O'Day, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Gilead Sciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 7, 2019

/s/ DANIEL P. O'DAY

Daniel P. O'Day
Chairman and Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, Robin L. Washington, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Gilead Sciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 7, 2019

/s/ ROBIN L. WASHINGTON

Robin L. Washington
Executive Vice President and Chief Financial Officer

Exhibit 32.1

CERTIFICATIONS

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. § 1350, as adopted), Daniel O'Day, the Chairman and Chief Executive Officer of Gilead Sciences, Inc. (the Company), and Robin L. Washington, the Executive Vice President and Chief Financial Officer of the Company, each hereby certifies that, to the best of his or her knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended March 31, 2019, to which this Certification is attached as Exhibit 32 (the Periodic Report), fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition of the Company at the end of the periods covered by the Periodic Report and results of operations of the Company for the periods covered by the Periodic Report.

Dated: May 7, 2019

/s/ DANIEL P. O'DAY

Daniel P. O'Day
Chairman and Chief Executive Officer

/s/ ROBIN L. WASHINGTON

Robin L. Washington
Executive Vice President and Chief Financial Officer

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