# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

			FORM	10-Q			
(Mark On	e)						
	QUARTI OF 1934	ERLY REPORT	PURSUANT TO SECTIO	ON 13 OR 15(d) OF T	THE SECURITIES	EXCHANGE AC	СТ
	For the quar	terly period ended Ma	arch 31, 2017				
	1	7 I	OR				
	TRANSI OF 1934	ΓΙΟΝ REPORT	PURSUANT TO SECTIO	ON 13 OR 15(d) OF T	THE SECURITIES	EXCHANGE AC	CT
	For the trans	sition period from	to				
			Commission File	No. 1-6571			
			Merck &	Co., Inc.			
			2000 Galloping Kenilworth, N (908) 740-	Hill Road .J. 07033			
	Inc	corporated in New Jers	rsey		I.R.S. Employer		
				Id	dentification No. 22-1918.	501	
The number	er of shares of com	mon stock outstanding	g as of the close of business on A	pril 30, 2017 : 2,735,164,5	10		
preceding		such shorter period that	has filed all reports required to be at the registrant was required to fil				
submitted	and posted pursua	ant to Rule 405 of Re	submitted electronically and post egulation S-T (§232,405 of this es). Yes ⊠ No □				
growth cor		finitions of "large acce	a large accelerated filer, an accele elerated filer," "accelerated filer,"				
Large acce	elerated filer			Accele	rated filer		
Non-accel	erated filer	☐ (Do not check i	if a smaller reporting company)	Smalle	r reporting company		
				Emergi	ng growth company		
			ck mark if the registrant has electron to Section 13(a) of the Exc		ed transition period for c	omplying with any no	ew 01
Indicate by	check mark whet	her the registrant is a s	shell company (as defined in Rule	12b-2 of the Exchange Ac	et). Yes $\square$ No $\boxtimes$		

# MERCK & CO., INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED STATEMENT OF INCOME (Unaudited, \$ in millions except per share amounts)

	 Three Mor Mar	nths End ch 31,	led
	2017		2016
Sales	\$ 9,434	\$	9,312
Costs, Expenses and Other			
Materials and production	3,015		3,572
Marketing and administrative	2,411		2,318
Research and development	1,796		1,659
Restructuring costs	151		91
Other (income) expense, net	58		48
	7,431		7,688
Income Before Taxes	2,003		1,624
Taxes on Income	447		494
Net Income	1,556		1,130
Less: Net Income Attributable to Noncontrolling Interests	5		5
Net Income Attributable to Merck & Co., Inc.	\$ 1,551	\$	1,125
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders	\$ 0.56	\$	0.41
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders	\$ 0.56	\$	0.40
Dividends Declared per Common Share	\$ 0.47	\$	0.46

# MERCK & CO., INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME (Unaudited, \$ in millions)

		Three Mor Mar	nths En	ıded
	2	2017		2016
Net Income Attributable to Merck & Co., Inc.	\$	1,551	\$	1,125
Other Comprehensive Income (Loss) Net of Taxes:				
Net unrealized loss on derivatives, net of reclassifications		(232)		(202)
Net unrealized gain on investments, net of reclassifications		43		63
Benefit plan net gain (loss) and prior service credit (cost), net of amortization		26		(28)
Cumulative translation adjustment		309		121
		146		(46)
Comprehensive Income Attributable to Merck & Co., Inc.	\$	1,697	\$	1,079

The accompanying notes are an integral part of these condensed consolidated financial statements.

# MERCK & CO., INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED BALANCE SHEET (Unaudited, \$ in millions except per share amounts)

	Mar	ch 31, 2017	Decer	mber 31, 2016
Assets				
Current Assets				
Cash and cash equivalents	\$	11,708	\$	6,515
Short-term investments		3,541		7,826
Accounts receivable (net of allowance for doubtful accounts of \$195 in 2017 and 2016)		7,066		7,018
Inventories (excludes inventories of \$1,090 in 2017 and \$1,117 in 2016 classified in Other assets - see Note 5)		5,146		4,866
Other current assets		4,069		4,389
Total current assets		31,530		30,614
Investments		11,896		11,416
Property, Plant and Equipment, at cost, net of accumulated depreciation of \$16,171 in 2017 and \$15,749 in 2016		12,042		12,026
Goodwill		18,358		18,162
Other Intangibles, Net		16,863		17,305
Other Assets		5,872		5,854
	\$	96,561	\$	95,377
Liabilities and Equity				
Current Liabilities				
Loans payable and current portion of long-term debt	\$	5,037	\$	568
Trade accounts payable		2,484		2,807
Accrued and other current liabilities		8,658		10,274
Income taxes payable		2,330		2,239
Dividends payable		1,314		1,316
Total current liabilities		19,823		17,204
Long-Term Debt		23,437		24,274
Deferred Income Taxes		4,889		5,077
Other Noncurrent Liabilities		8,324		8,514
Merck & Co., Inc. Stockholders' Equity				
Common stock, \$0.50 par value Authorized - 6,500,000,000 shares				
Issued - 3,577,103,522 shares in 2017 and 2016		1,788		1,788
Other paid-in capital		39,899		39,939
Retained earnings		44,387		44,133
Accumulated other comprehensive loss		(5,080)		(5,226)
		80,994		80,634
Less treasury stock, at cost: 836,667,641 shares in 2017 and 828,372,200 shares in 2016		41,157		40,546
Total Merck & Co., Inc. stockholders' equity		39,837		40,088
Noncontrolling Interests		251		220
Total equity		40,088		40,308
	\$	96,561	\$	95,377

The accompanying notes are an integral part of this condensed consolidated financial statement.

# MERCK & CO., INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS (Unaudited, \$ in millions)

Three Months Ended March 31, 2017 2016 **Cash Flows from Operating Activities** Net income \$ 1,556 1,130 Adjustments to reconcile net income to net cash provided by operating activities: Depreciation and amortization 1,193 1,561 Intangible asset impairment charges 80 277 Deferred income taxes (70)(54)Share-based compensation 74 68 Other 82 (28)Net changes in assets and liabilities (2,535)(875)Net Cash Provided by Operating Activities 286 2,173 **Cash Flows from Investing Activities** Capital expenditures (339)(279)Purchases of securities and other investments (2,929)(2,367)Proceeds from sales of securities and other investments 6,819 4,620 Acquisitions of businesses, net of cash acquired (306)(147)Other (52)(86)3,193 Net Cash Provided by Investing Activities 1,741 **Cash Flows from Financing Activities** 3,784 Net change in short-term borrowings Payments on debt (300)(851)Purchases of treasury stock (1,019)(913)Dividends paid to stockholders (1,294)(1,279)Proceeds from exercise of stock options 313 202 Other (23)(25)Net Cash Provided by (Used in) Financing Activities 1,461 (2,866)Effect of Exchange Rate Changes on Cash and Cash Equivalents 253 144 Net Increase in Cash and Cash Equivalents 5,193 1,192 8,524 Cash and Cash Equivalents at Beginning of Year 6,515 Cash and Cash Equivalents at End of Period \$ 11,708 9,716 \$

The accompanying notes are an integral part of this condensed consolidated financial statement.

#### 1. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of Merck & Co., Inc. (Merck or the Company) have been prepared pursuant to the rules and regulations for reporting on Form 10-Q. Accordingly, certain information and disclosures required by accounting principles generally accepted in the United States for complete consolidated financial statements are not included herein. These interim statements should be read in conjunction with the audited financial statements and notes thereto included in Merck's Form 10-K filed on February 28, 2017.

The results of operations of any interim period are not necessarily indicative of the results of operations for the full year. In the Company's opinion, all adjustments necessary for a fair statement of these interim statements have been included and are of a normal and recurring nature. Certain reclassifications have been made to prior year amounts to conform to the current presentation.

On December 31, 2016, Merck and Sanofi Pasteur S.A. terminated their equally-owned joint venture, Sanofi Pasteur MSD (SPMSD), which developed and marketed vaccines in Europe. Beginning in 2017, Merck is recording vaccine sales in the European markets that were previously part of the joint venture.

# Recently Issued Accounting Standards

In May 2014, the Financial Accounting Standards Board (FASB) issued amended accounting guidance on revenue recognition that will be applied to all contracts with customers. The objective of the new guidance is to improve comparability of revenue recognition practices across entities and to provide more useful information to users of financial statements through improved disclosure requirements. In August 2015, the FASB approved a one-year deferral of the effective date making this guidance effective for interim and annual periods beginning in 2018. The new standard permits two methods of adoption: retrospectively to each prior reporting period presented (full retrospective method), or retrospectively with the cumulative effect of adopting the guidance being recognized at the date of initial application (modified retrospective method). The Company will adopt the new standard on January 1, 2018 and currently plans to use the modified retrospective method. The majority of the Company's business is ship and bill and, on that primary revenue stream, Merck does not expect significant differences. However, the Company's analysis is preliminary and subject to change. Merck has not completed its assessment of multiple element arrangements and certain discount and trade promotion programs.

In January 2016, the FASB issued revised guidance for the accounting and reporting of financial instruments. The new guidance requires that equity investments with readily determinable fair values currently classified as available-for-sale be measured at fair value with changes in fair value recognized in net income. The new guidance also simplifies the impairment testing of equity investments without readily determinable fair values and changes certain disclosure requirements. This guidance is effective for interim and annual periods beginning in 2018. Early adoption is not permitted. The Company is currently assessing the impact of adoption on its consolidated financial statements.

In August 2016, the FASB issued guidance on the classification of certain cash receipts and payments in the statement of cash flows intended to reduce diversity in practice. The guidance is effective for interim and annual periods beginning in 2018. Early adoption is permitted. The guidance is to be applied retrospectively to all periods presented but may be applied prospectively if retrospective application would be impracticable. The Company is currently evaluating the effect of the standard on its Consolidated Statement of Cash Flows.

In October 2016, the FASB issued guidance on the accounting for the income tax consequences of intra-entity transfers of assets other than inventory. Under existing guidance, the recognition of current and deferred income taxes for an intra-entity asset transfer is prohibited until the asset has been sold to a third party. The new guidance will require the recognition of the income tax consequences of an intra-entity transfer of an asset (with the exception of inventory) when the intra-entity transfer occurs. The guidance is effective for interim and annual periods beginning in 2018. Early adoption is permitted. The new guidance is to be applied on a modified retrospective basis through a cumulative-effect adjustment directly to retained earnings in the beginning of the period of adoption. The Company does not anticipate the adoption of the new guidance will have a material effect on its consolidated financial statements.

In November 2016, the FASB issued guidance requiring that amounts generally described as restricted cash and restricted cash equivalents be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The guidance is effective for interim and annual periods beginning in 2018 and should be applied using a retrospective transition method to each period presented. Early adoption is permitted. The Company is currently evaluating the effect of the standard on its Consolidated Statement of Cash Flows.

In March 2017, the FASB amended the guidance related to net periodic benefit cost for defined benefit plans that requires entities to (1) disaggregate the current service cost component from the other components of net benefit cost and present it with other employee compensation costs in the income statement within operations if such a subtotal is presented; (2) present the other components of net benefit cost separately in the income statement and outside of income from operations; and (3) only capitalize the service cost component when applicable. The new guidance is effective for interim and annual periods in 2018.

Entities must use a retrospective transition method to adopt the requirement for separate presentation in the income statement of service costs and other components and a prospective transition method to adopt the requirement to limit the capitalization of benefit costs to the service cost component. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

In February 2016, the FASB issued new accounting guidance for the accounting and reporting of leases. The new guidance requires that lessees recognize a right-of-use asset and a lease liability recorded on the balance sheet for each of its leases (other than leases that meet the definition of a short-term lease). Leases will be classified as either operating or finance. Operating leases will result in straight-line expense in the income statement (similar to current operating leases) while finance leases will result in more expense being recognized in the earlier years of the lease term (similar to current capital leases). The new guidance will be effective for interim and annual periods beginning in 2019. Early adoption is permitted. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

In June 2016, the FASB issued amended guidance on the accounting for credit losses on financial instruments within its scope. The guidance introduces an expected loss model for estimating credit losses, replacing the incurred loss model. The new guidance also changes the impairment model for available-for-sale debt securities, requiring the use of an allowance to record estimated credit losses (and subsequent recoveries). The new guidance is effective for interim and annual periods beginning in 2020, with earlier application permitted in 2019. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

In January 2017, the FASB issued guidance that provides for the elimination of Step 2 from the goodwill impairment test. If impairment charges are recognized, the amount recorded will be the amount by which the carrying amount exceeds the reporting unit's fair value with certain limitations. The new guidance is effective for interim and annual periods in 2020. Early adoption is permitted. The Company does not anticipate the adoption of the new guidance will have a material effect on its consolidated financial statements.

## 2. Acquisitions, Divestitures, Research Collaborations and License Agreements

The Company continues to pursue the acquisition of businesses and establishment of external alliances such as research collaborations and licensing agreements to complement its internal research capabilities. These arrangements often include upfront payments, as well as expense reimbursements or payments to the third party, and milestone, royalty or profit share payments, contingent upon the occurrence of certain future events linked to the success of the asset in development. The Company also reviews its marketed products and pipeline to examine candidates which may provide more value through out-licensing and, as part of its portfolio assessment process, may also divest certain assets. Pro forma financial information for acquired businesses is not presented if the historical financial results of the acquired entity are not significant when compared with the Company's financial results.

In March 2017, Merck acquired a controlling interest in Vallée S.A. (Vallée), a leading privately held producer of animal health products in Brazil. Vallée has an extensive portfolio of products spanning parasiticides, anti-infectives and vaccines that include products for livestock, horses, and companion animals. Under the terms of the agreement, Merck acquired 93.5% of the shares of Vallée for \$358 million. Of the total purchase price, \$176 million was placed into escrow pending resolution of certain contingent items. The transaction was accounted for as an acquisition of a business. Merck recognized intangible assets of \$297 million related to currently marketed products, net deferred tax liabilities of \$95 million, other net assets of \$1 million and noncontrolling interest of \$25 million. In addition, the Company recorded liabilities of \$37 million for contingencies identified at the acquisition date and corresponding indemnification assets of \$37 million, representing the amounts to be reimbursed to Merck if and when the contingent liabilities are paid. The excess of the consideration transferred over the fair value of net assets acquired of \$180 million was recorded as goodwill. The goodwill was allocated to the Animal Health segment and is not deductible for tax purposes. The estimated fair values of identifiable intangible assets related to currently marketed products were determined using an income approach through which fair value is estimated based on market participant expectations of each asset's discounted projected net cash flows. The probability-adjusted future net cash flows of each product were then discounted to present value utilizing a discount rate of 15.5%. Actual cash flows are likely to be different than those assumed. The intangible assets related to currently marketed products are being amortized over their estimated useful lives of 15 years.

In January 2016, Merck acquired IOmet Pharma Ltd (IOmet), a privately held UK-based drug discovery company focused on the development of innovative medicines for the treatment of cancer, with a particular emphasis on the fields of cancer immunotherapy and cancer metabolism. The acquisition provides Merck with IOmet's preclinical pipeline of IDO (indoleamine-2,3-dioxygenase 1), TDO (tryptophan-2,3-dioxygenase), and dual-acting IDO/TDO inhibitors. The transaction was accounted for as an acquisition of a business. Total purchase consideration in the transaction included a cash payment of \$150 million and future additional milestone payments of up to \$250 million that are contingent upon certain clinical and regulatory milestones being achieved. The Company determined the fair value of the contingent consideration was \$94 million at the acquisition date utilizing a probability-weighted estimated cash flow stream adjusted for the expected timing of each payment utilizing a

discount rate of 10.5%. Merck recognized intangible assets for in-process research and development (IPR&D) of \$155 million and net deferred tax assets of \$32 million. The excess of the consideration transferred over the fair value of net assets acquired of \$57 million was recorded as goodwill that was allocated to the Pharmaceutical segment and is not deductible for tax purposes. The fair values of the identifiable intangible assets related to IPR&D were determined using an income approach. The assets' probability-adjusted future net cash flows were then discounted to present value also using a discount rate of 10.5%. Actual cash flows are likely to be different than those assumed.

Additionally, in January 2016, Merck sold the U.S. marketing rights to Cortrophin and Corticotropin Zinc Hydroxide to ANI Pharmaceuticals, Inc. (ANI). Under the terms of the agreement, ANI made a payment of \$75 million, which was recorded in *Sales* in the first quarter of 2016, and may make additional payments to the Company based on future sales. Merck does not have any ongoing supply or other performance obligations after the closing date.

# 3. Restructuring

The Company incurs substantial costs for restructuring program activities related to Merck's productivity and cost reduction initiatives, as well as in connection with the integration of certain acquired businesses. In 2010 and 2013, the Company commenced actions under global restructuring programs designed to streamline its cost structure. The actions under these programs include the elimination of positions in sales, administrative and headquarters organizations, as well as the sale or closure of certain manufacturing and research and development sites and the consolidation of office facilities. The Company also continues to reduce its global real estate footprint and improve the efficiency of its manufacturing and supply network. The non-facility related restructuring actions under these programs are substantially complete; the remaining activities primarily relate to ongoing facility rationalizations.

The Company recorded total pretax costs of \$215 million and \$196 million in the first quarter of 2017 and 2016, respectively, related to restructuring program activities. Since inception of the programs through March 31, 2017, Merck has recorded total pretax accumulated costs of approximately \$12.8 billion and eliminated approximately 41,445 positions comprised of employee separations, as well as the elimination of contractors and vacant positions. The Company expects to substantially complete the remaining actions under these programs by the end of 2017 and incur approximately \$500 million of additional pretax costs. The Company estimates that approximately two-thirds of the cumulative pretax costs will result in cash outlays, primarily related to employee separation expense. Approximately one-third of the cumulative pretax costs are non-cash, relating primarily to the accelerated depreciation of facilities to be closed or divested.

For segment reporting, restructuring charges are unallocated expenses.

The following tables summarize the charges related to restructuring program activities by type of cost:

		Thre	ee Months Ended	Marcl	h 31, 2017		
(\$ in millions)	oaration Costs		Accelerated Depreciation	Other			Total
Materials and production	\$ _	\$	51	\$	12	\$	63
Marketing and administrative	_		_		1		1
Research and development	_		(2)		2		_
Restructuring costs	84		_		67		151
	\$ 84	\$	49	\$	82	\$	215

	Three Months Ended March 31, 2016									
(\$ in millions)		paration Costs		Accelerated Depreciation		Other		Total		
Materials and production	\$	_	\$	22	\$	25	\$	47		
Marketing and administrative		_		3		_		3		
Research and development		_		55		_		55		
Restructuring costs		26		_		65		91		
	\$	26	\$	80	\$	90	\$	196		

Separation costs are associated with actual headcount reductions, as well as those headcount reductions which were probable and could be reasonably estimated. In the first quarter of 2017 and 2016, approximately 545 positions and 470 positions, respectively, were eliminated under restructuring program activities.

Accelerated depreciation costs primarily relate to manufacturing, research and administrative facilities and equipment to be sold or closed as part of the programs. Accelerated depreciation costs represent the difference between the depreciation expense to be recognized over the revised useful life of the asset, based upon the anticipated date the site will be closed or divested or the equipment disposed of, and depreciation expense as determined utilizing the useful life prior to the restructuring actions.

All of the sites have and will continue to operate up through the respective closure dates and, since future undiscounted cash flows were sufficient to recover the respective book values, Merck is recording accelerated depreciation over the revised useful life of the site assets. Anticipated site closure dates, particularly related to manufacturing locations, have been and may continue to be adjusted to reflect changes resulting from regulatory or other factors.

Other activity in 2017 and 2016 includes asset abandonment, shut-down and other related costs, as well as pretax gains and losses resulting from sales of facilities and related assets. Additionally, other activity includes certain employee-related costs associated with pension and other postretirement benefit plans (see Note 10) and share-based compensation.

The following table summarizes the charges and spending relating to restructuring program activities for the three months ended March 31, 2017:

(\$ in millions)	Separation Costs	Accelerated Depreciation	Other	Total
Restructuring reserves January 1, 2017	\$ 395	\$ _	\$ 146	\$ 541
Expense	84	49	82	215
(Payments) receipts, net	(103)	_	(118)	(221)
Non-cash activity	_	(49)	27	(22)
Restructuring reserves March 31, 2017 (1)	\$ 376	\$ _	\$ 137	\$ 513

<sup>(1)</sup> The remaining cash outlays are expected to be substantially completed by the end of 2017.

# 4. Financial Instruments

## **Derivative Instruments and Hedging Activities**

The Company manages the impact of foreign exchange rate movements and interest rate movements on its earnings, cash flows and fair values of assets and liabilities through operational means and through the use of various financial instruments, including derivative instruments.

A significant portion of the Company's revenues and earnings in foreign affiliates is exposed to changes in foreign exchange rates. The objectives and accounting related to the Company's foreign currency risk management program, as well as its interest rate risk management activities are discussed below.

## Foreign Currency Risk Management

The Company has established revenue hedging, balance sheet risk management and net investment hedging programs to protect against volatility of future foreign currency cash flows and changes in fair value caused by volatility in foreign exchange rates.

The objective of the revenue hedging program is to reduce the variability caused by changes in foreign exchange rates that would affect the U.S. dollar value of future cash flows derived from foreign currency denominated sales, primarily the euro and Japanese yen. To achieve this objective, the Company will hedge a portion of its forecasted foreign currency denominated third-party and intercompany distributor entity sales (forecasted sales) that are expected to occur over its planning cycle, typically no more than two years into the future. The Company will layer in hedges over time, increasing the portion of forecasted sales hedged as it gets closer to the expected date of the forecasted foreign currency denominated sales. The portion of forecasted sales hedged is based on assessments of cost-benefit profiles that consider natural offsetting exposures, revenue and exchange rate volatilities and correlations, and the cost of hedging instruments. The Company manages its anticipated transaction exposure principally with purchased local currency put options, forward contracts and purchased collar options.

The fair values of these derivative contracts are recorded as either assets (gain positions) or liabilities (loss positions) in the Condensed Consolidated Balance Sheet. Changes in the fair value of derivative contracts are recorded each period in either current earnings or *Other comprehensive income* ( *OCI* ), depending on whether the derivative is designated as part of a hedge transaction and, if so, the type of hedge transaction. For derivatives that are designated as cash flow hedges, the effective portion of the unrealized gains or losses on these contracts is recorded in *Accumulated other comprehensive income* ( *AOCI* ) and reclassified into *Sales* when the hedged anticipated revenue is recognized. The hedge relationship is highly effective and hedge ineffectiveness has been *de minimis*. For those derivatives which are not designated as cash flow hedges, but serve as economic hedges of forecasted sales, unrealized gains or losses are recorded in *Sales* each period. The cash flows from both designated and non-designated contracts are reported as operating activities in the Condensed Consolidated Statement of Cash Flows. The Company does not enter into derivatives for trading or speculative purposes.

The Company manages operating activities and net asset positions at each local subsidiary in order to mitigate the effects of exchange on monetary assets and liabilities. The Company also uses a balance sheet risk management program to mitigate the exposure of net monetary assets that are denominated in a currency other than a subsidiary's functional currency from the effects of volatility in foreign exchange. In these instances, Merck principally utilizes forward exchange contracts to offset the

effects of exchange on exposures denominated in developed country currencies, primarily the euro and Japanese yen. For exposures in developing country currencies, the Company will enter into forward contracts to partially offset the effects of exchange on exposures when it is deemed economical to do so based on a cost-benefit analysis that considers the magnitude of the exposure, the volatility of the exchange rate and the cost of the hedging instrument. The cash flows from these contracts are reported as operating activities in the Condensed Consolidated Statement of Cash Flows.

Monetary assets and liabilities denominated in a currency other than the functional currency of a given subsidiary are remeasured at spot rates in effect on the balance sheet date with the effects of changes in spot rates reported in *Other (income) expense, net*. The forward contracts are not designated as hedges and are marked to market through *Other (income) expense, net*. Accordingly, fair value changes in the forward contracts help mitigate the changes in the value of the remeasured assets and liabilities attributable to changes in foreign currency exchange rates, except to the extent of the spot-forward differences. These differences are not significant due to the short-term nature of the contracts, which typically have average maturities at inception of less than one year.

The Company may also use forward exchange contracts to hedge its net investment in foreign operations against movements in exchange rates. The forward contracts are designated as hedges of the net investment in a foreign operation. The Company hedges a portion of the net investment in certain of its foreign operations and measures ineffectiveness based upon changes in spot foreign exchange rates that are recorded in *Other (income) expense, net*. The effective portion of the unrealized gains or losses on these contracts is recorded in foreign currency translation adjustment within *OCI*, and remains in *AOCI* until either the sale or complete or substantially complete liquidation of the subsidiary. The cash flows from these contracts are reported as investing activities in the Condensed Consolidated Statement of Cash Flows.

Foreign exchange risk is also managed through the use of foreign currency debt. The Company's senior unsecured euro-denominated notes have been designated as, and are effective as, economic hedges of the net investment in a foreign operation. Accordingly, foreign currency transaction gains or losses due to spot rate fluctuations on the euro-denominated debt instruments are included in foreign currency translation adjustment within *OCI*. Included in the cumulative translation adjustment are pretax losses of \$135 million and \$58 million for the first three months of 2017 and 2016, respectively, from the euro-denominated notes.

#### Interest Rate Risk Management

The Company may use interest rate swap contracts on certain investing and borrowing transactions to manage its net exposure to interest rate changes and to reduce its overall cost of borrowing. The Company does not use leveraged swaps and, in general, does not leverage any of its investment activities that would put principal capital at risk.

At March 31, 2017, the Company was a party to 26 pay-floating, receive-fixed interest rate swap contracts designated as fair value hedges of fixed-rate notes in which the notional amounts match the amount of the hedged fixed-rate notes as detailed in the table below.

(\$ in millions)		March 31, 2017	
Debt Instrument	Par Value of Debt	Number of Interest Rate Swaps Held	wap Notional Amount
1.30% notes due 2018	\$ 1,000	4	\$ 1,000
5.00% notes due 2019	1,250	3	550
1.85% notes due 2020	1,250	5	1,250
3.875% notes due 2021	1,150	5	1,150
2.40% notes due 2022	1,000	4	1,000
2.35% notes due 2022	1,250	5	1,250

The interest rate swap contracts are designated hedges of the fair value changes in the notes attributable to changes in the benchmark London Interbank Offered Rate (LIBOR) swap rate. The fair value changes in the notes attributable to changes in the LIBOR swap rate are recorded in interest expense and offset by the fair value changes in the swap contracts. The cash flows from these contracts are reported as operating activities in the Condensed Consolidated Statement of Cash Flows.

Presented in the table below is the fair value of derivatives on a gross basis segregated between those derivatives that are designated as hedging instruments and those that are not designated as hedging instruments:

			March 31, 2					December 31, 2016								
			Fair Value	of D	erivative	U.S. Dollar			Fair Value of Derivative				J.S. Dollar			
(\$ in millions)	Balance Sheet Caption	Asset		Liability		Notional			Asset	Liability			Notional			
Derivatives Designated as Hedging Instruments																
Interest rate swap contracts	Other assets	\$	11	\$	_	\$	2,700	\$	20	\$	_	\$	2,700			
Interest rate swap contracts	Other noncurrent liabilities		_		35		3,500		_		29		3,500			
Foreign exchange contracts	Other current assets		330		_		5,049		616		_		6,063			
Foreign exchange contracts	Other assets		56		_		1,815		129		_		2,075			
Foreign exchange contracts	Accrued and other current liabilities		_		21		915		_		1		48			
Foreign exchange contracts	Other noncurrent liabilities		_		1		20		_		1		12			
		\$	397	\$	57	\$	13,999	\$	765	\$	31	\$	14,398			
Derivatives Not Designated as Hedging Instruments																
Foreign exchange contracts	Other current assets	\$	232	\$	_	\$	8,037	\$	230	\$	_	\$	8,210			
Foreign exchange contracts	Accrued and other current liabilities		_		89		6,479		_		103		2,931			
	·	\$	232	\$	89	\$	14,516	\$	230	\$	103	\$	11,141			
		\$	629	\$	146	\$	28,515	\$	995	\$	134	\$	25,539			

As noted above, the Company records its derivatives on a gross basis in the Condensed Consolidated Balance Sheet. The Company has master netting agreements with several of its financial institution counterparties (see *Concentrations of Credit Risk* below). The following table provides information on the Company's derivative positions subject to these master netting arrangements as if they were presented on a net basis, allowing for the right of offset by counterparty and cash collateral exchanged per the master agreements and related credit support annexes:

	 March 3	31, 201	7	December 31, 2		2016
(\$ in millions)	Asset	Li	ability	Asset	L	iability
Gross amounts recognized in the consolidated balance sheet	\$ 629	\$	146	\$ 995	\$	134
Gross amount subject to offset in master netting arrangements not offset in the consolidated balance sheet	(144)		(144)	(131)		(131)
Cash collateral received	(222)		_	(529)		_
Net amounts	\$ 263	\$	2	\$ 335	\$	3

The table below provides information on the location and pretax gain or loss amounts for derivatives that are: (i) designated in a fair value hedging relationship, (ii) designated in a foreign currency cash flow hedging relationship and (iii) not designated in a hedging relationship:

	 Three Mon Marc		led
(\$ in millions)	2017	2	2016
Derivatives designated in a fair value hedging relationship			
Interest rate swap contracts			
Amount of loss (gain) recognized in Other (income) expense, net on derivatives (1)	\$ 15	\$	(150)
Amount of (gain) loss recognized in Other (income) expense, net on hedged item (1)	(16)		147
Derivatives designated in foreign currency cash flow hedging relationships			
Foreign exchange contracts			
Amount of gain reclassified from AOCI to Sales	(94)		(143)
Amount of loss recognized in OCI on derivatives	263		167
Derivatives not designated in a hedging relationship			
Foreign exchange contracts			
Amount of (gain) loss recognized in Other (income) expense, net on derivatives (2)	(47)		24

<sup>(1)</sup> There was \$1 million and \$3 million of ineffectiveness on the hedge during the first quarter of 2017 and 2016, respectively.

At March 31, 2017, the Company estimates \$167 million of pretax net unrealized gains on derivatives maturing within the next 12 months that hedge foreign currency denominated sales over that same period will be reclassified from *AOCI* to *Sales*. The amount ultimately reclassified to *Sales* may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity.

<sup>(2)</sup> These derivative contracts mitigate changes in the value of remeasured foreign currency denominated monetary assets and liabilities attributable to changes in foreign currency exchange rates.

#### **Investments in Debt and Equity Securities**

Information on investments in debt and equity securities is as follows:

				March	31, 2	2017						Decemb	oer 31	, 2016		
	Fair Amortized Gross Unrealized					Fair		mortized		Gross U	lized					
(\$ in millions)		Value	Cost		Gains		Losses		Value		Cost		Gains			Losses
Corporate notes and bonds	\$	10,445	\$	10,455	\$	19	\$	(29)	\$	10,577	\$	10,601	\$	15	\$	(39)
U.S. government and agency securities		2,011		2,021		1		(11)		2,232		2,244		1		(13)
Asset-backed securities		1,410		1,411		2		(3)		1,376		1,380		1		(5)
Commercial paper		773		773		_		_		4,330		4,330		_		
Mortgage-backed securities		712		717		_		(5)		796		801		1		(6)
Foreign government bonds		560		561		1		(2)		519		521		_		(2)
Equity securities		356		278		79		(1)		349		281		71		(3)
	\$	16,267	\$	16,216	\$	102	\$	(51)	\$	20,179	\$	20,158	\$	89	\$	(68)

Available-for-sale debt securities included in *Short-term investments* totaled \$3.5 billion at March 31, 2017. Of the remaining debt securities, \$10.6 billion mature within five years. At March 31, 2017 and December 31, 2016, there were no debt securities pledged as collateral.

## **Fair Value Measurements**

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The Company uses a fair value hierarchy which maximizes the use of observable inputs and minimizes the use of unobservable inputs when measuring fair value. There are three levels of inputs used to measure fair value with Level 1 having the highest priority and Level 3 having the lowest:

- Level 1 Quoted prices (unadjusted) in active markets for identical assets or liabilities.
- Level 2 Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 Unobservable inputs that are supported by little or no market activity. Level 3 assets or liabilities are those whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques with significant unobservable inputs, as well as assets or liabilities for which the determination of fair value requires significant judgment or estimation.

If the inputs used to measure the financial assets and liabilities fall within more than one level described above, the categorization is based on the lowest level input that is significant to the fair value measurement of the instrument.

Financial Assets and Liabilities Measured at Fair Value on a Recurring Basis Financial assets and liabilities measured at fair value on a recurring basis are summarized below:

		Fai	r Value Meas	surem	ents Using		Fair Value Measurements Using						
	Quoted Prices In Active Markets for Identical Assets (Level 1)	(	Significant Other Observable Inputs (Level 2)		Significant Unobservable Inputs (Level 3)	Total	Quoted Prices In Active Markets for Identical Assets (Level 1)	C	Other Observable Inputs (Level 2)		Significant Unobservable Inputs (Level 3)		Total
(\$ in millions)			March 3	31, 20	17				December	r 31, 2	016		
Assets													
Investments													
Corporate notes and bonds	\$ _	\$	10,287	\$	_	\$ 10,287	\$ _	\$	10,389	\$	_	\$	10,389
U.S. government and agency securities	66		1,647		_	1,713	29		1,890		_		1,919
Asset-backed securities (1)	_		1,312		_	1,312	_		1,257		_		1,257
Commercial paper	_		773		_	773	_		4,330		_		4,330
Mortgage-backed securities (1)	_		595		_	595	_		628		_		628
Foreign government bonds	_		559		_	559	_		518		_		518
Equity securities	198		_		_	198	201		_		_		201
	264		15,173			15,437	230		19,012				19,242
Other assets													
U.S. government and agency securities	_		298		_	298	_		313		_		313
Corporate notes and bonds	_		158		_	158	_		188		_		188
Mortgage-backed securities (1)	_		117		_	117	_		168		_		168
Asset-backed securities (1)	_		98		_	98	_		119		_		119
Foreign government bonds	_		1		_	1	_		1		_		1
Equity securities	158					158	148				_		148
	158		672		_	830	148		789		_		937
Derivative assets (2)													
Purchased currency options	_		354		_	354	_		644		_		644
Forward exchange contracts	_		264		_	264	_		331		_		331
Interest rate swaps	_		11			11			20		_		20
	_		629			629	_		995		_		995
Total assets	\$ 422	\$	16,474	\$		\$ 16,896	\$ 378	\$	20,796	\$	_	\$	21,174
Liabilities													
Other liabilities													
Contingent consideration	\$ _	\$	_	\$	925	\$ 925	\$ _	\$	_	\$	891	\$	891
Derivative liabilities <sup>(2)</sup>													
Forward exchange contracts	_		110		_	110	_		93		_		93
Interest rate swaps	_		35		_	35	_		29		_		29
Written currency options	_		1		_	1	_		12		_		12
			146			146	_		134				134
Total liabilities	\$ 	\$	146	\$	925	\$ 1,071	\$ _	\$	134	\$	891	\$	1,025

There were no transfers between Level 1 and Level 2 during the first three months of 2017. As of March 31, 2017, Cash and cash equivalents of \$11.7 billion included \$10.9 billion of cash equivalents (considered Level 2 in the fair value hierarchy).

<sup>(1)</sup> Primarily all of the asset-backed securities are highly-rated (Standard & Poor's rating of AAA and Moody's Investors Service rating of Aaa), secured primarily by auto loan, credit card and student loan receivables, with weighted-average lives of primarily 5 years or less. Mortgage-backed securities represent AAA-rated securities issued or unconditionally guaranteed as to payment of principal and interest by U.S. government agencies.

<sup>(2)</sup> The fair value determination of derivatives includes the impact of the credit risk of counterparties to the derivatives and the Company's own credit risk, the effects of which were not significant.

## Contingent Consideration

Summarized information about the changes in liabilities for contingent consideration is as follows:

	Thr	ee Months	Ended	March 31,
(\$ in millions)		2017		2016
Fair value January 1	\$	891	\$	590
Changes in fair value (1)		34		10
Additions		_		77
Payments		_		(25)
Fair value March 31	\$	925	\$	652

<sup>(1)</sup> Recorded in Research and development expenses, Materials and production costs and Other (income) expense, net . Includes cumulative translation adjustments.

The additions to contingent consideration in the first quarter of 2016 relate to the acquisition of IOmet (see Note 2). The payments of contingent consideration in the first quarter of 2016 relate to the first commercial sale of *Zerbaxa* in the European Union.

## Other Fair Value Measurements

Some of the Company's financial instruments, such as cash and cash equivalents, receivables and payables, are reflected in the balance sheet at carrying value, which approximates fair value due to their short-term nature.

The estimated fair value of loans payable and long-term debt (including current portion) at March 31, 2017, was \$29.3 billion compared with a carrying value of \$28.5 billion and at December 31, 2016, was \$25.7 billion compared with a carrying value of \$24.8 billion. Fair value was estimated using recent observable market prices and would be considered Level 2 in the fair value hierarchy.

#### Concentrations of Credit Risk

On an ongoing basis, the Company monitors concentrations of credit risk associated with corporate and government issuers of securities and financial institutions with which it conducts business. Credit exposure limits are established to limit a concentration with any single issuer or institution. Cash and investments are placed in instruments that meet high credit quality standards as specified in the Company's investment policy guidelines.

The majority of the Company's accounts receivable arise from product sales in the United States and Europe and are primarily due from drug wholesalers and retailers, hospitals, government agencies, managed health care providers and pharmacy benefit managers. The Company monitors the financial performance and creditworthiness of its customers so that it can properly assess and respond to changes in their credit profile. The Company also continues to monitor economic conditions, including the volatility associated with international sovereign economies, and associated impacts on the financial markets and its business, taking into consideration global economic conditions and the ongoing sovereign debt issues in certain European countries. At March 31, 2017, the Company's total net accounts receivable outstanding for more than one year were approximately \$135 million. The Company does not expect to have write-offs or adjustments to accounts receivable which would have a material adverse effect on its financial position, liquidity or results of operations.

Derivative financial instruments are executed under International Swaps and Derivatives Association master agreements. The master agreements with several of the Company's financial institution counterparties also include credit support annexes. These annexes contain provisions that require collateral to be exchanged depending on the value of the derivative assets and liabilities, the Company's credit rating, and the credit rating of the counterparty. As of March 31, 2017 and December 31, 2016, the Company had received cash collateral of \$222 million and \$529 million, respectively, from various counterparties and the obligation to return such collateral is recorded in *Accrued and other current liabilities*. The Company had not advanced any cash collateral to counterparties as of March 31, 2017 or December 31, 2016.

#### 5. Inventories

Inventories consisted of:

(\$ in millions)	N	March 31, 2017	D	ecember 31, 2016
Finished goods	\$	1,355	\$	1,304
Raw materials and work in process		4,446		4,222
Supplies		160		155
Total (approximates current cost)		5,961		5,681
Increase to LIFO costs		275		302
	\$	6,236	\$	5,983
Recognized as:				
Inventories	\$	5,146	\$	4,866
Other assets		1,090		1,117

Amounts recognized as *Other assets* are comprised almost entirely of raw materials and work in process inventories. At March 31, 2017 and December 31, 2016, these amounts included \$1.0 billion of inventories not expected to be sold within one year. In addition, these amounts included \$80 million at March 31, 2017 and December 31, 2016 of inventories produced in preparation for product launches.

# 6. Other Intangibles

In connection with acquisitions, the Company measures the fair value of marketed products and research and development pipeline programs and capitalizes these amounts. See Note 2 for information on intangible assets acquired as a result of business acquisitions in the first quarter of 2017 and 2016.

During the first quarter of 2016, the Company recorded an intangible asset impairment charge of \$252 million within *Materials and production* costs related to *Zontivity*, a product for the reduction of thrombotic cardiovascular events in patients with a history of myocardial infarction or with peripheral arterial disease. In March 2016, following several business decisions that reduced sales expectations for *Zontivity* in the United States and Europe, the Company lowered its cash flow projections for *Zontivity*. The Company utilized market participant assumptions and considered several different scenarios to determine the fair value of the intangible asset related to *Zontivity* that, when compared with its related carrying value, resulted in the impairment charge noted above.

Also during the first quarter of 2016, the Company recorded \$25 million of IPR&D impairment charges within *Research and development* expenses primarily related to deprioritized pipeline programs that were deemed to have no alternative use during the period.

The Company may recognize additional non-cash impairment charges in the future related to other marketed products or pipeline programs and such charges could be material.

# 7. Contingencies

The Company is involved in various claims and legal proceedings of a nature considered normal to its business, including product liability, intellectual property, and commercial litigation, as well as certain additional matters including environmental matters. In the opinion of the Company, it is unlikely that the resolution of these matters will be material to the Company's financial position, results of operations or cash flows.

Given the nature of the litigation discussed below and the complexities involved in these matters, the Company is unable to reasonably estimate a possible loss or range of possible loss for such matters until the Company knows, among other factors, (i) what claims, if any, will survive dispositive motion practice, (ii) the extent of the claims, including the size of any potential class, particularly when damages are not specified or are indeterminate, (iii) how the discovery process will affect the litigation, (iv) the settlement posture of the other parties to the litigation and (v) any other factors that may have a material effect on the litigation.

The Company records accruals for contingencies when it is probable that a liability has been incurred and the amount can be reasonably estimated. These accruals are adjusted periodically as assessments change or additional information becomes available. For product liability claims, a portion of the overall accrual is actuarially determined and considers such factors as past experience, number of claims reported and estimates of claims incurred but not yet reported. Individually significant contingent losses are accrued when probable and reasonably estimable. Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable.

The Company's decision to obtain insurance coverage is dependent on market conditions, including cost and availability, existing at the time such decisions are made. The Company has evaluated its risks and has determined that the cost of obtaining product liability insurance outweighs the likely benefits of the coverage that is available and, as such, has no insurance for most product liabilities effective August 1, 2004.

#### **Product Liability Litigation**

#### Fosamax

As previously disclosed, Merck is a defendant in product liability lawsuits in the United States involving *Fosamax* (*Fosamax* Litigation). As of March 31, 2017, approximately 4,215 cases are filed and pending against Merck in either federal or state court. In approximately 20 of these actions, plaintiffs allege, among other things, that they have suffered osteonecrosis of the jaw (ONJ), generally subsequent to invasive dental procedures, such as tooth extraction or dental implants and/or delayed healing, in association with the use of *Fosamax*. In addition, plaintiffs in approximately 4,195 of these actions generally allege that they sustained femur fractures and/or other bone injuries (Femur Fractures) in association with the use of *Fosamax*.

Cases Alleging ONJ and/or Other Jaw Related Injuries

In August 2006, the Judicial Panel on Multidistrict Litigation (JPML) ordered that certain *Fosamax* product liability cases pending in federal courts nationwide should be transferred and consolidated into one multidistrict litigation (*Fosamax* ONJ MDL) for coordinated pre-trial proceedings.

In December 2013, Merck reached an agreement in principle with the Plaintiffs' Steering Committee (PSC) in the *Fosamax* ONJ MDL to resolve pending ONJ cases not on appeal in the *Fosamax* ONJ MDL and in the state courts for an aggregate amount of \$27.7 million. Merck and the PSC subsequently formalized the terms of this agreement in a Master Settlement Agreement (ONJ Master Settlement Agreement) that was executed in April 2014 and included over 1,200 plaintiffs. In July 2014, Merck elected to proceed with the ONJ Master Settlement Agreement at a reduced funding level of \$27.3 million since the participation level was approximately 95%. Merck has fully funded the ONJ Master Settlement Agreement and the escrow agent under the agreement has been making settlement payments to qualifying plaintiffs. The ONJ Master Settlement Agreement has no effect on the cases alleging Femur Fractures discussed below.

Discovery is currently ongoing in some of the approximately 20 remaining ONJ cases that are pending in various federal and state courts and the Company intends to defend against these lawsuits.

## Cases Alleging Femur Fractures

In March 2011, Merck submitted a Motion to Transfer to the JPML seeking to have all federal cases alleging Femur Fractures consolidated into one multidistrict litigation for coordinated pre-trial proceedings. The Motion to Transfer was granted in May 2011, and all federal cases involving allegations of Femur Fracture have been or will be transferred to a multidistrict litigation in the District of New Jersey (Femur Fracture MDL). In the only bellwether case tried to date in the Femur Fracture MDL, *Glynn v. Merck*, the jury returned a verdict in Merck's favor. In addition, in June 2013, the Femur Fracture MDL court granted Merck's motion for judgment as a matter of law in the *Glynn* case and held that the plaintiff's failure to warn claim was preempted by federal law. The *Glynn* decision was not appealed by plaintiff.

In August 2013, the Femur Fracture MDL court entered an order requiring plaintiffs in the Femur Fracture MDL to show cause why those cases asserting claims for a femur fracture injury that took place prior to September 14, 2010, should not be dismissed based on the court's preemption decision in the *Glynn* case. Pursuant to the show cause order, in March 2014, the Femur Fracture MDL court dismissed with prejudice approximately 650 cases on preemption grounds. Plaintiffs in approximately 515 of those cases appealed that decision to the U.S. Court of Appeals for the Third Circuit (Third Circuit). The Femur Fracture MDL court also dismissed without prejudice another approximately 540 cases pending plaintiffs' appeal of the preemption ruling to the Third Circuit. On March 22, 2017, the Third Circuit issued a decision reversing the Femur Fracture MDL court's preemption ruling and remanding the appealed cases back to the Femur Fracture MDL court. On April 5, 2017, Merck filed a petition seeking a rehearing on the Third Circuit's March 22, 2017 decision, which was denied on April 24, 2017.

In addition, in June 2014, the Femur Fracture MDL court granted Merck summary judgment in the *Gaynor v. Merck* case and found that Merck's updates in January 2011 to the *Fosamax* label regarding atypical femur fractures were adequate as a matter of law and that Merck adequately communicated those changes. The plaintiffs in *Gaynor* did not appeal the Femur Fracture MDL court's findings with respect to the adequacy of the 2011 label change but did appeal the dismissal of their case based on preemption grounds, and the Third Circuit subsequently reversed that dismissal in its March 22, 2017 decision. In August 2014, Merck filed a motion requesting that the Femur Fracture MDL court enter a further order requiring all plaintiffs in the Femur Fracture MDL who claim that the 2011 *Fosamax* label is inadequate and the proximate cause of their alleged injuries to show cause why their cases should not be dismissed based on the court's preemption decision and its ruling in the *Gaynor* case. In November 2014, the court granted Merck's motion and entered the requested show cause order. No plaintiffs responded to or appealed the November 2014 show cause order.

As of March 31, 2017, seven cases were pending in the Femur Fracture MDL, excluding the 515 cases dismissed with prejudice on preemption grounds that are pending the final resolution of all appeals of the Femur Fracture MDL court's March 2014 preemption decision and the 540 cases dismissed without prejudice that are also pending the final resolution of the aforementioned appeal.

As of March 31, 2017, approximately 2,855 cases alleging Femur Fractures have been filed in New Jersey state court and are pending before Judge Jessica Mayer in Middlesex County. The parties selected an initial group of 30 cases to be reviewed through fact discovery. Two additional groups of 50 cases each to be reviewed through fact discovery were selected in November 2013 and March 2014, respectively. A further group of 25 cases to be reviewed through fact discovery was selected by Merck in July 2015, and Merck has continued to select additional cases to be reviewed through fact discovery during 2016 and 2017.

As of March 31, 2017, approximately 280 cases alleging Femur Fractures have been filed and are pending in California state court. A petition was filed seeking to coordinate all Femur Fracture cases filed in California state court before a single judge in Orange County, California. The petition was granted and Judge Thierry Colaw is currently presiding over the coordinated proceedings. In March 2014, the court directed that a group of 10 discovery pool cases be reviewed through fact discovery and subsequently scheduled the *Galper v. Merck* case, which plaintiffs selected, as the first trial. The *Galper* trial began in February 2015 and the jury returned a verdict in Merck's favor in April 2015, and plaintiff has appealed that verdict to the California appellate court. Oral argument on plaintiff's appeal in *Galper* was held on November 17, 2016 and, on April 24, 2017, the California appellate court issued a decision affirming the lower court's judgment in favor of Merck. The next Femur Fracture trial in California that was scheduled to begin in April 2016 was stayed at plaintiffs' request and a new trial date has not been set.

Additionally, there are five Femur Fracture cases pending in other state courts.

Discovery is ongoing in the Femur Fracture MDL and in state courts where Femur Fracture cases are pending and the Company intends to defend against these lawsuits.

## Januvia/Janumet

As previously disclosed, Merck is a defendant in product liability lawsuits in the United States involving *Januvia* and/or *Janumet*. As of March 31, 2017, Merck is aware of approximately 1,200 product user claims alleging generally that use of *Januvia* and/or *Janumet* caused the development of pancreatic cancer and other injuries. These complaints were filed in several different state and federal courts.

Most of the claims were filed in a consolidated multidistrict litigation proceeding in the U.S. District Court for the Southern District of California called "In re Incretin-Based Therapies Products Liability Litigation" (MDL). The MDL includes federal lawsuits alleging pancreatic cancer due to use of the following medicines: *Januvia, Janumet*, Byetta and Victoza, the latter two of which are products manufactured by other pharmaceutical companies. The majority of claims not filed in the MDL were filed in the Superior Court of California, County of Los Angeles (California State Court).

In November 2015, the MDL and California State Court - in separate opinions - granted summary judgment to defendants on grounds of preemption. Of the approximately 1,200 product user claims, these rulings resulted in the dismissal of approximately 1,150 product user claims.

Plaintiffs are appealing the MDL and California State Court preemption rulings.

As of March 31, 2017, eight product users have claims pending against Merck in state courts other than the California State Court, including four active product user claims pending in Illinois state court. On March 30, 2017, the Illinois court held oral argument on Merck's motion for summary judgment on grounds of preemption. A decision is expected in May 2017.

In addition to the claims noted above, the Company has agreed, as of March 31, 2017, to toll the statute of limitations for approximately 50 additional claims. The Company intends to continue defending against these lawsuits.

# Propecia/Proscar

As previously disclosed, Merck is a defendant in product liability lawsuits in the United States involving *Propecia* and/or *Proscar*. As of March 31, 2017, approximately 1,260 lawsuits have been filed by plaintiffs who allege that they have experienced persistent sexual side effects following cessation of treatment with *Propecia* and/or *Proscar*. Approximately 50 of the plaintiffs also allege that *Propecia* or *Proscar* has caused or can cause prostate cancer, testicular cancer or male breast cancer. The lawsuits have been filed in various federal courts and in state court in New Jersey. The federal lawsuits have been consolidated for pretrial purposes in a federal multidistrict litigation before Judge Brian Cogan of the Eastern District of New York. The matters pending in state court in New Jersey have been consolidated before Judge Mayer in Middlesex County. In addition, there is one matter pending in state court in California and one matter pending in state court in Ohio. The Company intends to defend against these lawsuits.

#### **Commercial and Other Litigation**

#### K-DUR Antitrust Litigation

In June 1997 and January 1998, Schering-Plough Corporation (Schering-Plough) settled patent litigation with Upsher-Smith, Inc. (Upsher-Smith) and ESI Lederle, Inc. (Lederle), respectively, relating to generic versions of Schering-Plough's long-acting potassium chloride product supplement used by cardiac patients, for which Lederle and Upsher-Smith had filed Abbreviated New Drug Applications (ANDAs). Following the commencement of an administrative proceeding by the U.S. Federal Trade Commission in 2001 alleging anti-competitive effects from those settlements (which was resolved in Schering-Plough's favor), putative class and non-class action suits were filed on behalf of direct and indirect purchasers of K-DUR against Schering-Plough, Upsher-Smith and Lederle and were consolidated in a multidistrict litigation in the U.S. District Court for the District of New Jersey. These suits claimed violations of federal and state antitrust laws, as well as other state statutory and common law causes of action, and sought unspecified damages. In April 2008, the indirect purchasers voluntarily dismissed their case. In February 2016, the District Court denied the Company's motion for summary judgment relating to all of the direct purchasers' claims concerning the settlement with Upsher-Smith and granted the Company's motion for summary judgment relating to all of the direct purchasers' claims concerning the settlement with Lederle. In anticipation of trial, the parties filed motions to exclude certain expert opinions and other evidence, and defendants filed a motion for summary judgment.

As previously disclosed, in February 2017, Merck and Upsher-Smith reached a settlement in principle with the class of direct purchasers and the optouts to the class. Merck will contribute approximately \$80 million in the aggregate towards the overall settlement. On April 5, 2017, the claims of the optouts were dismissed with prejudice pursuant to a written settlement agreement with those parties. Merck and Upsher-Smith are working with the class of direct purchasers on a definitive settlement agreement of its claims, which will be subject to approval by the District Court.

## Merck KGaA Litigation

In January 2016, to protect its long-established brand rights in the United States, the Company filed a lawsuit against Merck KGaA, Darmstadt, Germany (KGaA), operating as the EMD Group in the United States, alleging it improperly uses the name "Merck" in the United States. KGaA has filed suit against the Company in France, the United Kingdom (UK), Germany, Switzerland, Mexico, and India alleging breach of the parties' co-existence agreement, unfair competition and/or trademark infringement. In December 2015, the Paris Court of First Instance issued a judgment finding that certain activities by the Company directed towards France did not constitute trademark infringement and unfair competition while other activities were found to infringe. The Company and KGaA have both appealed the decision, and the appeal is scheduled to be heard in May 2017. In January 2016, the UK High Court issued a judgment finding that the Company had breached the co-existence agreement and infringed KGaA's trademark rights as a result of certain activities directed towards the UK based on use of the word MERCK on promotional and information activity. As noted in the UK decision, this finding was not based on the Company's use of the sign MERCK in connection with the sale of products or any material pharmaceutical business transacted in the UK. The Company and KGaA have both appealed this decision, and the appeal is scheduled to be heard in June 2017.

## **Patent Litigation**

From time to time, generic manufacturers of pharmaceutical products file ANDAs with the U.S. Food and Drug Administration (FDA) seeking to market generic forms of the Company's products prior to the expiration of relevant patents owned by the Company. To protect its patent rights, the Company may file patent infringement lawsuits against such generic companies. Certain products of the Company (or products marketed via agreements with other companies) currently involved in such patent infringement litigation in the United States include: Invanz, Nasonex, Noxafil, and NuvaRing. Similar lawsuits defending the Company's patent rights may exist in other countries. The Company intends to vigorously defend its patents, which it believes are valid, against infringement by companies attempting to market products prior to the expiration of such patents. As with any litigation, there can be no assurance of the outcomes, which, if adverse, could result in significantly shortened periods of exclusivity for these products and, with respect to products acquired through acquisitions, potentially significant intangible asset impairment charges.

Invanz — In July 2014, a patent infringement lawsuit was filed in the United States against Hospira, Inc. (Hospira) in respect of Hospira's application to the FDA seeking pre-patent expiry approval to market a generic version of Invanz. The trial in this matter was held in April 2016 and, in October 2016, the district court ruled that the patent is valid and infringed. In August 2015, a patent infringement lawsuit was filed in the United States against Savior Lifetec Corporation (Savior) in respect of Savior's application to the FDA seeking pre-patent expiry approval to market a generic version of Invanz. The lawsuit automatically stays FDA approval of Savior's application until November 2017 or until an adverse court decision, if any, whichever may occur earlier.

Nasonex — In July 2014, a patent infringement lawsuit was filed in the United States against Teva Pharmaceuticals USA, Inc. (Teva Pharma) in respect of Teva Pharma's application to the FDA seeking pre-patent expiry approval to market a generic version of Nasonex. The trial in this matter was held in June 2016. In November 2016, the district court ruled that the patent was valid but not infringed. In March 2017, the parties reached a settlement whereby Teva Pharma can launch its generic version in September 2017, or earlier under certain conditions.

In March 2015, a patent infringement lawsuit was filed in the United States against Amneal Pharmaceuticals LLC (Amneal) in respect of Amneal's application to the FDA seeking pre-patent expiry approval to market a generic version of *Nasonex*. The trial in this matter was held in June 2016. In January 2017, the district court ruled that the patent was valid but not infringed. The Company has appealed this decision.

A previous decision, issued in June 2013, held that the Merck patent in the Teva Pharma and Amneal lawsuits covering mometasone furoate monohydrate was valid, but that it was not infringed by Apotex Corp.'s proposed product. In April 2015, a patent infringement lawsuit was filed against Apotex Inc. and Apotex Corp. (Apotex) in respect of Apotex's now-launched product that the Company believes differs from the generic version in the previous lawsuit.

Noxafil — In August 2015, the Company filed a lawsuit against Actavis Laboratories Fl, Inc. (Actavis) in the United States in respect of that company's application to the FDA seeking pre-patent expiry approval to sell a generic version of Noxafil. The lawsuit automatically stays FDA approval of Actavis's application until December 2017 or until an adverse court decision, if any, whichever may occur earlier. The trial in this matter is currently scheduled to begin in July 2017. In March 2016, the Company filed a lawsuit against Roxane Laboratories, Inc. (Roxane) in the United States in respect of that company's application to the FDA seeking pre-patent expiry approval to sell a generic version of Noxafil. The lawsuit automatically stays FDA approval of Roxane's application until August 2018 or until an adverse court decision, if any, whichever may occur earlier. In February 2016, the Company filed a lawsuit against Par Sterile Products LLC, Par Pharmaceutical, Inc., Par Pharmaceutical Companies, Inc. and Par Pharmaceutical Holdings, Inc. (collectively, Par) in the United States in respect of that company's application to the FDA seeking pre-patent expiry approval to sell a generic version of Noxafil. In October 2016, the parties reached a settlement whereby Par can launch its generic version in January 2023, or earlier under certain conditions.

NuvaRing — In December 2013, the Company filed a lawsuit against a subsidiary of Allergan plc in the United States in respect of that company's application to the FDA seeking pre-patent expiry approval to sell a generic version of NuvaRing. The trial in this matter was held in January 2016. In August 2016, the district court ruled that the patent was invalid and the Company has appealed this decision. In September 2015, the Company filed a lawsuit against Teva Pharma in the United States in respect of that company's application to the FDA seeking pre-patent expiry approval to sell a generic version of NuvaRing. Based on its ruling in the Allergan plc matter, the district court dismissed the Company's lawsuit in December 2016. The Company has appealed this decision.

# **Anti-PD-1 Antibody Patent Oppositions and Litigation**

As previously disclosed, Ono Pharmaceutical Co. (Ono) has a European patent (EP 1 537 878) ('878) that broadly claims the use of an anti-PD-1 antibody, such as the Company's immunotherapy, *Keytruda*, for the treatment of cancer. Ono has previously licensed its commercial rights to an anti-PD-1 antibody to Bristol-Myers Squibb (BMS) in certain markets. BMS and Ono also own European Patent EP 2 161 336 ('336) that, as granted, broadly claimed anti-PD-1 antibodies that could include *Keytruda*.

As previously disclosed, the Company and BMS and Ono were engaged in worldwide litigation, including in the United States, over the validity and infringement of the '878 patent, the '336 patent and their equivalents.

In January 2017, the Company announced that it had entered into a settlement and license agreement with BMS and Ono resolving the worldwide patent infringement litigation related to the use of an anti-PD-1 antibody for the treatment of cancer, such as *Keytruda*. Under the settlement and license agreement, the Company made a one-time payment of \$625 million (which was recorded as an expense in the Company's 2016 financial results) to BMS and will pay royalties on the worldwide sales of *Keytruda* for a non-exclusive license to market *Keytruda* in any market in which it is approved. For global net sales of *Keytruda*, the Company will pay royalties as follows:

- 6.5% of net sales occurring from January 1, 2017 through and including December 31, 2023; and
- 2.5% of net sales occurring from January 1, 2024 through and including December 31, 2026.

The parties also agreed to dismiss all claims worldwide in the relevant legal proceedings.

In October 2015, PDL Biopharma (PDL) filed a lawsuit in the United States against the Company alleging that the manufacture of *Keytruda* infringed US Patent No. 5,693,761 ('761 patent), which expired in December 2014. This patent claims platform technology used in the creation and manufacture of recombinant antibodies and PDL is seeking damages for pre-expiry infringement of the '761 patent. In April 2017, the parties reached a settlement pursuant to which, in exchange for a lump sum, PDL dismissed its lawsuit with prejudice and granted the Company a fully paid-up non-exclusive license to the '761 patent.

In July 2016, the Company filed a declaratory judgment action in the United States against Genentech and City of Hope seeking a ruling that US Patent No. 7,923,221 (the Cabilly III patent), which claims platform technology used in the creation and manufacture of recombinant antibodies, is invalid and that *Keytruda* and bezlotoxumab do not infringe the Cabilly III patent. In July 2016, the Company also filed a petition in the USPTO for *Inter Partes* Review (IPR) of certain claims of US Patent

No. 6,331,415 (the Cabilly II patent), which claims platform technology used in the creation and manufacture of recombinant antibodies and is also owned by Genentech and City of Hope, as being invalid. In December 2016, the USPTO denied the petition but allowed the Company to join an IPR filed previously by another party. In May 2017, the parties reached a settlement pursuant to which the Company dismissed its lawsuit with prejudice and moved to terminate the IPR and Genentech and City of Hope granted the Company a fully paid-up non-exclusive license to the Cabilly II and Cabilly III patents.

## **Gilead Patent Litigation and Opposition**

In August 2013, Gilead Sciences, Inc. (Gilead) filed a lawsuit in the U.S. District Court for the Northern District of California seeking a declaration that two Company patents were invalid and not infringed by the sale of their two sofosbuvir containing products, Solvadi and Harvoni. The Company filed a counterclaim that the sale of these products did infringe these two patents and sought a reasonable royalty for the past, present and future sales of these products. In March 2016, at the conclusion of a jury trial, the patents were found to be not invalid and infringed. The jury awarded the Company \$200 million as a royalty for sales of these products up to December 2015. After the conclusion of the jury trial, the court held a bench trial on the equitable defenses raised by Gilead. In June 2016, the court found for Gilead and determined that Merck could not collect the jury award and that the patents were unenforceable with respect to Gilead. The Company has appealed the court's decision. Gilead has also asked the court to overturn the jury's decision on validity. The court held a hearing on Gilead's motion in August 2016, and the court subsequently rejected Gilead's request. The Company will pay 20%, net of legal fees, of damages or royalties, if any, that it receives to Ionis Pharmaceuticals, Inc.

The Company, through its Idenix Pharmaceuticals, Inc. subsidiary, has pending litigation against Gilead in the United States, the UK, Norway, Canada, Germany, France, and Australia based on different patent estates that would also be infringed by Gilead's sales of these two products. Gilead has opposed the European patent at the European Patent Office (EPO). Trial in the United States was held in December 2016 and the jury returned a verdict for the Company, awarding damages of \$2.54 billion. The Company is currently briefing post-trial motions, including on the issues of enhanced damages and future royalties. Gilead is briefing post-trial motions for judgment as a matter of law. In Australia and Canada, the Company was initially unsuccessful and those cases are currently under appeal. In the UK and Norway, the patent was held invalid and no further appeal was filed. The EPO opposition division revoked the European patent, and the Company has appealed this decision. The cases in France and Germany have been stayed pending the final decision of the EPO.

## Other Litigation

There are various other pending legal proceedings involving the Company, principally product liability and intellectual property lawsuits. While it is not feasible to predict the outcome of such proceedings, in the opinion of the Company, either the likelihood of loss is remote or any reasonably possible loss associated with the resolution of such proceedings is not expected to be material to the Company's financial position, results of operations or cash flows either individually or in the aggregate.

## **Legal Defense Reserves**

Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable. Some of the significant factors considered in the review of these legal defense reserves are as follows: the actual costs incurred by the Company; the development of the Company's legal defense strategy and structure in light of the scope of its litigation; the number of cases being brought against the Company; the costs and outcomes of completed trials and the most current information regarding anticipated timing, progression, and related costs of pre-trial activities and trials in the associated litigation. The amount of legal defense reserves as of March 31, 2017 and December 31, 2016 of approximately \$175 million and \$185 million, respectively, represents the Company's best estimate of the minimum amount of defense costs to be incurred in connection with its outstanding litigation; however, events such as additional trials and other events that could arise in the course of its litigation could affect the ultimate amount of legal defense costs to be incurred by the Company. The Company will continue to monitor its legal defense costs and review the adequacy of the associated reserves and may determine to increase the reserves at any time in the future if, based upon the factors set forth, it believes it would be appropriate to do so.

# 8. Equity

	Com	mon Stock	_	Other Paid-In	Retair		Accumulated Other	Tre	asury	Stock	Non-	
(\$ and shares in millions)	Shares	Par Value		Capital	Earni		Comprehensive Loss	Shares		Cost	Controlling Interests	Total
Balance at January 1, 2016	3,577	\$ 1,788	\$	40,222	\$ 45,	348	\$ (4,148)	796	\$	(38,534) \$	91	\$ 44,767
Net income attributable to Merck & Co., Inc.	_	_		_	1,	125	_	_		_	_	1,125
Other comprehensive loss, net of tax	_	_		_		_	(46)	_		_	_	(46)
Cash dividends declared on common stock	_	_		_	(1,	281)	_	_		_	_	(1,281)
Treasury stock shares purchased	_	_		_		_	_	18		(913)	_	(913)
Share-based compensation plans and other	_	_		(77)		_	_	(6	)	322	_	245
Net income attributable to noncontrolling interests	_	_		_		_	_	_		_	5	5
Distributions attributable to noncontrolling interests	_	_		_		_	_	_		_	(1)	(1)
Balance at March 31, 2016	3,577	\$ 1,788	\$	40,145	\$ 45,	192	\$ (4,194)	808	\$	(39,125) \$	95	\$ 43,901
Balance at January 1, 2017	3,577	\$ 1,788	\$	39,939	\$ 44,	133	\$ (5,226)	828	\$	(40,546) \$	220	\$ 40,308
Net income attributable to Merck & Co., Inc.	_	_		_	1,	551	_	_		_	_	1,551
Other comprehensive income, net of tax	_	_		_		_	146	_		_	_	146
Cash dividends declared on common stock	_	_		_	(1,	297)	_	_		_	_	(1,297)
Treasury stock shares purchased	_	_		_		_	_	16		(1,019)	_	(1,019)
Share-based compensation plans and other	_	_		(40)		_	_	(7	)	408	_	368
Acquisition of Vallée	_	_		_		_	_	_		_	25	25
Net income attributable to noncontrolling interests	_	_		_		_	_	_		_	5	5
Other changes in noncontrolling ownership interests	_	_		_		_	_	_		_	1	1
Balance at March 31, 2017	3,577	\$ 1,788	\$	39,899	\$ 44,	387	\$ (5,080)	837	\$	(41,157) \$	251	\$ 40,088

# 9. Share-Based Compensation Plans

The Company has share-based compensation plans under which the Company grants restricted stock units (RSUs) and performance share units (PSUs) to certain management level employees. In addition, employees and non-employee directors may be granted options to purchase shares of Company common stock at the fair market value at the time of grant.

The following table provides the amounts of share-based compensation cost recorded in the Condensed Consolidated Statement of Income:

	 Three Mont Marc	ded
(\$ in millions)	2017	 2016
Pretax share-based compensation expense	\$ 74	\$ 68
Income tax benefit	(22)	(20)
Total share-based compensation expense, net of taxes	\$ 52	\$ 48

During the first three months of 2017 and 2016, the Company granted 86 thousand RSUs with a weighted-average grant date fair value of \$64.20 per RSU and 133 thousand RSUs with a weighted-average grant date fair value of \$48.83 per RSU, respectively. During the first three months of 2017 and 2016, the Company granted 190 thousand stock options with a weighted-average exercise price of \$64.20 per option and 74 thousand stock options with a weighted-average exercise price of \$48.83 per option, respectively. The weighted-average fair value of options granted for the first three months of 2017 and 2016 was \$7.89 and \$5.76 per option, respectively, and was determined using the following assumptions:

	Three Months End	led March 31,
	2017	2016
Expected dividend yield	3.7%	3.8%
Risk-free interest rate	2.0%	1.3%
Expected volatility	19.7%	21.0%
Expected life (years)	6.2	6.2

At March 31, 2017, there was \$681 million of total pretax unrecognized compensation expense related to nonvested stock options, RSU and PSU awards which will be recognized over a weighted-average period of 2.4 years. The Company typically communicates the value of annual share-based compensation awards to employees during the first quarter, but the related share amounts are not established and communicated until early May. Therefore, while the number of RSU and stock option grants disclosed above do not reflect any amounts relating to the annual grants, share-based compensation costs for the first quarter of 2017 and 2016 and unrecognized compensation expense at March 31, 2017 reflect an impact relating to the awards communicated to employees. For segment reporting, share-based compensation costs are unallocated expenses.

## 10. Pension and Other Postretirement Benefit Plans

The Company has defined benefit pension plans covering eligible employees in the United States and in certain of its international subsidiaries. The net periodic benefit cost (credit) of such plans consisted of the following components:

				Three Mo Mai	nths E rch 31			
	_		2017			2	2016	
(\$ in millions)		U.S.	Interr	national		U.S.	Interna	tional
Service cost	\$	77	\$	61	\$	73	\$	58
Interest cost		113		41		113		52
Expected return on plan assets		(218)		(94)		(210)		(95)
Amortization of unrecognized prior service credit		(13)		(2)		(14)		(3)
Net loss amortization		44		23		29		22
Termination benefits		5		1		4		_
Curtailments		3		_		_		1
	\$	11	\$	30	\$	(5)	\$	35

The Company provides medical benefits, principally to its eligible U.S. retirees and similar benefits to their dependents, through its other postretirement benefit plans. The net cost (credit) of such plans consisted of the following components:

			e Months Ender March 31,		
(\$ in millions)	2	2017		2016	
Service cost	\$	14	\$	13	
Interest cost		20		21	
Expected return on plan assets		(19)		(35)	
Amortization of unrecognized prior service credit		(25)		(26)	
Termination benefits		1		1	
Curtailments		(3)		(1)	
	\$	(12)	\$	(27)	

In connection with restructuring actions (see Note 3), termination charges were recorded on pension and other postretirement benefit plans related to expanded eligibility for certain employees exiting Merck. Also, in connection with these restructuring actions, curtailments were recorded on pension and other postretirement benefit plans as reflected in the tables above.

## 11. Other (Income) Expense, Net

Other (income) expense, net, consisted of:

	 Three Montl March	
(\$ in millions)	2017	2016
Interest income	\$ (97)	\$ (79)
Interest expense	182	172
Exchange (gains) losses	(8)	38
Equity loss (income) from affiliates	13	(34)
Other, net	(32)	(49)
	\$ 58	\$ 48

The change in equity loss (income) from affiliates in the first quarter of 2017 as compared with the first quarter of 2016 was driven primarily by certain research investment funds, which generated equity losses in the first quarter of 2017 compared with equity income in the first quarter of 2016, as well as by the termination of the SPMSD joint venture on December 31, 2016.

Interest paid for the three months ended March 31, 2017 and 2016 was \$162 million and \$160 million, respectively.

## 12. Taxes on Income

The effective income tax rates of 22.3% and 30.4% for the first quarter of 2017 and 2016, respectively, reflect the impacts of acquisition and divestiture-related costs and restructuring costs, partially offset by the beneficial impact of foreign earnings.

The Company is under examination by numerous tax authorities in various jurisdictions globally. The ultimate finalization of the Company's examinations with relevant taxing authorities can include formal administrative and legal proceedings, which could have a significant impact on the timing of the reversal of unrecognized tax benefits. The Company believes that its reserves for uncertain tax positions are adequate to cover existing risks or exposures. However, there is one item that is currently under discussion with the Internal Revenue Service relating to the 2006 through 2008 examination. The Company has concluded that its position should be sustained upon audit. However, if this item were to result in an unfavorable outcome or settlement, it could have a material adverse impact on the Company's financial position, liquidity and results of operations.

# 13. Earnings Per Share

The calculations of earnings per share are as follows:

	 Three Mor Mare	nths Ei	
(\$ and shares in millions except per share amounts)	2017		2016
Net income attributable to Merck & Co., Inc.	\$ 1,551	\$	1,125
Average common shares outstanding	2,745		2,774
Common shares issuable (1)	21		21
Average common shares outstanding assuming dilution	2,766		2,795
Basic earnings per common share attributable to Merck & Co., Inc. common shareholders	\$ 0.56	\$	0.41
Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	\$ 0.56	\$	0.40

<sup>(1)</sup> Issuable primarily under share-based compensation plans.

For the three months ended March 31, 2017 and 2016, 2 million and 10 million, respectively, of common shares issuable under share-based compensation plans were excluded from the computation of earnings per common share assuming dilution because the effect would have been antidilutive.

## 14. Other Comprehensive Income (Loss)

Changes in AOCI by component are as follows:

	Three Months Ended March 31,												
(\$ in millions)		rivatives	Investments		Employee Benefit Plans		Cumulative Translation Adjustment		C	Comprehensive Income (Loss)			
Balance January 1, 2016, net of taxes	\$	404	\$	41	\$	(2,407)	\$	(2,186)	\$	(4,148)			
Other comprehensive income (loss) before reclassification adjustments, pretax		(167)		54		(35)		99		(49)			
Tax		58		16		(1)		22		95			
Other comprehensive income (loss) before reclassification adjustments, net of taxes		(109)		70		(36)		121		46			
Reclassification adjustments, pretax		(143) (1)		(11) (2)	)	7 (3)		_		(147)			
Tax		50		4		1		_		55			
Reclassification adjustments, net of taxes		(93)		(7)		8		_		(92)			
Other comprehensive income (loss), net of taxes		(202)		63		(28)		121		(46)			
Balance March 31, 2016, net of taxes	\$	202	\$	104	\$	(2,435)	\$	(2,065)	\$	(4,194)			
Balance January 1, 2017, net of taxes	\$	338	\$	(3)	\$	(3,206)	\$	(2,355)	\$	(5,226)			
Other comprehensive income (loss) before reclassification adjustments, pretax		(263)		87		(4)		263		83			
Tax		92		(7)		9		46		140			
Other comprehensive income (loss) before reclassification adjustments, net of taxes		(171)		80		5		309		223			
Reclassification adjustments, pretax		(95) (1)		(57) <sup>(2)</sup>	)	28 (3)		_		(124)			
Tax		34		20		(7)		_		47			
Reclassification adjustments, net of taxes		(61)		(37)		21		_		(77)			
Other comprehensive income (loss), net of taxes		(232)		43		26		309		146			
Balance March 31, 2017, net of taxes	\$	106	\$	40	\$	(3,180)	\$	(2,046)	\$	(5,080)			

<sup>(1)</sup> Relates to foreign currency cash flow hedges that were reclassified from AOCI to Sales.

# 15. Segment Reporting

The Company's operations are principally managed on a products basis and include the Pharmaceutical, Animal Health, Healthcare Services and Alliances operating segments. The Animal Health, Healthcare Services and Alliances segments are not material for separate reporting.

The Pharmaceutical segment includes human health pharmaceutical and vaccine products. Human health pharmaceutical products consist of therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. The Company sells these human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions. Vaccine products consist of preventive pediatric, adolescent and adult vaccines, primarily administered at physician offices. The Company sells these human health vaccines primarily to physicians, wholesalers, physician distributors and government entities. A large component of pediatric and adolescent vaccine sales are made to the U.S. Centers for Disease Control and Prevention Vaccines for Children program, which is funded by the U.S. government. Additionally, the Company sells vaccines to the Federal government for placement into vaccine stockpiles. Sales of vaccines in most major European markets were marketed through the Company's SPMSD joint venture until its termination on December 31, 2016.

The Company also has animal health operations that discover, develop, manufacture and market animal health products, including vaccines, which the Company sells to veterinarians, distributors and animal producers. The Company's Healthcare Services segment provides services and solutions that focus on engagement, health analytics and clinical services to improve the value of care delivered to patients.

<sup>(2)</sup> Represents net realized (gains) losses on the sales of available-for-sale investments that were reclassified from AOCI to Other (income) expense, net .

<sup>(3)</sup> Includes net amortization of prior service cost and actuarial gains and losses included in net periodic benefit cost (see Note 10).

Sales of the Company's products were as follows:

	Three Month March	s Ended 31,	
(\$ in millions)	2017	2016	
Primary Care and Women's Health			
Cardiovascular			
Zetia	\$ 334 \$	61:	
Vytorin	241	27	
Liptruzet	49	2	
Adempas	84	3	
Diabetes			
Januvia	839	90	
Janumet	496	50	
General Medicine and Women's Health			
Implanon/Nexplanon	170	13	
NuvaRing	160	17	
Follistim AQ	81	Ģ	
lospital and Specialty	**		
Hepatitis			
Zepatier	378	4	
HIV	310		
Isentress	305	34	
Hospital Acute Care	300	,	
Bridion	148	9	
Noxafil	141	14	
Invanz	136	1	
Cancidas	121	1:	
Cubicin	96	2	
Primaxin	62	2.	
Immunology	02		
Remicade	229	34	
Simponi	184	13	
ncology	104	10	
Keytruda	584	24	
Emend			
Temodar	133	12	
Diversified Brands	66	(	
Respiratory			
Singulair	107	2	
Nasonex	186	23	
Dulera	139	2:	
Other	82	1	
Cozaar/Hyzaar			
Arcoxia	112	12	
Fosamax	103	1	
	61	•	
accines <sup>(1)</sup> Gardasil/Gardasil 9			
ProQuad/M-M-R II /Varivax	532	3′	
RotaTeq	355	3:	
Pneumovax 23	224	1	
Zostavax	163	1	
	154	10	
Other pharmaceutical (2)	1,037	1,08	
Total Pharmaceutical segment sales	8,185	8,10	
Other segment sales (3)	1,033	90	

Total segment sales	9,218	9,009
Other (4)	216	303
	\$ 9,434	\$ 9,312

<sup>(1)</sup> On December 31, 2016, Merck and Sanofi Pasteur terminated their equally-owned joint venture, SPMSD, which marketed vaccines in most major European markets. Accordingly, vaccine sales in 2017 include sales in the European markets that were previously part of SPMSD. Amounts for 2016 do not include sales of vaccines sold through SPMSD, the results of which are reflected in equity income from affiliates which is included in Other (income) expense, net. Amounts for 2016 do, however, include supply sales to SPMSD.

- (2) Other pharmaceutical primarily reflects sales of other human health pharmaceutical products, including products within the franchises not listed separately
- (3) Represents the non-reportable segments of Animal Health, Healthcare Services and Alliances.
- (4) Other is primarily comprised of miscellaneous corporate revenues, including revenue hedging activities, as well as third-party manufacturing sales. Other in the first quarter of 2017 and 2016 also includes \$50 million and \$75 million, respectively, related to the sale of the marketing rights to certain products.

A reconciliation of segment profits to *Income before taxes* is as follows:

		nths Ended rch 31,	
(\$ in millions)	2017	2016	
Segment profits:			
Pharmaceutical segment	\$ 5,180	\$ 5,117	
Other segments	452	355	
Total segment profits	5,632	5,472	
Other profits	142	227	
Unallocated:			
Interest income	97	79	
Interest expense	(182)	(172)	
Equity income from affiliates	(12)	20	
Depreciation and amortization	(370)	(428)	
Research and development	(1,599)	(1,373)	
Amortization of purchase accounting adjustments	(778)	(1,133)	
Restructuring costs	(151)	(91)	
Other unallocated, net	(776)	(977)	
	\$ 2,003	\$ 1,624	

Segment profits are comprised of segment sales less standard costs and certain operating expenses directly incurred by the segments. For internal management reporting presented to the chief operating decision maker, Merck does not allocate materials and production costs, other than standard costs, the majority of research and development expenses or general and administrative expenses, nor the cost of financing these activities. Separate divisions maintain responsibility for monitoring and managing these costs, including depreciation related to fixed assets utilized by these divisions and, therefore, they are not included in segment profits. In addition, costs related to restructuring activities, as well as the amortization of purchase accounting adjustments are not allocated to segments.

Other profits are primarily comprised of miscellaneous corporate profits, as well as operating profits related to third-party manufacturing sales.

Other unallocated, net includes expenses from corporate and manufacturing cost centers, goodwill and intangible asset impairment charges, gains or losses on sales of businesses, expense or income related to changes in the estimated fair value of contingent consideration, and other miscellaneous income or expense items.

#### Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

#### **Operating Results**

Sales

Worldwide sales were \$9.4 billion for the first quarter of 2017, an increase of 1% compared with the first quarter of 2016. Foreign exchange unfavorably affected global sales performance by 2% in the first quarter of 2017. Sales growth was driven primarily by higher sales in the oncology franchise largely from *Keytruda* (pembrolizumab), the ongoing launch of hepatitis C virus (HCV) treatment *Zepatier* (elbasvir and grazoprevir), and growth in vaccine products including *Gardasil* (Human Papillomavirus Quadrivalent [Types 6, 11, 16 and 18] Vaccine, Recombinant)/ *Gardasil* 9 (Human Papillomavirus 9-valent Vaccine, Recombinant) and *Pneumovax* 23 (pneumococcal vaccine polyvalent). Sales in the first quarter of 2017 benefited from the December 31, 2016 termination of Sanofi Pasteur MSD (SPMSD), a joint venture between Merck and Sanofi Pasteur, which marketed vaccines in most major European markets. In the first quarter of 2017, Merck began recording vaccine sales in the markets that were previously part of the SPMSD joint venture. Also contributing to sales growth in the first quarter of 2017 were higher sales of *Bridion* (sugammadex) Injection, Adempas (riociguat), and Animal Health products, particularly *Bravecto* (fluralaner). Partially offsetting revenue growth in the first quarter of 2017 were declines attributable to the effects of generic and biosimilar competition for certain products including *Zetia* (ezetimibe), which lost U.S. market exclusivity in December 2016, as well as *Cubicin* (daptomycin for injection), *Remicade* (infliximab), as well as lower sales of products within Diversified Brands including *Nasonex* (mometasone furoate monohydrate) and *Singulair* (montelukast). Declines in the diabetes franchise of *Januvia* (sitagliptin) and *Janumet* (sitagliptin/metformin HCl) also offset revenue growth in the first quarter.

Global efforts toward health care cost containment continue to exert pressure on product pricing and market access worldwide. In the United States, health care reform is contributing to an increase in the number of patients in the Medicaid program under which sales of pharmaceutical products are subject to substantial rebates. In many international markets, government-mandated pricing actions have reduced prices of generic and patented drugs. In addition, other austerity measures negatively affected the Company's revenue performance in the first quarter of 2017. The Company anticipates these pricing actions and other austerity measures will continue to negatively affect revenue performance for the remainder of 2017.

	Three Moi Mar	nths Ended ch 31,
(\$ in millions)	2017	2016
Primary Care and Women's Health		
Cardiovascular		
Zetia	\$ 334	\$ 61:
Vytorin	241	27
Liptruzet	49	2
Adempas	84	3
Diabetes		
Januvia	839	90
Janumet	496	50
General Medicine and Women's Health		
Implanon/Nexplanon	170	13
NuvaRing	160	17
Follistim AQ	81	ç
Hospital and Specialty	· · · · · · · · · · · · · · · · · · ·	
Hepatitis		
Zepatier	378	4
HIV	570	
Isentress	305	34
Hospital Acute Care	300	,
Bridion	148	Ģ
Noxafil	141	14
Invanz	136	11
Cancidas	121	13
Cubicin	96	29
Primaxin	62	7
Immunology	02	
Remicade	229	34
Simponi	184	18
Oncology	184	17
Keytruda	584	2
Emend		24
Temodar	133	12
Diversified Brands	66	(
Respiratory		
Singulair	107	20
Nasonex	186	23
Dulera	139	22
Other	82	11
Cozaar/Hyzaar		
Arcoxia	112	12
Fosamax	103	11
	61	7
Vaccines <sup>(1)</sup> Gardasil/Gardasil 9		
	532	37
ProQuad/M-M-R II /Varivax	355	3:
RotaTeq	224	18
Pneumovax 23	163	10
Zostavax	154	12
Other pharmaceutical (2)  Total Pharmaceutical segment sales	1,037	1,08

Other segment sales (3)	1,033	 905
Total segment sales	9,218	9,009
Other (4)	216	303
	\$ 9,434	\$ 9,312

<sup>(1)</sup> On December 31, 2016, Merck and Sanofi Pasteur terminated their equally-owned joint venture, SPMSD, which marketed vaccines in most major European markets. Accordingly, vaccine sales in 2017 include sales in the European markets that were previously part of SPMSD. Amounts for 2016 do not include sales of vaccines sold through SPMSD, the results of which are reflected in equity income from affiliates which is included in Other (income) expense, net . Amounts for 2016 do, however, include supply sales to SPMSD.

- (2) Other pharmaceutical primarily reflects sales of other human health pharmaceutical products, including products within the franchises not listed separately.
- ${\it (3)}\ \ Represents\ the\ non-reportable\ segments\ of\ Animal\ Health,\ Health care\ Services\ and\ Alliances.$
- (4) Other is primarily comprised of miscellaneous corporate revenues, including revenue hedging activities, as well as third-party manufacturing sales. Other in the first quarter of 2017 and 2016 also includes \$50 million and \$75 million, respectively, related to the sale of the marketing rights to certain products.

Product sales are recorded net of the provision for discounts, which includes indirect customer discounts that occur when a contracted customer purchases directly through an intermediary wholesale purchaser, known as chargebacks, as well as indirectly in the form of rebates owed based upon definitive contractual agreements or legal requirements with private sector and public sector (Medicaid and Medicare Part D) benefit providers, after the final dispensing of the product by a pharmacy to a benefit plan participant. These discounts, in the aggregate, reduced U.S. sales by \$2.5 billion and \$2.1 billion for the three months ended March 31, 2017 and 2016, respectively. Inventory levels at key U.S. wholesalers for each of the Company's major pharmaceutical products are generally less than one month.

#### **Pharmaceutical Segment**

Primary Care and Women's Health

#### Cardiovascular

Combined global sales of *Zetia* (marketed in most countries outside the United States as *Ezetrol*), *Vytorin* (ezetimibe and simvastatin) (marketed outside the United States as *Inegy*), and *Atozet* (ezetimibe and atorvastatin) (marketed in certain countries outside of the United States), medicines for lowering LDL cholesterol, were \$624 million in the first quarter of 2017, a decline of 32% compared with the first quarter of 2016 including a 1% unfavorable effect from foreign exchange. The sales decline primarily reflects lower volumes of *Zetia* in the United States from generic competition. By agreement, a generic manufacturer launched a generic version of *Zetia* in the United States in December 2016 and the Company is experiencing a rapid and substantial decline in U.S. *Zetia* sales. The Company anticipates the decline will accelerate in future periods. The U.S. patent and exclusivity periods for *Zetia* and *Vytorin* expired in April 2017 and the Company anticipates declines in U.S. *Zetia* and *Vytorin* sales. U.S. sales of *Zetia* and *Vytorin* were \$111 million and \$90 million, respectively, for the first quarter of 2017. The Company has market exclusivity in major European markets for *Ezetrol* until April 2018 and for *Inegy* until April 2019.

Pursuant to a collaboration with Bayer AG (Bayer), Merck acquired lead commercial rights for Adempas, a novel cardiovascular drug for the treatment of pulmonary arterial hypertension, in countries outside the Americas while Bayer has lead rights in the Americas, including the United States. In 2016, Merck began promoting and distributing Adempas in Europe. Transition from Bayer in other Merck territories will continue in 2017. Merck recorded sales of \$84 million and \$33 million for Adempas in the first quarter of 2017 and 2016, respectively, which includes sales in Merck's marketing territories, as well as Merck's share of profits from the sale of Adempas in Bayer's marketing territories.

## Diabetes

Worldwide combined sales of *Januvia* and *Janumet*, medicines that help lower blood sugar levels in adults with type 2 diabetes, were \$1.3 billion in the first quarter of 2017, a decline of 5% compared with the first quarter of 2016. The decline primarily reflects lower sales in the United States driven by the timing of customer purchases, as well as pricing pressures that were partially offset by higher demand. Volume and pricing declines in Europe and pricing declines in Japan also contributed to the sales decrease. These declines were partially offset by volume growth in Asia Pacific and Canada and price and volume growth in Latin America.

In April 2017, Merck announced that the U.S. Food and Drug Administration (FDA) issued a Complete Response Letter (CRL) regarding Merck's supplemental New Drug Applications for *Januvia*, *Janumet* and *Janumet* XR (sitagliptin and metformin HCl extended-release). With these applications, Merck is seeking to include data from TECOS (Trial Evaluating Cardiovascular Outcomes with Sitagliptin) in the prescribing information of sitagliptin-containing medicines. Merck is reviewing the letter and will discuss next steps with the FDA.

## General Medicine and Women's Health

Worldwide sales of *Implanon/Nexplanon* (etonogestrel implant), single-rod subdermal contraceptive implants, grew 27% to \$170 million in the first quarter of 2017 compared with the first quarter of 2016 primarily reflecting higher pricing, as well as volume growth in the United States. Foreign exchange unfavorably affected global sales performance by 1% for the first quarter of 2017.

Worldwide sales of *NuvaRing* (etonogestrel/ethinyl estradiol vaginal ring), a vaginal contraceptive product, were \$160 million in the first quarter of 2017, a decrease of 9% compared with the first quarter of 2016, driven largely by lower sales in the United States reflecting the timing of customer purchases. In August 2016, the U.S. District Court ruled that the Company's delivery system patent for *NuvaRing* is invalid. The Company is appealing this verdict to the U.S. Court of Appeals for the Federal Circuit. However, given the U.S. District Court's decision, there may be generic entrants into the U.S. market in advance of the April 2018 patent expiration. If this should occur, the Company anticipates a significant decline in U.S. *NuvaRing* sales thereafter. U.S. sales of *NuvaRing* were \$113 million for the first quarter of 2017. As a result of the unfavorable U.S. District Court decision, the Company evaluated the intangible asset related to *NuvaRing* for impairment and concluded that it was not impaired. The intangible asset value for *NuvaRing* was \$274 million at March 31, 2017.

Global sales of Follistim AQ (follitropin beta injection) (marketed in most countries outside the United States as Puregon), a fertility treatment, were \$81 million in the first quarter of 2017, a decline of 14% compared with the first quarter of

2016 including a 1% unfavorable effect from foreign exchange. The sales decline reflects pricing pressures and lower volumes in the United States.

#### Hospital and Specialty

# Hepatitis

Global sales of *Zepatier* were \$378 million in the first quarter of 2017 compared with \$50 million in the first quarter of 2016 driven by ongoing launches globally. In January 2016, the FDA approved *Zepatier* for the treatment of chronic hepatitis C virus (HCV) genotype (GT) 1 or GT4 infection in adults. *Zepatier* is recommended for use with ribavirin in certain patient populations. *Zepatier* became available in the United States in February 2016. *Zepatier* was approved by the European Commission (EC) in July 2016 and became available in European markets in late November 2016. Launches are expected to continue across the European Union (EU) in 2017. The Company is also launching *Zepatier* in Japan and in other international markets. Sales in the United States in the first quarter of 2017 reflect an approximately \$40 million favorable adjustment to rebate accruals due to mix of business.

## HIV

Global sales of *Isentress* (raltegravir), an HIV integrase inhibitor for use in combination with other antiretroviral agents for the treatment of HIV-1 infection, were \$305 million in the first quarter of 2017, a decline of 10% compared with the first quarter of 2016. The decline reflects lower demand in the United States and Europe due to competitive pressures, as well as lower volumes in Brazil.

#### Hospital Acute Care

Worldwide sales of *Bridion*, for the reversal of two types of neuromuscular blocking agents used during surgery, were \$148 million in the first quarter of 2017, an increase of 63% compared with the first quarter of 2016 including a 1% unfavorable effect from foreign exchange. Sales growth reflects volume growth in most markets, particularly in the United States.

Worldwide sales of *Noxafil* (posaconazole), for the prevention of invasive fungal infections, were \$141 million in the first quarter of 2017, a decline of 3% compared with the first quarter of 2016 reflecting a 3% unfavorable effect from foreign exchange.

Global sales of *Invanz* (ertapenem sodium), for the treatment of certain infections, were \$136 million in the first quarter of 2017, an increase of 20% compared with the first quarter of 2016 including a 1% favorable effect from foreign exchange. Sales growth primarily reflects higher pricing in the United States and price and volume growth in Latin America. The Company will lose U.S. patent protection for *Invanz* in November 2017 and the Company anticipates a significant decline in U.S. *Invanz* sales thereafter. U.S. sales of *Invanz* were \$82 million in the first quarter of 2017.

Global sales of *Cancidas* (caspofungin acetate), an anti-fungal product, were \$121 million in the first quarter of 2017, a decline of 9% compared with the first quarter of 2016 including a 3% unfavorable effect from foreign exchange. The decline was driven primarily by lower sales in certain emerging markets, as well as lower pricing in Europe. The EU compound patent for *Cancidas* expired in April 2017 and the Company anticipates a decline in *Cancidas* sales in those European markets thereafter. Sales of *Cancidas* in these European markets were \$68 million in the first quarter of 2017.

Sales of *Cubicin*, an I.V. antibiotic for complicated skin and skin structure infections or bacteremia when caused by designated susceptible organisms, were \$96 million in the first quarter of 2017, a decline of 67% compared with the first quarter of 2016. The U.S. composition patent for *Cubicin* expired in June 2016. Accordingly, the Company is experiencing a rapid and substantial decline in U.S. *Cubicin* sales and expects the decline to continue. The Company anticipates it will lose market exclusivity for *Cubicin* in Europe in mid-2017.

In October 2016, Merck announced that the FDA approved Zinplava Injection 25 mg/mL. Zinplava is indicated to reduce recurrence of Clostridium difficile infection (CDI) in patients 18 years of age or older who are receiving antibacterial drug treatment of CDI and are at high risk for CDI recurrence. Zinplava became available in the United States in February 2017. Zinplava was approved by the EC in January 2017 and became available in the EU in March 2017.

# Immunology

Sales of *Remicade*, a treatment for inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), were \$229 million in the first quarter of 2017, a decline of 34% compared with the first quarter of 2016. Foreign exchange unfavorably affected sales performance by 3% in the first quarter of 2017. The Company lost market exclusivity for *Remicade* in major European markets in 2015 and no longer has market exclusivity in any of its marketing territories. The Company is experiencing pricing and volume declines in these markets as a result of biosimilar competition and expects the declines to continue.

Sales of *Simponi* (golimumab), a once-monthly subcutaneous treatment for certain inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), were \$184 million in the first quarter of 2017, a decline of 2% compared with

the first quarter of 2016 including a 4% unfavorable effect from foreign exchange. Excluding the unfavorable effect of foreign exchange, sales performance was driven primarily by higher volumes.

## Oncology

Global sales of *Keytruda*, an anti-PD-1 (programmed death receptor-1) therapy, were \$584 million in the first quarter of 2017 compared with \$249 million in the first quarter of 2016 driven by volume growth in all markets, particularly in the United States, as the Company continues to launch *Keytruda* with new indications.

In October 2016, Merck announced that the FDA approved *Keytruda* for the first-line treatment of patients with non-small-cell lung cancer (NSCLC) whose tumors have high PD-L1 expression (tumor proportion score [TPS] of 50% or more) as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations. With this new indication, *Keytruda* is now the only anti-PD-1 therapy to be approved in the first-line treatment setting for these patients. In addition, the FDA approved a labeling update to include data from KEYNOTE-010 in the second-line or greater treatment setting for patients with metastatic NSCLC whose tumors express PD-L1 (TPS of 1% or more) as determined by an FDA-approved test, with disease progression on or after platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving *Keytruda*. In December 2016, *Keytruda* was approved in Japan for the treatment of certain patients with PD-L1-positive unresectable advanced/recurrent NSCLC in the first- and second-line treatment settings. Additionally, in January 2017, the EC approved *Keytruda* for the first-line treatment of metastatic NSCLC in adults whose tumors have high PD-L1 expression (TPS of 50% or more) with no EGFR or ALK positive tumor mutations.

In August 2016, Merck announced that the FDA approved *Keytruda* for the treatment of patients with recurrent or metastatic head and neck squamous cell carcinoma (HNSCC) with disease progression on or after platinum-containing chemotherapy.

In March 2017, the FDA approved *Keytruda* for the treatment of adult and pediatric patients with classical Hodgkin lymphoma (cHL) refractory to treatment, or who have relapsed after three or more prior lines of therapy. Also in May 2017, the EC approved *Keytruda* for the treatment of adult patients with relapsed or refractory cHL who have failed autologous stem cell transplant and brentuximab vedotin, or who are transplant-ineligible and have failed brentuximab vedotin.

*Keytruda* is now approved in the United States and in the EU for the treatment of previously untreated metastatic NSCLC in patients whose tumors express high levels of PD-L1 and previously treated metastatic NSCLC in patients whose tumors express PD-L1, as well as for the treatment of melanoma and previously treated cHL. *Keytruda* is also approved in the United States for previously treated recurrent or metastatic HNSCC.

Merck has four sBLAs under Priority Review with the FDA for *Keytruda* including: for use in combination with carboplatin and pemetrexed for the first-line treatment of patients with metastatic or advanced non-squamous NSCLC regardless of PD-L1 expression; for the treatment of previously treated patients with advanced microsatellite instability-high (MSI-H) cancer; for the first-line treatment of cisplatin-ineligible patients with locally advanced or metastatic urothelial cancer, including most bladder cancers; and for the second-line treatment of patients with locally advanced or metastatic urothelial cancer with disease progression on or after platinum-containing chemotherapy. The Company plans additional regulatory filings in the United States and other countries. The *Keytruda* clinical development program includes studies across a broad range of cancer types (see "Research and Development" below). Pursuant to the settlement of worldwide patent infringement litigation related to *Keytruda* (see Note 7 to the condensed consolidated financial statements), the Company will pay royalties of 6.5% on net sales of *Keytruda* in 2017 through 2023; and 2.5% on net sales of *Keytruda* in 2024 through 2026.

Global sales of *Emend* (aprepitant), for the prevention of chemotherapy-induced and post-operative nausea and vomiting, were \$133 million in the first quarter of 2017, an increase of 6% compared with the first quarter of 2016, driven primarily by volume growth in Japan and higher pricing in the United States, partially offset by volume declines in Europe.

# Diversified Brands

Merck's diversified brands include human health pharmaceutical products that are approaching the expiration of their marketing exclusivity or are no longer protected by patents in developed markets, but continue to be a core part of the Company's offering in other markets around the world.

# Respiratory

Worldwide sales of *Singulair*, a once-a-day oral medicine for the chronic treatment of asthma and for the relief of symptoms of allergic rhinitis, were \$186 million in the first quarter of 2017, a decline of 22% compared with the first quarter of 2016 including a 1% unfavorable effect from foreign exchange. The sales decline was largely driven by lower volumes in Japan. The patents that provided market exclusivity for *Singulair* in Japan expired in February and October of 2016. As a result, the Company is experiencing a significant and rapid decline in *Singulair* sales in Japan and expects the decline to continue. The Company no longer has market exclusivity for *Singulair* in any major market.

Global sales of *Nasonex*, an inhaled nasal corticosteroid for the treatment of nasal allergy symptoms, declined 40% to \$139 million in the first quarter of 2017 compared with the first quarter of 2016. Foreign exchange favorably affected global sales performance by 1% in the first quarter of 2017. The sales decline was driven by lower volumes in the United States from ongoing generic competition.

Global sales of *Dulera* Inhalation Aerosol (mometasone furoate/formoterol fumarate dihydrate), a combination medicine for the treatment of asthma, were \$82 million in the first quarter of 2017, a decline of 27% compared with the first quarter of 2016, driven by lower sales in the United States reflecting competitive pricing pressures.

## Other

Global sales of *Cozaar* (losartan potassium) and its companion agent *Hyzaar* (losartan potassium and hydrochlorothiazide) (a combination of *Cozaar* and hydrochlorothiazide), treatments for hypertension, were \$112 million in the first quarter of 2017 a decline of 11% compared with the first quarter of 2016. Foreign exchange unfavorably affected global sales performance by 2% in the first quarter of 2017. The patents that provided market exclusivity for *Cozaar* and *Hyzaar* in the United States and in most major international markets have expired. Accordingly, the Company is experiencing declines in *Cozaar* and *Hyzaar* sales and expects the declines to continue.

#### Vaccines

On December 31, 2016, Merck and Sanofi Pasteur S.A. terminated their equally-owned joint venture, SPMSD, which developed and marketed vaccines in Europe. Accordingly, vaccine sales in 2017 include sales of Merck vaccines in the European markets that were previously part of the SPMSD joint venture, whereas sales in periods prior to 2017 do not. Prior to 2017, vaccine sales in these European markets were sold through the SPMSD joint venture, the results of which are reflected in equity income from affiliates included in *Other (income) expense, net* (see Note 11 to the condensed consolidated financial statements). Supply sales to SPMSD, however, are included in vaccine sales in periods prior to 2017. Incremental vaccine sales in the first quarter of 2017 resulting from the termination of the SPMSD joint venture were approximately \$65 million, of which approximately \$50 million relate to *Gardasil/Gardasil* 9.

Merck's sales of *Gardasil/Gardasil* 9, vaccines to help prevent certain cancers and diseases caused by certain types of human papillomavirus (HPV), were \$532 million in the first quarter of 2017, an increase of 41% compared with the first quarter of 2016. Sales growth was driven primarily by higher sales in the United States, largely reflecting the timing of public sector purchases, demand and pricing, as well as higher sales in Europe resulting from the termination of the SPMSD joint venture as noted above, and higher demand in the Asia Pacific region. In October 2016, the FDA approved a 2-dose vaccination regimen for *Gardasil* 9, for use in girls and boys 9 through 14 years of age, and the U.S. Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices voted to recommend the 2-dose vaccination regimen for certain 9 through 14 year olds. The Company anticipates the transition from a 3-dose vaccine regimen to a 2-dose vaccination regimen will have an unfavorable effect on sales of *Gardasil* 9 during the period of transition.

Merck's sales of *ProQuad* (Measles, Mumps, Rubella and Varicella Virus Vaccine Live), a pediatric combination vaccine to help protect against measles, mumps, rubella and varicella, were \$103 million in the first quarter of 2017 compared with \$122 million in the first quarter of 2016 driven primarily by the effects of public sector purchasing in the United States. Merck's sales of *M-M-R* II (Measles, Mumps and Rubella Virus Vaccine Live), a vaccine to help protect against measles, mumps and rubella, were \$92 million for the first quarter of 2017 compared with \$76 million for the first quarter of 2016 driven primarily by higher sales in Europe resulting from the termination of the SPMSD joint venture and volume growth in certain emerging markets, particularly in Turkey. Merck's sales of *Varivax* (Varicella Virus Vaccine Live), a vaccine to help prevent chickenpox (varicella), were \$159 million for the first quarter of 2017 compared with \$158 million for the first quarter of 2016.

Merck's sales of *RotaTeq* (Rotavirus Vaccine, Live Oral, Pentavalent), a vaccine to help protect against rotavirus gastroenteritis in infants and children, were \$224 million in the first quarter of 2017, an increase of 19% compared with the first quarter of 2016, primarily reflecting the timing of public sector purchases in the United States, as well as higher sales in Europe resulting from the termination of the SPMSD joint venture.

Merck's sales of *Pneumovax* 23, a vaccine to help prevent pneumococcal disease, were \$163 million in the first quarter of 2017, an increase of 52% compared with the first quarter of 2016. Sales growth was driven primarily by higher demand in the United States, as well as in Japan.

Merck's sales of Zostavax (Zoster Vaccine Live), a vaccine to help prevent shingles (herpes zoster) in adults 50 years of age and older, were \$154 million in the first quarter of 2017, an increase of 23% compared with the first quarter of 2016 including a 1% favorable effect from foreign exchange. Sales growth was driven largely by volume growth in the Asia Pacific region.

# Other Segments

The Company's other segments are the Animal Health, Healthcare Services and Alliances segments, which are not material for separate reporting.

#### Animal Health

Animal Health includes pharmaceutical and vaccine products for the prevention, treatment and control of disease in all major farm and companion animal species. Animal Health sales are affected by competition and the frequent introduction of generic products. Global sales of Animal Health products totaled \$939 million for the first quarter of 2017, an increase of 13% compared with sales of \$829 million in the first quarter of 2016. Foreign exchange unfavorably affected global sales performance by 1% in the first quarter of 2017. Sales growth primarily reflects higher sales of companion animal products, driven by the *Bravecto* line of products that kill fleas and ticks in dogs and cats for up to 12 weeks, as well as ruminant, poultry and swine products.

In March 2017, Merck acquired a controlling interest in Vallée, a leading privately held producer of animal health products in Brazil (see Note 2 to the condensed consolidated financial statements).

## Costs, Expenses and Other

#### Materials and Production

Materials and production costs were \$3.0 billion for the first quarter of 2017, a decline of 16% compared with the same period of 2016. Costs in the first quarter of 2017 and 2016 include \$773 million and \$1.1 billion, respectively, of expenses for the amortization of intangible assets recorded in connection with business acquisitions. Additionally, costs in the first quarter of 2017 include a \$76 million intangible asset impairment charge related to a licensing agreement. Costs for the first quarter of 2016 also include an intangible asset impairment charge of \$252 million related to a marketed product (see Note 6 to the condensed consolidated financial statements). The Company may recognize additional non-cash impairment charges in the future related to intangible assets that were measured at fair value and capitalized in connection with business acquisitions and such charges could be material. Included in materials and production costs are expenses associated with restructuring activities which amounted to \$63 million and \$47 million in the first quarter of 2017 and 2016, respectively, including accelerated depreciation and asset write-offs related to the planned sale or closure of manufacturing facilities. Separation costs associated with manufacturing-related headcount reductions have been incurred and are reflected in *Restructuring costs* as discussed below.

Gross margin was 68.0% in the first quarter of 2017 compared with 61.6% in the first quarter of 2016. The improvement in gross margin was driven primarily by a lower net impact from the amortization of intangible assets, as well as intangible asset impairment and restructuring charges as noted above, which reduced gross margin by 9.8 percentage points in the first quarter of 2017 as compared with 15.4 percentage points in the first quarter of 2016. The gross margin improvement also reflects the favorable effects of foreign exchange and lower inventory write-offs.

#### Marketing and Administrative

Marketing and administrative expenses increased 4% to \$2.4 billion in the first quarter of 2017 compared with the first quarter of 2016. The increase was driven primarily by higher health care reform fee expenses, administrative costs, promotion and direct selling expenses, and acquisition and divestiture-related costs.

## Research and Development

Research and development (R&D) expenses were \$1.8 billion for the first quarter of 2017, an increase of 8% compared with the first quarter of 2016. The increase primarily reflects higher clinical development spending, partially offset by lower restructuring costs.

R&D expenses are comprised of the costs directly incurred by Merck Research Laboratories (MRL), the Company's research and development division that focuses on human health-related activities, which were approximately \$1.1 billion and \$980 million in the first quarter of 2017 and 2016, respectively. Also included in R&D expenses are costs incurred by other divisions in support of R&D activities, including depreciation, production and general and administrative, as well as licensing activity, and certain costs from operating segments, including the Pharmaceutical and Animal Health segments, which in the aggregate were approximately \$665 million and \$590 million for the first quarter of 2017 and 2016, respectively. In addition, R&D expenses include in-process research and development (IPR&D) impairment charges of \$25 million for the first quarter of 2016 (see Note 6 to the condensed consolidated financial statements). The Company may recognize additional non-cash impairment charges in the future related to the cancellation or delay of other pipeline programs that were measured at fair value and capitalized in connection with business acquisitions and such charges could be material. R&D expenses also reflect accelerated depreciation and asset abandonment costs associated with restructuring activities of \$55 million in the first quarter of 2016 (see Note 3 to the condensed consolidated financial statements).

#### Restructuring Costs

The Company incurs substantial costs for restructuring program activities related to Merck's productivity and cost reduction initiatives, as well as in connection with the integration of certain acquired businesses. In 2010 and 2013, the Company commenced actions under global restructuring programs designed to streamline its cost structure. The actions under these programs include the elimination of positions in sales, administrative and headquarters organizations, as well as the sale or closure of certain

manufacturing and research and development sites and the consolidation of office facilities. The Company also continues to reduce its global real estate footprint and improve the efficiency of its manufacturing and supply network. The non-facility related restructuring actions under these programs are substantially complete; the remaining activities primarily relate to ongoing facility rationalizations.

Restructuring costs, primarily representing separation and other related costs associated with these restructuring activities, were \$151 million and \$91 million for the first quarter of 2017 and 2016, respectively. Separation costs were incurred associated with actual headcount reductions, as well as estimated expenses under existing severance programs for headcount reductions that were probable and could be reasonably estimated. Merck eliminated approximately 545 positions and 470 positions in the first quarter of 2017 and 2016, respectively, related to these restructuring activities. Also included in restructuring costs are asset abandonment, shut-down and other related costs, as well as employee-related costs such as curtailment, settlement and termination charges associated with pension and other postretirement benefit plans and share-based compensation plan costs. For segment reporting, restructuring costs are unallocated expenses.

Additional costs associated with the Company's restructuring activities are included in *Materials and production*, *Marketing and administrative* and *Research and development* as discussed above. The Company recorded aggregate pretax costs of \$215 million and \$196 million in the first quarter of 2017 and 2016, respectively, related to restructuring program activities (see Note 3 to the condensed consolidated financial statements). The Company expects to substantially complete the remaining actions under the programs by the end of 2017 and incur approximately \$500 million of additional pretax costs.

#### Other (Income) Expense, Net

Other (income) expense, net was \$58 million of expense in the first quarter of 2017 compared with \$48 million of expense in the first quarter of 2016. For details on the components of *Other (income) expense, net*, see Note 11 to the condensed consolidated financial statements.

## Segment Profits

		Three Months Ended March 31,			
(\$ in millions)		2017		2016	
Pharmaceutical segment profits	\$	5,180	\$	5,117	
Other non-reportable segment profits		452		355	
Other		(3,629)		(3,848)	
Income before income taxes	\$	2,003	\$	1,624	

Segment profits are comprised of segment sales less standard costs, certain operating expenses directly incurred by the segment, components of equity income or loss from affiliates and certain depreciation and amortization expenses. For internal management reporting presented to the chief operating decision maker, Merck does not allocate materials and production costs, other than standard costs, the majority of research and development expenses or general and administrative expenses, nor the cost of financing these activities. Separate divisions maintain responsibility for monitoring and managing these costs, including depreciation related to fixed assets utilized by these divisions and, therefore, they are not included in segment profits. Also excluded from the determination of segment profits are acquisition and divestiture-related costs, including the amortization of purchase accounting adjustments, intangible asset impairment charges and changes in the estimated fair value of liabilities related to contingent consideration, restructuring costs, and a portion of equity income. Additionally, segment profits do not reflect other expenses from corporate and manufacturing cost centers and other miscellaneous income or expense. These unallocated items are reflected in "Other" in the above table. Also included in "Other" are miscellaneous corporate profits (losses), as well as operating profits (losses) related to third-party manufacturing sales.

Pharmaceutical segment profits grew 1% in the first quarter of 2017 compared with the first quarter of 2016 primarily reflecting higher sales and the favorable effects of product mix.

# Taxes on Income

The effective income tax rates of 22.3% and 30.4% for the first quarter of 2017 and 2016, respectively, reflect the impacts of acquisition and divestiture-related costs and restructuring costs, partially offset by the beneficial impact of foreign earnings.

The Company is under examination by numerous tax authorities in various jurisdictions globally. The ultimate finalization of the Company's examinations with relevant taxing authorities can include formal administrative and legal proceedings, which could have a significant impact on the timing of the reversal of unrecognized tax benefits. The Company believes that its reserves for uncertain tax positions are adequate to cover existing risks or exposures. However, there is one item that is currently under discussion with the Internal Revenue Service relating to the 2006 through 2008 examination. The Company

has concluded that its position should be sustained upon audit. However, if this item were to result in an unfavorable outcome or settlement, it could have a material adverse impact on the Company's financial position, liquidity and results of operations.

## Net Income and Earnings per Common Share

Net income attributable to Merck & Co., Inc. was \$1.6 billion for the first quarter of 2017 compared with \$1.1 billion for the first quarter of 2016. Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders (EPS) for the first quarter of 2017 were \$0.56 compared with \$0.40 in the first quarter of 2016.

#### Non-GAAP Income and Non-GAAP EPS

Non-GAAP income and non-GAAP EPS are alternative views of the Company's performance that Merck is providing because management believes this information enhances investors' understanding of the Company's results as it permits investors to understand how management assesses performance. Non-GAAP income and non-GAAP EPS exclude certain items because of the nature of these items and the impact that they have on the analysis of underlying business performance and trends. The excluded items (which should not be considered non-recurring) consist of acquisition and divestiture-related costs, restructuring costs and certain other items. These excluded items are significant components in understanding and assessing financial performance. Non-GAAP income and non-GAAP EPS are important internal measures for the Company. Senior management receives a monthly analysis of operating results that includes non-GAAP EPS. Management uses these measures internally for planning and forecasting purposes and to measure the performance of the Company along with other metrics. Senior management's annual compensation is derived in part using non-GAAP income and non-GAAP EPS. Since non-GAAP income and non-GAAP EPS are not measures determined in accordance with GAAP, they have no standardized meaning prescribed by GAAP and, therefore, may not be comparable to the calculation of similar measures of other companies. The information on non-GAAP income and non-GAAP EPS should be considered in addition to, but not as a substitute for or superior to, net income and EPS prepared in accordance with generally accepted accounting principles in the United States (GAAP).

A reconciliation between GAAP financial measures and non-GAAP financial measures is as follows:

	Three Months Ended March 31,			
(\$ in millions except per share amounts)	2017	,		2016
Pretax income as reported under GAAP	\$ 2,0	03	\$	1,624
Increase (decrease) for excluded items:				
Acquisition and divestiture-related costs	8	83		1,423
Restructuring costs	2	15		196
Other		(9)		_
	3,0	92		3,243
Taxes on income as reported under GAAP	4	47		494
Estimated tax benefit on excluded items (1)	2	03		252
	6	50		746
Non-GAAP net income	2,4	42		2,497
Less: Net income attributable to noncontrolling interests		5		5
Non-GAAP net income attributable to Merck & Co., Inc.	\$ 2,4	37	\$	2,492
EPS assuming dilution as reported under GAAP	\$ 0.	56	\$	0.40
EPS difference (2)	0.	32		0.49
Non-GAAP EPS assuming dilution	\$ 0.	88	\$	0.89

<sup>(1)</sup> The estimated tax impact on the excluded items is determined by applying the statutory rate of the originating territory of the non-GAAP adjustments.

## Acquisition and Divestiture-Related Costs

Non-GAAP income and non-GAAP EPS exclude the impact of certain amounts recorded in connection with business acquisitions and divestitures. These amounts include the amortization of intangible assets and amortization of purchase accounting adjustments to inventories, as well as intangible asset impairment charges and expense or income related to changes in the estimated fair value measurement of contingent consideration. Also excluded are integration, transaction, and certain other costs associated with business acquisitions, including severance costs which are not part of the Company's formal restructuring programs, as well as transaction and certain other costs associated with divestitures of businesses.

<sup>(2)</sup> Represents the difference between calculated GAAP EPS and calculated non-GAAP EPS, which may be different than the amount calculated by dividing the impact of the excluded items by the weighted-average shares for the applicable period.

#### Restructuring Costs

Non-GAAP income and non-GAAP EPS exclude costs related to restructuring actions (see Note 3 to the condensed consolidated financial statements). These amounts include employee separation costs and accelerated depreciation associated with facilities to be closed or divested. Accelerated depreciation costs represent the difference between the depreciation expense to be recognized over the revised useful life of the asset, based upon the anticipated date the site will be closed or divested or the equipment disposed of, and depreciation expense as determined utilizing the useful life prior to the restructuring actions. Restructuring costs also include asset abandonment, shut-down and other related costs, as well as employee-related costs such as curtailment, settlement and termination charges associated with pension and other postretirement benefit plans and share-based compensation costs.

#### Certain Other Items

Non-GAAP income and non-GAAP EPS exclude certain other items. These items are adjusted for after evaluating them on an individual basis, considering their quantitative and qualitative aspects, and typically consist of items that are unusual in nature, significant to the results of a particular period or not indicative of future operating results.

## Research and Development Update

*Keytruda* is an FDA-approved anti-PD-1 therapy in clinical development for expanded indications in different cancer types. *Keytruda* is currently approved for the treatment of certain patients with NSCLC, melanoma, cHL, and HNSCC (see "Pharmaceutical Segment" above).

In March 2017, Merck announced that the FDA extended the action date for the sBLA for *Keytruda* for the treatment of previously treated patients with advanced MSI-H cancer that it accepted for review in November 2016. The Company recently submitted additional data and analyses to the FDA related to the pending application. The submission of additional data is considered a major amendment to the sBLA under the Prescription Drug User Fee Act (PDUFA), thus extending the target action date by three months. The FDA target action date is now June 9, 2017. The sBLA is being reviewed under the FDA's Accelerated Approval program. The FDA recently granted Breakthrough Therapy designation to *Keytruda* for unresectable or metastatic MSI-H non-colorectal cancer, and previously granted it for the treatment of patients with unresectable or metastatic MSI-H colorectal cancer.

In February 2017, the FDA accepted for review two sBLAs for *Keytruda* in patients with locally advanced or metastatic urothelial cancer, including most bladder cancers. The application for first-line use was granted Priority Review for the treatment of these patients who are ineligible for cisplatin-containing therapy. The application for second-line use was granted Priority Review for these patients with disease progression on or after platinum-containing chemotherapy. The PDUFA action date for both applications is June 14, 2017. The FDA previously granted Breakthrough Therapy designation to *Keytruda* for the second-line treatment of patients with locally advanced or metastatic urothelial cancer with disease progression on or after platinum-containing chemotherapy. Filings for these indications are also under review in the EU.

In January 2017, the FDA accepted for review an sBLA for *Keytruda* plus carboplatin and pemetrexed for the first-line treatment of patients with metastatic or advanced non-squamous NSCLC regardless of PD-L1 expression. This is the first application for regulatory approval of *Keytruda* in combination with another treatment. The FDA granted Priority Review with a PDUFA action date of May 10, 2017. The sBLA is being reviewed under the FDA's Accelerated Approval program. This combination is also under review in the EU.

Additionally, *Keytruda* has also received Breakthrough Therapy designation from the FDA for the treatment of patients with primary mediastinal B-cell lymphoma that is refractory to or has relapsed after two prior lines of therapy.

The FDA's Breakthrough Therapy designation is intended to expedite the development and review of a candidate that is planned for use, alone or in combination, to treat a serious or life-threatening disease or condition when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints.

The *Keytruda* clinical development program consists of nearly 500 clinical trials, including more than 250 trials that combine *Keytruda* with other cancer treatments. These studies encompass more than 30 cancer types including: bladder, colorectal, esophageal, gastric, head and neck, hepatocellular, Hodgkin lymphoma, non-Hodgkin lymphoma, melanoma, multiple myeloma, nasopharyngeal, NSCLC, ovarian, prostate, renal, small-cell lung cancer and triple-negative breast, many of which are currently in Phase 3 clinical development. Further trials are being planned for other cancers.

In March 2017, Merck and Pfizer Inc. (Pfizer) announced that the FDA accepted for review three New Drug Applications (NDAs) for medicines containing ertugliflozin, an investigational SGLT2 inhibitor in development to help improve glycemic control in adults with type 2 diabetes: one for monotherapy, one for the fixed-dose combination of ertugliflozin and *Januvia*, and one for the fixed-dose combination of ertugliflozin and metformin. The PDUFA action date for the three NDAs is in December 2017. Additionally, the European Medicines Agency has validated for review three Marketing Authorization Applications for ertugliflozin monotherapy and the two fixed-dose combination products. Under the terms of the collaboration agreement with

Pfizer, Merck made a \$90 million milestone payment to Pfizer in the first quarter of 2017 recorded in *Research and development* expenses.

On March 31, 2017, Merck received a CRL from the FDA for MK-1293, an investigational follow-on biologic insulin glargine candidate for the treatment of people with type 1 and type 2 diabetes, which is being developed in collaboration with and partially funded by Samsung Bioepis. The CRL was issued as a result of Sanofi listing a new patent in the FDA's Orange Book for Lantus, the originator insulin glargine, on March 31, which was the FDA's PDUFA action date for MK-1293. Merck is reviewing the letter and discussing next steps with the FDA to address the patent certification required to secure tentative approval of the product. In September 2016, Sanofi initiated a lawsuit which, under the Hatch-Waxman Act, automatically invoked a stay on final FDA approval of MK-1293 for a period of up to 30 months, or in the event a court finds in favor of Merck, whichever comes sooner.

The chart below reflects the Company's research pipeline as of May 5, 2017. Candidates shown in Phase 3 include specific products and the date such candidate entered into Phase 3 development. Candidates shown in Phase 2 include the most advanced compound with a specific mechanism or, if listed compounds have the same mechanism, they are each currently intended for commercialization in a given therapeutic area. Small molecules and biologics are given MK-number designations and vaccine candidates are given V-number designations. Except as otherwise noted, candidates in Phase 1, additional indications in the same therapeutic area (other than with respect to *Keytruda*) and additional claims, line extensions or formulations for in-line products are not shown.

Phase 2	Phase 3 (Phase 3 entry date)	Under Review
Asthma MK-1029 Cancer MK-3475 Keytruda Advanced Solid Tumors Nasopharyngeal Ovarian PMBCL (Primary Mediastinal Large B-Cell Lymphoma) Prostate MK-2206 Cough, including cough with IPF MK-7264 Diabetes Mellitus MK-8521 Hepatitis C MK-3682B (MK-3682 (uprifosbuvir)/MK-5172 (grazoprevir)/MK-8408 (ruzasvir) MK-3682C (MK-3682 (uprifosbuvir)/MK-8408 (ruzasvir) Pneumoconjugate Vaccine  Alzheimer's Disease MK-891 (MK-891 (December 2013) Atherosclerosis MK-895 (anacetrapib) (May 2008) Bacterial Infection MK-7655A (relebactam+imipenem/cilastatin) (October 2015) Cancer MK-3475 Keytruda Breast (October 2015) Colorectal (November 2015) Esophageal (December 2015) Gastric (May 2015) Head and Neck (November 2014) (EU) Hepatocellular (May 2016) Multiple Myeloma (December 2015) Renal (October 2016) Small-Cell Lung (May 2017) CMV Prophylaxis in Transplant Patients MK-8228 (letermovir) (June 2014) Diabetes Mellitus		New Molecular Entities/Vaccines Diabetes Mellitus  MK-1293 (U.S.) (I)(2)  MK-8835 (ertugliflozin) (U.S./EU) (I)  MK-8835A (ertugliflozin+sitagliptin) (U.S./EU) (I)  MK-8835B (ertugliflozin+metformin) (U.S./EU) (I)  Pediatric Hexavalent Combination Vaccine  V419 (U.S.) (3)  Certain Supplemental Filings Cancer  Keytruda  Previously Treated Microsatellite Instability-High (U.S.)  Combination with carboplatin and pemetrexed in first-line non-squamous Non- Small-Cell Lung (U.S./EU)  First Line Cis-ineligible Bladder (U.S./EU)  Second Line Metastatic Bladder (U.S./EU)
Schizophrenia MK-8189	(October 2015) (Japan) (1)  Ebola Vaccine V920 (March 2015)  Heart Failure MK-1242 (vericiguat) (September 2016) (1)  Herpes Zoster V212 (inactivated VZV vaccine) (December 2010)  HIV MK-1439 (doravirine) (December 2014)	Footnotes:  (I) Being developed in a collaboration.  (2) On March 31, 2017, Merck received a CRL from the FDA for MK-1293; subject to an automatic 30 day stay.  (3) V419 is an investigational pediatric hexavalent combination vaccine, DTaP5-IPV-Hib-HepB, that is being developed and, if approved, will be commercialized through a partnership of Merck and Sanofi Pasteur. In November 2015, the FDA issued a CRL with respect to V419. Both companies are reviewing the CRL and plan to have further communication with the FDA.

### **Selected Joint Venture and Affiliate Information**

Sanofi Pasteur MSD

On December 31, 2016, Merck and Sanofi Pasteur terminated their equally-owned joint venture, SPMSD, which developed and marketed vaccines in Europe. Total vaccine sales reported by SPMSD were \$182 million in the first quarter of 2016, which included \$41 million sales of *Gardasil/Gardasil* 9. The Company recorded the results from its interest in SPMSD in *Other (income) expense, net* (see Note 11 to the condensed consolidated financial statements).

### **Liquidity and Capital Resources**

(\$ in millions)	March 31, 2017	De	cember 31, 2016
Cash and investments	\$ 27,145	\$	25,757
Working capital	11,707		13,410
Total debt to total liabilities and equity	29.5%		26.0%

Cash provided by operating activities was \$286 million in the first three months of 2017 compared with \$2.2 billion in the first three months of 2016. The decrease in cash provided by operating activities reflects a \$625 million payment made by the Company in the first quarter of 2017 related to the settlement of worldwide *Keytruda* patent litigation (see Note 7 to the condensed consolidated financial statements), as well as a tax refund and the receipt of insurance proceeds in the first quarter 2016. Cash provided by operating activities continues to be the Company's primary source of funds to finance operating needs, capital expenditures, a portion of treasury stock purchases and dividends paid to shareholders.

Cash provided by investing activities was \$3.2 billion in the first three months of 2017 compared with \$1.7 billion in the first three months of 2016. The increase in cash provided by investing activities in 2017 was driven primarily by higher proceeds from the sales of securities and other investments, partially offset by higher purchases of securities and other investments, the use of cash to fund the acquisition of Vallée and higher capital expenditures.

Cash provided by financing activities was \$1.5 billion in the first three months of 2017 compared with a use of cash in financing activities of \$2.9 billion in the first three months of 2016. The change was driven primarily by an increase in short-term borrowings and lower payments on debt, partially offset by higher purchases of treasury stock.

At March 31, 2017, the total of worldwide cash and investments was \$27.1 billion, including \$15.2 billion of cash, cash equivalents and short-term investments and \$11.9 billion of long-term investments. Generally 80%-90% of cash and investments are held by foreign subsidiaries that would be subject to significant tax payments if such cash and investments were repatriated in the form of dividends. The Company records U.S. deferred tax liabilities for certain unremitted earnings, but when amounts earned overseas are expected to be indefinitely reinvested outside of the United States, no accrual for U.S. taxes is provided. The amount of cash and investments held by U.S. and foreign subsidiaries fluctuates due to a variety of factors including the timing and receipt of payments in the normal course of business. Cash provided by operating activities in the United States continues to be the Company's primary source of funds to finance domestic operating needs, capital expenditures, a portion of treasury stock purchases and dividends paid to shareholders.

Capital expenditures totaled \$339 million and \$279 million for the first three months of 2017 and 2016, respectively.

Dividends paid to stockholders were \$1.3 billion for both the first three months of 2017 and 2016. In February 2017, the Board of Directors declared a quarterly dividend of \$0.47 per share on the Company's common stock that was paid in April 2017.

In March 2015, Merck's board of directors authorized additional purchases of up to \$10 billion of Merck's common stock for its treasury. The treasury stock purchase has no time limit and will be made over time in open-market transactions, block transactions on or off an exchange, or in privately negotiated transactions. During the first three months of 2017, the Company purchased \$1.0 billion (16 million shares) for its treasury. As of March 31, 2017, the Company's remaining share repurchase authorization was \$4.0 billion.

In February 2017, \$300 million of floating rate notes matured in accordance with their terms and were repaid. In January 2016, \$850 million of 2.2% notes matured in accordance with their terms and were repaid.

The Company has a \$6.0 billion, five-year credit facility that matures in June 2021. The facility provides backup liquidity for the Company's commercial paper borrowing facility and is to be used for general corporate purposes. The Company has not drawn funding from this facility.

## **Critical Accounting Policies**

The Company's significant accounting policies, which include management's best estimates and judgments, are included in Note 2 to the consolidated financial statements for the year ended December 31, 2016 included in Merck's Form 10-K filed on February 28, 2017. Certain of these accounting policies are considered critical as disclosed in the Critical Accounting Policies section of Management's Discussion and Analysis of Financial Condition and Results of Operations included in Merck's Form 10-K because of the potential for a significant impact on the financial statements due to the inherent uncertainty in such estimates. There have been no significant changes in the Company's critical accounting policies since December 31, 2016.

#### **Recently Issued Accounting Standards**

In May 2014, the Financial Accounting Standards Board (FASB) issued amended accounting guidance on revenue recognition that will be applied to all contracts with customers. The objective of the new guidance is to improve comparability of revenue recognition practices across entities and to provide more useful information to users of financial statements through improved disclosure requirements. In August 2015, the FASB approved a one-year deferral of the effective date making this guidance effective for interim and annual periods beginning in 2018. The new standard permits two methods of adoption: retrospectively to each prior reporting period presented (full retrospective method), or retrospectively with the cumulative effect of adopting the guidance being recognized at the date of initial application (modified retrospective method). The Company will adopt the new standard on January 1, 2018 and currently plans to use the modified retrospective method. The majority of the Company's business is ship and bill and, on that primary revenue stream, Merck does not expect significant differences. However, the Company's analysis is preliminary and subject to change. Merck has not completed its assessment of multiple element arrangements and certain discount and trade promotion programs.

In January 2016, the FASB issued revised guidance for the accounting and reporting of financial instruments. The new guidance requires that equity investments with readily determinable fair values currently classified as available-for-sale be measured at fair value with changes in fair value recognized in net income. The new guidance also simplifies the impairment testing of equity investments without readily determinable fair values and changes certain disclosure requirements. This guidance is effective for interim and annual periods beginning in 2018. Early adoption is not permitted. The Company is currently assessing the impact of adoption on its consolidated financial statements.

In August 2016, the FASB issued guidance on the classification of certain cash receipts and payments in the statement of cash flows intended to reduce diversity in practice. The guidance is effective for interim and annual periods beginning in 2018. Early adoption is permitted. The guidance is to be applied retrospectively to all periods presented but may be applied prospectively if retrospective application would be impracticable. The Company is currently evaluating the effect of the standard on its Consolidated Statement of Cash Flows.

In October 2016, the FASB issued guidance on the accounting for the income tax consequences of intra-entity transfers of assets other than inventory. Under existing guidance, the recognition of current and deferred income taxes for an intra-entity asset transfer is prohibited until the asset has been sold to a third party. The new guidance will require the recognition of the income tax consequences of an intra-entity transfer of an asset (with the exception of inventory) when the intra-entity transfer occurs. The guidance is effective for interim and annual periods beginning in 2018. Early adoption is permitted. The new guidance is to be applied on a modified retrospective basis through a cumulative-effect adjustment directly to retained earnings in the beginning of the period of adoption. The Company does not anticipate the adoption of the new guidance will have a material effect on its consolidated financial statements.

In November 2016, the FASB issued guidance requiring that amounts generally described as restricted cash and restricted cash equivalents be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The guidance is effective for interim and annual periods beginning in 2018 and should be applied using a retrospective transition method to each period presented. Early adoption is permitted. The Company is currently evaluating the effect of the standard on its Consolidated Statement of Cash Flows.

In March 2017, the FASB amended the guidance related to net periodic benefit cost for defined benefit plans that requires entities to (1) disaggregate the current service cost component from the other components of net benefit cost and present it with other employee compensation costs in the income statement within operations if such a subtotal is presented; (2) present the other components of net benefit cost separately in the income statement and outside of income from operations; and (3) only capitalize the service cost component when applicable. The new guidance is effective for interim and annual periods in 2018. Entities must use a retrospective transition method to adopt the requirement for separate presentation in the income statement of service costs and other components and a prospective transition method to adopt the requirement to limit the capitalization of benefit costs to the service cost component. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

In February 2016, the FASB issued new accounting guidance for the accounting and reporting of leases. The new guidance requires that lessees recognize a right-of-use asset and a lease liability recorded on the balance sheet for each of its leases (other than leases that meet the definition of a short-term lease). Leases will be classified as either operating or finance. Operating leases will result in straight-line expense in the income statement (similar to current operating leases) while finance leases will result in more expense being recognized in the earlier years of the lease term (similar to current capital leases). The new guidance will be effective for interim and annual periods beginning in 2019. Early adoption is permitted. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

In June 2016, the FASB issued amended guidance on the accounting for credit losses on financial instruments within its scope. The guidance introduces an expected loss model for estimating credit losses, replacing the incurred loss model. The new guidance also changes the impairment model for available-for-sale debt securities, requiring the use of an allowance to record

estimated credit losses (and subsequent recoveries). The new guidance is effective for interim and annual periods beginning in 2020, with earlier application permitted in 2019. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

In January 2017, the FASB issued guidance that provides for the elimination of Step 2 from the goodwill impairment test. If impairment charges are recognized, the amount recorded will be the amount by which the carrying amount exceeds the reporting unit's fair value with certain limitations. The new guidance is effective for interim and annual periods in 2020. Early adoption is permitted. The Company does not anticipate the adoption of the new guidance will have a material effect on its consolidated financial statements.

#### Item 4. Controls and Procedures

Management of the Company, with the participation of its Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures over financial reporting for the period covered by this Form 10–Q. Based on this assessment, the Company's Chief Executive Officer and Chief Financial Officer have concluded that as of March 31, 2017, the Company's disclosure controls and procedures are effective. For the period covered by this report, there have been no changes in internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

## CAUTIONARY FACTORS THAT MAY AFFECT FUTURE RESULTS

This report and other written reports and oral statements made from time to time by the Company may contain so-called "forward-looking statements," all of which are based on management's current expectations and are subject to risks and uncertainties which may cause results to differ materially from those set forth in the statements. One can identify these forward-looking statements by their use of words such as "anticipates," "expects," "plans," "will," "estimates," "forecasts," "projects" and other words of similar meaning. One can also identify them by the fact that they do not relate strictly to historical or current facts. These statements are likely to address the Company's growth strategy, financial results, product development, product approvals, product potential and development programs. One must carefully consider any such statement and should understand that many factors could cause actual results to differ materially from the Company's forward-looking statements. These factors include inaccurate assumptions and a broad variety of other risks and uncertainties, including some that are known and some that are not. No forward-looking statement can be guaranteed and actual future results may vary materially.

The Company does not assume the obligation to update any forward-looking statement. One should carefully evaluate such statements in light of factors, including risk factors, described in the Company's filings with the Securities and Exchange Commission, especially on Forms 10-K, 10-Q and 8-K. In Item 1A. "Risk Factors" of the Company's Annual Report on Form 10-K for the year ended December 31, 2016, as filed on February 28, 2017, the Company discusses in more detail various important risk factors that could cause actual results to differ from expected or historic results. The Company notes these factors for investors as permitted by the Private Securities Litigation Reform Act of 1995. One should understand that it is not possible to predict or identify all such factors. Consequently, the reader should not consider any such list to be a complete statement of all potential risks or uncertainties.

### PART II - Other Information

## Item 1. Legal Proceedings

The information called for by this Item is incorporated herein by reference to Note 7 included in Part I, Item 1, Financial Statements (unaudited) — Notes to Condensed Consolidated Financial Statements.

# <u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>

Issuer purchases of equity securities for the three months ended March 31, 2017 were as follows:

# ISSUER PURCHASES OF EQUITY SECURITIES

		_	(\$ in millions)
Period	Total Number of Shares Purchased (1)	Average Price Paid Per Share	Approximate Dollar Value of Shares That May Yet Be Purchased Under the Plans or Programs (1)
January 1 - January 31	5,191,378	\$60.83	\$4,739
February 1 - February 28	4,933,139	\$64.16	\$4,422
March 1 - March 31	5,965,277	\$64.81	\$4,036
Total	16,089,794	\$63.33	\$4,036

<sup>(1)</sup> Shares purchased during the period were made as part of a plan approved by the Board of Directors in March 2015 to purchase up to \$10 billion of Merck's common stock for its treasury.

# Item 6. Exhibits

Number		<u>Description</u>
3.1	_	Restated Certificate of Incorporation of Merck & Co., Inc. (November 3, 2009) – Incorporated by reference to Current Report on Form 8-K filed on November 4, 2009 (No. 1-6571)
3.2	_	By-Laws of Merck & Co., Inc. (effective July 22, 2015) – Incorporated by reference to Current Report on Form 8-K filed on July 28, 2015 (No. 1-6571)
31.1	_	Rule 13a – 14(a)/15d – 14(a) Certification of Chief Executive Officer
31.2	_	Rule 13a – 14(a)/15d – 14(a) Certification of Chief Financial Officer
32.1	_	Section 1350 Certification of Chief Executive Officer
32.2	_	Section 1350 Certification of Chief Financial Officer
101	_	The following materials from Merck & Co., Inc.'s Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, formatted in XBRL (Extensible Business Reporting Language): (i) the Condensed Consolidated Statement of Income, (ii) the Condensed Consolidated Statement of Comprehensive Income, (iii) the Condensed Consolidated Balance Sheet, (iv) the Condensed Consolidated Statement of Cash Flows, and (v) Notes to the Condensed Consolidated Financial Statements.

# Signatures

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

MERCK & CO., INC.

Date: May 9, 2017 /s/ Michael J. Holston

MICHAEL J. HOLSTON

Executive Vice President and General Counsel

Date: May 9, 2017 /s/ Rita A. Karachun

RITA A. KARACHUN

Senior Vice President Finance - Global Controller

# EXHIBIT INDEX

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#### CERTIFICATION

- I, Kenneth C. Frazier, certify that:
- 1. I have reviewed this quarterly report on Form 10-Q of Merck & Co., 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(s) 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(s) 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 9, 2017

By: /s/ Kenneth C. Frazier

KENNETH C. FRAZIER

Chairman, President and Chief Executive Officer

#### CERTIFICATION

- I, Robert M. Davis, certify that:
- 1. I have reviewed this quarterly report on Form 10-Q of Merck & Co., 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(s) 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(s) 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 9, 2017

By: /s/ Robert M. Davis

ROBERT M. DAVIS
Executive Vice President, Chief Financial Officer
& Global Services

# Section 1350 Certification of Chief Executive Officer

Pursuant to 18 U.S.C. Section 1350, the undersigned officer of Merck & Co., Inc. (the "Company"), hereby certifies that the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2017 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 9, 2017 /s/ Kenneth C. Frazier

Name: KENNETH C. FRAZIER

Title: Chairman, President and Chief Executive Officer

# Section 1350 Certification of Chief Financial Officer

Pursuant to 18 U.S.C. Section 1350, the undersigned officer of Merck & Co., Inc. (the "Company"), hereby certifies that the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2017 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 9, 2017 /s/ Robert M. Davis

Name: ROBERT M. DAVIS

Title: Executive Vice President, Chief Financial Officer

& Global Services