Merck & Co. Inc. Form 10-Q November 10, 2014

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

FORM 10-Q

(Mark One)

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

ACT OF 1934

For the quarterly period ended September 30, 2014

OR

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

For the transition period from _____ to ____

Commission File No. 1-6571

Merck & Co., Inc. One Merck Drive Whitehouse Station, N.J. 08889-0100 (908) 423-1000 Incorporated in New Jersey

I.R.S. Employer

Identification No. 22-1918501

The number of shares of common stock outstanding as of the close of business on October 31, 2014: 2,850,873,371 Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No "Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No "

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer x Accelerated filer " Non-accelerated filer " Smaller reporting company " (Do not check if a smaller reporting company)

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

Part I - Financial Information
Item 1. Financial Statements
MERCK & CO., INC. AND SUBSIDIARIES
INTERIM CONSOLIDATED STATEMENT OF INCOME
(Unaudited, \$ in millions except per share amounts)

	Three Months Ended September 30,				Nine Mont September			
	2014	2013			2014		2013	
Sales	\$10,557		\$11,032		\$31,755		\$32,713	
Costs, Expenses and Other								
Materials and production	4,223		4,104		13,019		12,347	
Marketing and administrative	2,975		2,803		8,681		8,929	
Research and development	1,659		1,660		4,897		5,668	
Restructuring costs	376		870		664		1,144	
Equity income from affiliates	(24)	(102)	(241)	(351)
Other (income) expense, net	(142)	172		(737)	656	
	9,067		9,507		26,283		28,393	
Income Before Taxes	1,490		1,525		5,472		4,320	
Taxes on Income	648		375		865		618	
Net Income	842		1,150		4,607		3,702	
Less: Net (Loss) Income Attributable to Noncontrolling Interests	(53)	26		3		79	
Net Income Attributable to Merck & Co., Inc.	\$895		\$1,124		\$4,604		\$3,623	
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders	\$0.31		\$0.38		\$1.58		\$1.22	
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders	\$ \$0.31		\$0.38		\$1.57		\$1.20	
Dividends Declared per Common Share	\$0.44		\$0.43		\$1.32		\$1.29	

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

	Three M Septemb	onths Ended ber 30,	Nine Mos Septemb	nths Ended per 30,	
	2014	2013	2014	2013	
Net Income Attributable to Merck & Co., Inc.	\$895	\$1,124	\$4,604	\$3,623	
Other Comprehensive Income (Loss) Net of Taxes:					
Net unrealized gain (loss) on derivatives, net of reclassifications	254	(102) 149	169	
Net unrealized (loss) gain on investments, net of reclassifications	(29) 43	33	(37)
Benefit plan net (loss) gain and prior service (cost) credit, net of amortization	(463) 49	(795) 261	
Cumulative translation adjustment	(316) 72	(188) (409)
	(554) 62	(801) (16)
Comprehensive Income Attributable to Merck & Co., Inc.	\$341	\$1,186	\$3,803	\$3,607	
The accompanying notes are an integral part of these consolidate	d financia	l statements.			

MERCK & CO., INC. AND SUBSIDIARIES CONSOLIDATED BALANCE SHEET

(Unaudited, \$ in millions except per share amounts)

	September 30, 2014	December 31, 2013
Assets		
Current Assets		
Cash and cash equivalents	\$11,370	\$15,621
Short-term investments	2,977	1,865
Accounts receivable (net of allowance for doubtful accounts of \$186 in 2014		
and \$146 in 2013) (excludes accounts receivable of \$275 in 2014 and 2013	6,515	7,184
classified in Other assets - see Note 4)		
Inventories (excludes inventories of \$1,774 in 2014 and \$1,704 in 2013	5,819	6,226
classified in Other assets - see Note 5)		
Deferred income taxes and other current assets	4,740	4,763
Assets held for sale	3,302	26
Total current assets	34,723	35,685
Investments	13,492	9,770
Property, Plant and Equipment, at cost, net of accumulated depreciation of \$18,761	13,438	14,973
in 2014 and \$18,121 in 2013	•	·
Goodwill	13,171	12,301
Other Intangibles, Net	20,395	23,801
Other Assets	6,589	9,115
*******	\$101,808	\$105,645
Liabilities and Equity		
Current Liabilities	40.277	4.72 4
Loans payable and current portion of long-term debt	\$9,275	\$4,521
Trade accounts payable	2,279	2,274
Accrued and other current liabilities	9,808	9,501
Income taxes payable	2,467	251
Dividends payable	1,288	1,321
Liabilities held for sale	810	
Total current liabilities	25,927	17,868
Long-Term Debt	18,566	20,539
Deferred Income Taxes	4,987	6,776
Other Noncurrent Liabilities	6,968	8,136
Merck & Co., Inc. Stockholders' Equity		
Common stock, \$0.50 par value		
Authorized - 6,500,000,000 shares	1,788	1,788
Issued - 3,577,103,522 shares in 2014 and 2013		
Other paid-in capital	40,340	40,508
Retained earnings	39,989	39,257
Accumulated other comprehensive loss		(2,197)
	79,119	79,356
Less treasury stock, at cost:	33,895	29,591
716,260,636 shares in 2014 and 649,576,808 shares in 2013	•	
Total Merck & Co., Inc. stockholders' equity	45,224	49,765

 Noncontrolling Interests
 136
 2,561

 Total equity
 45,360
 52,326

 \$101,808
 \$105,645

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

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

	Nine Months Ended				
	September 30,				
	2014	2013			
Cash Flows from Operating Activities					
Net income	\$4,607	\$3,702			
Adjustments to reconcile net income to net cash provided by operating activities:					
Depreciation and amortization	5,118	5,034			
Intangible asset impairment charges	1,209	594			
Gain on AstraZeneca option exercise	(741) —			
Gain on divestiture of certain ophthalmic products	(396) —			
Equity income from affiliates	(241) (351)		
Dividends and distributions from equity affiliates	132	178			
Deferred income taxes	(1,773) (532)		
Share-based compensation	209	210			
Other	(50) 287			
Net changes in assets and liabilities	950	(494)		
Net Cash Provided by Operating Activities	9,024	8,628			
Cash Flows from Investing Activities					
Capital expenditures	(827) (1,119)		
Purchases of securities and other investments	(16,231) (13,077)		
Proceeds from sales of securities and other investments	11,807	9,823			
Acquisition of Idenix Pharmaceuticals, Inc., net of cash acquired	(3,700) —			
Dispositions of businesses, net of cash divested	1,048				
Proceeds from AstraZeneca option exercise	419	_			
Other	(94) 48			
Net Cash Used in Investing Activities	(7,578) (4,325)		
Cash Flows from Financing Activities					
Net change in short-term borrowings	3,077	151			
Proceeds from issuance of debt	1	6,467			
Payments on debt	(7) (515)		
Purchases of treasury stock	(6,083) (6,320)		
Dividends paid to stockholders	(3,911) (3,897)		
Proceeds from exercise of stock options	1,381	809			
Other	72	(61)		
Net Cash Used in Financing Activities	(5,470) (3,366)		
Effect of Exchange Rate Changes on Cash and Cash Equivalents	(227) (298)		
Net (Decrease) Increase in Cash and Cash Equivalents	(4,251) 639			
Cash and Cash Equivalents at Beginning of Year	15,621	13,451			
Cash and Cash Equivalents at End of Period	\$11,370	\$14,090			
The accompanying notes are an integral part of this consolidated financial statement		-			

Notes to Interim Consolidated Financial Statements (unaudited)

1. Basis of Presentation

The accompanying unaudited interim 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 27, 2014. 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 presentation 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.

Recently Issued Accounting Standards

In May 2014, the Financial Accounting Standards Board 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. This guidance is effective for annual and interim periods beginning in 2017. Early adoption is not permitted. The Company is currently assessing the impact of adoption on its consolidated financial statements.

2. Restructuring

2013 Restructuring Program

In October 2013, the Company announced a global restructuring program (the "2013 Restructuring Program") as part of a global initiative to sharpen its commercial and research and development focus. As part of the program, the Company expects to reduce its total workforce by approximately 8,500 positions. These workforce reductions will primarily come from the elimination of positions in sales, administrative and headquarters organizations, as well as research and development. The Company will also reduce its global real estate footprint and continue to improve the efficiency of its manufacturing and supply network. The Company will continue to hire employees in strategic growth areas of the business as necessary.

The Company recorded total pretax costs of \$437 million and \$826 million in the third quarter and first nine months of 2014, respectively, and \$544 million in the third quarter and first nine months of 2013 related to this restructuring program. Since inception of the 2013 Restructuring Program through September 30, 2014, Merck has recorded total pretax accumulated costs of approximately \$2.1 billion and eliminated approximately 4,965 positions comprised of employee separations, as well as the elimination of contractors and vacant positions. The actions under the 2013 Restructuring Program are expected to be substantially completed by the end of 2015 with the cumulative pretax costs estimated to be approximately \$2.5 billion to \$3.0 billion. 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.

Merger Restructuring Program

In 2010, subsequent to the Merck and Schering-Plough Corporation ("Schering-Plough") merger (the "Merger"), the Company commenced actions under a global restructuring program (the "Merger Restructuring Program") designed to streamline the cost structure of the combined company. Further actions under this program were initiated in 2011. The actions under this program primarily reflect the elimination of positions in sales, administrative and headquarters organizations, as well as from the sale or closure of certain manufacturing and research and development sites and the consolidation of office facilities.

On October 1, 2013, the Company sold its active pharmaceutical ingredient ("API") manufacturing business, including the related manufacturing facility, in the Netherlands to Aspen Holdings ("Aspen") as part of planned manufacturing facility rationalizations under the Merger Restructuring Program. Also in connection with the sale, Aspen acquired certain branded products from Merck, which transferred to Aspen effective December 31, 2013. Consideration for the transaction included cash of \$705 million and notes receivable with a present value of \$198 million at the time of disposition. The Company received \$172 million of the cash portion of the consideration in the fourth quarter of 2013

and the remaining \$533 million was received by the Company in January 2014.

The Company recorded total pretax costs of \$175 million and \$423 million in the third quarter of 2014 and 2013, respectively, and \$533 million and \$841 million in the first nine months of 2014 and 2013, respectively, related to this restructuring program. Since inception of the Merger Restructuring Program through September 30, 2014, Merck has recorded total pretax accumulated costs of approximately \$7.7 billion and eliminated approximately 27,855 positions comprised of employee separations, as well as the elimination of contractors and vacant positions. Approximately 4,445 position eliminations remain pending under this program as of September 30, 2014, which include the remaining actions under the 2008 Restructuring Program that are being reported as part of the Merger Restructuring Program as discussed below. The non-manufacturing related restructuring actions

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under the Merger Restructuring Program were substantially completed by the end of 2013. The remaining actions under this program relate to ongoing manufacturing facility rationalizations, which are expected to be substantially completed by 2016. The Company expects the estimated total cumulative pretax costs for this program to be approximately \$7.9 billion to \$8.2 billion. The Company estimates that approximately two-thirds of the cumulative pretax costs relate to 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.

2008 Restructuring Program

In 2008, Merck announced a global restructuring program (the "2008 Restructuring Program") to reduce its cost structure, increase efficiency, and enhance competitiveness. Pretax costs of \$54 million were recorded in the first nine months of 2013 related to the 2008 Restructuring Program. Effective July 1, 2013, any remaining activities under the 2008 Restructuring Program are being accounted for as part of the Merger Restructuring Program.

For segment reporting, restructuring charges are unallocated expenses.

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

Three Months Ended September 30, 2014 Nine Months Ended September 30, 20								014		
(\$ in millions)		Accelerated Depreciation	Other		otal		Accelerated Depreciation	Other		Total
2013 Restructuring Program										
Materials and production	\$—	\$ 5	\$—	\$:	5	\$—	\$ 189	\$17		\$206
Marketing and administrative	_	45	_	45	.5	_	92	_		92
Research and development	_	75	6	81		_	160	14		174
Restructuring costs	310 310		(4)		06 37	387 387	— 441		_	354 826
Merger Restructuring Program	g									
Materials and production	_	67	15	82	2	_	219	(48)	171
Marketing and administrative	_	29	(6) 23	3	_	54	(3)	51
Research and development	_	_	_	_	_	_	_	1		1
Restructuring costs	5		65	70		104		206		310
	5	96	74		75	104	273	156		533
	\$315	\$ 221	\$76	\$0	612	\$491	\$ 714	\$154		\$1,359
		nths Ended Se	_	, 20	013		hs Ended Sep	tember 30,	, 2	013
(\$ in millions)	Separation Costs	Accelerated Depreciation	()ther	To	otal	Separation Costs	Accelerated Depreciation	Other		Total
2013 Restructuring Program										
Materials and production	\$—	\$ 20	\$ —	\$2	20	\$—	\$ 20	\$—		\$20
Marketing and administrative	_	15	_	15		_	15	_		15
	_	8	_	8			8	_		8

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Research and								
development								
Restructuring costs	501	_	_	501	501		_	501
	501	43		544	501	43		544
Merger Restructurin	ıg							
Program								
Materials and production	_	30	7	37	_	91	78	169
Marketing and administrative	_	20	(4) 16	_	44	1	45
Research and development	_	1	_	1	_	30		30
Restructuring costs	241	_	128	369	435		162	597
-	241	51	131	423	435	165	241	841
2008 Restructuring Program								
Materials and production	_	_	_		_	(2) 6	4
Marketing and administrative	_	_	_		_	4		4
Restructuring costs					34	_	12	46
-	_			_	34	2	18	54
	\$742	\$ 94	\$131	\$967	\$970	\$ 210	\$259	\$1,439

Separation costs are associated with actual headcount reductions, as well as those headcount reductions which were probable and could be reasonably estimated. In the third quarter and first nine months of 2014, approximately 830 positions and 3,425 positions, respectively, were eliminated under the 2013 Restructuring Program. In the third quarter of 2014 and 2013, approximately 185 positions and 1,070 positions, respectively, and in the first nine months of 2014 and 2013, approximately 975

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positions and 2,475 positions, respectively, were eliminated under the Merger Restructuring Program. In addition, approximately 55 positions were eliminated in the first nine months of 2013 under the 2008 Restructuring Program. These position eliminations were comprised of actual headcount reductions and the elimination of contractors and vacant positions.

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 site, based upon the anticipated date the site will be closed or divested, 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 was required to accelerate depreciation of the site assets rather than record an impairment charge. 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 2014 and 2013 includes pretax gains and losses resulting from sales of facilities and related assets, as well as asset abandonment, shut-down and other related costs. Additionally, other activity includes certain employee-related costs associated with pension and other postretirement benefit plans (see Note 12) and share-based compensation.

Adjustments to previously recorded amounts were not material in any period.

The following table summarizes the charges and spending relating to restructuring activities by program for the nine months ended September 30, 2014:

(\$ in millions)	Separation Costs	Accelerated Depreciation	Other	Total	
2013 Restructuring Program					
Restructuring reserves January 1, 2014	\$745	\$ —	\$23	\$768	
Expense	387	441	(2) 826	
(Payments) receipts, net	(596) —	(46) (642)
Non-cash activity		(441) 43	(398)
Restructuring reserves September 30, 2014 (1)	\$536	\$ —	\$18	\$554	
Merger Restructuring Program					
Restructuring reserves January 1, 2014	\$725	\$ —	\$12	\$737	
Expense	104	273	156	533	
(Payments) receipts, net	(237) —	(171) (408)
Non-cash activity		(273) 10	(263)
Restructuring reserves September 30, 2014 (1)	\$592	\$ —	\$7	\$599	

The cash outlays associated with the 2013 Restructuring Program are expected to be substantially completed by the end of 2015. The non-manufacturing cash outlays associated with the Merger Restructuring Program were substantially completed by the end of 2013; the remaining cash outlays are expected to be substantially completed by 2016.

3. Acquisitions, Divestitures, Research Collaborations and License Agreements

The Company continues its strategy of establishing external alliances to complement its substantial internal research capabilities, including research collaborations, licensing preclinical and clinical compounds to drive both near- and long-term growth. The Company supplements its internal research with a licensing and external alliance strategy focused on the entire spectrum of collaborations from early research to late-stage compounds, as well as access to new technologies. 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 pipeline to examine candidates which may provide more value through out-licensing and, as part of its portfolio assessment process, may also divest certain products.

In August 2014, Merck completed the acquisition of Idenix Pharmaceuticals, Inc. ("Idenix") for approximately \$3.9 billion in cash. Idenix is a biopharmaceutical company engaged in the discovery and development of medicines for the treatment of human viral diseases, whose primary focus is on the development of next-generation oral antiviral therapeutics to treat hepatitis C virus ("HCV") infection. The transaction was accounted for as an acquisition of a business; accordingly, the assets acquired and liabilities assumed were recorded at their respective fair values as of the acquisition date. The determination of fair value requires management to make significant estimates and assumptions. Merck recognized an intangible asset for in-process research and development ("IPR&D") of \$3.2 billion related to MK-3682 (in Phase 1 clinical development), deferred tax liabilities of \$1.2 billion and other net assets and liabilities of approximately \$350 million. MK-3682 is a nucleotide prodrug being evaluated for potential inclusion in the development of all oral, pan-genotypic fixed-dose combination regimens. The excess of the consideration

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transferred over the fair value of net assets acquired of \$1.5 billion was recorded as goodwill that was allocated to the Pharmaceutical segment and is not deductible for tax purposes. The fair value of the identifiable intangible asset related to IPR&D was determined using an income approach, through which fair value is estimated based upon the asset's probability adjusted future net cash flows, which reflects the stage of development of the project and the associated probability of successful completion. The net cash flows were then discounted to present value using a discount rate of 11.5%. This transaction closed on August 5, 2014, and accordingly, the results of operations of the acquired business have been included in the Company's results of operations beginning after that date. Pro forma financial information has not been included because Idenix's historical financial results are not significant when compared with the Company's financial results.

In May 2014, Merck entered into an agreement to sell certain ophthalmic products to Santen Pharmaceutical Co., Ltd. ("Santen") in Japan and markets in Europe and Asia Pacific. The ophthalmic products included in the agreement are Cosopt (dorzolamide hydrochloride-timolol maleate ophthalmic solution), Cosopt PF (dorzolamide hydrochloride-timolol maleate ophthalmic solution) 2%/0.5%, Trusopt (dorzolamide hydrochloride ophthalmic solution) sterile ophthalmic solution 2%, Trusopt PF (dorzolamide hydrochloride ophthalmic solution) preservative-free, Timoptic (timolol maleate ophthalmic solution), Timoptic PF (timolol maleate preservative free ophthalmic solution in unit dose dispenser), Timoptic XE (timolol maleate ophthalmic gel forming solution), Saflutan (tafluprost) and Taptiqom (tafluprost-timolol maleate ophthalmic solution, in development). The agreement provides that Santen make upfront payments and additional payments based on defined sales milestones. Santen will also purchase supply of ophthalmology products covered by the agreement for a two- to five-year period. Upon closing of the transaction in most markets on July 1, 2014, the Company received \$515 million of upfront payments from Santen, net of certain adjustments. Merck recognized a gain of \$396 million on the transaction in the third quarter and first nine months of 2014 included in Other (income) expense, net. Upon closing of the remaining markets on October 1, 2014, the Company received an additional payment of approximately \$50 million from Santen and will recognize an additional gain of approximately \$100 million in the fourth quarter of 2014.

In March 2014, Merck divested its Sirna Therapeutics, Inc. ("Sirna") subsidiary to Alnylam Pharmaceuticals, Inc. ("Alnylam") for consideration of \$25 million and 2,520,044 shares of Alnylam common stock. Merck is eligible to receive future payments associated with the achievement of certain regulatory and commercial milestones, as well as royalties on future sales. Under the terms of the agreement, Merck received 85% of the Alnylam shares in the first quarter of 2014 (valued at \$172 million at the time of closing) and the remaining 15% of the shares in the second quarter of 2014 (valued at \$22 million at the time the shares were received). Merck recorded gains of \$204 million in the first nine months of 2014 related to this transaction that are included in Other (income) expense, net. The excess of Merck's tax basis in its investment in Sirna over the value received resulted in an approximate \$300 million tax benefit recorded in the first nine months of 2014. In the second quarter of 2014, the Company recorded a \$36 million impairment charge within Other (income) expense, net on the Alnylam shares received in the first quarter of 2014 as the Company determined these shares were other than temporarily impaired.

In January 2014, Merck sold the U.S. marketing rights to Saphris (asenapine), an antipsychotic indicated for the treatment of schizophrenia and bipolar I disorder in adults to Forest Laboratories, Inc. ("Forest"). Under the terms of the agreement, Forest made upfront payments of \$232 million, which were recorded in Sales in the first nine months of 2014, and will make additional payments to Merck based on defined sales milestones. In addition, as part of this transaction, Merck has agreed to supply product to Forest (subsequently acquired by Actavis plc) until patent expiry. In April 2013, Merck and Pfizer Inc. ("Pfizer") announced that they had entered into a worldwide (except Japan) collaboration agreement for the development and commercialization of Pfizer's ertugliflozin, an investigational oral sodium glucose cotransporter ("SGLT2") inhibitor being evaluated for the treatment of type 2 diabetes. The Company has initiated Phase 3 clinical trials for ertugliflozin with Pfizer. Under the terms of the agreement, Merck and Pfizer will collaborate on the clinical development and commercialization of ertugliflozin and ertugliflozin-containing fixed-dose combinations with metformin and with Januvia (sitagliptin) tablets. Merck will continue to retain the rights to its existing portfolio of sitagliptin-containing products. Through the first nine months of 2013, Merck recorded research and development expenses of \$60 million for upfront and milestone payments made to Pfizer. Pfizer will be eligible for additional payments associated with the achievement of pre-specified future clinical, regulatory and

commercial milestones. The companies will share potential revenues and certain costs 60% to Merck and 40% to Pfizer. Each party will have certain manufacturing and supply obligations. The Company and Pfizer each have the right to terminate the agreement due to a material, uncured breach by, or insolvency of, the other party, or in the event of a safety issue. Pfizer has the right to terminate the agreement upon 12 months notice at any time following the first anniversary of the first commercial sale of a collaboration product, but must assign all rights to ertugliflozin to Merck. Upon termination of the agreement, depending upon the circumstances, the parties have varying rights and obligations with respect to the continued development and commercialization of ertugliflozin and certain payment obligations. In February 2013, Merck and Supera Farma Laboratorios S.A. ("Supera"), a Brazilian pharmaceutical company co-owned by Cristália and Eurofarma, established the previously announced joint venture that markets, distributes and sells a portfolio of pharmaceutical and branded generic products from Merck, Cristália and Eurofarma in Brazil. Merck owns 51% of the joint venture, and Cristália and Eurofarma collectively own 49%. The transaction was accounted for as an acquisition of a business;

accordingly, the assets acquired and liabilities assumed were recorded at their respective fair values. This resulted in Merck recognizing intangible assets for currently marketed products of \$89 million, IPR&D of \$100 million, goodwill of \$103 million, and deferred tax liabilities of \$64 million. The Company also recorded increases to Noncontrolling interests and Other paid-in capital in the amounts of \$112 million and \$116 million, respectively. This transaction closed on February 1, 2013, and accordingly, the results of operations of the acquired business have been included in the Company's results of operations beginning after that date. During the third quarter of 2014, as a result of changes in cash flow assumptions for certain compounds, the Company recorded \$31 million of asset impairment charges related to IPR&D recorded in the Supera transaction. The changes in cash flow assumptions for these compounds, as well as for certain currently marketed products, also resulted in the write-off of the goodwill balance related to the joint venture with Supera, which was \$93 million at current exchange rates. During the fourth quarter of 2013, as a result of changes in cash flow assumptions for certain compounds, the Company recorded \$15 million of impairment charges related to the IPR&D recorded in the Supera transaction.

Merck Consumer Care

On October 1, 2014, the Company completed the previously announced sale of its Merck Consumer Care ("MCC") business to Bayer AG ("Bayer") for \$14.2 billion, less customary closing adjustments as well as certain contingent amounts held back that will be payable upon the manufacturing site transfer in Canada and regulatory approval in Korea. Under the terms of the agreement, Bayer acquired Merck's existing over-the-counter ("OTC") business, including the global trademark and prescription rights for Claritin and Afrin. The Company expects the pretax gain from the sale of MCC to be approximately \$11.0 billion.

Information with respect to Consumer Care assets and liabilities held for sale at September 30 is as follows:

(\$ millions)	September 30,
(\$ millions)	2014
Assets	
Accounts receivable, net	\$79
Inventories	278
Deferred income taxes and other current assets	25
Property, plant and equipment, net	212
Goodwill	162
Other intangibles, net	2,194
Other assets	56
	\$3,006
Liabilities	
Trade accounts payable	\$84
Accrued and other current liabilities	114
Deferred income taxes	561
Other noncurrent liabilities	6
	\$765

The Company also entered into the previously announced worldwide clinical development collaboration with Bayer to market and develop its portfolio of soluble guanylate cyclase ("sGC") modulators. This includes Bayer's Adempas (riociguat), the first member of this novel class of compounds. Adempas is approved to treat pulmonary arterial hypertension ("PAH") and is the first and only drug treatment approved for patients with chronic thromboembolic pulmonary hypertension ("CTEPH"). Adempas is currently marketed in the United States and Europe for both PAH and CTEPH and in Japan for CTEPH. The two companies will equally share costs and profits from the collaboration and implement a joint development and commercialization strategy. The collaboration also includes clinical development of Bayer's vericiguat, which is currently in Phase 2 trials for worsening heart failure, as well as opt-in rights for other early-stage sGC compounds in development at Bayer. Merck will in turn make available its early-stage sGC compounds under similar terms. In return for these broad collaboration rights, Merck made an upfront payment to Bayer of \$1.0 billion with the potential for additional milestone payments upon the achievement of agreed-upon sales goals. For Adempas, Bayer will continue to lead commercialization in the Americas, while Merck will lead

commercialization in the rest of the world. For vericiguat and other potential opt-in products, Bayer will lead in the rest of world and Merck will lead in the Americas. For all products and candidates included in the agreement, both companies will share in development costs and profits on sales and will have the right to co-promote in territories where they are not the lead. The Company and Bayer each have the right to terminate the agreement for cause on a product-by-product basis, for all products being developed and commercialized under the agreement (other than Adempas for which Bayer has no termination rights) in the event of the other party's material, uncured breach related to any such product.

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Remicade/Simponi

In 1998, a subsidiary of Schering-Plough entered into a licensing agreement with Centocor Ortho Biotech Inc. ("Centocor"), a Johnson & Johnson ("J&J") company, to market Remicade, which is prescribed for the treatment of inflammatory diseases. In 2005, Schering-Plough's subsidiary exercised an option under its contract with Centocor for license rights to develop and commercialize Simponi, a fully human monoclonal antibody. The Company has exclusive marketing rights to both products throughout Europe, Russia and Turkey. In December 2007, Schering-Plough and Centocor revised their distribution agreement regarding the development, commercialization and distribution of both Remicade and Simponi, extending the Company's rights to exclusively market Remicade to match the duration of the Company's exclusive marketing rights for Simponi. In addition, Schering-Plough and Centocor agreed to share certain development costs relating to Simponi's auto-injector delivery system. On October 6, 2009, the European Commission approved Simponi as a treatment for rheumatoid arthritis and other immune system disorders in two presentations – a novel auto-injector and a prefilled syringe. As a result, the Company's marketing rights for both products extend for 15 years from the first commercial sale of Simponi in the European Union (the "EU") following the receipt of pricing and reimbursement approval within the EU. All profits derived from Merck's exclusive distribution of the two products in these countries are equally divided between Merck and J&J.

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 potential for longer-term unfavorable changes in foreign exchange rates to decrease the U.S. dollar value of future cash flows derived from foreign currency denominated sales, primarily the euro and Japanese ven. To achieve this objective, the Company will hedge a portion of its forecasted foreign currency denominated third-party and intercompany distributor entity sales that are expected to occur over its planning cycle, typically no more than three years into the future. The Company will layer in hedges over time, increasing the portion of third-party and intercompany distributor entity sales hedged as it gets closer to the expected date of the forecasted foreign currency denominated sales. The portion of 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 hedged anticipated sales are a specified component of a portfolio of similarly denominated foreign currency-based sales transactions, each of which responds to the hedged currency risk in the same manner. The Company manages its anticipated transaction exposure principally with purchased local currency put options, which provide the Company with a right, but not an obligation, to sell foreign currencies in the future at a predetermined price. If the U.S. dollar strengthens relative to the currency of the hedged anticipated sales, total changes in the options' cash flows offset the decline in the expected future U.S. dollar equivalent cash flows of the hedged foreign currency sales. Conversely, if the U.S. dollar weakens, the options' value reduces to zero, but the Company benefits from the increase in the U.S. dollar equivalent value of the anticipated foreign currency cash flows.

In connection with the Company's revenue hedging program, a purchased collar option strategy may be utilized. With a purchased collar option strategy, the Company writes a local currency call option and purchases a local currency put option. As compared to a purchased put option strategy alone, a purchased collar strategy reduces the upfront costs associated with purchasing puts through the collection of premium by writing call options. If the U.S. dollar weakens relative to the currency of the hedged anticipated sales, the purchased put option value of the collar strategy reduces to

zero and the Company benefits from the increase in the U.S. dollar equivalent value of its anticipated foreign currency cash flows; however, this benefit would be capped at the strike level of the written call. If the U.S. dollar strengthens relative to the currency of the hedged anticipated sales, the written call option value of the collar strategy reduces to zero and the changes in the purchased put cash flows of the collar strategy would offset the decline in the expected future U.S. dollar equivalent cash flows of the hedged foreign currency sales.

The Company may also utilize forward contracts in its revenue hedging program. If the U.S. dollar strengthens relative to the currency of the hedged anticipated sales, the increase in the fair value of the forward contracts offsets the decrease in the expected future U.S. dollar cash flows of the hedged foreign currency sales. Conversely, if the U.S. dollar weakens, the decrease in the fair value of the forward contracts offsets the increase in the value of the anticipated foreign currency cash flows.

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The fair values of these derivative contracts are recorded as either assets (gain positions) or liabilities (loss positions) in the 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 Consolidated Statement of Cash Flows. The Company does not enter into derivatives for trading or speculative purposes.

The primary objective of the balance sheet risk management program is to mitigate the exposure of foreign currency denominated net monetary assets of foreign subsidiaries where the U.S. dollar is the functional currency from the effects of volatility in foreign exchange. In these instances, Merck principally utilizes forward exchange contracts, which enable the Company to buy and sell foreign currencies in the future at fixed exchange rates and economically offset the consequences of changes in foreign exchange from the monetary assets. Merck routinely enters into 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 Company will also minimize the effect of exchange on monetary assets and liabilities by managing operating activities and net asset positions at the local level. The cash flows from these contracts are reported as operating activities in the Consolidated Statements 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 also uses 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. 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 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 gains (losses) of \$166 million and \$(33) million for the first nine months of 2014 and 2013, 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 September 30, 2014, the Company was party to a total of 11 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. There are four swaps maturing in 2016 with notional amounts of \$250 million each that effectively convert the Company's 0.70% fixed-rate notes due in 2016 to floating-rate instruments; four swaps maturing in 2018 with notional amounts of \$250 million each that effectively convert the Company's 1.30% fixed-rate notes due in 2018 to floating-rate instruments; and three swaps maturing in 2019, two with notional amounts of \$200 million each, and one with a notional amount of \$150 million, that effectively convert a portion of the Company's 5.00% notes due in 2019 to floating rate instruments. 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 are recorded in interest expense and offset by the fair value changes in the swap contracts. In September 2014, the Company terminated four interest rate swap contracts that

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Notes to Interim Consolidated Financial Statements (unaudited) (continued)

effectively converted the Company's 6.00% fixed-rate notes due in 2017 to floating-rate instruments. As result of the swap terminations, the Company received \$3 million in cash. The corresponding basis adjustment of the debt associated with the terminated interest rate swap contracts was deferred and is being amortized as a reduction of interest expense over the respective term of the notes. The cash flows from these contracts are reported as operating activities in the 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:

		September 30, 2014 Fair Value of Derivative U.S. Dollar			December Fair Valu	ntiye U.S. Dollar	
(\$ in millions)	Balance Sheet Caption	Asset		Notional	Asset		Notional Notional
Derivatives Designated as Hedging Instruments							
Interest rate swap contracts (non-current)	Other assets	\$8	\$ —	\$ 550	\$13	\$—	\$ 1,550
Interest rate swap contracts (non-current)	Other noncurrent liabilities	_	22	2,000	_	25	2,000
Foreign exchange contracts (current)	Deferred income taxes and other current assets	627	_	7,157	493	_	4,427
Foreign exchange contracts (non-current)	Other assets	491	_	6,238	515	_	6,676
Foreign exchange contracts (current)	Accrued and other current liabilities	—	1	464	_	19	1,659
Foreign exchange contracts (non-current)	Other noncurrent liabilities	_	1	120	_	_	
Derivatives Not Designated as Hedging Instruments		\$1,126	\$24	\$ 16,529	\$1,021	\$44	\$ 16,312
Foreign exchange contracts (current)	Deferred income taxes and other current assets	\$234	\$	\$ 9,192	\$69	\$—	\$ 5,705
Foreign exchange contracts (current)	Accrued and other current liabilities	· —	70	4,687	_	140	7,892
· · · · · · · · · · · · · · · · · · ·		\$234 \$1,360	\$70 \$94	\$ 13,879 \$ 30,408	\$69 \$1,090	\$140 \$184	\$ 13,597 \$ 29,909

As noted above, the Company records its derivatives on a gross basis in the 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:

	Septembe 2014	r 30,	December	r 31, 2013
(\$ in millions)	Asset	Liability	Asset	Liability
Gross amounts recognized in the consolidated balance sheet	\$1,360	\$94	\$1,090	\$184
Gross amount subject to offset in master netting arrangements not offset in the consolidated balance sheet	(91)	(91)	(147)	(147)

Cash collateral (received) posted	(942) —	(652) —
Net amounts	\$327 \$3	\$291 \$37

Notes to Interim Consolidated Financial Statements (unaudited) (continued)

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, (iii) designated in a foreign currency net investment hedging relationship and (iv) not designated in a hedging relationship:

	Three Months Ended September 30,			Nine Mo				
(\$ in millions)	2014	IUC	2013		2014	UCI	2013	
Derivatives designated in a fair value hedging relationship	2011		2015		201.		2015	
Interest rate swap contracts								
Amount of loss (gain) recognized in Other (income) expense, net on derivatives (1)	\$23		\$(33)	\$2		\$1	
Amount of (gain) loss recognized in Other (income) expense, net on hedged item	(23)	30		(3)	(2)
Derivatives designated in foreign currency cash flow hedging relationships								
Foreign exchange contracts								
Amount of (gain) loss reclassified from AOCI to Sales	(42)	1		(45)	36	
Amount of (gain) loss recognized in OCI on derivatives	(433)	165		(276)	(219)
Derivatives designated in foreign currency net investment hedging								
relationships								
Foreign exchange contracts								
Amount of gain recognized in Other (income) expense, net on derivatives (2)	(1)	(5)	(3)	(7)
Amount of gain recognized in OCI on derivatives	(116)	(15)	(67)	(259)
Derivatives not designated in a hedging relationship	`		`		`	Í	`	
Foreign exchange contracts								
Amount of (gain) loss recognized in Other (income) expense, net on derivatives (3)	(290)	154		(314)	146	
Amount of loss recognized in Sales	5		8		5		5	
	5		8		5		5	

⁽¹⁾ There was \$3 million of ineffectiveness on the hedge during the third quarter and first nine months of 2013.

At September 30, 2014, the Company estimates \$256 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.

Investments in Debt and Equity Securities

Information on available-for-sale investments is as follows:

	September 30, 2014				December 31, 2013					
	Fair	Amortized Gross Unrealized				Fair	Amortized Gross Unrealized			
(\$ in millions)	Value	Cost	Gains	Losses		Value	Cost	Gains	Losses	
Corporate notes and bonds	\$9,428	\$ 9,411	\$31	\$(14)	\$7,054	\$7,037	\$32	\$(15)
Commercial paper	2,121	2,121	_			1,206	1,206	_	_	
U.S. government and agency securities	2,039	2,042	_	(3)	1,236	1,239	1	(4)
Asset-backed securities	1,440	1,441	1	(2)	1,300	1,303	1	(4)
Mortgage-backed securities	538	540	1	(3)	476	479	2	(5)

⁽²⁾ There was no ineffectiveness on the hedge. Represents the amount excluded from hedge effectiveness testing.

⁽³⁾ 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.

Foreign government bonds	456	456	_		125	126	_	(1)
Equity securities	707	589	118		471	397	74	—	
	\$16,729	\$ 16,600	\$151	\$(22) \$11,868	\$ 11,787	\$110	\$(29)

Available-for-sale debt securities included in Short-term investments totaled \$3.0 billion at September 30, 2014. Of the remaining debt securities, \$12.1 billion mature within five years. At September 30, 2014 and December 31, 2013, 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 are those whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques with significant unobservable inputs, as well as instruments 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:

I maneral assets and machines measured at ran value on a recurring basis are summarized below.										
	Fair Value N	Measuremen	ts Using		Fair Value Measurements Using					
	Quoted Pric In Active Markets for Identical As (Level 1)	Other Observable Inputs	Unobservabl	e Total	Quoted Price In Active Markets for Identical As (Level 1)	Other Observable Inputs	Unobservabl	^e Total		
(\$ in millions)	September 3	30, 2014			December 3	1, 2013				
Assets										
Investments										
Corporate notes and bonds	\$—	\$ 9,428	\$ —	\$9,428	\$—	\$ 7,054	\$ —	\$7,054		
Commercial paper	_	2,121		2,121		1,206		1,206		
U.S. government and agency securities	_	2,039	_	2,039	_	1,236	_	1,236		
Asset-backed securities (1)	_	1,440	_	1,440	_	1,300	_	1,300		
Mortgage-backed securities (1)	_	538	_	538	_	476	_	476		
Foreign government bonds	_	456	_	456	_	125	_	125		
Equity securities	447		_	447	238	_	_	238		