

Merck & Co., Inc.
Form 10-Q
August 08, 2016

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 June 30, 2016

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.

2000 Galloping Hill Road

Kenilworth, N.J. 07033

(908) 740-4000

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 July 31, 2016: 2,765,208,203

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

Indicate by check mark whether the registrant has submitted electronically 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 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 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

Part I - Financial Information

Item 1. Financial Statements

MERCK & CO., INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENT OF INCOME

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Sales	\$9,844	\$9,785	\$19,156	\$19,210
Costs, Expenses and Other				
Materials and production	3,578	3,754	7,150	7,323
Marketing and administrative	2,458	2,624	4,776	5,226
Research and development	2,151	1,670	3,810	3,407
Restructuring costs	134	191	225	273
Other (income) expense, net	19	739	67	793
	8,340	8,978	16,028	17,022
Income Before Taxes	1,504	807	3,128	2,188
Taxes on Income	295	119	789	542
Net Income	1,209	688	2,339	1,646
Less: Net Income Attributable to Noncontrolling Interests	4	1	9	7
Net Income Attributable to Merck & Co., Inc.	\$1,205	\$687	\$2,330	\$1,639
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders	\$0.44	\$0.24	\$0.84	\$0.58
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders	\$0.43	\$0.24	\$0.83	\$0.57
Dividends Declared per Common Share	\$0.46	\$0.45	\$0.92	\$0.90

MERCK & CO., INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

(Unaudited, \$ in millions)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Net Income Attributable to Merck & Co., Inc.	\$1,205	\$687	\$2,330	\$1,639
Other Comprehensive Income (Loss) Net of Taxes:				
Net unrealized (loss) gain on derivatives, net of reclassifications	(91)	(176)	(293)	76
Net unrealized gain (loss) on investments, net of reclassifications	63	(14)	126	32
Benefit plan net (loss) gain and prior service (cost) credit, net of amortization	(108)	42	(136)	77
Cumulative translation adjustment	244	(17)	365	(194)
	108	(165)	62	(9)
Comprehensive Income Attributable to Merck & Co., Inc.	\$1,313	\$522	\$2,392	\$1,630

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)

	June 30, 2016	December 31, 2015
Assets		
Current Assets		
Cash and cash equivalents	\$6,608	\$8,524
Short-term investments	5,226	4,903
Accounts receivable (net of allowance for doubtful accounts of \$167 in 2016 and \$165 in 2015) (excludes accounts receivable of \$10 in 2016 and 2015 classified in Other assets)	6,916	6,484
Inventories (excludes inventories of \$1,195 in 2016 and \$1,569 in 2015 classified in Other assets - see Note 5)	5,248	4,700
Other current assets	3,928	5,140
Total current assets	27,926	29,751
Investments	11,879	13,039
Property, Plant and Equipment, at cost, net of accumulated depreciation of \$16,005 in 2016 and \$15,923 in 2015	11,987	12,507
Goodwill	17,809	17,723
Other Intangibles, Net	20,315	22,602
Other Assets	6,559	6,055
	\$96,475	\$101,677
Liabilities and Equity		
Current Liabilities		
Loans payable and current portion of long-term debt	\$644	\$2,583
Trade accounts payable	2,514	2,533
Accrued and other current liabilities	9,255	11,216
Income taxes payable	1,213	1,560
Dividends payable	1,292	1,309
Total current liabilities	14,918	19,201
Long-Term Debt	23,642	23,829
Deferred Income Taxes	6,091	6,535
Other Noncurrent Liabilities	8,378	7,345
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 2016 and 2015		
Other paid-in capital	39,911	40,222
Retained earnings	45,121	45,348
Accumulated other comprehensive loss	(4,086)	(4,148)
	82,734	83,210
Less treasury stock, at cost:		
811,476,036 shares in 2016 and 795,975,449 shares in 2015	39,377	38,534
Total Merck & Co., Inc. stockholders' equity	43,357	44,676
Noncontrolling Interests	89	91
Total equity	43,446	44,767

\$96,475 \$101,677

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

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

	Six Months Ended June 30,	
	2016	2015
Cash Flows from Operating Activities		
Net income	\$2,339	\$1,646
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	3,111	3,245
Intangible asset impairment charges	567	73
Foreign currency devaluation related to Venezuela	—	715
Equity income from affiliates	(38)	(147)
Dividends and distributions from equity affiliates	7	7
Deferred income taxes	(120)	(383)
Share-based compensation	148	146
Other	197	689
Net changes in assets and liabilities	(2,438)	(1,010)
Net Cash Provided by Operating Activities	3,773	4,981
Cash Flows from Investing Activities		
Capital expenditures	(654)	(474)
Purchases of securities and other investments	(6,355)	(8,621)
Proceeds from sales of securities and other investments	7,388	12,628
Acquisition of Cubist Pharmaceuticals, Inc., net of cash acquired	—	(7,598)
Acquisitions of other businesses, net of cash acquired	(157)	—
Dispositions of businesses, net of cash divested	—	25
Other	21	(40)
Net Cash Provided by (Used in) Investing Activities	243	(4,080)
Cash Flows from Financing Activities		
Net change in short-term borrowings	(9)	(1,529)
Proceeds from issuance of debt	8	7,940
Payments on debt	(2,351)	(2,905)
Purchases of treasury stock	(1,573)	(1,724)
Dividends paid to stockholders	(2,579)	(2,582)
Proceeds from exercise of stock options	381	377
Other	(109)	(19)
Net Cash Used in Financing Activities	(6,232)	(442)
Effect of Exchange Rate Changes on Cash and Cash Equivalents	300	(978)
Net Decrease in Cash and Cash Equivalents	(1,916)	(519)
Cash and Cash Equivalents at Beginning of Year	8,524	7,441
Cash and Cash Equivalents at End of Period	\$6,608	\$6,922
The accompanying notes are an integral part of this condensed consolidated financial statement.		

Notes to Condensed Consolidated Financial Statements (unaudited)

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 26, 2016.

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.

Recently Adopted Accounting Standards

In the first quarter of 2016, the Company adopted accounting guidance issued by the Financial Accounting Standards Board (FASB) in April 2015, which requires debt issuance costs to be presented as a direct deduction from the carrying amount of that debt on the balance sheet as opposed to being presented as a deferred charge. Approximately \$100 million of debt issuance costs were reclassified in the first quarter of 2016 as a result of the adoption of the new standard. Prior period amounts have been recast to conform to the new presentation.

In the second quarter of 2016, the Company elected to early adopt an accounting standards update issued by the FASB in March of 2016 intended to simplify the accounting and reporting for employee share-based payment transactions. Among other provisions, the new standard requires that excess tax benefits and deficiencies that arise upon vesting or exercise of share-based payments be recognized in the income statement (as opposed to existing guidance under which tax effects are recorded to Other paid-in-capital in certain instances). This aspect of the new guidance was adopted prospectively; accordingly, the Company recognized \$29 million of excess tax benefits in Taxes on income arising from share-based payments in the second quarter of 2016. The new guidance also amended the presentation of certain share-based payment items in the statement of cash flows. Cash flows related to excess income tax benefits are now classified as an operating activity (formerly included as a financing activity). The Company elected to adopt this aspect of the new guidance prospectively. The standard also clarified that cash payments made to taxing authorities on the employees' behalf for shares withheld should be presented as a financing activity. This aspect of the guidance was adopted retrospectively; accordingly, the Company reclassified \$112 million of such payments from operating activities to financing activities in the Condensed Consolidated Statement of Cash Flows for the six months ended June 30, 2015 to conform to the current presentation. The Company has elected to continue to estimate the impact of forfeitures when determining the amount of compensation cost to be recognized each period rather than account for them as they occur.

Recently Issued Accounting Standards

In May 2014, the 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. Reporting entities may choose to adopt the standard as of the original effective date. The Company is currently assessing the impact of adoption on its consolidated financial statements.

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 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

Notes to Condensed Consolidated Financial Statements (unaudited)

2020, with earlier application permitted in 2019. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

2. Acquisitions, Divestitures, Research Collaborations and License Agreements

The Company continues its strategy of establishing external alliances to complement its 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 July 2016, Merck acquired Afferent Pharmaceuticals (Afferent), a privately held pharmaceutical company focused on the development of therapeutic candidates targeting the P2X3 receptor for the treatment of common, poorly-managed, neurogenic conditions. Afferent's lead investigational candidate, MK-7264 (formerly AF-219), is a selective, non-narcotic, orally-administered P2X3 antagonist currently being evaluated in a Phase 2b clinical trial for the treatment of refractory, chronic cough as well as in a Phase 2 clinical trial in idiopathic pulmonary fibrosis with cough. Merck acquired all outstanding stock of Afferent in exchange for a payment of \$500 million in cash. In addition, former Afferent shareholders are eligible to receive a total of up to an additional \$750 million contingent upon the attainment of certain clinical development and commercial milestones for multiple indications and candidates, including MK-7264. The Company is in the process of determining the preliminary fair value of assets acquired, liabilities assumed and total consideration transferred for this business acquisition. The transaction closed on July 26, 2016; accordingly, the results of operations of the acquired business will be included in the Company's results of operations beginning after that date.

In July 2016, Merck, through its wholly owned subsidiary Healthcare Services & Solutions, LLC, acquired a majority ownership interest in The StayWell Company LLC (StayWell), a portfolio company of Vestar Capital Partners (Vestar). StayWell is a health engagement company that helps its clients engage and educate people to improve health and business results. Under the terms of the transaction, Merck paid \$150 million for a majority ownership interest. Merck has an option to buy, and Vestar has an option to require Merck to buy, an additional ownership interest at a future date. The Company is in the process of determining the preliminary fair value of assets acquired and liabilities assumed for this business acquisition. The transaction closed on July 1, 2016; accordingly, the results of operations of the acquired business will be included in the Company's results of operations beginning after that date.

Also in July 2016, Merck announced it had executed an agreement to acquire 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 more than 100 products spanning parasiticides, anti-infectives and vaccines that include products for livestock, horses, and companion animals. Under the terms of the agreement, Merck will acquire approximately 93% of the shares of Vallée in exchange for a payment estimated to be approximately \$400 million, based on exchange rates at the time of the announcement. This agreement is subject to regulatory review and certain closing conditions.

In June 2016, Merck and Moderna Therapeutics (Moderna) entered into a strategic collaboration and license agreement to develop and commercialize novel messenger RNA (mRNA)-based personalized cancer vaccines. The collaboration will combine Merck's established leadership in immuno-oncology with Moderna's mRNA vaccine technology and GMP manufacturing capabilities to advance individually tailored cancer vaccines for patients across a spectrum of cancers. Moderna and Merck will develop personalized cancer vaccines that utilize Moderna's mRNA vaccine technology to encode a patient's specific neoantigens, unique mutations present in that specific patient's tumor. The development program will entail multiple studies in several types of cancer and include the evaluation of mRNA-based personalized cancer vaccines in combination with Merck's Keytruda. Pursuant to the terms of the agreement, Merck made an upfront cash payment to Moderna of \$200 million in July 2016, which was accrued for and recorded in Research and development expenses in the second quarter of 2016. Following human proof of concept studies, Merck has the right to elect to make an additional payment to Moderna. If Merck exercises this right, the two

companies will then equally share cost and profits under a worldwide collaboration for the development of personalized cancer vaccines. Moderna will have the right to elect to co-promote the personalized cancer vaccines in the United States. The agreement entails exclusivity around combinations with Keytruda. Moderna and Merck will each have the ability to combine mRNA-based personalized cancer vaccines with other (non-PD-1) agents. Merck and Moderna have an existing collaboration and license agreement focused on the discovery and development of mRNA-based infectious disease vaccines and passive immunity treatments.

As previously disclosed, in 2014, the Company entered into a worldwide clinical development collaboration with Bayer AG (Bayer) to market and develop soluble guanylate cyclase (sGC) modulators, including Bayer's Adempas (riociguat). The arrangement provided for potential future milestone payments of up to \$1.1 billion based upon the achievement of agreed-upon

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

sales goals. During the second quarter of 2016, the Company determined it was probable that, in 2017, Adempas sales would exceed the threshold triggering a \$350 million milestone payment from Merck to Bayer. Accordingly, in the second quarter of 2016, the Company recorded a \$350 million liability and a corresponding intangible asset and also recognized \$50 million of cumulative amortization expense within Materials and production costs. The remaining intangible asset of \$300 million will be amortized over the remaining estimated useful life of the asset of 10.5 years as supported by projected future cash flows, subject to impairment testing. Additional potential future milestone payments of \$775 million have not yet been accrued as they are not deemed by the Company to be probable at this time.

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. Total purchase consideration in the transaction of \$227 million 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, which the Company determined had a fair value of \$77 million at the acquisition date. 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. Merck recognized intangible assets for in-process research and development (IPR&D) of \$155 million and net deferred tax assets of \$26 million. The excess of the consideration transferred over the fair value of net assets acquired of \$46 million 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 assets 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 10.5%. The fair value of the contingent consideration was determined utilizing a probability-weighted estimated cash flow stream adjusted for the expected timing of each payment also utilizing a discount rate of 10.5%. Actual cash flows are likely to be different than those assumed. This transaction closed on January 11, 2016; 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 IOmet's historical financial results are not significant when compared with the Company's financial results.

Also 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 six months 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.

In February 2015, Merck and NGM Biopharmaceuticals, Inc. (NGM), a privately held biotechnology company, entered into a multi-year collaboration to research, discover, develop and commercialize novel biologic therapies across a wide range of therapeutic areas. The collaboration includes multiple drug candidates currently in preclinical development at NGM, including NP201, which is being evaluated for the treatment of diabetes, obesity and nonalcoholic steatohepatitis. NGM will lead the research and development of the existing preclinical candidates and have the autonomy to identify and pursue other discovery stage programs at its discretion. Merck will have the option to license all resulting NGM programs following human proof-of-concept trials. If Merck exercises this option, Merck will lead global product development and commercialization for the resulting products, if approved. Under the terms of the agreement, Merck made an upfront payment to NGM of \$94 million, which is included in Research and development expenses, and purchased a 15% equity stake in NGM for \$106 million. Merck committed up to \$250 million to fund all of NGM's efforts under the initial five-year term of the collaboration, with the potential for additional funding if certain conditions are met. Prior to Merck initiating a Phase 3 study for a licensed program, NGM may elect to either receive milestone and royalty payments or, in certain cases, to co-fund development and participate in a global cost and revenue share arrangement of up to 50%. The agreement also provides NGM with the option to participate in the co-promotion of any co-funded program in the United States. Merck will have the option to extend the research agreement for two additional two-year terms. Each party has certain termination rights under the

agreement in the event of an uncured material breach by the other party. Additionally, Merck has certain termination rights in the event of the occurrence of certain defined conditions. Upon a termination event, depending on the circumstances, the parties have varying rights and obligations with respect to the continued development and commercialization of compounds discovered under the agreement and certain related payment obligations.

Acquisition of Cubist Pharmaceuticals, Inc.

In January 2015, Merck acquired Cubist Pharmaceuticals, Inc. (Cubist), a leader in the development of therapies to treat serious infections caused by a broad range of bacteria. This transaction closed on January 21, 2015; 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 first six months of 2015, the Company incurred \$324 million of transaction costs directly related to the acquisition of Cubist including share-based compensation costs, severance costs and legal and advisory fees which are reflected in Marketing and administrative expenses. Of this amount, \$226 million was recorded in the first quarter of 2015 and \$98 million was recorded in the second quarter of 2015, but should have been recorded in the first quarter of 2015 which was the period the acquisition closed.

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

The following unaudited supplemental pro forma data presents consolidated information as if the acquisition of Cubist had been completed on January 1, 2014:

	Three Months Ended June 30, 2015	Six Months Ended June 30, 2015
(\$ in millions, except per share amounts)		
Sales	\$ 9,785	\$ 19,296
Net income attributable to Merck & Co., Inc.	764	1,811
Basic earnings per common share attributable to Merck & Co., Inc. common shareholders	0.27	0.64
Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	0.27	0.63

The unaudited supplemental pro forma data reflects the historical information of Merck and Cubist adjusted to include additional amortization expense based on the fair value of assets acquired, additional interest expense that would have been incurred on borrowings used to fund the acquisition, transaction costs associated with the acquisition, and the related tax effects of these adjustments. The pro forma data should not be considered indicative of the results that would have occurred if the acquisition had been consummated on January 1, 2014, nor are they indicative of future results.

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 \$351 million and \$328 million in the second quarter of 2016 and 2015, respectively, and \$547 million and \$553 million for the first six months of 2016 and 2015, respectively, related to restructuring program activities. Since inception of the programs through June 30, 2016, Merck has recorded total pretax accumulated costs of approximately \$12.0 billion and eliminated approximately 39,330 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 \$1.0 billion 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:

(\$ in millions)	Three Months Ended June 30, 2016				Six Months Ended June 30, 2016			
	Separation Costs	Accelerated Depreciation	Other	Total	Separation Costs	Accelerated Depreciation	Other	Total
Materials and production	\$—	\$ 29	\$ 37	\$ 66	\$—	\$ 51	\$ 62	\$ 113
Marketing and administrative	—	4	83	87	—	7	83	90
Research and development	—	64	—	64	—	119	—	119
Restructuring costs	85	—	49	134	111	—	114	225
	\$ 85	\$ 97	\$ 169	\$ 351	\$ 111	\$ 177	\$ 259	\$ 547

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(\$ in millions)	Three Months Ended June 30, 2015				Six Months Ended June 30, 2015			
	Separate Costs	Accelerated Depreciation	Other	Total	Separate Costs	Accelerated Depreciation	Other	Total
Materials and production	\$—	\$ 17	\$88	\$105	\$—	\$ 30	\$180	\$210
Marketing and administrative	—	14	3	17	—	48	5	53
Research and development	—	16	(1)	15	—	16	1	17
Restructuring costs	59	—	132	191	88	—	185	273
	\$59	\$ 47	\$222	\$328	\$88	\$ 94	\$371	\$553

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

Separation costs are associated with actual headcount reductions, as well as those headcount reductions which were probable and could be reasonably estimated. In the second quarter of 2016 and 2015, approximately 585 positions and 860 positions, respectively, and for the first six months of 2016 and 2015, approximately 1,055 positions and 1,950 positions, respectively, were eliminated under the restructuring program activities. 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 recorded accelerated depreciation 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 2016 and 2015 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 11) and share-based compensation.

The following table summarizes the charges and spending relating to restructuring program activities for the six months ended June 30, 2016:

(\$ in millions)	Separation Costs	Accelerated Depreciation	Other	Total
Restructuring reserves January 1, 2016	\$ 592	\$ —	\$ 53	\$ 645
Expense	111	177	259	547
(Payments) receipts, net	(185)	—	(126)	(311)
Non-cash activity	—	(177)	(146)	(323)
Restructuring reserves June 30, 2016 ⁽¹⁾	\$ 518	\$ —	\$ 40	\$ 558

⁽¹⁾ 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 primary 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 yen. 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

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

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 premiums 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.

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 primary objective of the balance sheet risk management program is 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, 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 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 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 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

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

losses of \$29 million and pretax gains \$247 million for the first six months of 2016 and 2015, 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.

In May 2016, four interest rate swaps with notional amounts of \$250 million each matured. These swaps effectively converted the Company's \$1.0 billion, 0.70% fixed-rate notes due 2016 to variable rate debt. At June 30, 2016, 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)	June 30, 2016		
	Par Value of Debt	Number of Interest Rate Swaps Held	Total Swap 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:

(\$ in millions)	Balance Sheet Caption	June 30, 2016			December 31, 2015		
		Asset	Liability	U.S. Dollar Notional	Asset	Liability	U.S. Dollar Notional
Derivatives Designated as Hedging Instruments							
Interest rate swap contracts (noncurrent)	Other assets	\$ 217	\$ —	\$ 6,200	\$ 42	\$ —	\$ 2,700
Interest rate swap contracts (current)	Accrued and other current liabilities	—	—	—	—	1	1,000
Interest rate swap contracts (noncurrent)	Other noncurrent liabilities	—	—	—	—	23	3,500
Foreign exchange contracts (current)	Other current	346	—	4,722	579	—	4,171

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Foreign exchange contracts (noncurrent)	assets Other assets	169	—	2,746	386	—	4,136
Foreign exchange contracts (current)	Accrued and other current liabilities	—	10	438	—	1	77
Foreign exchange contracts (noncurrent)	Other noncurrent liabilities	—	1	150	—	—	—
		\$ 732	\$ 11	\$ 14,256	\$ 1,007	\$ 25	\$ 15,584
Derivatives Not Designated as Hedging Instruments							
Foreign exchange contracts (current)	Other current assets	\$ 180	\$ —	\$ 7,029	\$ 212	\$ —	\$ 8,783
Foreign exchange contracts (noncurrent)	Other assets	—	—	—	18	—	179
Foreign exchange contracts (current)	Accrued and other current liabilities	—	59	3,988	—	37	2,508
Foreign exchange contracts (noncurrent)	Other noncurrent liabilities	—	1	6	—	1	6
		\$ 180	\$ 60	\$ 11,023	\$ 230	\$ 38	\$ 11,476
		\$ 912	\$ 71	\$ 25,279	\$ 1,237	\$ 63	\$ 27,060

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

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:

(\$ in millions)	June 30, 2016		December 31, 2015	
	Asset	Liability	Asset	Liability
Gross amounts recognized in the consolidated balance sheet	\$912	\$ 71	\$1,237	\$ 63
Gross amount subject to offset in master netting arrangements not offset in the consolidated balance sheet	(47)	(47)	(59)	(59)
Cash collateral (received) posted	(595)	—	(862)	—
Net amounts	\$270	\$ 24	\$316	\$ 4

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:

(\$ in millions)	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Derivatives designated in a fair value hedging relationship				
Interest rate swap contracts				
Amount of (gain) loss recognized in Other (income) expense, net on derivatives ⁽¹⁾	\$(48)	\$57	\$(198)	\$32
Amount of loss (gain) recognized in Other (income) expense, net on hedged item ⁽¹⁾	47	(56)	194	(34)
Derivatives designated in foreign currency cash flow hedging relationships				
Foreign exchange contracts				
Amount of gain reclassified from AOCI to Sales	(65)	(191)	(207)	(358)
Amount of loss (gain) recognized in OCI on derivatives	75	84	242	(481)
Derivatives designated in foreign currency net investment hedging relationships				
Foreign exchange contracts				