Johnson & Johnson and Subsidiaries

Consolidated Balance Sheets

At January 3, 2016 and December 28, 2014
(Dollars in Millions Except Share and Per Share Amounts) (Note 1)

	2015	2014
Assets		
Current assets		
Cash and cash equivalents (Notes 1 and 2)	$13,732	14,523
Marketable securities (Notes 1 and 2)	24,644	18,566
Accounts receivable trade, less allowances for doubtful accounts $268 (2014, $275)	10,734	10,985
Inventories (Notes 1 and 3)	8,053	8,184
Prepaid expenses and other receivables	3,047	3,486
Total current assets	**60,210**	**55,744**
Property, plant and equipment, net (Notes 1 and 4)	15,905	16,126
Intangible assets, net (Notes 1 and 5)	25,764	27,222
Goodwill (Notes 1 and 5)	21,629	21,832
Deferred taxes on income (Note 1 and 8)	5,490	6,202
Other assets	4,413	3,232
Total assets	**$133,411**	**130,358**
Liabilities and Shareholders' Equity		
Current liabilities		
Loans and notes payable (Note 7)	$7,004	3,638
Accounts payable	6,668	7,633
Accrued liabilities	5,411	6,553
Accrued rebates, returns and promotions	5,440	4,010
Accrued compensation and employee related obligations	2,474	2,751
Accrued taxes on income (Note 8)	750	446
Total current liabilities	**27,747**	**25,031**
Long-term debt (Note 7)	12,857	15,122
Deferred taxes on income (Note 1 & 8)	2,562	2,447
Employee related obligations (Notes 9 and 10)	8,854	9,972
Other liabilities	10,241	8,034
Total liabilities	**62,261**	**60,606**
Shareholders' equity		
Preferred stock – without par value (authorized and unissued 2,000,000 shares)	–	–
Common stock – par value $1.00 per share (Note 12) (authorized 4,320,000,000 shares; issued 3,119,843,000 shares)	3,120	3,120
Accumulated other comprehensive income (Note 13)	(13,165)	(10,722)
Retained earnings	103,879	97,245
	93,834	89,643
Less: common stock held in treasury, at cost (Note 12) (364,681,000 shares and 336,620,000 shares)	22,684	19,891
Total shareholders' equity	**71,150**	**69,752**
Total liabilities and shareholders' equity	**$133,411**	**130,358**

See Notes to Consolidated Financial Statements

Johnson & Johnson and Subsidiaries

Consolidated Statements of Earnings

(Dollars and Shares in Millions Except Per Share Amounts) (Note 1)

	2015	2014	2013
Sales to customers	$70,074	74,331	71,312
Cost of products sold	21,536	22,746	22,342
Gross profit	48,538	51,585	48,970
Selling, marketing and administrative expenses	21,203	21,954	21,830
Research and development expense	9,046	8,494	8,183
In-process research and development	224	178	580
Interest income	(128)	(67)	(74)
Interest expense, net of portion capitalized (Note 4)	552	533	482
Other (income) expense, net	(2,064)	(70)	2,498
Restructuring (Note 22)	509	–	–
Earnings before provision for taxes on income	19,196	20,563	15,471
Provision for taxes on income (Note 8)	3,787	4,240	1,640
Net earnings	**$15,409**	**16,323**	**13,831**
Net earnings per share (Notes 1 and 15)			
Basic	**$5.56**	**5.80**	**4.92**
Diluted	**$5.48**	**5.70**	**4.81**
Cash dividends per share	**$2.95**	**2.76**	**2.59**
Average shares outstanding (Notes 1 and 15)			
Basic	**2,771.8**	**2,815.2**	**2,809.2**
Diluted	**2,812.9**	**2,863.9**	**2,877.0**

See Notes to Consolidated Financial Statements

Johnson & Johnson and Subsidiaries

Consolidated Statements of Comprehensive Income

(Dollars in Millions) (Note 1)

	2015	2014	2013
Net earnings	$15,409	16,323	13,831
Other comprehensive income (loss), net of tax			
Foreign currency translation	(3,632)	(4,601)	94
Securities:			
Unrealized holding gain (loss) arising during period	471	156	225
Reclassifications to earnings	(124)	(5)	(314)
Net change	347	151	(89)
Employee benefit plans:			
Prior service cost amortization during period	(21)	(18)	9
Prior service credit (cost) – current year	(39)	211	(27)
Gain amortization during period	624	400	515
Gain (loss) – current year	307	(4,098)	2,203
Effect of exchange rates	148	197	8
Net change	1,019	(3,308)	2,708
Derivatives & hedges:			
Unrealized gain (loss) arising during period	(115)	92	344
Reclassifications to earnings	(62)	(196)	(107)
Net change	(177)	(104)	237
Other comprehensive income (loss)	(2,443)	(7,862)	2,950
Comprehensive income	$12,966	8,461	16,781

The tax effects in other comprehensive income for the fiscal years ended 2015, 2014 and 2013 respectively: Securities; $187 million, $81 million and $48 million, Employee Benefit Plans; $519 million, $1,556 million and $1,421 million, Derivatives & Hedges; $95 million, $56 million and $128 million.

See Notes to Consolidated Financial Statements

Johnson & Johnson and Subsidiaries

Consolidated Statements of Equity

(Dollars in Millions) (Note 1)

	Total	Retained Earnings	Accumulated Other Comprehensive Income	Common Stock Issued Amount	Treasury Stock Amount
Balance, December 30, 2012	**$64,826**	**85,992**	**(5,810)**	**3,120**	**(18,476)**
Net earnings	13,831	13,831			
Cash dividends paid	(7,286)	(7,286)			
Employee compensation and stock option plans	3,285	(82)			3,367
Repurchase of common stock	(3,538)	(2,947)			(591)
Other	(15)	(15)			
Other comprehensive income (loss), net of tax	2,950		2,950		
Balance, December 29, 2013	**74,053**	**89,493**	**(2,860)**	**3,120**	**(15,700)**
Net earnings	16,323	16,323			
Cash dividends paid	(7,768)	(7,768)			
Employee compensation and stock option plans	2,164	(769)			2,933
Repurchase of common stock	(7,124)				(7,124)
Other	(34)	(34)			
Other comprehensive income (loss), net of tax	(7,862)		(7,862)		
Balance, December 28, 2014	**69,752**	**97,245**	**(10,722)**	**3,120**	**(19,891)**
Net earnings	15,409	15,409			
Cash dividends paid	(8,173)	(8,173)			
Employee compensation and stock option plans	1,920	(577)			2,497
Repurchase of common stock	(5,290)				(5,290)
Other	(25)	(25)			
Other comprehensive income (loss), net of tax	(2,443)		(2,443)		
Balance, January 3, 2016	**$71,150**	**103,879**	**(13,165)**	**3,120**	**(22,684)**

See Notes to Consolidated Financial Statements

Johnson & Johnson and Subsidiaries

Consolidated Statements of Cash Flows

(Dollars in Millions) (Note 1)

	2015	2014	2013
Cash flows from operating activities			
Net earnings	$15,409	16,323	13,831
Adjustments to reconcile net earnings to cash flows from operating activities:			
Depreciation and amortization of property and intangibles	3,746	3,895	4,104
Stock based compensation	874	792	728
Venezuela adjustments	122	87	108
Asset write-downs	624	410	739
Net gain on sale of assets/businesses	(2,583)	(2,383)	(113)
Net gain on equity investment transactions	–	–	(417)
Deferred tax provision	(270)	441	(607)
Accounts receivable allowances	18	(28)	(131)
Changes in assets and liabilities, net of effects from acquisitions and divestitures:			
Increase in accounts receivable	(433)	(247)	(632)
Increase in inventories	(449)	(1,120)	(622)
(Decrease)/Increase in accounts payable and accrued liabilities	(3)	955	1,821
Decrease/(Increase) in other current and non-current assets	65	442	(1,693)
Increase/(Decrease) in other current and non-current liabilities	2,159	(1,096)	298
Net cash flows from operating activities	**19,279**	**18,471**	**17,414**
Cash flows from investing activities			
Additions to property, plant and equipment	(3,463)	(3,714)	(3,595)
Proceeds from the disposal of assets/businesses, net	3,464	4,631	458
Acquisitions, net of cash acquired (Note 20)	(954)	(2,129)	(835)
Purchases of investments	(40,828)	(34,913)	(18,923)
Sales of investments	34,149	24,119	18,058
Other (primarily intangibles)	(103)	(299)	(266)
Net cash used by investing activities	**(7,735)**	**(12,305)**	**(5,103)**
Cash flows from financing activities			
Dividends to shareholders	(8,173)	(7,768)	(7,286)
Repurchase of common stock	(5,290)	(7,124)	(3,538)
Proceeds from short-term debt	2,416	1,863	1,411
Retirement of short-term debt	(1,044)	(1,267)	(1,397)
Proceeds from long-term debt	75	2,098	3,607
Retirement of long-term debt	(68)	(1,844)	(1,593)
Proceeds from the exercise of stock options/excess tax benefits	1,295	1,782	2,649
Other	(57)	–	56
Net cash used by financing activities	**(10,846)**	**(12,260)**	**(6,091)**
Effect of exchange rate changes on cash and cash equivalents	(1,489)	(310)	(204)
(Decrease)/Increase in cash and cash equivalents	(791)	(6,404)	6,016
Cash and cash equivalents, beginning of year (Note 1)	14,523	20,927	14,911
Cash and cash equivalents, end of year (Note 1)	**$13,732**	**14,523**	**20,927**
Supplemental cash flow data			
Cash paid during the year for:			
Interest	$617	603	596
Interest, net of amount capitalized	515	488	491
Income taxes	2,865	3,536	3,155
Supplemental schedule of non-cash investing and financing activities			
Treasury stock issued for employee compensation and stock option plans, net of cash proceeds	1,196	1,170	743
Conversion of debt	16	17	22
Acquisitions			
Fair value of assets acquired	$1,174	2,167	1,028
Fair value of liabilities assumed and noncontrolling interests	(220)	(38)	(193)
Net cash paid for acquisitions	**$954**	**2,129**	**835**

See Notes to Consolidated Financial Statements

Notes to Consolidated Financial Statements

1. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of Johnson & Johnson and its subsidiaries (the Company). Intercompany accounts and transactions are eliminated.

Description of the Company and Business Segments

The Company has approximately 127,100 employees worldwide engaged in the research and development, manufacture and sale of a broad range of products in the health care field. The Company conducts business in virtually all countries of the world and its primary focus is on products related to human health and well-being.

The Company is organized into three business segments: Consumer, Pharmaceutical and Medical Devices. The Consumer segment includes a broad range of products used in the baby care, oral care, skin care, over-the-counter pharmaceutical, women's health and wound care markets. These products are marketed to the general public and sold both to retail outlets and distributors throughout the world. The Pharmaceutical segment is focused on five therapeutic areas, including immunology, infectious diseases, neuroscience, oncology, and cardiovascular and metabolic diseases. Products in this segment are distributed directly to retailers, wholesalers, hospitals and health care professionals for prescription use. The Medical Devices segment includes a broad range of products used in the orthopaedic, surgery, cardiovascular, diabetes care and vision care fields, which are distributed to wholesalers, hospitals and retailers, and used principally in the professional fields by physicians, nurses, hospitals, eye care professionals and clinics.

New Accounting Pronouncements
Recently Adopted Accounting Pronouncements

During the fiscal second quarter of 2015, the Financial Accounting Standards Board (FASB) issued Accounting Standard Update 2015-04: Practical Expedient for the Measurement Date of an Employer's Defined Benefit Obligation and Plan Assets. This update provides a practical expedient option to entities that have defined benefit plans and have a fiscal year-end that does not coincide with a calendar month-end. This option allows an entity to elect to measure defined benefit plan assets and obligations using the calendar month-end that is closest to its fiscal year-end. This update will be effective for the Company for all annual and interim periods beginning after December 15, 2015 and if the practical expedient is elected by an entity, it is required to be adopted on a prospective basis. Early adoption is permitted. The Company has elected to adopt the practical expedient to measure its defined benefit plans. This election did not have a material impact on the Company's consolidated financial statements.

During the fiscal fourth quarter of 2015, the FASB issued Accounting Standard Update 2015-17 Income Taxes: Balance Sheet Classification of Deferred Taxes. To simplify the presentation of deferred income taxes, the amendments in this update require that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. This update is required to be effective for all public Companies for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Earlier application is permitted. The Company has elected to early adopt this standard on a retrospective basis. The 2014 Consolidated Balance Sheet reclassification reduced current assets by $3.6 billion, increased non-current assets by $2.8 billion and reduced liabilities by $0.8 billion.

Recently Issued Accounting Standards
Not Adopted as of January 3, 2016

During the fiscal first quarter of 2016, the FASB issued Accounting Standard Update 2016-01: Recognition and Measurement of Financial Assets and Financial Liabilities. The amendments in this update supersede the guidance to classify equity securities with readily determinable fair values into different categories (that is, trading or available-for-sale) and require equity securities to be measured at fair value with changes in the fair value recognized through net income. The standard amends financial reporting by providing relevant information about an entity's equity investments and reducing the number of items that are recognized in other comprehensive income. This update will be effective for the Company for annual periods beginning after December 15, 2017, and interim periods within those annual periods. The Company is currently assessing the impact of the future adoption of this standard on its financial statements.

During the fiscal second quarter of 2015, the FASB issued Accounting Standard Update 2015-03: Simplifying the Presentation of Debt Issuance Costs. This update requires capitalized debt issuance costs to be presented as a reduction to the carrying value of debt instead of being classified as a deferred charge, as currently required. This update will be effective for the Company for all annual and interim periods beginning after December 15, 2015 and is required to be applied retroactively for all periods presented. This update will not have a material impact on the presentation of the Company's financial position.

During the fiscal second quarter of 2015, the FASB issued Accounting Standard Update 2015-11: Simplifying the Measurement of Inventory. This update requires inventory to be measured at the lower of cost or net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. This update will be effective for the Company for all annual and interim periods beginning after December 15, 2016. The amendments in this update should be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. This update will not have a material impact on the presentation of the Company's financial position.

During the fiscal third quarter of 2015, the FASB issued Accounting Standard Update 2015-16 Business Combinations: Simplifying the Accounting for Measurement-Period Adjustments. The amendments in this update require that an acquirer recognize adjustments to provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined. This update will be effective for the Company for all annual and interim periods beginning after December 15, 2015. The amendments in this update should be applied prospectively to adjustments to provisional amounts that occur after the effective date of this update with earlier application permitted for financial statements that have not been issued. This update is not expected to have a material impact on the Company's consolidated financial statements.

During the fiscal second quarter of 2014, the FASB issued Accounting Standards Update 2014-09: Revenue from Contracts with Customers. This standard replaces substantially all current revenue recognition accounting guidance. During the fiscal third quarter of 2015, the FASB approved a one year deferral to the effective date to be adopted by all public companies for all annual periods and interim reporting periods beginning after December 15, 2017. Early adoption of this standard is permitted but not before the original effective date for all annual periods and interim reporting periods beginning after December 15, 2016. The Company is currently assessing the impact of the future adoption of this standard on its financial statements.

During the fiscal second quarter of 2014, the FASB issued amended guidance Accounting Standards Update No. 2014-10: Development Stage Entities: Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entity Guidance in Topic 810, Consolidation. The change in the current guidance will require the Company to determine if it should consolidate one of these entities based on the change in the consolidation analysis. This update to the consolidation analysis will become effective for all annual periods and interim reporting periods beginning after December 15, 2015. The adoption of this standard is not expected to have a material impact on the presentation of the Company's consolidated financial statements.

During the fiscal third quarter of 2014, the FASB issued Accounting Standards Update No. 2014-15: Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. This standard requires management to evaluate, for each annual and interim reporting period, whether there are conditions and events, considered in the aggregate, that raise substantial doubt about an entity's ability to continue as a going concern within one year after the date the financial statements are issued or are available to be issued. If substantial doubt is raised, additional disclosures around management's plan to alleviate these doubts are required. This update will become effective for all annual periods and interim reporting periods ending after December 15, 2016. This standard is not expected to have any impact on current disclosures in the financial statements.

Cash Equivalents

The Company classifies all highly liquid investments with stated maturities of three months or less from date of purchase as cash equivalents and all highly liquid investments with stated maturities of greater than three months from the date of purchase as current marketable securities. The Company has a policy of making investments only with commercial institutions that have at least an investment grade credit rating. The Company invests its cash primarily in reverse repurchase agreements (RRAs), government securities and obligations, corporate debt securities and money market funds.

RRAs are collateralized by deposits in the form of 'Government Securities and Obligations' for an amount not less than 102% of their value. The Company does not record an asset or liability as the Company is not permitted to sell or

repledge the associated collateral. The Company has a policy that the collateral has at least an A (or equivalent) credit rating. The Company utilizes a third party custodian to manage the exchange of funds and ensure that collateral received is maintained at 102% of the value of the RRAs on a daily basis. RRAs with stated maturities of greater than three months from the date of purchase are classified as marketable securities.

Investments

Investments classified as held to maturity investments are reported at amortized cost and realized gains or losses are reported in earnings. Investments classified as available-for-sale are carried at estimated fair value with unrealized gains and losses recorded as a component of accumulated other comprehensive income. Available-for-sale securities available for current operations are classified as current assets. Management determines the appropriate classification of its investment in debt and equity securities at the time of purchase and re-evaluates such determination at each balance sheet date. The Company periodically reviews its investments in equity securities for impairment and adjusts these investments to their fair value when a decline in market value is deemed to be other than temporary. If losses on these securities are considered to be other than temporary, the loss is recognized in earnings.

Property, Plant and Equipment and Depreciation

Property, plant and equipment are stated at cost. The Company utilizes the straight-line method of depreciation over the estimated useful lives of the assets:

Building and building equipment	20 - 30 years
Land and leasehold improvements	10 - 20 years
Machinery and equipment	2 - 13 years

The Company capitalizes certain computer software and development costs, included in machinery and equipment, when incurred in connection with developing or obtaining computer software for internal use. Capitalized software costs are amortized over the estimated useful lives of the software, which generally range from 3 to 8 years.

The Company reviews long-lived assets to assess recoverability using undiscounted cash flows. When certain events or changes in operating or economic conditions occur, an impairment assessment may be performed on the recoverability of the carrying value of these assets. If the asset is determined to be impaired, the loss is measured based on the difference between the asset's fair value and its carrying value. If quoted market prices are not available, the Company will estimate fair value using a discounted value of estimated future cash flows.

Revenue Recognition

The Company recognizes revenue from product sales when the goods are shipped or delivered and title and risk of loss pass to the customer. Provisions for certain rebates, sales incentives, trade promotions, coupons, product returns and discounts to customers are accounted for as reductions in sales in the same period the related sales are recorded.

Product discounts granted are based on the terms of arrangements with direct, indirect and other market participants, as well as market conditions, including prices charged by competitors. Rebates, which include Medicaid, are estimated based on contractual terms, historical experience, patient outcomes, trend analysis and projected market conditions in the various markets served. The Company evaluates market conditions for products or groups of products primarily through the analysis of wholesaler and other third-party sell-through and market research data, as well as internally generated information.

Sales returns are generally estimated and recorded based on historical sales and returns information. Products that exhibit unusual sales or return patterns due to dating, competition or other marketing matters are specifically investigated and analyzed as part of the accounting for sales returns accruals.

Sales returns allowances represent a reserve for products that may be returned due to expiration, destruction in the field, or in specific areas, product recall. The returns reserve is based on historical return trends by product and by market as a percent to gross sales. In accordance with the Company's accounting policies, the Company generally issues credit to customers for returned goods. The Company's sales returns reserves are accounted for in accordance with U.S. GAAP guidance for revenue recognition when right of return exists. Sales returns reserves are recorded at full sales value. Sales returns in the Consumer and Pharmaceutical segments are almost exclusively not resalable. Sales returns for certain franchises in the Medical Devices segment are typically resalable but are not material. The Company infrequently

exchanges products from inventory for returned products. The sales returns reserve for the total Company has been approximately 1.0% of annual sales to customers during the fiscal reporting years 2015, 2014 and 2013.

Promotional programs, such as product listing allowances and cooperative advertising arrangements, are recorded in the year incurred. Continuing promotional programs include coupons and volume-based sales incentive programs. The redemption cost of consumer coupons is based on historical redemption experience by product and value. Volume-based incentive programs are based on the estimated sales volumes for the incentive period and are recorded as products are sold. The Company also earns service revenue for co-promotion of certain products and includes it in sales to customers. These arrangements are evaluated to determine the appropriate amounts to be deferred or recorded as a reduction of revenue.

Shipping and Handling

Shipping and handling costs incurred were $996 million, $1,068 million and $1,128 million in 2015, 2014 and 2013, respectively, and are included in selling, marketing and administrative expense. The amount of revenue received for shipping and handling is less than 0.5% of sales to customers for all periods presented.

Inventories

Inventories are stated at the lower of cost or market determined by the first-in, first-out method.

Intangible Assets and Goodwill

The authoritative literature on U.S. GAAP requires that goodwill and intangible assets with indefinite lives be assessed annually for impairment. The Company completed the annual impairment test for 2015 in the fiscal fourth quarter. Future impairment tests will be performed annually in the fiscal fourth quarter, or sooner if warranted. Purchased in-process research and development is accounted for as an indefinite lived intangible asset until the underlying project is completed, at which point the intangible asset will be accounted for as a definite lived intangible asset, or abandoned, at which point the intangible asset will be written off or partially impaired.

Intangible assets that have finite useful lives continue to be amortized over their useful lives, and are reviewed for impairment when warranted by economic conditions. See Note 5 for further details on Intangible Assets and Goodwill.

Financial Instruments

As required by U.S. GAAP, all derivative instruments are recorded on the balance sheet at fair value. Fair value is the exit price that would be received to sell an asset or paid to transfer a liability. Fair value is a market-based measurement determined using assumptions that market participants would use in pricing an asset or liability. The authoritative literature establishes a three-level hierarchy to prioritize the inputs used in measuring fair value, with Level 1 having the highest priority and Level 3 having the lowest. Changes in the fair value of derivatives are recorded each period in current earnings or other comprehensive income, depending on whether the derivative is designated as part of a hedge transaction, and if so, the type of hedge transaction.

The Company documents all relationships between hedged items and derivatives. The overall risk management strategy includes reasons for undertaking hedge transactions and entering into derivatives. The objectives of this strategy are: (1) minimize foreign currency exposure's impact on the Company's financial performance; (2) protect the Company's cash flow from adverse movements in foreign exchange rates; (3) ensure the appropriateness of financial instruments; and (4) manage the enterprise risk associated with financial institutions. See Note 6 for additional information on Financial Instruments.

Product Liability

Accruals for product liability claims are recorded, on an undiscounted basis, when it is probable that a liability has been incurred and the amount of the liability can be reasonably estimated based on existing information and actuarially determined estimates where applicable. The accruals are adjusted periodically as additional information becomes available. The Company accrues an estimate of the legal defense costs needed to defend each matter when those costs are probable and can be reasonably estimated.

As a result of cost and availability factors, effective November 1, 2005, the Company ceased purchasing third-party product liability insurance. The Company has self insurance through a wholly-owned captive insurance company. In addition to accruals in the self insurance program, claims that exceed the insurance coverage are accrued when losses are probable and amounts can be reasonably estimated. Based on the availability of prior coverage, receivables for insurance

recoveries related to product liability claims are recorded on an undiscounted basis, when it is probable that a recovery will be realized. As appropriate, reserves against these receivables are recorded for estimated amounts that may not be collected from third-party insurers.

Concentration of Credit Risk

Global concentration of credit risk with respect to trade accounts receivables continues to be limited due to the large number of customers globally and adherence to internal credit policies and credit limits. Economic challenges in Italy, Spain, Greece and Portugal (the Southern European Region) have impacted certain payment patterns, which have historically been longer than those experienced in the U.S. and other international markets. The total net trade accounts receivable balance in the Southern European Region was approximately $1.3 billion as of January 3, 2016 and approximately $1.8 billion as of December 28, 2014. Approximately $0.8 billion as of January 3, 2016 and approximately $1.1 billion as of December 28, 2014 of the Southern European Region net trade accounts receivable balance related to the Company's Consumer, Vision Care and Diabetes Care businesses as well as certain Pharmaceutical and Medical Devices customers which are in line with historical collection patterns.

The remaining balance of net trade accounts receivable in the Southern European Region has been negatively impacted by the timing of payments from certain government owned or supported health care customers, as well as certain distributors of the Pharmaceutical and Medical Devices local affiliates. The total net trade accounts receivable balance for these customers were approximately $0.5 billion at January 3, 2016 and $0.7 billion at December 28, 2014. The Company continues to receive payments from these customers and, in some cases, late payments with interest. For customers where payment is expected over periods of time longer than one year, revenue and trade receivables have been discounted over the estimated period of time for collection. Allowances for doubtful accounts have been increased for these customers, but have been immaterial to date. The Company will continue to work closely with these customers on payment plans, monitor the economic situation and take appropriate actions as necessary.

Research and Development

Research and development expenses are expensed as incurred. Upfront and milestone payments made to third parties in connection with research and development collaborations are expensed as incurred up to the point of regulatory approval. Payments made to third parties subsequent to regulatory approval are capitalized and amortized over the remaining useful life of the related product. Amounts capitalized for such payments are included in other intangibles, net of accumulated amortization.

The Company enters into collaborative arrangements, typically with other pharmaceutical or biotechnology companies, to develop and commercialize drug candidates or intellectual property. These arrangements typically involve two (or more) parties who are active participants in the collaboration and are exposed to significant risks and rewards dependent on the commercial success of the activities. These collaborations usually involve various activities by one or more parties, including research and development, marketing and selling and distribution. Often, these collaborations require upfront, milestone and royalty or profit share payments, contingent upon the occurrence of certain future events linked to the success of the asset in development. Amounts due from collaborative partners related to development activities are generally reflected as a reduction of research and development expense because the performance of contract development services is not central to the Company's operations. In general, the income statement presentation for these collaborations is as follows:

Nature/Type of Collaboration	Statement of Earnings Presentation
Third-party sale of product	Sales to customers
Royalties/milestones paid to collaborative partner (post-regulatory approval)*	Cost of products sold
Royalties received from collaborative partner	Other income (expense), net
Upfront payments & milestones paid to collaborative partner (pre-regulatory approval)	Research and development expense
Research and development payments to collaborative partner	Research and development expense
Research and development payments received from collaborative partner	Reduction of Research and development expense

* Milestones are capitalized as intangible assets and amortized to cost of goods sold over the useful life.

For all years presented, there was no individual project that represented greater than 5% of the total annual consolidated research and development expense.

The Company has a number of products and compounds developed in collaboration with strategic partners including XARELTO®, co-developed with Bayer HealthCare AG and IMBRUVICA®, developed in collaboration and co-marketed with Pharmacyclics LLC, an AbbVie company.

Advertising

Costs associated with advertising are expensed in the year incurred and are included in selling, marketing and administrative expenses. Advertising expenses worldwide, which comprised television, radio, print media and Internet advertising, were $2.5 billion, $2.6 billion and $2.5 billion in 2015, 2014 and 2013, respectively.

Income Taxes

Income taxes are recorded based on amounts refundable or payable for the current year and include the results of any difference between U.S. GAAP accounting and tax reporting, recorded as deferred tax assets or liabilities. The Company estimates deferred tax assets and liabilities based on enacted tax regulations and rates. Future changes in tax laws and rates may affect recorded deferred tax assets and liabilities in the future.

The Company has unrecognized tax benefits for uncertain tax positions. The Company follows U.S. GAAP which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Management believes that changes in these estimates would not have a material effect on the Company's results of operations, cash flows or financial position.

At January 3, 2016 and December 28, 2014, the cumulative amounts of undistributed international earnings were approximately $58.0 billion and $53.4 billion, respectively. At January 3, 2016 and December 28, 2014, the Company's foreign subsidiaries held balances of cash, cash equivalents and marketable securities in the amounts of $38.2 billion and $32.9 billion, respectively. The Company has not provided deferred taxes on the undistributed earnings from certain international subsidiaries where the earnings are considered to be permanently reinvested. The Company intends to continue to reinvest these earnings in international operations. If the Company decided at a later date to repatriate these earnings to the U.S., the Company would be required to provide for the net tax effects on these amounts. The Company does not determine the deferred tax liability associated with these undistributed earnings, as such determination is not practical.

See Note 8 to the Consolidated Financial Statements for further information regarding income taxes.

Net Earnings Per Share

Basic earnings per share is computed by dividing net earnings available to common shareholders by the weighted average number of common shares outstanding for the period. Diluted earnings per share reflects the potential dilution that could occur if securities were exercised or converted into common stock using the treasury stock method.

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the amounts reported. Estimates are used when accounting for sales discounts, rebates, allowances and incentives, product liabilities, income taxes, depreciation, amortization, employee benefits, contingencies and intangible asset and liability valuations. Actual results may or may not differ from those estimates.

The Company follows the provisions of U.S. GAAP when recording litigation related contingencies. A liability is recorded when a loss is probable and can be reasonably estimated. The best estimate of a loss within a range is accrued; however, if no estimate in the range is better than any other, the minimum amount is accrued.

Annual Closing Date

The Company follows the concept of a fiscal year, which ends on the Sunday nearest to the end of the month of December. Normally each fiscal year consists of 52 weeks, but every five or six years the fiscal year consists of 53 weeks, as was the case in 2015, and will be the case again in 2020.

Reclassification

Certain prior period amounts have been reclassified to conform to current year presentation.

2. Cash, Cash Equivalents and Current Marketable Securities

At the end of 2015 and 2014, cash, cash equivalents and current marketable securities were comprised of:

	2015					
(Dollars in Millions)	Carrying Amount	Unrecognized Gain	Unrecognized Loss	Estimated Fair Value	Cash Equivalents	Current Marketable Securities
Cash	$1,832	–	–	1,832	1,832	–
U.S. Gov't Securities[1]	14,641	1	(2)	14,640	650	13,991
Other Sovereign Securities[1]	2,122	–	–	2,122	933	1,189
U.S. Reverse repurchase agreements[1]	1,579	–	–	1,579	1,579	–
Other Reverse repurchase agreements[1]	2,200	–	–	2,200	2,200	–
Corporate debt securities[1]	2,941	–	–	2,941	1,793	1,148
Money market funds	3,855	–	–	3,855	3,855	–
Time deposits[1]	890	–	–	890	890	–
	Carrying Amount	Unrealized Gain	Unrealized Loss	Estimated Fair Value		
Gov't Securities	7,307	1	(34)	7,274	–	7,274
Corporate debt securities	1,046	1	(5)	1,042	–	1,042
Available for Sale[2]	$8,353	2	(39)	8,316	–	8,316
Total cash, cash equivalents and current marketable securities					$13,732	24,644

	2014					
(Dollars in Millions)	Carrying Amount	Unrecognized Gain	Unrecognized Loss	Estimated Fair Value	Cash Equivalents	Current Marketable Securities
Cash	$2,336	–	–	2,336	2,336	–
U.S. Gov't Securities[1]	16,345	1	(1)	16,345	1,950	14,395
Other Sovereign Securities[1]	4,265	–	–	4,265	978	3,287
U.S. Reverse repurchase agreements[1]	4,387	–	–	4,387	4,387	–
Other Reverse repurchase agreements[1]	2,348	–	–	2,348	2,348	–
Corporate debt securities[1]	1,343	–	–	1,343	459	884
Money market funds	1,352	–	–	1,352	1,352	–
Time deposits[1]	$713	–	–	713	713	–
Total cash, cash equivalents and current marketable securities					$14,523	18,566

(1) Held to maturity investments are reported at amortized cost and realized gains or losses are reported in earnings.

(2) Available for sale securities are reported at fair value with unrealized gains and losses reported net of taxes in other comprehensive income.

Fair value of government securities and obligations and corporate debt securities were estimated using quoted broker prices and significant other observable inputs.

The contractual maturities of substantially all available for sale securities are from one to five years at January 3, 2016.

The Company invests its excess cash in both deposits with major banks throughout the world and other high-quality money market instruments. The Company has a policy of making investments only with commercial institutions that have at least an investment grade credit rating.

3. Inventories

At the end of 2015 and 2014, inventories were comprised of:

(Dollars in Millions)	2015	2014
Raw materials and supplies	$936	1,214
Goods in process	2,241	2,461
Finished goods	4,876	4,509
Total inventories	**$8,053**	**8,184**

4. Property, Plant and Equipment

At the end of 2015 and 2014, property, plant and equipment at cost and accumulated depreciation were:

(Dollars in Millions)	2015	2014
Land and land improvements	$780	833
Buildings and building equipment	9,829	10,046
Machinery and equipment	22,511	22,206
Construction in progress	3,528	3,600
Total property, plant and equipment, gross	$36,648	36,685
Less accumulated depreciation	20,743	20,559
Total property, plant and equipment, net	**$15,905**	**16,126**

The Company capitalizes interest expense as part of the cost of construction of facilities and equipment. Interest expense capitalized in 2015, 2014 and 2013 was $102 million, $115 million and $105 million, respectively.

Depreciation expense, including the amortization of capitalized interest in 2015, 2014 and 2013, was $2.5 billion, $2.5 billion and $2.7 billion, respectively.

Upon retirement or other disposal of property, plant and equipment, the costs and related amounts of accumulated depreciation or amortization are eliminated from the asset and accumulated depreciation accounts, respectively. The difference, if any, between the net asset value and the proceeds are recorded in earnings.

5. Intangible Assets and Goodwill

At the end of 2015 and 2014, the gross and net amounts of intangible assets were:

(Dollars in Millions)	2015	2014
Intangible assets with definite lives:		
Patents and trademarks – gross	$8,299	9,074
Less accumulated amortization	4,745	4,700
Patents and trademarks – net	**$3,554**	**4,374**
Customer relationships and other intangibles – gross	$17,583	17,970
Less accumulated amortization	5,816	5,227
Customer relationships and other intangibles – net	**$11,767**	**12,743**
Intangible assets with indefinite lives:		
Trademarks	$7,023	7,263
Purchased in-process research and development	3,420	2,842
Total intangible assets with indefinite lives	**$10,443**	**10,105**
Total intangible assets – net	**$25,764**	**27,222**

Goodwill as of January 3, 2016 and December 28, 2014, as allocated by segment of business, was as follows:

(Dollars in Millions)	Consumer	Pharmaceutical	Med Devices	Total
Goodwill at December 29, 2013	$8,531	2,068	12,199	22,798
Goodwill, related to acquisitions	13	665	–	678
Goodwill, related to divestitures	(138)	–	(603)	(741)
Currency translation/other	(731)	(107)	(65)	(903)
Goodwill at December 28, 2014	$7,675	2,626	11,531	21,832
Goodwill, related to acquisitions	110	366	34	510
Goodwill, related to divestitures	(119)	(17)	(57)	(193)
Currency translation/other	(426)	(86)	(8)	(520)
Goodwill at January 3, 2016	**$7,240**	**2,889**	**11,500**	**21,629**

The weighted average amortization periods for patents and trademarks and customer relationships and other intangible assets are 18 years and 24 years, respectively. The amortization expense of amortizable assets included in cost of products sold was $1.2 billion, $1.4 billion and $1.4 billion before tax, for the fiscal years ended January 3, 2016, December 28, 2014 and December 29, 2013, respectively. The estimated amortization expense for the five succeeding years approximates $1.2 billion before tax, per year. Intangible asset write-downs are included in Other (income) expense, net.

See Note 20 to the Consolidated Financial Statements for additional details related to acquisitions and divestitures.

6. Fair Value Measurements

The Company uses forward foreign exchange contracts to manage its exposure to the variability of cash flows, primarily related to the foreign exchange rate changes of future intercompany products and third-party purchases of materials denominated in a foreign currency. The Company uses cross currency interest rate swaps to manage currency risk primarily related to borrowings. Both types of derivatives are designated as cash flow hedges.

Additionally, the Company uses interest rate swaps as an instrument to manage interest rate risk related to fixed rate borrowings. These derivatives are treated as fair value hedges. The Company may use forward foreign exchange contracts designated as net investment hedges. Additionally, the Company uses forward foreign exchange contracts to offset its exposure to certain foreign currency assets and liabilities. These forward foreign exchange contracts are not designated as hedges and therefore, changes in the fair values of these derivatives are recognized in earnings, thereby offsetting the current earnings effect of the related foreign currency assets and liabilities.

The Company does not enter into derivative financial instruments for trading or speculative purposes, or that contain credit risk related contingent features or requirements to post collateral by either the Company or the counter-party. On an ongoing basis, the Company monitors counterparty credit ratings. The Company considers credit non-performance risk to be low, because the Company primarily enters into agreements with commercial institutions that have at least an investment grade credit rating. Refer to the table on significant financial assets and liabilities measured at fair value contained in this footnote for receivables and payables with these commercial institutions. As of January 3, 2016, the Company had notional amounts outstanding for forward foreign exchange contracts, cross currency interest rate swaps and interest rate swaps of $31.2 billion, $2.3 billion and $2.2 billion, respectively.

All derivative instruments are recorded on the balance sheet at fair value. Changes in the fair value of derivatives are recorded each period in current earnings or other comprehensive income, depending on whether the derivative is designated as part of a hedge transaction, and if so, the type of hedge transaction.

The designation as a cash flow hedge is made at the entrance date of the derivative contract. At inception, all derivatives are expected to be highly effective. Changes in the fair value of a derivative that is designated as a cash flow hedge and is highly effective are recorded in accumulated other comprehensive income until the underlying transaction affects earnings, and are then reclassified to earnings in the same account as the hedged transaction. Gains and losses associated with interest rate swaps and changes in fair value of hedged debt attributable to changes in interest rates are recorded to interest expense in the period in which they occur. Gains and losses on net investment hedges are accounted for through the currency translation account and are insignificant. On an ongoing basis, the Company assesses whether each derivative continues to be highly effective in offsetting changes of hedged items. If and when a derivative is no longer

expected to be highly effective, hedge accounting is discontinued. Hedge ineffectiveness, if any, is included in current period earnings in Other (income) expense, net for forward foreign exchange contracts and cross currency interest rate swaps. For interest rate swaps designated as fair value hedges, hedge ineffectiveness, if any, is included in current period earnings within interest expense. For the current reporting period, hedge ineffectiveness associated with interest rate swaps was not material.

As of January 3, 2016, the balance of deferred net losses on derivatives included in accumulated other comprehensive income was $36 million after-tax. For additional information, see the Consolidated Statements of Comprehensive Income and Note 13. The Company expects that substantially all of the amounts related to forward foreign exchange contracts will be reclassified into earnings over the next 12 months as a result of transactions that are expected to occur over that period. The maximum length of time over which the Company is hedging transaction exposure is 18 months, excluding interest rate contracts. The amount ultimately realized in earnings may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity of the derivative.

The following table is a summary of the activity related to derivatives designated as cash flow hedges for the fiscal years ended January 3, 2016 and December 28, 2014:

(Dollars in Millions)	Gain/(Loss) Recognized In Accumulated OCI[1]		Gain/(Loss) Reclassified From Accumulated OCI Into Income[1]		Gain/(Loss) Recognized In Other Income/Expense[2]	
Cash Flow Hedges by Income Statement Caption	**2015**	**2014**	**2015**	**2014**	**2015**	**2014**
Sales to customers[3]	$(83)	(106)	(126)	(3)	(5)	(5)
Cost of products sold[3]	(22)	58	122	204	14	2
Research and development expense[3]	(3)	39	6	7	1	—
Interest (income)/Interest expense, net[4]	(40)	21	—	(15)	—	—
Other (income) expense, net[3]	33	80	60	3	1	—
Total	**$(115)**	**92**	**62**	**196**	**11**	**(3)**

All amounts shown in the table above are net of tax.

(1) Effective portion

(2) Ineffective portion

(3) Forward foreign exchange contracts

(4) Cross currency interest rate swaps

For the fiscal years ended January 3, 2016 and December 28, 2014, a loss of $34 million and a gain of $5 million, respectively, was recognized in Other (income) expense, net, relating to forward foreign exchange contracts not designated as hedging instruments.

Fair value is the exit price that would be received to sell an asset or paid to transfer a liability. Fair value is a market-based measurement determined using assumptions that market participants would use in pricing an asset or liability. The authoritative literature establishes a three-level hierarchy to prioritize the inputs used in measuring fair value. The levels within the hierarchy are described below with Level 1 having the highest priority and Level 3 having the lowest.

The fair value of a derivative financial instrument (i.e. forward foreign exchange contracts, interest rate contracts) is the aggregation by currency of all future cash flows discounted to its present value at the prevailing market interest rates and subsequently converted to the U.S. Dollar at the current spot foreign exchange rate. The Company does not believe that fair values of these derivative instruments materially differ from the amounts that could be realized upon settlement or maturity, or that the changes in fair value will have a material effect on the Company's results of operations, cash flows or financial position. The Company also holds equity investments which are classified as Level 1 and debt securities which are classified as Level 2. The Company did not have any other significant financial assets or liabilities which would require revised valuations under this standard that are recognized at fair value.

The following three levels of inputs are used to measure fair value:

Level 1 — Quoted prices in active markets for identical assets and liabilities.

Level 2 — Significant other observable inputs.

Level 3 — Significant unobservable inputs.

The Company's significant financial assets and liabilities measured at fair value as of January 3, 2016 and December 28, 2014 were as follows:

(Dollars in Millions)	2015				2014
	Level 1	Level 2	Level 3	Total	Total[1]
Derivatives designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts[7]	$ –	452	–	452	996
Interest rate contracts[2][4][7]	–	28	–	28	31
Total	**–**	**480**	**–**	**480**	**1,027**
Liabilities:					
Forward foreign exchange contracts[8]	–	358	–	358	751
Interest rate contracts[3][4][8]	–	241	–	241	8
Total	**–**	**599**	**–**	**599**	**759**
Derivatives not designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts[7]	–	33	–	33	29
Liabilities:					
Forward foreign exchange contracts[8]	–	41	–	41	51
Available For Sale Other Investments:					
Equity investments[5]	1,494	–	–	1,494	679
Debt securities[6]	$ –	8,316	–	8,316	–

(1) 2014 assets and liabilities are all classified as Level 2 with the exception of equity investments of $679 million, which are classified as Level 1.

(2) Includes $20 million and $29 million of non-current assets for the fiscal years ending January 3, 2016 and December 28, 2014, respectively.

(3) Includes $239 million and $8 million of non-current liabilities for the fiscal years ending January 3, 2016 and December 28, 2014, respectively.

(4) Includes cross currency interest rate swaps and interest rate swaps.

(5) Classified as non-current other assets. The carrying amount of the equity investments were $528 million and $284 million as of January 3, 2016 and December 28, 2014, respectively. The unrealized gains were $979 million and $406 million as of January 3, 2016 and December 28, 2014, respectively. The unrealized losses were $13 million and $11 million as of January 3, 2016 and December 28, 2014, respectively.

(6) Classified as current marketable securities.

(7) Classified as other current assets.

(8) Classified as accounts payable.

See Notes 2 and 7 for financial assets and liabilities held at carrying amount on the Consolidated Balance Sheet.

7. Borrowings

The components of long-term debt are as follows:

(Dollars in Millions)	2015	Effective Rate %	2014	Effective Rate %
2.15% Notes due 2016	$900	2.22%	898	2.22
3 month LIBOR+0.07% FRN due 2016	800	0.48	800	0.31
0.70% Notes due 2016	398	0.74	398	0.74
5.55% Debentures due 2017	1,000	5.55	1,000	5.55
1.125% Notes due 2017	700	1.15	697	1.15
5.15% Debentures due 2018	899	5.15	898	5.15
1.65% Notes due 2018	602	1.70	597	1.70
4.75% Notes due 2019 (1B Euro 1.0882)[2]/(1B Euro 1.2199)[3]	1,085[2]	5.83	1,216[3]	5.83
1.875% Notes due 2019	502	1.93	497	1.93
3% Zero Coupon Convertible Subordinated Debentures due 2020	137	3.00	158	3.00
2.95% Debentures due 2020	545	3.15	543	3.15
3.55% Notes due 2021	448	3.67	446	3.67
2.45% Notes due 2021	349	2.48	349	2.48
6.73% Debentures due 2023	250	6.73	250	6.73
3.375% Notes due 2023	811	3.17	812	3.17
5.50% Notes due 2024 (500MM GBP 1.4818)[2]/(500MM GBP 1.5542)[3]	737[2]	6.75	772[3]	6.75
6.95% Notes due 2029	297	7.14	297	7.14
4.95% Debentures due 2033	500	4.95	500	4.95
4.375% Notes due 2033	864	4.24	865	4.23
5.95% Notes due 2037	996	5.99	995	5.99
5.85% Debentures due 2038	700	5.86	700	5.86
4.50% Debentures due 2040	540	4.63	539	4.63
4.85% Notes due 2041	298	4.89	298	4.89
4.50% Notes due 2043	499	4.52	499	4.52
Other	104	—	105	—
Subtotal	**14,961[4]**	**4.06%[1]**	**15,129[4]**	**4.08[1]**
Less current portion	2,104		7	
Total long-term debt	**$12,857**		**15,122**	

(1) Weighted average effective rate.

(2) Translation rate at January 3, 2016.

(3) Translation rate at December 28, 2014.

(4) The excess of the fair value over the carrying value of debt was $1.7 billion in 2015 and $2.2 billion in 2014.

Fair value of the non-current debt was estimated using market prices, which were corroborated by quoted broker prices and significant other observable inputs.

The Company has access to substantial sources of funds at numerous banks worldwide. In September 2015, the Company secured a new 364-day Credit Facility. Total credit available to the Company approximates $10 billion, which expires on September 15, 2016. Interest charged on borrowings under the credit line agreements is based on either bids provided by banks, the prime rate or London Interbank Offered Rates (LIBOR), plus applicable margins. Commitment fees under the agreements are not material.

Throughout 2015, the Company continued to have access to liquidity through the commercial paper market. Short-term borrowings and the current portion of long-term debt amounted to approximately $7.0 billion at the end of 2015, of which $4.6 billion was borrowed under the Commercial Paper Program. The remainder principally represents local borrowing by international subsidiaries.

Aggregate maturities of long-term obligations commencing in 2016 are:

(Dollars in Millions) 2016	2017	2018	2019	2020	After 2020
$2,104	1,790	1,501	1,587	683	7,296

8. Income Taxes

The provision for taxes on income consists of:

(Dollars in Millions)	2015	2014	2013
Currently payable:			
U.S. taxes	$2,748	2,625	594
International taxes	1,309	1,174	1,653
Total currently payable	4,057	3,799	2,247
Deferred:			
U.S. taxes	37	(258)	(251)
International taxes	(307)	699	(356)
Total deferred	(270)	441	(607)
Provision for taxes on income	**$3,787**	**4,240**	**1,640**

A comparison of income tax expense at the U.S. statutory rate of 35% in 2015, 2014 and 2013, to the Company's effective tax rate is as follows:

(Dollars in Millions)	2015	2014	2013
U.S.	$8,179	8,001	4,261
International	11,017	12,562	11,210
Earnings before taxes on income:	$19,196	20,563	15,471
Tax rates:			
U.S. statutory rate	35.0%	35.0	35.0
International operations excluding Ireland	(6.7)	(7.0)	(10.6)
Ireland and Puerto Rico operations[1]	(8.7)	(6.9)	(9.0)
Research and orphan drug tax credits	(0.2)	(0.3)	(0.8)
U.S. state and local	0.4	1.0	0.4
U.S. manufacturing deduction	(0.6)	(0.6)	(0.8)
U.S. tax on international income	0.2	1.4	1.7
U.S. tax benefit on asset/business disposals	–	(1.9)	(5.1)
All other	0.3	(0.1)	(0.2)
Effective tax rate	19.7%	20.6	10.6

(1) The Company has subsidiaries operating in Puerto Rico under various tax incentives.

The 2015 effective tax rate decrease as compared to 2014 was primarily attributable to the increases in taxable income in lower tax jurisdictions relative to higher tax jurisdictions and a tax benefit resulting from a restructuring of international affiliates. Additionally, the 2014 effective tax rate was affected by the items mentioned below.

The increase in the 2014 effective tax rate, as compared to 2013, was attributable to the following: the divestiture of the Ortho-Clinical Diagnostics business at an approximate 44% effective tax rate, litigation accruals at low tax rates, the mix of earnings into higher tax jurisdictions, primarily the U.S., the accrual of an additional year of the Branded Prescription Drug Fee, which is not tax deductible, and additional U.S. tax expense related to a planned increase in dividends from current year foreign earnings as compared to the prior year. These increases to the 2014 effective tax rate were partially offset by a tax benefit of $0.4 billion associated with the Conor Medsystems divestiture.

The 2013 effective tax rate was reduced by a tax benefit associated with the write-off of assets for tax purposes associated with Scios, Inc., and the inclusion of both the 2013 and 2012 benefit from the Research and Development tax credit and the Controlled Foreign Corporation look-through provisions, because those provisions were enacted into law in January 2013 and were retroactive to January 1, 2012.

The 2014 effective tax rate was also reduced as the Company adjusted its unrecognized tax benefits as a result of (i) the federal appeals court's decision in OMJ Pharmaceuticals, Inc.'s litigation regarding credits under former Section 936 of the Internal Revenue Code (see Note 21 to the Consolidated Financial Statements for additional information), and (ii) a settlement of substantially all issues related to the Company's U.S. Internal Revenue Service audit of tax years 2006—2009. The impact of the settlement is reflected in the U.S. tax on international income and the All other line items within the above reconciliation.

The items noted above reflect the key drivers of the rate reconciliation.

Temporary differences and carryforwards for 2015 and 2014 were as follows:

	2015 Deferred Tax		2014 Deferred Tax	
(Dollars in Millions)	**Asset**	**Liability**	**Asset**	**Liability**
Employee related obligations	$2,863		3,426	
Stock based compensation	790		799	
Depreciation		(247)		(564)
Non-deductible intangibles		(6,663)		(6,671)
International R&D capitalized for tax	1,318		1,433	
Reserves & liabilities	1,801		1,497	
Income reported for tax purposes	960		1,067	
Net operating loss carryforward international	997		949	
Miscellaneous international	922[1]	(249)	1,128[1]	(305)
Miscellaneous U.S.	436		996	
Total deferred income taxes	**$10,087**	**(7,159)**	**11,295**	**(7,540)**

(1) The $922 million in 2015 was net of a valuation allowance related to Belgium of $196 million . The $1,128 million in 2014 was net of a valuation allowance related to Belgium of $172 million.

The Company has wholly-owned international subsidiaries that have cumulative net losses. The Company believes that it is more likely than not that these subsidiaries will realize future taxable income sufficient to utilize these deferred tax assets.

The following table summarizes the activity related to unrecognized tax benefits:

(Dollars in Millions)	**2015**	**2014**	**2013**
Beginning of year	$2,465	2,729	3,054
Increases related to current year tax positions	570	281	643
Increases related to prior period tax positions	182	295	80
Decreases related to prior period tax positions	(79)	(288)	(574)
Settlements	(4)	(477)	(418)
Lapse of statute of limitations	(54)	(75)	(56)
End of year	**$3,080**	**2,465**	**2,729**

The unrecognized tax benefits of $3.1 billion at January 3, 2016, if recognized, would affect the Company's annual effective tax rate. The Company conducts business and files tax returns in numerous countries and currently has tax audits in progress with a number of tax authorities. The IRS has completed its audit for the tax years through 2009 and is currently auditing the tax years 2010-2012. In other major jurisdictions where the Company conducts business, the years remain open generally back to the year 2004. The Company believes it is possible that audits may be completed by tax authorities in some jurisdictions over the next twelve months. However, the Company is not able to provide a reasonably reliable estimate of the timing of any other future tax payments relating to uncertain tax positions.

The Company classifies liabilities for unrecognized tax benefits and related interest and penalties as long-term liabilities. Interest expense and penalties related to unrecognized tax benefits are classified as income tax expense. The Company recognized after tax interest expense of $44 million, $12 million and $40 million in 2015, 2014 and 2013, respectively. The total amount of accrued interest was $366 million and $298 million in 2015 and 2014, respectively.

9. Employee Related Obligations

At the end of 2015 and 2014, employee related obligations recorded on the Consolidated Balance Sheets were:

(Dollars in Millions)	2015	2014
Pension benefits	$3,857	4,547
Postretirement benefits	2,738	3,161
Postemployment benefits	2,092	2,062
Deferred compensation	584	599
Total employee obligations	9,271	10,369
Less current benefits payable	417	397
Employee related obligations – non-current	**$8,854**	**9,972**

Prepaid employee related obligations of $256 million and $233 million for 2015 and 2014, respectively, are included in Other assets on the Consolidated Balance Sheets.

10. Pensions and Other Benefit Plans

The Company sponsors various retirement and pension plans, including defined benefit, defined contribution and termination indemnity plans, which cover most employees worldwide. The Company also provides post-retirement benefits, primarily health care, to all eligible U.S. retired employees and their dependents.

Many international employees are covered by government-sponsored programs and the cost to the Company is not significant.

Retirement plan benefits for employees hired before January 1, 2015 are primarily based on the employee's compensation during the last three to five years before retirement and the number of years of service. In 2014, the Company announced that the U.S. Defined Benefit plan was amended to adopt a new benefit formula, effective for employees hired on or after January 1, 2015. The benefits are calculated using a new formula based on employee compensation over total years of service.

International subsidiaries have plans under which funds are deposited with trustees, annuities are purchased under group contracts, or reserves are provided.

The Company does not fund retiree health care benefits in advance and has the right to modify these plans in the future.

As described in Note 1 to the Consolidated Financial Statements, the Company has elected to early adopt a practical expedient beginning for the fiscal year end 2015 to measure its defined benefit plans using the calendar month end closest to its fiscal year end. In 2015 and 2014 the Company used December 31, 2015 and December 28, 2014, respectively, as the measurement date for all U.S. and international retirement and other benefit plans.

Net periodic benefit costs for the Company's defined benefit retirement plans and other benefit plans for 2015, 2014 and 2013 include the following components:

	Retirement Plans			Other Benefit Plans		
(Dollars in Millions)	2015	2014	2013	2015	2014	2013
Service cost	$1,037	882	906	257	211	196
Interest cost	988	1,018	908	186	197	151
Expected return on plan assets	(1,809)	(1,607)	(1,447)	(7)	(7)	(6)
Amortization of prior service cost (credit)	2	6	6	(33)	(34)	(2)
Amortization of net transition obligation	–	1	1	–	–	–
Recognized actuarial losses	745	460	681	201	136	111
Curtailments and settlements	8	(17)	–	–	–	2
Net periodic benefit cost	**$971**	**743**	**1,055**	**604**	**503**	**452**

Amounts expected to be recognized in net periodic benefit cost in the coming year for the Company's defined benefit retirement plans and other post-retirement plans:

(Dollars in Millions)	
Amortization of net transition obligation	$ –
Amortization of net actuarial losses	638
Amortization of prior service credit	29

Unrecognized gains and losses for the U.S. pension plans are amortized over the average remaining future service for each plan. For plans with no active employees, they are amortized over the average life expectancy. The amortization of gains and losses for the other U.S. benefit plans is determined by using a 10% corridor of the greater of the market value of assets or the accumulated postretirement benefit obligation. Total unamortized gains and losses in excess of the corridor are amortized over the average remaining future service.

Prior service costs/benefits for the U.S. pension plans are amortized over the average remaining future service of plan participants at the time of the plan amendment. Prior service cost/benefit for the other U.S. benefit plans is amortized over the average remaining service to full eligibility age of plan participants at the time of the plan amendment.

The following table represents the weighted-average actuarial assumptions:

	Retirement Plans			Other Benefit Plans		
Worldwide Benefit Plans	**2015**	**2014**	**2013**	**2015**	**2014**	**2013**
Net Periodic Benefit Cost						
Discount rate	3.78%	4.78	4.25	4.31	5.25	4.55
Rate of increase in compensation levels	4.05%	4.08	4.08	4.11	4.29	4.28
Expected long-term rate of return on plan assets	8.53%	8.46	8.45			
Benefit Obligation						
Discount rate	4.11%	3.78	4.78	4.63	4.31	5.25
Rate of increase in compensation levels	4.01%	4.05	4.08	4.28	4.11	4.29

The Company's discount rates are determined by considering current yield curves representing high quality, long-term fixed income instruments. The resulting discount rates are consistent with the duration of plan liabilities. For the fiscal year 2016, the Company will change its methodology in determining service and interest cost from the single weighted average discount rate approach to duration specific spot rates along that yield curve to the plans' liability cash flows, which management has concluded is a more precise estimate. Prior to this change in methodology, the Company measured service and interest costs utilizing a single weighted-average discount rate derived from the yield curve used to measure the plan obligations. The Company has accounted for this change as a change in accounting estimate and, accordingly, has accounted for it on a prospective basis. This change will not impact the benefit obligation and will not have a material impact to the 2016 full year results.

The expected rates of return on plan asset assumptions represent the Company's assessment of long-term returns on diversified investment portfolios globally. The assessment is determined using projections from external financial sources, long-term historical averages, actual returns by asset class and the various asset class allocations by market.

In 2014, for measurement of U.S. retirement benefit obligations, the mortality assumption was updated to a newly established 2014 mortality table resulting in an increase to the projected benefit obligation.

The following table displays the assumed health care cost trend rates, for all individuals:

Health Care Plans	2015	2014
Health care cost trend rate assumed for next year	6.60%	6.00%
Rate to which the cost trend rate is assumed to decline (ultimate trend)	4.50%	4.50%
Year the rate reaches the ultimate trend rate	2038	2032

A one-percentage-point change in assumed health care cost trend rates would have the following effect:

(Dollars in Millions)	One-Percentage-Point Increase	One-Percentage-Point Decrease
Health Care Plans		
Total interest and service cost	$36	(29)
Post-retirement benefit obligation	$417	(326)

The following table sets forth information related to the benefit obligation and the fair value of plan assets at year-end 2015 and 2014 for the Company's defined benefit retirement plans and other post-retirement plans:

	Retirement Plans		Other Benefit Plans	
(Dollars in Millions)	2015	2014	2015	2014
Change in Benefit Obligation				
Projected benefit obligation – beginning of year	$26,889	21,488	5,081	4,407
Service cost	1,037	882	257	211
Interest cost	988	1,018	186	197
Plan participant contributions	48	59	–	–
Amendments	60	(60)	–	(254)
Actuarial (gains) losses	(1,578)	5,395	(400)	1,030
Divestitures & acquisitions	(5)	(121)	–	–
Curtailments, settlements & restructuring	(20)	(53)	(3)	–
Benefits paid from plan	(773)	(813)	(420)	(493)
Effect of exchange rates	(791)	(906)	(32)	(17)
Projected benefit obligation – end of year	**$25,855**	**26,889**	**4,669**	**5,081**
Change in Plan Assets				
Plan assets at fair value – beginning of year	$22,575	20,901	79	87
Actual return on plan assets	298	2,078	1	8
Company contributions	752	1,176	414	477
Plan participant contributions	48	59	–	–
Settlements	(20)	(40)	–	–
Divestitures & acquisitions	(5)	(109)	–	–
Benefits paid from plan assets	(773)	(813)	(420)	(493)
Effect of exchange rates	(621)	(677)	–	–
Plan assets at fair value – end of year	**$22,254**	**22,575**	**74**	**79**
Funded status – end of year	**$(3,601)**	**(4,314)**	**(4,595)**	**(5,002)**
Amounts Recognized in the Company's Balance Sheet consist of the following:				
Non-current assets	$256	233	–	–
Current liabilities	(77)	(74)	(324)	(309)
Non-current liabilities	(3,780)	(4,473)	(4,271)	(4,693)
Total recognized in the consolidated balance sheet – end of year	**$(3,601)**	**(4,314)**	**(4,595)**	**(5,002)**
Amounts Recognized in Accumulated Other Comprehensive Income consist of the following:				
Net actuarial loss	$6,501	7,547	2,013	2,611
Prior service cost (credit)	34	(33)	(185)	(225)
Unrecognized net transition obligation	–	1	–	–
Total before tax effects	**$6,535**	**7,515**	**1,828**	**2,386**
Accumulated Benefit Obligations – end of year	**$23,262**	**23,816**		

(Dollars in Millions)	Retirement Plans		Other Benefit Plans	
	2015	2014	2015	2014
Amounts Recognized in Net Periodic Benefit Cost and Other Comprehensive Income				
Net periodic benefit cost	**$971**	**743**	**604**	**503**
Net actuarial (gain) loss	(75)	4,942	(389)	1,015
Amortization of net actuarial loss	(745)	(460)	(201)	(136)
Prior service cost (credit)	60	(60)	–	(253)
Amortization of prior service (cost) credit	(2)	(6)	33	34
Effect of exchange rates	(218)	(273)	(1)	–
Total recognized in other comprehensive income, before tax	**$(980)**	**4,143**	**(558)**	**660**
Total recognized in net periodic benefit cost and other comprehensive income	**$(9)**	**4,886**	**46**	**1,163**

The Company plans to continue to fund its U.S. Qualified Plans to comply with the Pension Protection Act of 2006. International Plans are funded in accordance with local regulations. Additional discretionary contributions are made when deemed appropriate to meet the long-term obligations of the plans. For certain plans, funding is not a common practice, as funding provides no economic benefit. Consequently, the Company has several pension plans that are not funded.

In 2015, the Company contributed $435 million and $317 million to its U.S. and international pension plans, respectively.

The following table displays the funded status of the Company's U.S. Qualified & Non-Qualified pension plans and international funded and unfunded pension plans at December 31, 2015 and December 28, 2014, respectively:

	U.S. Plans				International Plans			
	Qualified Plans		Non-Qualified Plans		Funded Plans		Unfunded Plans	
(Dollars in Millions)	2015	2014	2015	2014	2015	2014	2015	2014
Plan Assets	$15,113	15,201	–	–	7,141	7,374	–	–
Projected Benefit Obligation	15,280	15,571	1,675	1,683	8,542	9,203	358	432
Accumulated Benefit Obligation	13,876	13,875	1,411	1,363	7,661	8,205	314	373
Over (Under) Funded Status								
Projected Benefit Obligation	$(167)	(370)	(1,675)	(1,683)	(1,401)	(1,829)	(358)	(432)
Accumulated Benefit Obligation	1,237	1,326	(1,411)	(1,363)	(520)	(831)	(314)	(373)

Plans with accumulated benefit obligations in excess of plan assets have an accumulated benefit obligation, projected benefit obligation and plan assets of $4.5 billion, $5.3 billion and $1.9 billion, respectively, at the end of 2015, and $8.2 billion, $9.4 billion and $5.3 billion, respectively, at the end of 2014.

The following table displays the projected future benefit payments from the Company's retirement and other benefit plans:

(Dollars in Millions)	2016	2017	2018	2019	2020	2021-2025
Projected future benefit payments						
Retirement plans	$839	872	911	967	1,031	6,098
Other benefit plans	$331	322	315	312	310	1,499

The following table displays the projected future minimum contributions to the unfunded retirement plans. These amounts do not include any discretionary contributions that the Company may elect to make in the future.

(Dollars in Millions)	2016	2017	2018	2019	2020	2021-2025
Projected future contributions	$76	77	82	88	93	559

Each pension plan is overseen by a local committee or board that is responsible for the overall administration and investment of the pension plans. In determining investment policies, strategies and goals, each committee or board considers factors including, local pension rules and regulations; local tax regulations; availability of investment vehicles

(separate accounts, commingled accounts, insurance funds, etc.); funded status of the plans; ratio of actives to retirees; duration of liabilities; and other relevant factors including: diversification, liquidity of local markets and liquidity of base currency. A majority of the Company's pension funds are open to new entrants and are expected to be on-going plans. Permitted investments are primarily liquid and/or listed, with little reliance on illiquid and non-traditional investments such as hedge funds.

The Company's retirement plan asset allocation at the end of 2015 and 2014 and target allocations for 2016 are as follows:

	Percent of Plan Assets		Target Allocation
	2015	2014	2016
Worldwide Retirement Plans			
Equity securities	79%	77%	74%
Debt securities	21	23	26
Total plan assets	**100%**	**100%**	**100%**

Determination of Fair Value of Plan Assets

The Plan has an established and well-documented process for determining fair values. Fair value is based upon quoted market prices, where available. If listed prices or quotes are not available, fair value is based upon models that primarily use, as inputs, market-based or independently sourced market parameters, including yield curves, interest rates, volatilities, equity or debt prices, foreign exchange rates and credit curves.

While the Plan believes its valuation methods are appropriate and consistent with other market participants, the use of different methodologies or assumptions to determine the fair value of certain financial instruments could result in a different estimate of fair value at the reporting date.

Valuation Hierarchy

The authoritative literature establishes a three-level hierarchy to prioritize the inputs used in measuring fair value. The levels within the hierarchy are described in the table below with Level 1 having the highest priority and Level 3 having the lowest.

A financial instrument's categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

Following is a description of the valuation methodologies used for the investments measured at fair value.

- *Short-term investments* – Cash and quoted short-term instruments are valued at the closing price or the amount held on deposit by the custodian bank. Other investments are through investment vehicles valued using the Net Asset Value (NAV) provided by the administrator of the fund. The NAV is based on the value of the underlying assets owned by the fund, minus its liabilities, and then divided by the number of shares outstanding. The NAV is a quoted price in a market that is not active and classified as Level 2.
- *Government and agency securities* – A limited number of these investments are valued at the closing price reported on the major market on which the individual securities are traded. Where quoted prices are available in an active market, the investments are classified within Level 1 of the valuation hierarchy. If quoted market prices are not available for the specific security, then fair values are estimated by using pricing models, quoted prices of securities with similar characteristics or discounted cash flows. When quoted market prices for a security are not available in an active market, they are classified as Level 2.
- *Debt instruments* – A limited number of these investments are valued at the closing price reported on the major market on which the individual securities are traded. Where quoted prices are available in an active market, the investments are classified as Level 1. If quoted market prices are not available for the specific security, then fair values are estimated by using pricing models, quoted prices of securities with similar characteristics or discounted cash flows and are classified as Level 2. Level 3 debt instruments are priced based on unobservable inputs.
- *Equity securities* – Common stocks are valued at the closing price reported on the major market on which the individual securities are traded. Substantially all common stock is classified within Level 1 of the valuation hierarchy.
- *Commingled funds* – These investment vehicles are valued using the NAV provided by the fund administrator. The NAV is based on the value of the underlying assets owned by the fund, minus its liabilities, and then divided by the number of shares outstanding. Assets in the Level 2 category have a quoted market price in a market that is not active.

- *Insurance contracts* – The instruments are issued by insurance companies. The fair value is based on negotiated value and the underlying investments held in separate account portfolios as well as considering the credit worthiness of the issuer. The underlying investments are government, asset-backed and fixed income securities. In general, insurance contracts are classified as Level 3 as there are no quoted prices nor other observable inputs for pricing.
- *Other assets* – Other assets are represented primarily by limited partnerships and real estate investments, as well as commercial loans and commercial mortgages that are not classified as corporate debt. Other assets that are exchange listed and actively traded are classified as Level 1, while inactively traded assets are classified as Level 2. Most limited partnerships represent investments in private equity and similar funds that are valued by the general partners. Certain of these limited partnerships, as well as any other assets valued using unobservable inputs, are classified as Level 3.

The following table sets forth the Retirement Plans' investments measured at fair value as of December 31, 2015 and December 28, 2014:

	Quoted Prices in Active Markets for Identical Assets (Level 1)		Significant Other Observable Inputs (Level 2)		Significant Unobservable Inputs (Level 3)		Total Assets	
(Dollars in Millions)	**2015**	**2014**	**2015**	**2014**	**2015**	**2014**	**2015**	**2014**
Short-term investment funds	$184	168	312	551	–	–	496	719
Government and agency securities	–	–	1,767	1,934	–	–	1,767	1,934
Debt instruments	–	–	1,050	1,143	1	1	1,051	1,144
Equity securities	11,317	11,204	11	21	–	–	11,328	11,225
Commingled funds	–	–	7,189	7,205	33	46	7,222	7,251
Insurance contracts	–	–	–	–	23	24	23	24
Other assets	–	1	314	214	53	63	367	278
Investments at fair value	**$11,501**	**11,373**	**10,643**	**11,068**	**110**	**134**	**22,254**	**22,575**

The Company's Other Benefit Plans are unfunded except for U.S. commingled funds (Level 2) of $74 million and $79 million at December 31, 2015 and December 28, 2014, respectively.

The fair value of Johnson & Johnson Common Stock directly held in plan assets was $751 million (3.4% of total plan assets) at December 31, 2015 and $778 million (3.4% of total plan assets) at December 28, 2014.

Level 3 Gains and Losses

The table below sets forth a summary of changes in the fair value of the Plan's Level 3 assets for the years ended December 31, 2015 and December 28, 2014:

(Dollars in Millions)	**Debt Instruments**	**Equity Securities**	**Commingled Funds**	**Insurance Contracts**	**Other Assets**	**Total Level 3**
Balance December 29, 2013	$1	4	44	23	69	141
Realized gains (losses)	–	–	–	–	(5)	(5)
Unrealized gains (losses)	–	–	2	–	–	2
Purchases, sales, issuances and settlements, net	–	–	(2)	3	(1)	–
Transfers in/out and exchange rate changes	–	(4)	2	(2)	–	(4)
Balance December 28, 2014	1	–	46	24	63	134
Realized gains (losses)	–	–	1	–	(2)	(1)
Unrealized gains (losses)	–	–	(11)	–	(5)	(16)
Purchases, sales, issuances and settlements, net	–	–	(2)	1	(2)	(3)
Transfers in/out and exchange rate changes	–	–	(1)	(2)	(1)	(4)
Balance December 31, 2015	**$1**	**–**	**33**	**23**	**53**	**110**

11. Savings Plan

The Company has voluntary 401(k) savings plans designed to enhance the existing retirement programs covering eligible employees. The Company matches a percentage of each employee's contributions consistent with the provisions of the plan for which he/she is eligible. Total Company matching contributions to the plans were $187 million, $172 million and $164 million in 2015, 2014 and 2013, respectively.

12. Capital and Treasury Stock

Changes in treasury stock were:

(Amounts in Millions Except Treasury Stock Shares in Thousands)	Treasury Stock	
	Shares	Amount
Balance at December 30, 2012	341,354	$18,476
Employee compensation and stock option plans	(48,555)	(3,367)
Repurchase of common stock	6,416	591
Balance at December 29, 2013	299,215	15,700
Employee compensation and stock option plans	(32,302)	(2,933)
Repurchase of common stock	69,707	7,124
Balance at December 28, 2014	336,620	19,891
Employee compensation and stock option plans	(24,413)	(2,497)
Repurchase of common stock	52,474	5,290
Balance at January 3, 2016	364,681	$22,684

Aggregate shares of common stock issued were approximately 3,119,843,000 shares at the end of 2015, 2014 and 2013.

Cash dividends paid were $2.95 per share in 2015, compared with dividends of $2.76 per share in 2014, and $2.59 per share in 2013.

On October 13, 2015, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $10.0 billion of the Company's shares of common stock. The repurchase program has no time limit and may be suspended for periods or discontinued at any time. Any shares acquired will be available for general corporate purposes. The Company intends to finance the share repurchase program through available cash and access to the capital markets. As of January 3, 2016, $1.0 billion has been repurchased under the program.

On July 21, 2014, the Company announced that its Board of Directors approved a share repurchase program, authorizing the Company to purchase up to $5.0 billion of the Company's shares of common stock. This share repurchase program was completed on April 28, 2015.

13. Accumulated Other Comprehensive Income

Components of other comprehensive income (loss) consist of the following:

(Dollars in Millions)	Foreign Currency Translation	Gain/ (Loss) On Securities	Employee Benefit Plans	Gain/ (Loss) On Derivatives & Hedges	Total Accumulated Other Comprehensive Income (Loss)
December 30, 2012	$(296)	195	(5,717)	8	(5,810)
Net 2013 changes	94	(89)	2,708	237	2,950
December 29, 2013	(202)	106	(3,009)	245	(2,860)
Net 2014 changes	(4,601)	151	(3,308)	(104)	(7,862)
December 28, 2014	(4,803)	257	(6,317)	141	(10,722)
Net 2015 changes	(3,632)	347	1,019	(177)	(2,443)
January 3, 2016	$(8,435)	604	(5,298)	(36)	(13,165)

Amounts in accumulated other comprehensive income are presented net of the related tax impact. Foreign currency translation is not adjusted for income taxes where it relates to permanent investments in international subsidiaries. For additional details on comprehensive income see the Consolidated Statements of Comprehensive Income.

Details on reclassifications out of Accumulated Other Comprehensive Income:

Gain/(Loss) On Securities – reclassifications released to Other (income) expense, net.

Employee Benefit Plans – reclassifications are included in net periodic benefit cost. See Note 10 for additional details.

Gain/(Loss) On Derivatives & Hedges – reclassifications to earnings are recorded in the same account as the hedged transaction. See Note 6 for additional details.

14. International Currency Translation

For translation of its subsidiaries operating in non-U.S. Dollar currencies, the Company has determined that the local currencies of its international subsidiaries are the functional currencies except those in highly inflationary economies, which are defined as those which have had compound cumulative rates of inflation of 100% or more during the past three years, or where a substantial portion of its cash flows are not in the local currency.

In consolidating international subsidiaries, balance sheet currency effects are recorded as a component of accumulated other comprehensive income. This equity account includes the results of translating certain balance sheet assets and liabilities at current exchange rates and some accounts at historical rates, except for those located in highly inflationary economies. The translation of balance sheet accounts for highly inflationary economies are reflected in the operating results.

A rollforward of the changes during 2015, 2014 and 2013 for foreign currency translation adjustments is included in Note 13.

Net currency transaction gains and losses included in Other (income) expense were losses of $104 million, $156 million and $186 million in 2015, 2014 and 2013, respectively.

15. Earnings Per Share

The following is a reconciliation of basic net earnings per share to diluted net earnings per share for the fiscal years ended January 3, 2016, December 28, 2014 and December 29, 2013:

(In Millions Except Per Share Amounts)	2015	2014	2013
Basic net earnings per share	$5.56	5.80	4.92
Average shares outstanding – basic	2,771.8	2,815.2	2,809.2
Potential shares exercisable under stock option plans	141.5	142.6	148.5
Less: shares repurchased under treasury stock method	(102.6)	(96.5)	(103.3)
Convertible debt shares	2.2	2.6	3.0
Accelerated share repurchase program	–	–	19.6
Adjusted average shares outstanding – diluted	2,812.9	2,863.9	2,877.0
Diluted net earnings per share	$5.48	5.70	4.81

The diluted net earnings per share calculation included the dilutive effect of convertible debt that is offset by the related reduction in interest expense of $3 million after-tax for years 2015 and 2014 and $4 million for year 2013.

The diluted net earnings per share calculation for 2015, 2014 and 2013 included all shares related to stock options, as the exercise price of all options was less than the average market value of the Company's stock.

The diluted net earnings per share calculation for the fiscal year ended December 29, 2013 included the dilutive effect of 19.6 million shares, related to the accelerated share repurchase program, associated with the acquisition of Synthes, Inc. in the fiscal year 2012.

16. Rental Expense and Lease Commitments

Rentals of space, vehicles, manufacturing equipment and office and data processing equipment under operating leases were approximately $316 million, $341 million and $363 million in 2015, 2014 and 2013, respectively.

The approximate minimum rental payments required under operating leases that have initial or remaining non-cancelable lease terms in excess of one year at January 3, 2016 are:

(Dollars in Millions) 2016	2017	2018	2019	2020	After 2020	Total
$224	194	136	90	74	109	827

Commitments under capital leases are not significant.

17. Common Stock, Stock Option Plans and Stock Compensation Agreements

At January 3, 2016, the Company had 2 stock-based compensation plans. The shares outstanding are for contracts under the Company's 2005 Long-Term Incentive Plan and the 2012 Long-Term Incentive Plan. The 2005 Long-Term Incentive Plan expired April 26, 2012. All options and restricted shares granted subsequent to that date were under the 2012 Long-Term Incentive Plan. Under the 2012 Long-Term Incentive Plan, the Company may issue up to 650 million shares of common stock, plus any shares canceled, expired, forfeited, or not issued from the 2005 Long-Term Incentive Plan subsequent to April 26, 2012. Shares available for future grants under the 2012 Long-Term Incentive Plan were 486 million at the end of 2015.

The compensation cost that has been charged against income for these plans was $874 million, $792 million and $728 million for 2015, 2014 and 2013, respectively. The total income tax benefit recognized in the income statement for share-based compensation costs was $253 million, $259 million and $243 million for 2015, 2014 and 2013, respectively. The total unrecognized compensation cost was $744 million, $722 million and $636 million for 2015, 2014 and 2013, respectively. The weighted average period for this cost to be recognized was 0.98 years, 1.18 years and 1.26 years for 2015, 2014 and 2013, respectively. Share-based compensation costs capitalized as part of inventory were insignificant in all periods.

The Company settles employee benefit equity issuances with treasury shares. Treasury shares are replenished throughout the year for the number of shares used to settle employee benefit equity issuances.

Stock Options

Stock options expire 10 years from the date of grant and vest over service periods that range from 6 months to 4 years. All options are granted at the average of the high and low prices of the Company's Common Stock on the New York Stock Exchange on the date of grant.

The fair value of each option award was estimated on the date of grant using the Black-Scholes option valuation model that uses the assumptions noted in the following table. For 2014 and 2013 grants, expected volatility represents a blended rate of 4-year daily historical average volatility rate, and a 5-week average implied volatility rate based on at-the-money traded Johnson & Johnson options with a life of 2 years. For 2015 grants, expected volatility represents a blended rate of 10-year weekly historical overall volatility rate, and a 5-week average implied volatility rate based on at-the-money traded Johnson & Johnson options with a life of 2 years. For all grants, historical data is used to determine the expected life of the option. The risk-free rate was based on the U.S. Treasury yield curve in effect at the time of grant.

The average fair value of options granted was $10.68, $8.42 and $4.88, in 2015, 2014 and 2013, respectively. The fair value was estimated based on the weighted average assumptions of:

	2015	2014	2013
Risk-free rate	1.77%	1.87%	1.01%
Expected volatility	15.48%	14.60%	14.04%
Expected life (in years)	7.0	6.0	6.0
Expected dividend yield	2.90%	3.10%	3.40%

A summary of option activity under the Plan as of January 3, 2016, December 28, 2014 and December 29, 2013, and changes during the years ending on those dates is presented below:

(Shares in Thousands)	Outstanding Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value (Dollars in Millions)
Shares at December 30, 2012	134,351	$61.58	$1,061
Options granted	29,010	72.54	
Options exercised	(41,357)	59.99	
Options canceled/forfeited	(2,448)	65.89	
Shares at December 29, 2013	119,556	64.70	3,306
Options granted	24,356	90.44	
Options exercised	(25,319)	62.31	
Options canceled/forfeited	(2,881)	75.48	
Shares at December 28, 2014	115,712	70.37	4,014
Options granted	20,484	100.06	
Options exercised	(16,683)	62.53	
Options canceled/forfeited	(2,996)	82.22	
Shares at January 3, 2016	**116,517**	**$76.41**	**$3,065**

The total intrinsic value of options exercised was $644 million, $954 million and $941 million in 2015, 2014 and 2013, respectively.

The following table summarizes stock options outstanding and exercisable at January 3, 2016:

(Shares in Thousands)	Outstanding			Exercisable	
Exercise Price Range	Options	Average Life[1]	Average Exercise Price	Options	Average Exercise Price
$52.13-$58.33	8,694	3.1	$58.32	8,694	$58.32
$58.34-$62.20	17,644	2.6	$61.21	17,644	$61.21
$62.62-$65.62	22,139	3.4	$64.55	21,726	$64.54
$66.07-$72.54	25,617	7.0	$72.52	217	$69.77
$90.44-$100.48	42,423	8.6	$94.98	64	$90.47
	116,517	**5.9**	**$76.41**	**48,345**	**$62.26**

(1) Average contractual life remaining in years.

Stock options outstanding at December 28, 2014 and December 29, 2013 were 115,712 and an average life of 5.7 years and 119,556 and an average life of 5.1 years, respectively. Stock options exercisable at December 28, 2014 and December 29, 2013 were 57,846 at an average price of $61.94 and 75,210 at an average price of $62.01, respectively.

Restricted Share Units and Performance Share Units

The Company grants restricted share units which vest over service periods that range from 6 months to 3 years . The Company also grants performance share units, which are paid in shares of Johnson & Johnson Common Stock after the end of a three -year performance period. Whether any performance share units vest, and the amount that does vest, is tied to the completion of service periods that range from 6 months to 3 years and the achievement, over a three-year period, of three equally-weighted goals that directly align with or help drive long-term total shareholder return: operational sales, adjusted operational earnings per share, and relative total shareholder return. The number of shares actually earned at the end of the three-year period will vary, based only on actual performance, from 0% to 200% of the target number of performance share units granted.

A summary of the restricted share units and performance share units activity under the Plans as of January 3, 2016 is presented below:

(Shares in Thousands)	Outstanding Restricted Share Units	Outstanding Performance Share Units
Shares at December 30, 2012	31,834	285
Granted	10,582	1,290
Issued	(10,078)	–
Canceled/forfeited	(1,721)	(40)
Shares at December 29, 2013	30,617	1,535
Granted	8,487	1,113
Issued	(9,685)	(19)
Canceled/forfeited	(1,726)	(98)
Shares at December 28, 2014	27,693	2,531
Granted	7,637	931
Issued	(10,164)	(285)
Canceled/forfeited	(1,281)	(99)
Shares at January 3, 2016	23,885	3,078

The average fair value of the restricted share units granted was $91.65, $83.01 and $65.90 in 2015, 2014 and 2013, respectively, using the fair market value at the date of grant. The fair value of restricted share units was discounted for dividends, which are not paid on the restricted share units during the vesting period. The fair value of restricted share units issued was $597.6 million, $541.0 million and $569.2 million in 2015, 2014 and 2013, respectively.

The weighted average fair value of the performance share units granted was $93.54, $85.94 and $73.42 in 2015, 2014 and 2013, calculated using the weighted average fair market value for each of the three component goals at the date of grant.

The fair values for the sales and earnings per share goals of each performance share unit were estimated on the date of grant using the fair market value of the shares at the time of the award discounted for dividends, which are not paid on the performance share units during the vesting period. The fair value for the relative total shareholder return goal of each performance share unit was estimated on the date of grant using the Monte Carlo valuation model. The fair value of performance share units issued was $16.7 million and $1.4 million in 2015 and 2014, respectively. No performance share units vested in 2013.

18. Segments of Business and Geographic Areas

	Sales to Customers		
(Dollars in Millions)	2015	2014	2013
Consumer –			
United States	$5,222	5,096	5,162
International	8,285	9,400	9,535
Total	**13,507**	**14,496**	**14,697**
Pharmaceutical –			
United States	18,333	17,432	13,948
International	13,097	14,881	14,177
Total	**31,430**	**32,313**	**28,125**
Medical Devices –			
United States	12,132	12,254	12,800
International	13,005	15,268	15,690
Total	**25,137**	**27,522**	**28,490**
Worldwide total	**$70,074**	**74,331**	**71,312**

(Dollars in Millions)	Income Before Tax			Identifiable Assets	
	2015[3]	2014[4]	2013[5]	2015	2014
Consumer	$1,787	1,941	1,973	20,772	21,813
Pharmaceutical	11,734	11,696	9,178	26,144	25,803
Medical Devices	6,826	7,953	5,261	40,979	41,445
Total	20,347	21,590	16,412	87,895	89,061
Less: Expense not allocated to segments [1]	1,151	1,027	941		
General corporate [2]				45,516	41,297
Worldwide total	**$19,196**	**20,563**	**15,471**	**$133,411**	**130,358**

(Dollars in Millions)	Additions to Property, Plant & Equipment			Depreciation and Amortization		
	2015	2014	2013	2015	2014	2013
Consumer	$544	581	533	$559	577	539
Pharmaceutical	1,063	977	856	929	1,053	1,075
Medical Devices	1,631	1,807	1,724	1,945	1,974	2,224
Segments total	3,238	3,365	3,113	3,433	3,604	3,838
General corporate	225	349	482	313	291	266
Worldwide total	**$3,463**	**3,714**	**3,595**	**$3,746**	**3,895**	**4,104**

(Dollars in Millions)	Sales to Customers			Long-Lived Assets[6]	
	2015	2014	2013	2015	2014
United States	$35,687	34,782	31,910	36,609	36,835
Europe	15,995	18,947	18,599	20,167	21,559
Western Hemisphere excluding U.S.	6,045	7,160	7,421	2,881	3,210
Asia-Pacific, Africa	12,347	13,442	13,382	2,493	2,438
Segments total	70,074	74,331	71,312	62,150	64,042
General corporate				1,148	1,138
Other non long-lived assets				70,113	65,178
Worldwide total	**$70,074**	**74,331**	**71,312**	**133,411**	**130,358**

See Note 1 for a description of the segments in which the Company operates.

Export sales are not significant. In 2015 and 2014, the Company had one wholesaler distributing products for all three segments that represented approximately 12.5% and 11.0%, respectively, of the total consolidated revenues. In 2013, the Company did not have a customer that represented 10.0% of total revenues.

(1) Amounts not allocated to segments include interest (income) expense, noncontrolling interests and general corporate (income) expense.

(2) General corporate includes cash, cash equivalents and marketable securities.

(3) The Medical Devices segment includes a restructuring charge of $590 million, an intangible asset write-down of $346 million related to Acclarent, Synthes integration costs of $196 million and $148 million expense for the cost associated with the DePuy ASR ™ Hip program. Includes $224 million of in-process research and development expense, comprised of $214 million and $10 million in the Pharmaceutical and Medical Devices segments, respectively. Includes net litigation expense of $141 million comprised of $136 million in the Pharmaceutical segment and $5 million in the Medical Devices segment, which included the gain from the litigation settlement agreement with Guidant for $600 million. The Medical Devices Segment includes a gain of $1.3 billion from the divestiture of the Cordis business. The Pharmaceutical segment includes a gain of $981 million from the U.S. divestiture of NUCYNTA® and a positive adjustment of $0.5 billion to previous reserve estimates, including Managed Medicaid rebates. The Consumer segment includes a gain of $229 million from the divestiture of SPLENDA® brand.

(4) Includes net litigation expense of $1,253 million comprised of $907 million, $259 million and $87 million in the Medical Devices, Pharmaceutical and Consumer segments, respectively. Includes $178 million of in-process research and development expense, comprised of $147 million and $31 million in the Pharmaceutical and Medical Devices segments, respectively. The Medical Devices segment includes a net gain of $1,899 million from the divestiture of the Ortho-Clinical Diagnostics business, Synthes integration

costs of $754 million and $126 million expense for the cost associated with the DePuy ASR ™ Hip program. The Pharmaceutical segment includes an additional year of the Branded Prescription Drug Fee of $220 million and a positive adjustment of $0.1 billion to previous reserve estimates.

(5) Includes $2,276 million of net litigation expense comprised of $1,975 million and $301 million in the Medical Devices and Pharmaceutical segments, respectively. Includes $683 million of Synthes integration/transaction costs in the Medical Devices segment. Includes $580 million of in-process research and development expense, comprised of $514 million and $66 million in the Pharmaceutical and Medical Devices segments, respectively. The Medical Devices segment also includes $251 million expense for the cost associated with the DePuy ASR ™ Hip program. Includes $98 million of income related to other adjustments comprised of $55 million and $43 million in the Consumer and Pharmaceutical segments, respectively.

(6) Long-lived assets include property, plant and equipment, net for 2015, and 2014 of $15,905 and $16,126, respectively, and intangible assets and goodwill, net for 2015 and 2014 of $47,393 and $49,054, respectively.

19. Selected Quarterly Financial Data (unaudited)

Selected unaudited quarterly financial data for the years 2015 and 2014 are summarized below:

	2015				2014			
(Dollars in Millions Except Per Share Data)	First Quarter(1)	Second Quarter(2)	Third Quarter(3)	Fourth Quarter(4)	First Quarter(5)	Second Quarter(6)	Third Quarter(7)	Fourth Quarter(8)
Segment sales to customers								
Consumer	$3,390	3,483	3,314	3,320	3,557	3,744	3,589	3,606
Pharmaceutical	7,726	7,946	7,694	8,064	7,498	8,509	8,307	7,999
Medical Devices	6,258	6,358	6,094	6,427	7,060	7,242	6,571	6,649
Total sales	17,374	17,787	17,102	17,811	18,115	19,495	18,467	18,254
Gross profit	12,092	12,430	11,878	12,138	12,660	13,456	13,068	12,401
Earnings before provision for taxes on income	5,575	5,741	4,122	3,758	5,424	5,626	6,810	2,703
Net earnings	4,320	4,516	3,358	3,215	4,727	4,326	4,749	2,521
Basic net earnings per share	$1.55	1.63	1.21	1.16	1.67	1.53	1.69	0.90
Diluted net earnings per share	$1.53	1.61	1.20	1.15	1.64	1.51	1.66	0.89

(1) The first quarter of 2015 includes a net litigation gain of $253 million after-tax ($402 million before-tax) and $122 million after-tax ($139 million before-tax) for costs associated with the DePuy ASR™ Hip program.

(2) The second quarter of 2015 includes net litigation expense of $23 million after-tax ($134 million before-tax).

(3) The third quarter of 2015 includes net litigation expense of $348 million after-tax ($409 million before-tax).

(4) The fourth quarter of 2015 includes a restructuring charge of $415 million after-tax ($590 million before-tax), $156 million after-tax ($214 million before-tax) from impairment of in-process research and development and Synthes integration costs of $59 million after-tax ($83 million before-tax). Additionally, the fourth quarter of 2015 includes the gain on the Cordis divestiture.

(5) The first quarter of 2014 includes Synthes integration costs of $84 million after-tax ($118 million before-tax) and a $398 million tax benefit associated with Conor Medsystems.

(6) The second quarter of 2014 includes litigation expense of $342 million after-tax ($276 million before-tax) and Synthes integration costs of $104 million after-tax ($144 million before-tax).

(7) The third quarter of 2014 includes an additional year of the Branded Prescription Drug Fee of $220 million after and before tax, litigation expense of $231 million after-tax ($285 million before-tax), Synthes integration costs of $130 million after-tax ($167 million before-tax) and $111 million after-tax ($126 million before-tax) for costs associated with the DePuy ASR™ Hip program. Additionally, the fiscal third quarter of 2014 includes a net gain of $1.1 billion after-tax ($1.9 billion before-tax) for the divestiture of the Ortho-Clinical Diagnostics business.

(8) The fourth quarter of 2014 includes litigation expense, primarily related to product liability and patent litigation of $652 million after-tax ($692 million before-tax), Synthes integration costs of $237 million after-tax ($325 million before-tax) and $115 million after-tax ($156 million before-tax) from impairment of in-process research and development.

20. Business Combinations and Divestitures

Certain businesses were acquired for $954 million in cash and $220 million of liabilities assumed during 2015. The assumed liabilities primarily represent the fair value of the contingent consideration of $210 million. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The 2015 acquisitions primarily included: XO1 Limited, a privately-held biopharmaceutical company developing an anti-thrombin antibody and Novira Therapeutics, Inc., a privately held clinical-stage biopharmaceutical company developing innovative therapies for curative treatment of chronic hepatitis B virus infection.

The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $1,173 million and has been assigned to identifiable intangible assets, with any residual recorded to goodwill. Of this amount, approximately $839 million has been identified as the value of IPR&D primarily associated with the acquisitions of XO1 Limited and Novira Therapeutics, Inc. The value of the IPR&D was calculated using cash flow projections discounted for the inherent risk in the projects.

The IPR&D related to the acquisition of XO1 Limited of $360 million is associated with a recombinant human antibody developed to mimic the activity of a human antibody which appears to produce an anticoagulated state without predisposition to bleeding. A probability of success factor of 36.0% was used to reflect inherent clinical and regulatory risk. The discount rate applied was 11.75%.

The IPR&D related to the acquisition of Novira Therapeutics, Inc. of $396 million is associated with its lead candidate NVR 3-778 which is an investigational small molecule, direct-acting antiviral, for oral administration in patients with HBV that inhibits the HBV core or capsid protein. A probability of success factor of 51.0% was used to reflect inherent clinical and regulatory risk. The discount rate applied was 16.0%.

Certain businesses were acquired for $2,129 million in cash and $38 million of liabilities assumed during 2014. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The 2014 acquisitions included: Covagen AG, a privately-held, biopharmaceutical company specializing in the development of multispecific protein therapeutics through the FynomAb® technology platform; Alios BioPharma, Inc., a privately-held, clinical stage biopharmaceutical company focused on developing therapies for viral diseases; and the ORSL™ electrolyte ready-to-drink brand from Jagdale Industries Ltd. The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $2,069 million and has been assigned to identifiable intangible assets, with any residual recorded to goodwill. Of this amount, approximately $1,913 million has been identified as the value of IPR&D associated with the acquisitions of Covagen AG and Alios BioPharma, Inc. The value of the IPR&D was calculated using cash flow projections discounted for the inherent risk in the projects.

The IPR&D related to the acquisition of Alios BioPharma, Inc. (Alios) of $1,688 million is associated with Alios' lead compound AL-8176, an orally administered antiviral therapy for treatment of infants with respiratory syncytial virus (RSV). A probability of success factor of 60.0% was used to reflect inherent clinical and regulatory risk. The discount rate applied was 11.4%. The IPR&D related to the acquisition of Covagen AG of $225 million is associated with Covagen's lead compound COVA-322, currently in Phase 1b study for psoriasis and holding potential as a treatment for a broad range of inflammatory diseases including rheumatoid arthritis. A probability of success factor of 26.0% was used to reflect inherent clinical and regulatory risk. The discount rate applied was 12.5% . During 2015, the Company recorded a charge for the impairment of the IPR&D related to the acquisition of Covagen AG.

Certain businesses were acquired for $835 million in cash and $193 million of liabilities assumed during 2013. These acquisitions were accounted for using the acquisition method and, accordingly, results of operations have been included in the financial statements from their respective dates of acquisition.

The assumed liabilities primarily represent the fair value of the contingent consideration which may be payable related to the acquisition of Aragon Pharmaceuticals, Inc., a privately-held, pharmaceutical discovery and development company focused on drugs to treat hormonally-driven cancers. As per terms of the agreement, additional payments of up to $350 million may be paid in the future based on reaching predetermined milestones.

The 2013 acquisitions included: Flexible Stenting Solutions, Inc., a leading developer of innovative flexible peripheral arterial, venous and biliary stents; Shanghai Elsker Mother & Baby Co., Ltd, a baby care company in China and Aragon Pharmaceuticals, Inc.

The excess of purchase price over the estimated fair value of tangible assets acquired amounted to $941 million and has been assigned to identifiable intangible assets, with any residual recorded to goodwill. Of this amount, approximately $831 million has been identified as the value of IPR&D primarily associated with the acquisitions of Aragon Pharmaceuticals, Inc.

The IPR&D related to the acquisition of Aragon Pharmaceuticals, Inc. of $810 million is associated with Aragon's androgen receptor antagonist program for treatment of hormonally-driven cancers. The value of the IPR&D was calculated using cash flow projections discounted for the inherent risk in such projects. Probability of success factors ranging from 37%-52.0% were used to reflect inherent clinical and regulatory risk. The discount rate applied was 15.5% .

In 2012, the Company completed the acquisition of Synthes, Inc. for a purchase price of $20.2 billion in cash and stock. In connection with the acquisition of Synthes, Inc. the Company entered into two accelerated share repurchase (ASR) agreements. In 2013, the Company settled the remaining liabilities under the ASR agreements. While the Company believes that the transactions under each ASR agreement and a series of related internal transactions were consummated in a tax efficient manner in accordance with applicable law, it is possible that the Internal Revenue Service could assert one or more contrary positions to challenge the transactions from a tax perspective. If challenged, an amount up to the total purchase price for the Synthes shares could be treated as subject to applicable U.S. tax at approximately the statutory rate to the Company, plus interest.

Supplemental pro forma information for 2015, 2014 and 2013 in accordance with U.S. GAAP standards related to business combinations, and goodwill and other intangible assets, is not provided, as the impact of the aforementioned acquisitions did not have a material effect on the Company's results of operations, cash flows or financial position.

During 2015, the Company divestitures included: The Cordis business to Cardinal Health; the SPLENDA® brand to Heartland Food Products Group and the U.S. license rights to NUCYNTA® (tapentadol), NUCYNTA® ER (tapentadol extended-release tablets), and NUCYNTA® (tapentadol) oral solution. In 2015, the pre-tax gains on the divestitures of businesses were approximately $2.6 billion. As of January 3, 2016, assets held for sale were not material.

During 2014, the Company divestitures included: The Ortho-Clinical Diagnostics business to The Carlyle Group; the K-Y® brand to Reckitt Benckiser Group PLC in the U.S. and certain other markets; and the BENECOL® brand to Raisio plc. In 2014, the pre-tax gains on the divestitures of businesses were approximately $2.4 billion. The Company completed the divestiture of its Ortho-Clinical Diagnostics business to The Carlyle Group for approximately $4.0 billion and the Company recorded a pre-tax gain of approximately $1.9 billion. Ortho-Clinical Diagnostics' results are included in the Company's Medical Devices segment.

During 2013, the Company divestitures included: women's sanitary protection products in the U.S., Canada and the Caribbean to Energizer Holdings, Inc.; Rolaids® to Chattem, Inc.; DORIBAX® rights to Shionogi; and the sale of certain consumer brands and certain pharmaceutical products. In 2013, the pre-tax gains on the divestitures of businesses were $0.1 billion.

21. Legal Proceedings

Johnson & Johnson and certain of its subsidiaries are involved in various lawsuits and claims regarding product liability, intellectual property, commercial and other matters; governmental investigations; and other legal proceedings that arise from time to time in the ordinary course of their business.

The Company records accruals for loss contingencies associated with these legal matters when it is probable that a liability will be incurred and the amount of the loss can be reasonably estimated. As of January 3, 2016, the Company has determined that the liabilities associated with certain litigation matters are probable and can be reasonably estimated. The Company has accrued for these matters and will continue to monitor each related legal issue and adjust accruals as might be warranted based on new information and further developments in accordance with ASC 450-20-25. For these and other litigation and regulatory matters discussed below for which a loss is probable or reasonably possible, the Company is unable to estimate the possible loss or range of loss beyond the amounts already accrued. Amounts accrued for legal contingencies often result from a complex series of judgments about future events and uncertainties that rely heavily on estimates and assumptions. The ability to make such estimates and judgments can be affected by various factors, including whether damages sought in the proceedings are unsubstantiated or indeterminate; scientific and legal discovery has not commenced or is not complete; proceedings are in early stages; matters present legal uncertainties; there are significant facts in dispute; or there are numerous parties involved.

In the Company's opinion, based on its examination of these matters, its experience to date and discussions with counsel, the ultimate outcome of legal proceedings, net of liabilities accrued in the Company's balance sheet, is not expected to have a material adverse effect on the Company's financial position. However, the resolution of, or increase in accruals for, one or more of these matters in any reporting period may have a material adverse effect on the Company's results of operations and cash flows for that period.

Product Liability

Certain subsidiaries of Johnson & Johnson are involved in numerous product liability claims and lawsuits involving multiple products. Claimants in these cases seek substantial compensatory and, where available, punitive damages. While these subsidiaries believe they have substantial defenses, it is not feasible to predict the ultimate outcome of litigation. The

Company has established accruals for product liability claims and lawsuits in compliance with ASC 450-20 based on currently available information, which in some cases may be limited. The Company accrues an estimate of the legal defense costs needed to defend each matter. For certain of these matters, the Company has accrued additional amounts such as estimated costs associated with settlements, damage and other losses. Product liability accruals can represent projected product liability for thousands of claims around the world, each in different litigation environments and with different fact patterns. Changes to the accruals may be required in the future as additional information becomes available.

The most significant of these cases include the DePuy ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System, the PINNACLE® Acetabular Cup System, pelvic meshes, RISPERDAL®, and XARELTO®. As of January 3, 2016, in the United States there were approximately 5,300 plaintiffs with direct claims in pending lawsuits regarding injuries allegedly due to the DePuy ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System, 8,700 with respect to the PINNACLE® Acetabular Cup System, 46,700 with respect to pelvic meshes, 10,700 with respect to RISPERDAL®, and 5,000 with respect to XARELTO®.

In August 2010, DePuy Orthopaedics, Inc. (DePuy) announced a worldwide voluntary recall of its ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System used in hip replacement surgery. Claims for personal injury have been made against DePuy and Johnson & Johnson. The number of pending lawsuits is expected to fluctuate as certain lawsuits are settled or dismissed and additional lawsuits are filed. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Northern District of Ohio. Litigation has also been filed in countries outside of the United States, primarily in the United Kingdom, Canada and Australia. In November 2013, DePuy reached an agreement with a Court-appointed committee of lawyers representing ASR™ Hip System plaintiffs to establish a program to settle claims with eligible ASR Hip patients in the United States who had surgery to replace their ASR Hips, known as revision surgery, as of August 31, 2013. This settlement covered approximately 8,000 patients. In February 2015, DePuy reached an additional agreement which would effectively extend the existing settlement program to ASR Hip patients who had revision surgeries after August 31, 2013 and prior to February 1, 2015. This second agreement is estimated to cover approximately 1,800 additional patients. The estimated cost of these agreements is covered by existing accruals. This settlement program is expected to bring to a close significant ASR Hip litigation activity in the United States. However, many lawsuits in the United States will remain, and the settlement program does not address litigation outside of the United States. The Company continues to receive information with respect to potential costs associated with this recall on a worldwide basis. The Company has established accruals for the costs associated with the DePuy ASR™ Hip program and related product liability litigation. Changes to these accruals may be required in the future as additional information becomes available.

Claims for personal injury have also been made against DePuy and Johnson & Johnson relating to DePuy's PINNACLE® Acetabular Cup System used in hip replacement surgery. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Northern District of Texas. Litigation has also been filed in countries outside of the United States, primarily in the United Kingdom. The Company has established an accrual to cover only defense costs in connection with product liability litigation associated with DePuy's PINNACLE® Acetabular Cup System. Changes to this accrual may be required in the future as additional information becomes available.

Claims for personal injury have been made against Ethicon, Inc. (Ethicon) and Johnson & Johnson arising out of Ethicon's pelvic mesh devices used to treat stress urinary incontinence and pelvic organ prolapse. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Southern District of West Virginia. In addition, class actions and individual personal injury cases or claims have been commenced in Australia, Belgium, Canada, England, Israel, Italy, the Netherlands, Scotland and Venezuela, seeking damages for alleged injury resulting from Ethicon's pelvic mesh devices. The Company has established an accrual with respect to product liability litigation associated with Ethicon's pelvic mesh products. Changes to this accrual may be required in the future as additional information becomes available.

Claims for personal injury have been made against Janssen Pharmaceuticals, Inc. and Johnson & Johnson arising out of the use of RISPERDAL®, indicated for the treatment of schizophrenia, acute manic or mixed episodes associated with bipolar I disorder and irritability associated with autism, and related compounds. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. The Company has established an accrual with respect to product liability litigation associated with RISPERDAL®. Changes to this accrual may be required in the future as additional information becomes available.

Claims for personal injury have been made against Janssen Pharmaceuticals, Inc. and Johnson & Johnson arising out of the use of XARELTO®, an oral anticoagulant. The number of pending product liability lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Eastern District of Louisiana. In addition, cases have been filed in state courts across the United States and many cases have been consolidated into a state mass tort litigation in Philadelphia, Pennsylvania. Class action lawsuits also have been filed in Canada. The Company has established an accrual with respect to product liability litigation associated with XARELTO®. Changes to this accrual may be required in the future as additional information becomes available.

Intellectual Property

Certain subsidiaries of Johnson & Johnson are subject, from time to time, to legal proceedings and claims related to patent, trademark and other intellectual property matters arising out of their businesses. Many of these matters involve challenges to the coverage and/or validity of the patents on various products and allegations that certain of the Company's products infringe the patents of third parties. Although these subsidiaries believe that they have substantial defenses to these challenges and allegations with respect to all significant patents, there can be no assurance as to the outcome of these matters. A loss in any of these cases could adversely affect the ability of these subsidiaries to sell their products, result in loss of sales due to loss of market exclusivity, and require the payment of past damages and future royalties, and which may result in a non-cash impairment charge for any associated intangible asset. The most significant of these matters are described below.

Medical Devices

In January 2010, Tyco Healthcare Group, LP (Tyco) and U.S. Surgical Corporation (now Covidien plc) filed a lawsuit against Ethicon Endo-Surgery, Inc. (EES) in the United States District Court for the District of Connecticut alleging that EES's HARMONIC® shears infringed three Tyco patents. The case was tried in July 2012, and in March 2013, the Court ruled that some of EES's HARMONIC® shears infringed Tyco's patents and ordered EES to pay damages of approximately $176 million, but declined to order injunctive relief. EES appealed and in December 2014, the United States Court of Appeals for the Federal Circuit reversed the District Court's ruling and found all the asserted claims invalid. In July 2015, Tyco filed a motion for review with the United States Supreme Court. In July 2014, Covidien filed another patent infringement lawsuit against EES in the United States District Court for the District of Connecticut seeking damages and a preliminary injunction, alleging that EES's newest version of its harmonic scalpels, the HARMONIC ACE® + 7 Shears and the HARMONIC ACE® + Shears, infringed the three Tyco patents asserted in the previous case. The claims asserted by Covidien in this case are the same claims that were declared invalid in December 2014 by the Court of Appeals in the Tyco case discussed above. In November 2015, the United States Supreme Court denied Tyco's petition for review; therefore, both cases have been dismissed.

In November 2007, Roche Diagnostics Operations, Inc., et al. (Roche) filed a patent infringement lawsuit against LifeScan, Inc. (LifeScan) in the United States District Court for the District of Delaware, alleging LifeScan's OneTouch® Line of Blood Glucose Monitoring Systems infringe two patents related to the use of microelectrode sensors. Roche is seeking monetary damages and injunctive relief. In September 2009, LifeScan obtained a favorable ruling on claim construction that precluded a finding of infringement. Roche appealed and the Court of Appeals reversed the District Court's ruling on claim construction and remanded the case to the District Court for new findings on the issue. In December 2014, the District Court ruled in LifeScan's favor and reinstated the original claim construction. In February 2015, Roche appealed the ruling, and in February 2016, oral argument took place at the Court of Appeals. The parties are awaiting a decision.

In June 2009, Rembrandt Vision Technologies, L.P. (Rembrandt) filed a patent infringement lawsuit against Johnson & Johnson Vision Care, Inc. (JJVC) in the United States District Court for the Eastern District of Texas alleging that JJVC's manufacture and sale of its ACUVUE® ADVANCE® and ACUVUE® OASYS® Hydrogel Contact Lenses infringe their U.S. Patent No. 5,712,327 (the '327 patent). Rembrandt is seeking monetary relief. The case was transferred to the United States District Court for the Middle District of Florida. In May 2012, the jury returned a verdict holding that neither of the accused lenses infringes the '327 patent. Rembrandt appealed, and in August 2013, the United States Court of Appeals for the Federal Circuit affirmed the District Court's judgment. Rembrandt asked the District Court to grant it a new trial based on alleged new evidence, and in July 2014, the District Court denied Rembrandt's motion. Rembrandt has appealed the District Court's denial of its motion for a new trial.

In December 2009, the State of Israel filed a lawsuit in the District Court in Tel Aviv Jaffa against Omrix Biopharmaceuticals, Inc. and various affiliates (Omrix). In the lawsuit, the State claims that an employee of a government-owned hospital was the inventor on several patents related to fibrin glue technology that the employee developed while he

was a government employee. The State claims that he had no right to transfer any intellectual property to Omrix because it belongs to the State. The State is seeking damages plus royalties on QUIXIL™ and EVICEL® products, or alternatively, transfer of the patents to the State. The case remains active, but no trial date has been set.

In September 2011, LifeScan, Inc. (LifeScan) filed a lawsuit against Shasta Technologies, LLC (Shasta), Instacare Corp (now Pharmatech Solutions, Inc. (Pharmatech)) and Conductive Technologies, Inc. (Conductive) in the United States District Court for the Northern District of California for patent infringement and false advertising for the making and marketing of a strip for use in LifeScan's OneTouch® Blood Glucose Meters. The defendants alleged that the three LifeScan patents-in-suit are invalid and challenged the validity of the asserted patents in the United States Patent and Trademark Office (USPTO). In April 2013, the defendants brought counterclaims for alleged antitrust violations and false advertising and those claims were stayed pending resolution of the patent infringement case. The validity of two of the patents was confirmed by the USPTO, but the USPTO determined that the third patent, U.S. Patent No. 7,250,105 (the '105 patent), is invalid. LifeScan lost an appeal of that decision, but is seeking a rehearing. LifeScan entered into a settlement agreement with Shasta and Conductive. A motion brought by Pharmatech for summary judgment of patent invalidity was argued in February 2016 and the parties are awaiting a decision. LifeScan's patent infringement and false advertising claims are scheduled to be tried in August 2016.

LifeScan filed a patent infringement lawsuit against UniStrip Technologies, LLC (UniStrip) in the United States District Court for the District of North Carolina in May 2014, alleging that the making and marketing of Unistrip's strips infringe the same patents asserted against Shasta above. That case has been stayed pending the outcome of the appeal of the USPTO's decision on the validity of the '105 patent. In July 2014, UniStrip brought a lawsuit against LifeScan in the United States District Court for the Eastern District of Pennsylvania, alleging antitrust violations relating to marketing practices for LifeScan strips.

In March 2013, Medinol Ltd. (Medinol) filed a patent infringement lawsuit against Cordis Corporation (Cordis) and Johnson & Johnson in the United States District Court for the Southern District of New York alleging that all of Cordis's sales of the CYPHER ® and CYPHER SELECT™ Stents made in the United States since 2005 willfully infringed four of Medinol's patents directed to the geometry of articulated stents. Medinol is seeking damages and attorney's fees. After trial in January 2014, the District Court dismissed the case, finding Medinol unreasonably delayed bringing its claims, and Medinol did not appeal the decision. In September 2014, the District Court denied a motion by Medinol to vacate the judgment and grant it a new trial. Medinol's appeal of this decision has been dismissed. Medinol has filed a petition for review with the United States Supreme Court. Following the divestiture of Cordis, the Company retains any liability that may result from this case.

In December 2014, Bonutti Skeletal Innovations LLC (Bonutti) sued DePuy Synthes Sales, Inc. and DePuy Synthes Products, Inc. in the United States District Court for the District of Massachusetts, alleging that DePuy Synthes's product line of spine implants infringes six patents owned by Bonutti, generally covering wedge implants and their methods of implantation. Bonutti is seeking monetary damages and injunctive relief.

Pharmaceutical

In 2012 and 2013, Noramco, Inc. (Noramco) moved to intervene in several patent infringement lawsuits filed in the United States District Court for the Southern District of New York by Purdue Pharma L.P. and others (Purdue) against Noramco oxycodone customers, Impax Laboratories, Inc. (Impax), Teva Pharmaceuticals USA, Inc. (Teva), Amneal Pharmaceuticals, LLC (Amneal), Watson Laboratories, Inc.- Florida (Watson) and Andrx Labs, LLC (Andrx). The lawsuits are in response to the defendants' respective Abbreviated New Drug Applications seeking approval to market generic extended release oxycodone products before the expiration of certain Purdue patents. Three of the asserted patents relate to oxycodone and processes for making oxycodone, and Noramco has agreed to defend the lawsuits on behalf of Impax, Teva, Amneal, Watson, and Andrx. In April 2013, Watson and Andrx entered into a settlement with Purdue. The trial against Impax and Teva (and others) took place in September 2013, and Noramco defended Teva and Impax. In November 2013, Impax entered into a settlement with Purdue, and in December 2014, Teva entered into a settlement with Purdue. The District Court issued a decision in January 2014 invalidating the relevant Purdue patents and, based on that decision, subsequently dismissed the lawsuit against Amneal (and other parties not defended by Noramco). Purdue appealed the Court's decision. In February 2016, the Federal Circuit affirmed the District Court decision invalidating the Purdue patents. If Purdue ultimately prevails in its appeal of the invalidity decision, it can reinstitute its action against Amneal. In December 2015, Purdue filed another patent infringement action against Amneal in the District of Delaware asserting, among others, the three above-referenced patents and a newly issued patent relating to oxycodone and processes for making oxycodone.

Johnson & Johnson acquired the prostate cancer business of Aragon Pharmaceuticals, Inc. (Aragon), including ARN-509, a compound being tested for treatment of prostate cancer, in September 2013. Prior to the acquisition, in May 2011, Medivation, Inc. (Medivation) had sued Aragon and the University of California seeking rights to ARN-509. In December 2012, the State Court granted summary judgment to Aragon on Medivation's claims, awarding the rights of the ARN-509 compound to Aragon, and in January 2013, the Court dismissed the case against Aragon. Medivation has appealed.

REMICADE® Related Cases

In September 2013, JBI and NYU Langone Medical Center (NYU Medical Center) received an Office Action from the United States Patent and Trademark Office (USPTO) rejecting the claims in U.S. Patent No. 6,284,471 relating to REMICADE® (the '471 patent) in a reexamination proceeding instituted by a third party. The '471 patent is co-owned by JBI and NYU Medical Center, and NYU Medical Center granted JBI an exclusive license to NYU Medical Center's rights under the patent. Currently, the '471 patent in the United States expires in September 2018. JBI responded to that rejection in December 2013 and in August 2014, JBI and NYU Medical Center received a further rejection. JBI responded to the rejection by filing a further amendment and in November 2014, JBI's petition to enter the amendment was granted. The application was returned to the examiner for issuance of a new Office Action, which occurred in February 2015, further rejecting the patent. JBI responded to that rejection and in April 2015, the USPTO issued a further action maintaining its rejection of the '471 patent. In May 2015, JBI filed a notice of appeal to the USPTO's Patent Trial and Appeal Board, and the appeal is currently pending. The '471 patent remains a valid and enforceable patent as it undergoes reexamination at the USPTO. JBI will continue to defend the patent and, if necessary, will pursue all available appeals.

In August 2014, Celltrion filed for FDA approval to make and sell its own biosimilar version of REMICADE®. In March 2015, JBI filed a lawsuit in the United States District Court for the District of Massachusetts against Celltrion and Hospira seeking a declaratory judgment that their biosimilar product for which they are seeking FDA approval under the new Biologics Price Competition and Innovation Act (the BPCIA) infringes or potentially infringes six JBI patents. JBI is also seeking a declaratory judgment that defendants have failed to comply with certain procedural requirements of the BPCIA. In addition, JBI has moved for a preliminary and permanent injunction to prohibit Celltrion and Hospira from launching their biosimilar product until 180 days after they have given JBI a Notice of Commercial Marketing, such notice not to be given before FDA approval of Celltrion's product. Also in March 2015, JBI moved to stay all proceedings in the District Court with respect to the '471 patent, pending the USPTO re-examination proceeding. In August 2015, JBI also filed a motion seeking the District Court's permission to file a patent infringement lawsuit asserting U.S. Patent No. 7,598,083 (the '083 patent) against Celltrion and the manufacturer of the cell culture media that Celltrion uses to make its biosimilar product. Although the '083 patent is already asserted in the existing lawsuit, this would expand the claims to include any use of the cell media made in the United States to manufacture Celltrion's biosimilar. In February 2016, Celltrion and Hospira agreed not to launch their biosimilar product before June 30, 2016 and the '471 and '083 patents will be the two remaining patents in the lawsuit. In light of this representation, and because the Federal Circuit Court of Appeals is expected to decide this issue in an unrelated but similar case before June 29th, the Court denied JBI's motion for preliminary injunction, but noted that JBI may renew its motion following the Court of Appeals decision, if necessary, or if the Court of Appeals fails to decide the issue by June 29th. In addition, in February 2016, Celltrion and Hospira filed a motion for summary judgment of invalidity of the '471 patent.

In March 2013, Hospira Healthcare Corporation (Hospira) filed an impeachment proceeding against The Kennedy Institute of Rheumatology (Kennedy) challenging the validity of a Canadian patent related to REMICADE® (a Feldman patent), which is exclusively licensed to Janssen Biotech, Inc. (JBI). In October 2013, Kennedy, along with JBI, Janssen Inc. and Cilag GmbH International (both affiliates of JBI), filed a counterclaim for infringement against Celltrion Healthcare Co., Ltd., Celltrion Inc. (together, Celltrion) and Hospira. The counterclaim alleges that the products described in Celltrion's and Hospira's marketing applications to Health Canada for their subsequent entry biologics (SEB) to REMICADE® would infringe the Feldman patents owned by Kennedy. Discovery in the patent action is ongoing. Trial has been scheduled for September 2016.

In January 2014, Health Canada approved Celltrion's SEB to REMICADE®, allowing Celltrion to market its biosimilar version of REMICADE® in Canada, regardless of the pending patent action. In June 2014, Hospira received approval for its SEB to REMICADE®. In July 2014, Janssen Inc. (Janssen) filed a lawsuit to compel the Canadian Minister of Health to withdraw the Notice of Compliance for Hospira's SEB because Hospira did not serve a Notice of Allegation on Janssen to address the patent listed by Janssen on the Patent Register. In March 2015, the parties entered into a settlement agreement whereby Health Canada agreed to a Consent Judgment setting aside Hospira's Notice of Compliance, subject to Health Canada's right to appeal, which appeal was filed in June 2015. Nevertheless, Hospira began marketing a biosimilar version of REMICADE® as a distributor under Celltrion's Notice of Compliance.

If any of the REMICADE® related patents discussed above is found to be invalid, any such patent could not be relied upon to prevent the introduction of biosimilar versions of REMICADE®. Biosimilar versions of REMICADE® have been introduced in certain markets outside the United States, resulting in a reduction in sales of REMICADE® in those markets. The timing of the possible introduction of a biosimilar version of REMICADE® in the United States is subject to enforcement of patent rights, approval by the FDA and compliance with the 180-day notice provisions of the BPCIA. In February 2016, the Arthritis Advisory Committee of the FDA recommended approval of Celltrion's investigational biosimilar version of REMICADE® by a vote of 21-3 across all eligible indications in the United States. There is a risk that a competitor could launch a biosimilar version of REMICADE® following FDA approval (subject to compliance with the 180-day notice provisions of the BPCIA), even though one or more valid patents are in place. Introduction to the U.S. market of a biosimilar version of REMICADE® will result in a reduction in U.S. sales of REMICADE®.

Litigation Against Filers of Abbreviated New Drug Applications (ANDAs)

The following summarizes lawsuits pending against generic companies that have filed Abbreviated New Drug Applications (ANDAs) with the FDA, or undertaken similar regulatory processes outside of the United States, seeking to market generic forms of products sold by various subsidiaries of Johnson & Johnson prior to expiration of the applicable patents covering those products. These ANDAs typically include allegations of non-infringement, invalidity and unenforceability of the applicable patents. In the event the subsidiaries are not successful in these actions, or the statutory 30-month stays of the ANDAs expire before the United States District Court rulings are obtained, the third-party companies involved will have the ability, upon approval of the FDA, to introduce generic versions of the products at issue to the market, resulting in the potential for substantial market share and revenue losses for those products, and which may result in a non-cash impairment charge in any associated intangible asset. In addition, from time to time, subsidiaries may settle these actions and such settlements can involve the introduction of generic versions of the products at issue to the market prior to the expiration of the relevant patents.

PREZISTA®

A number of generic companies have filed ANDAs seeking approval to market generic versions of PREZISTA® . In November 2010, Tibotec, Inc. (now Tibotec, LLC) and Tibotec Pharmaceuticals (now Janssen R&D Ireland) (collectively, Tibotec) filed a patent infringement lawsuit against Lupin, Ltd., Lupin Pharmaceuticals, Inc. (collectively, Lupin), Mylan, Inc. and Mylan Pharmaceuticals, Inc. (collectively, Mylan) in the United States District Court for the District of New Jersey in response to Lupin's and Mylan's respective ANDAs seeking approval to market generic versions of Tibotec's PREZISTA® product before the expiration of Tibotec's patent relating to PREZISTA® . Lupin and Mylan each filed counterclaims alleging non-infringement and invalidity. In July 2011, Tibotec filed another patent infringement lawsuit against Lupin in the United States District Court for the District of New Jersey in response to Lupin's supplement to its ANDA to add new dosage strengths for its proposed product. In August 2011, Tibotec and G.D. Searle & Company (G.D. Searle) filed a patent infringement lawsuit against Lupin and Mylan in response to their notice letters advising that their ANDAs are seeking approval to market generic versions of Tibotec's PREZISTA® product before the expiration of two additional patents relating to PREZISTA® that Tibotec exclusively licenses from G.D. Searle. In September 2011, the Court consolidated the above lawsuits (referred to here as the First Consolidated Action).

The approved New Drug Application for PREZISTA® was transferred from Tibotec, Inc. to Janssen Products, LP in December 2011. In 2012 and 2013, Janssen Products, LP and Janssen R&D Ireland (collectively, Janssen) added several patents that they own or exclusively license from G.D. Searle to the First Consolidated Action against Mylan and Lupin. In June 2013, Janssen and G.D. Searle dismissed their claims relating to the patents owned by G.D. Searle against Lupin and Mylan, based on those parties' agreement not to seek FDA approval of their respective ANDAs until the November 2017 expiration of the G.D. Searle patents. After a trial regarding the remaining patents in the First Consolidated Action, the Court issued a decision in August 2014 in favor of Janssen, holding that the asserted patents are valid and would be infringed by Lupin's and Mylan's marketing of their proposed products. Mylan and Lupin filed an appeal.

In July 2014, Janssen filed a patent infringement lawsuit against Mylan in the United States District Court for the District of New Jersey, alleging infringement of United States Patent No. 8,153,829. In November 2015, Janssen and Mylan entered into a confidential settlement. Pursuant to the settlement agreement, the parties are in the process of seeking a dismissal of this action. In addition, the appeal of the August 2014 decision as it relates to Mylan has been dismissed and remanded to the District Court where the parties are seeking a modification of the Court's 2014 order in accordance with the settlement agreement.

In May 2013, Lupin notified Janssen that it filed an ANDA seeking approval to market a new dosage strength of its generic version of PREZISTA® . In response, Janssen filed a patent infringement lawsuit in the United States District Court for the District of New Jersey, alleging that Lupin's new dosage strength would infringe the same patents that Janssen is asserting against Lupin in the original action. In March 2014, Janssen filed a patent infringement lawsuit against Lupin in the United States District Court for the District of New Jersey, alleging infringement of United States Patent No 8,518,987 (the '987 patent). In January 2015, the Court consolidated these lawsuits (referred to here as the Second Consolidated Action), and stayed them pending Lupin's appeal of the Court's decision in the First Consolidated Action. In April 2015, Lupin filed an Inter Partes Review in the USPTO seeking to invalidate the '987 patent and in October 2015, the USPTO denied Lupin's petition. In January 2016, Janssen received a patent notice from Lupin advising that Lupin has amended its ANDA to reflect a new formulation of darunavir that Lupin alleges does not infringe the relevant Janssen patents, and in February 2016, Janssen filed a lawsuit asserting those patents against Lupin in the United States District Court for the District of New Jersey. In addition, in January 2016, Lupin filed a motion to stay and deactivate its appeal of the above-referenced August 2014 decision, and to remand the matter to the District Court where Lupin intends to modify the 2014 District Court order and injunction to allow Lupin to market its new formulation of darunavir before the expiration of the relevant patents.

Janssen filed a patent infringement lawsuit against Hetero Drugs, Ltd. Unit III and Hetero USA Inc. in March 2013 in the United States District Court for the District of New Jersey, alleging infringement of United States Patent Nos. 7,126,015 and 7,595,408. In October 2015, the parties stipulated to a Consent Judgment wherein the Hetero defendants admitted that the patents-in-suit are valid and would be infringed by the manufacture, importation, use or sale of Hetero's ANDA product, and agreed to an injunction with respect to such product during the life of the patents-in-suit. Hetero reserved the right to develop non-infringing darunavir products and processes.

In August 2014, Janssen filed patent infringement lawsuits against Cipla Ltd. and Cipla USA, Inc. (collectively, Cipla) in the United States District Courts for the Districts of New Jersey and Delaware in response to Cipla's ANDA seeking approval to market a generic version of Janssen's PREZISTA® product before the expiration of certain of Janssen's patents relating to PREZISTA® . Cipla filed counterclaims seeking declarations of noninfringement and invalidity of the patents-in-suit. In May 2015, Janssen and Cipla entered into a settlement agreement.

In response to its Notice of Allegation seeking approval to market a generic version of PREZISTA® in Canada before the expiration of Canadian Patent No. 2,485,834, Janssen Inc. and Janssen R&D Ireland filed a Notice of Application against Mylan Pharmaceuticals ULC in July 2014. In December 2014, Janssen R&D Ireland transferred its PREZISTA® patents to Janssen Sciences Ireland UC, and Janssen Sciences Ireland UC was substituted for Janssen R&D Ireland as plaintiff in the above-referenced actions. In February 2016, the parties entered into a confidential settlement and the Notice of Application has been dismissed.

In January 2015, Janssen Inc. and Janssen Sciences Ireland UC filed a Notice of Application against Teva Canada Limited in response to its Notice of Allegation seeking approval to market a generic version of PREZISTA® before the expiration of Canadian Patent No. 2,485,834. In October 2015, the parties entered into a settlement wherein Teva Canada Limited agreed to withdraw its Notice of Allegation without prejudice to file a new one in the future, and Janssen Inc. and Janssen Sciences Ireland UC agreed to dismiss their Notice of Application.

In each of the above lawsuits, Janssen sought or is seeking an Order enjoining the defendants from marketing their generic versions of PREZISTA® before the expiration of the relevant patents.

CONCERTA®

In May 2014, ALZA Corporation (ALZA) and Janssen Pharmaceuticals, Inc. (JPI) filed a patent infringement lawsuit in the United States District Court for the District of West Virginia against Mylan, Inc. and Mylan Pharmaceuticals, Inc. (Mylan) in response to its ANDA seeking approval to market a generic version of CONCERTA® before the expiration of United States Patent No. 8,163,798 (the '798 patent). Mylan filed counterclaims seeking declarations of invalidity and non-infringement of the patents-in-suit. In May 2015, Mylan sought leave to add a counterclaim for invalidity and non-infringement of U.S. Patent No. 8,629,179 (the '179 patent) and the Court denied Mylan's motion. In July 2015, Mylan filed a declaratory judgment action in the Eastern District of Pennsylvania seeking a declaration of invalidity and non-infringement of the '179 patent. In October 2015, the parties entered into a confidential settlement of both the West Virginia and Pennsylvania actions.

In December 2014, Janssen Inc. and ALZA filed a Notice of Application against Actavis Pharma Company (Actavis) in response to its Notice of Allegation seeking approval to market a generic version of CONCERTA® before the expiration of Canadian Patent No. 2,264,852 (the '852 patent). The hearing is scheduled for September 2016.

In February 2015, Janssen Inc. and ALZA filed a Notice of Application against Apotex Inc. (Apotex) in response to its Notice of Allegation seeking approval to market a generic version of CONCERTA® before the expiration of the '852 patent. In August 2015, Janssen Inc. and ALZA voluntarily dismissed the Notice of Application.

In each of the above lawsuits, ALZA and/or JPI sought or are seeking an Order enjoining the defendants from marketing their generic versions of CONCERTA® before the expiration of the relevant patents.

ZYTIGA®

In June and July 2015, Janssen Biotech, Inc. (JBI) received notices of paragraph IV certification from several companies advising of their respective ANDAs seeking approval for a generic version of ZYTIGA® before the expiration of one or more patents relating to ZYTIGA®. In July 2015, JBI, Janssen Oncology, Inc. and Janssen Research & Development, LLC (collectively, Janssen) and BTG International Ltd. (BTG) filed a patent infringement lawsuit in the United States District Court for the District of New Jersey against several generic ANDA applicants (and certain of their affiliates and/or suppliers) in response to their respective ANDAs seeking approval to market a generic version of ZYTIGA® before the expiration of United States Patent Nos. 5,604,213 (the '213 patent) (expiring December 2016) and/or 8,822,438 (the '438 patent) (expiring August 2027). The generic companies include Actavis Laboratories, FL, Inc. (Actavis); Amneal Pharmaceuticals, LLC and Amneal Pharmaceuticals of New York, LLC (collectively, Amneal); Apotex Inc. and Apotex Corp. (collectively, Apotex); Citron Pharma LLC (Citron); Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, Dr. Reddy's); Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively, Mylan); Par Pharmaceuticals, Inc. and Par Pharmaceutical Companies, Inc. (collectively, Par); Sun Pharmaceutical Industries Ltd. and Sun Pharmaceuticals Industries, Inc. (collectively, Sun); Teva Pharmaceuticals USA, Inc. (Teva); Wockhardt Bio A.G.; Wockhardt USA LLC and Wockhardt Ltd. (collectively, Wockhardt); West-Ward Pharmaceutical Corp. (West-Ward); and Hikma Pharmaceuticals, LLC (Hikma). The Court entered a stay of the New Jersey lawsuit against each of Par and Citron, as each agreed to be bound by the decision against the other defendants in the New Jersey action. In February 2016, the New Jersey Court set a trial date of October 2017.

In August 2015, Janssen and BTG filed an additional jurisdictional protective lawsuit against the Mylan defendants in the United States District Court for the Northern District of West Virginia. In October 2015, Mylan filed a motion to dismiss the New Jersey lawsuit for lack of personal jurisdiction and improper venue. In February 2016, the West Virginia Court stayed the West Virginia case pending a decision on Mylan's motion to dismiss in the New Jersey lawsuit, but set a conditional trial date of February 2018. The Court will dismiss the West Virginia lawsuit if Mylan's motion to dismiss in New Jersey is denied.

In August 2015, JBI received a notice of paragraph IV certification from Hetero USA Inc., the U.S. Regulatory Agent for Hetero Labs Limited Unit-V, a division of Hetero Labs Limited (collectively, Hetero) advising of Hetero's ANDA seeking approval for a generic version of ZYTIGA® before expiration of the '438 patent. In September 2015, Janssen and BTG filed an amended complaint in the New Jersey lawsuit to allege infringement of the '438 patent by Hetero.

The filing of the above-referenced lawsuits triggered a stay until October 2018 during which the FDA will not grant final approval of the generics' ANDAs unless there is an earlier district court decision finding the patents-in-suit invalid or not infringed.

In December 2015, Amerigen Pharmaceuticals Limited filed a petition for an Inter Partes Review in the USPTO seeking to invalidate the '438 patent.

In each of the above lawsuits, Janssen is seeking an Order enjoining the defendants from marketing their generic versions of ZYTIGA® before the expiration of the relevant patents.

COMPLERA®

In August and September 2015, Janssen Pharmaceutica NV and Janssen Sciences Ireland UC (collectively, Janssen) and Gilead Sciences, Inc. and Gilead Sciences Ireland UC (collectively, Gilead) filed patent infringement lawsuits in the United States District Court for the District of Delaware and West Virginia against Mylan, Inc. and Mylan Pharmaceuticals, Inc. (collectively, Mylan) in response to their ANDA seeking approval to market a generic version of COMPLERA® before the expiration of United States Patent Nos. 8,841,310; 7,125,879; and 8,101,629. In September 2015, Mylan filed an Answer in the West Virginia action that included counterclaims seeking declarations of invalidity and non-infringement of the patents-in-suit as well as United States Patent No. 8,080,551. In September 2015, Mylan filed a motion to dismiss the Delaware lawsuit for lack of personal jurisdiction. In January 2016, Janssen and Gilead filed a first amended complaint in the New Jersey Action adding claims for patent infringement with respect to United States Patent Nos. 7,399,856 and

7,563,922. In addition, in the New Jersey Action, the Court dismissed Mylan's motion to dismiss and set a trial date of February 2018, and in the West Virginia Action, the Court set a trial date of December 2017. In February 2016, Mylan renewed its motion to dismiss for lack of jurisdiction.

In each of the above lawsuits, Janssen is seeking an Order enjoining the defendants from marketing their generic versions of COMPLERA® before the expiration of the relevant patents.

XARELTO®

A number of generic companies have filed ANDAs seeking approval to market generic versions of XARELTO® . In October 2015, Janssen Pharmaceuticals, Inc. (JPI) and Bayer Pharma AG and Bayer Intellectual Property GmbH (collectively, Bayer) filed a patent infringement lawsuit against Aurobindo Pharma Limited, Aurobindo Pharma USA, Inc., Breckenridge Pharmaceutical, Inc., Micro Labs USA Inc., Micro Labs Ltd., Mylan Pharmaceuticals Inc., Mylan Inc., Prinston Pharmaceutical, Inc., Sigmapharm Laboratories, LLC, Torrent Pharmaceuticals, Limited and Torrent Pharma Inc. in the United States District Court for the District of Delaware in response to those parties' respective ANDAs seeking approval to market generic versions of XARELTO® before the expiration of Bayer's United States Patent Nos. 7,157,456, 7,585,860 and 7,592,339 relating to XARELTO® . JPI is the exclusive licensee of the asserted patents. JPI is seeking an Order enjoining the defendants from marketing their generic versions of XARELTO® before the expiration of the relevant patents. In November 2015, Mylan moved to dismiss the action. In December 2015, JPI, Bayer, and Mylan stipulated and agreed to dismiss the claims against Mylan Inc. and suspend further briefing and argument on Mylan's motion to dismiss pending appeals relating to personal jurisdiction over Mylan Pharmaceuticals Inc. in the District of Delaware.

In January 2016, JPI and Bayer received a paragraph IV notice from Invagen Pharmaceuticals Inc. (Invagen) advising that it is seeking FDA approval for a generic XARELTO® product before expiration of the relevant patents. In February 2016, JPI and Bayer filed a patent infringement action against Invagen asserting the same XARELTO® patents asserted in the original case, and the Invagen case has been consolidated with the original case. The Court set a trial date of March 2018.

Government Proceedings

Like other companies in the pharmaceutical and medical devices industries, Johnson & Johnson and certain of its subsidiaries are subject to extensive regulation by national, state and local government agencies in the United States and other countries in which they operate. As a result, interaction with government agencies is ongoing. The most significant litigation brought by, and investigations conducted by, government agencies are listed below. It is possible that criminal charges and substantial fines and/or civil penalties or damages could result from government investigations or litigation.

Average Wholesale Price (AWP) Litigation

Johnson & Johnson and several of its pharmaceutical subsidiaries (the J&J AWP Defendants), along with numerous other pharmaceutical companies, are defendants in a series of lawsuits in state and federal courts involving allegations that the pricing and marketing of certain pharmaceutical products amounted to fraudulent and otherwise actionable conduct because, among other things, the companies allegedly reported an inflated Average Wholesale Price (AWP) for the drugs at issue. Payors alleged that they used those AWPs in calculating provider reimbursement levels. Many of these cases, both federal actions and state actions removed to federal court, were consolidated for pre-trial purposes in a Multi-District Litigation (MDL) in the United States District Court for the District of Massachusetts.

The plaintiffs in these cases included three classes of private persons or entities that paid for any portion of the purchase of the drugs at issue based on AWP, and state government entities that made Medicaid payments for the drugs at issue based on AWP. In June 2007, after a trial on the merits, the MDL Court dismissed the claims of two of the plaintiff classes against the J&J AWP Defendants. In March 2011, the Court dismissed the claims of the third class against the J&J AWP Defendants without prejudice.

AWP cases brought by various Attorneys General have proceeded to trial against other manufacturers. Several state cases against certain subsidiaries of Johnson & Johnson have been settled, including the case in Alaska, which settled in April 2014, and cases are still pending in Illinois, New Jersey, Wisconsin and Utah. The cases in Illinois, New Jersey and Wisconsin have not yet proceeded to trial. In Utah, the claims brought by the Attorney General were dismissed by the Court in 2013, but the State may appeal the dismissal after the conclusion of similar pending matters against other defendants. The AWP case against the J&J AWP Defendants brought by the Attorney General of the Commonwealth of Pennsylvania was tried in Commonwealth Court in 2010. The Court found in the Commonwealth's favor with regard to certain of its claims under the Pennsylvania Unfair Trade Practices and Consumer Protection Law ("UTPL"), entered an

injunction, and awarded $45 million in restitution and $6.5 million in civil penalties. The Court found in the J&J AWP Defendants' favor on the Commonwealth's claims of unjust enrichment, misrepresentation/fraud, civil conspiracy, and on certain of the Commonwealth's claims under the UTPL. The J&J AWP Defendants appealed the Commonwealth Court's UTPL ruling, and in June 2014, the Pennsylvania Supreme Court vacated the judgment entered by the Commonwealth Court and remanded the case for further proceedings. On remand, in January 2015, the Commonwealth Court dismissed the monetary awards against the J&J AWP Defendants. In March 2015, the ruling was appealed back to the Pennsylvania Supreme Court. In December 2015, the Pennsylvania Supreme Court affirmed the Order of the Commonwealth Court dismissing the monetary awards against the J&J AWP Defendants.

RISPERDAL®

In November 2013, Johnson & Johnson and its subsidiary, Janssen Pharmaceuticals, Inc. (JPI), finalized previously disclosed settlement agreements with the United States Department of Justice and forty-five states resolving federal investigations and state Medicaid claims related to past promotional practices of RISPERDAL® from 1999 through 2005, and other matters. JPI had also settled alleged consumer fraud claims in connection with the sale and marketing of RISPERDAL® with thirty-six states and the District of Columbia in September 2012. In addition to these actions, the Attorneys General of several states brought actions against JPI, related to the sale and marketing of RISPERDAL®, seeking one or more of the following remedies: reimbursement of Medicaid or other public funds for RISPERDAL® prescriptions written for off-label use, compensation for treating their citizens for alleged adverse reactions to RISPERDAL®, civil fines or penalties for violations of state false claims acts or consumer fraud statutes, punitive damages, or other relief relating to alleged unfair business practices. Certain of these actions also sought injunctive relief relating to the promotion of RISPERDAL®. Many of the actions and claims brought by the state Attorneys General have been settled, either individually or as part of the settlements described above. The cases brought by the Attorneys General of Mississippi and Kentucky were settled in December 2015, without any admission of wrongdoing on the part of JPI. State cases that went to judgment after trial are discussed below.

In 2004, the Attorney General of West Virginia commenced a lawsuit against Janssen Pharmaceutica, Inc. (now JPI) based on claims of alleged consumer fraud as to DURAGESIC®, as well as RISPERDAL®. JPI was found liable and damages were assessed at $4.5 million. JPI filed an appeal, and in November 2010, the West Virginia Supreme Court of Appeals reversed the trial court's decision. In December 2010, the Attorney General of West Virginia dismissed the case as it related to RISPERDAL® without any payment. Thereafter, JPI settled the case insofar as it related to DURAGESIC®.

In 2004, the Attorney General of Louisiana filed a multi-count Complaint against Janssen Pharmaceutica, Inc. (now JPI). Johnson & Johnson was later added as a defendant. The case was tried in October 2010. The issue tried to the jury was whether Johnson & Johnson or JPI had violated the State's Medical Assistance Program Integrity Law (the Act) through misrepresentations allegedly made in the mailing of a November 2003 Dear Health Care Professional letter regarding RISPERDAL®. The jury returned a verdict that JPI and Johnson & Johnson had violated the Act and awarded $257.7 million in damages. The trial judge subsequently awarded the Attorney General counsel fees and expenses in the amount of $73 million. In January 2014, the Louisiana Supreme Court reversed the District Court's judgment in favor of the Attorney General, and rendered judgment in favor of Johnson & Johnson and JPI. In April 2014, the Louisiana Supreme Court denied the Attorney General's petition seeking a rehearing of the appellate arguments, resulting in final dismissal of the case.

In 2007, the Office of General Counsel of the Commonwealth of Pennsylvania filed a lawsuit against Janssen Pharmaceutica, Inc. (now JPI) on a multi-Count Complaint related to Janssen Pharmaceutica's sale of RISPERDAL® to the Commonwealth's Medicaid program. The trial occurred in June 2010. The trial judge dismissed the case after the close of the plaintiff's evidence. The Commonwealth filed an appeal and in July 2012, the Pennsylvania Appeals Court upheld the dismissal of the Commonwealth's case.

In 2007, the Attorney General of South Carolina filed a lawsuit against Johnson & Johnson and Janssen Pharmaceutica, Inc. (now JPI) on several counts. In March 2011, the matter was tried to a jury on liability only, at which time the lawsuit was limited to claims of violation of the South Carolina Unfair Trade Practices Act, including, among others, questions of whether Johnson & Johnson or JPI engaged in unfair or deceptive acts or practices in the conduct of any trade or commerce by distributing the November 2003 Dear Health Care Professional letter regarding RISPERDAL® or in their use of the product's FDA-approved label. The jury found in favor of Johnson & Johnson and against JPI. In June 2011, the Court awarded civil penalties of approximately $327.1 million against JPI. JPI appealed this judgment and in February 2015, the South Carolina Supreme Court affirmed the trial court's decision in part, reversed it in part and remanded the case back to the trial court. The net effect of the decision was to reduce the judgment to approximately $136 million, plus

interest. In the first fiscal quarter of 2015, the Company accrued $136 million. In March 2015, JPI filed a Petition for Rehearing. In July 2015, the South Carolina Supreme Court granted the Petition and filed a substituted opinion. The new opinion reduced the judgment from approximately $136 million to approximately $124 million. In January 2016, the United States Supreme Court denied JPI's request for review, putting an end to this case.

In April 2012, in the lawsuit brought by the Attorney General of Arkansas, the jury found against both JPI and Johnson & Johnson, and the Court imposed penalties in the amount of approximately $1.2 billion. In January 2013, the trial court awarded attorney fees of approximately $181 million. JPI and Johnson & Johnson appealed both awards to the Arkansas Supreme Court, and in March 2014, the Arkansas Supreme Court dismissed the State's claim under the Arkansas Medicaid Fraud False Claims Act, as well as the approximately $1.2 billion in penalties, and reversed and remanded a claim under the Arkansas Deceptive Trade Practices Act. In April 2014, the Arkansas Supreme Court rejected a petition by the State for rehearing on the case. In May 2015, the matter settled for $7.75 million.

McNeil Consumer Healthcare

Starting in June 2010, McNeil Consumer Healthcare Division of McNEIL-PPC, Inc. (now Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division) (McNeil Consumer Healthcare) and certain affiliates, including Johnson & Johnson (the Companies), received grand jury subpoenas from the United States Attorney's Office for the Eastern District of Pennsylvania requesting documents broadly relating to recalls of various products of McNeil Consumer Healthcare, and the FDA inspections of the Fort Washington, Pennsylvania and Lancaster, Pennsylvania manufacturing facilities, as well as certain documents relating to recalls of a small number of products of other subsidiaries. In addition, in February 2011, the government served McNEIL-PPC, Inc. (McNEIL-PPC) with a Civil Investigative Demand seeking records relevant to its investigation to determine if there was a violation of the Federal False Claims Act. In March 2015, McNEIL-PPC entered a guilty plea in the United States District Court for the Eastern District of Pennsylvania to a misdemeanor violation of the U.S. Food, Drug and Cosmetic Act. McNEIL- PPC agreed to pay a $20 million fine and a $5 million forfeiture to resolve the matter.

The Companies have also received Civil Investigative Demands from multiple State Attorneys General Offices broadly relating to the McNeil recall issues. The Companies continue to cooperate with these inquiries, which are being coordinated through a multi-state coalition. If a resolution cannot be reached with this multi-state coalition, it is possible that individual State Attorneys General Offices may file civil monetary claims against the Companies. In January 2011, the Oregon Attorney General filed a civil complaint against Johnson & Johnson, McNEIL-PPC and McNeil Healthcare LLC in state court alleging civil violations of the Oregon Unlawful Trade Practices Act relating to an earlier recall of a McNeil OTC product. In November 2012, the state court granted a motion by the Companies to dismiss Oregon's complaint in its entirety, with prejudice, and Oregon appealed that decision. In November 2015, the Court of Appeals of the State of Oregon reversed the trial court and reinstated Oregon's consumer protection claims. In December 2015, the Companies filed a petition for review with the Oregon Supreme Court.

Opioids Litigation

Along with other pharmaceutical companies, Johnson & Johnson (J&J) and Janssen Pharmaceuticals, Inc. (JPI) have been named in two lawsuits alleging claims related to marketing of opioids, including DURAGESIC®, NUCYNTA® and NUCYNTA® ER. In May 2014, Santa Clara and Orange Counties in California (the Counties) filed a complaint in state court in Orange County, California against numerous pharmaceutical manufacturers, including J&J and JPI, alleging claims related to opioid marketing practices, including false advertising, unfair competition, and public nuisance. The Counties seek injunctive and monetary relief. In February 2015, the defendants filed motions challenging the sufficiency of the complaint. In August 2015, the Court stayed the case until the FDA concludes its ongoing inquiry into the safety and effectiveness of long-term opioid treatment.

In June 2014, the City of Chicago filed a complaint in Cook County Circuit Court against the same group of pharmaceutical manufacturers, including J&J and JPI, alleging a number of claims related to opioid marketing practices, including consumer fraud violations and false claims, and seeking injunctive and monetary relief. The case was later removed to the United States District Court for the Northern District of Illinois, and in December 2014, J&J and JPI filed a motion to dismiss the City of Chicago's First Amended Complaint for failure to state a claim. In November 2015, J&J and JPI filed a motion to dismiss the City of Chicago's Second Amended Complaint for failure to state a claim.

In September 2014, the Tennessee Attorney General Division of Consumer Affairs issued a Request for Information to JPI and other pharmaceutical companies related to opioids marketing practices.

In August 2015, the New Hampshire Attorney General, Consumer Protection and Antitrust Bureau issued a subpoena to JPI and other pharmaceutical companies related to opioids marketing practices. JPI objected to private contingent fee counsel's participation in the investigation on the State's behalf, and in October 2015, the State moved to enforce the subpoena.

In December 2015, the State of Mississippi filed a complaint in the Chancery Court of the First Judicial District of Hinds County against the same group of pharmaceutical manufacturers, including J&J and JPI, alleging a number of claims related to opioid marketing practices. The State of Mississippi is seeking penalties and injunctive and monetary relief.

Other

In September 2011, Synthes, Inc. (Synthes) received a Civil Investigative Demand issued pursuant to the False Claims Act from the United States Attorney's Office for the Eastern District of Pennsylvania. The Demand sought information regarding allegations that fellowships had been offered to hospitals in exchange for agreements to purchase products. Synthes has produced documents and information in response to the Demand and is cooperating with the inquiry.

In May 2012, Acclarent, Inc. (Acclarent) received a subpoena from the United States Attorney's Office for the District of Massachusetts requesting documents broadly relating to the sales, marketing and alleged off-label promotion by Acclarent of the RELIEVA STRATUS® MicroFlow Spacer product (the STRATUS® Spacer). In April 2015, an Indictment was filed in the United States District Court for the District of Massachusetts charging the former President/CEO and Vice President of Sales of Acclarent (the former Acclarent officers). The Indictment charges the former Acclarent officers with various violations related to the off-label promotion of the STRATUS® Spacer. The allegations against the former Acclarent officers relate to the development, sale and marketing of the STRATUS® Spacer, as well as actions allegedly taken by the former Acclarent officers in connection with the acquisition of Acclarent by Ethicon, Inc. in 2010. There are no charges against Acclarent, Ethicon, Inc. or Johnson & Johnson.

In August 2012, DePuy Orthopaedics, Inc., DePuy, Inc. (now DePuy Synthes, Inc.), and Johnson & Johnson Services, Inc. (the Companies) received an informal request from the United States Attorney's Office for the District of Massachusetts and the Civil Division of the United States Department of Justice (the United States) for the production of materials relating to the ASR™ XL Hip device. In July 2014, the United States notified the United States District Court for the District of Massachusetts that it had declined to intervene in a *qui tam* case filed pursuant to the False Claims Act against the Companies. The District Court issued an order in August 2014 that publicly unsealed the United States' declination notice; however, the complaint in the matter remains under seal. In addition, in October 2013, a group of state Attorneys General issued Civil Investigative Demands relating to the development, sales and marketing of several of DePuy Orthopaedics, Inc.'s hip products. In July 2014, the Oregon Department of Justice, which was investigating these matters independently of the other states, announced a settlement of its ASR™ XL Hip device investigation for a total payment of $4 million to the State of Oregon.

In October 2012, Johnson & Johnson was contacted by the California Attorney General's office regarding a multi-state Attorney General investigation of the marketing of surgical mesh products for hernia and urogynecological purposes by Johnson & Johnson's subsidiary, Ethicon, Inc. (Ethicon). Johnson & Johnson and Ethicon have since entered into a series of tolling agreements with the 47 states and the District of Columbia participating in the multi-state investigation and have responded to Civil Investigative Demands served by certain of the participating states. The states are seeking monetary and injunctive relief.

In December 2012, Therakos, Inc. (Therakos), formerly a subsidiary of Johnson & Johnson and part of the Ortho-Clinical Diagnostics, Inc. (OCD) franchise, received a letter from the civil division of the United States Attorney's Office for the Eastern District of Pennsylvania informing Therakos that the United States Attorney's Office was investigating the sales and marketing of Uvadex® (methoxsalen) and the Uvar Xts® System during the period 2000 to the present. The United States Attorney's Office requested that OCD and Johnson & Johnson preserve documents that could relate to the investigation. Therakos was subsequently acquired by an affiliate of Gores Capital Partners III, L.P. in January 2013. OCD and Johnson & Johnson retain certain liabilities that may result from the investigation for activity that occurred prior to the sale of Therakos. In March 2014, the United States Attorney's Office requested that Johnson & Johnson produce certain documents, and Johnson & Johnson is cooperating with the request. Following the divestiture of OCD, Johnson & Johnson retains OCD's portion of any liability that may result from the investigation for activity that occurred prior to the sale of Therakos.

In recent years, Johnson & Johnson has received numerous requests from a variety of United States Congressional Committees to produce information relevant to ongoing congressional inquiries. It is the policy of Johnson & Johnson to cooperate with these inquiries by producing the requested information.

General Litigation

In September 2006, Johnson & Johnson filed a lawsuit against Guidant Corporation (Guidant) in the United States District Court for the Southern District of New York, alleging that Guidant breached provisions of a merger agreement between Johnson & Johnson and Guidant. In June 2011, Guidant filed a motion for summary judgment and in July 2014, the judge denied Guidant's motion. The trial concluded in January 2015 and in February 2015, before a decision was issued by the Court, Johnson & Johnson and Guidant entered into a settlement agreement, pursuant to which Guidant agreed to pay Johnson & Johnson $600 million and agreed that it will not sue Johnson & Johnson or its affiliates for patent infringement regarding certain stent products. Johnson & Johnson dismissed its action against Guidant with prejudice. The Company recorded a gain associated with this transaction in fiscal first quarter of 2015.

In June 2009, following the public announcement that Ortho-Clinical Diagnostics, Inc. (OCD) had received a grand jury subpoena from the United States Department of Justice, Antitrust Division, in connection with an investigation that has since been closed, multiple class action complaints were filed against OCD by direct purchasers seeking damages for alleged price fixing. These cases were consolidated for pre-trial purposes in the United States District Court for the Eastern District of Pennsylvania as *In re Blood Reagent Antitrust Litigation* . Following the divestiture of OCD, Johnson & Johnson retains any liability that may result from these cases. In August 2012, the District Court granted a motion filed by Plaintiffs for class certification. In April 2015, the United States Court of Appeals for the Third Circuit reversed the class certification ruling and remanded the case to the District Court for further proceedings. In October 2015, the District Court again granted the motion by Plaintiffs for class certification.

In September 2011, Johnson & Johnson, Johnson & Johnson Inc. and McNeil Consumer Healthcare Division of Johnson & Johnson Inc. received a Notice of Civil Claim filed by Nick Field in the Supreme Court of British Columbia, Canada (the BC Civil Claim). The BC Civil Claim is a putative class action brought on behalf of persons who reside in British Columbia and who purchased during the period between September 20, 2001 and in or about December 2010 one or more various McNeil infants' or children's over-the-counter medicines that were manufactured at the Fort Washington facility. The BC Civil Claim alleges that the defendants violated the BC Business Practices and Consumer Protection Act, and other Canadian statutes and common laws, by selling medicines that were allegedly not safe and/or effective or did not comply with Canadian Good Manufacturing Practices. The class certification hearing scheduled for October 2015 was adjourned, and there is currently no date set for that hearing.

In August 2014, United States Customs and Border Protection (US CBP) issued a Penalty Notice against Janssen Ortho LLC (Janssen Ortho), assessing penalties for the alleged improper classification of darunavir ethanolate (PREZISTA®) in connection with its importation into the United States. In October 2014, Janssen Ortho submitted a Petition for Relief in response to the Penalty Notice. In May 2015, US CBP issued an Amended Penalty Notice assessing substantial penalties and Janssen Ortho filed its Petition for Relief in July 2015.

In March 2015, Costco Wholesale Corporation (Costco) filed a complaint against Johnson & Johnson Vision Care, Inc. (JJVCI) in the United States District Court of the Northern District of California, alleging antitrust claims of an unlawful vertical price fixing agreement between JJVCI, Costco and unnamed other distributors and retailers. Costco alleges that the alleged agreements harmed competition by causing increases in the price Costco customers pay for JJVCI contact lenses. Costco is seeking an injunction and monetary damages. In June 2015, the case was transferred to the United States District Court for the Middle District of Florida along with related class action cases described below. In November 2015, the Court denied a JJVCI motion to dismiss.

In March and April 2015, over 30 putative class action complaints were filed by contact lens patients in a number of courts around the United States against Johnson & Johnson Vision Care, Inc. (JJVCI), other contact lens manufacturers, distributors, and retailers, alleging vertical and horizontal conspiracies to fix the retail prices of contact lenses. The complaints alleged that the manufacturers reached agreements between each other and certain distributors and retailers concerning the prices at which some contact lenses could be sold to consumers. The plaintiffs are seeking damages. All of the class action cases were transferred to the United States District Court for the Middle District of Florida in June 2015 along with the related case filed by Costco Wholesale Corporation described above. The plaintiffs filed a Consolidated Class Action complaint in November 2015, and in December 2015, JJVCI and other defendants filed motions to dismiss.

In April 2015, Johnson & Johnson Vision Care, Inc. (JJVCI) filed a complaint in the United States District Court for the District of Utah against the State of Utah seeking a declaratory judgment that a law passed by the state to ban unilateral pricing policies solely in the contact lens market violates the Commerce Clause of the United States Constitution. The Court denied JJVCI's motion for a preliminary injunction. JJVCI appealed. Argument on the appeal was held in August 2015.

In April 2015, Adimmune Corporation Ltd (Adimmune) commenced an arbitration in the International Court of Arbitration—International Chamber of Commerce against Crucell Switzerland AG (now Janssen Vaccines AG) and Crucell Holland BV (collectively, Crucell). Adimmune claims that Crucell breached certain agreements relating to the supply of flu antigen when Crucell ceased purchasing flu antigen from Adimmune. In December 2015, Adimmune filed its Statement of Claim seeking monetary damages.

In August 2015, two third-party payors filed a purported class action in the United States District Court for the Eastern District of Louisiana against Janssen Research & Development, LLC, Janssen Ortho LLC, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, and Johnson & Johnson (as well as certain Bayer entities), alleging that the defendants improperly marketed and promoted XARELTO® as safer and more effective than less expensive alternative medications while failing to fully disclose its risks. The complaint seeks damages in an unspecified amount.

Johnson & Johnson or its subsidiaries are also parties to a number of proceedings brought under the Comprehensive Environmental Response, Compensation, and Liability Act, commonly known as Superfund, and comparable state, local or foreign laws in which the primary relief sought is the cost of past and/or future remediation.

22. Restructuring

The Company announced restructuring actions in its Medical Devices segment to better serve the needs of patients and customers in today's evolving healthcare marketplace. The Company is undertaking actions to strengthen its go-to-market model, accelerate the pace of innovation, further prioritize key platforms and geographies, and streamline operations while maintaining high quality standards.

The Company estimates that, in connection with its plans, it will record pre-tax restructuring charges of approximately $2.0 billion to $2.4 billion, most of which are expected to be incurred by 2017. In the fiscal fourth quarter of 2015, the Company recorded a pre-tax charge of $590 million, of which $81 million is included in cost of products sold. The $590 million restructuring charge consists of severance costs of $484 million, asset write-offs of $86 million and $20 million in other costs, primarily related to supply contracts.

Additionally, as part of the plan, the Company expects that the restructuring actions will result in position eliminations of approximately 4 to 6 percent of the Medical Devices segment's global workforce over the next two years, subject to any consultation procedures in countries, where required.

The Company estimates that approximately one half of the cumulative pre-tax costs will result in cash outlays, including approximately $500 million of employee severance. Approximately one half of the cumulative pre-tax costs are non-cash, relating primarily to facility rationalization, inventory write-offs and intangible asset write-offs.

The following table summarizes the severance charges and the associated spending for the fiscal year ended 2015:

(Dollars in Millions)	Severance	Asset Write-offs	Other	Total
2015 restructuring charge	$484	86	20	590
Current year activity	–	86	3	89
Reserve balance, January 3, 2016*	$484	–	17	501

* Cash outlays for severance are expected to be substantially paid out over the next 24 months in accordance with the Company's plans and local laws.

Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors of Johnson & Johnson

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of earnings, statements of comprehensive income, statements of equity, and statements of cash flows present fairly, in all material respects, the financial position of Johnson & Johnson and its subsidiaries at January 3, 2016 and December 28, 2014, and the results of their operations and their cash flows for each of the three years in the period ended January 3, 2016 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of January 3, 2016, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying "Management's Report on Internal Control over Financial Reporting." Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

As discussed in Note 1 to the consolidated financial statements, the Company changed the manner in which it classifies deferred tax assets and liabilities in 2015.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PricewaterhouseCoopers LLP

PricewaterhouseCoopers LLP

Florham Park, New Jersey
February 24, 2016

Management's Report on Internal Control Over Financial Reporting

Under Section 404 of the Sarbanes-Oxley Act of 2002, management is required to assess the effectiveness of the Company's internal control over financial reporting as of the end of each fiscal year and report, based on that assessment, whether the Company's internal control over financial reporting is effective.

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. The Company's internal control over financial reporting is designed to provide reasonable assurance as to the reliability of the Company's financial reporting and the preparation of external financial statements in accordance with generally accepted accounting principles.

Internal controls over financial reporting, no matter how well designed, have inherent limitations. Therefore, internal control over financial reporting determined to be effective can provide only reasonable assurance with respect to financial statement preparation and may not prevent or detect all misstatements. Moreover, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The Company's management has assessed the effectiveness of the Company's internal control over financial reporting as of January 3, 2016. In making this assessment, the Company used the criteria established by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in "Internal Control-Integrated Framework (2013)." These criteria are in the areas of control environment, risk assessment, control activities, information and communication, and monitoring. The Company's assessment included extensive documenting, evaluating and testing the design and operating effectiveness of its internal controls over financial reporting.

Based on the Company's processes and assessment, as described above, management has concluded that, as of January 3, 2016, the Company's internal control over financial reporting was effective.

The effectiveness of the Company's internal control over financial reporting as of January 3, 2016 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which appears herein.

/s/ Alex Gorsky
Alex Gorsky
Chairman, Board of Directors
Chief Executive Officer

/s/ Dominic J. Caruso
Dominic J. Caruso
Vice President, Finance
Chief Financial Officer