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

FORM 10-Q

☑ **Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

for the quarterly period ended June 28, 2020

or

☐ **Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
for the transition period from to

Commission file number 1-3215

Johnson & Johnson

(Exact name of registrant as specified in its charter)

New Jersey	22-1024240
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933
(Address of principal executive offices)

Registrant's telephone number, including area code (732) 524-0400

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). ☑ Yes ☐ No

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

Large accelerated filer	☑	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

If an emerging growth company, indicated by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, Par Value $1.00	JNJ	New York Stock Exchange
0.250% Notes Due January 2022	JNJ	New York Stock Exchange
0.650% Notes Due May 2024	JNJ	New York Stock Exchange
5.50% Notes Due November 2024	JNJ	New York Stock Exchange
1.150% Notes Due November 2028	JNJ	New York Stock Exchange
1.650% Notes Due May 2035	JNJ	New York Stock Exchange

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

On July 20, 2020, 2,632,823,475 shares of Common Stock, $1.00 par value, were outstanding.

JOHNSON & JOHNSON AND SUBSIDIARIES

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q and Johnson & Johnson's other publicly available documents contain "forward-looking statements" within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. Management and representatives of Johnson & Johnson and its subsidiaries (the Company) also may from time to time make forward-looking statements. Forward-looking statements do not relate strictly to historical or current facts and reflect management's assumptions, views, plans, objectives and projections about the future. Forward-looking statements may be identified by the use of words such as "plans," "expects," "will," "anticipates," "estimates," and other words of similar meaning in conjunction with, among other things: discussions of future operations, expected operating results, financial performance; impact of planned acquisitions and dispositions; impact and timing of restructuring initiatives including associated cost savings and other benefits; the Company's strategy for growth; product development activities; regulatory approvals; market position and expenditures.

Because forward-looking statements are based on current beliefs, expectations and assumptions regarding future events, they are subject to uncertainties, risks and changes that are difficult to predict and many of which are outside of the Company's control. Investors should realize that if underlying assumptions prove inaccurate, or known or unknown risks or uncertainties materialize, the Company's actual results and financial condition could vary materially from expectations and projections expressed or implied in its forward-looking statements. Investors are therefore cautioned not to rely on these forward-looking statements. Risks and uncertainties include, but are not limited to:

Risks Related to Product Development, Market Success and Competition

- Challenges and uncertainties inherent in innovation and development of new and improved products and technologies on which the Company's continued growth and success depend, including uncertainty of clinical outcomes, additional analysis of existing clinical data, obtaining regulatory approvals, health plan coverage and customer access, and initial and continued commercial success;
- Challenges to the Company's ability to obtain and protect adequate patent and other intellectual property rights for new and existing products and technologies in the United States and other important markets;
- The impact of patent expirations, typically followed by the introduction of competing biosimilars and generics and resulting revenue and market share losses;
- Increasingly aggressive and frequent challenges to the Company's patents by competitors and others seeking to launch competing generic, biosimilar or other products and increased receptivity of courts, the United States Patent and Trademark Office and other decision makers to such challenges, potentially resulting in loss of market exclusivity and rapid decline in sales for the relevant product sooner than expected;
- Competition in research and development of new and improved products, processes and technologies, which can result in product and process obsolescence;
- Competition to reach agreement with third parties for collaboration, licensing, development and marketing agreements for products and technologies;
- Competition based on cost-effectiveness, product performance, technological advances and patents attained by competitors; and
- Allegations that the Company's products infringe the patents and other intellectual property rights of third parties, which could adversely affect the Company's ability to sell the products in question and require the payment of money damages and future royalties.

Risks Related to Product Liability, Litigation and Regulatory Activity

- Product efficacy or safety concerns, whether or not based on scientific evidence, potentially resulting in product withdrawals, recalls, regulatory action on the part of the United States Food and Drug Administration (or international counterparts), declining sales, reputational damage, increased litigation expense and share price impact;
- Impact, including declining sales and reputational damage, of significant litigation or government action adverse to the Company, including product liability claims and allegations related to pharmaceutical marketing practices and contracting strategies;
- Impact of an adverse judgment or settlement and the adequacy of reserves related to legal proceedings, including patent litigation, product liability, personal injury claims, securities class actions, government investigations, employment and other legal proceedings;

- Increased scrutiny of the health care industry by government agencies and state attorneys general resulting in investigations and prosecutions, which carry the risk of significant civil and criminal penalties, including, but not limited to, debarment from government business;
- Failure to meet compliance obligations in the McNEIL-PPC, Inc. Consent Decree or any other compliance agreements with governments or government agencies, which could result in significant sanctions;
- Potential changes to applicable laws and regulations affecting United States and international operations, including relating to: approval of new products; licensing and patent rights; sales and promotion of health care products; access to, and reimbursement and pricing for, health care products and services; environmental protection and sourcing of raw materials;
- Compliance with local regulations and laws that may restrict the Company's ability to manufacture or sell its products in relevant markets including, requirements to comply with medical device reporting regulations and other requirements such as the European Union's Medical Devices Regulation;
- Changes in domestic and international tax laws and regulations, including changes related to The Tax Cuts and Jobs Act in the United States, the Federal Act on Tax Reform and AHV Financing in Switzerland, increasing audit scrutiny by tax authorities around the world and exposures to additional tax liabilities potentially in excess of existing reserves; and
- Issuance of new or revised accounting standards by the Financial Accounting Standards Board and regulations by the Securities and Exchange Commission.

Risks Related to the Company's Strategic Initiatives and Healthcare Market Trends

- Pricing pressures resulting from trends toward health care cost containment, including the continued consolidation among health care providers and other market participants, trends toward managed care, the shift toward governments increasingly becoming the primary payers of health care expenses, significant new entrants to the health care markets seeking to reduce costs and government pressure on companies to voluntarily reduce costs and price increases;
- Restricted spending patterns of individual, institutional and governmental purchasers of health care products and services due to economic hardship and budgetary constraints;
- Challenges to the Company's ability to realize its strategy for growth including through externally sourced innovations, such as development collaborations, strategic acquisitions, licensing and marketing agreements, and the potential heightened costs of any such external arrangements due to competitive pressures;
- The potential that the expected strategic benefits and opportunities from any planned or completed acquisition or divestiture by the Company may not be realized or may take longer to realize than expected; and
- The potential that the expected benefits and opportunities related to past and ongoing restructuring actions may not be realized or may take longer to realize than expected.

Risks Related to Economic Conditions, Financial Markets and Operating Internationally

- The risks associated with global operations, including the impact of global public health crises and pandemics, such as the outbreak of the novel coronavirus (COVID-19), on the Company and its customers and suppliers, including foreign governments in countries in which the Company operates.
- Impact of inflation and fluctuations in interest rates and currency exchange rates and the potential effect of such fluctuations on revenues, expenses and resulting margins;
- Potential changes in export/import and trade laws, regulations and policies of the United States and other countries, including any increased trade restrictions or tariffs and potential drug reimportation legislation;
- The impact on international operations from financial instability in international economies, sovereign risk, possible imposition of governmental controls and restrictive economic policies, and unstable international governments and legal systems;
- Changes to global climate, extreme weather and natural disasters that could affect demand for the Company's products and services, cause disruptions in manufacturing and distribution networks, alter the availability of goods and services within the supply chain, and affect the overall design and integrity of the Company's products and operations;
- The impact of armed conflicts and terrorist attacks in the United States and other parts of the world including social and economic disruptions and instability of financial and other markets; and

Risks Related to Supply Chain and Operations

- Difficulties and delays in manufacturing, internally through third party providers or otherwise within the supply chain, that may lead to voluntary or involuntary business interruptions or shutdowns, product shortages, withdrawals or suspensions of products from the market, and potential regulatory action;
- Interruptions and breaches of the Company's information technology systems or those of the Company's vendors which, could result in reputational, competitive, operational or other business harm as well as financial costs and regulatory action;
- Reliance on global supply chains and production and distribution processes that are complex and subject to increasing regulatory requirements that may adversely affect supply, sourcing and pricing of materials used in the Company's products; and
- The potential that the expected benefits and opportunities related to restructuring actions contemplated for the global supply chain, including the Company's transaction with Jabil Inc., may not be realized or may take longer to realize than expected, including due to any required approvals from applicable regulatory authorities. Disruptions associated with the announced global supply chain actions may adversely affect supply and sourcing of materials used in the Company's products.

Investors also should carefully read the Risk Factors described in Item 1A of the Company's Annual Report on Form 10-K for the fiscal year ended December 29, 2019, for a description of certain risks that could, among other things, cause the Company's actual results to differ materially from those expressed in its forward-looking statements. Investors should understand that it is not possible to predict or identify all such factors and should not consider the risks described above to be a complete statement of all potential risks and uncertainties. The Company does not undertake to publicly update any forward-looking statement that may be made from time to time, whether as a result of new information or future events or developments.

Part I — FINANCIAL INFORMATION

Item 1 — FINANCIAL STATEMENTS

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(Unaudited; Dollars in Millions Except Share and Per Share Data)

		June 28, 2020	December 29, 2019
ASSETS			
Current assets:			
Cash and cash equivalents	$	11,174	17,305
Marketable securities		7,961	1,982
Accounts receivable, trade, less allowances for doubtful accounts and credit losses $334 (2019, $226)		14,645	14,481
Inventories (Note 2)		9,424	9,020
Prepaid expenses and other		2,588	2,392
Assets held for sale (Note 10)		100	94
Total current assets		45,892	45,274
Property, plant and equipment at cost		44,056	43,332
Less: accumulated depreciation		(26,458)	(25,674)
Property, plant and equipment, net		17,598	17,658
Intangible assets, net (Note 3)		47,413	47,643
Goodwill (Note 3)		33,890	33,639
Deferred taxes on income (Note 5)		7,805	7,819
Other assets		5,782	5,695
Total assets	$	158,380	157,728
LIABILITIES AND SHAREHOLDERS' EQUITY			
Current liabilities:			
Loans and notes payable	$	5,332	1,202
Accounts payable		6,765	8,544
Accrued liabilities		8,940	9,715
Accrued rebates, returns and promotions		11,790	10,883
Accrued compensation and employee related obligations		2,313	3,354
Accrued taxes on income (Note 5)		1,632	2,266
Total current liabilities		36,772	35,964
Long-term debt (Note 4)		25,062	26,494
Deferred taxes on income (Note 5)		5,532	5,958
Employee related obligations (Note 6)		10,411	10,663
Long-term taxes payable (Note 5)		6,591	7,444
Other liabilities		11,034	11,734
Total liabilities		95,402	98,257
Commitments and Contingencies (Note 11)			
Shareholders' equity:			
Common stock — par value $1.00 per share (authorized 4,320,000,000 shares; issued 3,119,843,000 shares)	$	3,120	3,120
Accumulated other comprehensive income (loss) (Note 7)		(15,533)	(15,891)
Retained earnings		113,898	110,659
Less: common stock held in treasury, at cost (487,466,000 and 487,336,000 shares)		38,507	38,417
Total shareholders' equity		62,978	59,471
Total liabilities and shareholders' equity	$	158,380	157,728

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF EARNINGS
(Unaudited; Dollars & Shares in Millions Except Per Share Amounts)

	Fiscal Second Quarter Ended			
	June 28, 2020	Percent to Sales	June 30, 2019	Percent to Sales
Sales to customers (Note 9)	$ 18,336	100.0 %	$ 20,562	100.0 %
Cost of products sold	6,579	35.9	6,940	33.8
Gross profit	11,757	64.1	13,622	66.2
Selling, marketing and administrative expenses	4,993	27.2	5,546	27.0
Research and development expense	2,707	14.8	2,666	13.0
In-process research and development	6	0.0	—	—
Interest income	(19)	(0.1)	(88)	(0.4)
Interest expense, net of portion capitalized	45	0.3	83	0.4
Other (income) expense, net	24	0.1	(1,683)	(8.2)
Restructuring (Note 12)	61	0.3	57	0.2
Earnings before provision for taxes on income	3,940	21.5	7,041	34.2
Provision for taxes on income (Note 5)	314	1.7	1,434	6.9
NET EARNINGS	$ 3,626	19.8 %	$ 5,607	27.3 %
NET EARNINGS PER SHARE (Note 8)				
Basic	$ 1.38		$ 2.11	
Diluted	$ 1.36		$ 2.08	
AVG. SHARES OUTSTANDING				
Basic	2,632.9		2,652.5	
Diluted	2,665.5		2,691.7	

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF EARNINGS
(Unaudited; Dollars & Shares in Millions Except Per Share Amounts)

	Fiscal Six Months Ended			
	June 28, 2020	Percent to Sales	June 30, 2019	Percent to Sales
Sales to customers (Note 9)	$ 39,027	100.0 %	$ 40,583	100.0 %
Cost of products sold	13,641	35.0	13,555	33.4
Gross profit	25,386	65.0	27,028	66.6
Selling, marketing and administrative expenses	10,196	26.1	10,765	26.5
Research and development expense	5,287	13.5	5,524	13.6
In-process research and development	6	0.0	890	2.2
Interest income	(86)	(0.2)	(187)	(0.5)
Interest expense, net of portion capitalized	70	0.2	185	0.5
Other (income) expense, net	(655)	(1.7)	(1,705)	(4.2)
Restructuring (Note 12)	119	0.3	93	0.3
Earnings before provision for taxes on income	10,449	26.8	11,463	28.2
Provision for taxes on income (Note 5)	1,027	2.7	2,107	5.1
NET EARNINGS	$ 9,422	24.1 %	$ 9,356	23.1 %
NET EARNINGS PER SHARE (Note 8)				
Basic	$ 3.58		$ 3.52	
Diluted	$ 3.53		$ 3.47	
AVG. SHARES OUTSTANDING				
Basic	2,633.3		2,656.7	
Diluted	2,671.0		2,697.0	

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(Unaudited; Dollars in Millions)

	Fiscal Second Quarter Ended		Fiscal Six Months Ended	
	June 28, 2020	June 30, 2019	June 28, 2020	June 30, 2019
Net earnings	$ 3,626	5,607	$ 9,422	9,356
Other comprehensive income (loss), net of tax				
Foreign currency translation	556	350	(963)	92
Securities:				
Unrealized holding gain (loss) arising during period	(2)	1	—	1
Reclassifications to earnings	—	—	—	—
Net change	(2)	1	—	1
Employee benefit plans:				
Prior service cost amortization during period	(5)	(5)	(11)	(12)
Gain (loss) amortization during period	200	142	401	318
Net change	195	137	390	306
Derivatives & hedges:				
Unrealized gain (loss) arising during period	21	86	853	(216)
Reclassifications to earnings	(60)	(26)	78	70
Net change	(39)	60	931	(146)
Other comprehensive income (loss)	710	548	358	253
Comprehensive income	$ 4,336	6,155	$ 9,780	9,609

See Notes to Consolidated Financial Statements

The tax effects in other comprehensive income for the fiscal second quarter were as follows for 2020 and 2019, respectively: Foreign Currency Translation: $114 million and $106 million; Securities: $1 million for 2020, Employee Benefit Plans: $55 million and $34 million; Derivatives & Hedges: $10 million and $16 million.

The tax effects in other comprehensive income for the fiscal six months were as follows for 2020 and 2019, respectively: Foreign Currency Translation: $68 million and $44 million; Employee Benefit Plans: $111 million and $35 million; Derivatives & Hedges: $246 million and $39 million.

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF EQUITY
(Unaudited; Dollars in Millions)

Fiscal Second Quarter Ended June 28, 2020

	Total	Retained Earnings	Accumulated Other Comprehensive Income	Common Stock Issued Amount	Treasury Stock Amount
Balance, March 29, 2020	**$ 61,294**	**112,901**	**(16,243)**	**3,120**	**(38,484)**
Net earnings	3,626	3,626	—	—	—
Cash dividends paid ($1.01 per share)	(2,659)	(2,659)	—	—	—
Employee compensation and stock option plans	712	29	—	—	683
Repurchase of common stock	(706)	—	—	—	(706)
Other	1	1	—	—	—
Other comprehensive income (loss), net of tax	710	—	710	—	—
Balance, June 28, 2020	**$ 62,978**	**113,898**	**(15,533)**	**3,120**	**(38,507)**

Fiscal Six Months Ended June 28, 2020

	Total	Retained Earnings	Accumulated Other Comprehensive Income	Common Stock Issued Amount	Treasury Stock Amount
Balance, December 29, 2019	**$ 59,471**	**110,659**	**(15,891)**	**3,120**	**(38,417)**
Net earnings	9,422	9,422	—	—	—
Cash dividends paid ($1.96 per share)	(5,164)	(5,164)	—	—	—
Employee compensation and stock option plans	1,307	(1,020)	—	—	2,327
Repurchase of common stock	(2,417)	—	—	—	(2,417)
Other	1	1	—	—	
Other comprehensive income (loss), net of tax	358		358	—	—
Balance, June 28, 2020	**$ 62,978**	**113,898**	**(15,533)**	**3,120**	**(38,507)**

Fiscal Second Quarter Ended June 30, 2019

	Total	Retained Earnings	Accumulated Other Comprehensive Income	Common Stock Issued Amount	Treasury Stock Amount
Balance, March 31, 2019	**$ 58,955**	**106,650**	**(15,517)**	**3,120**	**(35,298)**
Net earnings	5,607	5,607	—	—	—
Cash dividends paid ($0.95 per share)	(2,522)	(2,522)	—	—	—
Employee compensation and stock option plans	683	74	—	—	609
Repurchase of common stock	(2,486)	—	—	—	(2,486)
Other comprehensive income (loss), net of tax	548	—	548	—	—
Balance, June 30, 2019	**$ 60,785**	**109,809**	**(14,969)**	**3,120**	**(37,175)**

Fiscal Six Months Ended June 30, 2019

	Total	Retained Earnings	Accumulated Other Comprehensive Income	Common Stock Issued Amount	Treasury Stock Amount
Balance, December 30, 2018	**$ 59,752**	**106,216**	**(15,222)**	**3,120**	**(34,362)**
Net earnings	9,356	9,356	—	—	—
Cash dividends paid ($1.85 per share)	(4,918)	(4,918)	—	—	—
Employee compensation and stock option plans	1,034	(845)	—	—	1,879
Repurchase of common stock	(4,692)	—	—	—	(4,692)
Other comprehensive income (loss), net of tax	253	—	253	—	—
Balance, June 30, 2019	**$ 60,785**	**109,809**	**(14,969)**	**3,120**	**(37,175)**

See Notes to Consolidated Financial Statements

JOHNSON & JOHNSON AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited; Dollars in Millions)

	Fiscal Six Months Ended	
	June 28, 2020	June 30, 2019
CASH FLOWS FROM OPERATING ACTIVITIES		
Net earnings	$ 9,422	9,356
Adjustments to reconcile net earnings to cash flows from operating activities:		
Depreciation and amortization of property and intangibles	3,473	3,466
Stock based compensation	589	572
Asset write-downs	33	989
Contingent consideration reversal	(983)	—
Net gain on sale of assets/businesses	(60)	(2,079)
Deferred tax provision	(428)	(694)
Credit losses and accounts receivable allowances	117	1
Changes in assets and liabilities, net of effects from acquisitions and divestitures:		
Increase in accounts receivable	(520)	(336)
Increase in inventories	(637)	(423)
Decrease in accounts payable and accrued liabilities	(2,319)	(444)
Increase in other current and non-current assets	(1,048)	(862)
Decrease in other current and non-current liabilities	(829)	(55)
NET CASH FLOWS FROM OPERATING ACTIVITIES	6,810	9,491
CASH FLOWS FROM INVESTING ACTIVITIES		
Additions to property, plant and equipment	(1,287)	(1,493)
Proceeds from the disposal of assets/businesses, net	87	3,018
Acquisitions, net of cash acquired	(949)	(5,346)
Purchases of investments	(8,551)	(1,517)
Sales of investments	2,417	2,132
Proceeds from credit support agreements, net	672	—
Other (primarily licenses and milestones)	(492)	1
NET CASH USED BY INVESTING ACTIVITIES	(8,103)	(3,205)
CASH FLOWS FROM FINANCING ACTIVITIES		
Dividends to shareholders	(5,164)	(4,918)
Repurchase of common stock	(2,417)	(4,692)
Proceeds from short-term debt	2,717	15
Repayment of short-term debt	(17)	(12)
Proceeds from long-term debt, net of issuance costs	1	1
Repayment of long-term debt	(11)	(1,005)
Proceeds from the exercise of stock options/employee withholding tax on stock awards, net	708	463
Other	(489)	98
NET CASH USED BY FINANCING ACTIVITIES	(4,672)	(10,050)
Effect of exchange rate changes on cash and cash equivalents	(166)	33
Decrease in cash and cash equivalents	(6,131)	(3,731)
Cash and Cash equivalents, beginning of period	17,305	18,107
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 11,174	14,376
Acquisitions		
Fair value of assets acquired	$ 1,173	6,744
Fair value of liabilities assumed and noncontrolling interests	(224)	(1,398)
Net cash paid for acquisitions	$ 949	5,346

See Notes to Consolidated Financial Statements

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 — The accompanying unaudited interim consolidated financial statements and related notes should be read in conjunction with the audited Consolidated Financial Statements of Johnson & Johnson and its subsidiaries (the Company) and related notes as contained in the Company's Annual Report on Form 10-K for the fiscal year ended December 29, 2019. The unaudited interim financial statements include all adjustments (consisting only of normal recurring adjustments) and accruals necessary in the judgment of management for a fair statement of the results for the periods presented.

Columns and rows within tables may not add due to rounding. Percentages have been calculated using actual, non-rounded figures.

Use of Estimates
The extent to which COVID-19 impacts the Company's business and financial results will depend on numerous evolving factors including, but not limited to: the magnitude and duration of COVID-19, the extent to which it will impact worldwide macroeconomic conditions including interest rates, employment rates and health insurance coverage, the speed of the anticipated recovery, and governmental and business reactions to the pandemic. The Company assessed certain accounting matters that generally require consideration of forecasted financial information in context with the information reasonably available to the Company and the unknown future impacts COVID-19 as of June 28, 2020 and through the date of this report. The accounting matters assessed included, but were not limited to, the Company's allowance for doubtful accounts and credit losses, inventory and related reserves, accrued rebates and associated reserves, and the carrying value of the goodwill and other long-lived assets. While there was not a material impact to the Company's consolidated financial statements as of and for the quarter ended June 28, 2020, the Company's future assessment of the magnitude and duration of COVID-19, as well as other factors, could result in material impacts to the Company's consolidated financial statements in future reporting periods.

New Accounting Standards
The Company assesses the adoption impacts of recently issued accounting standards by the Financial Accounting Standards Board on the Company's financial statements as well as material updates to previous assessments, if any, from the Company's Annual Report on Form 10-K for the fiscal year ended December 29, 2019. There were no new material accounting standards issued in the fiscal second quarter of 2020 that impacted the Company.

Recently Adopted Accounting Standards
There were no new accounting standards adopted in the fiscal second quarter of 2020.

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

NOTE 2 — INVENTORIES

(Dollars in Millions)	June 28, 2020	December 29, 2019
Raw materials and supplies	$ 1,303	1,117
Goods in process	1,962	1,832
Finished goods	6,159	6,071
Total inventories [1]	$ 9,424	9,020

[1] See Note 10 to the Consolidated Financial Statements for details on assets held for sale and the related divestitures.

NOTE 3 — INTANGIBLE ASSETS AND GOODWILL

Intangible assets that have finite useful lives are amortized over their estimated useful lives. The latest annual impairment assessment of goodwill and indefinite lived intangible assets was completed in the fiscal fourth quarter of 2019. Future impairment tests for goodwill and indefinite lived intangible assets will be performed annually in the fiscal fourth quarter, or sooner, if warranted.

(Dollars in Millions)	June 28, 2020	December 29, 2019
Intangible assets with definite lives:		
Patents and trademarks — gross	$ 37,313	36,634
Less accumulated amortization	14,834	13,154
Patents and trademarks — net	22,479	23,480
Customer relationships and other intangibles — gross	22,272	22,056
Less accumulated amortization	10,072	9,462
Customer relationships and other intangibles — net*	12,200	12,594
Intangible assets with indefinite lives:		
Trademarks	6,927	6,922
Purchased in-process research and development [1]	5,807	4,647
Total intangible assets with indefinite lives	12,734	11,569
Total intangible assets — net	$ 47,413	47,643

*The majority is comprised of customer relationships

[1] In the fiscal first quarter of 2020, the Company completed the acquisition of bermekimab and certain related assets from XBiotech Inc., as well as the acquisition of all outstanding shares in Verb Surgical Inc., and recorded in-process research and development intangible assets of $0.8 billion and $0.4 billion, respectively.

Goodwill as of June 28, 2020 was allocated by segment of business as follows:

(Dollars in Millions)	Consumer Health	Pharmaceutical	Medical Devices	Total
Goodwill at December 29, 2019	$ 9,736	9,169	14,734	33,639
Goodwill, related to acquisitions	—	1	183	184
Currency translation/Other	10	45	12	67
Goodwill at June 28, 2020	$ 9,746	9,215	14,929	33,890

The weighted average amortization period for patents and trademarks is 12 years. The weighted average amortization period for customer relationships and other intangible assets is 21 years. The amortization expense of amortizable intangible assets included in cost of products sold was $1.1 billion for each of the fiscal second quarters ended June 28, 2020 and June 30, 2019. The amortization expense of amortizable intangible assets included in cost of products sold was $2.2 billion for each of the fiscal six months ended June 28, 2020 and June 30, 2019. Intangible asset write-downs are included in Other (income) expense, net.

The estimated amortization expense for approved products, before tax, for the five succeeding years is approximately:

(Dollars in Millions)				
2020	**2021**	**2022**	**2023**	**2024**
$4,500	4,300	4,100	4,100	4,000

See Note 10 to the Consolidated Financial Statements for additional details related to acquisitions and divestitures.

NOTE 4 — 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 product 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 designated as fair value hedges. The Company uses cross currency interest rate swaps and 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. The Company maintains credit support agreements (CSA) with certain derivative counterparties establishing collateral thresholds based on respective credit ratings and netting agreements. As of June 28, 2020, the total amount of cash collateral held by the Company under the credit support agreements (CSA) amounted to $926 million, net. On an ongoing basis, the Company monitors counter-party 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 June 28, 2020, the Company had notional amounts outstanding for forward foreign exchange contracts and cross currency interest rate swaps of $43.9 billion and $22.2 billion, respectively. As of December 29, 2019, the Company had notional amounts outstanding for forward foreign exchange contracts and cross currency interest rate swaps of $45.3 billion and $20.1 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. Foreign exchange contracts designated as cash flow hedges are accounted for under the forward method and all gains/losses associated with these contracts will be recognized in the income statement when the hedged item impacts earnings. Changes in the fair value of these derivatives 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 within accumulated other comprehensive income. The portion excluded from effectiveness testing is recorded through interest (income) expense using the spot method. 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.

The Company designated its Euro denominated notes issued in May 2016 with due dates ranging from 2022 to 2035 as a net investment hedge of the Company's investments in certain of its international subsidiaries that use the Euro as their functional currency in order to reduce the volatility caused by changes in exchange rates.

As of June 28, 2020, the balance of deferred net gain on derivatives included in accumulated other comprehensive income was $636 million after-tax. For additional information, see the Consolidated Statements of Comprehensive Income and Note 7. 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 and net investment hedge 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 and hedges for the fiscal second quarters ended in 2020 and 2019, net of tax:

(Dollars in Millions)	June 28, 2020 Sales	Cost of Products Sold	R&D Expense	Interest (Income) Expense	Other (Income) Expense	June 30, 2019 Sales	Cost of Products Sold	R&D Expense	Interest (Income) Expense	Other (Income) Expense
The effects of fair value, net investment and cash flow hedging:										
Gain (Loss) on net investment hedging relationship:										
Cross currency interest rate swaps contracts:										
Amount of gain or (loss) recognized in income on derivative amount excluded from effectiveness testing	—	—	—	39	—	—	—	—	39	—
Amount of gain or (loss) recognized in AOCI	—	—	—	39	—	—	—	—	39	—
Gain (Loss) on cash flow hedging relationship:										
Forward foreign exchange contracts:										
Amount of gain or (loss) reclassified from AOCI into income	(2)	(62)	2	—	—	(14)	(101)	36	—	2
Amount of gain or (loss) recognized in AOCI	(2)	(128)	(10)	—	22	—	(50)	18	—	(3)
Cross currency interest rate swaps contracts:										
Amount of gain or (loss) reclassified from AOCI into income	—	—	—	83	—	—		—	64	—
Amount of gain or (loss) recognized in AOCI	$ —	—	—	100	—	—	—	—	82	—

The following table is a summary of the activity related to derivatives and hedges for the fiscal six months ended in 2020 and 2019, net of tax:

(Dollars in Millions)	June 28, 2020 Sales	Cost of Products Sold	R&D Expense	Interest (Income) Expense	Other (Income) Expense	June 30, 2019 Sales	Cost of Products Sold	R&D Expense	Interest (Income) Expense	Other (Income) Expense
The effects of fair value, net investment and cash flow hedging:										
Gain (Loss) on net investment hedging relationship:										
Cross currency interest rate swaps contracts:										
Amount of gain or (loss) recognized in income on derivative amount excluded from effectiveness testing	—	—	—	79	—	—	—	—	78	—
Amount of gain or (loss) recognized in AOCI	—	—	—	79	—	—	—	—	78	—
Gain (Loss) on cash flow hedging relationship:										
Forward foreign exchange contracts:										
Amount of gain or (loss) reclassified from AOCI into income	7	(235)	(108)	—	(2)	(35)	(136)	(103)	—	8
Amount of gain or (loss) recognized in AOCI	9	174	(120)	—	(14)	(6)	(346)	(92)	—	10
Cross currency interest rate swaps contracts:										
Amount of gain or (loss) reclassified from AOCI into income	—	—	—	181	—	—	—	—	118	—
Amount of gain or (loss) recognized in AOCI	$ —	—	—	725	—	—	—	—	140	—

The following table is the effect of derivatives not designated as hedging instruments for the fiscal second quarters and fiscal six months ended in 2020 and 2019:

(Dollars in Millions)	**Location of Gain /(Loss) Recognized in Income on Derivative**	**Gain/(Loss) Recognized In Income on Derivative** Fiscal Second Quarter Ended		**Gain/(Loss) Recognized In Income on Derivative** Fiscal Six Months Ended	
Derivatives Not Designated as Hedging Instruments		June 28, 2020	June 30, 2019	June 28, 2020	June 30, 2019
Foreign Exchange Contracts	Other (income) expense	$ (24)	(50)	65	(88)

The following table is the effect of net investment hedges for the fiscal second quarters ended in 2020 and 2019

	Gain/(Loss) Recognized In Accumulated OCI		Location of Gain or (Loss) Reclassified from Accumulated Other Comprehensive Income Into Income	Gain/(Loss) Reclassified From Accumulated OCI Into Income	
(Dollars in Millions)	June 28, 2020	June 30, 2019		June 28, 2020	June 30, 2019
Debt	$ (95)	(57)	Interest (income) expense	—	—
Cross Currency interest rate swaps	$ (186)	(57)	Interest (income) expense	—	—

The following table is the effect of net investment hedges for the fiscal six months ended in 2020 and 2019

	Gain/(Loss) Recognized In Accumulated OCI		Location of Gain or (Loss) Reclassified from Accumulated Other Comprehensive Income Into Income	Gain/(Loss) Reclassified From Accumulated OCI Into Income	
(Dollars in Millions)	June 28, 2020	June 30, 2019		June 28, 2020	June 30, 2019
Debt	$ (48)	14	Interest (income) expense	—	—
Cross Currency interest rate swaps	$ 641	313	Interest (income) expense	—	—

The Company holds equity investments with readily determinable fair values and equity investments without readily determinable fair values. The Company has elected to measure equity investments that do not have readily determinable fair values at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer.

The following table is a summary of the activity related to equity investments:

(Dollars in Millions)	December 29, 2019			June 28, 2020	
	Carrying Value	Changes in Fair Value Reflected in Net Income [1]	Sales/ Purchases/Other [2]	Carrying Value	Non Current Other Assets
Equity Investments with readily determinable value	$ 1,148	196	144	1,488	1,488
Equity Investments without readily determinable value	$ 712	(28)	28	712	712

[1] Recorded in Other Income/Expense
[2] Other includes impact of currency

For equity investments without readily determinable market values, $39 million of the decrease in the fair value reflected in net income were the result of impairments. There were $11 million of increase in fair value reflected in net income due to changes in observable prices.

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. In accordance with ASC 820, a three-level hierarchy was established to prioritize the inputs used in measuring fair value. The levels within the hierarchy are described below with Level 1 inputs having the highest priority and Level 3 inputs 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 holds acquisition related contingent liabilities based upon certain regulatory and commercial events, which are classified as Level 3, whose values are determined using discounted cash flow methodologies or similar techniques for which the determination of fair value requires significant judgment or estimations.

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 June 28, 2020 and December 29, 2019 were as follows:

	June 28, 2020				December 29, 2019
(Dollars in Millions)	Level 1	Level 2	Level 3	Total	Total[1]
Derivatives designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts	$ —	395	—	395	209
Interest rate contracts [2][3]	—	1,126	—	1,126	693
Total	—	1,521	—	1,521	902
Liabilities:					
Forward foreign exchange contracts	—	260	—	260	426
Interest rate contracts [3]	—	251	—	251	193
Total	—	511	—	511	619
Derivatives not designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts	—	38	—	38	23
Liabilities:					
Forward foreign exchange contracts	—	47	—	47	33
Other Investments:					
Equity investments [4]	1,488	—	—	1,488	1,148
Debt securities[5]	$ —	10,047	—	10,047	4,368
Other Liabilities					
Contingent consideration [6]			796	796	1,715

Gross to Net Derivative Reconciliation	June 28, 2020	December 29, 2019
(Dollars in Millions)		
Total Gross Assets	$ 1,559	925
Credit Support Agreement (CSA)	(1,437)	(841)
Total Net Asset	122	84
Total Gross Liabilities	558	652
Credit Support Agreement (CSA)	(510)	(586)
Total Net Liabilities	$ 48	66

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

	June 28, 2020	June 30, 2019
(Dollars in Millions)		
Beginning Balance	$ 1,715	$ 397
Changes in estimated fair value [7]	(938)	35
Additions	106	1,133
Payments	(87)	(3)
Ending Balance	$ 796	$ 1,562

[1] December 30, 2019 assets and liabilities are all classified as Level 2 with the exception of equity investments of $1,148 million, which are classified as Level 1 and contingent consideration of $1,715 million, classified as Level 3.
[2] Includes $1 million of non-current other assets as of December 29, 2019.
[3] Includes cross currency interest rate swaps and interest rate swaps.
[4] Classified as non-current other assets.
[5] Classified within cash equivalents and current marketable securities.
[6] Includes $793 million and $1,631 million (primarily related to Auris Health), classified as non-current other liabilities as of June 28, 2020 and December 29, 2019, respectively. Includes $3 million and $84 million classified as current liabilities as of June 28, 2020 and December 29, 2019, respectively.
[7] Ongoing fair value adjustment amounts are primarily recorded in Research and Development expense.
During the fiscal first quarter of 2020, the Company recorded a contingent consideration reversal of $983 million related to the timing of certain developmental milestones associated with the Auris Health acquisition. The one-time reversal of the contingent consideration was recorded in Other income and expense. As of June 28, 2020, the estimated fair value of the remaining contingent consideration is $169 million. For additional details see Note 10 to the Consolidated Financial Statements.

The Company's cash, cash equivalents and current marketable securities as of June 28, 2020 comprised:

(Dollars in Millions)	Carrying Amount	Unrecognized Gain	Unrecognized Loss	Estimated Fair Value	Cash & Cash Equivalents	Current Marketable Securities
Cash	$ 2,215	—	—	2,215	2,215	
Non-U.S. sovereign securities[1]	655	—	—	655	225	430
U.S. reverse repurchase agreements	2,372	—	—	2,372	2,372	—
Other reverse repurchase agreements	460	—	—	460	460	
Corporate debt securities[1]	1,279	—	—	1,279	301	978
Money market funds	1,528	—	—	1,528	1,528	
Time deposits[1]	579	—	—	579	579	
Subtotal	9,088	—	—	9,088	7,680	1,408
		Unrealized Gain	Unrealized Loss			
U.S. Gov't securities	9,786	—	—	9,786	3,480	6,306
Other sovereign securities	5	—	—	5	—	5
Corporate debt securities	255	1	—	256	14	242
Subtotal available for sale debt[2]	$ 10,046	1	—	10,047	3,494	6,553
Total cash, cash equivalents and current marketable securities	$ 19,134	1	—	19,135	11,174	7,961

[1] Held to maturity investments are reported at amortized cost and gains or losses are reported in earnings.
[2] Available for sale debt securities are reported at fair value with unrealized gains and losses reported net of taxes in other comprehensive income.

In the fiscal year ended December 29, 2019 the carrying amount was the same as the estimated fair value.

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

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. Available for sale securities with stated maturities of greater than one year from the date of purchase are available to fund current operations and are classified as cash equivalents and current marketable securities.

The contractual maturities of the available for sale securities as of June 28, 2020 are as follows:

(Dollars in Millions)	Cost Basis	Fair Value
Due within one year	$ 10,023	10,024
Due after one year through five years	23	23
Due after five years through ten years	—	—
Total debt securities	$ 10,046	10,047

Financial Instruments not measured at Fair Value:
The following financial liabilities are held at carrying amount on the consolidated balance sheet as of June 28, 2020:

(Dollars in Millions)	Carrying Amount	Estimated Fair Value
Financial Liabilities		
Current Debt	$ 5,332	5,388
Non-Current Debt		
2.45% Notes due 2021	350	360
0.250% Notes due 2022 (1B Euro 1.1217)	1,121	1,131
2.25% Notes due 2022	998	1,029
6.73% Debentures due 2023	250	302
3.375% Notes due 2023	803	891
2.05% Notes due 2023	499	523
0.650% Notes due 2024 (750MM Euro 1.1217)	839	864
5.50% Notes due 2024 (500 MM GBP 1.2431)	618	749
2.625% Notes due 2025	748	813
2.45% Notes due 2026	1,993	2,179
2.95% Notes due 2027	997	1,111
2.90% Notes due 2028	1,494	1,681
1.150% Notes due 2028 (750MM Euro 1.1217)	835	917
6.95% Notes due 2029	297	435
4.95% Debentures due 2033	498	689
4.375% Notes due 2033	856	1,127
1.650% Notes due 2035 (1.5B Euro 1.1217)	1,667	1,974
3.55% Notes due 2036	989	1,170
5.95% Notes due 2037	992	1,531
3.625% Notes due 2037	1,487	1,791
3.40% Notes due 2038	991	1,168
5.85% Debentures due 2038	696	1,060
4.50% Debentures due 2040	539	736
4.85% Notes due 2041	297	420
4.50% Notes due 2043	495	685
3.70% Notes due 2046	1,974	2,467
3.75% Notes due 2047	991	1,255
3.50% Notes due 2048	742	923
Other	6	10
Total Non-Current Debt	$ 25,062	29,991

The weighted average effective interest rate on non-current debt is 3.24%.

The excess of the estimated fair value over the carrying value of debt was $3.0 billion at December 29, 2019.

The Current Debt balance as of June 28, 2020 includes $2.7 billion of commercial paper which has a weighted average interest rate of 0.15% and a weighted average maturity of 3.7 months. There was no commercial paper as of December 29, 2019.

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

NOTE 5 — INCOME TAXES

The worldwide effective income tax rates for the fiscal six months of 2020 and 2019 were 9.8% and 18.4%, respectively. In the third fiscal quarter of 2019, Switzerland enacted the Federal Act on Tax Reform and AHV Financing (TRAF), which became effective on January 1, 2020. More information on the provisions of TRAF, including the step-up transitional provisions, can be found in the Company's Annual Report on Form 10-K for the fiscal year ended December 29, 2019. During the first fiscal quarter of 2020, the final canton where the Company maintains significant operations enacted TRAF legislation and, accordingly, the Company recorded an estimated deferred tax benefit of approximately $0.3 billion for the remeasurement of existing deferred tax liabilities offset by a related $0.2 billion increase in U.S. GILTI deferred taxes. During the second fiscal quarter of 2020, the Company received rulings from the Swiss Federal and cantonal tax authorities in the remaining jurisdictions where it has significant operations. These rulings resulted in the Company revising its estimate on the tax basis adjustment (i.e., "step-up") for its assets. As a result, the Company recorded additional deferred tax benefits in the second fiscal quarter of 2020 to recognize this step-up. Consequently, the benefit recorded related to Swiss Tax reform in the first six months of fiscal 2020 was approximately $0.4 billion, or 3.8% benefit to the Company's fiscal six months effective tax rate, inclusive of the impact of U.S. GILTI deferred taxes. The Company does not expect to receive future rulings regarding the transitional provisions of TRAF.

During the second fiscal quarter of 2020, the Company reversed some of its international unrecognized tax benefits due to the completion of several years of tax examinations in certain jurisdictions. This reserve reversal benefited the Company's effective tax rate by approximately 1.0% for the first fiscal six months of fiscal 2020. In the first fiscal quarter of 2020, the Company reduced a contingent consideration liability related to the 2019 Auris Health acquisition that has benefited the year to date overall effective tax rate by approximately 1.0% (see Note 10 to the Consolidated Financial Statements for more details.)

Additionally, the Company had less income in higher tax jurisdictions relative to lower tax jurisdictions as compared to the same period in the prior fiscal year primarily due to:

- the 2019 divestiture gain related to Advanced Sterilization Products (ASP) which was primarily taxed in the U.S.
- the accrual of additional legal costs, at the U.S. statutory rate, in the second fiscal quarter of 2020 (see Notes 9 and 11 to the Consolidated Financial Statements for more details)

partially offset by:

- the reduced income in lower tax jurisdictions due to the ongoing COVID-19 pandemic.

The Company also generated additional tax benefits from stock-based compensation that were either exercised or vested during the first and second fiscal quarters.

As of June 28, 2020, the Company had approximately $3.1 billion of liabilities from unrecognized tax benefits. The Company conducts business and files tax returns in numerous countries and currently has tax audits in progress in a number of jurisdictions. With respect to the United States, the IRS has completed its audit for the tax years through 2009 and is currently auditing the tax years 2010 through 2012. The Company currently expects completion of this audit and settlement of the related tax liabilities in the fiscal year 2020. As of June 28, 2020, the Company has classified unrecognized tax benefits and related interest of approximately $0.2 billion as a current liability on the "Accrued taxes on Income" line of the Consolidated Balance Sheet. This is the amount expected to be paid over the next 12 months with respect to the IRS audit. During the first fiscal quarter of 2020, the Company made a payment of approximately $0.6 billion to the U.S. Treasury with respect to the 2010-2012 tax audit in anticipation of a final settlement later in the fiscal year 2020. The completion of this tax audit may result in additional adjustments to the Company's unrecognized tax benefit liability.

In other major jurisdictions where the Company conducts business, the years that remain open to tax audit go back to the year 2006. The Company believes it is possible that tax audits may be completed over the next twelve months by taxing authorities in some jurisdictions outside of the United States. 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.

NOTE 6 — PENSIONS AND OTHER BENEFIT PLANS

Components of Net Periodic Benefit Cost
Net periodic benefit costs for the Company's defined benefit retirement plans and other benefit plans for the fiscal second quarters and fiscal six months of 2020 and 2019 include the following components:

	Retirement Plans		Other Benefit Plans		Retirement Plans		Other Benefit Plans	
(Dollars in Millions)	June 28, 2020	June 30, 2019	June 28, 2020	June 30, 2019	June 28, 2020	June 30, 2019	June 28, 2020	June 30, 2019
Service cost	$ 323	277	72	69	649	553	144	137
Interest cost	237	274	33	46	477	549	66	92
Expected return on plan assets	(608)	(581)	(1)	(1)	(1,222)	(1,164)	(3)	(3)
Amortization of prior service cost/(credit)	1	1	(8)	(8)	1	2	(16)	(16)
Recognized actuarial losses	222	146	35	33	445	290	71	65
Curtailments and settlements	—	8	—	—	19	7	—	—
Net periodic benefit cost	$ 175	125	131	139	369	237	262	275

The service cost component of net periodic benefit cost is presented in the same line items on the Consolidated Statement of Earnings where other employee compensation costs are reported. All other components of net periodic benefit cost are presented as part of Other (income) expense, net on the Consolidated Statement of Earnings.

Company Contributions
For the fiscal six months ended June 28, 2020, the Company contributed $144 million and $18 million to its U.S. and international retirement plans, respectively. The Company plans to continue to fund its U.S. defined benefit plans to comply with the Pension Protection Act of 2006. International plans are funded in accordance with local regulations.

NOTE 7 — 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 29, 2019	$ (8,705)	—	(6,891)	(295)	(15,891)
Net change	(963)	—	390	931	358
June 28, 2020	$ (9,668)	—	(6,501)	636	(15,533)

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 6 for additional details.
Gain/(Loss) On Derivatives & Hedges - reclassifications to earnings are recorded in the same account as the underlying transaction. See Note 4 for additional details.

NOTE 8 — EARNINGS PER SHARE

The following is a reconciliation of basic net earnings per share to diluted net earnings per share for the fiscal second quarters and fiscal six months ended June 28, 2020 and June 30, 2019:

	Fiscal Second Quarter Ended		Fiscal Six Months Ended	
(Shares in Millions)	June 28, 2020	June 30, 2019	June 28, 2020	June 30, 2019
Basic net earnings per share	$ 1.38	2.11	3.58	3.52
Average shares outstanding — basic	2,632.9	2,652.5	2,633.3	2,656.7
Potential shares exercisable under stock option plans	119.6	140.8	122.6	138.6
Less: shares which could be repurchased under treasury stock method	(87.5)	(102.3)	(85.4)	(99.0)
Convertible debt shares	0.5	0.7	0.5	0.7
Average shares outstanding — diluted	2,665.5	2,691.7	2,671.0	2,697.0
Diluted net earnings per share	$ 1.36	2.08	3.53	3.47

The diluted net earnings per share calculation for both the fiscal second quarters ended June 28, 2020 and June 30, 2019 included the dilutive effect of convertible debt that was offset by the related reduction in interest expense. The diluted net earnings per share calculation for the fiscal second quarter ended June 28, 2020 excluded 20 million shares related to stock options, as the exercise price of these options was greater than their average market value. The diluted net earnings per share calculation for the fiscal second quarter ended June 30, 2019 excluded an insignificant number of shares related to stock options, as the exercise price of these options was greater than their average market value.

The diluted net earnings per share calculation for both the fiscal six months ended June 28, 2020 and June 30, 2019 included the dilutive effect of convertible debt that was offset by the related reduction in interest expense. The diluted net earnings per share calculation for the fiscal six months ended June 28, 2020 excluded 15 million shares related to stock options, as the exercise price of these options was greater than their average market value. The diluted net earnings per share calculation for the fiscal six months ended June 30, 2019 excluded an insignificant number of shares related to stock options, as the exercise price of these options was greater than their average market value.

NOTE 9 — SEGMENTS OF BUSINESS AND GEOGRAPHIC AREAS

SALES BY SEGMENT OF BUSINESS

(Dollars in Millions)	Fiscal Second Quarter Ended June 28, 2020	June 30, 2019	Percent Change	Fiscal Six Months Ended June 28, 2020	June 30, 2019	Percent Change
Consumer Health*						
Baby Care						
U.S.	$ 96	99	(3.5)%	$ 188	186	1.2 %
International	260	344	(24.3)	529	651	(18.7)
Worldwide	356	443	(19.7)	717	837	(14.3)
Oral Care						
U.S.	170	155	9.7	346	306	12.9
International	227	234	(2.8)	446	450	(0.8)
Worldwide	397	389	2.2	792	756	4.8
OTC						
U.S.	627	484	29.6	1,316	991	32.8
International	522	580	(10.1)	1,181	1,160	1.8
Worldwide	1,149	1,064	7.9	2,497	2,151	16.1
Skin Health/Beauty						
U.S.	536	663	(19.2)	1,195	1,251	(4.5)
International	471	539	(12.5)	929	1,041	(10.7)
Worldwide	1,007	1,202	(16.2)	2,124	2,292	(7.3)
Women's Health						
U.S.	3	3	(2.9)	7	6	14.3
International	199	250	(20.4)	427	472	(9.6)
Worldwide	202	253	(20.1)	434	478	(9.3)
Wound Care/Other						
U.S.	126	132	(4.7)	245	234	4.7
International	59	61	(2.4)	111	114	(1.9)
Worldwide	185	193	(4.0)	356	348	2.6
TOTAL Consumer Health						
U.S.	1,557	1,537	1.3	3,297	2,975	10.8
International	1,739	2,007	(13.4)	3,624	3,887	(6.8)
Worldwide	3,296	3,544	(7.0)	6,921	6,862	0.9

* Previously referred to as Consumer

PHARMACEUTICAL						
Immunology						
U.S.	2,362	2,379	(0.7)	4,772	4,542	5.1
International	1,161	1,087	6.8	2,389	2,175	9.8
Worldwide	3,523	3,466	1.6	7,161	6,717	6.6
REMICADE®						
U.S.	593	801	(25.8)	1,218	1,575	(22.7)
U.S. Exports	133	62	*	243	138	75.7
International	208	244	(14.5)	464	496	(6.4)
Worldwide	935	1,107	(15.5)	1,925	2,209	(12.9)
SIMPONI / SIMPONI ARIA®						
U.S.	256	281	(8.7)	528	544	(2.9)
International	289	282	2.6	547	543	0.8
Worldwide	546	563	(3.0)	1,075	1,087	(1.1)
STELARA®						
U.S.	1,138	1,058	7.5	2,355	1,940	21.4
International	558	499	11.9	1,161	1,022	13.6
Worldwide	1,697	1,558	8.9	3,516	2,963	18.7
TREMFYA®						
U.S.	241	176	36.7	428	344	24.4%
International	101	59	71.0	210	108	94.0
Worldwide	342	235	45.4	638	452	41.1%
OTHER IMMUNOLOGY						
U.S.	—	—	—	—	—	—
International	3	3	11.8	6	6	2.7
Worldwide	3	3	11.8	6	6	2.7
Infectious Diseases						
U.S.	416	387	7.4	852	744	14.5
International	463	475	(2.5)	946	964	(1.8)
Worldwide	878	862	1.9	1,798	1,708	5.3
EDURANT® / rilpivirine						
U.S.	10	12	(14.0)	22	24	(6.9)
International	246	198	24.5	458	397	15.4
Worldwide	256	210	22.2	480	421	14.1
PREZISTA® / PREZCOBIX® / REZOLSTA® / SYMTUZA®						
U.S.	379	344	10.5	775	659	17.7
International	130	191	(32.0)	314	399	(21.4)
Worldwide	510	535	(4.7)	1,089	1,058	2.9
OTHER INFECTIOUS DISEASES						
U.S.	25	31	(18.7)	54	61	(11.2)
International	87	86	1.0	174	168	3.8
Worldwide	113	117	(4.2)	229	229	(0.2)

Neuroscience						
U.S.	778	664	17.4	1,526	1,387	10.1
International	809	875	(7.6)	1,719	1,780	(3.5)
Worldwide	1,587	1,538	3.2	3,245	3,167	2.5
CONCERTA® / methylphenidate						
U.S.	55	15	*	107	112	(4.2)
International	94	123	(23.0)	212	239	(11.0)
Worldwide	149	137	8.7	320	351	(8.9)
INVEGA SUSTENNA® / XEPLION® / INVEGA TRINZA® / TREVICTA®						
U.S.	576	506	13.8	1,120	989	13.2
International	303	312	(2.8)	642	619	3.7
Worldwide	879	818	7.5	1,762	1,608	9.5
RISPERDAL CONSTA®						
U.S.	74	81	(9.3)	150	158	(4.9)
International	79	101	(21.2)	173	203	(14.9)
Worldwide	153	182	(15.9)	323	361	(10.5)
OTHER NEUROSCIENCE						
U.S.	75	62	21.5	150	128	16.8
International	331	340	(2.5)	691	719	(3.9)
Worldwide	406	401	1.2	841	847	(0.7)
Oncology						
U.S.	1,181	1,013	16.6	2,356	1,975	19.3
International	1,609	1,684	(4.4)	3,448	3,240	6.4
Worldwide	2,791	2,697	3.5	5,804	5,215	11.3
DARZALEX®						
U.S.	492	369	32.9	955	721	32.3
International	409	405	1.2	883	682	29.6
Worldwide	901	774	16.3	1,838	1,403	31.0
ERLEADA®						
U.S.	136	62	*	255	120	*
International	33	7	*	57	10	*
Worldwide	170	69	*	313	130	*
IMBRUVICA®						
U.S.	447	367	21.5	879	716	22.6
International	502	463	8.3	1,101	898	22.6
Worldwide	949	831	14.1	1,980	1,615	22.6
VELCADE®						
U.S.	—	—	—	—	—	—
International	98	224	(56.1)	206	487	(57.7)
Worldwide	98	224	(56.1)	206	487	(57.7)
ZYTIGA® / abiraterone acetate						
U.S.	87	198	(55.6)	226	383	(40.9)
International	480	500	(3.9)	1,032	994	3.8
Worldwide	568	698	(18.6)	1,258	1,377	(8.6)

OTHER ONCOLOGY						
U.S.	20	16	22.9	42	34	21.4
International	87	85	2.2	169	169	(0.3)
Worldwide	106	101	5.5	210	203	3.4
Pulmonary Hypertension						
U.S.	545	439	24.2	1,031	869	18.7
International	243	251	(3.3)	503	477	5.3
Worldwide	789	690	14.2	1,534	1,346	13.9
OPSUMIT®						
U.S.	256	203	26.1	485	375	29.3
International	150	146	3.0	310	279	11.2
Worldwide	406	348	16.5	795	654	21.6
UPTRAVI®						
U.S.	254	175	44.5	466	351	32.6
International	28	28	4.0	66	50	33.6
Worldwide	282	203	39.0	532	401	32.7
OTHER PULMONARY HYPERTENSION						
U.S.	37	61	(40.2)	81	143	(43.5)
International	64	78	(17.6)	126	149	(15.1)
Worldwide	101	140	(27.5)	207	292	(29.0)
Cardiovascular / Metabolism / Other						
U.S.	837	902	(7.2)	1,643	1,849	(11.1)
International	347	373	(7.0)	701	771	(9.1)
Worldwide	1,184	1,275	(7.1)	2,344	2,620	(10.5)
XARELTO®						
U.S.	559	549	1.7	1,086	1,091	(0.5)
International	—	—	—	—	—	—
Worldwide	559	549	1.7	1,086	1,091	(0.5)
INVOKANA® / INVOKAMET®						
U.S.	132	132	(0.8)	249	286	(13.0)
International	47	43	9.1	105	92	14.1
Worldwide	179	177	1.6	354	379	(6.4)
PROCRIT® / EPREX®						
U.S.	70	113	(38.3)	146	261	(44.1)
International	66	70	(5.0)	145	148	(2.2)
Worldwide	136	183	(25.6)	291	409	(28.9)
OTHER						
U.S.	78	107	(27.7)	163	211	(22.9)
International	234	260	(10.2)	451	531	(15.0)
Worldwide	312	368	(15.3)	614	742	(17.3)
TOTAL PHARMACEUTICAL						
U.S.	6,120	5,783	5.8	12,181	11,365	7.2
International	4,632	4,746	(2.4)	9,705	9,408	3.2
Worldwide	10,752	10,529	2.1	21,886	20,773	5.4

MEDICAL DEVICES

Interventional Solutions						
U.S.	255	366	(30.5)	620	709	(12.6)
International	335	385	(12.8)	697	774	(9.9)
Worldwide	590	750	(21.5)	1,317	1,482	(11.2)
Orthopaedics						
U.S.	869	1,331	(34.7)	2,119	2,649	(20.0)
International	583	894	(34.8)	1,371	1,779	(22.9)
Worldwide	1,451	2,224	(34.7)	3,489	4,428	(21.2)
HIPS						
U.S.	137	216	(36.5)	343	429	(20.1)
International	88	147	(39.8)	220	295	(25.4)
Worldwide	226	364	(37.8)	563	725	(22.3)
KNEES						
U.S.	108	218	(50.5)	322	441	(27.1)
International	66	153	(56.8)	196	299	(34.6)
Worldwide	174	372	(53.1)	517	741	(30.1)
TRAUMA						
U.S.	354	407	(12.9)	761	824	(7.6)
International	198	265	(25.2)	445	533	(16.5)
Worldwide	553	672	(17.8)	1,207	1,357	(11.1)
SPINE, SPORTS & OTHER						
U.S.	270	490	(45.0)	693	955	(27.4)
International	230	328	(29.9)	510	651	(21.7)
Worldwide	499	818	(39.0)	1,202	1,606	(25.1)
Surgery						
U.S.	490	926	(47.0)	1,334	1,927	(30.8)
International	1,060	1,427	(25.7)	2,317	2,821	(17.9)
Worldwide	1,551	2,353	(34.1)	3,651	4,748	(23.1)
ADVANCED						
U.S.	277	396	(30.0)	658	800	(17.7)
International	498	633	(21.2)	1,065	1,209	(11.9)
Worldwide	775	1,029	(24.6)	1,723	2,009	(14.2)
GENERAL						
U.S.	213	530	(59.8)	676	1,127	(40.0)
International	562	794	(29.2)	1,252	1,612	(22.4)
Worldwide	775	1,325	(41.5)	1,928	2,739	(29.6)
Vision						
U.S.	248	461	(46.1)	687	907	(24.2)
International	447	701	(36.1)	1,075	1,383	(22.3)
Worldwide	695	1,161	(40.1)	1,762	2,290	(23.0)
CONTACT LENSES / OTHER						
U.S.	203	333	(39.0)	549	654	(16.1)
International	352	509	(30.9)	819	1,011	(19.0)
Worldwide	554	842	(34.1)	1,368	1,666	(17.9)

SURGICAL						
U.S.	45	128	(64.6)	138	253	(45.3)
International	96	191	(49.9)	256	371	(31.0)
Worldwide	141	319	(55.8)	394	624	(36.8)
TOTAL MEDICAL DEVICES						
U.S.	1,862	3,083	(39.6)	4,760	6,192	(23.1)
International	2,426	3,406	(28.8)	5,460	6,756	(19.2)
Worldwide	4,288	6,489	(33.9)	10,220	12,948	(21.1)
WORLDWIDE						
U.S.	9,539	10,403	(8.3)	20,238	20,532	(1.4)
International	8,797	10,159	(13.4)	18,789	20,051	(6.3)
Worldwide	$ 18,336	20,562	(10.8)%	$ 39,027	40,583	(3.8)%

*Percentage greater than 100% or not meaningful

EARNINGS BEFORE PROVISION FOR TAXES BY SEGMENT

	Fiscal Second Quarter Ended			Fiscal Six Months Ended		
(Dollars in Millions)	June 28, 2020	June 30, 2019	Percent Change	June 28, 2020	June 30, 2019	Percent Change
Consumer Health [1]	$ 32	406	(92.1)%	$ 802	1,147	(30.1)%
Pharmaceutical[2]	4,514	3,677	22.8	8,348	6,008	38.9
Medical Devices[3]	(354)	3,189	*	1,671	4,686	(64.3)
Segment earnings before provision for taxes	4,192	7,272	(42.4)	10,821	11,841	(8.6)
Less: Expense not allocated to segments [4]	252	231		372	378	
Worldwide income before tax	$ 3,940	7,041	(44.0)%	$ 10,449	11,463	(8.8)%

*Percentage greater than 100% or not meaningful

[1] Includes a gain of $0.3 billion related to the Company's previously held equity investment in Ci:z Holdings Co., Ltd. (DR. CI: LABO) in the fiscal six months of 2019. Includes litigation expense of $0.6 billion and $0.2 billion in both the fiscal second quarters of 2020 and 2019, primarily talc related costs, respectively. Includes litigation expense of $0.6 billion and $0.2 billion in both the fiscal six months of 2020 and 2019, primarily talc related costs, respectively. Includes amortization expense of $0.1 billion in both the fiscal second quarters of 2020 and 2019, respectively and $0.2 billion in both the fiscal six months of 2020 and 2019, respectively.

[2] Includes an in-process research and development expense of $0.9 billion related to the Alios asset in the fiscal six months of 2019. Includes litigation expense of $0.4 billion in the fiscal six months of 2019. Includes an unrealized gain on securities of $0.5 billion and $0.2 billion in the fiscal second quarter of 2020 and 2019, respectively. Includes an unrealized gain on securities of $0.2 billion and $0.3 billion in the fiscal six months of 2020 and 2019, respectively. Additionally, the fiscal six months of 2019 includes a research and development expense of $0.3 billion for an upfront payment related to argenx. Includes amortization expense of $0.8 billion in both the fiscal second quarters of 2020 and 2019. Includes amortization expense of $1.6 billion in both the fiscal six months of 2020 and 2019. In the fiscal second quarter and early in the third quarter of 2020, the Company entered into a series of contract manufacturing arrangements for vaccine production with third party contract manufacturing organizations. These arrangements provide the Company with future supplemental commercial capacity for vaccine production and potentially transferable rights to such production if capacity is not required. Amounts paid and contractually obligated to be paid to these contract manufacturing organizations are reflected in the prepaid expenses and other and the accrued liabilities accounts in the Company's consolidated balance sheet upon execution of each agreement. Additionally, the Company has entered into certain vaccine development cost sharing arrangements with government related organizations. The costs associated with these arrangements have not been significant through the fiscal second quarter of 2020.

[3] Includes a contingent consideration reversal of $1.0 billion in the fiscal six months of 2020 related to the timing of certain developmental milestones associated with the Auris Health acquisition. Includes a gain of $2.0 billion from the divestiture of the ASP business in the fiscal second quarter and six months of 2019. Includes litigation expense of $0.2 billion and $0.3 billion in the fiscal second quarter and fiscal six months of 2019, respectively. Includes a restructuring related charge of $0.1 billion and

amortization expense of $0.2 billion in both the fiscal second quarters of 2020 and 2019. Includes a restructuring related charge of $0.2 billion and amortization expense of $0.5 billion in both the fiscal six months of 2020 and 2019.

(4) Amounts not allocated to segments include interest income/expense and general corporate income/expense.

SALES BY GEOGRAPHIC AREA

	Fiscal Second Quarter Ended			Fiscal Six Months Ended		
(Dollars in Millions)	June 28, 2020	June 30, 2019	Percent Change	June 28, 2020	June 30, 2019	Percent Change
United States	$ 9,539	10,403	(8.3)%	$ 20,238	20,532	(1.4)%
Europe	4,063	4,733	(14.2)	8,890	9,342	(4.8)
Western Hemisphere, excluding U.S.	1,133	1,455	(22.1)	2,635	2,958	(10.9)
Asia-Pacific, Africa	3,601	3,971	(9.3)	7,264	7,751	(6.3)
Total	$ 18,336	20,562	(10.8)%	$ 39,027	40,583	(3.8)%

NOTE 10— BUSINESS COMBINATIONS AND DIVESTITURES

Subsequent to the quarter, on July 9, 2020, the Company sold 11.8 million shares of Idorsia LTD ("Idorsia"), or its 8.3% ownership in the company, via an accelerated bookbuild offering. The transaction resulted in gross proceeds of approximately CHF337 million ($357 million) based on a sales price of CHF 28.55/share.

The Company currently has rights to at least an additional 38.7 million shares (or approximately 20% of Idorsia equity) through a convertible loan with a principal amount of CHF 445 million (due June 2027). Idorsia also has access to an approximate CHF 243 million credit facility with the Company. As of June 28, 2020, Idorsia has not made any draw-downs under the credit facility.

During the fiscal first quarter of 2020, the Company completed the acquisition of all rights to the investigational compound bermekimab, which has multiple dermatological indications, along with certain employees from XBiotech Inc., for a purchase price of $0.8 billion. The fair value of the acquisition was allocated primarily to non-amortizable intangible assets, primarily IPR&D, for $0.8 billion. XBiotech may be eligible to receive additional payments upon the receipt of certain commercialization authorizations. The transaction was accounted for as a business combination and included in the Pharmaceutical segment. Additionally, the Company completed the acquisition of all outstanding shares in Verb Surgical Inc., a company with world-class robotics and data science capabilities, including those shares previously held by Verily. The transaction was accounted for as a business combination and included in the Medical Devices segment. The fair value of the acquisition was allocated primarily to non-amortizable intangible assets, primarily IPR&D, for $0.4 billion, goodwill for $0.2 billion, other assets of $0.2 billion and liabilities assumed of $0.3 billion. The fair value of the Company's previously held equity investment in Verb Surgical Inc. was $0.4 billion.

On April 1, 2019, the Company completed the divestiture of its ASP business to Fortive Corporation for an aggregate value of approximately $2.8 billion, consisting of $2.7 billion of cash proceeds and $0.1 billion of retained net receivables. The Company recognized a pre-tax gain recorded in Other (income) expense, net, of approximately $2.0 billion.

On April 1, 2019, the Company completed the acquisition of Auris Health, Inc. for approximately $3.4 billion, net of cash acquired. Additional contingent payments of up to $2.35 billion, in the aggregate, may be payable upon reaching certain predetermined milestones. Auris Health was a privately held developer of robotic technologies, initially focused in lung cancer, with an FDA-cleared platform currently used in bronchoscopic diagnostic and therapeutic procedures. The Company treated this transaction as a business combination and included it in the Medical Devices segment. The fair value of the acquisition was allocated primarily to amortizable and non-amortizable intangible assets, primarily IPR&D, for $3.0 billion, goodwill for $2.0 billion, marketable securities of $0.2 billion and liabilities assumed of $1.8 billion, which includes the fair value of the contingent payments mentioned above. During the fiscal second quarter of 2020, the Company finalized the purchase price allocation. There were no valuation adjustments to the assets acquired but during the fiscal first quarter of 2020, the Company recorded Other income of approximately $1.0 billion for the reversal of the contingent consideration related to the timing of certain developmental and commercial milestones, which are not expected to be met based on the Company's current timelines. As of June 28, 2020, the fair value of the remaining contingent consideration is $0.2 billion. Further, the Company re-assessed the current value of the Auris IPR&D assets in connection with the modified development timeline and determined the fair value still exceeds the carrying value.
On January 17, 2019, the Company acquired DR. CI:LABO, a Japanese company focused on the marketing, development and distribution of a broad range of dermocosmetic, cosmetic and skincare products for a total purchase price of approximately ¥230 billion, which equates to approximately $2.1 billion, using the exchange rate of 109.06 Japanese Yen to each U.S. Dollar on January 16, 2019. Additionally, in the fiscal first quarter of 2019, the Company recognized a pre-tax gain recorded in Other (income) expense, net, of approximately $0.3 billion related to the Company's previously held equity investment in DR. CI:LABO.

The Company treated this transaction as a business combination and included it in the Consumer Health segment. During the fiscal first quarter of 2020, the Company finalized the purchase price allocation. The fair value of the acquisition was allocated primarily to amortizable intangible assets for $1.5 billion, goodwill for $1.2 billion and liabilities assumed of $0.4 billion. The adjustments made since the date of acquisition were $0.1 billion to intangible assets, accrued liabilities, deferred taxes on income and property, plant and equipment with the offset to goodwill. The amortizable intangible assets were comprised of brand/trademarks and customer relationships with a weighted average life of 15.3 years. The goodwill is primarily attributable to synergies expected to arise from the business acquisition and is not expected to be deductible for tax purposes.

During the fiscal third quarter of 2018, the Company accepted a binding offer to form a strategic collaboration with Jabil Inc., one of the world's leading manufacturing services providers for health care products and technology products. The Company is

expanding a 12-year relationship with Jabil Inc. to produce a range of products within the Ethicon Endo-Surgery and DePuy Synthes businesses. This transaction includes the transfer of certain employees and manufacturing sites. The majority of the transfers were completed in 2019 with a minor amount remaining in 2020. As of June 28, 2020, the assets held for sale on the Consolidated Balance Sheet were $0.1 billion of inventory and property, plant and equipment, net. For additional details on the global supply chain restructuring see Note 12 to the Consolidated Financial Statements.

NOTE 11 — LEGAL PROCEEDINGS

Johnson & Johnson and certain of its subsidiaries are involved in various lawsuits and claims regarding product liability; intellectual property; commercial; supplier indemnification and other matters; governmental investigations; and other legal proceedings that arise from time to time in the ordinary course of their business. Due to the ongoing impacts of the COVID-19 pandemic, certain trials have been rescheduled or delayed. The Company continues to monitor its legal proceedings as the situation develops.

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 June 28, 2020, 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 including timing of related payments. The ability to make such estimates and judgments can be affected by various factors including, among other things, 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; procedural or jurisdictional issues; the uncertainty and unpredictability of the number of potential claims; or there are numerous parties involved. To the extent adverse verdicts have been rendered against the Company, the Company does not record an accrual until a loss is determined to be probable and can be reasonably estimated.
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

Johnson & Johnson and certain of its subsidiaries 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 the Company believes it has substantial defenses, it is not feasible to predict the ultimate outcome of litigation. From time to time, even if it has substantial defenses, the Company considers isolated settlements based on a variety of circumstances. 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 when those costs are probable and can be reasonably estimated. For certain of these matters, the Company has accrued additional amounts such as estimated costs associated with settlements, damages 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®; XARELTO®; body powders containing talc, primarily JOHNSONS® Baby Powder; INVOKANA®; and ETHICON PHYSIOMESH® Flexible Composite Mesh. As of June 28, 2020, in the United States there were approximately 800 plaintiffs with direct claims in pending lawsuits regarding injuries allegedly due to the DePuy ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System; 8,600 with respect to the PINNACLE® Acetabular Cup System; 15,600 with respect to pelvic meshes; 10,600 with respect to RISPERDAL®; 21,000 with respect to XARELTO®; 20,600 with respect to body powders containing talc; 300 with respect to INVOKANA®; and 3,700 with respect to ETHICON PHYSIOMESH® Flexible Composite Mesh.

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, Australia, Ireland, Germany, India and Italy. 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. DePuy reached additional agreements in February 2015 and March 2017, which further extended the settlement program to include ASR Hip patients who had revision surgeries after August 31, 2013 and prior to February 15, 2017. This settlement program has resolved more than 10,000 claims, therefore bringing to resolution significant ASR Hip litigation activity in the United States. However, lawsuits in the United States remain, and the settlement program does not address litigation outside of the United States. In Australia, a class action settlement was reached that resolved the claims of the majority of ASR Hip patients in that country. In Canada, the Company has reached agreements to settle two pending class actions which have been approved by the Québec Superior Court and the Supreme Court of British Columbia. The British Columbia order is currently the subject of the Company's appeal to broaden the scope of participants. The Company continues to receive information with respect to potential additional costs associated with this recall on a worldwide basis. The Company has established accruals for the costs associated with the United States settlement program and DePuy ASR™ Hip-related product liability litigation.

Claims for personal injury have also been made against DePuy Orthopaedics, Inc. and Johnson & Johnson (collectively, DePuy) relating to the PINNACLE® Acetabular Cup System used in hip replacement surgery. Product liability lawsuits continue to be filed, 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 some state courts and in countries outside of the United States. Several adverse verdicts have been rendered against DePuy, one of which was reversed on appeal and remanded for retrial. During the first quarter of 2019, DePuy established a United States settlement program to resolve these cases. As part of the settlement program, adverse verdicts have been settled. The Company has established an accrual for product liability litigation associated with the PINNACLE® Acetabular Cup System and the related settlement program.

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 Company continues to receive information with respect to potential costs and additional cases. Cases filed in federal courts in the United States had been organized as a multi-district litigation (MDL) in the United States District Court for the Southern District of West Virginia. The MDL Court is remanding cases for trial to the jurisdictions where the case was originally filed and additional pelvic mesh lawsuits have been filed, and remain, outside of the MDL. The Company has settled or otherwise resolved a majority of the United States cases and the estimated costs associated with these settlements and the remaining cases are reflected in the Company's accruals. In addition, class actions and individual personal injury cases or claims have been commenced in various countries outside of the United States, including claims and cases in the United Kingdom, the Netherlands, and class actions in Israel, Australia and Canada, seeking damages for alleged injury resulting from Ethicon's pelvic mesh devices. In November 2019, the Federal Court of Australia issued a judgment regarding its findings with respect to liability in relation to the three Lead Applicants and generally in relation to the design, manufacture, pre and post-market assessments and testing, and supply and promotion of the devices in Australia used to treat stress urinary incontinence and pelvic organ prolapse. In March 2020, the Court entered damages awards to the three Lead Applicants. With respect to other group members, there will be an individual case assessment process which will require proof of use and causally related loss. The class actions in Canada are expected to be discontinued in 2020 as a result of a settlement of a group of cases. The Company has established accruals with respect to product liability litigation associated with Ethicon's pelvic mesh products.

Following a June 2016 worldwide market withdrawal of ETHICON PHYSIOMESH® Flexible Composite Mesh, claims for personal injury have been made against Ethicon, Inc. and Johnson & Johnson alleging personal injury arising out of the use of this hernia mesh device. Cases filed in federal courts in the United States have been organized as a multi-district litigation (MDL) in the United States District Court for the Northern District of Georgia. A multi-county litigation (MCL) has also been formed in New Jersey state court and assigned to Atlantic County for cases pending in New Jersey. In addition to the matters in the MDL and MCL, there are additional lawsuits pending in the United States District Court for the Southern District of Ohio, which are part of the MDL for polypropylene mesh devices manufactured by C.R. Bard, Inc., and lawsuits pending outside the United States.

Along with ETHICON PHYSIOMESH® lawsuits, there were a number of filings related to the PROCEED® Mesh and PROCEED® Ventral Patch products. In March 2019, the New Jersey Supreme Court entered an order consolidating all

PROCEED® and PROCEED® Ventral Patch cases as an MCL in Atlantic County Superior Court. Additional cases have been filed in various federal and state courts in the US, and in jurisdictions outside the US. The Company continues to receive information with respect to potential costs and the anticipated number of cases. The Company has established accruals with respect to product liability litigation associated with ETHICON PHYSIOMESH® Flexible Composite Mesh, PROCEED® Mesh and PROCEED® Ventral Patch products. In September 2019, plaintiffs' attorney filed an application with the New Jersey Supreme Court seeking centralized management of 107 PROLENE™ Polypropylene Hernia System cases. The New Jersey Supreme Court granted plaintiffs application in January 2020 and those cases have been transferred to an MCL in Atlantic County Superior Court.

Claims for personal injury have been made against Janssen Pharmaceuticals, Inc. and Johnson & Johnson arising out of the use of RISPERDAL®, and related compounds, indicated for the treatment of schizophrenia, acute manic or mixed episodes associated with bipolar I disorder and irritability associated with autism. Lawsuits have been primarily filed in state courts in Pennsylvania, California, and Missouri. Other actions are pending in various courts in the United States and Canada. Product liability lawsuits continue to be filed, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. The Company has successfully defended a number of these cases but there have been verdicts against the Company, including a recent verdict in October 2019 of $8 billion of punitive damages related to one single plaintiff which was subsequently reduced in January 2020 to $6.8 million by the trial judge. The Company will appeal the final judgment. The Company has settled or otherwise resolved many of the United States cases and the costs associated with these settlements are reflected in the Company's accruals.

Claims for personal injury arising out of the use of XARELTO®, an oral anticoagulant, have been made against Janssen Pharmaceuticals, Inc. (JPI); Johnson & Johnson (J&J); and JPI's collaboration partner for XARELTO®, Bayer AG and certain of its affiliates. 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. Many of these cases have been consolidated into a state mass tort litigation in Philadelphia, Pennsylvania and in a coordinated proceeding in Los Angeles, California. Class action lawsuits also have been filed in Canada. In March 2019, JPI and J&J announced an agreement in principle to the settle the XARELTO® cases in the United States; the settlement agreement was executed in May 2019, the settlement became final in December 2019, and the settlement was funded in January 2020. This resolved the majority of cases pending in the United States. The Company has established accruals for its costs associated with the United States settlement program and XARELTO® related product liability litigation.

Personal injury claims alleging that talc causes cancer have been made against Johnson & Johnson Consumer Inc. and Johnson & Johnson arising out of the use of body powders containing talc, primarily JOHNSON'S® Baby Powder. The number of pending personal injury lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Lawsuits have been primarily filed in state courts in Missouri, New Jersey and California, and suits have also been filed outside the United States. The majority of cases are pending in federal court, organized into a multi-district litigation in the United States District Court for the District of New Jersey. In the multi-district litigation, the parties have sought to exclude experts, through Daubert motions. In April 2020, the Court issued rulings that limit the scope of testimony, including some theories and testing methods, for certain plaintiff expert witnesses and denied plaintiffs' attempt to limit the scope of testimony of certain of the Company's witnesses. With this ruling made, the court has now ordered case-specific discovery to proceed. In talc cases that have previously gone to trial, the Company has obtained defense verdicts in a number of these cases but there have also been verdicts against the Company, many of which have been reversed on appeal. Most recently, in June 2020, the Missouri Court of Appeals reversed in part and affirmed in part a July 2018 verdict of $4.7 billion, reducing the overall award to $2.1 billion. The Company believes that it has strong grounds to seek further review and/or appeal of this verdict, as well as other verdicts that it has appealed. Notwithstanding the Company's confidence in the safety of its talc products, in certain circumstances the Company has and may settle cases. The Company has established an accrual primarily for defense costs, and reserves for potential settlement of currently pending mesothelioma cases, in connection with product liability litigation associated with body powders containing talc.

In February 2019, the Company's talc supplier, Imerys Talc America, Inc. and two of its affiliates, Imerys Talc Vermont, Inc. and Imerys Talc Canada, Inc. (collectively, Imerys) filed a voluntary chapter 11 petition commencing a reorganization under the United States Bankruptcy Code in the United States Bankruptcy Court for the District of Delaware (Imerys Bankruptcy). The Imerys Bankruptcy relates to Imerys' potential liability for personal injury from exposure to talcum powder sold by Imerys (Talc Claims). In its bankruptcy filing, Imerys noted certain claims it alleges it has against the Company for indemnification and rights to joint insurance proceeds. Based on such claims as well as indemnity and insurance claims the Company has against Imerys, the Company petitioned the United States District Court for the District of Delaware to establish federal jurisdiction of the state court talc lawsuits under the Bankruptcy Code. The Company's petition was denied and the state court talc lawsuits that have been removed to federal court on such basis have been remanded. The Company previously proposed to resolve Imerys' (and the Company's) obligations arising out of the Talc Claims by agreeing to assume the defense of litigation

of all Talc Claims involving the Company's products, waiving the Company's indemnification claims against Imerys, and lifting the automatic stay to enable the Talc Claims to proceed outside the bankruptcy forum with the Company agreeing to settle or pay any judgment against Imerys. In May 2020, Imerys and the asbestos claimants' committee filed their Plan of Reorganization and the Disclosure Statement related thereto agreeing to put its North American operations up for auction. The Bankruptcy Court will hold a hearing to consider approval of the Disclosure Statement on August 26, 2020 and the Company is disputing any indemnification objections and the scope of coverage in the reorganization plan. Additionally, in June 2020, Cyprus Mines Corporation and its parent filed an adversary proceeding against the Company as well as Imerys seeking a declaration of indemnity under certain contractual agreements. The Company denies such indemnification is owed and is in the process of responding to the complaint

In February 2018, a securities class action lawsuit was filed against Johnson & Johnson and certain named officers in the United States District Court for the District of New Jersey, alleging that Johnson & Johnson violated the federal securities laws by failing to disclose alleged asbestos contamination in body powders containing talc, primarily JOHNSON'S® Baby Powder, and that purchasers of Johnson & Johnson's shares suffered losses as a result. Plaintiffs are seeking damages. In April 2019, the Company moved to dismiss the complaint and briefing on the motion was complete as of August 2019. In December 2019, the Court denied, in part, the motion to dismiss. In March 2020, Defendants answered the complaint. Discovery is underway.

In June 2019, a shareholder filed a complaint initiating a summary proceeding in New Jersey state court for a books and records inspection. In August 2019, Johnson & Johnson responded to the books and records complaint and filed a cross motion to dismiss. In September 2019, Plaintiff replied and the Court heard oral argument. The Court has not yet ruled in the books and records action. In October 2019, December 2019, and January 2020, four shareholders filed four separate derivative lawsuits against Johnson & Johnson as the nominal defendant and its current directors and certain officers as defendants in the United States District Court for the District of New Jersey, alleging a breach of fiduciary duties related to the alleged asbestos contamination in body powders containing talc, primarily JOHNSON'S® Baby Powder, and that Johnson & Johnson has suffered damages as a result of those alleged breaches. In February 2020, the four cases were consolidated into a single action under the caption *In re Johnson & Johnson Talc Stockholder Derivative Litigation*, and the shareholders have until August 2020 to file a consolidated complaint or identify a previously filed complaint as the operative complaint.

In July 2020, a report was delivered to the Company's Board of Directors by independent counsel retained by the Board to investigate the allegations in the derivative lawsuits and in a series of shareholder letters that the Board received raising similar issues. The independent counsel recommended that the Company reject the shareholder demands and take the steps that are necessary or appropriate to secure dismissal of the derivative lawsuits. The Board unanimously adopted the recommendations of the independent counsel's report.

In January 2019, two ERISA class action lawsuits were filed by participants in the Johnson & Johnson Savings Plan against Johnson & Johnson, its Pension and Benefits Committee, and certain named officers in the United States District Court for the District of New Jersey, alleging that the defendants breached their fiduciary duties by offering Johnson & Johnson stock as a Johnson & Johnson Savings Plan investment option when it was imprudent to do so because of failures to disclose alleged asbestos contamination in body powders containing talc, primarily JOHNSON'S® Baby Powder. Plaintiffs are seeking damages and injunctive relief. In September 2019, Defendants filed a motion to dismiss. In April 2020, the Court granted Defendants' motion but granted leave to amend. On June 15, 2020, Plaintiffs filed an amended complaint.

A lawsuit is pending in the Superior Court of California for the County of San Diego alleging violations of California's Consumer Legal Remedies Act relating to JOHNSON'S® Baby Powder. In that lawsuit, the plaintiffs allege that Johnson & Johnson violated the CLRA by failing to provide required Proposition 65 warnings. In July 2019, the Company filed a notice of removal to the United States District Court for the Southern District of California and plaintiffs filed a second amended complaint shortly thereafter. In October 2019, the Company moved to dismiss the second amended complaint for failure to state a claim upon which relief may be granted. In response to those motions, plaintiffs filed a third amended complaint. In December 2019, the Company moved to dismiss the third amended complaint for failure to state a claim upon which relief may be granted. In April 2020, the Court granted the motion to dismiss but granted leave to amend. In May 2020, plaintiffs filed a Fourth Amended Complaint but indicated that they would be filing a motion for leave to file a fifth amended complaint.

In January 2020, the Abtahi Law Group filed an action under Proposition 65 against Johnson & Johnson and Johnson & Johnson Consumer Inc. as well as a number of other alleged talcum powder manufacturers and distributors, including one California company. In that action, the plaintiff alleges contamination of talcum powder products with unsafe levels of arsenic, hexavalent chromium and lead. The plaintiff seeks civil penalties and injunctive relief.

In addition, the Company has received preliminary inquiries and subpoenas to produce documents regarding these matters from Senator Murray, a member of the Senate Committee on Health, Education, Labor and Pensions, the Department of Justice, the

Securities and Exchange Commission and the U.S. Congressional Subcommittee on Economic and Consumer Policy. The Company is cooperating with government inquiries and continues to produce documents in response.

Claims for personal injury have been made against a number of Johnson & Johnson companies, including Janssen Pharmaceuticals, Inc. and Johnson & Johnson, arising out of the use of INVOKANA®, a prescription medication indicated to improve glycemic control in adults with Type 2 diabetes. Lawsuits filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the District of New Jersey. Cases have also been filed in state courts. Class action lawsuits have been filed in Canada. Product liability lawsuits continue to be filed, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. The Company has settled or otherwise resolved many of the cases and claims in the United States and the costs associated with these settlements are reflected in the Company's accruals.

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, require the payment of past damages and future royalties, and 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 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 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. Although Johnson & Johnson has since sold Cordis, it has retained liability for this case. After the trial in January 2014, the district court dismissed the case, finding Medinol unreasonably delayed bringing its claims (the laches defense). In September 2014, the district court denied a motion by Medinol to vacate the judgment and grant it a new trial. Medinol appealed the decision to the United States Court of Appeals for the Federal Circuit. In March 2017, the United States Supreme Court held that the laches defense is not available in patent cases. In April 2018, the United States Court of Appeals for the Federal Circuit remanded the case back to the district court to reconsider Medinol's motion for a new trial. In March 2019, the district court denied Medinol's motion for a new trial. Medinol appealed, and in June 2020, the United States Court of Appeals for the Federal Circuit affirmed the district court's decision.

In November 2016, MedIdea, L.L.C. (MedIdea) filed a patent infringement lawsuit against DePuy Orthopaedics, Inc. in the United States District Court for the Northern District of Illinois alleging infringement by the ATTUNE® Knee System. In April 2017, MedIdea filed an amended complaint adding DePuy Synthes Products, Inc. and DePuy Synthes Sales, Inc. as named defendants (collectively, DePuy). MedIdea alleges infringement of United States Patent Nos. 6,558,426 ('426); 8,273,132 ('132); 8,721,730 ('730) and 9,492,280 ('280) relating to posterior stabilized knee systems. Specifically, MedIdea alleges that the SOFCAM™ Contact feature of the ATTUNE® posterior stabilized knee products infringes the patents-in-suit. MedIdea is seeking monetary damages and injunctive relief. In June 2017, the case was transferred to the United States District Court for the District of Massachusetts. A claim construction hearing was held in October 2018, and a claim construction order was issued in November 2018. In December 2018, MedIdea stipulated to non-infringement of the '132, '730 and '280 patents, based on the district court's claim construction and reserving its right to appeal that construction, leaving only the '426 patent at issue before the district court. In May 2019, DePuy filed a motion for summary judgment of non-infringement of the claims of the '426 patent. In November 2019, judgment was entered in favor of DePuy. In December 2019, MedIdea filed a notice of appeal.

In December 2016, Ethicon Endo-Surgery, Inc. and Ethicon Endo-Surgery, LLC (now known as Ethicon LLC) sued Covidien, Inc. in the United States District Court for the District of Massachusetts seeking a declaration that United States Patent Nos. 6,585,735 (the '735 patent); 7,118,587; 7,473,253; 8,070,748 and 8,241,284 (the '284 patent), are either invalid or not infringed by Ethicon's ENSEAL® X1 Large Jaw Tissue Sealer product. In April 2017, Covidien LP, Covidien Sales LLC, and Covidien AG (collectively, Covidien) answered and counterclaimed, denying the allegations, asserting willful infringement of the '735 patent, the '284 patent and United States Patent Nos. 8,323,310 (the '310 patent); 9,084,608; 9,241,759 (the '759 patent) and 9,113,882, and seeking damages and an injunction. In June 2020, after a bench trial, the district court entered judgment in Ethicon's favor. In July 2020, Covidien filed a notice of appeal.

In December 2016, Dr. Ford Albritton sued Acclarent, Inc. (Acclarent) in United States District Court for the Northern District of Texas alleging that Acclarent's RELIEVA® Spin and RELIEVEA SpinPlus® products infringe U.S. Patent No. 9,011,412 (the '412 patent). Dr. Albritton also alleges breach of contract, fraud and that he is the true owner of Acclarent's U.S. Patent No. 8,414,473. Trial is scheduled to begin in March 2021.

In November 2017, Board of Regents, The University of Texas System and TissueGen, Inc. (collectively, UT) filed a lawsuit in the United States District Court for the Western District of Texas against Ethicon, Inc. and Ethicon US, LLC alleging the manufacture and sale of VICRYL® Plus Antibacterial Sutures, MONOCRYL® Plus Antibacterial Sutures, PDS® Plus Antibacterial Sutures, STRATAFIX® PDS® Antibacterial Sutures and STRATAFIX® MONOCRYL® Plus Antibacterial Sutures infringe plaintiffs' United States Patent Nos. 6,596,296 (the '296 patent) and 7,033,603 (the '603 patent) directed to implantable polymer drug releasing biodegradable fibers containing a therapeutic agent. UT is seeking damages and an injunction. In December 2018, Ethicon filed petitions with the United States Patent and Trademark Office (USPTO), seeking Inter Partes Review (IPR) of both asserted patents. In June 2020,the USPTO denied institution of the '296 patent IPR and granted institution of the '603 patent IPR. UT dismissed the '603 patent from the suit and no longer accuses PDS® Plus Antibacterial Sutures or STRATAFIX® PDS® Plus Antibacterial Sutures of infringement. The previously scheduled district court trial has been postponed.

In August 2018, Intuitive Surgical, Inc. and Intuitive Surgical Operations, Inc. ("Intuitive") filed a patent infringement suit against Auris Health, Inc. ("Auris") in United States District Court for the District of Delaware. In the suit, Intuitive alleges willful infringement of U.S. Patent Nos. 6,246,200 ('200 patent); 6,491,701 ('701 patent); 6,522,906 ('906 patent); 6,800,056 ('056 patent); 8,142,447 ('447 patent); 8,620,473 ('473 patent); 8,801,601 ('601 patent); and 9,452,276 ('276 patent) based on Auris' Monarch™ Platform. Auris filed IPR Petitions with the USPTO regarding the '200, '056, '601 '701, '447, '276 and '906 patents. Intuitive subsequently dropped the '200 and '701 patents from the suit. In December 2019, the USPTO instituted review of the '601 patent and denied review of the '056 patent. In February and March 2020, the USPTO instituted review of the '200, '447, '701 and '906 patents and denied review of the '276 patent. The district court trial is scheduled to begin in January 2021.

In August 2019, RSB Spine LLC ("RSB Spine") filed a patent infringement suit against DePuy Synthes, Inc. in United States District Court for the District of Delaware. In October 2019, RSB Spine amended the complaint to change the named defendants to DePuy Synthes Sales, Inc. and DePuy Synthes Products, Inc. In the suit, RSB Spine alleges willful infringement of United States Patent Nos. 6,984,234 and 9,713, 537 by one or more of the following products: ZERO-P-VA™ Spacer, ZERO-P® Spacer, ZERO-P NATURAL™ Plate, SYNFIX® LR Spacer and SYNFIX® Evolution System. RSB Spine seeks monetary damages and injunctive relief. In November 2019, the suit was consolidated for pre-trial purposes with other patent infringement suits brought by RSB Spine in the United States District Court for the District of Delaware against Life Spine, Inc., Medacta USA, Inc., Precision Spine, Inc., and Xtant Medical Holdings, Inc. In June 2020, the case was stayed pending IPR proceedings involving the asserted patents.

In March 2020, Osteoplastics, LLC filed a patent infringement suit against DePuy Synthes, Inc., DePuy Synthes Products, Inc., Medical Device Business Services, Inc., and Synthes, Inc. (collectively, DePuy Synthes) in the United States District Court for the District of Delaware. In the suit, Osteoplastics alleges willful infringement of U.S. Patent Nos. 8,781,557; 9,929,920; 9,330,206; 9,626,756; 9,672,617; 9,672,302; and 9,275,191 based on the PROPLAN CMF® Virtual Surgical Planning Services and the TruMatch® CMF Personalize Solutions. In April 2020, Osteoplastics filed an amended complaint to substitute U.S. Patent No. 9, 292,920 for U.S. Patent No. 9,929,920. Osteoplastics seeks monetary damages and injunctive relief. In June 2020, DePuy Synthes filed a motion to dismiss the complaint.

Pharmaceutical

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 and invalidity of the applicable patents. In the event the subsidiaries are not successful in an action, or the automatic statutory stay of the ANDAs expires before the United States District Court rulings are obtained, the third-party companies involved would have the ability, upon approval of the FDA, to introduce generic versions of their products to the market, resulting in the potential for substantial market share and revenue losses for the applicable 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 types of 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. The IPR process with the USPTO, created under the 2011 America Invents Act, is also being used at times by generic companies in conjunction with ANDAs and lawsuits, to challenge the applicable patents.

ZYTIGA®

In November 2017, Janssen initiated a Notice of Application under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Apotex Inc. (Apotex) and the Minister of Health in Canada in response to Apotex's filing of an Abbreviated New Drug Submission (ANDS) seeking approval to market a generic version of ZYTIGA® before the expiration of Canadian Patent No. 2,661,422 (the '422 patent). The final hearing concluded in May 2019. In October 2019, the court issued an order prohibiting the Canadian Minister of Health from approving Apotex's ANDS until the expiration of the '422 patent. In November 2019, Apotex filed an appeal.

In January 2019, Janssen initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Apotex in Canada in response to Apotex's filing of an Abbreviated New Drug Submission (ANDS) seeking approval to market a film-coated generic version of ZYTIGA® before the expiration of the '422 patent. The final hearing is scheduled to begin in October 2020.

In January 2019, Janssen initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Pharmascience Inc. (Pharmascience) in Canada in response to Pharmascience's filing of an Abbreviated New Drug Submission (ANDS) seeking approval to market a generic version of ZYTIGA® 250 mg, before the expiration of the '422 patent. The final hearing is scheduled to begin in October 2020.

In November 2019, Janssen initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Pharmascience in Canada in response to Pharmascience's filing of an ANDS seeking approval to market a generic version of ZYTIGA®, 500 mg, before the expiration of the '422 patent. The final hearing is scheduled to begin in October 2020.

In June 2019, Janssen initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, DRL) in Canada in response to DRL's filing of an Abbreviated New Drug Submission (ANDS) seeking approval to market a generic version of ZYTIGA® before the expiration of the '422 patent. The final hearing is scheduled to begin in October 2020.

In each of these Canadian actions, Janssen is seeking an order enjoining the defendants from marketing their generic versions of ZYTIGA® before the expiration of the '422 patent.

XARELTO®

Beginning in April 2017, Janssen Pharmaceuticals, Inc. (JPI) and Bayer Pharma AG and Bayer Intellectual Property GmbH (collectively, Bayer) filed patent infringement lawsuits in the United States District Court for the District of Delaware against Taro Pharmaceutical Industries Ltd. and Taro Pharmaceuticals U.S.A., Inc. (collectively, Taro) and InvaGen Pharmaceuticals Inc. (InvaGen) who filed ANDAs seeking approval to market generic versions of XARELTO® before expiration of Bayer AG's United States Patent No. 9,539,218 ('218) relating to XARELTO®. JPI is the exclusive sublicensee of the asserted patent. The case against InvaGen has been stayed. In May 2020, JPI and Bayer AG entered into a settlement agreement with Taro.

In May 2020, JPI and Bayer AG filed a patent infringement lawsuit in the United States District Court for the District of New Jersey against Unichem Inc. (a/k/a Unichem Laboratories, Ltd.) and Unichem Pharmaceuticals (USA), Inc.(collectively, Unichem) who filed an ANDA seeking approval to market a generic version of XARELTO® before expiration of the '218 patent and United States Patent No. 7,157,456 relating to XARELTO®.

In each of these lawsuits, JPI is seeking an order enjoining the defendants from marketing their generic versions of XARELTO® before the expiration of the relevant patents.

PREZISTA®

In January 2020, Janssen Products, L.P. and Janssen Sciences Ireland Unlimited Company (collectively, Janssen) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Zydus Pharmaceuticals (USA), Inc. and Cadila Healthcare Ltd. (collectively, Zydus), who filed an ANDA seeking approval to market a generic version of PREZISTA® before the expiration of United States Patent Nos. 7,700,645, 8,518,987, 7,126,015 and 7,595,408. Janssen was

seeking an order enjoining Zydus from marketing its generic version of PREZISTA® before the expiration of the relevant patents. In June 2020, Janssen entered into a settlement agreement with Zydus.

In April 2020, Janssen initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Marcan Pharmaceuticals Inc. (Marcan) in Canada in response to Marcan's filing of an ANDS seeking approval to market a generic version of Prezista before the expiration of Canadian Patent No. 2,485,834 (the '834 patent). Janssen was seeking an order enjoining Marcan from marketing its generic version of PREZISTA® before the expiration of the '834 patent. In May 2020, Janssen discontinued the action against Marcan.

INVOKANA®/INVOKAMET®/INVOKAMET XR®

Beginning in July 2017, Janssen Pharmaceuticals, Inc., Janssen Research & Development, LLC, Cilag GmbH International and Janssen Pharmaceutica NV (collectively, Janssen) and Mitsubishi Tanabe Pharma Corporation (MTPC) filed patent infringement lawsuits in the United States District Court for the District of New Jersey against a number of generic companies who filed ANDAs seeking approval to market generic versions of INVOKANA®, INVOKAMET® and/or INVOKAMET® XR before expiration of MTPC's United States Patent Nos. 7,943,582 (the '582 patent) and/or 8,513,202 (the '202 patent) relating to INVOKANA®, INVOKAMET® and/or INVOKAMET® XR. Janssen is the exclusive licensee of the asserted patents. The following generic companies were named as defendants: Apotex Inc. and Apotex Corp. (Apotex); Aurobindo Pharma USA Inc. (Aurobindo); Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc.; InvaGen Pharmaceuticals, Inc. (InvaGen); Prinston Pharmaceuticals Inc.; Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories Ltd (DRL); Hetero USA, Inc., Hetero Labs Limited Unit V and Hetero Labs Limited; MSN Laboratories Private Ltd. and MSN Pharmaceuticals, Inc. (MSN); Laurus Labs Ltd.; Indoco Remedies Ltd.; Zydus Pharmaceuticals (USA) Inc. (Zydus); Sandoz, Inc. (Sandoz); Teva Pharmaceuticals USA, Inc.; and Lupin Ltd. and Lupin Pharmaceuticals, Inc. (Lupin). These cases were consolidated into one action (Polymorph Main Action), which was scheduled for trial starting in June 2020 but is being rescheduled.

Beginning in July 2017, Janssen and MTPC filed patent infringement lawsuits in the United States District Court for the District of New Jersey against a number of generic companies who filed ANDAs seeking approval to market generic versions of INVOKANA®, INVOKAMET® and/or INVOKAMET® XR before expiration of MTPC's United States Patent No. 7,943,788 (the '788 patent), 8,222,219 (the '219 patent) and/or 8,785,403 (the '403 patent) relating to INVOKANA®, INVOKAMET® and/or INVOKAMET® XR Janssen is the exclusive licensee of the asserted patents. The following generic companies were named as defendants: Sandoz, Zydus and Aurobindo. These cases were consolidated into one action (Compound Main Action), which was scheduled for trial in May 2020 but is being rescheduled.

In July 2019, Janssen and MTPC filed a patent infringement lawsuit in the United States District Court for the District of New Jersey against MSN, who filed an ANDA seeking approval to market a generic version of INVOKAMET XR® before expiration of the '582 patent and '202 patent relating to INVOKAMET XR®. In October 2019, Janssen and MTPC initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against MSN, who filed ANDAs seeking approval to market generic versions of INVOKANA® and INVOKAMET XR® before expiration of the '788 patent. In October 2019, Janssen and MTPC initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against DRL, who filed an ANDA seeking approval to market a generic version of INVOKAMET® before expiration of the '788 patent. In March 2020, Janssen and MTPC initiated patent infringement lawsuits in the United States District Court for the District of New Jersey against Aurobindo, who filed an ANDA seeking approval to market a generic version of INVOKAMET XR® before expiration of the '788 patent, '219 patent, '403 patent, '582 patent, and '202 patent. These lawsuits have not been consolidated with the Main Actions.

In May 2020, Janssen and MTPC entered into a settlement agreement with Aurobindo. In June 2020, Janssen and MTPC entered into a settlement agreement with Laurus.

In each of these lawsuits, Janssen and MTPC are seeking an order enjoining the defendants from marketing their generic versions of INVOKANA®, INVOKAMET® and/or, INVOKAMET XR® before the expiration of the relevant patents.

OPSUMIT®

In January 2018, Actelion Pharmaceuticals Ltd (Actelion) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Zydus Pharmaceuticals (USA) Inc. (Zydus) who filed an ANDA seeking approval to market a generic version of OPSUMIT® before the expiration of United States Patent No. 7,094,781 (the '781 patent). In the lawsuit, Actelion is seeking an order enjoining Zydus from marketing generic versions of OPSUMIT® before the expiration of the patent. Trial is scheduled to commence in October 2020.

In July 2019, Actelion Pharmaceuticals Ltd. filed suit against Aurobindo Pharma USA Inc. and Aurobindo Pharma Limited (Aurobindo). Aurobindo filed an ANDA seeking approval to market a generic version of OPSUMIT® before the expiration of the ’781 patent. Actelion was seeking an order enjoining Defendants from marketing a generic version of OPSUMIT® before the expiration of the ’781 patent. In July 2020, Actelion and Aurobindo entered into a settlement agreement.

In May 2020, Janssen Inc. (Janssen) and Actelion initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Sandoz Canada Inc. (Sandoz) in Canada in response to Sandoz’s filing of an Abbreviated New Drug Submission (ANDS) seeking approval to market a generic version of OPSUMIT® 10 mg, before the expiration of Canadian Patent No. 2,659,770 (the ’770 patent). A final hearing has not yet been scheduled.

In May 2020, Janssen and Actelion initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Apotex Inc. (Apotex) in Canada in response to Apotex’s filing of an ANDS seeking approval to market a generic version of OPSUMIT® 10 mg, before the expiration of the ’770 patent. A final hearing has not yet been scheduled.

In July 2020, Janssen and Actelion initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against JAMP Pharma Corporation (JAMP) in Canada in response to JAMP’s filing of an ANDS seeking approval to market a generic version of OPSUMIT® 10 mg before the expiration of the ’770 patent and Canadian Patent No. 2,621,273. A final hearing has not yet been scheduled.

In each of these Canadian actions, Janssen and Actelion are seeking an order enjoining the defendants from marketing their generic versions of OPSUMIT® before the expiration of the ’770 patent.

INVEGA SUSTENNA®

In January 2018, Janssen Pharmaceutica NV and Janssen Pharmaceuticals, Inc. (collectively, Janssen) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Teva Pharmaceuticals USA, Inc. (Teva), who filed an ANDA seeking approval to market a generic version of INVEGA SUSTENNA® before the expiration of United States Patent No. 9,439,906 (the ’906 patent). Trial is scheduled to begin in September 2020.

In August 2019, Janssen Pharmaceutica NV and Janssen Pharmaceuticals, Inc. (collectively, Janssen) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Mylan Laboratories Limited (Mylan), who filed an ANDA seeking approval to market a generic version of INVEGA SUSTENNA® before the expiration of the ’906 patent. In February 2020, Mylan filed a Petition for Inter Partes Review with the USPTO seeking to invalidate the ’906 patent.

In December 2019, Janssen Pharmaceutica NV and Janssen Pharmaceuticals, Inc. (collectively, Janssen) initiated a patent infringement lawsuit in the United States District Courts for the Districts of New Jersey and Delaware against Pharmascience Inc., Mallinckrodt PLC and Specgx LLC (collectively, Pharmascience), who filed an ANDA seeking approval to market a generic version of INVEGA SUSTENNA® before the expiration of the ’906 patent.

In February 2018, Janssen Inc. and Janssen Pharmaceutica NV (collectively, Janssen) initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Teva Canada Limited (Teva) in response to Teva's filing of an Abbreviated New Drug Submission (ANDS) seeking approval to market a generic version of INVEGA SUSTENNA® before the expiration of Canadian Patent Nos. 2,309,629 (the ’629 patent) and 2,655,335 (the ’335 patent). Janssen subsequently discontinued the portion of the lawsuit relating to the ’629 patent. In May 2020, the Canadian Federal Court issued a Public Judgment and Reasons declaring that Teva’s generic version of INVEGA SUSTENNA®, if approved, would infringe claims of the ’335 patent and that the claims of the ’335 patent are not invalid for obviousness. Teva appealed the court’s decision.

In April 2020, Janssen Inc. and Janssen Pharmaceutica NV (together, Janssen) initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Pharmascience Inc. (Pharmascience) in response to Pharmascience's filing of an Abbreviated New Drug Submission (ANDS) seeking approval to market a generic version of INVEGA SUSTENNA® before the expiration of the ’335 patent. Trial is scheduled to begin in January 2022.

In each of these lawsuits, Janssen is seeking an order enjoining the defendant from marketing a generic version of INVEGA SUSTENNA® before the expiration of the patent.

IMBRUVICA®

Beginning in January 2018, Pharmacyclics LLC (Pharmacyclics) and Janssen Biotech, Inc. (JBI) filed patent infringement lawsuits in the United States District Court for the District of Delaware against a number of generic companies who filed ANDAs seeking approval to market generic versions of IMBRUVICA® 140 mg capsules before expiration of Pharmacyclics' United States Patent Nos. 8,008,309, 7,514,444, 8,697,711, 8,735,403, 8,957,079, 9,181,257, 8,754,091, 8,497,277, 8,925,015, 8,476,284, 8,754,090, 8,999,999, 9,125,889, 9,801,881, 9,801,883, 9,814,721, 9,795,604, 9,296,753, 9,540,382, 9,713,617 and/or 9,725,455 relating to IMBRUVICA®. JBI is the exclusive licensee of the asserted patents. The named defendants include the following generic companies: Cipla Limited and Cipla USA Inc. (Cipla); Sandoz Inc. and Lek Pharmaceuticals d.d. (Sandoz); Sun Pharma Global FZE and Sun Pharmaceutical Industries Limited (Sun); and Zydus Worldwide DMCC and Cadila Healthcare Limited (Zydus). The trial is scheduled to begin in October 2020.

In October 2018, Pharmacyclics and JBI filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Sun asserting United States Patent No. 10,004,746.

In January 2019, Pharmacyclics and JBI filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Zydus, who filed an ANDA seeking approval to market a generic version of IMBRUVICA® 70 mg before the expiration of U.S. Patent Nos. 7,514,444, 8,003,309, 8,476,284, 8,497,277, 8,697,711, 8,753,403, 8,754,090, 8,754,091, 8,952,015, 8,957,079, 9,181,257, 9,296,753, 9,540,382, 9,713,617, 9,725,455, 10,106,548, and 10,125,140.

In February 2019, Pharmacyclics and JBI amended their complaints against Cipla and Sun to allege infringement of United States Patent Nos. 10,106,548, and 10,125,140.

In March 2019, Pharmacyclics and JBI filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Alvogen Pine Brook LLC and Natco Pharma Ltd. (Alvogen), who filed an ANDA seeking approval to market generic versions of IMBRUVICA® tablets, asserting infringement of United States Patent Nos. 7,514,444, 8,003,309, 8,476,284, 8,497,277, 8,697,711, 8,753,403, 8,754,090, 8,754,091, 8,952,015, 8,957,079, 9,181,257, 9,296,753, 9,655,857, 9,725,455, 10,010,507, 10,106,548, and 10,125,140.

In May 2019, Pharmacyclics and JBI amended their complaint against Cipla to further allege infringement of United States Patent No. 10,016,435. In June 2019, Pharmacyclics and JBI amended their complaint against Alvogen to further allege infringement of United States Patent No. 10,213,386.

In August 2019, Pharmacyclics and JBI amended their complaints against Cipla, and Sandoz to further allege infringement of U.S. Patent Nos. 10,294,231 and 10,294,232 and amended their complaint against Sun to further allege infringement of U.S. Patent No. 10,294,232.

In March 2019, Sandoz filed an IPR Petition with the USPTO, seeking to invalidate United States Patent No. 9,795,604. The IPR was instituted in September 2019, and a final written decision is expected by September 2020.

In March 2020, Pharmacyclics and JBI filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Alvogen, Zydus, Sun and Sandoz asserting infringement of United States Patent No. 10,478,439. In April 2020, Pharmacyclics and JBI amended their complaint against Sandoz to further allege infringement of U.S. Patent No. 10,463,668.

In April 2020, Pharmacyclics and JBI filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Zydus, who filed an ANDA seeking approval to market generic versions of IMBRUVICA® tablets, asserting infringement of United States Patent Nos. 7,514,444, 8,003,309, 8,476,284, 8,497,277, 8,697,711, 8,753,403, 8,754,090, 8,754,091, 8,952,015, 8,957,079, 9,181,257, 9,296,753, 9,655,857, 9,725,455, 10,010,507, 10,106,548, 10,125,140, 10,213,286 and 10,478,439.

In May 2020, Pharmacyclics and JBI entered into a settlement agreement with Sun Pharmaceuticals.

In each of the lawsuits, Pharmacyclics and JBI are seeking an order enjoining the defendants from marketing generic versions of IMBRUVICA® before the expiration of the relevant patents.

TRACLEER®

In December 2019, Actelion Pharmaceuticals Ltd and Actelion Pharmaceuticals US, Inc. initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Zydus Pharmaceuticals (USA), Inc. and Cadila Healthcare Limited (collectively, Zydus), who filed an ANDA seeking approval to market a generic version of TRACLEER®, 32 mg, before the expiration of U.S. Patent No. 8,309,126 (the '126 patent). Actelion was seeking an order enjoining Zydus from marketing its generic version of TRACLEER® before the expiration of the '126 patent. In July 2020, Actelion entered into a settlement agreement with Zydus.

UPTRAVI®

In April 2020, Actelion Pharmaceuticals Ltd and Nippon Shinyaku Co., Ltd. initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against a number of generic companies who filed ANDAs seeking approval to market generic versions of UPTRAVI® before expiration of Nippon Shinyaku's United States Patent Nos. 7,205,302; 8,791,122; and 9,284,280 relating to UPTRAVI® . Actelion is the exclusive licensee of the asserted patents. The following generics are named defendants in the complaint: Alembic Pharmaceuticals Limited and Alembic Pharmaceuticals Inc. (Alembic); MSN Laboratories Private Limited and MSN Pharmaceuticals Inc. (MSN); Aizant Drug Research Solutions Private Limited (Aizant); VGYAAN Pharmaceuticals LLC (VGYAAN); and Zydus Pharmaceuticals (USA), Inc. and Zydus Worldwide DMCC (Zydus). In June 2020, the court entered a joint stipulation dismissing Aizant from suit.

Actelion and Nippon Shinyaku are seeking an order enjoining the defendants from marketing generic versions of UPTRAVI® before the expiration of the relevant patents.

GOVERNMENT PROCEEDINGS

Like other companies in the pharmaceutical, consumer 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, were named as 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. 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. 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 in the United States District Court for the District of Massachusetts, where all claims against the J&J AWP Defendants were ultimately dismissed. The J&J AWP Defendants also prevailed in a case brought by the Commonwealth of Pennsylvania. Other AWP cases have been resolved through court order or settlement. The case brought by Illinois was settled after trial. In New Jersey, a putative class action based upon AWP allegations is pending against Centocor, Inc. and Ortho Biotech Inc. (both now Janssen Biotech, Inc.), Johnson & Johnson and ALZA Corporation. All other cases have been resolved.

Opioid Litigation

Beginning in 2014 and continuing to the present, Johnson & Johnson and Janssen Pharmaceuticals, Inc. (JPI), along with other pharmaceutical companies, have been named in more than 2,900 lawsuits related to the marketing of opioids, including DURAGESIC®, NUCYNTA® and NUCYNTA® ER. The suits also raise allegations related to previously owned active pharmaceutical ingredient supplier subsidiaries, Tasmanian Alkaloids Pty, Ltd. and Noramco, Inc. (both subsidiaries were divested in 2016). The majority of the cases have been filed by state and local governments. Similar lawsuits have also been filed by private plaintiffs and organizations, including but not limited to the following: individual plaintiffs on behalf of children suffering from Neonatal Abstinence Syndrome; hospitals; and health insurers/payors. To date, complaints against pharmaceutical companies, including Johnson & Johnson and JPI, have been filed by the state Attorneys General in Arkansas, Florida, Idaho, Illinois, Kentucky, Louisiana, Mississippi, Missouri, New Hampshire, New Jersey, New Mexico, New York,

Ohio, Oklahoma, South Dakota, Texas, Washington and West Virginia. Complaints against the manufacturers also have been filed in state or federal court by city, county and local government agencies in the following states: Alabama, Arizona, Arkansas, California, Connecticut, Florida, Georgia, Illinois, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Mississippi, Missouri, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina; Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Washington, West Virginia and Wisconsin. The Government of Puerto Rico filed suit in Superior Court of San Juan. There are more than 370 cases pending in various state courts. There are over 2,700 federal cases coordinated in a federal Multi-District Litigation (MDL) pending in the U.S. District Court for the Northern District of Ohio (MDL No. 2804). In addition, the Province of British Columbia filed suit in Canada. In October 2019, an anti-trust complaint was filed by private plaintiffs in federal court in Tennessee and is pending transfer to the MDL. These actions allege a variety of claims related to opioid marketing practices, including false advertising, unfair competition, public nuisance, consumer fraud violations, deceptive acts and practices, false claims and unjust enrichment. The suits generally seek penalties and/or injunctive and monetary relief and, in some of the suits, the plaintiffs are seeking joint and several liability among the defendants. An adverse judgment in any of these lawsuits could result in the imposition of large monetary penalties and significant damages including, punitive damages, cost of abatement, substantial fines, equitable remedies and other sanctions.

The trial in the matter filed by the Oklahoma Attorney General resulted in a judgment against Johnson & Johnson and JPI in the amount of $572 million, subject to a final order to be issued by the court. The court issued a final judgment reducing the amount to $465 million. Johnson & Johnson and JPI have appealed the judgment. The Company believes that it has strong grounds to overturn this judgment. In October 2019 Johnson & Johnson and JPI announced a settlement of the first case set for trial in the MDL with two counties in Ohio.

Johnson & Johnson, JPI and other pharmaceutical companies have also received subpoenas or requests for information related to opioids marketing practices from the following state Attorneys General: Alaska, Indiana, Montana, New Hampshire, South Carolina, Tennessee, Texas and Washington. In September 2017, Johnson & Johnson and JPI were contacted by the Texas and Colorado Attorney General's Offices on behalf of approximately 38 states regarding a multi-state Attorney General investigation. In October 2019, the Company announced a proposed agreement in principle that would include the Company paying $4 billion as settlement of these lawsuits, subject to various conditions and an agreement being finalized. This agreement in principle is not an admission of liability or wrong-doing and would resolve opioid lawsuits filed and future claims by states, cities and counties. The Company cannot predict if or when the agreement will be finalized and individual cases are ongoing.
In August 2019, Johnson & Johnson received a grand jury subpoena from the United States Attorney's Office for the Eastern District of New York for documents related to the Company's anti-diversion policies and procedures and distribution of its opioid medications, in what the Company understands to be part of a broader investigation into manufacturers' and distributors' monitoring programs and reporting under the Controlled Substances Act. In September 2019, Johnson & Johnson received subpoenas from the New York State Department of Financial Services (NYDFS) as part of an industry-wide inquiry into the effect of opioid prescriptions on New York health insurance premiums. The Company is cooperating and producing documents in response to the various subpoenas and requests for information.

In November 2019, a shareholder filed a derivative complaint against Johnson & Johnson as the nominal defendant and certain current and former directors and officers as defendants in the Superior Court of New Jersey. The complaint alleges breaches of fiduciary duties related to the marketing of opioids, and that Johnson & Johnson has suffered damages as a result of those alleged breaches. In December 2019, two additional shareholders filed two separate derivative complaints making similar allegations against Johnson & Johnson as the nominal defendant and certain current and former directors and officers as defendants in the United States District for the District of New Jersey. In April 2020, the two federal cases were consolidated into a single action captioned *In re Johnson & Johnson Opioid Stockholder Derivative Litigation*. Pursuant to an agreed stipulation entered by the Court, the shareholders have until July 2020 to file a consolidated complaint or identify a previously filed complaint as the operative complaint. In July 2020, an additional shareholder filed a derivative complaint in the United States District Court for the District of New Jersey making similar allegations against the same defendants named in the consolidated action. Pursuant to an order in the consolidated action, the newly-filed case will be consolidated into the consolidated action.

In April 2020, a report was delivered to the Company's Board of Directors by independent counsel retained by the Board to investigate the allegations in the derivative lawsuits and in a series of shareholder letters that the Board received raising similar issues. The independent counsel recommended that the Company reject the shareholder demands and take the steps that are necessary or appropriate to secure dismissal of the derivative litigation. The Board unanimously adopted the recommendations of the independent counsel's report.

Other

In August 2012, DePuy Orthopaedics, Inc., DePuy, Inc. (now known as DePuy Synthes, Inc.), and Johnson & Johnson Services, Inc. (collectively DePuy) 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 DePuy 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. In February 2016, the district court granted the companies' motion to dismiss with prejudice, unsealed the *qui tam* complaint, and denied the *qui tam* relators' request for leave to file a further amended complaint. The *qui tam* relators appealed the case to the United States Court of Appeals for the First Circuit. In July 2017, the First Circuit affirmed the district court's dismissal in part, reversed in part, and affirmed the decision to deny the relators' request to file a third amended complaint. The relators' remaining claims are now pending before the district court. In July 2020, the Court ordered the relators to complete discovery by August 2020.

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). In May 2016, California and Washington filed civil complaints against Johnson & Johnson, Ethicon and Ethicon US, LLC alleging violations of their consumer protection statutes. Similar complaints were filed against the companies by the following states: Kentucky, Mississippi, West Virginia and Oregon. In April 2019, Johnson & Johnson and Ethicon settled the Washington case. The California case started trial in July 2019 and concluded in September 2019. The trial date for the Kentucky case was scheduled for September 2019 but has been adjourned and no new trial date has been scheduled. The trial date for the Mississippi case is scheduled for April 2021. In October 2019, Johnson & Johnson and Ethicon settled the multi-state investigation with 41 other states and the District of Columbia. In January 2020, the Court in California issued a statement of decision, finding in favor of the State of California, and awarded civil penalties in the amount of $344 million. The Company intends to appeal the decision. In April 2020, the Company settled the West Virginia case. In April 2020, the Court in California denied the Company's motion for a new trial. In June 2020, the Court denied the Attorney General's request for injunctive relief. In June 2020 the Court in Oregon denied the Company's motion to dismiss. Trial in Oregon is set for February 2022. The Attorney General of Mississippi filed a second amended complaint in April 2020 and the Company filed a motion to dismiss in May 2020. The motion to dismiss argument will be heard in August 2020.

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® and Cellex® Systems 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, and OCD was divested in June 2014. 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 March 2014 and March 2016, the United States Attorney's Office requested that Johnson & Johnson produce certain documents, and Johnson & Johnson is cooperating with those requests.

In June 2014, the Mississippi Attorney General filed a complaint in Chancery Court of The First Judicial District of Hinds County, Mississippi against Johnson & Johnson and Johnson & Johnson Consumer Companies, Inc. (now known as Johnson & Johnson Consumer Inc.) (JJCI). The complaint alleges that defendants violated the Mississippi Consumer Protection Act by
failing to disclose alleged health risks associated with female consumers' use of talc contained in JOHNSON'S® Baby Powder and JOHNSON'S® Shower to Shower (a product divested in 2012) and seeks injunctive and monetary relief. The matter is stayed pending interlocutory appeal of a December 2018 denial of Johnson & Johnson and JJCI's motion for summary judgment. The Mississippi Supreme Court granted J&J and JJCI's request to file an interlocutory appeal of the denial of the motion for summary judgment in late 2019.

In January 2020, the State of New Mexico filed a consumer protection case alleging that the Company deceptively marketed and sold its talcum powder products by making misrepresentations about the safety of the products and the presence of carcinogens, including asbestos. The State of New Mexico filed an Amended Complaint in March 2020. The Company has filed a motion to dismiss certain of the claims in the Amended Complaint.

Forty-one states have commenced a joint investigation into the Company's marketing of its talcum powder products. At this time, the multi-state group has not asserted any claims against the Company. Several states have issued Civil Investigative Demands seeking documents and other information.

In March 2016, Janssen Pharmaceuticals, Inc. (JPI) received a Civil Investigative Demand from the United States Attorney's Office for the Southern District of New York related to JPI's contractual relationships with pharmacy benefit managers over the

period from January 1, 2006 to the present with regard to certain of JPI's pharmaceutical products. The demand was issued in connection with an investigation under the False Claims Act.

In July 2016, Johnson & Johnson and Janssen Products LP were served with a *qui tam* complaint pursuant to the False Claims Act filed in the United States District Court for the District of New Jersey alleging the off-label promotion of two HIV products, PREZISTA® and INTELENCE®, and anti-kickback violations in connection with the promotion of these products. The complaint was filed under seal in December 2012. The federal and state governments have declined to intervene, and the lawsuit is being prosecuted by the relators.

In March 2017, Janssen Biotech, Inc. received a Civil Investigative Demand from the United States Department of Justice regarding a False Claims Act investigation concerning management and advisory services provided to rheumatology and gastroenterology practices that purchased REMICADE® or SIMPONI ARIA®. In August 2019, the Unites States Department of Justice notified Janssen Biotech, Inc. that it was closing the investigation. Subsequently, the United States District Court for the District of Massachusetts unsealed a qui tam False Claims Act complaint, which was served on the Company. The Department of Justice had declined to intervene in the qui tam lawsuit in August 2019. The Company has filed a motion to dismiss the relator’s complaint.

In April and September 2017, Johnson & Johnson received subpoenas from the United States Attorney for the District of Massachusetts seeking documents broadly relating to pharmaceutical copayment support programs for DARZALEX®, OLYSIO®, REMICADE®, SIMPONI®, STELARA® and ZYTIGA®. The subpoenas also seek documents relating to Average Manufacturer Price and Best Price reporting to the Center for Medicare and Medicaid Services related to those products, as well as rebate payments to state Medicaid agencies.

In June 2017, Johnson & Johnson received a subpoena from the United States Attorney's Office for the District of Massachusetts seeking information regarding practices pertaining to the sterilization of DePuy Synthes, Inc. spinal implants at three hospitals in Boston as well as interactions of employees of Company subsidiaries with physicians at these hospitals. Johnson & Johnson and DePuy Synthes, Inc. have produced documents in response to the subpoena and are fully cooperating with the government’s investigation.

In July 2018 the Public Prosecution Service in Rio de Janeiro and representatives from the Brazilian antitrust authority CADE inspected the offices of more than 30 companies including Johnson & Johnson do Brasil Indústria e Comércio de Produtos para Saúde Ltda. The authorities appear to be investigating allegations of possible anti-competitive behavior and possible improper payments in the medical device industry. We continue to actively respond to inquiries regarding the Foreign Corrupt Practices Act from the United States Department of Justice and the United States Securities and Exchange Commission.

From time to time, the Company has received 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 May 2014, two purported class actions were filed in federal court, one in the United States District Court for the Central District of California and one in the United States District Court for the Southern District of Illinois, against Johnson & Johnson and Johnson & Johnson Consumer Companies, Inc. (now known as Johnson & Johnson Consumer Inc.) (JJCI) alleging violations of state consumer fraud statutes based on nondisclosure of alleged health risks associated with talc contained in JOHNSON'S® Baby Powder and JOHNSON'S® Shower to Shower (a product no longer sold by JJCI). Both cases seek injunctive relief and monetary damages; neither includes a claim for personal injuries. In October 2016, both cases were transferred to the United States District Court for the District Court of New Jersey as part of a newly created federal multi-district litigation. In July 2017, the district court granted Johnson & Johnson's and JJCI’s motion to dismiss one of the cases. In September 2018, the United States Court of Appeals for the Third Circuit affirmed this dismissal. In September 2017, the plaintiff in the second case voluntarily dismissed the complaint. In March 2018, the plaintiff in the second case refiled in Illinois State Court.

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 (the active pharmaceutical ingredient in 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 a Petition for Relief in July 2015. In May 2019, US CBP issued its Mitigation Decision and determined that Janssen Ortho had negligently misrepresented that darunavir ethanolate is entitled to duty free

treatment. In June 2019, Janssen Ortho filed a Supplemental Petition for Relief. The Penalties Proceeding will be impacted by the related Classification Litigation pending in the United States Court of International Trade. The Classification Litigation will determine whether darunavir ethanolate was properly classified as exempt from duties upon importation into the United States. The trial in the Classification Litigation was held in July 2019. In February 2020, the Court ruled that darunavir ethanolate is eligible for duty free treatment. In April 2020, the United States filed a Notice of Appeal to the United States Court of Appeals for the Federal Circuit.

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) and other contact lens manufacturers, distributors, and retailers, alleging vertical and horizontal conspiracies to fix the retail prices of contact lenses. The complaints allege that the manufacturers reached agreements with 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 and injunctive relief. All of the class action cases were transferred to the United States District Court for the Middle District of Florida in June 2015. The plaintiffs filed a consolidated class action complaint in November 2015. In December 2018, the district court granted the plaintiffs' motion for class certification. Defendants filed two motions for interlocutory appeal of class certification to the United States Court of Appeals for the Eleventh Circuit. Both motions were denied. Defendants' motions for summary judgment were denied in November 2019. The parties await a trial date.

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, Inc. 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 September 2017, Pfizer, Inc. (Pfizer) filed an antitrust complaint against Johnson & Johnson and Janssen Biotech, Inc. (collectively, Janssen) in United States District Court for the Eastern District of Pennsylvania. Pfizer alleges that Janssen has violated federal antitrust laws through its contracting strategies for REMICADE®. The complaint seeks damages and injunctive relief. Discovery is ongoing.

Beginning in September 2017, multiple purported class actions of direct and indirect purchasers were filed against Johnson & Johnson and Janssen Biotech, Inc. (collectively, Janssen) alleging that Janssen's REMICADE® contracting strategies violated federal and state antitrust and consumer laws and seeking damages and injunctive relief. In November 2017, the cases were consolidated for pre-trial purposes in United States District Court for the Eastern District of Pennsylvania as In re Remicade Antitrust Litigation. Motions to dismiss were denied in both the direct and indirect purchaser cases. A motion to compel arbitration of the direct purchaser case was denied by the district court. The United States Court of Appeals for the Third Circuit reversed the district court's ruling.

In June 2018, Walgreen Co. and Kroger Co, filed an antitrust complaint against Johnson & Johnson and Janssen Biotech, Inc. (collectively, Janssen) in the United States District Court for the Eastern District of Pennsylvania. The complaint alleges that Janssen has violated federal antitrust laws through its contracting strategies for REMICADE®. The complaint seeks damages and injunctive relief. In March 2019, summary judgment was granted in favor of Janssen. In February 2020, the United States Court of Appeals for the Third Circuit reversed the District Court's decision.

In June 2019, the United States Federal Trade Commission (FTC) issued a Civil Investigative Demand to Johnson & Johnson in connection with its investigation of whether Janssen's REMICADE® contracting practices violate federal antitrust laws. The Company has produced documents and information responsive to the Civil Investigative Demand.

In October 2017, certain United States service members and their families brought a complaint against a number of pharmaceutical and medical devices companies, including Johnson & Johnson and certain of its subsidiaries, alleging that the defendants violated the United States Anti-Terrorism Act. The complaint alleges that the defendants provided funding for terrorist organizations through their sales practices pursuant to pharmaceutical and medical device contracts with the Iraqi Ministry of Health. In January 2020, plaintiffs filed a Third Amended Complaint adding further plaintiffs to the lawsuit. In July 2020, the District Court dismissed the Third Amended Complaint.

In October 2018, two separate putative class actions were filed against Actelion Pharmaceutical Ltd., Actelion Pharmaceuticals US, Inc., and Actelion Clinical Research, Inc. (collectively Actelion) in United States District Court for the District of Maryland and United States District Court for the District of Columbia. The complaints allege that Actelion violated state and federal antitrust and unfair competition laws by allegedly refusing to supply generic pharmaceutical manufacturers with samples of TRACLEER®. TRACLEER® is subject to a Risk Evaluation and Mitigation Strategy, which imposes restrictions on

distribution of the product. In January 2019, the plaintiffs dismissed the District of Columbia case and filed a consolidated complaint in the United States District Court for the District of Maryland. In October 2019, the Court granted Actelion's motion to dismiss the amended complaint. Plaintiffs have appealed the decision.

In December 2018, Janssen Biotech, Inc., Janssen Oncology, Inc, Janssen Research & Development, LLC, and Johnson & Johnson (collectively, Janssen) were served with a *qui tam* complaint filed on behalf of the United States, 28 states, and the District of Columbia. The complaint, which was filed in December 2017 in United States District Court for the Northern District of California, alleges that Janssen violated the federal False Claims Act and state law when providing pricing information for ZYTIGA® to the government in connection with direct government sales and government-funded drug reimbursement programs. At this time, the federal and state governments have declined to intervene. The case has been transferred to United States District Court for the District of New Jersey. In September 2019, Janssen moved to dismiss the complaint.

In April 2019, Blue Cross & Blue Shield of Louisiana and HMO Louisiana, Inc. filed a class action complaint against Janssen Biotech, Inc, Janssen Oncology, Inc, Janssen Research & Development, LLC and BTG International Limited in the United States District Court for the Eastern District of Virginia on behalf of indirect purchasers of ZYTIGA®. Several additional complaints were filed thereafter in Virginia and New Jersey. The indirect purchaser complaints generally allege that the defendants violated the antitrust and consumer protections laws of several states and the Sherman Act by pursuing patent litigation relating to ZYTIGA® in order to delay generic entry and seek damages. The Virginia cases have been transferred to the United States District Court for the District of New Jersey and consolidated with the New Jersey case for pretrial purposes. In May 2020, a class action complaint was filed against Janssen Biotech Inc., Janssen Oncology, Inc., Janssen Research & Development LLC and BTG International Limited in the United States District Court for the District of New Jersey, on behalf of direct purchasers of ZYTIGA®. The direct purchaser complaint alleges that defendants violated the Sherman Act by pursuing patent litigation relating to ZYTIGA® in order to delay generic entry, and seek damages and injunctive relief.

In May 2019, a class action antitrust complaint was filed against Janssen R&D Ireland (Janssen) and Johnson & Johnson in the United States District Court for the Northern District of California. The complaint alleges that Janssen violated federal and state antitrust and consumer protection laws by agreeing to exclusivity provisions in its agreements with Gilead concerning the development and marketing of combination antiretroviral therapies (cART) to treat HIV. The complaint also alleges that Gilead entered into similar agreements with Bristol-Myers-Squibb and Japan Tobacco. In March 2020, the Court granted in part and denied in part defendants' motions to dismiss. Plaintiffs filed an amended complaint in April 2020.

In October 2019, Innovative Health, LLC filed a complaint against Biosense Webster, Inc. (BWI) in the United States District Court for the Middle District of California. The complaint alleges that certain of BWI's business practices and contractual terms violate the antitrust laws of the United States and the State of California by restricting competition in the sale of High Density Mapping Catheters and Ultrasound Catheters. In January 2020, BWI filed a motion to dismiss the complaint.

In November 2019, Johnson & Johnson received a demand for indemnification from Pfizer Inc., pursuant to the 2006 Stock and Asset Purchase Agreement between the Company and Pfizer. Also in November 2019, Johnson & Johnson, Inc. received a demand for indemnification from Sanofi Consumer Health, Inc., pursuant to the 2016 Asset Purchase Agreement between J&J, Inc. and Sanofi. In January 2020, Johnson & Johnson received a demand for indemnification from Boehringer Ingelheim Pharmaceuticals, Inc., pursuant to the 2006 Asset Purchase Agreement among the Company, Pfizer, and Boehringer Ingelheim. The notices seek indemnification for legal claims related to over-the-counter Zantac (ranitidine) products. Plaintiffs in the underlying actions allege that Zantac and other over-the-counter ranitidine medications contain unsafe levels of NDMA (N-nitrosodimethylamine) and can cause and/or have caused various cancers in patients using the products, and seek injunctive and monetary relief.

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.

NOTE 12— RESTRUCTURING

The Company announced plans to implement a series of actions across its Global Supply Chain that are intended to focus resources and increase investments in the critical capabilities, technologies and solutions necessary to manufacture and supply its product portfolio, enhance agility and drive growth. The Global Supply Chain actions will include expanding the use of strategic collaborations and bolstering initiatives to reduce complexity, improve cost-competitiveness, enhance capabilities and optimize the Supply Chain network. For additional details on the global supply chain restructuring strategic collaborations see Note 10 to the Consolidated Financial Statements. In the fiscal second quarter of 2020, the Company recorded a pre-tax charge of $115 million, which is included on the following lines of the Consolidated Statement of Earnings, $61 million in restructuring, $22 million in cost of products sold and $32 million in other (income) expense. In the first fiscal six months of 2020, the Company recorded a pre-tax charge of $233 million, which is included on the following lines of the Consolidated Statement of Earnings, $119 million in restructuring, $37 million in cost of products sold and $77 million in other (income) expense.Total project costs of approximately $1.1 billion have been recorded since the restructuring was announced. See the following table for additional details on the restructuring program.

In total, the Company expects the Global Supply Chain actions to generate approximately $0.6 billion to $0.8 billion in annual pre-tax cost savings that will be substantially delivered by 2022. The Company expects to record pre-tax restructuring charges of approximately $1.9 billion to $2.3 billion, over the 4 to 5 year period of this activity. These costs are associated with network optimizations, exit costs and accelerated depreciation and amortization.

The following table summarizes the severance related reserves and the associated restructuring expenses through the first fiscal six months of 2020:

(Dollars in Millions)	**Severance**	**Asset Write-offs**	**Other[2]**	**Total**
Reserve balance, December 29, 2019	$ 164	—	16	180
Current year activity:				
Charges	—	27	206	233
Cash payments	(12)	—	(197)	(209)
Settled non cash	—	(27)	(17) [3]	(44)
Reserve balance, June 28, 2020[1]	$ 152	—	8	160

[1] Cash outlays for severance are expected to be substantially paid out over the next 2 years in accordance with the Company's plans and local laws.
[2] Other includes project expense such as salaries for employees supporting these initiatives and consulting expenses.
[3] Relates to pension related actuarial losses associated with the transfer of employees to Jabil Inc. as part of the strategic collaboration.

The Company continuously reevaluates its severance reserves related to restructuring and the timing of payments due to the planned release of associates regarding several longer-term projects. The Company believes that the existing severance reserves are sufficient to cover the Global Supply Chain plans given the period over which the actions will take place. The Company will continue to assess and make adjustments as necessary if additional amounts become probable and estimable.

Item 1A. RISK FACTORS

The Company faces a number of uncertainties and risks that are difficult to predict and many of which are outside of the Company's control. For a detailed discussion of the risks that affect our business, please refer to Part I, Item IA, “Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 29, 2019. There have been no material changes to the risk factors as previously disclosed in the Company's Annual Report on Form 10-K, except as follows:

Global health crises and pandemics, such as the global outbreak of the novel coronavirus (COVID-19), could cause disruptions in our business.

The recent global outbreak of COVID-19 could cause disruptions to the Company's business and have a negative impact on the Company's revenues and operating results. While the Company has robust business continuity plans in place across its global supply chain network to help mitigate the impact of COVID-19, these efforts may not completely prevent its business from being adversely affected. The extent to which COVID-19 impacts the Company's operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak and any prolonged restrictive measures implemented in order to control the spread of the disease. In particular, the continued global spread of COVID-19 could adversely impact the Company's operations, including, among other things, its manufacturing operations, supply chain, sales and marketing and clinical trial operations. Any of these factors could adversely affect the Company's business, operating results or financial condition.

Item 2 — MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

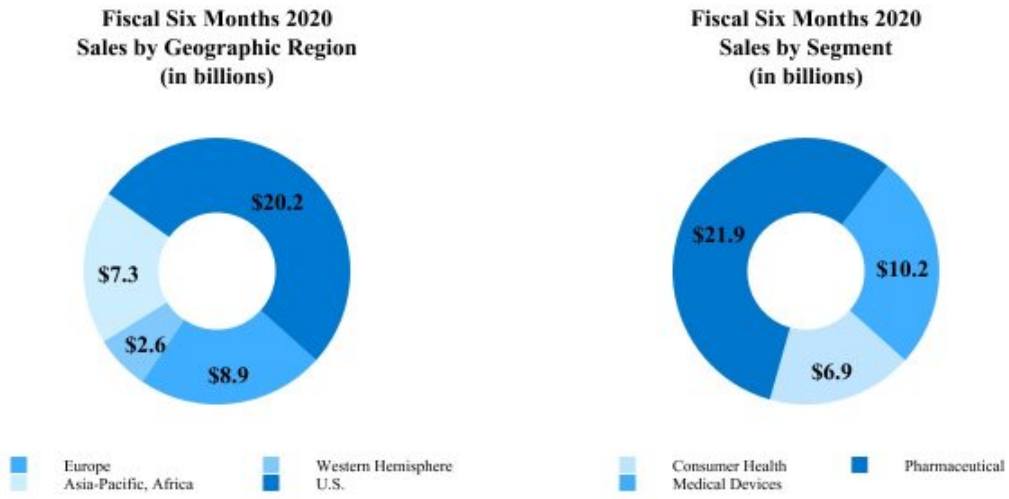
RESULTS OF OPERATIONS

Sales to Customers

Analysis of Consolidated Sales
For the first fiscal six months of 2020, worldwide sales were $39.0 billion, a total decrease of 3.8%, including an operational decline of 2.2% as compared to 2019 first fiscal six months sales of $40.6 billion. Currency fluctuations had a negative impact of 1.6% for the fiscal six months of 2020. In the first fiscal six months of 2020, the net impact of acquisitions and divestitures on worldwide operational sales growth was a negative 0.5%.

Sales by U.S. companies were $20.2 billion in the first fiscal six months of 2020, which represented a decrease of 1.4% as compared to the prior year. In the first fiscal six months of 2020, the net impact of acquisitions and divestitures on the U.S. operational sales growth was a negative 0.6%. Sales by international companies were $18.8 billion, a decrease of 6.3%, including operational decline of 2.9%, and a negative currency impact of 3.4% as compared to the fiscal six months sales of 2019. In the first fiscal six months of 2020, the net impact of acquisitions and divestitures on the international operational sales growth was a negative 0.3%.

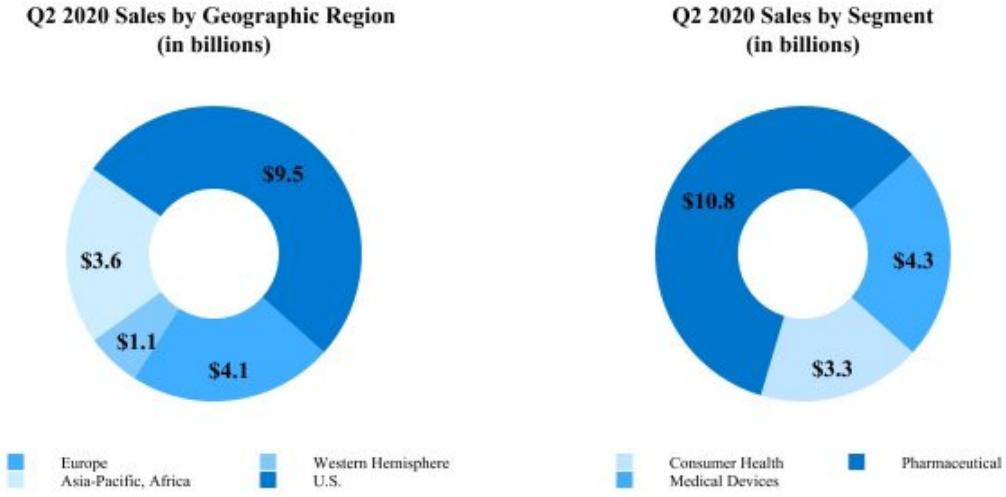
In the first fiscal six months of 2020, sales by companies in Europe experienced a decline of 4.8%, which included an operational decline of 2.1% and a negative currency impact of 2.7%. Sales by companies in the Western Hemisphere, excluding the U.S., experienced a decline of 10.9%, which included an operational decline of 0.1%, and a negative currency impact of 10.8%. Sales by companies in the Asia-Pacific, Africa region experienced a decline of 6.3%, including an operational decline of 4.9% and a negative currency impact of 1.4%.



For the fiscal second quarter of 2020, worldwide sales were $18.3 billion, a total decrease of 10.8%, including an operational decline of 9.0% as compared to 2019 fiscal second quarter sales of $20.6 billion. Currency fluctuations had a negative impact of 1.8% for the fiscal second quarter of 2020. In the fiscal second quarter of 2020, the net impact of acquisitions and divestitures on worldwide operational sales growth was a negative 0.2%.

Sales by U.S. companies were $9.5 billion in the fiscal second quarter of 2020, which represented a decrease of 8.3% as compared to the prior year. In the fiscal second quarter of 2020, the net impact of acquisitions and divestitures on the U.S. operational sales growth was a negative 0.2%. Sales by international companies were $8.8 billion, a decrease of 13.4%, including an operational decline of 9.6%, and a negative currency impact of 3.8% as compared to the fiscal second quarter sales of 2019. In the fiscal second quarter of 2020, the net impact of acquisitions and divestitures on the international operational sales growth was a negative 0.2%.

In the fiscal second quarter of 2020, sales by companies in Europe experienced a decline of 14.2%, which included an operational decline of 11.5% and a negative currency impact of 2.7%. Sales by companies in the Western Hemisphere, excluding the U.S., experienced a decline of 22.1%, which included an operational decline of 8.9%, and a negative currency impact of 13.2%. Sales by companies in the Asia-Pacific, Africa region experienced a decline of 9.3%, including an operational decline of 7.7% and a negative currency impact of 1.6%.



Note: values may have been rounded

Analysis of Sales by Business Segments

Consumer Health*
Consumer Health segment sales in the first fiscal six months of 2020 were $6.9 billion, an increase of 0.9% as compared to the same period a year ago, including operational growth of 3.6% and a negative currency impact of 2.7%. U.S. Consumer Health segment sales increased by 10.8%. International Consumer Health segment sales decreased by 6.8%, including an operational decline of 1.9% and a negative currency impact of 4.9%. In the first fiscal six months of 2020, the net impact of acquisitions and divestitures on the Consumer Health segment operational sales growth was negligible.

Major Consumer Health* Franchise Sales — Fiscal Six Months Ended

(Dollars in Millions)	June 28, 2020	June 30, 2019	Total Change	Operations Change	Currency Change
OTC	$ 2,497	$ 2,151	16.1 %	18.3 %	(2.2) %
Skin Health/Beauty**	2,124	2,292	(7.3)	(5.8)	(1.5)
Oral Care	792	756	4.8	8.0	(3.2)
Baby Care	717	837	(14.3)	(9.5)	(4.8)
Women's Health	434	478	(9.3)	(1.9)	(7.4)
Wound Care/Other	356	348	2.6	4.1	(1.5)
Total Consumer Health* Sales	**$ 6,921**	**$ 6,862**	**0.9 %**	**3.6 %**	**(2.7) %**

* Previously referred to as Consumer
** Previously referred to as Beauty

Consumer Health segment sales in the fiscal second quarter of 2020 were $3.3 billion, a decrease of 7.0% as compared to the same period a year ago, including an operational decline of 3.6% and a negative currency impact of 3.4%. U.S. Consumer Health segment sales increased by 1.3%. International Consumer Health segment sales decreased by 13.4%, including an operational decline of 7.4% and a negative currency impact of 6.0%. In the fiscal second quarter of 2020, the net impact of acquisitions and divestitures on the Consumer Health segment operational sales growth was a negative 0.2%.

Major Consumer Health* Franchise Sales — Fiscal Second Quarter Ended

(Dollars in Millions)	June 28, 2020	June 30, 2019	Total Change	Operations Change	Currency Change
OTC	$ 1,149	$ 1,064	7.9 %	10.7 %	(2.8) %
Skin Health/Beauty**	1,007	1,202	(16.2)	(14.3)	(1.9)
Oral Care	397	389	2.2	6.3	(4.1)
Baby Care	356	443	(19.7)	(13.6)	(6.1)
Women's Health	202	253	(20.1)	(11.8)	(8.3)
Wound Care/Other	185	193	(4.0)	(2.1)	(1.9)
Total Consumer Health* Sales	**$ 3,296**	**$ 3,544**	**(7.0) %**	**(3.6) %**	**(3.4) %**

* Previously referred to as Consumer
** Previously referred to as Beauty

The OTC franchise achieved operational growth of 10.7% as compared to the prior year fiscal second quarter. Growth was primarily attributable to sales from TYLENOL® driven by COVID-19 stocking demand, digestive health products and ZARBEES® Naturals.

The Skin Health/Beauty franchise experienced an operational decline of 14.3% as compared to the prior year fiscal second quarter. The decline was primarily driven by COVID-19 related impacts in the U.S. and Asia Pacific region as well as reduced consumption impacting NEUTROGENA® and AVEENO® products.

The Oral Care franchise achieved operational growth of 6.3% as compared to the prior year fiscal second quarter primarily due to sales of LISTERINE® mouthwash related to COVID-19 stocking demand primarily in the U.S. and promotional activity and new product innovation in Asia Pacific.

The Baby Care franchise experienced an operational decline of 13.6% as compared to the prior year fiscal second quarter. The decline was primarily due to COVID-19 related impacts outside the U.S. and the Baby Center divestiture in the U.S. partially offset by strength in AVEENO® baby.

The Women's Health franchise experienced an operational decline of 11.8% as compared to the prior year fiscal second quarter driven by COVID-19 impacts.
The Wound Care/Other franchise experienced an operational decline of 2.1% as compared to the prior year fiscal second quarter driven by COVID-19 impacts.

Pharmaceutical

Pharmaceutical segment sales in the first fiscal six months of 2020 were $21.9 billion, an increase of 5.4% as compared to the same period a year ago, with an operational increase of 7.0% and a negative currency impact of 1.6%. U.S. Pharmaceutical sales increased 7.2% as compared to the same period a year ago. International Pharmaceutical sales increased by 3.2%, including operational growth of 6.7% and a negative currency impact of 3.5%. In the first fiscal six months of 2020, the net impact of acquisitions and divestitures on the Pharmaceutical segment operational sales growth was negligible.

Major Pharmaceutical Therapeutic Area Sales** — Fiscal Six Months Ended

(Dollars in Millions)	June 28, 2020	June 30, 2019	Total Change	Operations Change	Currency Change
Total Immunology	**$ 7,161**	**$ 6,717**	**6.6 %**	**7.9 %**	**(1.3) %**
REMICADE®	1,925	2,209	(12.9)	(11.8)	(1.1)
SIMPONI®/ SIMPONI ARIA®	1,075	1,087	(1.1)	1.0	(2.1)
STELARA®	3,516	2,963	18.7	19.8	(1.1)
TREMFYA®	638	452	41.1	41.8	(0.7)
Other Immunology	6	6	2.7	8.4	(5.7)
Total Infectious Diseases	**1,798**	**1,708**	**5.3**	**7.8**	**(2.5)**
EDURANT®/rilpivirine	480	421	14.1	17.0	(2.9)
PREZISTA®/ PREZCOBIX®/ REZOLSTA®/ SYMTUZA®	1,089	1,058	2.9	5.0	(2.1)
Other Infectious Diseases	229	229	(0.2)	3.9	(4.1)
Total Neuroscience	**3,245**	**3,167**	**2.5**	**4.1**	**(1.6)**
CONCERTA®/methylphenidate	320	351	(8.9)	(7.2)	(1.7)
INVEGA SUSTENNA®/ XEPLION®/ INVEGA TRINZA®/ TREVICTA®	1,762	1,608	9.5	10.7	(1.2)
RISPERDAL CONSTA®	323	361	(10.5)	(8.9)	(1.6)
Other Neuroscience	841	847	(0.7)	1.8	(2.5)
Total Oncology	**5,804**	**5,215**	**11.3**	**13.5**	**(2.2)**
DARZALEX®	1,838	1,403	31.0	33.5	(2.5)
ERLEADA®(1)	313	130	*	*	*
IMBRUVICA®	1,980	1,615	22.6	25.3	(2.7)
VELCADE®	206	487	(57.7)	(56.9)	(0.8)
ZYTIGA®/ abiraterone acetate	1,258	1,377	(8.6)	(7.0)	(1.6)
Other Oncology	210	203	3.4	6.3	(2.9)
Pulmonary Hypertension	**1,534**	**1,346**	**13.9**	**14.9**	**(1.0)**
OPSUMIT®	795	654	21.6	22.8	(1.2)
UPTRAVI®	532	401	32.7	33.2	(0.5)
Other Pulmonary Hypertension(2)	207	292	(29.0)	(28.3)	(0.7)
Cardiovascular / Metabolism / Other	**2,344**	**2,620**	**(10.5)**	**(9.5)**	**(1.0)**
XARELTO®	1,086	1,091	(0.5)	(0.5)	—
INVOKANA®/ INVOKAMET®	354	379	(6.4)	(5.5)	(0.9)
PROCRIT®/EPREX®	291	409	(28.9)	(28.2)	(0.7)
Other	614	742	(17.3)	(14.6)	(2.7)
Total Pharmaceutical Sales	**$ 21,886**	**$ 20,773**	**5.4 %**	**7.0 %**	**(1.6) %**

* Percentage greater than 100% or not meaningful
**Certain prior year amounts have been reclassified to conform to current year presentation
(1) Previously included in Other Oncology
(2) Inclusive of TRACLEER® which was previously disclosed separately

Pharmaceutical segment sales in the fiscal second quarter of 2020 were $10.8 billion, an increase of 2.1% as compared to the same period a year ago, with an operational increase of 3.9% and a negative currency impact of 1.8%. U.S. Pharmaceutical sales increased 5.8% as compared to the same period a year ago. International Pharmaceutical sales decreased by 2.4%, including operational growth of 1.4% offset by a negative currency impact of 3.8%. In the fiscal second quarter of 2020, the net impact of acquisitions and divestitures on the Pharmaceutical segment operational sales growth was negligible.

Major Pharmaceutical Therapeutic Area Sales** — Fiscal Second Quarter Ended

(Dollars in Millions)	June 28, 2020	June 30, 2019	Total Change	Operations Change	Currency Change
Immunology	**$ 3,523**	**$ 3,466**	**1.6 %**	**3.0 %**	**(1.4) %**
REMICADE®	935	1,107	(15.5)	(14.2)	(1.3)
SIMPONI®/ SIMPONI ARIA®	546	563	(3.0)	(0.9)	(2.1)
STELARA®	1,697	1,558	8.9	10.1	(1.2)
TREMFYA®	342	235	45.4	46.0	(0.6)
Other Immunology	3	3	11.8	21.6	(9.8)
Infectious Diseases	**878**	**862**	**1.9**	**4.7**	**(2.8)**
EDURANT®/rilpivirine	256	210	22.2	25.2	(3.0)
PREZISTA®/ PREZCOBIX®/ REZOLSTA®/ SYMTUZA®	510	535	(4.7)	(2.6)	(2.1)
Other Infectious Diseases	113	117	(4.2)	1.5	(5.7)
Neuroscience	**1,587**	**1,538**	**3.2**	**5.2**	**(2.0)**
CONCERTA®/ methylphenidate	149	137	8.7	11.2	(2.5)
INVEGA SUSTENNA®/ XEPLION®/ INVEGA TRINZA®/ TREVICTA®	879	818	7.5	8.6	(1.1)
RISPERDAL CONSTA®	153	182	(15.9)	(14.2)	(1.7)
Other Neuroscience	406	401	1.2	4.7	(3.5)
Oncology	**2,791**	**2,697**	**3.5**	**5.7**	**(2.2)**
DARZALEX®	901	774	16.3	18.8	(2.5)
ERLEADA®(1)	170	69	*	*	*
IMBRUVICA®	949	831	14.1	17.0	(2.9)
VELCADE®	98	224	(56.1)	(55.2)	(0.9)
ZYTIGA®/ abiraterone acetate	568	698	(18.6)	(17.2)	(1.4)
Other Oncology	106	101	5.5	8.6	(3.1)
Pulmonary Hypertension	**789**	**690**	**14.2**	**15.0**	**(0.8)**
OPSUMIT®	406	348	16.5	17.6	(1.1)
UPTRAVI®	282	203	39.0	39.5	(0.5)
Other Pulmonary Hypertension(2)	101	140	(27.5)	(26.9)	(0.6)
Cardiovascular / Metabolism / Other	**1,184**	**1,275**	**(7.1)**	**(5.8)**	**(1.3)**
XARELTO®	559	549	1.7	1.7	—
INVOKANA®/ INVOKAMET®	179	177	1.6	3.1	(1.5)
PROCRIT®/ EPREX®	136	183	(25.6)	(24.6)	(1.0)
Other	312	368	(15.3)	(11.8)	(3.5)
Total Pharmaceutical Sales	**$ 10,752**	**$ 10,529**	**2.1 %**	**3.9 %**	**(1.8) %**

* Percentage greater than 100% or not meaningful
**Certain prior year amounts have been reclassified to conform to current year presentation
(1) Previously included in Other Oncology
(2) Inclusive of TRACLEER® which was previously disclosed separately

Immunology products achieved operational growth of 3.0% as compared to the same period a year ago driven by strong uptake of STELARA® (ustekinumab) in Crohn's disease and Ulcerative Colitis, strength in TREMFYA® (guselkumab) in Psoriasis, and U.S. immunology market growth. This was partially offset by COVID-19 related demand. Immunology was negatively impacted by lower sales of REMICADE® (infliximab) due to increased discounts/rebates and biosimilar competition.

The patents for REMICADE® (infliximab) in certain countries in Europe expired in February 2015. 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. Additional biosimilar competition will likely result in a further reduction in REMICADE® sales in markets outside the United States. In the United States, a biosimilar version of REMICADE® was introduced in 2016, and additional competitors continue to enter the market. Continued infliximab biosimilar competition in the U.S. market will result in a further reduction in U.S. sales of REMICADE®.

Infectious disease products achieved operational growth of 4.7% as compared to the same period a year ago primarily due to strong sales of SYMTUZA® in the U.S. and the launch uptake of JULUCA®. This was partially offset by lower sales of PREZISTA® and PREZCOBIX®/REZOLSTA® due to increased competition, loss of exclusivity of PREZISTA® in certain countries outside the U.S. and the negative impact of COVID-19.

Neuroscience products achieved operational sales growth of 5.2% as compared to the same period a year ago. Paliperidone long-acting injectables growth was driven by strong sales of INVEGA SUSTENNA®/XEPLION® (paliperidone palmitate) and INVEGA TRINZA®/TREVICTA® from new patient starts and persistence. The growth was partially offset by cannibalization of RISPERDAL CONSTA® (risperidone) and the negative impact of COVID-19.
Oncology products achieved strong operational sales growth of 5.7% as compared to the same period a year ago. Contributors to the growth were strong sales of DARZALEX® (daratumumab) driven by patient uptake in all lines of therapy, IMBRUVICA® (ibrutinib) due to increased patient uptake globally and the continued global launch uptake of ERLEADA® (apalutamide). The growth was partially offset by declining sales of ZYTIGA® (abiraterone acetate) and VELCADE® (bortezomib) due to generic competition and a positive one-time adjustment for DARZALEX® sales in the fiscal second quarter of 2019 related to the completion of pricing and reimbursement discussions in certain European countries. In addition, Oncology products were negatively impacted by delayed diagnosis and reversal of the fiscal first quarter 2020 stocking related to COVID-19.

Pulmonary Hypertension achieved operational sales growth of 15.0% as compared to the same period a year ago. Sales growth of OPSUMIT® (macitentan) and UPTRAVI® (selexipag) were due to increased market penetration and market growth.

Cardiovascular / Metabolism / Other products experienced an operational decline of 5.8% as compared to the same period a year ago. Sales growth of INVOKANA®/INVOKAMET® (canagliflozin) were due to uptake in the European and Latin America regions and a one-time adjustment in 2020 to previous reserve estimates in the U.S. The growth of XARELTO® (rivaroxaban) included a one-time adjustment in 2020 to previous reserve estimates in the U.S. partially offset by higher rebates and the negative impacts of COVID-19. Lower sales of PROCRIT®/ EPREX® (epoetin alfa) were due to biosimilar competition.

Medical Devices

The Medical Devices segment sales in the first fiscal six months of 2020 were $10.2 billion, a decrease of 21.1% as compared to the same period a year ago, with an operational decline of 19.8% and a negative currency impact of 1.3%. U.S. Medical Devices sales decreased 23.1%. International Medical Devices sales decreased by 19.2%, including an operational decline of 16.8% and a negative currency impact of 2.4%. In the first fiscal six months of 2020, the net impact of acquisitions and divestitures on the Medical Devices segment operational sales growth was a negative 1.0% primarily due to the divestiture of the ASP business.

Major Medical Devices Franchise Sales* — Fiscal Six Months Ended

(Dollars in Millions)	June 28, 2020	June 30, 2019	Total Change	Operations Change	Currency Change
Surgery	**$ 3,651**	**$ 4,748**	**(23.1)%**	**(21.3)%**	**(1.8)%**
Advanced	1,723	2,009	(14.2)	(12.4)	(1.8)
General[1]	1,928	2,739	(29.6)	(27.8)	(1.8)
Orthopaedics	**3,489**	**4,428**	**(21.2)**	**(20.3)**	**(0.9)**
Hips	563	725	(22.3)	(21.2)	(1.1)
Knees	517	741	(30.1)	(29.3)	(0.8)
Trauma	1,207	1,357	(11.1)	(10.0)	(1.1)
Spine, Sports & Other[2]	1,202	1,606	(25.1)	(24.3)	(0.8)
Vision	**1,762**	**2,290**	**(23.0)**	**(22.2)**	**(0.8)**
Contact Lenses/Other	1,368	1,666	(17.9)	(17.0)	(0.9)
Surgical	394	624	(36.8)	(36.0)	(0.8)
Interventional Solutions	**1,317**	**1,482**	**(11.2)**	**(10.2)**	**(1.0)**
Total Medical Devices Sales	**$ 10,220**	**$ 12,948**	**(21.1)%**	**(19.8)%**	**(1.3)%**

*Certain prior year amounts have been reclassified to conform to current year presentation

(1) Includes Specialty Surgery which was previously disclosed separately

(2) Previously referred to as Spine & Other

The Medical Devices segment sales in the fiscal second quarter of 2020 were $4.3 billion, a decrease of 33.9% as compared to the same period a year ago, with an operational decline of 32.7% and a negative currency impact of 1.2%. U.S. Medical Devices sales decreased 39.6%. International Medical Devices sales decreased by 28.8%, including an operational decline of 26.4% and a negative currency impact of 2.4%. In the fiscal second quarter of 2020, the net impact of acquisitions and divestitures on the Medical Devices segment operational sales growth was a negative 0.2%. While results in the fiscal second quarter were net negatively impacted by COVID-19, primarily related to reduced procedures, the Company did see improvement throughout the quarter as countries and states began to gradually re-open. For example, sales in China returned to growth in the second quarter. However, the ultimate COVID-19 impact on Medical Devices fiscal year sales remains highly fluid and will continue to evolve with geographical re-openings and virus waves.

Major Medical Devices Franchise Sales* — Fiscal Second Quarter Ended

(Dollars in Millions)	June 28, 2020	June 30, 2019	Total Change	Operations Change	Currency Change
Surgery	**$ 1,551**	**$ 2,353**	**(34.1)%**	**(32.2)%**	**(1.9)%**
Advanced	775	1,029	(24.6)	(22.9)	(1.7)
General[1]	775	1,325	(41.5)	(39.5)	(2.0)
Orthopaedics	**1,451**	**2,224**	**(34.7)**	**(33.9)**	**(0.8)**
Hips	226	364	(37.8)	(36.8)	(1.0)
Knees	174	372	(53.1)	(52.5)	(0.6)
Trauma	553	672	(17.8)	(16.7)	(1.1)
Spine, Sports & Other[2]	499	818	(39.0)	(38.2)	(0.8)
Vision	**695**	**1,161**	**(40.1)**	**(39.3)**	**(0.8)**
Contact Lenses/Other	554	842	(34.1)	(33.3)	(0.8)
Surgical	141	319	(55.8)	(55.2)	(0.6)
Interventional Solutions	**590**	**750**	**(21.5)**	**(20.5)**	**(1.0)**
Total Medical Devices Sales	**$ 4,288**	**$ 6,489**	**(33.9)%**	**(32.7)%**	**(1.2)%**

*Certain prior year amounts have been reclassified to conform to current year presentation
[1] Includes Specialty Surgery which was previously disclosed separately
[2] Previously referred to as Spine & Other

The Surgery franchise experienced an operational sales decline of 32.2% as compared to the prior year fiscal second quarter. The operational decline in Advanced Surgery was primarily driven by the negative impact of COVID-19 and competitive pressures in the U.S. partially offset in Biosurgery which was positively impacted due to the recovery of an isolated supply disruption of SURGIFLO® in the prior year fiscal second quarter. The operational decline in General Surgery was primarily driven by the negative impact of COVID-19 and a one-time unfavorable prior period pricing adjustment in the U.S.

The Orthopaedics franchise experienced an operational sales decline of 33.9% as compared to the prior year fiscal second quarter. The operational decline in hips was driven by the negative impact of COVID-19 partially offset by leadership position in the anterior approach. The operational decline in knees was driven by the negative impact of COVID-19. The operational decline in Trauma was driven by the negative impact of COVID-19. The operational decline in Spine, Sports & Other was driven by the negative impact of COVID-19 partially offset by the uptake of the SYMPHONY™ Occipito-Cervico-Thoracic (OCT) System in Spine.

The Vision franchise experienced an operational sales decline of 39.3% as compared to the prior year fiscal second quarter. The operational decline in Contact Lenses/Other was due to the negative impact of COVID-19. The Surgical operational decline was primarily driven by the negative impact of COVID-19 and competitive pressures in the U.S.

The Interventional Solutions franchise experienced an operational sales decline of 20.5% as compared to the prior year fiscal second quarter driven by the negative impact of COVID-19 partially offset by strong growth in China.

ANALYSIS OF CONSOLIDATED EARNINGS BEFORE PROVISION FOR TAXES ON INCOME
Consolidated earnings before provision for taxes on income for the first fiscal six months of 2020 was $10.4 billion representing 26.8% of sales as compared to $11.5 billion in the first fiscal six months of 2019, representing 28.2% of sales.

Consolidated earnings before provision for taxes on income for the fiscal second quarter of 2020 was $3.9 billion representing 21.5% of sales as compared to $7.0 billion in the fiscal second quarter of 2019, representing 34.2% of sales.

Cost of Products Sold

(Dollars in billions. Percentages in chart are as a percent to total sales)

Fiscal Six months Q2 2020 versus Fiscal Six months Q2 2019
Cost of products sold increased as a percent to sales driven by:

- Medical Device idle capacity costs associated with COVID-19 related production slow downs and fixed cost deleveraging.
- Establishment of incremental inventory reserves associated with the impact of COVID-19 in the Medical Devices business

The intangible asset amortization expense included in cost of products sold for each of the first fiscal six months of 2020 and 2019 was $2.2 billion.

Q2 2020 versus Q2 2019
Cost of products sold increased as a percent to sales driven by:

- Medical Device idle capacity costs associated with COVID-19 related production slow downs and fixed cost deleveraging.
- Establishment of incremental inventory reserves associated with the impact of COVID-19 in the Medical Devices business

The intangible asset amortization expense included in cost of products sold for each of the fiscal second quarters of 2020 and 2019 was $1.1 billion.

Selling, Marketing and Administrative Expenses

(Dollars in billions. Percentages in chart are as a percent to total sales)

Fiscal Six Months Q2 2020 versus Fiscal Six Months Q2 2019
Selling, Marketing and Administrative Expenses decreased as a percent to sales driven by:

- Leveraging in the Pharmaceutical business
- Planned prioritization and reduced brand marketing expense in the Consumer Health business
- Favorable product mix with a higher percentage of sales coming from the Pharmaceutical business

partially offset by:

- Deleveraging in the Medical Devices business resulting from the COVID-19 impact on sales

Q2 2020 versus Q2 2019
Selling, Marketing and Administrative Expenses increased as a percent to sales driven by:

- Deleveraging in the Medical Devices business resulting from the COVID-19 impact on sales

partially offset by:

- Expense leveraging in the Pharmaceutical business
- Planned prioritization and reduced brand marketing expense in the Consumer Health business
- Favorable product mix with a higher percentage of sales coming from the Pharmaceutical business

Research and Development Expense

(Dollars in billions. Percentages in chart are as a percent to total sales)

Fiscal Six Months Q2 2020 versus Fiscal Six Months Q2 2019
Research and Development decreased slightly as a percent to sales driven by:

- Higher upfront payments in the fiscal six months of 2019, primarily related to the argenx collaboration

partially offset by:

- The negative COVID-19 impact on Medical Devices sales
- Increased investment in the Medical Devices business related to robotics and digital programs

Q2 2020 versus Q2 2019
Research and Development increased as a percent to sales driven by:

- The negative COVID-19 impact on Medical Devices sales
- Segment mix with a higher percentage of sales coming from the Pharmaceutical business

In-Process Research and Development (IPR&D)

In the fiscal first quarter of 2019, the Company recorded an IPR&D charge of $0.9 billion for the remaining intangible asset value related to the development program of AL-8176, an investigational drug for the treatment of Respiratory Syncytial Virus (RSV) and human metapneumovirus (hMPV) acquired with the 2014 acquisition of Alios Biopharma Inc. The impairment charge was based on additional information, including clinical data, which became available and led to the Company's decision to abandon the development of AL-8176.

Interest (Income) Expense

Interest (Income) Expense in the first fiscal six months of 2020 was a net interest income of $16 million and was slightly higher than the $2 million in same period a year ago. This was primarily due to the positive effect of net investment hedging arrangements and certain cross currency swaps and a lower average debt balance with a lower average interest rate. This was partially offset by reduced interest income resulting from lower rates of interest earned on cash balances. Interest (Income) Expense in the fiscal second quarter of 2020 was a net interest expense of $26 million as compared to income of $5 million in

the same period a year ago. This was primarily due to reduced interest income resulting from lower rates of interest earned on cash balances. The balance of cash, cash equivalents and current marketable securities was $19.1 billion at the end of the fiscal second quarter of 2020 as compared to $15.3 billion at the end of the fiscal second quarter of 2019. The Company's debt position was $30.4 billion as of June 28, 2020 as compared to $29.4 billion the same period a year ago.

Other (Income) Expense, Net

Fiscal Six Months Q2 2020 versus Fiscal Six Months Q2 2019

Other (income) expense, net for the first fiscal six months of 2020 was unfavorable by $1.1 billion as compared to the prior year primarily due to the following:

Fiscal Six Months

(Dollars in Billions)(Income)/Expense	2020	2019	Change
Litigation expense	$ 0.7	0.8	(0.1)
Acquisition and Integration related[1]	(0.9)	0.1	(1.0)
Unrealized (gains)/losses on securities	(0.2)	(0.3)	0.1
Equity step-up gain related to DR. CI:LABO	0.0	(0.3)	0.3
Divestiture Gains[2]	(0.1)	(2.1)	2.0
Restructuring related	0.1	0.1	0.0
Other	(0.2)	0.0	(0.2)
Total Other (Income) Expense, Net	$ (0.6)	(1.7)	1.1

[1] 2020 is primarily driven by a contingent consideration reversal of approximately $1.0 billion related to the timing of certain developmental milestones associated with the Auris Health acquisition.
[2] 2019 included the divestiture of ASP

Q2 2020 versus Q2 2019

Other (income) expense, net for the fiscal second quarter of 2020 was unfavorable by $1.7 billion as compared to the prior year primarily due to the following:

Fiscal Second Quarter

(Dollars in Billions)(Income)/Expense	2020	2019	Change
Litigation expense	$ 0.6	0.4	0.2
Acquisition and Integration related	0.0	0.1	(0.1)
Unrealized (gains)/losses on securities	(0.5)	(0.2)	(0.3)
Divestiture Gains[1]	0.0	(2.0)	2.0
Other	(0.1)	0.0	(0.1)
Total Other (Income) Expense, Net	$ 0.0	(1.7)	1.7

[1] 2019 included the divestiture of ASP

EARNINGS BEFORE PROVISION FOR TAXES BY SEGMENT

Income before tax by segment of business for the first fiscal six months were as follows:

	Income Before Tax		Segment Sales		Percent of Segment Sales	
(Dollars in Millions)	June 28, 2020	June 30, 2019	June 28, 2020	June 30, 2019	June 28, 2020	June 30, 2019
Consumer Health	$ 802	$ 1,147	$ 6,921	$ 6,862	11.6 %	16.7 %
Pharmaceutical	8,348	6,008	21,886	20,773	38.1	28.9
Medical Devices	1,671	4,686	10,220	12,948	16.4	36.2
Segment earnings before tax	10,821	11,841	39,027	40,583	27.7	29.2
Less: Expenses not allocated to segments [1]	372	378				
Worldwide income before tax	$ 10,449	$ 11,463	$ 39,027	$ 40,583	26.8 %	28.2 %

Income before tax by segment of business for the fiscal second quarters were as follows:

	Income Before Tax		Segment Sales		Percent of Segment Sales	
(Dollars in Millions)	June 28, 2020	June 30, 2019	June 28, 2020	June 30, 2019	June 28, 2020	June 30, 2019
Consumer Health	$ 32	$ 406	$ 3,296	$ 3,544	1.0 %	11.5 %
Pharmaceutical	4,514	3,677	10,752	10,529	42.0	34.9
Medical Devices	(354)	3,189	4,288	6,489	(8.3)	49.1
Segment earnings before tax	4,192	7,272	18,336	20,562	22.9	35.4
Less: Expenses not allocated to segments [1]	252	231				
Worldwide income before tax	$ 3,940	$ 7,041	$ 18,336	$ 20,562	21.5 %	34.2 %

[1] Amounts not allocated to segments include interest (income) expense and general corporate (income) expense.

Consumer Health Segment

The Consumer Health segment income before tax as a percent of sales in the first fiscal six months of 2020 was 11.6% versus 16.7% for the same period a year ago. The decrease in the income before tax as a percent of sales in the first fiscal six months of 2020 as compared to the prior year was primarily driven by the following:

- Higher litigation expense of $0.6 billion in 2020 vs. $0.2 billion in 2019 (primarily associated with talc related costs)
- The first fiscal six months of 2019 included a gain of $0.3 billion related to the Company's previously held equity investment in DR. CI:LABO

partially offset by:

- Planned prioritization and reduced brand marketing expense in the fiscal six months of 2020

The Consumer Health segment income before tax as a percent of sales in the fiscal second quarter of 2020 was 1.0% versus 11.5% for the same period a year ago. The decrease in the income before tax as a percent of sales in the fiscal second quarter of 2020 as compared to the prior year was primarily driven by the following:

- Higher litigation expense of $0.6 billion in 2020 vs. $0.2 billion in 2019 (primarily associated with talc related costs)

partially offset by:

- Planned prioritization and reduced brand marketing expense in the fiscal second quarter of 2020

Pharmaceutical Segment

The Pharmaceutical segment income before tax as a percent of sales in the first fiscal six months of 2020 was 38.1% versus 28.9% for the same period a year ago. The increase in the income before tax as a percent of sales for the first fiscal six months of 2020 as compared to the prior year was primarily driven by the following:

- Lower litigation expense of $0.0 billion in 2020 vs. $0.4 billion in 2019
- An in-process research and development charge of $0.9 billion in the fiscal six months of 2019
- Lower research and development expense in 2020. The fiscal six months of 2019 included a $0.3 billion upfront payment to argenx

- Leveraging in selling, marketing and administrative expense

partially offset by:

- Lower unrealized gains on securities of $0.2 billion in the fiscal six months of 2020 vs. unrealized gains of $0.3 billion in the fiscal six months of 2019

The Pharmaceutical segment income before tax as a percent of sales in the fiscal second quarter of 2020 was 42.0% versus 34.9% for the same period a year ago. The increase in the income before tax as a percent of sales for the fiscal second quarter of 2020 as compared to the prior year was primarily driven by the following:

- Unrealized gains on securities of $0.5 billion in Q2 2020 vs. $0.2 billion in Q2 2019
- Leveraging in selling, marketing and administrative expense
- Favorable product mix

Medical Devices Segment

The Medical Devices segment income before tax as a percent of sales in the first fiscal six months of 2020 was 16.4% versus 36.2% for the same period a year ago. The decrease in the income before tax as a percent of sales for the first fiscal six months was primarily driven by the following:

- A gain of $2.0 billion related to the ASP divestiture recorded in the fiscal six months of 2019
- COVID-19 period costs and fixed costs deleveraging and idle capacity charges in Cost of Products Sold in the fiscal six months of 2020
- The negative impact of COVID-19 on sales in the fiscal six months of 2020

partially offset by:

- A contingent consideration reversal of approximately $1.0 billion in the fiscal six months of 2020 related to the timing of certain developmental milestones associated with the Auris Health acquisition
- Lower litigation expense of $0.1 billion in 2020 vs. $0.3 billion in 2019

The Medical Devices segment income before tax as a percent of sales in the fiscal second quarter of 2020 was (8.3)% versus 49.1% for the same period a year ago. The decrease in the income before tax as a percent of sales for the fiscal second quarter was primarily driven by the following:

- A gain of $2.0 billion related to the ASP divestiture recorded in the fiscal second quarter of 2019
- COVID-19 period costs and fixed costs deleveraging and idle capacity charges in Cost of Products Sold in the fiscal second quarter of 2020
- The negative impact of COVID-19 on sales in the fiscal second quarter of 2020

partially offset by:

- Lower litigation expense of $0.0 billion in Q2 2020 vs. $0.2 billion in Q2 2019

Restructuring

In the second quarter of 2018, the Company announced plans to implement actions across its global supply chain that are intended to enable the Company to focus resources and increase investments in critical capabilities, technologies and solutions necessary to manufacture and supply its product portfolio of the future, enhance agility and drive growth. The Company expects these supply chain actions will include expanding its use of strategic collaborations, and bolstering its initiatives to reduce complexity, improving cost-competitiveness, enhancing capabilities and optimizing its network. Discussions regarding specific future actions are ongoing and are subject to all relevant consultation requirements before they are finalized. In total, the Company expects these actions to generate approximately $0.6 to $0.8 billion in annual pre-tax cost savings that will be substantially delivered by 2022. The Company expects to record pre-tax restructuring charges of approximately $1.9 to $2.3 billion. In the first fiscal six months of 2020, the Company recorded a pre-tax charge of $233 million, which is included on the following lines of the Consolidated Statement of Earnings, $119 million in restructuring, $37 million in cost of products sold and $77 million in other (income) expense. In the fiscal second quarter of 2020, the Company recorded a pre-tax charge of $115 million, which is included on the following lines of the Consolidated Statement of Earnings, $61 million in restructuring, $22 million in cost of products sold and $32 million in other (income) expense. In the first fiscal six months of 2019, the Company recorded a pre-tax charge of $232 million, which is included on the following lines of the Consolidated Statement of Earnings, $93 million in restructuring, $61 million in cost of products sold and $78 million in other (income) expense. In the fiscal second quarter of 2019, the Company recorded a pre-tax charge of $142 million, which is included on the following lines of the Consolidated Statement of Earnings, $57 million in restructuring, $38 million in cost of products sold and $47 million in other (income) expense. Restructuring charges of approximately $1.1 billion have been recorded since the restructuring was announced.

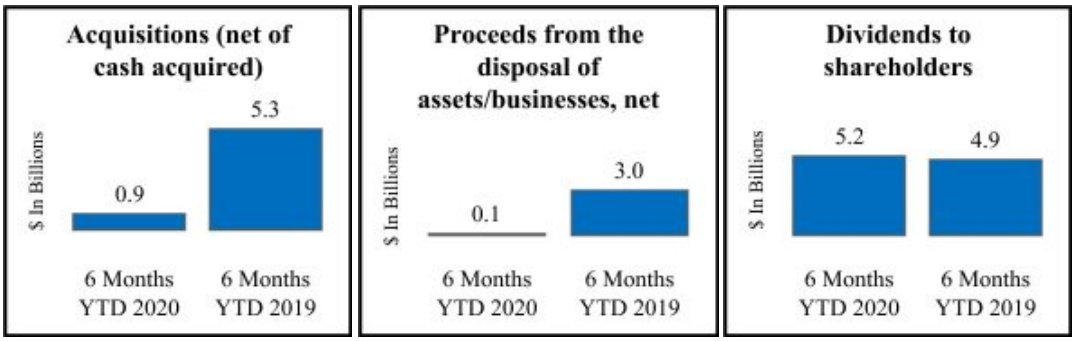
See Note 12 to the Consolidated Financial Statements for additional details related to the restructuring.

Provision for Taxes on Income

For discussion related to the fiscal six months of 2020 provision for taxes refer to Note 5 to the Consolidated Financial Statements.

During the second quarter of 2020, the Internal Revenue Service proposed regulations that may, if issued in their current form, limit the tax deductibility of the payments under the agreement in principle to settle opioid litigation that was accrued for in fiscal 2019 for $4.0 billion at an effective rate of 23.5% (for more information see Note 21 in the Company's Annual Report on Form 10-K for the fiscal year ended December 29, 2019). The financial impact of these regulations may be material to the Company's financial results in the period in which they are finalized which could be later in fiscal 2020.

LIQUIDITY AND CAPITAL RESOURCES



Cash Flows

Cash and cash equivalents were $11.2 billion at the end of the fiscal second quarter of 2020 as compared with $17.3 billion at the end of fiscal year 2019. The primary sources and uses of cash that contributed to the $6.1 billion decrease were:

(Dollars In Billions)		
$	17.3	Q4 2019 Cash and cash equivalents balance
	6.8	cash generated from operating activities
	(8.1)	net cash used by investing activities
	(4.7)	net cash used by financing activities
	(0.1)	effect of exchange rate and rounding
$	11.2	Q2 2020 Cash and cash equivalents balance

In addition, the Company had $8.0 billion in marketable securities at the end of the fiscal second quarter of 2020 and $2.0 billion at the end of fiscal year 2019.

Cash flow from operations of $6.8 billion was the result of:

(Dollars In Billions)		
$	9.4	Net Earnings
	3.7	non-cash expenses and other adjustments primarily for depreciation and amortization, stock-based compensation and accounts receivable allowances and credit losses partially offset by the deferred tax provision and net gain on sale of assets/businesses
	(3.1)	decrease in accounts payable and accrued liabilities and other current and non-current liabilities
	(2.2)	an increase in accounts receivable, inventories and other current and non-current assets
	(1.0)	contingent consideration reversal (related to the timing of certain developmental milestones associated with the Auris Health acquisition)
$	6.8	Cash Flow from operations

Investing activities use of $8.1 billion of cash was primarily used for:

(Dollars In Billions)		
$	(0.9)	primarily related to the acquisitions of bermekimab and related assets from XBiotech Inc. as well as the acquisition of all outstanding shares in Verb Surgical Inc.
	(1.3)	additions to property, plant and equipment
	(6.1)	net purchases of investments
	0.7	proceeds from credit support agreements, net
	(0.5)	other (primarily licenses and milestones)
$	(8.1)	Net cash used for investing activities

Financing activities use of $4.7 billion of cash was primarily used for:

(Dollars In Billions)		
$	(5.2)	dividends to shareholders
	(2.4)	repurchase of common stock
	2.7	net proceeds from short and long term debt
	0.7	proceeds from stock options exercised/employee withholding tax on stock awards, net
	(0.5)	other
$	(4.7)	Net cash used for financing activities

The Company has access to substantial sources of funds at numerous banks worldwide. In September 2019, the Company secured a new 364-day Credit Facility. Total credit available to the Company approximates $10 billion, which expires on September 10, 2020. Interest charged on borrowings under the credit line agreement is based on either bids provided by banks, the prime rate, London Interbank Offered Rates (LIBOR), or other applicable market rates as allowed under the terms of the agreement, plus applicable margins. Commitment fees under the agreement are not material.

In the fiscal second quarter of 2020, the Company's notes payable and long-term debt was in excess of cash, cash equivalents and marketable securities. As of June 28, 2020, the net debt position was $11.3 billion as compared to the prior year of $14.1 billion. Considering recent market conditions and the on-going COVID-19 crisis, the Company has re-evaluated its operating cash flows and liquidity profile and does not foresee any significant incremental risk. The Company anticipates that operating cash flows, the ability to raise funds from external sources, borrowing capacity from existing committed credit facilities and access to the commercial paper markets will continue to provide sufficient resources to fund operating needs, including the agreement in principle to settle opioid litigation to be potentially paid over the next two to three years. In addition, the Company monitors the global capital markets on an ongoing basis and from time to time may raise capital when market conditions are favorable. In the fiscal second quarter of 2020, the Company issued approximately $3.0 billion of commercial paper, with approximately $2.7 billion outstanding at quarter end, for additional liquidity at favorable interest rates. Additionally, as a result of the TCJA, the Company has access to its cash outside the U.S. at a significantly reduced cost.

In the fiscal second quarter of 2020, the Company paid approximately $1.3 billion to the U.S. Treasury related to the normal estimated tax payment for the fiscal first and second quarters of 2020 and the current installment due on foreign undistributed

earnings as part of the TCJA (see Note 8 to the Consolidated Financial Statements as contained in the Company's Annual Report on Form 10-K for the fiscal year ended December 29, 2019).

Dividends

On April 14, 2020, the Board of Directors declared a regular cash dividend of $1.01 per share, payable on June 9, 2020 to shareholders of record as of May 26, 2020.

On July 20, 2020, the Board of Directors declared a regular cash dividend of $1.01 per share, payable on September 8, 2020 to shareholders of record as of August 25, 2020. The Company expects to continue the practice of paying regular quarterly cash dividends.

OTHER INFORMATION

New Accounting Pronouncements

Refer to Note 1 to the Consolidated Financial Statements for new accounting pronouncements.

Economic and Market Factors

COVID-19 considerations and business continuity
The Company has considered various internal and external factors in assessing the potential impact of COVID-19 on its business and financial results based upon information available at this time, as follows:

- *Operating Model:* The Company has a diversified business model across the healthcare industry with flexibility designed into its manufacturing, research and development clinical operations and commercial capabilities.
- *Supply Chain:* The Company continues to leverage its global manufacturing footprint and dual-source capabilities while closely monitoring and maintaining critical inventory at major distribution centers away from high-risk areas to ensure adequate and effective distribution.
- *Business Continuity:* The robust, active business continuity plans across the Company's network have been instrumental in preparing the Company for events like COVID-19 and the ability to meet the majority of patient and consumer needs remains uninterrupted.
- *Workforce:* The Company has put procedures in place to protect its essential workforce in manufacturing, distribution, commercial and research operations while ensuring appropriate remote working protocols have been established for other employees
- *Liquidity:* The Company's high-quality credit rating allows the Company superior access to the financial capital markets for the foreseeable future. In the fiscal second quarter of 2020, the Company issued approximately $3.0 billion of commercial paper, with approximately $2.7 billion outstanding at quarter end, for additional liquidity at favorable interest rates.
- *Domestic and Foreign Legislation:* The Company will continue to assess and evaluate the on-going global legislative efforts to combat the COVID-19 impact on economies and the sectors in which it participates. Currently, the recent legislative acts put in place are not expected to have a material impact on the Company's operations.

In the fiscal second quarter and early in the third quarter of 2020, the Company entered into a series of contract manufacturing arrangements for vaccine production with third party contract manufacturing organizations. These arrangements provide the Company with future supplemental commercial capacity for vaccine production and potentially transferable rights to such production if capacity is not required. Amounts paid and contractually obligated to be paid to these contract manufacturing organizations are reflected in the prepaid expenses and other and the accrued liabilities accounts in the Company's consolidated balance sheet upon execution of each agreement. Additionally, the Company has entered into certain vaccine development cost sharing arrangements with government related organizations. The costs associated with these arrangements have not been significant through the fiscal second quarter of 2020.

The Company operates in certain countries where the economic conditions continue to present significant challenges. The Company continues to monitor these situations and take appropriate actions. Inflation rates and currency exchange rates continue to have an effect on worldwide economies and, consequently, on the way the Company operates. The Company has accounted for operations in Venezuela and Argentina as highly inflationary, as the prior three-year cumulative inflation rate surpassed 100%. This did not have a material impact on the Company's results in the period. In the face of increasing costs, the Company strives to maintain its profit margins through cost reduction programs, productivity improvements and periodic price increases.

In June 2016, the United Kingdom (U.K.) held a referendum in which voters approved an exit from the European Union (E.U.), commonly referred to as "Brexit" and on January 31, 2020, the U.K. formally exited the E.U. Given the lack of comparable precedent, it is unclear what the ultimate financial, trade, regulatory and legal implications the withdrawal of the U.K. from the E.U. will have. Brexit creates global political and economic uncertainty, which may cause, among other consequences, volatility in exchange rates and interest rates, additional cost containment by third-party payors and changes in regulations. However, the Company currently does not believe that these and other related effects will have a material impact on the Company's consolidated financial position or operating results. As of June 28, 2020 and for the fiscal six months, the business of the Company's U.K. subsidiaries represented less than 3% of both the Company's consolidated assets and fiscal six months revenues, respectively.

Governments around the world consider various proposals to make changes to tax laws and regulations, which may include increasing or decreasing existing statutory tax rates. A change in statutory tax rate in any country would result in the revaluation of the Company's deferred tax assets and liabilities related to that particular jurisdiction in the period in which the new tax law is enacted. This change would result in an expense or benefit recorded to the Company's Consolidated Statement of Earnings. The Company closely monitors these proposals as they arise in the countries where it operates. Changes to the statutory tax rate may occur at any time, and any related expense or benefit recorded may be material to the fiscal quarter and year in which the law change is enacted.

The Company faces various worldwide health care changes that may continue to result in pricing pressures that include health care cost containment and government legislation relating to sales, promotions and reimbursement of health care products.

Changes in the behavior and spending patterns of purchasers of health care products and services, including delaying medical procedures, rationing prescription medications, reducing the frequency of physician visits and foregoing health care insurance coverage, may continue to impact the Company's businesses.

The Company also operates in an environment increasingly hostile to intellectual property rights. Firms have filed Abbreviated New Drug Applications or Biosimilar Biological Product Applications with the FDA, initiated Inter Partes Review proceedings in the United States Patent and Trademark Office, or otherwise challenged the coverage and/or validity of the Company's patents, seeking to market generic or biosimilar forms of many of the Company's key pharmaceutical products prior to expiration of the applicable patents covering those products. In the event the Company is not successful in defending the patent claims challenged in these actions, generic or biosimilar versions of the products at issue may be introduced 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. There is also a risk that one or more competitors could launch a generic or biosimilar version of the product at issue following regulatory approval even though one or more valid patents are in place. For further information, see the discussion on "Litigation Against Filers of Abbreviated New Drug Applications" in Note 11 to the Consolidated Financial Statements.

Item 3 — QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

There has been no material change in the Company's assessment of its sensitivity to market risk since its presentation set forth in Item 7A, "Quantitative and Qualitative Disclosures About Market Risk," in its Annual Report on Form 10-K for the fiscal year ended December 29, 2019.

Item 4 — CONTROLS AND PROCEDURES

Disclosure controls and procedures. At the end of the period covered by this report, the Company evaluated the effectiveness of the design and operation of its disclosure controls and procedures. The Company's disclosure controls and procedures are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Securities Exchange Act is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure. Alex Gorsky, Chairman and Chief Executive Officer, and Joseph J. Wolk, Executive Vice President, Chief Financial Officer, reviewed and participated in this evaluation. Based on this evaluation, Messrs. Gorsky and Wolk concluded that, as of the end of the period covered by this report, the Company's disclosure controls and procedures were effective.

Internal control. During the period covered by this report, there were no changes in the Company's internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting. The Company has not experienced any material impact to its internal controls over financial reporting despite the fact that most of its employees are working remotely due to the COVID-19 pandemic. The Company proactively took actions to re-evaluate and refine its financial reporting process through additional monitoring controls to provide reasonable assurance that the financial results are reported accurately and timely. The Company continues to monitor and assess the effectiveness of the design and operation of its disclosure controls and procedures.

The Company is implementing a multi-year, enterprise-wide initiative to integrate, simplify and standardize processes and systems for the human resources, information technology, procurement, supply chain and finance functions. These are enhancements to support the growth of the Company's financial shared service capabilities and standardize financial systems. This initiative is not in response to any identified deficiency or weakness in the Company's internal control over financial reporting. In conjunction with this initiative, the Company has and will continue to align and streamline the design and operation of its financial control environment.

Part II — OTHER INFORMATION

Item 1 — LEGAL PROCEEDINGS

The information called for by this item is incorporated herein by reference to Note 11 included in Part I, Item 1, Financial Statements (unaudited) — Notes to Consolidated Financial Statements.

Item 2 — UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

(c) Purchases of Equity Securities by the Issuer and Affiliated Purchasers.

The following table provides information with respect to Common Stock purchases by the Company during the fiscal second quarter of 2020. The repurchases below also include the stock-for-stock option exercises that settled in the fiscal second quarter.

Fiscal Month Period	Total Number of Shares Purchased[1]	Avg. Price Per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs
March 30, 2020 through April 26, 2020	352,899	150.60		—
April 27, 2020 through May 24, 2020	3,474,619	150.35		—
May 25, 2020 through June 28, 2020	901,712	145.16		—
Total	4,729,230			

[1] During the fiscal second quarter of 2020, the Company repurchased an aggregate of 4,729,230 shares of Johnson & Johnson Common Stock in open-market transactions, all of which were purchased as part of a systematic plan to meet the needs of the Company's compensation programs.

Item 6 — EXHIBITS

Exhibit 31.1 Certification of Chief Executive Officer under Rule 13a-14(a) of the Securities Exchange Act pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 — Filed with this document.

Exhibit 31.2 Certification of Chief Financial Officer under Rule 13a-14(a) of the Securities Exchange Act pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 — Filed with this document.

Exhibit 32.1 Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 — Furnished with this document.

Exhibit 32.2 Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 — Furnished with this document.

Exhibit 101:

EX-101.INS	Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
EX-101.SCH	Inline XBRL Taxonomy Extension Schema
EX-101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase
EX-101.LAB	Inline XBRL Taxonomy Extension Label Linkbase
EX-101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase
EX-101.DEF	Inline XBRL Taxonomy Extension Definition Document

Exhibit 104:	Cover Page Interactive Data File—the cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.

SIGNATURES

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

JOHNSON & JOHNSON
(Registrant)

Date: July 24, 2020

By /s/ J. J. WOLK

J. J. WOLK

Executive Vice President, Chief Financial Officer (Principal Financial Officer)

Date: July 24, 2020

By /s/ R. J. DECKER Jr.

R. J. DECKER Jr.

Controller (Principal Accounting Officer)

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT

I, Alex Gorsky, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarterly period ended June 28, 2020 (the “report”) of Johnson & Johnson (the "Company");

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

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

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

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

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

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

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

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

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

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

/s/ Alex Gorsky

Alex Gorsky
Chief Executive Officer

Date: July 24, 2020

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT

I, Joseph J. Wolk, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarterly period ended June 28, 2020 (the "report") of Johnson & Johnson (the "Company");

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

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

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

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

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

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

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

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

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

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

/s/ Joseph J. Wolk

Joseph J. Wolk
Chief Financial Officer

Date: July 24, 2020

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT

The undersigned, Alex Gorsky, the Chief Executive Officer of Johnson & Johnson, a New Jersey corporation (the "Company"), pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, hereby certifies that, to the best of my knowledge:

(1) the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 28, 2020 (the"Report") fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Alex Gorsky

Alex Gorsky

Chief Executive Officer

Dated: July 24, 2020

This certification is being furnished to the SEC with this Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by such Act, be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to liability of that section.

Exhibit 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT

The undersigned, Joseph J. Wolk, the Chief Financial Officer of Johnson & Johnson, a New Jersey corporation (the "Company"), pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, hereby certifies that, to the best of my knowledge:

(1) the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 28, 2020 (the "Report") fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Joseph J. Wolk

Joseph J. Wolk

Chief Financial Officer

Dated: July 24, 2020

This certification is being furnished to the SEC with this Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by such Act, be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to liability of that section.