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 October 3, 2021

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	JNJ22	New York Stock Exchange
0.650% Notes Due May 2024	JNJ24C	New York Stock Exchange
5.50% Notes Due November 2024	JNJ24BP	New York Stock Exchange
1.150% Notes Due November 2028	JNJ28	New York Stock Exchange
1.650% Notes Due May 2035	JNJ35	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 October 22, 2021, 2,632,596,969 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 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, 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 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;
- The impact of global public health crises and pandemics, including the outbreak of the novel coronavirus (COVID-19) pandemic;
- 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; and
- 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.

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 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 January 3, 2021, 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)

		October 3, 2021	January 3, 2021
ASSETS			
Current assets:			
Cash and cash equivalents	$	17,604	13,985
Marketable securities		13,397	11,200
Accounts receivable, trade, less allowances for doubtful accounts and credit losses $223 (2020, $293)		14,911	13,576
Inventories (Note 2)		10,387	9,344
Prepaid expenses and other		3,590	3,132
Total current assets		59,889	51,237
Property, plant and equipment at cost		47,347	46,804
Less: accumulated depreciation		(28,869)	(28,038)
Property, plant and equipment, net		18,478	18,766
Intangible assets, net (Note 3)		47,776	53,402
Goodwill (Note 3)		35,569	36,393
Deferred taxes on income (Note 5)		10,646	8,534
Other assets		6,870	6,562
Total assets	$	179,228	174,894
LIABILITIES AND SHAREHOLDERS' EQUITY			
Current liabilities:			
Loans and notes payable	$	3,798	2,631
Accounts payable		8,961	9,505
Accrued liabilities		13,812	13,968
Accrued rebates, returns and promotions		12,683	11,513
Accrued compensation and employee related obligations		3,146	3,484
Accrued taxes on income (Note 5)		2,161	1,392
Total current liabilities		44,561	42,493
Long-term debt (Note 4)		30,130	32,635
Deferred taxes on income (Note 5)		7,147	7,214
Employee related obligations (Note 6)		10,171	10,771
Long-term taxes payable (Note 5)		5,770	6,559
Other liabilities		11,177	11,944
Total liabilities	$	108,956	111,616
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)		(15,415)	(15,242)
Retained earnings		121,092	113,890
Less: common stock held in treasury, at cost (487,358,000 and 487,331,000 shares)		38,525	38,490
Total shareholders' equity		70,272	63,278
Total liabilities and shareholders' equity	$	179,228	174,894

See Notes to Consolidated Financial Statements

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

	Fiscal Third Quarter Ended			
	October 3, 2021	Percent to Sales	September 27, 2020	Percent to Sales
Sales to customers (Note 9)	$ 23,338	100.0 %	$ 21,082	100.0 %
Cost of products sold	7,250	31.1	6,972	33.1
Gross profit	16,088	68.9	14,110	66.9
Selling, marketing and administrative expenses	6,000	25.7	5,431	25.8
Research and development expense	3,422	14.7	2,840	13.5
In-process research and development	900	3.9	138	0.6
Interest income	(13)	(0.1)	(12)	(0.1)
Interest expense, net of portion capitalized	20	0.1	44	0.2
Other (income) expense, net	1,850	7.9	1,200	5.7
Restructuring (Note 12)	60	0.2	68	0.3
Earnings before provision for taxes on income	3,849	16.5	4,401	20.9
Provision for taxes on income (Note 5)	182	0.8	847	4.0
NET EARNINGS	$ 3,667	15.7 %	$ 3,554	16.9 %
NET EARNINGS PER SHARE (Note 8)				
Basic	$ 1.39		$ 1.35	
Diluted	$ 1.37		$ 1.33	
AVG. SHARES OUTSTANDING				
Basic	2,632.6		2,632.5	
Diluted	2,674.9		2,669.3	

See Notes to Consolidated Financial Statements

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

	Fiscal Nine Months Ended			
	October 3, 2021	Percent to Sales	September 27, 2020	Percent to Sales
Sales to customers (Note 9)	$ 68,971	100.0 %	$ 60,109	100.0 %
Cost of products sold	21,900	31.8	20,613	34.3
Gross profit	47,071	68.2	39,496	65.7
Selling, marketing and administrative expenses	17,505	25.4	15,627	26.0
Research and development expense	9,994	14.5	8,127	13.5
In-process research and development	900	1.3	144	0.3
Interest income	(40)	(0.1)	(98)	(0.2)
Interest expense, net of portion capitalized	123	0.2	114	0.2
Other (income) expense, net	480	0.7	545	0.9
Restructuring (Note 12)	169	0.2	187	0.3
Earnings before provision for taxes on income	17,940	26.0	14,850	24.7
Provision for taxes on income (Note 5)	1,798	2.6	1,874	3.1
NET EARNINGS	$ 16,142	23.4 %	$ 12,976	21.6 %
NET EARNINGS PER SHARE (Note 8)				
Basic	$ 6.13		$ 4.93	
Diluted	$ 6.04		$ 4.86	
AVG. SHARES OUTSTANDING				
Basic	2,632.2		2,633.0	
Diluted	2,674.6		2,670.8	

See Notes to Consolidated Financial Statements

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

	Fiscal Third Quarter Ended		Fiscal Nine Months Ended	
	October 3, 2021	September 27, 2020	October 3, 2021	September 27, 2020
Net earnings	$ 3,667	3,554	$ 16,142	12,976
Other comprehensive income (loss), net of tax				
Foreign currency translation	(382)	222	(241)	(741)
Securities:				
Unrealized holding gain (loss) arising during period	—	1	(1)	1
Reclassifications to earnings	—	—	—	—
Net change	—	1	(1)	1
Employee benefit plans:				
Prior service cost amortization during period	(40)	(6)	(122)	(17)
Gain (loss) amortization during period	273	203	822	604
Net change	233	197	700	587
Derivatives & hedges:				
Unrealized gain (loss) arising during period	67	199	(55)	1,052
Reclassifications to earnings	(233)	(24)	(576)	54
Net change	(166)	175	(631)	1,106
Other comprehensive income (loss)	(315)	595	(173)	953
Comprehensive income	$ 3,352	4,149	$ 15,969	13,929

See Notes to Consolidated Financial Statements

The tax effects in other comprehensive income for the fiscal third quarter were as follows for 2021 and 2020, respectively: Foreign Currency Translation: $86 million and $139 million; Employee Benefit Plans: $65 million and $56 million; Derivatives & Hedges: $43 million and $47 million.

The tax effects in other comprehensive income for the fiscal nine months were as follows for 2021 and 2020, respectively: Foreign Currency Translation: $315 million and $207 million; Employee Benefit Plans: $197 million and $167 million; Derivatives & Hedges: $167 million and $293 million.

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

Fiscal Third Quarter Ended October 3, 2021

		Total	Retained Earnings	Accumulated Other Comprehensive Income	Common Stock Issued Amount	Treasury Stock Amount
Balance, July 4, 2021	**$**	**69,580**	**120,154**	**(15,100)**	**3,120**	**(38,594)**
Net earnings		3,667	3,667	—	—	—
Cash dividends paid ($1.06 per share)		(2,791)	(2,791)	—	—	—
Employee compensation and stock option plans		522	62	—	—	460
Repurchase of common stock		(391)	—	—	—	(391)
Other comprehensive income (loss), net of tax		(315)	—	(315)	—	—
Balance, October 3, 2021	**$**	**70,272**	**121,092**	**(15,415)**	**3,120**	**(38,525)**

Fiscal Nine Months Ended October 3, 2021

		Total	Retained Earnings	Accumulated Other Comprehensive Income	Common Stock Issued Amount	Treasury Stock Amount
Balance, January 3, 2021	**$**	**63,278**	**113,890**	**(15,242)**	**3,120**	**(38,490)**
Net earnings		16,142	16,142	—	—	—
Cash dividends paid ($3.13 per share)		(8,241)	(8,241)	—	—	—
Employee compensation and stock option plans		1,726	(699)	—	—	2,425
Repurchase of common stock		(2,460)	—	—	—	(2,460)
Other comprehensive income (loss), net of tax		(173)	—	(173)	—	—
Balance, October 3, 2021	**$**	**70,272**	**121,092**	**(15,415)**	**3,120**	**(38,525)**

Fiscal Third Quarter Ended September 27, 2020

		Total	Retained Earnings	Accumulated Other Comprehensive Income	Common Stock Issued Amount	Treasury Stock Amount
Balance, June 28, 2020	**$**	**62,978**	**113,898**	**(15,533)**	**3,120**	**(38,507)**
Net earnings		3,554	3,554	—	—	—
Cash dividends paid ($1.01 per share)		(2,659)	(2,659)	—	—	—
Employee compensation and stock option plans		559	109	—	—	450
Repurchase of common stock		(483)	—	—	—	(483)
Other		(71)	(71)	—	—	—
Other comprehensive income (loss), net of tax		595	—	595	—	—
Balance, September 27, 2020	**$**	**64,473**	**114,831**	**(14,938)**	**3,120**	**(38,540)**

Fiscal Nine Months Ended September 27, 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		12,976	12,976	—	—	—
Cash dividends paid ($2.97 per share)		(7,823)	(7,823)	—	—	—
Employee compensation and stock option plans		1,866	(911)	—	—	2,777
Repurchase of common stock		(2,900)	—	—	—	(2,900)
Other		(70)	(70)	—	—	—
Other comprehensive income (loss), net of tax		953	—	953	—	—
Balance, September 27, 2020	**$**	**64,473**	**114,831**	**(14,938)**	**3,120**	**(38,540)**

See Notes to Consolidated Financial Statements

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

	Fiscal Nine Months Ended	
	October 3, 2021	September 27, 2020
CASH FLOWS FROM OPERATING ACTIVITIES		
Net earnings	$ 16,142	12,976
Adjustments to reconcile net earnings to cash flows from operating activities:		
Depreciation and amortization of property and intangibles	5,547	5,291
Stock based compensation	920	845
Asset write-downs	964	198
Contingent consideration reversal	—	(1,148)
Net gain on sale of assets/businesses	(601)	(60)
Deferred tax provision	(2,564)	(238)
Credit losses and accounts receivable allowances	(60)	74
Changes in assets and liabilities, net of effects from acquisitions and divestitures:		
Increase in accounts receivable	(1,818)	(440)
Increase in inventories	(1,178)	(784)
Increase/(Decrease) in accounts payable and accrued liabilities	182	(119)
Decrease/(Increase) in other current and non-current assets	2,082	(1,983)
(Decrease)/Increase in other current and non-current liabilities	(1,938)	581
NET CASH FLOWS FROM OPERATING ACTIVITIES	17,678	15,193
CASH FLOWS FROM INVESTING ACTIVITIES		
Additions to property, plant and equipment	(2,237)	(2,024)
Proceeds from the disposal of assets/businesses, net (Note 10)	666	100
Acquisitions, net of cash acquired (Note 10)	—	(949)
Purchases of investments	(18,843)	(16,243)
Sales of investments	16,809	6,585
Credit support agreements activity, net	696	125
Other (primarily licenses and milestones)	(414)	(516)
NET CASH USED BY INVESTING ACTIVITIES	(3,323)	(12,922)
CASH FLOWS FROM FINANCING ACTIVITIES		
Dividends to shareholders	(8,241)	(7,823)
Repurchase of common stock	(2,460)	(2,900)
Proceeds from short-term debt	1,283	3,335
Repayment of short-term debt	(821)	(310)
Proceeds from long-term debt, net of issuance costs	3	7,431
Repayment of long-term debt	(1,452)	(562)
Proceeds from the exercise of stock options/employee withholding tax on stock awards, net	808	922
Credit support agreements activity, net	168	—
Other	101	(569)
NET CASH USED BY FINANCING ACTIVITIES	(10,611)	(476)
Effect of exchange rate changes on cash and cash equivalents	(125)	(135)
Increase in cash and cash equivalents	3,619	1,660
Cash and Cash equivalents, beginning of period	13,985	17,305
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 17,604	18,965
Acquisitions		
Fair value of assets acquired	$ —	1,173
Fair value of liabilities assumed and noncontrolling interests	—	(224)
Net cash paid for acquisitions	$ —	949

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 January 3, 2021. 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 October 3, 2021 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 along with the Company's on-going vaccine development and distribution efforts. While there was not a material impact to the Company's consolidated financial statements as of and for the quarter ended October 3, 2021, 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 January 3, 2021. There were no new material accounting standards issued in the fiscal nine months of 2021 that impacted the Company.

Recently Adopted Accounting Standards
There were no new material accounting standards adopted in the fiscal nine months of 2021.

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

NOTE 2 — INVENTORIES

(Dollars in Millions)		October 3, 2021	January 3, 2021
Raw materials and supplies	$	1,587	1,410
Goods in process		2,164	2,040
Finished goods		6,636	5,894
Total inventories	$	10,387	9,344

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 2020. 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)		October 3, 2021	January 3, 2021
Intangible assets with definite lives:			
Patents and trademarks — gross	$	39,176	39,990
Less accumulated amortization		(19,569)	(17,618)
Patents and trademarks — net		19,607	22,372
Customer relationships and other intangibles — gross		22,950	22,898
Less accumulated amortization		(11,637)	(10,912)
Customer relationships and other intangibles — net*		11,313	11,986
Intangible assets with indefinite lives:			
Trademarks		7,013	7,195
Purchased in-process research and development [(1)]		9,843	11,849
Total intangible assets with indefinite lives		16,856	19,044
Total intangible assets — net	$	47,776	53,402

*The majority is comprised of customer relationships

[(1)]In the fiscal third quarter of 2021, the Company recorded a partial IPR&D impairment charge of $0.9 billion primarily related to expected development delays in the general surgery digital robotics platform (Ottava) acquired with the Auris Health acquisition in 2019. The impairment charge was calculated based on revisions to the discounted cash flow valuation model reflecting a delay of first in human procedures of approximately two years from the initial acquisition model assumption of the second half of 2022. The remaining reduction was driven by assets that reached commercialization and are now classified as having definite lives.

Goodwill as of October 3, 2021 was allocated by segment of business as follows:

(Dollars in Millions)		Consumer Health	Pharmaceutical	Medical Devices	Total
Goodwill at January 3, 2021	$	10,336	11,009	15,048	36,393
Goodwill, related to acquisitions		—	—	—	—
Goodwill, related to divestitures		(7)	—	—	(7)
Currency translation/Other		(347)	(283)	(187)	(817)
Goodwill at October 3, 2021	$	9,982	10,726	14,861	35,569

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 and $1.2 billion for the fiscal third quarters ended October 3, 2021 and September 27, 2020, respectively. The amortization expense of amortizable intangible assets included in cost of products sold was $3.6 billion and $3.4 billion for the fiscal nine months ended October 3, 2021 and September 27, 2020, respectively. 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)				
2021	**2022**	**2023**	**2024**	**2025**
$4,700	4,500	4,500	4,300	3,600

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 October 3, 2021, the cumulative amount of cash collateral paid by the Company under the CSA amounted to $202 million net, related to net investment and cash flow hedges. 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 October 3, 2021, the Company had notional amounts outstanding for forward foreign exchange contracts, cross currency interest rate swaps and interest rate swaps of $45.8 billion, $35.1 billion and $10.0 billion, respectively. As of January 3, 2021, the Company had notional amounts outstanding for forward foreign exchange contracts and cross currency interest rate swaps of $37.8 billion and $30.6 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 October 3, 2021, the balance of deferred net gain on derivatives included in accumulated other comprehensive income was $21 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 third quarters ended in 2021 and 2020, net of tax:

	October 3, 2021					September 27, 2020				
(Dollars in Millions)	Sales	Cost of Products Sold	R&D Expense	Interest (Income) Expense	Other (Income) Expense	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 fair value hedging relationship:										
Interest rate swaps contracts:										
Hedged items	$ —	—	—	(62)	—	—	—	—		—
Derivatives designated as hedging instruments	—	—	—	62	—	—	—	—		—
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	—	—	—	34	—	—	—	—	39	—
Amount of gain or (loss) recognized in AOCI	—	—	—	34	—	—	—	—	39	—
Gain (Loss) on cash flow hedging relationship:										
Forward foreign exchange contracts:										
Amount of gain or (loss) reclassified from AOCI into income	(3)	58	8	—	19	3	(81)	(13)	—	(8)
Amount of gain or (loss) recognized in AOCI	(35)	(155)	37	—	42	16	156	(36)	—	(41)
Cross currency interest rate swaps contracts:										
Amount of gain or (loss) reclassified from AOCI into income	—	—	—	117	—	—		—	84	—
Amount of gain or (loss) recognized in AOCI	$ —	—	—	144	—	—	—	—	65	—

The following table is a summary of the activity related to derivatives and hedges for the fiscal nine months ended in 2021 and 2020, net of tax:

	October 3, 2021					September 27, 2020				
(Dollars in Millions)	Sales	Cost of Products Sold	R&D Expense	Interest (Income) Expense	Other (Income) Expense	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 fair value hedging relationship:										
Interest rate swaps contracts:										
Hedged items	$ —	—	—	(56)	—	—	—	—		—
Derivatives designated as hedging instruments	—	—	—	56	—	—	—	—		—
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	—	—	—	115	—	—	—	—	118	—
Amount of gain or (loss) recognized in AOCI	—	—	—	115	—	—	—	—	118	—
Gain (Loss) on cash flow hedging relationship:										
Forward foreign exchange contracts:										
Amount of gain or (loss) reclassified from AOCI into income	25	106	(1)	—	24	10	(316)	(121)	—	(10)
Amount of gain or (loss) recognized in AOCI	(41)	(398)	80	—	67	25	330	(156)	—	(55)
Cross currency interest rate swaps contracts:										
Amount of gain or (loss) reclassified from AOCI into income	—	—	—	307	—	—	—	—	265	—
Amount of gain or (loss) recognized in AOCI	$ —	—	—	122	—	—	—	—	790	—

As of October 3, 2021, and January 3, 2021, the following amounts were recorded on the Consolidated Balance Sheet related to cumulative basis adjustment for fair value hedges

Line item in the Consolidated Balance Sheet in which the hedged item is included	Carrying Amount of the Hedged Liability		Cumulative Amount of Fair Value Hedging Adjustment Included in the Carrying Amount of the Hedged Liability	
(Dollars in Millions)	October 3, 2021	January 3, 2021	October 3, 2021	January 3, 2021
Long-term Debt	9,851	—	(73)	—

The following table is the effect of derivatives not designated as hedging instruments for the fiscal third quarters and fiscal nine months in 2021 and 2020:

		Gain/(Loss) Recognized In Income on Derivative		Gain/(Loss) Recognized In Income on Derivative	
(Dollars in Millions)	Location of Gain /(Loss) Recognized in Income on Derivative	Fiscal Third Quarter Ended		Fiscal Nine Months Ended	
Derivatives Not Designated as Hedging Instruments		October 3, 2021	September 27, 2020	October 3, 2021	September 27, 2020
Foreign Exchange Contracts	Other (income) expense	$ (13)	1	(50)	66

The following table is the effect of net investment hedges for the fiscal third quarters ended in 2021 and 2020:

	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)	October 3, 2021	September 27, 2020		October 3, 2021	September 27, 2020
Debt	$ 115	(169)	Interest (income) expense	—	—
Cross Currency interest rate swaps	$ 141	(234)	Interest (income) expense	—	—

The following table is the effect of net investment hedges for the fiscal nine months ended in 2021 and 2020:

	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)	October 3, 2021	September 27, 2020		October 3, 2021	September 27, 2020
Debt	$ 279	(217)	Interest (income) expense	—	—
Cross Currency interest rate swaps	$ 432	407	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)	January 3, 2021			October 3, 2021	
	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	$ 1,481	(83)	469	1,867	1,867
Equity Investments without readily determinable value	$ 738	392	(545)	585	585

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

For equity investments without readily determinable market values, there was a decrease of $25 million in the fair value reflected in net income as a result of impairments. There was an offsetting increase of $417 million in the fair value reflected in net income due to changes in observable prices and gains on the disposal of the Grail investment.

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 October 3, 2021 and January 3, 2021 were as follows:

(Dollars in Millions)	October 3, 2021 Level 1	Level 2	Level 3	Total	January 3, 2021 Total[1]
Derivatives designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts	$ —	459	—	459	849
Interest rate contracts [2]	—	707	—	707	240
Total	—	1,166	—	1,166	1,089
Liabilities:					
Forward foreign exchange contracts	—	768	—	768	702
Interest rate contracts [2]	—	468	—	468	1,569
Total	—	1,236	—	1,236	2,271
Derivatives not designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts	—	51	—	51	49
Liabilities:					
Forward foreign exchange contracts	—	48	—	48	38
Other Investments:					
Equity investments [3]	1,867	—	—	1,867	1,481
Debt securities [4]	—	18,911	—	18,911	14,042
Other Liabilities					
Contingent consideration [5]	$ —	—	613	613	633

Gross to Net Derivative Reconciliation (Dollars in Millions)	October 3, 2021	January 3, 2021
Total Gross Assets	$ 1,217	1,138
Credit Support Agreement (CSA)	(1,058)	(1,107)
Total Net Asset	159	31
Total Gross Liabilities	1,284	2,309
Credit Support Agreement (CSA)	(1,260)	(2,172)
Total Net Liabilities	$ 24	137

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

	October 3, 2021	September 27, 2020
(Dollars in Millions)		
Beginning Balance	$ 633	$ 1,715
Changes in estimated fair value [6]	28	(1,088)
Additions	—	107
Payments	(48)	(98)
Ending Balance	$ 613	$ 636

[1] 2020 assets and liabilities are all classified as Level 2 with the exception of equity investments of $1,481 million, which are classified as Level 1 and contingent consideration of $633 million, classified as Level 3.
[2] Includes cross currency interest rate swaps and interest rate swaps as of October 3, 2021. Includes cross currency interest rate swaps as of January 3, 2021.
[3] Classified as non-current other assets.
[4] Classified within cash equivalents and current marketable securities.
[5] Includes $595 million and $594 million, classified as non-current other liabilities as of October 3, 2021 and January 3, 2021, respectively. Includes $18 million and $39 million classified as current liabilities as of October 3, 2021 and January 3, 2021, respectively.
[6] Ongoing fair value adjustment amounts are primarily recorded in Research and Development expense.
The Company recorded a contingent consideration reversal of $1,148 million in 2020 related to the timing of certain developmental milestones associated with the Auris Health acquisition. The reversal of the contingent consideration was recorded in Other income and expense, net.

The Company's cash, cash equivalents and current marketable securities as of October 3, 2021 comprised:

(Dollars in Millions)	Carrying Amount	Unrecognized Gain	Unrecognized Loss	Estimated Fair Value	Cash & Cash Equivalents	Current Marketable Securities
Cash	$ 2,607	—	—	2,607	2,607	—
Non-U.S. sovereign securities[1]	870	—	—	870	—	870
U.S. reverse repurchase agreements	1,715	—	—	1,715	1,715	—
Corporate debt securities[1]	3,604	—	—	3,604	274	3,330
Money market funds	2,120	—	—	2,120	2,120	—
Time deposits[1]	1,174	—	—	1,174	1,174	—
Subtotal	12,090	—	—	12,090	7,890	4,200
		Unrealized Gain	Unrealized Loss			
U.S. Gov't securities	18,657	—	—	18,657	9,697	8,960
Other sovereign securities	3	—	—	3	2	1
Corporate debt securities	251	—	—	251	15	236
Subtotal available for sale debt[2]	$ 18,911	—	—	18,911	9,714	9,197
Total cash, cash equivalents and current marketable securities	$ 31,001	—	—	31,001	17,604	13,397

[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.

As of the fiscal year ended January 3, 2021 the carrying amount was approximately 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 October 3, 2021 are as follows:

(Dollars in Millions)		Cost Basis	Fair Value
Due within one year	$	18,895	18,895
Due after one year through five years		16	16
Due after five years through ten years		—	—
Total debt securities	$	18,911	18,911

Financial Instruments not measured at Fair Value:
The following financial liabilities are held at carrying amount on the consolidated balance sheet as of October 3, 2021:

(Dollars in Millions)	Carrying Amount	Estimated Fair Value
Financial Liabilities		
Current Debt	$ 3,798	3,808
Non-Current Debt		
6.73% Debentures due 2023	250	285
3.375% Notes due 2023	802	857
2.05% Notes due 2023	499	511
0.650% Notes due 2024 (750MM Euro 1.1581)	867	889
5.50% Notes due 2024 (500 MM GBP 1.3465)	671	769
2.625% Notes due 2025	749	794
0.55% Notes due 2025	993	982
2.45% Notes due 2026	1,995	2,119
2.95% Notes due 2027	989	1,078
0.95% Notes due 2027	1,489	1,464
2.90% Notes due 2028	1,495	1,622
1.150% Notes due 2028 (750MM Euro 1.1581)	863	932
6.95% Notes due 2029	297	414
1.30% Notes due 2030	1,733	1,678
4.95% Debentures due 2033	498	647
4.375% Notes due 2033	855	1,059
1.650% Notes due 2035 (1.5B Euro 1.1581)	1,723	1,963
3.55% Notes due 2036	980	1,134
5.95% Notes due 2037	993	1,439
3.625% Notes due 2037	1,481	1,721
3.40% Notes due 2038	992	1,122
5.85% Debentures due 2038	696	1,013
4.50% Debentures due 2040	540	693
2.10% Notes due 2040	979	933
4.85% Notes due 2041	297	393
4.50% Notes due 2043	496	640
3.70% Notes due 2046	1,975	2,319
3.75% Notes due 2047	974	1,157
3.50% Notes due 2048	743	860
2.25% Notes due 2050	986	928
2.45% Notes due 2060	1,225	1,150
Other	5	6
Total Non-Current Debt	$ 30,130	33,571

The weighted average effective interest rate on non-current debt is 2.98%.

The excess of the estimated fair value over the carrying value of debt was $5.4 billion at January 3, 2021.

The current debt balance as of October 3, 2021 includes $1.3 billion of commercial paper which has a weighted average interest rate of 0.08% and a weighted average maturity of approximately three months.

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 nine months of 2021 and 2020 were 10.0% and 12.6%, respectively.
In the second fiscal quarter of 2021, the Company reorganized the ownership structure of certain wholly-owned international subsidiaries. As part of this reorganization, the Company increased the tax basis of certain assets to fair value in accordance with applicable local regulations. Accordingly, the Company recorded a local deferred tax benefit of approximately $2.3 billion, which was partially offset by a related increase in the U.S. GILTI deferred tax liability of approximately $1.7 billion. The net impact of this restructuring was approximately $0.6 billion net benefit or 3.4% decrease to the 2021 year-to-date effective tax rate.

In 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 can be found in the Company's Annual Report on Form 10-K for the year ended January 3, 2021. During the first fiscal quarter of 2020, the final canton where the Company maintains significant operations enacted TRAF legislation and, accordingly, the Company recorded a 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 increasing the tax basis of certain assets to fair value. As a result, the Company recorded additional deferred tax benefits in the second fiscal quarter of 2020 to recognize this step-up. The total benefit recorded related to Swiss Tax reform in the fiscal nine months of 2020 was approximately $0.4 billion, or 2.7% net benefit to the Company's year-to-date effective tax rate, inclusive of the impact of U.S. GILTI deferred taxes.

Additionally the following items impacted the Company's effective tax rate as compared to the same period in the prior fiscal year:

- as a result of the recent filing of the 2020 U.S. tax return, as well as the impact of non-recurring favorable tax items, the Company recorded a 1.0% net benefit to the effective tax rate for the fiscal nine months of 2021.
- in the third quarter of 2021 the Company accrued additional legal expenses, $1.4 billion for the Talc related litigation at an effective tax rate of 23.5% and $0.8 billion for the Risperdal settlement at an effective tax rate of 16.4% (See note 11 to the Consolidated Financial Statements for more details).
- in the third quarter of 2021 the Company recorded a partial IPR&D charge of $0.9 billion for the Ottava intangible asset (acquired with the Auris Health acquisition in 2019) at an effective rate of 22.4% (See Notes 3 and 9 to the Consolidated Financial Statements for more details).
- in the fiscal nine months of 2020, the Company reduced a contingent consideration liability related to the 2019 Auris Health acquisition that benefited the fiscal nine months of 2020 tax rate by approximately 1.0% (see Note 4 to the Consolidated Financial Statements for more details).
- the Company had lower income in higher tax jurisdictions relative to lower tax jurisdictions as compared to the same period in the prior year.

The Company also generated additional tax benefits from stock-based compensation that were either exercised or vested during the first three fiscal quarters of 2021 and 2020. Additionally the company has reversed unrecognized tax benefit liabilities in 2021 as a result of the completion of tax examinations in certain international jurisdictions.

As of October 3, 2021, the Company had approximately $3.3 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 2012 and is currently auditing tax years 2013 through 2016. In other major jurisdictions where the Company conducts business, the years that remain open to tax audit or are under appeal go back to the year 2008. 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 include the following components:

	Fiscal Third Quarter Ended				Fiscal Nine Months Ended			
	Retirement Plans		Other Benefit Plans		Retirement Plans		Other Benefit Plans	
(Dollars in Millions)	October 3, 2021	September 27, 2020	October 3, 2021	September 27, 2020	October 3, 2021	September 27, 2020	October 3, 2021	September 27, 2020
Service cost	$ 339	330	78	72	1,019	979	232	216
Interest cost	192	238	20	33	578	715	61	99
Expected return on plan assets	(661)	(617)	(1)	(2)	(1,988)	(1,839)	(5)	(5)
Amortization of prior service cost/(credit)	(46)	—	(8)	(7)	(136)	1	(23)	(23)
Recognized actuarial losses	314	224	38	36	944	669	113	107
Curtailments and settlements	—	—	—	—	1	19	—	—
Net periodic benefit cost	$ 138	175	127	132	418	544	378	394

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 nine months ended October 3, 2021, the Company contributed $71 million and $232 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)
January 3, 2021	$ (8,938)	1	(6,957)	652	(15,242)
Net change	(241)	(1)	700	(631)	(173)
October 3, 2021	$ (9,179)	—	(6,257)	21	(15,415)

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:

	Fiscal Third Quarter Ended		Fiscal Nine Months Ended	
(Shares in Millions)	October 3, 2021	September 27, 2020	October 3, 2021	September 27, 2020
Basic net earnings per share	$ 1.39	1.35	6.13	4.93
Average shares outstanding — basic	2,632.6	2,632.5	2,632.2	2,633.0
Potential shares exercisable under stock option plans	138.3	115.7	139.1	120.2
Less: shares which could be repurchased under treasury stock method	(96.0)	(78.9)	(96.7)	(82.4)
Average shares outstanding — diluted	2,674.9	2,669.3	2,674.6	2,670.8
Diluted net earnings per share	$ 1.37	1.33	6.04	4.86

The diluted net earnings per share calculation for the fiscal third quarter ended October 3, 2021 included all shares related to stock options, as the exercise price of all options was less than the average market value of the Company’s stock.

The diluted net earnings per share calculation for the fiscal third quarter ended September 27, 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 nine months ended October 3, 2021 included all shares related to stock options, as the exercise price of all options was less than the average market value of the Company's stock.

The diluted net earnings per share calculation for the fiscal nine months ended September 27, 2020 excluded 17 million 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 Third Quarter Ended			Fiscal Nine Months Ended		
	October 3, 2021	September 27, 2020	Percent Change	October 3, 2021	September 27, 2020	Percent Change
Consumer Health						
OTC						
U.S.	$ 686	601	14.0 %	$ 1,960	1,917	2.2 %
International	686	541	26.9	1,894	1,722	10.0
Worldwide	1,372	1,142	20.1	3,854	3,639	5.9
Skin Health/Beauty						
U.S.	569	572	(0.5)	1,862	1,767	5.4
International	555	577	(3.8)	1,595	1,506	5.9
Worldwide	1,124	1,149	(2.2)	3,457	3,273	5.6
Oral Care						
U.S.	150	164	(8.4)	478	510	(6.2)
International	248	248	0.1	762	694	9.9
Worldwide	398	412	(3.3)	1,240	1,204	3.0
Baby Care						
U.S.	95	91	5.2	288	279	3.3
International	296	302	(2.0)	879	831	5.8
Worldwide	391	393	(0.3)	1,167	1,110	5.2
Women's Health						
U.S.	3	3	20.1	9	10	(5.7)
International	229	227	0.5	675	654	3.1
Worldwide	232	230	0.8	684	664	3.0
Wound Care/Other						
U.S.	122	125	(2.6)	390	370	5.3
International	61	64	(5.2)	186	175	5.8
Worldwide	182	189	(3.5)	575	545	5.4
TOTAL Consumer Health						
U.S.	1,625	1,556	4.5	4,987	4,853	2.8
International	2,075	1,958	5.9	5,991	5,582	7.3
Worldwide	3,700	3,514	5.3	10,978	10,435	5.2

PHARMACEUTICAL						
Immunology						
U.S.	2,771	2,558	8.3	7,932	7,330	8.2
International	1,480	1,230	20.3	4,464	3,619	23.3
Worldwide	4,250	3,789	12.2	12,395	10,950	13.2
REMICADE®						
U.S.	480	634	(24.3)	1,508	1,852	(18.6)
U.S. Exports	47	78	(40.2)	197	321	(38.7)
International	234	209	12.2	721	673	7.1
Worldwide	761	921	(17.4)	2,426	2,846	(14.8)
SIMPONI / SIMPONI ARIA®						
U.S.	295	312	(5.3)	840	840	0.0
International	276	280	(1.1)	877	827	6.1
Worldwide	571	592	(3.3)	1,717	1,667	3.0
STELARA®						
U.S.	1,569	1,313	19.5	4,396	3,668	19.9
International	809	634	27.7	2,404	1,795	33.9
Worldwide	2,378	1,947	22.2	6,800	5,463	24.5
TREMFYA®						
U.S.	376	222	69.7	975	650	50.1
International	161	105	52.5	459	316	45.4
Worldwide	537	327	64.1	1,434	965	48.5
OTHER IMMUNOLOGY						
U.S.	3	—	*	15	—	*
International	0	3	*	3	9	(68.6)
Worldwide	3	3	(26.4)	18	9	91.6
Infectious Diseases						
U.S.	679	413	64.3	1,635	1,265	29.2
International	709	451	57.2	1,788	1,397	28.0
Worldwide	1,389	864	60.6	3,424	2,662	28.6
COVID-19 VACCINE						
U.S.	270	—	*	421	—	*
International	233	—	*	346	—	*
Worldwide	502	—	*	766	—	*
EDURANT® / rilpivirine						
U.S.	12	11	8.4	31	33	(4.8)
International	247	226	9.7	733	684	7.2
Worldwide	259	236	9.6	764	716	6.7
PREZISTA® / PREZCOBIX® / REZOLSTA® / SYMTUZA®						
U.S.	380	379	0.4	1,128	1,154	(2.2)
International	137	147	(7.1)	440	461	(4.6)
Worldwide	517	526	(1.7)	1,568	1,615	(2.9)

OTHER INFECTIOUS DISEASES						
U.S.	18	24	(26.0)	55	79	(29.6)
International	93	78	18.3	270	252	6.9
Worldwide	110	102	7.8	325	331	(1.8)
Neuroscience						
U.S.	835	759	10.2	2,448	2,285	7.2
International	854	846	0.8	2,770	2,565	8.0
Worldwide	1,689	1,605	5.3	5,218	4,850	7.6
CONCERTA® / methylphenidate						
U.S.	35	43	(19.5)	117	150	(22.1)
International	122	107	14.2	372	319	16.4
Worldwide	157	149	4.5	489	469	4.1
INVEGA SUSTENNA® / XEPLION® / INVEGA TRINZA® / TREVICTA®						
U.S.	648	585	11.0	1,882	1,704	10.4
International	355	341	4.3	1,111	983	13.0
Worldwide	1,004	926	8.5	2,994	2,688	11.4
RISPERDAL CONSTA®						
U.S.	71	70	1.3	210	220	(4.7)
International	69	81	(16.7)	242	254	(5.1)
Worldwide	140	152	(8.4)	452	475	(4.9)
OTHER NEUROSCIENCE						
U.S.	81	60	34.7	239	210	13.9
International	307	317	(2.9)	1,045	1,008	3.7
Worldwide	388	377	3.1	1,284	1,218	5.5
Oncology						
U.S.	1,525	1,267	20.3	4,364	3,623	20.4
International	2,140	1,862	14.9	6,406	5,310	20.6
Worldwide	3,665	3,129	17.1	10,770	8,933	20.6
DARZALEX®						
U.S.	841	585	43.7	2,302	1,540	49.5
International	739	514	43.7	2,076	1,397	48.6
Worldwide	1,580	1,099	43.7	4,378	2,937	49.1
ERLEADA®						
U.S.	214	152	40.5	578	407	41.8
International	130	55	*	329	112	*
Worldwide	344	206	66.7	907	519	74.7
IMBRUVICA®						
U.S.	413	450	(8.3)	1,311	1,329	(1.3)
International	654	581	12.6	1,996	1,682	18.7
Worldwide	1,066	1,031	3.5	3,307	3,011	9.9
ZYTIGA® / abiraterone acetate						
U.S.	25	58	(57.0)	96	284	(66.2)
International	523	532	(1.8)	1,653	1,564	5.7
Worldwide	548	590	(7.2)	1,749	1,848	(5.4)

OTHER ONCOLOGY[1]						
U.S.	32	21	49.6	76	63	21.0
International	94	181	(48.0)	352	556	(36.6)
Worldwide	126	203	(37.6)	428	619	(30.7)
Pulmonary Hypertension						
U.S.	610	510	19.7	1,778	1,541	15.4
International	258	239	7.9	821	742	10.7
Worldwide	868	749	15.9	2,599	2,283	13.9
OPSUMIT®						
U.S.	299	244	22.8	861	729	18.2
International	159	148	7.4	510	458	11.3
Worldwide	458	392	17.0	1,371	1,187	15.5
UPTRAVI®						
U.S.	265	226	17.3	792	692	14.6
International	44	34	30.4	135	100	34.6
Worldwide	309	260	19.0	927	792	17.1
OTHER PULMONARY HYPERTENSION						
U.S.	47	40	14.4	125	121	2.8
International	54	57	(4.4)	176	183	(3.7)
Worldwide	101	97	3.4	301	304	(1.1)
Cardiovascular / Metabolism / Other						
U.S.	800	931	(14.0)	2,379	2,574	(7.6)
International	333	351	(5.1)	1,007	1,052	(4.2)
Worldwide	1,133	1,281	(11.5)	3,386	3,625	(6.6)
XARELTO®						
U.S.	636	630	0.8	1,794	1,716	4.5
International	—	—	—	—	—	—
Worldwide	636	630	0.8	1,794	1,716	4.5
INVOKANA® / INVOKAMET®						
U.S.	66	156	(57.4)	249	405	(38.4)
International	67	68	(1.0)	194	173	11.9
Worldwide	133	224	(40.3)	443	578	(23.4)
PROCRIT® / EPREX®						
U.S.	47	69	(30.9)	168	215	(21.7)
International	65	63	3.1	198	208	(4.7)
Worldwide	112	132	(14.6)	366	423	(13.4)
OTHER						
U.S.	51	75	(32.6)	168	238	(29.3)
International	200	219	(8.7)	615	670	(8.3)
Worldwide	251	294	(14.8)	783	908	(13.8)
TOTAL PHARMACEUTICAL						
U.S.	7,221	6,438	12.2	20,536	18,619	10.3
International	5,773	4,980	15.9	17,256	14,685	17.5
Worldwide	12,994	11,418	13.8	37,792	33,304	13.5

MEDICAL DEVICES						
Interventional Solutions						
U.S.	444	399	11.1	1,353	1,019	32.7
International	513	437	17.7	1,599	1,134	41.1
Worldwide	957	836	14.5	2,952	2,153	37.1
Orthopaedics						
U.S.	1,249	1,308	(4.5)	3,821	3,427	11.5
International	843	774	8.8	2,611	2,145	21.7
Worldwide	2,093	2,083	0.5	6,433	5,572	15.4
HIPS						
U.S.	210	221	(5.3)	654	564	15.9
International	146	124	18.8	451	344	31.3
Worldwide	356	345	3.3	1,105	908	21.8
KNEES						
U.S.	184	205	(9.8)	579	527	10.0
International	131	102	28.1	403	298	35.4
Worldwide	316	308	2.8	983	825	19.2
TRAUMA						
U.S.	455	433	5.3	1,352	1,194	13.3
International	260	253	2.4	805	698	15.2
Worldwide	715	685	4.2	2,157	1,892	14.0
SPINE, SPORTS & OTHER						
U.S.	400	449	(11.1)	1,236	1,142	8.2
International	306	295	3.5	952	805	18.2
Worldwide	705	745	(5.3)	2,187	1,947	12.3
Surgery						
U.S.	948	913	3.9	2,881	2,247	28.2
International	1,457	1,239	17.6	4,418	3,556	24.2
Worldwide	2,405	2,152	11.8	7,299	5,803	25.8
ADVANCED						
U.S.	440	421	4.6	1,304	1,079	20.9
International	705	579	21.8	2,126	1,644	29.3
Worldwide	1,144	1,000	14.6	3,430	2,723	26.0
GENERAL						
U.S.	508	492	3.3	1,577	1,168	35.0
International	752	660	13.9	2,292	1,912	19.9
Worldwide	1,261	1,152	9.4	3,869	3,080	25.6
Vision						
U.S.	475	473	0.6	1,414	1,160	21.9
International	714	608	17.4	2,103	1,683	25.0
Worldwide	1,189	1,081	10.1	3,517	2,843	23.7
CONTACT LENSES / OTHER						
U.S.	359	375	(4.3)	1,082	924	17.0
International	522	455	14.9	1,525	1,274	19.8
Worldwide	882	830	6.2	2,607	2,198	18.6

SURGICAL						
U.S.	117	98	19.6	333	236	41.1
International	191	153	24.7	577	409	41.1
Worldwide	308	251	22.7	910	645	41.1
TOTAL MEDICAL DEVICES						
U.S.	3,117	3,092	0.8	9,470	7,852	20.6
International	3,527	3,058	15.4	10,731	8,518	26.0
Worldwide	6,644	6,150	8.0	20,201	16,370	23.4
WORLDWIDE						
U.S.	11,963	11,086	7.9	34,993	31,324	11.7
International	11,375	9,996	13.8	33,978	28,785	18.0
Worldwide	$ 23,338	21,082	10.7 %	$ 68,971	60,109	14.7 %

*Percentage greater than 100% or not meaningful
(1) Inclusive of VELCADE® which was previously disclosed separately

EARNINGS BEFORE PROVISION FOR TAXES BY SEGMENT

	Fiscal Third Quarter Ended			Fiscal Nine Months Ended		
(Dollars in Millions)	October 3, 2021	September 27, 2020	Percent Change	October 3, 2021	September 27, 2020	Percent Change
Consumer Health (1)	$ (636)	191	*	$ 956	993	(3.7)%
Pharmaceutical(2)	4,259	3,439	23.8	13,838	11,787	17.4
Medical Devices(3)	423	1,010	(58.1)	3,798	2,681	41.7
Segment earnings before provision for taxes	4,046	4,640	(12.8)	18,592	15,461	20.3
Less: Expense not allocated to segments (4)	197	239		652	611	
Worldwide income before tax	$ 3,849	4,401	(12.5)%	$ 17,940	14,850	20.8%

*Percentage greater than 100% or not meaningful
(1) Consumer Health

- Includes intangible amortization expense of $0.1 billion in both the fiscal third quarter of 2021 and 2020 and $0.3 billion in both the fiscal nine months of 2021 and 2020.
- Includes litigation expense of $1.4 billion and $0.5 billion in the fiscal third quarter of 2021 and 2020, respectively. Includes litigation expense of $1.5 billion and $1.2 billion in the fiscal nine months of 2021 and 2020, respectively. Litigation expense in both periods is primarily related to talc.
- Includes a restructuring related charge of $0.1 billion in both the fiscal nine months of 2021 and 2020.

(2) Pharmaceutical

- Includes divestiture gains of $0.6 billion in the fiscal nine months of 2021 related to two brands outside the U.S.
- Includes intangible amortization expense of $0.8 billion in both the fiscal third quarter of 2021 and 2020. Includes intangible amortization expense of $2.5 billion and $2.4 billion in the fiscal nine months of 2021 and 2020, respectively.
- Includes net litigation expense of $0.8 billion and $1.0 billion in the fiscal third quarter of 2021 and 2020, respectively. Includes net litigation expense of $0.7 billion and $1.0 billion in the fiscal nine months of 2021 and 2020, respectively. Litigation expense in 2021 is primarily related to Risperdal. Litigation expense in 2020 is related to the opioid settlement.
- Includes a gain on securities of $0.1 billion in the fiscal third quarter of 2021 and $0.2 billion in both the fiscal nine months of 2021 and 2020, respectively.
- Includes a restructuring related charge of $0.1 billion in both the fiscal nine months of 2021 and 2020, respectively.

In fiscal 2020 and 2021, 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 for services to be delivered and contractually obligated to be paid to these contract manufacturing organizations of approximately $1.2 billion are reflected in the prepaid expenses and other, other assets, accrued liabilities and other 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.

[3] Medical Devices

- Includes a contingent consideration reversal of $0.2 billion in the fiscal third quarter of 2020 and $1.1 billion in the fiscal nine months of 2020 related to the timing of certain developmental milestones associated with the Auris Health acquisition.
- Includes a restructuring related charge of $0.1 billion in both the fiscal third quarter of 2021 and 2020, respectively. Includes a restructuring related charge of $0.2 billion in both the fiscal nine months of 2021 and 2020, respectively.
- Includes intangible amortization expense of $0.3 billion and $0.2 billion in the fiscal third quarter of 2021 and 2020, respectively. Includes intangible amortization expense of $0.8 billion and $0.7 billion in the fiscal nine months of 2021 and 2020, respectively.
- Includes a gain on securities of $0.1 billion in the fiscal nine months of 2021.
- Includes an in-process research and development expense of $0.9 billion related to the general surgery offering in digital robotics (Ottava) acquired with the Auris Health acquisition in 2019 in both the fiscal third quarter and fiscal nine months of 2021. See Note 3 to the Consolidated Financial Statements for more details.

[4] Amounts not allocated to segments include interest income/expense and general corporate income/expense.

SALES BY GEOGRAPHIC AREA

	Fiscal Third Quarter Ended			Fiscal Nine Months Ended		
(Dollars in Millions)	October 3, 2021	September 27, 2020	Percent Change	October 3, 2021	September 27, 2020	Percent Change
United States	$ 11,963	11,086	7.9 %	$ 34,993	31,324	11.7 %
Europe	5,587	4,819	15.9	16,669	13,709	21.6
Western Hemisphere, excluding U.S.	1,500	1,296	15.7	4,291	3,931	9.2
Asia-Pacific, Africa	4,288	3,881	10.5	13,018	11,145	16.8
Total	$ 23,338	21,082	10.7 %	$ 68,971	60,109	14.7 %

NOTE 10— ACQUISITIONS AND DIVESTITURES

During the first fiscal quarter of 2021, in separate transactions, the Company divested two brands outside the U.S. within the Pharmaceutical segment. The Company recognized a pre-tax gain recorded in Other (income) expense, net, of approximately $0.6 billion.

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.

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 evolves and in person trials resume.

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 October 3, 2021, 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 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; ability to achieve comprehensive multi-party settlements; complexity of related cross-claims and counterclaims; and/or there are numerous parties involved. To the extent adverse awards, judgments or 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 October 3, 2021, in the United States there were approximately 300 plaintiffs with direct claims in pending lawsuits regarding injuries allegedly due to the DePuy ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System; 5,400 with respect to the PINNACLE® Acetabular Cup System; 10,700 with respect to pelvic meshes; 9,000 with respect to RISPERDAL®; 6,600 with respect to XARELTO®; 38,200 with respect to body powders containing talc; 100 with respect to INVOKANA®; and 4,700 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, thereby 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 the class actions filed in that country. 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 also has 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. In March 2021, the MDL Court entered an order closing the MDL. The MDL Court has remanded 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 seeking damages for alleged injury resulting from Ethicon's pelvic mesh devices 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. 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 issued a decision and entered damages awards to the three Lead Applicants. The Company appealed the decision to the intermediate appellate court, the Full Court. The appeal was heard in February 2021 and, in March 2021, the Full Court entered a judgment dismissing the appeal. An application for special leave to the High Court of Australia was filed in April 2021, and in July 2021, the High Court agreed to hear oral argument on the application, which is scheduled to occur in November 2021. With respect to class members other than the Lead Applicants, the Federal Court will conduct an individual case assessment process that will require proof of use and causally related loss, although the form of that process has not yet been decided. The class actions in Canada were discontinued in 2020 as a result of a settlement of a group of cases and an agreement to resolve the Israeli class action was reached in May 2021, which is subject to court approval. 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. (Ethicon) 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) also has 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., one multi-plaintiff lawsuit pending in Oklahoma state court and lawsuits pending outside the United States. In May 2021, Ethicon and lead counsel for the plaintiffs entered into a term sheet to resolve approximately 3,600 Physiomesh cases (covering approximately 4,300 plaintiffs) pending in the MDL and MCL at that time. A master settlement agreement was entered into in September 2021. All deadlines and trial settings in those proceedings are currently stayed pending the completion of the settlement agreement. The costs associated with this proposed settlement are reflected in the Company’s accruals.

Claims have also been filed against Ethicon and Johnson & Johnson alleging personal injuries arising from the PROCEED® Mesh and PROCEED® Ventral Patch hernia mesh products. In March 2019, the New Jersey Supreme Court entered an order consolidating these cases pending in New Jersey 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. Discovery is underway in the MCL proceedings.

Ethicon and Johnson & Johnson also have been subject to claims for personal injuries arising from the PROLENE™ Polypropylene Hernia System (PHS). In January 2020, New Jersey Supreme Court created an MCL in Atlantic County Superior Court to handle such cases. Cases involving this product have also been filed in other federal and state courts in the United States.

The Company has established accruals with respect to product liability litigation associated with ETHICON PHYSIOMESH® Flexible Composite Mesh, PROCEED® Mesh and PROCEED® Ventral Patch, and PROLENE™ Polypropylene Hernia System products.

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 primarily have been 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 verdict in October 2019 of $8.0 billion of punitive damages related to one plaintiff, which the trial judge reduced to $6.8 million in January 2020. In September 2021, the Company entered into a settlement in principle with the counsel representing plaintiffs in this matter and in substantially all of the outstanding cases in the United States. The costs associated with this and other 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; 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 were 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 Johnson & Johnson announced an agreement in principle to 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.

A significant number of personal injury claims alleging that talc causes cancer were 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 these personal injury lawsuits, filed in state and federal courts in the United States as well as outside of the United States, continued to increase through, and including, October 2021.

In talc cases that previously have gone to trial, the Company has obtained a number of defense verdicts, but there also have been verdicts against the Company, many of which have been reversed on appeal. In June 2020, the Missouri Court of Appeals reversed in part and affirmed in part a July 2018 verdict of $4.7 billion in *Ingham v. Johnson & Johnson, et al.,* No. ED 207476 (Mo. App.), reducing the overall award to $2.1 billion. An application for transfer of the case to the Missouri Supreme Court was subsequently denied and in June 2021, a petition for certiorari, seeking a review of the *Ingham* decision by the United States Supreme Court was denied. In June 2021, the Company paid the award, which, including interest, totaled approximately $2.5 billion. The facts and circumstances, including the terms of the award, were unique to the *Ingham* decision and not representative of other claims brought against the Company. The Company continues to believe that it has strong legal grounds to contest the other talc 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.

In October 2021, Johnson & Johnson Consumer Inc. (Old JJCI) implemented a corporate restructuring (the 2021 Corporate Restructuring). As a result of that restructuring, Old JJCI ceased to exist and three new entities were created: (a) LTL Management LLC, a North Carolina limited liability company (LTL or Debtor), (b) Royalty A&M LLC, a North Carolina limited liability company and a direct subsidiary of LTL (RAM); and (c) the Debtor's direct parent, Johnson & Johnson Consumer Inc., a New Jersey company (New JJCI). The Debtor received certain of Old JJCI's assets and became solely responsible for the talc-related liabilities of Old JJCI, including all liabilities related in any way to injury or damage, or alleged injury or damage, sustained or incurred in the purchase or use of, or exposure to, talc, including talc contained in any product, or to the risk of, or responsibility for, any such damage or injury, except for any liabilities for which the exclusive remedy is provided under a workers' compensation statute or act (the Talc-Related Liabilities).

In October 2021, notwithstanding the Company's confidence in the safety of its talc products, the Debtor filed a voluntary petition with the United States Bankruptcy Court for the Western District of North Carolina, Charlotte Division, seeking relief under chapter 11 of the Bankruptcy Code (the LTL Bankruptcy Filing). As a result of the LTL Bankruptcy Filing, the Court entered a temporary restraining order staying all litigation against LTL and Old JJCI. Further hearings on whether a permanent restraining order staying all litigation against those entities, as well other entities, such as Johnson & Johnson, its affiliates, and certain other third parties, are scheduled in November 2021. The Company has agreed to provide funding to LTL for the payment of amounts the Bankruptcy Court determines are owed by LTL through the establishment of a $2 billion trust in furtherance of this purpose. The Company has established a reserve for approximately $2 billion in connection with the aforementioned trust, resulting in an incremental $1.4 billion litigation charge. Subsequent to the fiscal third quarter, the

Company has de-consolidated LTL as a result of the bankruptcy filing. The impact of the de-consolidation is not material to the Company.

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 under chapter 11 of title 11 of the United States Code (the Bankruptcy Code) in the United States Bankruptcy Court for the District of Delaware (Imerys Bankruptcy). The Imerys Bankruptcy relates to Imerys's potential liability for personal injury from exposure to talcum powder sold by Imerys (Talc Claims). In its bankruptcy, Imerys alleges it has claims against the Company for indemnification and rights to joint insurance proceeds. During the bankruptcy, the Company proposed to resolve Imerys's (and the Company's) obligations arising out of Talc Claims involving the Company's products by agreeing to assume the defense of litigation of all such Talc Claims, 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. Imerys rejected that proposal. In May 2020, Imerys, its parent Imerys S.A., the Tort Claimants' Committee (TCC), and the Future Claimants' Representative (FCR) (collectively, the Plan Proponents) filed their Plan of Reorganization (the Plan) and the Disclosure Statement related thereto. The Plan Proponents have since filed numerous amendments to the Plan and Disclosure Statement. A hearing on the Plan Proponent's Disclosure Statement was held in January 2021, and the Court entered an order approving the Disclosure Statement, allowing Imerys to proceed with soliciting votes on the Plan. In March 2021, the Company voted to reject the Plan and opted out of the consensual releases in the Plan. In April 2021, the Plan Proponents announced the Plan had received the requisite number of accepting votes to confirm the Plan. In October 2021, the Bankruptcy Court issued a ruling deeming almost 16,000 votes in favor of the Plan as withdrawn, based upon evidence that no due diligence had been done by the plaintiff's counsel to ascertain whether the votes were cast on behalf of individuals who used the Company's products. The Bankruptcy Court also ruled that more than 1,500 votes cast by another firm should count as rejecting instead of accepting. In October 2021, Imerys filed a notice on the docket cancelling the confirmation hearing on its Plan that was scheduled to begin in November 2021.

In July 2021, Imerys commenced an adversary proceeding against the Company in the Imerys Bankruptcy (the Imerys adversary proceeding). The Imerys adversary proceeding sought, among other things, certain declarations with respect to the indemnification obligations allegedly owed by the Company to Imerys. The TCC and FCR simultaneously filed a motion for temporary restraining order and preliminary injunction seeking to enjoin the Company from undergoing a corporate restructuring that would separate the Company's talc liabilities from its other assets. The bankruptcy court denied the motion. The Company thereafter filed a motion to dismiss the adversary proceeding. The Bankruptcy Court has not yet decided the motion to dismiss. In October 2021, the Company filed a Notice of Bankruptcy Filing and Stay of Proceedings clarifying that the automatic stay arising upon the LTL Bankruptcy Filing should apply to the Imerys adversary proceeding.

In June 2020, Cyprus Mines Corporation and its parent (together, Cyprus), which had owned certain Imerys talc mines, filed an adversary proceeding against the Company and Imerys in the Imerys Bankruptcy seeking a declaration of indemnity rights under certain contractual agreements (the Cyprus adversary proceeding). The Company denies such indemnification is owed, and filed a motion to dismiss the adversary complaint. In February 2021, Cyprus filed a voluntary petition for relief under chapter 11 of the Bankruptcy Code and filed its Disclosure Statement and Plan. The Plan contemplates a settlement with Imerys and talc claimants where Cyprus would make a monetary contribution to a trust established under the Imerys Plan in exchange for an injunction against Talc Claims asserted against it. Cyprus has not yet sought approval of its Disclosure Statement and Plan. In October 2021, the Company filed a Notice of Bankruptcy Filing and Stay of Proceedings clarifying that the automatic stay arising upon the LTL Bankruptcy Filing should apply to the Cyprus adversary proceeding.

In February 2021, several of the Company's insurers involved in coverage litigation in New Jersey State Court (the Coverage Action) filed a motion in the Imerys Bankruptcy Court proceeding seeking a determination that the automatic stay does not apply to the Coverage Action and, in the alternative, seeking relief from the automatic stay to allow them to continue to litigate their claims in the Coverage Action. In March 2021, the Company filed a limited response and reservation of rights with respect to the motion. The Court entered an agreed order modifying the stay to allow the litigation in the Coverage Action to continue. In October 2021, LTL filed a Notice of Bankruptcy Filing and Stay of Proceedings clarifying that the automatic stay arising upon the LTL Bankruptcy Filing should apply to the Coverage Action.

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. Plaintiff is 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. In April 2021 briefing on Plaintiffs' motion for class certification was completed. Discovery is ongoing.

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*. 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 and demanding that suit be brought against certain Directors. Four of the shareholders who sent demands are plaintiffs in the *In re Johnson & Johnson Talc Stockholder Derivative Litigation*. 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 October 2020, the shareholders filed a consolidated complaint, and in January 2021, Johnson & Johnson moved to dismiss the consolidated complaint. In March 2021, Plaintiffs filed a motion for discovery. The Court temporarily terminated Johnson & Johnson's motion to dismiss pending a decision on Plaintiff's motion for discovery. In October 2021, the Court requested supplemental briefing on Plaintiff's motion for discovery.

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. In June 2020, Plaintiffs filed an amended complaint, and in July 2020, Defendants moved to dismiss the amended complaint. As of October 2020, briefing on Defendants' motion was complete. In February 2021, the Court granted Defendants' motion, and granted Plaintiffs leave to amend. In April 2021, Plaintiffs informed the Court that they did not intend to file an amended complaint, and the Court dismissed the case with prejudice. In May 2021, Plaintiffs filed a notice of appeal with the Third Circuit. In July 2021, Plaintiffs filed their opening brief in the Third Circuit and in September 2021, Defendants filed their response brief. In October 2021, Plaintiffs filed their reply brief.

A lawsuit was brought against the Company in the Superior Court of California for the County of San Diego alleging violations of California's Consumer Legal Remedies Act (CLRA) 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. Plaintiffs filed a Fifth Amended Complaint in August 2020. The Company moved to dismiss the Fifth Amended Complaint for failure to state a claim upon which relief may be granted. In January 2021, the Court issued an Order and opinion ruling in the Company's favor and granting the motion to dismiss with prejudice. In February 2021, Plaintiffs filed a Notice of Appeal with the Ninth Circuit. In October 2021, a Notice of Suggestion of Bankruptcy was filed with the Ninth Circuit.

In addition, the Company has received preliminary inquiries and subpoenas to produce documents regarding talc matters from Senator Murray, a member of the Senate Committee on Health, Education, Labor and Pensions, the Department of Justice and the U.S. Congressional Subcommittee on Economic and Consumer Policy. The Company produced documents as required in response and will continue to cooperate with government inquiries.

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. In December 2016, lawsuits filed in federal courts in the United States were 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.

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 ELMIRON®, a prescription medication indicated for the relief of bladder pain or discomfort associated with interstitial cystitis. These lawsuits, which allege that ELMIRON® contributes to the development of permanent retinal injury and vision loss, have been filed in both state and federal courts across the United States. In December 2020, lawsuits filed in federal courts in the United States, including putative class action cases seeking medical monitoring, were organized as a multi-district litigation in the United States District Court for the District of New Jersey. Cases also have been filed in various state courts. In addition, three 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 established accruals for defense costs associated with ELMIRON® related product liability litigation.

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. Significant matters are described below.

Medical Devices

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. 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 began in October 2021, and shortly thereafter, the parties reached an agreement to settle the case. Plaintiff's motion to dismiss with prejudice was filed in October 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 (collectively, Ethicon) 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 ('296) and 7,033,603 ('603) 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. In August 2021, the parties entered into a settlement agreement, and the case was dismissed.

In August 2018, Intuitive Surgical, Inc. and Intuitive Surgical Operations, Inc. (collectively, 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); 6,491,701 ('701); 6,522,906 ('906); 6,800,056 ('056); 8,142,447 ('447); 8,620,473 ('473); 8,801,601 ('601); and 9,452,276 ('276) based on Auris' Monarch™ Platform. Auris filed IPR Petitions with the U.S. Patent and Trademark Office (USPTO) regarding the '200, '056, '601 '701, '447, '276 and '906 patents. Intuitive subsequently dropped the '200, '473 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. In December 2020, the USPTO declared all of the challenged claims in the '601 patent to be invalid. Intuitive has appealed that decision. In March 2021, the USPTO ruled that the challenged claims of the '447 and '906 patents are not invalid. Auris has appealed that decision. Trial is scheduled to begin in January 2023.

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., and Precision Spine, Inc. A stay that had been entered pending Inter Partes Review at the U.S. Patent & Trademark Office has been lifted, and trial is scheduled to begin in December 2022.

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. In October 2020, the Court dismissed Medical Device Business Services, Inc. from the case but otherwise denied the motion. In June 2021, Osteoplastics admitted that the PROPLAN CMF® Virtual Surgical Planning Services do not infringe any asserted patents. Trial is scheduled for October 2022.

Pharmaceutical

Litigation Against Filers of Abbreviated New Drug Applications (ANDAs)

The following summarizes lawsuits the Company's subsidiaries have brought against generic companies that have filed 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 Company's 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 generic 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, the Company's 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 Inter Partes Review (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®

Beginning in January 2019, Janssen Inc. and Janssen Oncology Inc. (collectively, Janssen) initiated Statements of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations in Canada against Apotex Inc. (Apotex), Pharmascience Inc. (Pharmascience) and Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, DRL) in response to those parties' filing of Abbreviated New Drug Submissions (ANDS) seeking approval to market generic versions of ZYTIGA® before the expiration of the Canadian Patent No. 2,661,422 ('422). The trial in these actions concluded in November 2020, and the Court issued a decision holding the '422 patent invalid in January 2021. In February 2021, Janssen appealed the decision.

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®

In March 2021, Janssen Pharmaceuticals, Inc. (JPI) and Bayer Pharma AG and Bayer AG (collectively, Bayer) filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Lupin Limited and Lupin Pharmaceuticals, Inc. which filed an ANDA seeking approval to market a generic version of XARELTO® before expiration of U.S. Patent No. 10,828,310 ('310).

In April 2021, JPI and Bayer filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Accord Healthcare Inc., Accord Healthcare Limited, and Intas Pharmaceuticals Limited which filed an ANDA seeking approval to market a generic version of XARELTO® before expiration of the '310 patent. In July 2021, the parties entered into a confidential settlement agreement, and the action was dismissed.

In May 2021, JPI and Bayer filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. which filed an ANDA seeking approval to market a generic version of XARELTO® before expiration of the '310 patent.

In July 2021, JPI and Bayer filed a patent infringement lawsuit 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) which filed an ANDA seeking approval to market a generic version of XARELTO® before expiration of the ’310 patent.

In July 2021, JPI and Bayer filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. which filed an ANDA seeking approval to market a generic version of XARELTO® before expiration of the ’310 patent. In August 2021, the court entered a joint stipulation dismissing Teva Pharmaceutical Industries Ltd.

In July 2021, JPI and Bayer filed a patent infringement lawsuit in the United States District Court for the Northern District of West Virginia against Mylan Pharmaceuticals Inc. and Mylan Inc. which filed an ANDA seeking approval to market a generic version of XARELTO® before expiration of the ’310 patent.

In each of these lawsuits, JPI and Bayer are seeking an order enjoining defendants from marketing their generic version of XARELTO® before the expiration of the ’310 patent.

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 that 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 (’582) and/or 8,513,202 (’202) relating to INVOKANA®, INVOKAMET® and/or INVOKAMET® XR. Janssen is the exclusive licensee of the asserted patents. Named defendants include MSN Laboratories Private Ltd. and MSN Pharmaceuticals, Inc. (MSN); Zydus Pharmaceuticals (USA) Inc. (Zydus). These cases were consolidated into one action (Polymorph Main Action).

In July 2017, Janssen and MTPC filed a patent infringement lawsuit in the United States District Court for the District of New Jersey against Zydus which filed ANDAs seeking approval to market generic versions of INVOKANA® and INVOKAMET® before expiration of MTPC’s United States Patent No. 7,943,788 (’788), 8,222,219 (’219) and/or 8,785,403 (’403) relating to INVOKANA® and INVOKAMET® (Compounds Main Action). Janssen is the exclusive licensee of the asserted patents. Trial concluded in October 2020. The Court issued a decision holding that the patents are not invalid and would be infringed by Zydus’ generic products. Zydus has appealed the decision. In July 2021, Janssen and Zydus entered into a confidential settlement.

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, which 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, which filed ANDAs seeking approval to market generic versions of INVOKANA® and INVOKAMET XR® before expiration of the ’788 patent. In July 2021, Janssen and MSN entered into a confidential settlement and the lawsuits were dismissed.

In October 2019, Janssen and MTPC initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Dr. Reddy’s Laboratories, Inc. and Dr. Reddy’s Laboratories Ltd (DRL), who filed an ANDA seeking approval to market a generic version of INVOKAMET® before expiration of the ’788 patent. In January 2021, Janssen and MTPC filed a patent infringement lawsuit in the United States District Court for the District of New Jersey against Macleods Pharmaceuticals, Ltd. and Macleods Pharma USA, Inc. (Macleods), which 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 February 2021, Janssen filed a patent infringement lawsuit in the United States District Court for the District of New Jersey against Macleods Pharmaceuticals, Ltd. and Macleods Pharma USA, Inc. (Macleods), which filed an ANDA seeking approval to market a generic version of INVOKANA® before expiration of United States Patent No. 10,617,668 (’668) relating to INVOKANA®. In September 2021, Janssen and MTPC dismissed the lawsuit against Macleods relating to the ’668 patent. These lawsuits have not been consolidated with the Polymorph Main Action or Compound Main Action.

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

In October 2020, Janssen Inc., Janssen Pharmaceutica NV and MTPC 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 ANDS seeking approval to market a generic version of INVOKANA® before the expiration of the Canadian Patent Nos. 2,799,204, 2,534,024 and 2,671,357. Janssen Inc., Janssen Pharmaceutica NV and MTPC are seeking an

order enjoining Sandoz from marketing its generic version of INVOKANA® before the expiration of the relevant patents. The trial is scheduled to begin in August 2022.

OPSUMIT®

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 ANDS seeking approval to market a generic version of OPSUMIT® 10 mg, before the expiration of Canadian Patent No. 2,659,770 ('770). Trial is scheduled to begin in January 2022.

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. Trial is scheduled to begin in February 2022.

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 ('273). Trial is scheduled to begin in April 2022.

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 relevant patents.

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), which filed an ANDA seeking approval to market a generic version of INVEGA SUSTENNA® before the expiration of United States Patent No. 9,439,906 ('906). Trial concluded in October 2020. In October 2021, the court issued a decision in Janssen's favor.

In August 2019, Janssen initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Mylan Laboratories Limited (Mylan), which filed an ANDA seeking approval to market a generic version of INVEGA SUSTENNA® before the expiration of the '906 patent.

In December 2019, 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), which filed an ANDA seeking approval to market a generic version of INVEGA SUSTENNA® before the expiration of the '906 patent.

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

In February 2018, Janssen Inc. and Janssen Pharmaceutica NV (collectively, Janssen Canada) initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Teva Canada Limited (Teva Canada) in response to Teva's filing of an ANDS seeking approval to market a generic version of INVEGA SUSTENNA® before the expiration of Canadian Patent Nos. 2,309,629 ('629) and 2,655,335 ('335). 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 Canada's generic version of INVEGA SUSTENNA®, if approved, would infringe certain claims of the '335 patent and that the claims of the '335 patent are not invalid for obviousness. Teva Canada appealed.

In November 2020, Janssen Canada initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Pharmascience Inc. in response to Pharmascience Inc.'s filing of an ANDS seeking approval to market a generic version of INVEGA SUSTENNA® before the expiration of the '335 patent. A summary trial on the issue of infringement is scheduled for November 2021. The trial is scheduled to begin in July 2022.

In January 2021, Janssen Canada initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Apotex Inc. (Apotex) in response to Apotex's filing of an ANDS seeking approval to market a generic version of INVEGA SUSTENNA® before the expiration of the '335 patent. A summary trial on the issue of infringement is scheduled for December 2021. The trial is scheduled to begin in September 2022.

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

INVEGA TRINZA®

In September 2020, Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica NV, and Janssen Research & Development, LCC (collectively, Janssen) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Mylan Laboratories Limited, Mylan Pharmaceuticals Inc., and Mylan Institutional LLC (collectively, Mylan). Mylan filed an ANDA seeking approval to market generic versions of INVEGA TRINZA® (546 mg) before expiration of United States Patent No. 10,143,693 ('693) relating to INVEGA TRINZA® (546 mg). Janssen is seeking an order enjoining Mylan from marketing a generic version of INVEGA TRINZA® before the expiration of the '693 patent. Trial is scheduled to begin in October 2022.

In August 2021, Janssen initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Mylan. Mylan filed an ANDA seeking approval to market generic versions of INVEGA TRINZA® (819 mg) before expiration of the '693 patent. Janssen is seeking an order enjoining Mylan from marketing a generic version of INVEGA TRINZA® (819 mg) before the expiration of the '693 patent.

In October 2021, Janssen initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Mylan. Mylan filed an ANDA seeking approval to market generic versions of INVEGA TRINZA® (273 mg and 410 mg) before expiration of the '693 patent. Janssen is seeking an order enjoining Mylan from marketing a generic version of INVEGA TRINZA® (273 mg and 410 mg) before the expiration of the '693 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 that 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: Sandoz Inc. and Lek Pharmaceuticals d.d. (collectively, Sandoz). In January 2019 and February 2019, Pharmacyclics and JBI amended their complaint against Sandoz to allege infringement of United States Patent Nos. 10,125,140 and 10,106,548. In August 2019, Pharmacyclics and JBI amended their complaint against Sandoz to further allege infringement of U.S. Patent Nos. 10,294,231 and 10,294,232.

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. (collectively, Alvogen), which 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 June 2019, Pharmacyclics and JBI amended their complaint against Alvogen to further allege infringement of United States Patent No. 10,213,386. Pharmacyclics and JBI are seeking an order enjoining the defendants from marketing generic versions of IMBRUVICA® before the expiration of the relevant patents.

Trial in the foregoing actions against Sandoz and Alvogen took place in October 2020. In May 2021, JBI, Pharmacyclics and Sandoz entered into a confidential settlement agreement. In August 2021, the District Court issued a decision in favor of Pharmacyclics and Janssen finding the asserted claims against Alvogen to be infringed and not invalid. Alvogen has appealed that decision.

In September 2021, Pharmacyclics and Janssen Inc. (Janssen Canada) initiated Statements of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Natco Pharma (Canada) Inc. (Natco) in response to Natco's filing of two ANDSs seeking approval to market generic versions of IMBRUVICA® capsules before the expiration of Canadian Patent Nos. 2,663,116; 2,928,721; 2,800,913; 3,007,787; 3,007,788, 2,875,986; and 3,022,256. The trial is scheduled to begin in July 2023. Pharmacyclics and Janssen are seeking an order enjoining Natco from marketing its generic versions of IMBRUVICA® before the expiration of the relevant patents.

UPTRAVI®

In April 2020, Actelion Pharmaceuticals Ltd (Actelion) and Nippon Shinyaku Co., Ltd. (Nippon Shinyaku) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Zydus Pharmaceuticals (USA),

Inc. and Zydus Worldwide DMCC (collectively, Zydus), who filed an ANDA seeking approval to market a generic version of UPTRAVI® before expiration of Nippon Shinyaku's United States Patent Nos. 7,205,302 ('302); 8,791,122 ('122); and 9,284,280 ('280) relating to UPTRAVI®. In January 2021, the court entered a joint stipulation dismissing the claims against Zydus related to the '122 and '280 patents. Actelion is the exclusive licensee of the '302 patent.

Actelion and Nippon Shinyaku are seeking an order enjoining Zydus from marketing a generic version of UPTRAVI® before the expiration of the '302 patent.

GOVERNMENT PROCEEDINGS

Like other companies in the pharmaceutical, consumer health 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. Such regulation has been the basis of government investigations and litigations. 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 approximately 3,300 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 manufacturers, including Johnson & Johnson and JPI, have been filed by the state Attorneys General in Arkansas, Florida, Idaho, Illinois, Kentucky, Louisiana, Mississippi, Missouri, Nevada, 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 approximately 390 cases pending in various state courts. There are over 2,900 federal cases coordinated in a federal Multi-District Litigation (MDL) pending in the U.S. District Court for the Northern District of Ohio. In addition, the Province of British Columbia filed suit against Johnson & Johnson and its Canadian affiliate Janssen Inc., and many other industry members, in Canada, and is seeking to have that action certified as an opt in class action on behalf of other provincial/territorial and the federal governments in Canada. Additional proposed class actions have been filed in Canada against Johnson & Johnson and Janssen Inc., and many other industry members, by and on behalf of people who used opioids (for personal injuries), municipalities and First Nations bands. 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 $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. In April 2021, three California counties and the City of Oakland commenced a trial in California state court against Johnson & Johnson and JPI, and other affiliates, as well as three other pharmaceutical manufacturers. The trial concluded in October 2021 and the parties are awaiting a ruling.

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. In September 2020, the Company learned that NYDFS filed a statement of charges related to this investigation.

In June 2021, the Company and JPI announced a settlement agreement with the State of New York and its participating subdivisions, including Nassau County and Suffolk County, resolving their opioid-related claims against the Company on terms consistent with the Company's previously announced agreement in principle to contribute up to $5 billion to all-in settlement of opioid-related claims by states, cities, counties, and tribal governments. The settlement provides New York and its participating subdivisions with up to $263 million to address opioid-related issues, reimburses attorney fees and costs, and removes the Company and Janssen from a multi-defendant trial of opioid-related claims that commenced in Suffolk County in June 2021. In exchange, the Company and JPI receive releases from the claims asserted by New York and the participating parties, including NYDFS.

In October 2021, the Company and JPI announced a settlement agreement with the State of Texas and its participating subdivisions, including Dallas County, Bexar County, and Tarrant County, resolving their opioid-related claims against the Company on terms consistent with the Company's previously announced agreement to contribute up to $5 billion to all-in settlement of opioid-related claims by states, cities, counties, and tribal governments. The settlement provides Texas and its participating subdivisions with up to $297 million to address opioid-related issues and reimburse attorney fees and costs, and removes the Company and Janssen from multi-defendant bellwether trials of opioid-related claims scheduled to commence in Texas state courts in early 2022. In exchange, the Company and JPI will receive releases from the claims asserted by Texas and the participating subdivisions.

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 matters. In October 2020, the Company agreed to contribute up to an additional $1 billion to an all-in settlement amount that would resolve opioid lawsuits filed and future claims by states, cities, counties and tribal governments, for a total of $5 billion which has been accrued, subject to various conditions and an agreement being finalized. This agreement in principle is not an admission of liability or wrong-doing. In July 2021, the Company announced that the terms of the agreement to settle the state and subdivision claims have been finalized and up to 25% of the all-in settlement is expected to be paid within the next 12 months, depending upon the level of participation by the states and their subdivisions. The terms provide a period of time for states to elect to participate in the agreement and, thereafter, a period for the subdivisions of the participating states to opt-in. The opt-in period expires in January 2022. The Company retains the right to opt-out of the agreement if, in its sole discretion, there is insufficient participation.

From June 2017 through December 2019, the Company's Board of Directors received a series of shareholder demand letters alleging breaches of fiduciary duties related to the marketing of opioids. The Board retained independent counsel to investigate the allegations in the demands, and in April 2020, independent counsel delivered a report to the Board recommending that the Company reject the shareholder demands and take the steps that are necessary or appropriate to secure dismissal of related derivative litigation. The Board unanimously adopted the recommendations of the independent counsel's report.

In November 2019, one of the shareholders who sent a demand 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 May 2020, the shareholder filed an amended complaint challenging the

Board's rejection of his demand. In August 2020, Johnson & Johnson moved to dismiss the amended complaint. In February 2021, the Court held oral argument on Johnson & Johnson's motion. In August 2020, another shareholder who sent a demand filed a separate derivative complaint in the same court making similar allegations. In October 2020, the Court granted defendants' request to reassign the second-filed case to the division where the first-filed case is pending.

In December 2019, two additional shareholders who sent demands 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*. In July 2020, the shareholders filed a consolidated complaint. In September 2020, Johnson & Johnson moved to dismiss the consolidated complaint, and in December 2020, the shareholders opposed Johnson & Johnson's motion. Johnson & Johnson filed its reply in February 2021. In July 2020, an additional shareholder who sent a demand filed a derivative complaint in the same federal court making similar allegations against the same defendants named in the consolidated action. In January 2021, pursuant to an order in the consolidated action, the third case was consolidated into the consolidated action. In February 2021, the Court granted the shareholders motion to voluntarily dismiss the consolidated action without prejudice, and the shareholders' counsel then filed a notice of association in the first-filed derivative action pending in the Superior Court of New Jersey.

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 concerning the hip devices. 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, and the District Court has not yet closed the fact discovery time period. In March 2021, DePuy filed its motion to strike and dismiss the relators' second amended complaint; the District Court denied DePuy's motion to strike and dismiss on July 6, 2021. DePuy filed a motion for reconsideration of the District Court's July 6, 2021 ruling. On August 18, 2021, the District Court stated that it was reviewing DePuy's motion for reconsideration, and on September 16, 2021, in connection with the District Court's review of the motion for reconsideration, the District Court ordered the parties to file additional submissions by September 30, 2021, which are now under review by the District Court.

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. 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. In April 2020, the Court in California denied the Company's motion for a new trial. In August 2020, the Court entered judgment with respect to the penalties of $344 million, but denied the Attorney General's request for injunctive relief. The Company is appealing the penalty judgment. In April 2020, the Company settled the West Virginia case. In October 2020, the Company settled with the Attorney General of Oregon. In November 2020, the Company settled with the Attorney General of Mississippi.

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 Mississippi Supreme Court granted Johnson & Johnson and JJCI's request to file an interlocutory appeal of the denial of the motion for summary judgment in late 2019. Johnson & Johnson and JJCI moved for summary judgment on the grounds that the State's claim was barred by preemption. In April 2021, the Mississippi Supreme Court dismissed the Company's interlocutory appeal and remanded the case back to the Hinds County Chancery Court. Discovery is now proceeding in that court. In August 2021, Johnson & Johnson and JJCI filed a Petition for Writ of Certiorari in the US Supreme Court.

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 moved to dismiss certain of the claims in the Amended Complaint, which was granted. The Company then filed a motion for partial judgment on the pleadings in December 2020, which was denied. The Company made its first document production in February 2021 and discovery is ongoing.

Forty-two 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. Five states have issued Civil Investigative Demands seeking documents and other information. The Company has produced documents to Arizona, North Carolina, Texas, and Washington. The Company has entered into a tolling agreement with thirty-three States, which is set to expire in November 2021.

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. The Company has provided documents in response to the demand.

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. Summary judgment and Daubert motions are currently pending with the Court.

In March 2017, Janssen Biotech, Inc. (JBI) 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 United States Department of Justice notified JBI 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 filed a motion to dismiss, which was granted in part and denied in part. Discovery is underway.

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. The Company has provided documents in response to the subpoenas.

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.(DePuy) 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 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. The Company continues to 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 March 2018, a purported class action was filed in the Circuit Court Third Judicial District Madison County, Illinois against 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. The complaint seeks damages but does not allege personal injury. In August 2021, the Court granted JJCI's motion to dismiss the complaint.

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. Discovery and pre-trial motion practice are complete. Trial is scheduled to begin in March 2022.

Beginning in September 2017, multiple purported class actions were filed on behalf of indirect purchasers of REMICADE® against Johnson & Johnson and Janssen Biotech, Inc. (collectively, Janssen) alleging that Janssen has violated federal antitrust laws through its contracting strategies for REMICADE®. The cases were consolidated for pre-trial purposes as *In re REMICADE® Antitrust Litigation* in United States District Court for the Eastern District of Pennsylvania. The consolidated complaint seeks damages and injunctive relief. Discovery is ongoing.

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. Discovery is ongoing.

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 in United States District Court for the District of Columbia, 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 July 2020, the District Court dismissed the complaint. In January 2021, plaintiffs appealed the District Court's decision to the United States Court of Appeals for the District of Columbia Circuit.

In October 2018, two separate putative class actions were filed against Actelion Pharmaceutical Ltd., Actelion Pharmaceuticals U.S., 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 required by the Food and Drug Administration, 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. In April 2021, the United States Court of Appeals for the Fourth Circuit reversed and remanded. Discovery is ongoing.

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 February 2021, the judge has set a renewed schedule for the Company's motion to dismiss, with briefs to be fully submitted by early July 2021. In April 2021, Janssen renewed its motion to dismiss pursuant to Court order.

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 (collectively, Janssen) 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. A consolidated amended complaint was filed in February 2021. In April 2021, Janssen moved to dismiss the Indirect Purchaser Action. Discovery in the Indirect Purchaser Action is ongoing. 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 April 2021, Janssen moved to compel arbitration of the Direct Purchaser Action. In October 2021, the Court granted Janssen's motion and compelled arbitration of the Direct Purchaser Action.

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. Defendants moved to dismiss the amended complaint. In July 2020, the Court granted in part and denied in part the renewed motion to dismiss. Discovery is ongoing.

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 August 2020, the Court granted in part and denied in part BWI's motion to dismiss. Discovery is ongoing.

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.

In October 2020, Fortis Advisors LLC (Fortis), in its capacity as representative of the former stockholders of Auris Health Inc. (Auris), filed a complaint against Johnson & Johnson, Ethicon Inc., and certain named officers and employees (collectively, Ethicon) in the Court of Chancery of the State of Delaware. The complaint alleges breach of contract, fraud, and other causes of action against Ethicon in connection with Ethicon's acquisition of Auris in 2019. The complaint seeks damages and other relief. In December 2020, Ethicon moved to dismiss certain causes of action in the complaint. Discovery is ongoing.

Beginning in May 2021, multiple putative class actions were filed in state and federal courts (California, Florida, New York, and New Jersey) against various Johnson & Johnson entities alleging violations of state consumer fraud statutes based on nondisclosure of alleged benzene contamination of certain Neutrogena and Aveeno sunscreen products and the affirmative promotion of those products as "safe"; and, in at least one case, alleging a strict liability manufacturing defect and failure to warn claims, asserting that the named plaintiffs suffered unspecified injuries as a result of alleged exposure to benzene. The Judicial Panel on Multi-District Litigation has consolidated all pending actions, except one product liability matter, in the United States District Court-Southern District of Florida-Fort Lauderdale Division. In October 2021, the Company reached an agreement in principle for the settlement of a nationwide class, encompassing the claims of the consolidated actions, subject to approval by the Florida federal Court.

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

In the fiscal second quarter of 2018 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. In the fiscal third quarter of 2021, the Company recorded a pre-tax charge of $121 million, which is included on the following lines of the Consolidated Statement of Earnings, $60 million in restructuring, $18 million in cost of products sold and $43 million in other (income) expense, net. In the fiscal nine months of 2021, the Company recorded a pre-tax charge of $333 million, which is included on the following lines of the Consolidated Statement of Earnings, $169 million in restructuring, $65 million in cost of products sold and $99 million in other (income) expense, net. Total project costs of approximately $1.6 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 fiscal third quarter of 2021:

(Dollars in Millions)		Severance	Asset Write-offs	Other[2]	Total
Reserve balance, January 3, 2021	$	135	—	9	144
Current year activity:					
Charges		—	38	295	333
Cash payments		(17)	—	(270)	(287)
Settled non cash		—	(38)		(38)
Reserve balance, October 3, 2021[1]	$	118	—	34	152

[1] Cash outlays for severance are expected to be substantially paid out over the next 18 months 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.

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

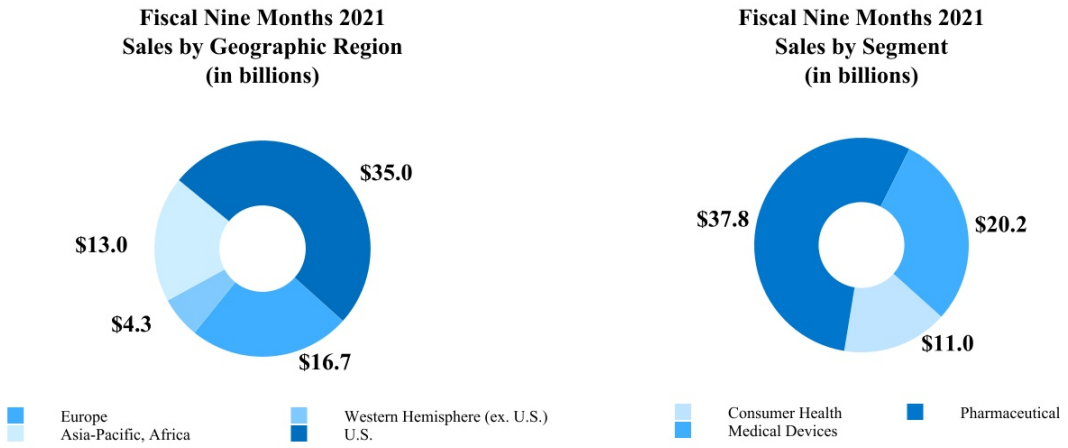
RESULTS OF OPERATIONS

Sales to Customers

Analysis of Consolidated Sales
For the fiscal nine months of 2021, worldwide sales were $69.0 billion, a total increase of 14.7%, including an operational increase of 12.4% as compared to 2020 fiscal nine months sales of $60.1 billion. Currency fluctuations had a positive impact of 2.3% for the fiscal nine months of 2021. In the fiscal nine months of 2021, the net impact of acquisitions and divestitures on worldwide operational sales growth was a negative 0.7%.

Sales by U.S. companies were $35.0 billion in the fiscal nine months of 2021, which represented an increase of 11.7% as compared to the prior year. In the fiscal nine months of 2021, the net impact of acquisitions and divestitures on the U.S. operational sales growth was a negative 0.1%. Sales by international companies were $34.0 billion, an increase of 18.0%, including an operational increase of 13.1%, and a positive currency impact of 4.9% as compared to the fiscal nine months sales of 2020. In the fiscal nine months of 2021, the net impact of acquisitions and divestitures on the international operational sales growth was a negative 1.3%.

In the fiscal nine months of 2021, sales by companies in Europe achieved growth of 21.6%, which included an operational increase of 15.3% and a positive currency impact of 6.3%. Sales by companies in the Western Hemisphere, excluding the U.S., achieved growth of 9.2%, which included an operational increase of 8.1%, and a positive currency impact of 1.1%. Sales by companies in the Asia-Pacific, Africa region achieved growth of 16.8%, including an operational increase of 12.3% and a positive currency impact of 4.5%.

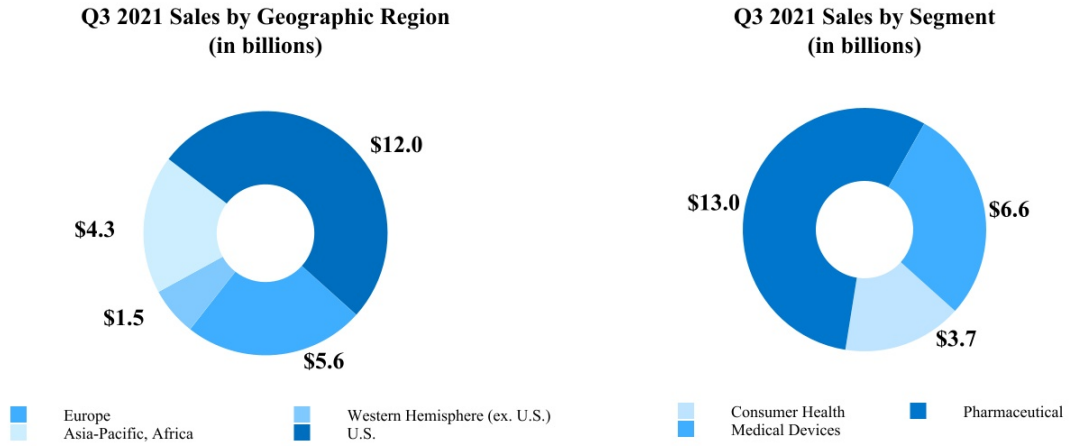


Note: values may have been rounded

For the fiscal third quarter of 2021, worldwide sales were $23.3 billion, a total increase of 10.7%, which included operational growth of 9.9% and a positive currency impact of 0.8% as compared to 2020 fiscal third quarter sales of $21.1 billion. In the fiscal third quarter of 2021, the net impact of acquisitions and divestitures on worldwide operational sales growth was a negative 0.7%.

Sales by U.S. companies were $12.0 billion in the fiscal third quarter of 2021, which represented an increase of 7.9% as compared to the prior year. In the fiscal third quarter of 2021, the net impact of acquisitions and divestitures on the U.S. operational sales growth was a negative 0.1%. Sales by international companies were $11.4 billion, a total increase of 13.8%, which included operational growth of 12.1% and a positive currency impact of 1.7%. In the fiscal third quarter of 2021, the net impact of acquisitions and divestitures on the international operational sales growth was a negative 1.4%.

In the fiscal third quarter of 2021, sales by companies in Europe achieved growth of 15.9%, which included operational growth of 14.6% and a positive currency impact of 1.3%. Sales by companies in the Western Hemisphere, excluding the U.S., achieved growth of 15.7%, including operational growth of 13.4% and a positive currency impact of 2.3%. Sales by companies in the Asia-Pacific, Africa region achieved growth 10.5%, including operational growth of 8.5% and a positive currency impact of 2.0%.



Note: values may have been rounded

Analysis of Sales by Business Segments

Consumer Health
Consumer Health segment sales in the fiscal nine months of 2021 were $11.0 billion, an increase of 5.2% as compared to the same period a year ago, including operational growth of 3.1% and a positive currency impact of 2.1%. U.S. Consumer Health segment sales increased by 2.8%. International Consumer Health segment sales increased by 7.3%, including operational growth of 3.5% and a positive currency impact of 3.8%. In the fiscal nine months of 2021, the net impact of acquisitions and divestitures on the Consumer Health segment operational sales growth was a negative 1.0%.

Major Consumer Health Franchise Sales — Fiscal Nine Months Ended

(Dollars in Millions)	October 3, 2021	September 27, 2020	Total Change	Operations Change	Currency Change
OTC	$ 3,854	$ 3,639	5.9 %	3.0 %	2.9 %
Skin Health/Beauty	3,457	3,273	5.6	3.9	1.7
Oral Care	1,240	1,204	3.0	0.8	2.2
Baby Care	1,167	1,110	5.2	4.3	0.9
Women's Health	684	664	3.0	2.1	0.9
Wound Care/Other	575	545	5.4	3.6	1.8
Total Consumer Health Sales	**$ 10,978**	**$ 10,435**	**5.2 %**	**3.1 %**	**2.1 %**

Consumer Health segment sales in the fiscal third quarter of 2021 were $3.7 billion, an increase of 5.3% as compared to the same period a year ago, including operational growth of 4.1% and a positive currency impact of 1.2%. U.S. Consumer Health segment sales increased by 4.5%. International Consumer Health segment sales increased by 5.9% including operational growth of 3.7% and a positive currency impact of 2.2%. In the fiscal third quarter of 2021, the net impact of acquisitions and divestitures on the Consumer Health segment operational sales growth was a negative 1.6% primarily due to the DR. CI:LABO - Sedona divestiture in Asia Pacific.

Major Consumer Health Franchise Sales — Fiscal Third Quarter Ended

(Dollars in Millions)	October 3, 2021	September 27, 2020	Total Change	Operations Change	Currency Change
OTC	$ 1,372	$ 1,142	20.1 %	18.2 %	1.9 %
Skin Health/Beauty	1,124	1,149	(2.2)	(3.0)	0.8
Oral Care	398	412	(3.3)	(4.5)	1.2
Baby Care	391	393	(0.3)	(1.2)	0.9
Women's Health	232	230	0.8	0.8	0.0
Wound Care/Other	182	189	(3.5)	(4.8)	1.3
Total Consumer Health Sales	**$ 3,700**	**$ 3,514**	**5.3 %**	**4.1 %**	**1.2 %**

The OTC franchise achieved operational growth of 18.2% as compared to the prior year fiscal third quarter. Growth was driven by Analgesics, TYLENOL® and MOTRIN®, digestive health and the hydration benefit offering (ORSL).

The Skin Health/Beauty franchise experienced an operational decline of 3.0% as compared to the prior year fiscal third quarter. The decline was driven by the DR. CI:LABO - Sedona divestiture in Asia Pacific, U.S. external supply constraints and the aerosol sunscreen voluntary recall partially offset by worldwide COVID-19 recovery and e-commerce growth as well as strong growth outside the U.S. of AVEENO® and NEUTROGENA®.

The Oral Care franchise experienced an operational decline of 4.5% as compared to the prior year fiscal third quarter. The decline was primarily driven by divestitures and U.S. external supply constraints partially offset by market growth in the U.S. along with strong performance in Asia Pacific due to successful brand building and promotional campaigns.

The Baby Care franchise experienced an operational decline of 1.2% as compared to the prior year fiscal third quarter. The decline was driven by COVID-19 related lockdowns in parts of Asia Pacific coupled with competitive pressures in that region partially offset by worldwide AVEENO® Baby strength.

The Women's Health franchise achieved operational growth of 0.8% as compared to the prior year fiscal third quarter primarily driven by COVID-19 market recovery and favorable price in Latin America partially offset by disruptions in Europe due to flooding.
The Wound Care/Other franchise experienced an operational decline of 4.8% as compared to the prior year fiscal third quarter primarily driven by competitive pressures outside the U.S. and impacts from prior year stocking partially offset by U.S. category growth.

Pharmaceutical

Pharmaceutical segment sales in the fiscal nine months of 2021 were $37.8 billion, an increase of 13.5% as compared to the same period a year ago, with an operational increase of 11.3% and a positive currency impact of 2.2%. U.S. Pharmaceutical sales increased 10.3% as compared to the same period a year ago. International Pharmaceutical sales increased by 17.5%, including operational growth of 12.5% and a positive currency impact of 5.0%. In the fiscal nine months of 2021, the net impact of acquisitions and divestitures on the Pharmaceutical segment operational sales growth was a negative 0.5%.

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

(Dollars in Millions)	October 3, 2021	September 27, 2020	Total Change	Operations Change	Currency Change
Immunology	**$ 12,395**	**$ 10,950**	**13.2 %**	**11.3 %**	**1.9 %**
REMICADE®	2,426	2,846	(14.8)	(16.1)	1.3
SIMPONI®/ SIMPONI ARIA®	1,717	1,667	3.0	1.4	1.6
STELARA®	6,800	5,463	24.5	22.4	2.1
TREMFYA®	1,434	965	48.5	46.1	2.4
Other Immunology	18	9	91.6	89.5	2.1
Infectious Diseases	**3,424**	**2,662**	**28.6**	**26.1**	**2.5**
COVID-19 VACCINE	766	—	*	*	—
EDURANT®/rilpivirine	764	716	6.7	1.4	5.3
PREZISTA®/ PREZCOBIX®/ REZOLSTA®/ SYMTUZA®	1,568	1,615	(2.9)	(4.1)	1.2
Other Infectious Diseases	325	331	(1.8)	(5.0)	3.2
Neuroscience	**5,218**	**4,850**	**7.6**	**5.5**	**2.1**
CONCERTA®/methylphenidate	489	469	4.1	0.8	3.3
INVEGA SUSTENNA®/ XEPLION®/ INVEGA TRINZA®/ TREVICTA®	2,994	2,688	11.4	9.4	2.0
RISPERDAL CONSTA®	452	475	(4.9)	(6.6)	1.7
Other Neuroscience	1,284	1,218	5.5	3.6	1.9
Oncology	**10,770**	**8,933**	**20.6**	**17.4**	**3.2**
DARZALEX®	4,378	2,937	49.1	46.0	3.1
ERLEADA®	907	519	74.7	72.2	2.5
IMBRUVICA®	3,307	3,011	9.9	6.7	3.2
ZYTIGA®/ abiraterone acetate	1,749	1,848	(5.4)	(9.4)	4.0
Other Oncology[(1)]	428	619	(30.7)	(32.4)	1.7
Pulmonary Hypertension	**2,599**	**2,283**	**13.9**	**12.7**	**1.2**
OPSUMIT®	1,371	1,187	15.5	14.1	1.4
UPTRAVI®	927	792	17.1	16.2	0.9
Other Pulmonary Hypertension	301	304	(1.1)	(1.9)	0.8
Cardiovascular / Metabolism / Other	**3,386**	**3,625**	**(6.6)**	**(8.1)**	**1.5**
XARELTO®	1,794	1,716	4.5	4.5	—
INVOKANA®/ INVOKAMET®	443	578	(23.4)	(25.2)	1.8
PROCRIT®/EPREX®	366	423	(13.4)	(15.8)	2.4
Other	783	908	(13.8)	(17.3)	3.5
Total Pharmaceutical Sales	**$ 37,792**	**$ 33,304**	**13.5 %**	**11.3 %**	**2.2 %**

* Percentage greater than 100% or not meaningful

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

(1) Inclusive of VELCADE® which was previously disclosed separately

Pharmaceutical segment sales in the fiscal third quarter of 2021 were $13.0 billion, an increase of 13.8% as compared to the same period a year ago, including an operational increase of 13.2% and a positive currency impact of 0.6%. U.S. Pharmaceutical sales increased 12.2% as compared to the same period a year ago. International Pharmaceutical sales increased by 15.9%, including operational growth of 14.6% and a positive currency impact of 1.3%. In the fiscal third quarter of 2021, the net impact of acquisitions and divestitures on the Pharmaceutical segment operational sales growth was a negative 0.6%. Adjustments to previous sales reserve estimates were approximately $0.2 billion in both fiscal third quarters of 2021 and 2020.

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

(Dollars in Millions)	October 3, 2021	September 27, 2020	Total Change	Operations Change	Currency Change
Immunology	**$ 4,250**	**$ 3,789**	**12.2 %**	**11.7 %**	**0.5 %**
REMICADE®	761	921	(17.4)	(18.3)	0.9
SIMPONI®/ SIMPONI ARIA®	571	592	(3.3)	(3.1)	(0.2)
STELARA®	2,378	1,947	22.2	21.7	0.5
TREMFYA®	537	327	64.1	63.5	0.6
Other Immunology	3	3	(26.4)	(27.5)	1.1
Infectious Diseases	**1,389**	**864**	**60.6**	**59.8**	**0.8**
COVID-19 VACCINE	502	—	*	*	—
EDURANT®/rilpivirine	259	236	9.6	8.6	1.0
PREZISTA®/ PREZCOBIX®/ REZOLSTA®/ SYMTUZA®	517	526	(1.7)	(2.2)	0.5
Other Infectious Diseases	110	102	7.8	5.4	2.4
Neuroscience	**1,689**	**1,605**	**5.3**	**4.6**	**0.7**
CONCERTA®/ methylphenidate	157	149	4.5	3.3	1.2
INVEGA SUSTENNA®/ XEPLION®/ INVEGA TRINZA®/ TREVICTA®	1,004	926	8.5	8.1	0.4
RISPERDAL CONSTA®	140	152	(8.4)	(8.0)	(0.4)
Other Neuroscience	388	377	3.1	1.5	1.6
Oncology	**3,665**	**3,129**	**17.1**	**16.5**	**0.6**
DARZALEX®	1,580	1,099	43.7	42.9	0.8
ERLEADA®	344	206	66.7	65.8	0.9
IMBRUVICA®	1,066	1,031	3.5	2.5	1.0
ZYTIGA®/ abiraterone acetate	548	590	(7.2)	(7.5)	0.3
Other Oncology[(1)]	126	203	(37.6)	(36.9)	(0.7)
Pulmonary Hypertension	**868**	**749**	**15.9**	**16.1**	**(0.2)**
OPSUMIT®	458	392	17.0	17.1	(0.1)
UPTRAVI®	309	260	19.0	18.8	0.2
Other Pulmonary Hypertension	101	97	3.4	4.8	(1.4)
Cardiovascular / Metabolism / Other	**1,133**	**1,281**	**(11.5)**	**(12.4)**	**0.9**
XARELTO®	636	630	0.8	0.8	—
INVOKANA®/ INVOKAMET®	133	224	(40.3)	(41.3)	1.0
PROCRIT®/ EPREX®	112	132	(14.6)	(15.8)	1.2
Other	251	294	(14.8)	(17.2)	2.4
Total Pharmaceutical Sales	**$ 12,994**	**$ 11,418**	**13.8 %**	**13.2 %**	**0.6 %**

* Percentage greater than 100% or not meaningful
**Certain prior year amounts have been reclassified to conform to current year presentation
[(1)] Inclusive of VELCADE® which was previously disclosed separately

Immunology products achieved operational growth of 11.7% as compared to the same period a year ago driven by continued strong uptake of STELARA® (ustekinumab) in Crohn's disease and Ulcerative Colitis, strength of TREMFYA® (guselkumab) in Psoriasis and uptake in Psoriatic Arthritis and market and share gains in SIMPONI ARIA®. This was partially offset by lower sales of REMICADE® (infliximab) due to biosimilar competition.

Biosimilar versions of REMICADE® have been introduced in the United States and certain markets outside the United States and additional competitors continue to enter the market. Continued infliximab biosimilar competition will result in a further reduction in sales of REMICADE®.

Infectious disease products achieved operational growth of 59.8% as compared to the same period a year ago. Growth was primarily driven by the contribution of the COVID-19 vaccine. This was partially offset by lower sales of PREZISTA® and PREZCOBIX®/REZOLSTA® (darunavir/cobicistat) due to increased competition and loss of exclusivity of PREZISTA® in certain countries outside the U.S.

Neuroscience products achieved operational sales growth of 4.6% as compared to the same period a year ago. Growth of Paliperidone long-acting injectables INVEGA SUSTENNA®/XEPLION® (paliperidone palmitate) and INVEGA TRINZA®/TREVICTA® was due to increased new patient starts and persistence of treatment.
Oncology products achieved operational sales growth of 16.5% as compared to the same period a year ago. Contributors to the growth were strong sales of DARZALEX® (daratumumab) driven by continued strong market growth, share gains in all regions and solid uptake of the subcutaneous formulation launched in 2020; the continued global launch uptake of ERLEADA® (apalutamide) and IMBRUVICA® (ibrutinib) growth primarily driven by market and continued share leadership. The growth of IMBRUVICA® (ibrutinib) was partially offset by COVID-19 related market dynamics including delays in new patient starts as well as competitive pressures from novel oral agents.

Pulmonary Hypertension achieved operational sales growth of 16.1% as compared to the same period a year ago. Sales growth of OPSUMIT® (macitentan) and UPTRAVI® (selexipag) were due to continued share gains and market growth.

Cardiovascular / Metabolism / Other products experienced an operational decline of 12.4% as compared to the same period a year ago. The decline was primarily attributable to lower sales of INVOKANA®/INVOKAMET® (canagliflozin) due to competitive pressures and PROCRIT®/ EPREX® (epoetin alfa) due to biosimilar competition.

Medical Devices

The Medical Devices segment sales in the fiscal nine months of 2021 were $20.2 billion, an increase of 23.4% as compared to the same period a year ago, with an operational increase of 20.5% and a positive currency impact of 2.9%. U.S. Medical Devices sales increased 20.6%. International Medical Devices sales increased by 26.0%, including an operational increase of 20.5% and a positive currency impact of 5.5%. In the fiscal nine months of 2021, the net impact of acquisitions and divestitures on the Medical Devices segment operational sales growth was a negative 0.9% primarily due to the divestiture of the Advanced Sterilization Products (ASP) business.

Major Medical Devices Franchise Sales — Fiscal Nine Months Ended

(Dollars in Millions)	October 3, 2021	September 27, 2020	Total Change	Operations Change	Currency Change
Surgery	**$ 7,299**	**$ 5,803**	**25.8 %**	**22.2 %**	**3.6 %**
Advanced	3,430	2,723	26.0	22.2	3.8
General	3,869	3,080	25.6	22.3	3.3
Orthopaedics	**6,433**	**5,572**	**15.4**	**13.0**	**2.4**
Hips	1,105	908	21.8	19.0	2.8
Knees	983	825	19.2	16.6	2.6
Trauma	2,157	1,892	14.0	11.9	2.1
Spine, Sports & Other	2,187	1,947	12.3	9.7	2.6
Vision	**3,517**	**2,843**	**23.7**	**22.0**	**1.7**
Contact Lenses/Other	2,607	2,198	18.6	17.2	1.4
Surgical	910	645	41.1	38.3	2.8
Interventional Solutions	**2,952**	**2,153**	**37.1**	**33.6**	**3.5**
Total Medical Devices Sales	**$ 20,201**	**$ 16,370**	**23.4 %**	**20.5 %**	**2.9 %**

The Medical Devices segment sales in the fiscal third quarter of 2021 were $6.6 billion, an increase of 8.0% as compared to the same period a year ago, which included operational growth of 7.0% and a positive currency impact of 1.0%. U.S. Medical Devices sales increased 0.8%. International Medical Devices sales increased by 15.4%, including operational growth of 13.3% and a positive currency impact of 2.1%. In the fiscal third quarter of 2021, the net impact of acquisitions and divestitures on the Medical Devices segment operational sales growth was a negative 0.6% primarily due to the divestiture of the ASP business.

The Company has seen a general recovery in global procedural volumes in the Medical Devices segment as compared to the prior year which had significant negative impacts from COVID-19. This procedural volume recovery is the primary driver of sales and earnings growth in the current quarter as compared to the prior year.

Major Medical Devices Franchise Sales — Fiscal Third Quarter Ended

(Dollars in Millions)	October 3, 2021	September 27, 2020	Total Change	Operations Change	Currency Change
Surgery	**$ 2,405**	**$ 2,152**	**11.8 %**	**10.2 %**	**1.6 %**
Advanced	1,144	1,000	14.6	12.6	2.0
General	1,261	1,152	9.4	8.1	1.3
Orthopaedics	**2,093**	**2,083**	**0.5**	**(0.3)**	**0.8**
Hips	356	345	3.3	2.3	1.0
Knees	316	308	2.8	2.1	0.7
Trauma	715	685	4.2	3.7	0.5
Spine, Sports & Other	705	745	(5.3)	(6.1)	0.8
Vision	**1,189**	**1,081**	**10.1**	**10.0**	**0.1**
Contact Lenses/Other	882	830	6.2	6.4	(0.2)
Surgical	308	251	22.7	22.1	0.6
Interventional Solutions	**957**	**836**	**14.5**	**13.2**	**1.3**
Total Medical Devices Sales	**$ 6,644**	**$ 6,150**	**8.0 %**	**7.0 %**	**1.0 %**

The Surgery franchise achieved operational sales growth of 10.2% as compared to the prior year fiscal third quarter. The operational growth in Advanced Surgery was primarily driven Endocutter, Biosurgery and Energy products attributable to market recovery, market expansion and the success of new products offsetting competitive pressures in the U.S. The operational growth in General Surgery was primarily driven by market recovery and the continued strength of the suture portfolio partially offset by the impact of the ASP divestiture in the prior year.

The Orthopaedics franchise experienced an operational decline of 0.3% as compared to the prior year fiscal third quarter. The operational growth in hips reflects the market recovery combined with continued strength of the portfolio including the ACTIS® stem and enabling technologies – KINCISE™ and VELYS™ Hip Navigation. The operational growth in knees was primarily driven by procedure recovery and timing of a tender outside the U.S. The operational growth in Trauma was driven by global market recovery and uptake of new products. The operational decline in Spine, Sports & Other was driven by COVID-19 related impacts on the market partially offset by new products.

The Vision franchise achieved operational sales growth of 10.0% as compared to the prior year fiscal third quarter. The Contact Lenses/Other operational growth was due to market recovery and new products partially offset by prior year higher level of stocking in the U.S. The Surgical operational growth was primarily due to market recovery and uptake of recently launched products.

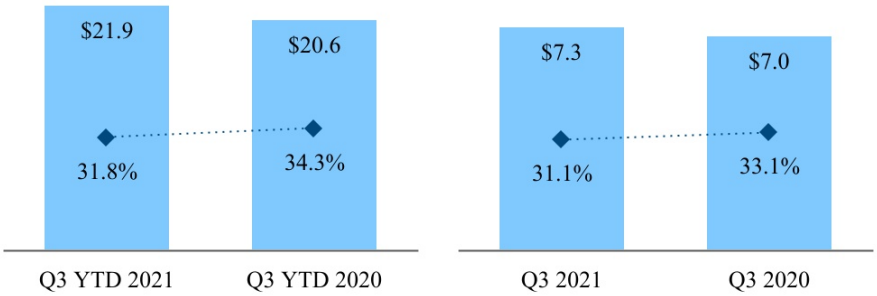
The Interventional Solutions franchise achieved operational sales growth of 13.2% as compared to the prior year fiscal third quarter driven by the market recovery and success of new products and commercial strategies.

ANALYSIS OF CONSOLIDATED EARNINGS BEFORE PROVISION FOR TAXES ON INCOME

Consolidated earnings before provision for taxes on income for the fiscal nine months of 2021 was $17.9 billion representing 26.0% of sales as compared to $14.9 billion in the fiscal nine months of 2020, representing 24.7% of sales.

Consolidated earnings before provision for taxes on income for the fiscal third quarter of 2021 was $3.8 billion representing 16.5% of sales as compared to $4.4 billion in the fiscal third quarter of 2020, representing 20.9% of sales.

Cost of Products Sold



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

Fiscal Nine months Q3 2021 versus Fiscal Nine months Q3 2020
Cost of products sold decreased as a percent to sales driven by:

- Non-recurring prior year COVID-19 production related slow downs and related inventory impacts
- Fixed cost deleveraging in the Medical Devices business in the fiscal 2020

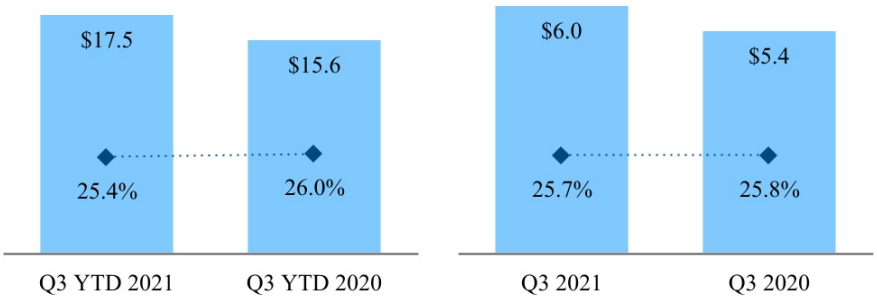
The intangible asset amortization expense included in cost of products sold for the fiscal nine months of 2021 and 2020 was $3.6 billion and $3.4 billion, respectively.

Q3 2021 versus Q3 2020
Cost of products decreased as a percent to sales driven by:

- Non-recurring prior year COVID-19 production related slow-downs and related inventory impacts
- Fixed cost deleveraging in the Medical Devices business in the fiscal 2020
- Favorable mix within the Pharmaceutical business as well as at the enterprise level with a higher percentage of sales coming from the Pharmaceutical business

The intangible asset amortization expense included in cost of products sold for the fiscal third quarters of 2021 and 2020 was $1.1 billion and $1.2 billion, respectively.

Selling, Marketing and Administrative Expenses



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

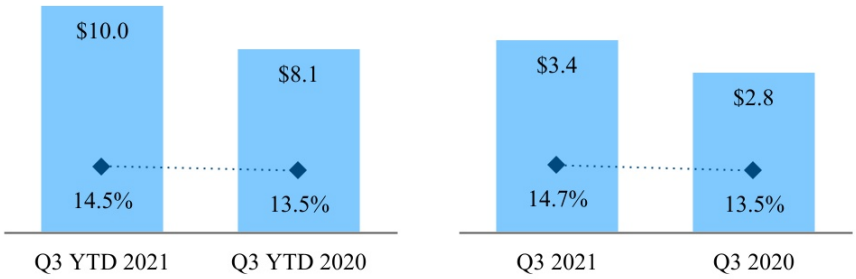
Fiscal Nine months Q3 2021 versus Fiscal Nine months Q3 2020
Selling, Marketing and Administrative Expenses decreased as a percent to sales driven by:

- Leveraging in the Medical Devices business resulting from the recovery of sales from the prior years impact of COVID-19 partially offset by:
- Segment mix with a higher percentage of sales coming from the Medical Devices business in the current year

Q3 2021 versus Q3 2020
Selling, Marketing and Administrative Expenses slightly decreased as a percent to sales driven by:

- Leveraging in the Medical Devices business resulting from the recovery of sales from the prior years impact of COVID-19
- Segment 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 Nine months Q3 2021 versus Fiscal Nine months Q3 2020
Research and Development increased as a percent to sales driven by:

- COVID-19 vaccine expenses, net of governmental reimbursements
- Portfolio progression in the Pharmaceutical business

partially offset by:

- Recovery of Medical Devices sales from the prior year's negative COVID-19 impact

Q3 2021 versus Q3 2020
Research and Development increased as a percent to sales driven by:

- Portfolio progression in the Pharmaceutical business

In-Process Research and Development (IPR&D)

In the fiscal third quarter and fiscal nine months of 2021, the Company recorded a partial IPR&D charge of $0.9 billion primarily related to expected development delays in the general surgery digital robotics platform (Ottava) acquired with the Auris Health acquisition in 2019. The impairment charge was calculated based on revisions to the discounted cash flow valuation model reflecting a delay of first in human procedures of approximately two years from the initial acquisition model assumption of the second half of 2022. The Company will continue to monitor the remaining $1.5 billion Ottava platform intangible asset as development program activities continue.

Interest (Income) Expense

Interest (Income) Expense in the fiscal nine months of 2021 was a net interest expense of $83 million as compared to net interest expense of $16 million in the same period a year ago primarily due to reduced interest income. Interest (Income) Expense in the fiscal third quarter of 2021 was a net interest expense of $7 million as compared to $32 million in the same period a year ago primarily due to the benefit from net investment hedging. The balance of cash, cash equivalents and current marketable securities was $31.0 billion at the end of the fiscal third quarter of 2021 as compared to $30.8 billion at the end of the fiscal third quarter of 2020. The Company's debt position was $33.9 billion as of October 3, 2021 as compared to $37.8 billion the same period a year ago.

Other (Income) Expense, Net*

Fiscal Nine months Q3 2021 versus Fiscal Nine months Q3 2020

Other (income) expense, net for the fiscal nine months of 2021 was flat as compared to the prior year primarily due to the following:

Fiscal Nine Months *(Dollars in Billions)(Income)/Expense*	2021	2020	Change
Acquisition, Integration and Divestiture Related[1]	$ (0.5)	(1.1)	0.6
Gains on securities	(0.3)	(0.2)	(0.1)
Litigation related[2]	2.1	2.2	(0.1)
Restructuring related	0.1	0.1	0.0
Employee benefit plan related	(0.5)	(0.3)	(0.2)
Other	(0.4)	(0.2)	(0.2)
Total Other (Income) Expense, Net	$ 0.5	0.5	—

Q3 2021 versus Q3 2020

Other (income) expense, net for the fiscal third quarter of 2021 was unfavorable by $0.7 billion as compared to the prior year primarily due to the following:

Fiscal Third Quarter *(Dollars in Billions)(Income)/Expense*	2021	2020	Change
Gains on securities	$ (0.1)	0.0	(0.1)
Litigation related[2]	2.1	1.5	0.6
Employee benefit plan related	(0.2)	(0.1)	(0.1)
Other	0.1	(0.2)	0.3
Total Other (Income) Expense, Net	$ 1.9	$ 1.2	$ 0.7

[1] Primarily related to divestiture gains of two pharmaceutical brands outside the U.S. in the fiscal nine months of 2021. Primarily related to a contingent consideration reversal related to the timing of certain developmental milestones associated with the Auris Health acquisition in the fiscal nine months of 2020.

[2] Primarily related to talc and Risperdal in the fiscal third quarter and fiscal nine months of 2021. Primarily related to talc and the opioid litigation settlement in the fiscal third quarter and fiscal nine months of 2020.

*Other (income) expense, net is the account where the Company records gains and losses related to the sale and write-down of certain investments in equity securities held by Johnson & Johnson Innovation - JJDC, Inc. (JJDC), unrealized gains and losses on investments, gains and losses on divestitures, certain transactional currency gains and losses, acquisition-related costs, litigation accruals and settlements, investment (income)/loss related to employee benefit plans, as well as royalty income.

EARNINGS BEFORE PROVISION FOR TAXES BY SEGMENT

Income before tax by segment of business for the fiscal nine months ended were as follows:

	Income Before Tax		Segment Sales		Percent of Segment Sales	
(Dollars in Millions)	October 3, 2021	September 27, 2020	October 3, 2021	September 27, 2020	October 3, 2021	September 27, 2020
Consumer Health	$ 956	$ 993	$ 10,978	$ 10,435	8.7 %	9.5 %
Pharmaceutical	13,838	11,787	37,792	33,304	36.6	35.4
Medical Devices	3,798	2,681	20,201	16,370	18.8	16.4
Segment earnings before tax	18,592	15,461	68,971	60,109	27.0	25.7
Less: Expenses not allocated to segments[(1)]	652	611				
Worldwide income before tax	$ 17,940	$ 14,850	$ 68,971	$ 60,109	26.0 %	24.7 %

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

The Consumer Health segment income before tax as a percent of sales in the fiscal nine months of 2021 was 8.7% versus 9.5% for the same period a year ago. The decline in the income before tax as a percent of sales in the fiscal nine months of 2021 as compared to the prior year was primarily driven by the following:

- Higher litigation expense, primarily talc ($1.5 billion in 2021 vs. $1.2 billion in 2020)
- Increased brand marketing expense

partially offset by:

- Supply chain efficiencies

The Pharmaceutical segment income before tax as a percent of sales in the fiscal nine months of 2021 was 36.6% versus 35.4% for the same period a year ago. The increase in the income before tax as a percent of sales for the fiscal nine months of 2021 as compared to the prior year was primarily driven by the following:

- Divestiture gains of $0.6 billion related to two pharmaceutical brands outside the U.S. in the fiscal nine months of 2021
- Lower litigation expense ($0.7 billion in 2021 primarily related to Risperdal vs. $1.0 billion in 2020 primarily related to opioid litigation settlement)

partially offset by:

- Research & Development investment in the COVID-19 vaccine net of governmental reimbursements and general portfolio progression

The Medical Devices segment income before tax as a percent of sales in the fiscal nine months of 2021 was 18.8% versus 16.4% for the same period a year ago. The increase in the income before tax as a percent of sales for the fiscal nine months of 2021 was primarily driven by the following:

- Recovery of prior year COVID-19 production related slow downs and related inventory impacts
- Overall expense leveraging resulting from the Medical Devices sales recovery

partially offset by:

- A contingent consideration reversal of approximately $1.1 billion in the fiscal nine months of 2020 related to the timing of certain developmental milestones associated with the Auris Health acquisition
- A higher IPR&D charge of $0.8 billion ($0.9 billion in 2021 related to the general surgery offering in digital robotics (Ottava) acquired with the Auris Health acquisition in 2019)

Income (loss) before tax by segment of business for the fiscal third quarters were as follows:

(Dollars in Millions)	Income Before Tax		Segment Sales		Percent of Segment Sales	
	October 3, 2021	September 27, 2020	October 3, 2021	September 27, 2020	October 3, 2021	September 27, 2020
Consumer Health	$ (636)	$ 191	$ 3,700	$ 3,514	(17.2)%	5.4 %
Pharmaceutical	4,259	3,439	12,994	11,418	32.8	30.1
Medical Devices	423	1,010	6,644	6,150	6.4	16.4
Segment earnings before tax	4,046	4,640	23,338	21,082	17.3	22.0
Less: Expenses not allocated to segments [(1)]	197	239				
Worldwide income before tax	$ 3,849	$ 4,401	$ 23,338	$ 21,082	16.5 %	20.9 %

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

Consumer Health Segment

The Consumer Health segment income/(loss) before tax as a percent of sales in the fiscal third quarter of 2021 was a negative 17.2% versus 5.4% for the same period a year ago. The decrease in the income before tax as a percent of sales in the fiscal third quarter of 2021 as compared to the prior year was primarily driven by the following:

- Higher litigation expense, primarily associated with talc ($1.4 billion in 2021 vs. $0.5 billion in 2020)
- Increased brand marketing expense

partially offset by:

- Supply chain efficiencies

Pharmaceutical Segment

The Pharmaceutical segment income before tax as a percent of sales in the fiscal third quarter of 2021 was 32.8% versus 30.1% for the same period a year ago. The increase in the income before tax as a percent of sales for the fiscal third quarter of 2021 as compared to the prior year was primarily driven by the following:

- Lower litigation expense ($0.8 billion in 2021 primarily related to Risperdal vs. $1.0 billion in 2020 primarily related to opioid litigation settlement)
- Higher gains on securities ($0.1 billion in 2021 vs. $0.0 billion in 2020)

partially offset by:

- Research & Development investment for general portfolio progression

Medical Devices Segment

The Medical Devices segment income before tax as a percent of sales in the fiscal third quarter of 2021 was 6.4% versus 16.4% for the same period a year ago. The decrease in the income before tax as a percent of sales for the fiscal third quarter was primarily driven by the following:

- A higher IPR&D charge of $0.8 billion ($0.9 billion in 2021 related to the general surgery offering in digital robotics (Ottava) acquired with the Auris Health acquisition in 2019)
- A contingent consideration reversal of approximately $0.2 billion in the fiscal third quarter of 2020 related to the timing of certain developmental milestones associated with the Auris Health acquisition

partially offset by:

- Recovery of prior year COVID-19 production related slow downs and related inventory impacts
- Overall expense leveraging resulting from the Medical Devices sales recovery

Restructuring

In the fiscal 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 fiscal third quarter of 2021, the Company recorded a pre-tax charge of $121 million, which is included on the following lines of the Consolidated Statement of Earnings, $60 million in restructuring, $18 million in cost of products sold and $43 million in other (income) expense, net. In the fiscal third quarter of 2020, the Company recorded a pre-tax charge of $130 million, which is included on the following lines of the Consolidated Statement of Earnings, $68 million in restructuring, $32 million in cost of products sold and $30 million in other (income) expense, net. In the fiscal nine months of 2021, the Company recorded a pre-tax charge of $333 million, which is included on the following lines of the Consolidated Statement of Earnings, $169 million in restructuring, $65 million in cost of products sold and $99 million in other (income) expense, net. In the fiscal nine months of 2020, the Company recorded a pre-tax charge of $363 million, which is included on the following lines of the Consolidated Statement of Earnings, $187 million in restructuring, $69 million in cost of products sold and $107 million in other (income) expense, net. Restructuring charges of approximately $1.6 billion have been recorded since the restructuring was announced.

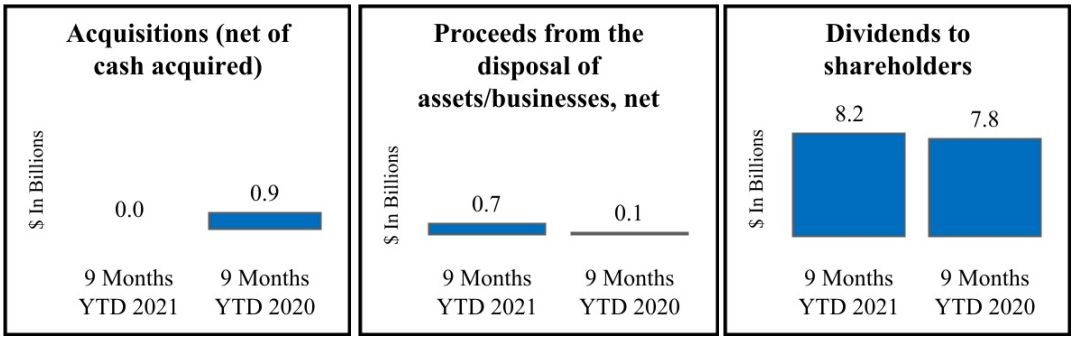
See Note 12 to the Consolidated Financial Statements for additional details related to the restructuring.

Provision for Taxes on Income

For discussion related to the fiscal nine months of 2021 provision for taxes refer to Note 5 to the Consolidated Financial Statements.

In the fiscal second quarter of 2021, the Company reorganized the ownership structure of certain wholly-owned international subsidiaries. As part of this reorganization, the Company increased the tax basis of certain assets to fair value in accordance with applicable local regulations. Accordingly, the Company recorded a local deferred tax benefit of approximately $2.3 billion, which was partially offset by a related increase in the U.S. GILTI deferred tax liability of approximately $1.7 billion. The net impact of this restructuring was approximately $0.6 billion net benefit or a 3.4% decrease to the 2021 year-to-date effective tax rate. This restructuring is not expected to have material impact to the Company's future effective tax rate.

LIQUIDITY AND CAPITAL RESOURCES



Cash Flows

Cash and cash equivalents were $17.6 billion at the end of the fiscal third quarter of 2021 as compared with $14.0 billion at the end of fiscal year 2020. The primary sources and uses of cash that contributed to the $3.6 billion increase were:

(Dollars In Billions)	
$ 14.0	Q4 2020 Cash and cash equivalents balance
17.7	cash generated from operating activities
(3.3)	net cash used by investing activities
(10.6)	net cash used by financing activities
(0.2)	effect of exchange rate and rounding
$ 17.6	Q3 2021 Cash and cash equivalents balance

In addition, the Company had $13.4 billion in marketable securities at the end of the fiscal third quarter of 2021 and $11.2 billion at the end of fiscal year 2020.

Cash flow from operations of $17.7 billion was the result of:

(Dollars In Billions)	
$ 16.1	Net Earnings
4.2	non-cash expenses and other adjustments primarily for depreciation and amortization, stock-based compensation, asset write-downs partially offset by the deferred tax provision, net gain on sale of assets/businesses and credit losses and accounts receivable allowances
(1.9)	a decrease in other current and non-current liabilities
(3.0)	an increase in accounts receivable and inventories
0.2	an increase accounts payable and accrued liabilities
2.1	a decrease in other current and non-current assets
$ 17.7	Cash Flow from operations

Investing activities use of $3.3 billion of cash was primarily used for:

(Dollars In Billions)	
$ (2.2)	additions to property, plant and equipment
0.7	proceeds from the disposal of assets/businesses, net
(2.0)	net purchases of investments
0.7	credit support agreements activity, net
(0.5)	Other (primarily licenses and milestones) and rounding
$ (3.3)	Net cash used for investing activities

Financing activities use of $10.6 billion of cash was primarily used for:

(Dollars In Billions)	
$ (8.2)	dividends to shareholders
(2.5)	repurchase of common stock
(1.0)	net repayment of short and long term debt
0.8	proceeds from stock options exercised/employee withholding tax on stock awards, net
0.2	credit support agreements activity, net
0.1	other and rounding
$ (10.6)	Net cash used for financing activities

The Company has access to substantial sources of funds at numerous banks worldwide. In September 2021, the Company secured a new 364-day Credit Facility. Total credit available to the Company approximates $10 billion, which expires on September 8, 2022. Interest charged on borrowings under the credit line agreement is based on either Term Secured Overnight Financing Rate (SOFR) Reference Rate 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 third quarter of 2021, the Company's notes payable and long-term debt was in excess of cash, cash equivalents and marketable securities. As of October 3, 2021, the net debt position was $2.9 billion as compared to the prior year of $7.0 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 Company's

approximate $1.2 billion in contractual supply commitments associated with its development of the COVID-19 vaccine, the agreement to settle opioid litigation for $5 billion and the establishment of the $2 billion trust for talc related liabilities (See Note 11 to the Consolidated Financial Statements for additional details). 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. Additionally, as a result of the Tax Cuts and Jobs Act (TCJA), the Company has access to its cash outside the U.S. at a significantly reduced cost. During the fiscal third quarter of 2021, in accordance with the terms of the agreement associated with the acquisition of Actelion, the Company's undrawn credit facility with Idorsia was terminated.

During the fiscal nine months of 2021, the Company paid approximately $1.7 billion to the U.S. Treasury which included $0.8 billion related to the current installment due on foreign undistributed earnings as part of the TCJA (see Note 1 to the Consolidated Financial Statements in the Company’s Annual Report on Form 10-K for the fiscal year ended January 3, 2021) and $0.9 billion primarily related to the normal estimated payment for the fiscal first, second and third quarters of 2021.

Dividends

On July 19, 2021, the Board of Directors declared a regular cash dividend of $1.06 per share, payable on September 7, 2021 to shareholders of record as of August 24, 2021.

On October 21, 2021, the Board of Directors declared a regular cash dividend of $1.06 per share, payable on December 7, 2021 to shareholders of record as of November 23, 2021. 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.
- *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 fiscal 2020 and 2021, 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 for services to be delivered and contractually obligated to be paid to these contract manufacturing organizations of approximately $1.2 billion are reflected in the prepaid expenses and other, other assets, accrued liabilities and other 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 Company continues to evaluate and monitor both its internal and external supply arrangements, including its contract with Emergent BioSolutions and related production activities at its Bayview, Maryland facility. The Company has established a

global vaccine supply network, where, in addition to its internal manufacturing site in Leiden, the Netherlands, ten other manufacturing sites will be involved in the production of vaccine across different countries and continents. The Company does not believe that a disruption at a vaccine manufacturing site, or the resulting delay would have a material financial impact on the Company's consolidated financial statements or results.

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". The U.K. officially exited the E.U. on January 31, 2020, however, there was a transition period to allow time to agree the terms of a new trade deal. On December 30, 2020, the U.K., E.U. and the European Atomic Energy Community (Euratom) signed the EU–UK Trade and Cooperation Agreement (TCA). Over the last few years, Brexit has created global political and economic uncertainty and has led to volatility in exchange rates and interest rates, additional cost containment by third-party payors and changes in regulations. While the UK and EU have now agreed on a future trade and cooperation agreement, it is still unclear what the ultimate financial, trade, regulatory and legal implications the withdrawal of the U.K. from the E.U. will have. 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 October 3, 2021, and for the fiscal nine months, the business of the Company's U.K. subsidiaries represented less than 6% of the Company's consolidated assets and less than 3% of the fiscal nine months revenues.

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 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 the resulting lawsuits, generic or biosimilar versions of the products at issue will 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.

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 January 3, 2021.

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.

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 third quarter of 2021. Common stock purchases on the open market are made as part of a systematic plan to meet the needs of the Company's compensation programs. The repurchases below also include the stock-for-stock option exercises that settled in the fiscal third 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
July 5, 2021 through August 1, 2021	—	—		—
August 2, 2021 through August 29, 2021	2,220,897	176.18		—
August 30, 2021 through October 3, 2021	—	—		—
Total	2,220,897			

(1) During the fiscal third quarter of 2021, the Company repurchased an aggregate of 2,220,897 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: October 29, 2021

By /s/ J. J. WOLK

J. J. WOLK

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

Date: October 29, 2021

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 October 3, 2021 (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: October 29, 2021

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 October 3, 2021 (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: October 29, 2021

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 October 3, 2021 (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: October 29, 2021

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 October 3, 2021 (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: October 29, 2021

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.