

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

**FORM 10-Q**

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**Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934  
for the quarterly period ended July 4, 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**

(State or other jurisdiction of  
incorporation or organization)

22-1024240

(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	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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

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

<b>Title of each class</b>	<b>Trading Symbol</b>	<b>Name of each exchange on which registered</b>
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 July 23, 2021, 2,632,482,092 shares of Common Stock, \$1.00 par value, were outstanding.

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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;
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- 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.
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***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.

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## 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)

	July 4, 2021	January 3, 2021
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 14,332	13,985
Marketable securities	10,974	11,200
Accounts receivable, trade, less allowances for doubtful accounts and credit losses \$234 (2020, \$293)	14,871	13,576
Inventories (Note 2)	10,100	9,344
Prepaid expenses and other	3,492	3,132
Total current assets	53,769	51,237
Property, plant and equipment at cost	47,201	46,804
Less: accumulated depreciation	(28,569)	(28,038)
Property, plant and equipment, net	18,632	18,766
Intangible assets, net (Note 3)	50,244	53,402
Goodwill (Note 3)	35,819	36,393
Deferred taxes on income (Note 5)	10,804	8,534
Other assets	7,172	6,562
Total assets	\$ 176,440	174,894
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Loans and notes payable	\$ 3,173	2,631
Accounts payable	8,704	9,505
Accrued liabilities	10,485	13,968
Accrued rebates, returns and promotions	12,450	11,513
Accrued compensation and employee related obligations	2,709	3,484
Accrued taxes on income (Note 5)	1,200	1,392
Total current liabilities	38,721	42,493
Long-term debt (Note 4)	30,310	32,635
Deferred taxes on income (Note 5)	9,016	7,214
Employee related obligations (Note 6)	10,367	10,771
Long-term taxes payable (Note 5)	5,722	6,559
Other liabilities	12,724	11,944
Total liabilities	\$ 106,860	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)	(15,100)	(15,242)
Retained earnings	120,154	113,890
Less: common stock held in treasury, at cost (487,854,000 and 487,331,000 shares)	38,594	38,490
Total shareholders' equity	69,580	63,278
Total liabilities and shareholders' equity	\$ 176,440	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)

	July 4, 2021	Fiscal Second Quarter Ended Percent to Sales	June 28, 2020	Percent to Sales
Sales to customers (Note 9)	\$ 23,312	100.0 %	\$ 18,336	100.0 %
Cost of products sold	7,587	32.5	6,579	35.9
Gross profit	15,725	67.5	11,757	64.1
Selling, marketing and administrative expenses	6,073	26.1	4,993	27.2
Research and development expense	3,394	14.6	2,707	14.8
In-process research and development	0	0.0	6	0.0
Interest income	(12)	(0.1)	(19)	(0.1)
Interest expense, net of portion capitalized	40	0.2	45	0.3
Other (income) expense, net	(488)	(2.1)	24	0.1
Restructuring (Note 12)	56	0.2	61	0.3
Earnings before provision for taxes on income	6,662	28.6	3,940	21.5
Provision for taxes on income (Note 5)	384	1.7	314	1.7
NET EARNINGS	\$ 6,278	26.9 %	\$ 3,626	19.8 %
NET EARNINGS PER SHARE (Note 8)				
Basic	\$ 2.38		\$ 1.38	
Diluted	\$ 2.35		\$ 1.36	
AVG. SHARES OUTSTANDING				
Basic	2,632.5		2,632.9	
Diluted	2,671.6		2,665.5	

See Notes to Consolidated Financial Statements



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

	Fiscal Six Months Ended			
	July 4, 2021	Percent to Sales	June 28, 2020	Percent to Sales
Sales to customers (Note 9)	\$ 45,633	100.0 %	\$ 39,027	100.0 %
Cost of products sold	14,650	32.1	13,641	35.0
Gross profit	30,983	67.9	25,386	65.0
Selling, marketing and administrative expenses	11,505	25.2	10,196	26.1
Research and development expense	6,572	14.4	5,287	13.5
In-process research and development	0	0.0	6	0.0
Interest income	(27)	0.0	(86)	(0.2)
Interest expense, net of portion capitalized	103	0.2	70	0.2
Other (income) expense, net	(1,370)	(3.0)	(655)	(1.7)
Restructuring (Note 12)	109	0.2	119	0.3
Earnings before provision for taxes on income	14,091	30.9	10,449	26.8
Provision for taxes on income (Note 5)	1,616	3.6	1,027	2.7
NET EARNINGS	\$ 12,475	27.3 %	\$ 9,422	24.1 %
NET EARNINGS PER SHARE (Note 8)				
Basic	\$ 4.74		\$ 3.58	
Diluted	\$ 4.67		\$ 3.53	
AVG. SHARES OUTSTANDING				
Basic	2,632.0		2,633.3	
Diluted	2,674.0		2,671.0	

See Notes to Consolidated Financial Statements

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

	Fiscal Second Quarter Ended		Fiscal Six Months Ended	
	July 4, 2021	June 28, 2020	July 4, 2021	June 28, 2020
Net earnings	\$ 6,278	3,626	\$ 12,475	9,422
Other comprehensive income (loss), net of tax				
Foreign currency translation	(135)	556	141	(963)
Securities:				
Unrealized holding gain (loss) arising during period	(1)	(2)	(1)	—
Reclassifications to earnings	—	—	—	—
Net change	(1)	(2)	(1)	—
Employee benefit plans:				
Prior service cost amortization during period	(41)	(5)	(82)	(11)
Gain (loss) amortization during period	275	200	549	401
Net change	234	195	467	390
Derivatives & hedges:				
Unrealized gain (loss) arising during period	400	21	(122)	853
Reclassifications to earnings	(270)	(60)	(343)	78
Net change	130	(39)	(465)	931
Other comprehensive income (loss)	228	710	142	358
Comprehensive income	\$ 6,506	4,336	\$ 12,617	9,780

See Notes to Consolidated Financial Statements

The tax effects in other comprehensive income for the fiscal second quarter were as follows for 2021 and 2020, respectively: Foreign Currency Translation: \$90 million and \$114 million; Employee Benefit Plans: \$66 million and \$55 million; Derivatives & Hedges: \$33 million and \$10 million.

The tax effects in other comprehensive income for the fiscal six months were as follows for 2021 and 2020, respectively: Foreign Currency Translation: \$229 million and \$68 million; Employee Benefit Plans: \$132 million and \$111 million; Derivatives & Hedges: \$124 million and \$246 million.

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

Fiscal Second Quarter Ended July 4, 2021

	<b>Total</b>	<b>Retained Earnings</b>	<b>Accumulated Other Comprehensive Income</b>	<b>Common Stock Issued Amount</b>	<b>Treasury Stock Amount</b>
<b>Balance, April 4, 2021</b>	<b>\$ 65,834</b>	<b>116,508</b>	<b>(15,328)</b>	<b>3,120</b>	<b>(38,466)</b>
Net earnings	6,278	6,278	—	—	—
Cash dividends paid (\$1.06 per share)	(2,791)	(2,791)	—	—	—
Employee compensation and stock option plans	662	159	—	—	503
Repurchase of common stock	(631)	—	—	—	(631)
Other comprehensive income (loss), net of tax	228	—	228	—	—
<b>Balance, July 4, 2021</b>	<b>\$ 69,580</b>	<b>120,154</b>	<b>(15,100)</b>	<b>3,120</b>	<b>(38,594)</b>

Fiscal Six Months Ended July 4, 2021

	<b>Total</b>	<b>Retained Earnings</b>	<b>Accumulated Other Comprehensive Income</b>	<b>Common Stock Issued Amount</b>	<b>Treasury Stock Amount</b>
<b>Balance, January 3, 2021</b>	<b>\$ 63,278</b>	<b>113,890</b>	<b>(15,242)</b>	<b>3,120</b>	<b>(38,490)</b>
Net earnings	12,475	12,475	—	—	—
Cash dividends paid (\$2.07 per share)	(5,450)	(5,450)	—	—	—
Employee compensation and stock option plans	1,204	(761)	—	—	1,965
Repurchase of common stock	(2,069)	—	—	—	(2,069)
Other comprehensive income (loss), net of tax	142	—	142	—	—
<b>Balance, July 4, 2021</b>	<b>\$ 69,580</b>	<b>120,154</b>	<b>(15,100)</b>	<b>3,120</b>	<b>(38,594)</b>

## Fiscal Second Quarter Ended June 28, 2020

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

## Fiscal Six Months Ended June 28, 2020

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

See Notes to Consolidated Financial Statements

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

	Fiscal Six Months Ended	
	July 4, 2021	June 28, 2020
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net earnings	\$ 12,475	9,422
Adjustments to reconcile net earnings to cash flows from operating activities:		
Depreciation and amortization of property and intangibles	3,733	3,473
Stock based compensation	661	589
Asset write-downs	26	33
Contingent consideration reversal	—	(983)
Net gain on sale of assets/businesses	(601)	(60)
Deferred tax provision	(685)	(428)
Credit losses and accounts receivable allowances	(52)	117
Changes in assets and liabilities, net of effects from acquisitions and divestitures:		
Increase in accounts receivable	(1,566)	(520)
Increase in inventories	(818)	(637)
Decrease in accounts payable and accrued liabilities	(4,050)	(2,319)
Decrease/(Increase) in other current and non-current assets	1,415	(1,048)
Decrease in other current and non-current liabilities	(1,150)	(829)
<b>NET CASH FLOWS FROM OPERATING ACTIVITIES</b>	<b>9,388</b>	<b>6,810</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Additions to property, plant and equipment	(1,490)	(1,287)
Proceeds from the disposal of assets/businesses, net (Note 10)	654	87
Acquisitions, net of cash acquired (Note 10)	—	(949)
Purchases of investments	(12,264)	(8,551)
Sales of investments	12,453	2,417
Credit support agreements activity, net	441	672
Other (primarily licenses and milestones)	(398)	(492)
<b>NET CASH USED BY INVESTING ACTIVITIES</b>	<b>(604)</b>	<b>(8,103)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Dividends to shareholders	(5,450)	(5,164)
Repurchase of common stock	(2,069)	(2,417)
Proceeds from short-term debt	498	2,717
Repayment of short-term debt	(689)	(17)
Proceeds from long-term debt, net of issuance costs	1	1
Repayment of long-term debt	(1,451)	(11)
Proceeds from the exercise of stock options/employee withholding tax on stock awards, net	543	708
Credit support agreements activity, net	130	—
Other	83	(489)
<b>NET CASH USED BY FINANCING ACTIVITIES</b>	<b>(8,404)</b>	<b>(4,672)</b>
Effect of exchange rate changes on cash and cash equivalents	(33)	(166)
Increase/(Decrease) in cash and cash equivalents	347	(6,131)
Cash and Cash equivalents, beginning of period	13,985	17,305
<b>CASH AND CASH EQUIVALENTS, END OF PERIOD</b>	<b>\$ 14,332</b>	<b>11,174</b>
<b>Acquisitions</b>		
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 July 4, 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 July 4, 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 six months of 2021 that impacted the Company.

**Recently Adopted Accounting Standards**

There were no new material accounting standards adopted in the fiscal six months of 2021.

**Reclassification**

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

## NOTE 2 — INVENTORIES

(Dollars in Millions)	July 4, 2021	January 3, 2021
Raw materials and supplies	\$ 1,576	1,410
Goods in process	2,307	2,040
Finished goods	6,217	5,894
Total inventories	\$ 10,100	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)	July 4, 2021	January 3, 2021
Intangible assets with definite lives:		
Patents and trademarks — gross	\$ 39,815	39,990
Less accumulated amortization	(19,009)	(17,618)
Patents and trademarks — net	20,806	22,372
Customer relationships and other intangibles — gross	22,976	22,898
Less accumulated amortization	(11,379)	(10,912)
Customer relationships and other intangibles — net*	11,597	11,986
Intangible assets with indefinite lives:		
Trademarks	7,105	7,195
Purchased in-process research and development	10,736	11,849
Total intangible assets with indefinite lives	17,841	19,044
Total intangible assets — net	\$ 50,244	53,402

\*The majority is comprised of customer relationships

Goodwill as of July 4, 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	(242)	(204)	(121)	(567)
Goodwill at July 4, 2021	\$ 10,087	10,805	14,927	35,819

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 \$1.2 billion and \$1.1 billion for the fiscal second quarters ended July 4, 2021 and June 28, 2020, respectively. The amortization expense of amortizable intangible assets included in cost of products sold was \$2.4 billion and \$2.2 billion for the fiscal six months ended July 4, 2021 and June 28, 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)	<u>2021</u>	<u>2022</u>	<u>2023</u>	<u>2024</u>	<u>2025</u>
	\$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 July 4, 2021, the cumulative amount of cash collateral paid by the Company under the CSA amounted to \$494 million net, primarily 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 July 4, 2021, the Company had notional amounts outstanding for forward foreign exchange contracts, cross currency interest rate swaps and interest rate swaps of \$46.2 billion, \$34.8 billion and \$2.0 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 July 4, 2021, the balance of deferred net gain on derivatives included in accumulated other comprehensive income was \$187 million after-tax. For additional information, see the Consolidated Statements of Comprehensive Income and Note 7. The Company expects that substantially all of the amounts related to forward foreign exchange contracts will be reclassified into earnings over the next 12 months as a result of transactions that are expected to occur over that period. The maximum length of time over which the Company is hedging transaction exposure is 18 months, excluding interest rate contracts and net investment hedge contracts. The amount ultimately realized in earnings may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity of the derivative.



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

(Dollars in Millions)	July 4, 2021					June 28, 2020				
	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:										
<b>Gain (Loss) on fair value hedging relationship:</b>										
<b>Interest rate swaps contracts:</b>										
Hedged items	\$	—	—	—	(6)	—	—	—	—	—
Derivatives designated as hedging instruments		—	—	—	6	—	—	—	—	—
<b>Gain (Loss) on net investment hedging relationship:</b>										
<b>Cross currency interest rate swaps contracts:</b>										
Amount of gain or (loss) recognized in income on derivative amount excluded from effectiveness testing		—	—	—	40	—	—	—	39	—
Amount of gain or (loss) recognized in AOCI		—	—	—	40	—	—	—	39	—
<b>Gain (Loss) on cash flow hedging relationship:</b>										
<b>Forward foreign exchange contracts:</b>										
Amount of gain or (loss) reclassified from AOCI into income	11	14	104	—	2	(2)	(62)	2	—	—
Amount of gain or (loss) recognized in AOCI	(3)	(50)	119	—	8	(2)	(128)	(10)	—	22
<b>Cross currency interest rate swaps contracts:</b>										
Amount of gain or (loss) reclassified from AOCI into income		—	—	—	99	—	—	—	83	—
Amount of gain or (loss) recognized in AOCI	\$	—	—	—	286	—	—	—	100	—

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

(Dollars in Millions)	July 4, 2021					June 28, 2020				
	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:										
<b>Gain (Loss) on fair value hedging relationship:</b>										
<b>Interest rate swaps contracts:</b>										
Hedged items	\$	—	—	(6)	—	—	—	—	—	—
Derivatives designated as hedging instruments		—	—	6	—	—	—	—	—	—
<b>Gain (Loss) on net investment hedging relationship:</b>										
<b>Cross currency interest rate swaps contracts:</b>										
Amount of gain or (loss) recognized in income on derivative amount excluded from effectiveness testing		—	—	80	—	—	—	—	79	—
Amount of gain or (loss) recognized in AOCI		—	—	80	—	—	—	—	79	—
<b>Gain (Loss) on cash flow hedging relationship:</b>										
<b>Forward foreign exchange contracts:</b>										
Amount of gain or (loss) reclassified from AOCI into income	28	48	(9)	—	5	7	(235)	(108)	—	(2)
Amount of gain or (loss) recognized in AOCI	(6)	(243)	43	—	25	9	174	(120)	—	(14)
<b>Cross currency interest rate swaps contracts:</b>										
Amount of gain or (loss) reclassified from AOCI into income	—	—	—	191	—	—	—	—	181	—
Amount of gain or (loss) recognized in AOCI	\$	—	—	(21)	—	—	—	—	725	—

As of July 4, 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 (Dollars in Millions)	Carrying Amount of the Hedged Liability		Cumulative Amount of Fair Value Hedging Adjustment Included in the Carrying Amount of the Hedged Liability	
	July 4, 2021	January 3, 2021	July 4, 2021	January 3, 2021
Long-term Debt	1,975	—	8	—

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

(Dollars in Millions)	Location of Gain / (Loss) Recognized in Income on Derivative	Gain/(Loss) Recognized In Income on Derivative		Gain/(Loss) Recognized In Income on Derivative	
		Fiscal Second Quarter Ended		Fiscal Six Months Ended	
Derivatives Not Designated as Hedging Instruments		July 4, 2021	June 28, 2020	July 4, 2021	June 28, 2020
Foreign Exchange Contracts	Other (income) expense	\$ (21)	(24)	(37)	65

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

(Dollars in Millions)	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	
	July 4, 2021	June 28, 2020		July 4, 2021	June 28, 2020
Debt	\$ (45)	(95)	Interest (income) expense	—	—
Cross Currency interest rate swaps	\$ (70)	(186)	Interest (income) expense	—	—

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

(Dollars in Millions)	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	
	July 4, 2021	June 28, 2020		July 4, 2021	June 28, 2020
Debt	\$ 164	(48)	Interest (income) expense	—	—
Cross Currency interest rate swaps	\$ 291	641	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			July 4, 2021		
	Carrying Value	Changes in Fair Value Reflected in Net Income <sup>(1)</sup>	Sales/Purchases/Other <sup>(2)</sup>	Carrying Value	Non Current Assets	Other Assets
Equity Investments with readily determinable value	\$ 1,481	171	26	1,678		1,678
Equity Investments without readily determinable value	\$ 738	22	64	824		824

<sup>(1)</sup> Recorded in Other Income/Expense

<sup>(2)</sup> Other includes impact of currency

For equity investments without readily determinable market values, \$15 million of the decrease in the fair value reflected in net income were the result of impairments. There were \$37 million of increase in fair value reflected in net income due to changes in observable prices.

Fair value is the exit price that would be received to sell an asset or paid to transfer a liability. Fair value is a market-based measurement determined using assumptions that market participants would use in pricing an asset or liability. In accordance with ASC 820, a three-level hierarchy was established to prioritize the inputs used in measuring fair value. The levels within the hierarchy are described below with Level 1 inputs having the highest priority and Level 3 inputs having the lowest.

The fair value of a derivative financial instrument (i.e., forward foreign exchange contracts, interest rate contracts) is the aggregation by currency of all future cash flows discounted to its present value at the prevailing market interest rates and subsequently converted to the U.S. Dollar at the current spot foreign exchange rate. The Company does not believe that fair values of these derivative instruments materially differ from the amounts that could be realized upon settlement or maturity, or that the changes in fair value will have a material effect on the Company's results of operations, cash flows or financial position. The Company also holds equity investments which are classified as Level 1 and debt securities which are classified as Level 2. The Company holds acquisition related contingent liabilities based upon certain regulatory and commercial events, which are classified as Level 3, whose values are determined using discounted cash flow methodologies or similar techniques for which the determination of fair value requires significant judgment or estimations.

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

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

Level 2 — Significant other observable inputs.

Level 3 — Significant unobservable inputs.

The Company's significant financial assets and liabilities measured at fair value as of July 4, 2021 and January 3, 2021 were as follows:

(Dollars in Millions)	July 4, 2021			January 3, 2021		
	Level 1	Level 2	Level 3	Total	Total <sup>(1)</sup>	
<b>Derivatives designated as hedging instruments:</b>						
<b>Assets:</b>						
Forward foreign exchange contracts	\$	—	405	—	405	849
Interest rate contracts <sup>(2)</sup>		—	451	—	451	240
<b>Total</b>		—	856	—	856	1,089
<b>Liabilities:</b>						
Forward foreign exchange contracts		—	620	—	620	702
Interest rate contracts <sup>(2)</sup>		—	674	—	674	1,569
<b>Total</b>		—	1,294	—	1,294	2,271
<b>Derivatives not designated as hedging instruments:</b>						
<b>Assets:</b>						
Forward foreign exchange contracts		—	64	—	64	49
<b>Liabilities:</b>						
Forward foreign exchange contracts		—	58	—	58	38
<b>Other Investments:</b>						
Equity investments <sup>(3)</sup>		1,678	—	—	1,678	1,481
Debt securities <sup>(4)</sup>		—	13,056	—	13,056	14,042
<b>Other Liabilities</b>						
Contingent consideration <sup>(5)</sup>	\$	—	—	593	593	633

Gross to Net Derivative Reconciliation	July 4, 2021		January 3, 2021
(Dollars in Millions)			
Total Gross Assets	\$	920	1,138
Credit Support Agreement (CSA)		(833)	(1,107)
Total Net Asset		87	31
Total Gross Liabilities		1,352	2,309
Credit Support Agreement (CSA)		(1,327)	(2,172)
Total Net Liabilities	\$	25	137

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

	July 4, 2021		June 28, 2020	
(Dollars in Millions)				
Beginning Balance	\$	633	\$	1,715
Changes in estimated fair value <sup>(6)</sup>		8		(938)
Additions		—		106
Payments		(48)		(87)
Ending Balance	\$	593	\$	796

<sup>(1)</sup> 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.

<sup>(2)</sup> Includes cross currency interest rate swaps and interest rate swaps as of July 4, 2021. Includes cross currency interest rate swaps as of January 3, 2021.

<sup>(3)</sup> Classified as non-current other assets.

<sup>(4)</sup> Classified within cash equivalents and current marketable securities.

<sup>(5)</sup> Includes \$579 million and \$594 million, classified as non-current other liabilities as of July 4, 2021 and January 3, 2021, respectively. Includes \$14 million and \$39 million classified as current liabilities as of July 4, 2021 and January 3, 2021, respectively.

<sup>(6)</sup> Ongoing fair value adjustment amounts are primarily recorded in Research and Development expense.

The Company recorded a contingent consideration reversal of \$983 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 July 4, 2021 comprised:

(Dollars in Millions)	Carrying Amount	Unrecognized Gain	Unrecognized Loss	Estimated Fair Value	Cash & Cash Equivalents	Current Marketable Securities
Cash	\$ 2,313	—	—	2,313	2,313	—
Non-U.S. sovereign securities <sup>(1)</sup>	869	—	—	869	75	794
U.S. reverse repurchase agreements	2,091	—	—	2,091	2,091	—
Corporate debt securities <sup>(1)</sup>	3,230	—	—	3,230	2,191	1,039
Money market funds	2,618	—	—	2,618	2,618	—
Time deposits <sup>(1)</sup>	1,129	—	—	1,129	1,129	—
Subtotal	12,250	—	—	12,250	10,417	1,833
		Unrealized Gain	Unrealized Loss			
U.S. Gov't securities	12,798	—	—	12,798	3,890	8,908
Other sovereign securities	1	—	—	1	—	1
Corporate debt securities	257	—	—	257	25	232
Subtotal available for sale debt <sup>(2)</sup>	\$ 13,056	—	—	13,056	3,915	9,141
Total cash, cash equivalents and current marketable securities	\$ 25,306	—	—	25,306	14,332	10,974

<sup>(1)</sup> Held to maturity investments are reported at amortized cost and gains or losses are reported in earnings.

<sup>(2)</sup> 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 July 4, 2021 are as follows:

(Dollars in Millions)	Cost Basis	Fair Value
Due within one year	\$ 13,043	13,043
Due after one year through five years	13	13
Due after five years through ten years	—	—
Total debt securities	\$ 13,056	13,056

Financial Instruments not measured at Fair Value:

The following financial liabilities are held at carrying amount on the consolidated balance sheet as of July 4, 2021:

(Dollars in Millions)	Carrying Amount	Estimated Fair Value
<b>Financial Liabilities</b>		
<b>Current Debt</b>	\$ 3,173	3,192
<b>Non-Current Debt</b>		
6.73% Debentures due 2023	250	288
3.375% Notes due 2023	802	863
2.05% Notes due 2023	499	512
0.650% Notes due 2024 (750MM Euro 1.1870)	888	912
5.50% Notes due 2024 (500 MM GBP 1.3809)	688	801
2.625% Notes due 2025	749	798
0.55% Notes due 2025	997	988
2.45% Notes due 2026	1,994	2,127
2.95% Notes due 2027	997	1,092
0.95% Notes due 2027	1,494	1,471
2.90% Notes due 2028	1,495	1,639
1.150% Notes due 2028 (750MM Euro 1.1870)	884	958
6.95% Notes due 2029	297	419
1.30% Notes due 2030	1,743	1,697
4.95% Debentures due 2033	498	659
4.375% Notes due 2033	855	1,075
1.650% Notes due 2035 (1.5B Euro 1.1870)	1,766	2,033
3.55% Notes due 2036	990	1,156
5.95% Notes due 2037	993	1,456
3.625% Notes due 2037	1,488	1,743
3.40% Notes due 2038	991	1,132
5.85% Debentures due 2038	696	1,018
4.50% Debentures due 2040	540	701
2.10% Notes due 2040	986	942
4.85% Notes due 2041	297	398
4.50% Notes due 2043	496	649
3.70% Notes due 2046	1,975	2,359
3.75% Notes due 2047	992	1,198
3.50% Notes due 2048	743	867
2.25% Notes due 2050	991	932
2.45% Notes due 2060	1,229	1,169
Other	7	6
<b>Total Non-Current Debt</b>	<b>\$ 30,310</b>	<b>34,058</b>

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 July 4, 2021 includes \$0.6 billion of commercial paper which has a weighted average interest rate of 0.05% and a weighted average maturity of approximately two 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 six months of 2021 and 2020 were 11.5% and 9.8%, 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 4.4% 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 six months of 2020 was approximately \$0.4 billion, or 3.8% net benefit to the Company's six months effective tax rate, inclusive of the impact of U.S. GILTI deferred taxes.

During the second fiscal quarter of 2020, the Company reversed some of its international unrecognized tax benefits due to the completion of several years of tax examinations in certain jurisdictions. This reserve reversal benefited the Company's effective tax rate by approximately 1.0% for the fiscal six months of 2020. In the first fiscal quarter of 2020, the Company reduced a contingent consideration liability related to the 2019 Auris Health acquisition that benefited the 2020 tax rate by approximately 1.0% (for additional details see Note 18 to the Consolidated Financial Statements in the Company's Annual Report on Form 10-K for the fiscal year ended January 3, 2021).

Additionally, the Company had more income in higher tax jurisdictions relative to lower tax jurisdictions as compared to the same period in the prior fiscal year. This was primarily driven by the additional legal costs accrued in the second fiscal quarter of 2020 at the U.S. statutory rate versus 2021 (for additional details see Note 11 to the Consolidated Financial Statements). The Company also generated additional tax benefits from stock-based compensation that were either exercised or vested during the first and second fiscal quarters of 2021 and 2020.

As of July 4, 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. Subsequent to July 4, 2021, the IRS began its audit of the years 2013 through 2016. In other major jurisdictions where the Company conducts business, the years that remain open to tax audit go back to the year 2006. The Company believes it is possible that tax audits may be completed over the next twelve months by taxing authorities in some jurisdictions outside of the United States. However, the Company is not able to provide a reasonably reliable estimate of the timing of any other future tax payments relating to uncertain tax positions.

## NOTE 6 — PENSIONS AND OTHER BENEFIT PLANS

## Components of Net Periodic Benefit Cost

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

(Dollars in Millions)	Fiscal Second Quarter Ended				Fiscal Six Months Ended			
	Retirement Plans		Other Benefit Plans		Retirement Plans		Other Benefit Plans	
	July 4, 2021	June 28, 2020	July 4, 2021	June 28, 2020	July 4, 2021	June 28, 2020	July 4, 2021	June 28, 2020
Service cost	\$ 327	323	77	72	680	649	154	144
Interest cost	193	237	21	33	386	477	41	66
Expected return on plan assets	(647)	(608)	(2)	(1)	(1,327)	(1,222)	(4)	(3)
Amortization of prior service cost/(credit)	(45)	1	(7)	(8)	(90)	1	(15)	(16)
Recognized actuarial losses	316	222	37	35	630	445	75	71
Curtailments and settlements	—	—	—	—	1	19	—	—
Net periodic benefit cost	\$ 144	175	126	131	280	369	251	262

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

## Company Contributions

For the fiscal six months ended July 4, 2021, the Company contributed \$46 million and \$222 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	141	(1)	467	(465)	142
July 4, 2021	\$ (8,797)	—	(6,490)	187	(15,100)

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:

(Shares in Millions)	Fiscal Second Quarter Ended		Fiscal Six Months Ended	
	July 4, 2021	June 28, 2020	July 4, 2021	June 28, 2020
Basic net earnings per share	\$ 2.38	1.38	4.74	3.58
Average shares outstanding — basic	2,632.5	2,632.9	2,632.0	2,633.3
Potential shares exercisable under stock option plans	141.9	119.6	126.0	122.6
Less: shares which could be repurchased under treasury stock method	(102.8)	(87.5)	(84.0)	(85.4)
Convertible debt shares	—	0.5	—	0.5
Average shares outstanding — diluted	2,671.6	2,665.5	2,674.0	2,671.0
Diluted net earnings per share	\$ 2.35	1.36	4.67	3.53

The diluted net earnings per share calculation for the fiscal second quarter ended July 4, 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. In the fiscal second quarter ended July 4, 2021, the Company did not have convertible debt.

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

The diluted net earnings per share calculation for the first fiscal six months ended July 4, 2021 excluded 14 million shares related to stock options, as the exercise price of these options was greater than their average market value. In the first fiscal six months ended July 4, 2021, the Company did not have convertible debt.

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

## NOTE 9 — SEGMENTS OF BUSINESS AND GEOGRAPHIC AREAS

## SALES BY SEGMENT OF BUSINESS

(Dollars in Millions)	Fiscal Second Quarter Ended			Fiscal Six Months Ended		
	July 4, 2021	June 28, 2020	Percent Change	July 4, 2021	June 28, 2020	Percent Change
<b>Consumer Health</b>						
<b>OTC</b>						
U.S.	\$ 675	627	7.7 %	\$ 1,274	1,316	(3.2)%
International	633	522	21.2	1,208	1,181	2.3
Worldwide	1,307	1,149	13.8	2,482	2,497	(0.6)
<b>Skin Health/Beauty</b>						
U.S.	659	536	23.0	1,293	1,195	8.2
International	511	471	8.4	1,040	929	12.0
Worldwide	1,170	1,007	16.2	2,333	2,124	9.8
<b>Oral Care</b>						
U.S.	165	170	(3.1)	328	346	(5.2)
International	260	227	14.6	514	446	15.3
Worldwide	426	397	7.0	843	792	6.3
<b>Baby Care</b>						
U.S.	97	96	0.8	193	188	2.4
International	290	260	11.5	583	529	10.2
Worldwide	387	356	8.6	776	717	8.1
<b>Women's Health</b>						
U.S.	3	3	(3.1)	6	7	(16.0)
International	227	199	14.2	446	427	4.5
Worldwide	230	202	13.9	452	434	4.2
<b>Wound Care/Other</b>						
U.S.	153	126	20.9	268	245	9.3
International	64	59	7.3	125	111	12.1
Worldwide	216	185	16.6	393	356	10.2
<b>TOTAL Consumer Health</b>						
U.S.	1,751	1,557	12.4	3,362	3,297	2.0
International	1,984	1,739	14.1	3,916	3,624	8.1
Worldwide	3,735	3,296	13.3	7,278	6,921	5.2

**PHARMACEUTICAL****Immunology**

U.S.	2,748	2,362	16.4	5,161	4,772	8.2
International	1,483	1,161	27.7	2,984	2,389	24.9
Worldwide	4,231	3,523	20.1	8,145	7,161	13.7
<b>REMICADE®</b>						
U.S.	540	593	(9.1)	1,029	1,218	(15.6)
U.S. Exports	93	133	(30.0)	150	243	(38.2)
International	255	208	22.4	487	464	4.9
Worldwide	888	935	(5.1)	1,665	1,925	(13.5)
<b>SIMPONI / SIMPONIARIA®</b>						
U.S.	290	256	12.8	545	528	3.2
International	294	289	1.7	601	547	9.8
Worldwide	584	546	6.9	1,146	1,075	6.6
<b>STELARA®</b>						
U.S.	1,496	1,138	31.4	2,827	2,355	20.0
International	778	558	39.2	1,595	1,161	37.3
Worldwide	2,274	1,697	34.0	4,422	3,516	25.8
<b>TREMFYA®</b>						
U.S.	325	241	35.0	599	428	40.0
International	155	101	52.3	298	210	41.8
Worldwide	479	342	40.2	897	638	40.6
<b>OTHER IMMUNOLOGY</b>						
U.S.	5	—	*	12	—	*
International	1	3	(61.3)	3	6	(51.2)
Worldwide	7	3	*	15	6	*

**Infectious Diseases**

U.S.	444	416	6.8	956	852	12.2
International	585	463	26.3	1,079	946	14.1
Worldwide	1,028	878	17.1	2,035	1,798	13.2
<b>COVID-19 vaccine</b>						
U.S.	51	—	*	151	—	*
International	113	—	*	113	—	*
Worldwide	164	—	*	264	—	*
<b>EDURANT® / rilpivirine</b>						
U.S.	9	10	(9.3)	19	22	(10.9)
International	253	246	2.8	486	458	6.0
Worldwide	262	256	2.3	505	480	5.2
<b>PREZISTA® / PREZCOBIX® / REZOLSTA® / SYMTUZA®</b>						
U.S.	368	379	(3.2)	748	775	(3.5)
International	137	130	5.5	303	314	(3.5)
Worldwide	505	510	(1.0)	1,051	1,089	(3.5)

<b><u>OTHER INFECTIOUS DISEASES</u></b>						
U.S.	16	25	(36.2)	37	54	(31.3)
International	81	87	(6.2)	177	174	1.8
Worldwide	98	113	(13.0)	215	229	(6.1)
<b>Neuroscience</b>						
U.S.	842	778	8.0	1,613	1,526	5.6
International	967	809	19.6	1,916	1,719	11.5
Worldwide	1,808	1,587	13.9	3,529	3,245	8.7
<b><u>CONCERTA® / methylphenidate</u></b>						
U.S.	35	55	(36.0)	82	107	(23.1)
International	127	94	33.7	250	212	17.5
Worldwide	161	149	8.1	332	320	3.9
<b><u>INVEGA SUSTENNA® / XEPLION® / INVEGA TRINZA® / TREVICTA®</u></b>						
U.S.	645	576	11.9	1,234	1,120	10.2
International	380	303	25.1	756	642	17.7
Worldwide	1,024	879	16.4	1,989	1,762	12.9
<b><u>RISPERDAL CONSTA®</u></b>						
U.S.	72	74	(3.0)	139	150	(7.5)
International	84	79	6.4	173	173	0.4
Worldwide	155	153	1.9	312	323	(3.3)
<b><u>OTHER NEUROSCIENCE</u></b>						
U.S.	91	75	20.9	158	150	5.6
International	377	331	13.8	738	691	6.7
Worldwide	468	406	15.1	896	841	6.5
<b>Oncology</b>						
U.S.	1,462	1,181	23.7	2,839	2,356	20.5
International	2,073	1,609	28.8	4,266	3,448	23.7
Worldwide	3,535	2,791	26.7	7,105	5,804	22.4
<b><u>DARZALEX®</u></b>						
U.S.	770	492	56.7	1,461	955	53.1
International	663	409	62.1	1,337	883	51.4
Worldwide	1,433	901	59.2	2,798	1,838	52.2
<b><u>ERLEADA®</u></b>						
U.S.	193	136	41.5	364	255	42.7
International	109	33	*	199	57	*
Worldwide	302	170	77.6	563	313	80.0
<b><u>IMBRUVICA®</u></b>						
U.S.	454	447	1.7	898	879	2.2
International	662	502	31.9	1,342	1,101	21.9
Worldwide	1,116	949	17.7	2,241	1,980	13.2
<b><u>ZYTIGA® / abiraterone acetate</u></b>						
U.S.	21	87	(75.3)	71	226	(68.5)
International	542	480	12.8	1,130	1,032	9.5
Worldwide	563	568	(0.8)	1,201	1,258	(4.5)

<u>OTHER ONCOLOGY<sup>(1)</sup></u>						
U.S.	23	20	18.8	44	42	6.3
International	97	185	(47.2)	258	375	(31.0)
Worldwide	120	204	(40.9)	302	416	(27.3)
<b>Pulmonary Hypertension</b>						
U.S.	595	545	9.0	1,168	1,031	13.2
International	275	243	13.5	563	503	12.1
Worldwide	870	789	10.4	1,731	1,534	12.9
<u>OPSUMIT®</u>						
U.S.	290	256	13.6	562	485	15.9
International	172	150	14.9	351	310	13.1
Worldwide	463	406	14.1	913	795	14.8
<u>UPTRAVI®</u>						
U.S.	268	254	6.0	527	466	13.3
International	45	28	54.9	91	66	36.8
Worldwide	313	282	11.0	618	532	16.2
<u>OTHER PULMONARY HYPERTENSION</u>						
U.S.	36	37	(2.4)	78	81	(3.0)
International	59	64	(8.2)	122	126	(3.5)
Worldwide	95	101	(6.1)	200	207	(3.3)
<b>Cardiovascular / Metabolism / Other</b>						
U.S.	780	837	(6.9)	1,579	1,643	(3.9)
International	346	347	(0.3)	674	701	(3.8)
Worldwide	1,126	1,184	(5.0)	2,253	2,344	(3.9)
<u>XARELTO®</u>						
U.S.	569	559	1.8	1,158	1,086	6.6
International	—	—	—	—	—	—
Worldwide	569	559	1.8	1,158	1,086	6.6
<u>INVOKANA® / INVOKAMET®</u>						
U.S.	96	132	(27.0)	183	249	(26.6)
International	64	47	33.8	127	105	20.3
Worldwide	160	179	(10.9)	310	354	(12.6)
<u>PROCRT® / EPREX®</u>						
U.S.	59	70	(16.3)	121	146	(17.3)
International	69	66	3.7	133	145	(8.2)
Worldwide	127	136	(6.6)	254	291	(12.8)
<u>OTHER</u>						
U.S.	57	78	(26.7)	117	163	(27.8)
International	214	234	(8.4)	415	451	(8.1)
Worldwide	271	312	(13.0)	532	614	(13.3)
<b>TOTAL PHARMACEUTICAL</b>						
U.S.	6,869	6,120	12.2	13,315	12,181	9.3
International	5,730	4,632	23.7	11,483	9,705	18.3
Worldwide	12,599	10,752	17.2	24,798	21,886	13.3

<b>MEDICAL DEVICES</b>						
<b>Interventional Solutions</b>						
U.S.	475	255	86.5	909	620	46.7
International	572	335	70.5	1,086	697	55.7
Worldwide	1,046	590	77.4	1,995	1,317	51.5
<b>Orthopaedics</b>						
U.S.	1,323	869	52.3	2,572	2,119	21.4
International	904	583	55.1	1,768	1,371	29.0
Worldwide	2,227	1,451	53.4	4,340	3,489	24.4
<b>HIPS</b>						
U.S.	234	137	70.5	444	343	29.6
International	159	88	78.6	305	220	38.3
Worldwide	392	226	73.7	749	563	33.0
<b><u>KNEES</u></b>						
U.S.	210	108	94.3	395	322	22.7
International	140	66	*	272	196	39.2
Worldwide	350	174	*	667	517	28.9
<b><u>TRAUMA</u></b>						
U.S.	447	354	26.0	897	761	17.8
International	263	198	32.7	545	445	22.5
Worldwide	710	553	28.4	1,443	1,207	19.6
<b><u>SPINE, SPORTS &amp; OTHER</u></b>						
U.S.	433	270	60.6	836	693	20.7
International	343	230	49.0	646	510	26.7
Worldwide	776	499	55.3	1,482	1,202	23.2
<b>Surgery</b>						
U.S.	1,035	490	*	1,933	1,334	44.9
International	1,487	1,060	40.2	2,961	2,317	27.8
Worldwide	2,522	1,551	62.6	4,894	3,651	34.0
<b><u>ADVANCED</u></b>						
U.S.	459	277	65.4	864	658	31.3
International	708	498	42.2	1,421	1,065	33.4
Worldwide	1,168	775	50.5	2,286	1,723	32.6
<b><u>GENERAL</u></b>						
U.S.	576	213	*	1,069	676	58.1
International	779	562	38.5	1,540	1,252	23.0
Worldwide	1,354	775	74.7	2,608	1,928	35.3
<b>Vision</b>						
U.S.	467	248	88.3	939	687	36.6
International	716	447	60.0	1,389	1,075	29.2
Worldwide	1,183	695	70.1	2,328	1,762	32.1
<b><u>CONTACT LENSES / OTHER</u></b>						
U.S.	352	203	73.3	723	549	31.6
International	517	352	47.0	1,003	819	22.5
Worldwide	868	554	56.7	1,725	1,368	26.1



<b><u>SURGICAL</u></b>						
U.S.	115	45	*	216	138	56.3
International	199	96	*	386	256	50.9
Worldwide	314	141	*	602	394	52.8
<b>TOTAL MEDICAL DEVICES</b>						
U.S.	3,299	1,862	77.2	6,353	4,760	33.5
International	3,679	2,426	51.6	7,204	5,460	31.9
Worldwide	6,978	4,288	62.7	13,557	10,220	32.7
<b>WORLDWIDE</b>						
U.S.	11,919	9,539	24.9	23,030	20,238	13.8
International	11,393	8,797	29.5	22,603	18,789	20.3
Worldwide	\$ 23,312	18,336	27.1 %	\$ 45,633	39,027	16.9 %

\*Percentage greater than 100% or not meaningful

<sup>(1)</sup> Inclusive of VELCADE® which was previously disclosed separately

#### EARNINGS BEFORE PROVISION FOR TAXES BY SEGMENT

(Dollars in Millions)	Fiscal Second Quarter Ended			Fiscal Six Months Ended		
	July 4, 2021	June 28, 2020	Percent Change	July 4, 2021	June 28, 2020	Percent Change
Consumer Health <sup>(1)</sup>	\$ 804	32	*	\$ 1,592	802	98.5%
Pharmaceutical <sup>(2)</sup>	4,356	4,514	(3.5)	9,579	8,348	14.7
Medical Devices <sup>(3)</sup>	1,746	(354)	*	3,375	1,671	*
Segment earnings before provision for taxes	6,906	4,192	64.7	14,546	10,821	34.4
Less: Expense not allocated to segments <sup>(4)</sup>	244	252		455	372	
Worldwide income before tax	\$ 6,662	3,940	69.1%	\$ 14,091	10,449	34.9%

\*Percentage greater than 100% or not meaningful

<sup>(1)</sup> Consumer Health

- Includes intangible amortization expense of \$0.1 billion in both the fiscal second quarter of 2021 and 2020 and \$0.2 billion in both the fiscal six months of 2021 and 2020.
- Includes litigation expense of \$0.1 billion and \$0.6 billion in both the fiscal second quarter and fiscal six months of 2021 and 2020, primarily talc related costs, respectively.

<sup>(2)</sup> Pharmaceutical

- Includes divestiture gains of \$0.6 billion in the fiscal six months of 2021 related to two brands outside the U.S.
- Includes an unrealized gain on securities of \$0.2 billion and \$0.5 billion in the fiscal second quarter and \$0.1 billion and \$0.2 billion in the fiscal six months of 2021 and 2020, respectively.
- Includes intangible amortization expense of \$0.8 billion in both the fiscal second quarter of 2021 and 2020. Includes intangible amortization expense of \$1.7 billion and \$1.6 billion in the fiscal six months of 2021 and 2020.

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 and contractually obligated to be paid to these contract manufacturing organizations of approximately \$1.3 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.

<sup>(3)</sup> Medical Devices

- Includes a contingent consideration reversal of \$1.0 billion in the fiscal second quarter 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 second quarter of 2021 and 2020, respectively.
- Includes intangible amortization expense of \$0.3 billion and \$0.2 billion in the fiscal second quarter and \$0.5 billion in both the fiscal six months of 2021 and 2020, respectively.
- Includes an unrealized gain on securities of \$0.1 billion in both the fiscal second quarter and the fiscal six months of 2021.

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

## SALES BY GEOGRAPHIC AREA

(Dollars in Millions)	Fiscal Second Quarter Ended			Fiscal Six Months Ended		
	July 4, 2021	June 28, 2020	Percent Change	July 4, 2021	June 28, 2020	Percent Change
United States	\$ 11,919	9,539	24.9 %	\$ 23,030	20,238	13.8 %
Europe	5,668	4,063	39.5	11,082	8,890	24.7
Western Hemisphere, excluding U.S.	1,367	1,133	20.6	2,791	2,635	5.9
Asia-Pacific, Africa	4,358	3,601	21.0	8,730	7,264	20.2
Total	\$ 23,312	18,336	27.1 %	\$ 45,633	39,027	16.9 %

## 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 July 4, 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 July 4, 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; 6,300 with respect to the PINNACLE® Acetabular Cup System; 11,600 with respect to pelvic meshes; 9,200 with respect to RISPERDAL®, 7,800 with respect to XARELTO®, 34,600 with respect to body powders containing talc; 200 with respect to INVOKANA®, and 4,600 with respect to ETHICON PHYSIOMESH® Flexible Composite Mesh.

In August 2010, DePuy Orthopaedics, Inc. (DePuy) announced a worldwide voluntary recall of its ASR™ XL Acetabular System and DePuy ASR™ Hip Resurfacing System used in hip replacement surgery. Claims for personal injury have been made against DePuy and Johnson & Johnson. The number of pending lawsuits is expected to fluctuate as certain lawsuits are settled or dismissed and additional lawsuits are filed. Cases filed in federal courts in the United States have been organized as a multi-district litigation in the United States District Court for the Northern District of Ohio. Litigation has also been filed in countries outside of the United States, primarily in the United Kingdom, Canada, Australia, Ireland, Germany, India and Italy. In November 2013, DePuy reached an agreement with a Court-appointed committee of lawyers representing ASR Hip System plaintiffs to establish a program to settle claims with eligible ASR Hip patients in the United States who had surgery to replace their ASR Hips, known as revision surgery, as of August 31, 2013. DePuy reached additional agreements in February 2015 and March 2017, which further extended the settlement program to include ASR Hip patients who had revision surgeries after August 31, 2013 and prior to February 15, 2017. This settlement program has resolved more than 10,000 claims, therefore bringing to resolution significant ASR Hip litigation activity in the United States. However, lawsuits in the United States remain, and the settlement program does not address litigation outside of the United States. In Australia, a class action settlement was reached that resolved the claims of the majority of ASR Hip patients in that country. In Canada, the Company has reached agreements to settle 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 expect to occur in or after October 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. 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 Physiomes mesh cases pending at that time. The term sheet will be supplanted by a master settlement agreement, which is currently being negotiated. All deadlines and trial settings are currently stayed pending the completion of the settlement agreement. The costs associated with this proposed settlement is 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 these cases.

Ethicon and Johnson & Johnson also have been subject to claims for personal injuries arising from the PROLENETM Polypropylene Hernia System (PHS). In September 2019, plaintiffs' attorney filed an application with the New Jersey Supreme Court seeking centralized management of the PHS cases. The New Jersey Supreme Court granted plaintiffs application in January 2020 and those cases have also been transferred to an MCL in Atlantic County Superior Court. Cases have been filed in other various federal and state courts in the United States and discovery is underway in a subset of these cases.

The Company has established accruals with respect to product liability litigation associated with ETHICON PHYSIOMESH® Flexible Composite Mesh, PROCEED® Mesh and PROCEED® Ventral Patch, and PROLENETM 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. The Company and plaintiff each are appealing this judgment. The Company has settled or otherwise resolved many of the United States cases and the costs associated with these settlements are reflected in the Company's accruals.

Claims for personal injury arising out of the use of XARELTO<sup>®</sup>, an oral anticoagulant, have been made against Janssen Pharmaceuticals, Inc. (JPI); Johnson & Johnson; and JPI's collaboration partner for XARELTO<sup>®</sup>, 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<sup>®</sup> 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<sup>®</sup> related product liability litigation.

Personal injury claims alleging that talc causes cancer have been made against Johnson & Johnson Consumer Inc. and Johnson & Johnson arising out of the use of body powders containing talc, primarily JOHNSON'S<sup>®</sup> Baby Powder. The number of pending personal injury lawsuits continues to increase, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. Lawsuits primarily have been filed in state courts in Missouri, New Jersey and California, and suits have also been filed outside the United States. The majority of cases are pending in federal court, organized into a multi-district litigation (MDL) in the United States District Court for the District of New Jersey. In the MDL, the parties sought to exclude experts through Daubert motions. In April 2020, the Court issued rulings that limit the scope of testimony, including some theories and testing methods, for certain plaintiff expert witnesses and denied plaintiffs' attempt to limit the scope of testimony of certain of the Company's witnesses. Case-specific discovery is proceeding per the Court's directive.

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. The Company has established an accrual for defense costs and reserves for the resolution of certain cases and claims in connection with product liability litigation associated with body powders containing talc.

In February 2019, the Company's talc supplier, Imerys Talc America, Inc. and two of its affiliates, Imerys Talc Vermont, Inc. and Imerys Talc Canada, Inc. (collectively, Imerys) filed a voluntary chapter 11 petition commencing a reorganization under the United States Bankruptcy Code in the United States Bankruptcy Court for the District of Delaware (Imerys Bankruptcy). The Imerys Bankruptcy relates to Imerys' potential liability for personal injury from exposure to talcum powder sold by Imerys (Talc Claims). In its bankruptcy filing, Imerys noted certain claims it alleges it has against the Company for indemnification and rights to joint insurance proceeds. The Company previously proposed to resolve Imerys' (and the Company's) obligations arising out of the Talc Claims by agreeing to assume the defense of litigation of all Talc Claims involving the Company's products, waiving the Company's indemnification claims against Imerys, and lifting the automatic stay to enable the Talc Claims to proceed outside the bankruptcy forum with the Company agreeing to settle or pay any judgment against Imerys. That proposal was rejected. In May 2020, Imerys and the asbestos claimants' committee (Plan Proponents) filed their Plan of Reorganization (the Plan) and the Disclosure Statement related thereto agreeing to put its North American operations up for auction. The Plan Proponents filed numerous amendments to the Plan and Disclosure Statement to which the Company objected. A hearing on the Plan Proponent's Disclosure Statement was held in January 2021, and the Court entered an order approving the amended Plan, allowing Debtors Imerys to proceed with soliciting votes on the Plan. In March 2021, the Company voted to reject the Debtors' Plan and opted out of the consensual releases in the Plan. Discovery with respect to the Debtors' Plan is ongoing. A confirmation hearing is currently contemplated in November 2021.

In June 2020, Cyprus Mines Corporation and its parent (Cyprus), which had owned certain Imerys talc mines, filed an adversary proceeding against the Company and Imerys seeking a declaration of indemnity under certain contractual agreements. The Company denies such indemnification is owed, and filed a motion to dismiss the adversary complaint arguing, among other things, that the Court does not have subject matter jurisdiction over Cyprus's claims against the Company. In February 2021,

Cyprus filed a voluntary petition for relief under Chapter 11 of the Bankruptcy Code and filed its Disclosure Statement and Plan.

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 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. 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 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.

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 January 2020, the Abtahi Law Group filed an action under Proposition 65 against Johnson & Johnson and Johnson & Johnson Consumer Inc. as well as a number of other alleged talcum powder manufacturers and distributors, including one California company. In that action, the plaintiff alleges contamination of talcum powder products with unsafe levels of arsenic, hexavalent chromium and lead. The plaintiff seeks civil penalties and injunctive relief. Defendants filed a motion for summary judgment in January 2021, and a hearing on the motion was held in April 2021. In May 2021, the court entered an order granting summary judgment in favor of Defendants. Plaintiff agreed to forego an appeal in exchange for a waiver of costs.

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 is scheduled to begin 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. Trial is scheduled to begin in September 2021.

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. The District Court postponed trial until the appeal of the invalidity decision on the '601 patent is complete.

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 pending 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 subsidiaries are not successful in an action, or the automatic statutory stay of the ANDAs expires before the United States District Court rulings are obtained, the third-party companies involved would have the ability, upon approval of the FDA, to introduce generic versions of their products to the market, resulting in the potential for substantial market share and revenue losses for the applicable products, and which may result in a non-cash impairment charge in any associated intangible asset. In addition, from time to time, subsidiaries may settle these types of actions and such settlements can involve the introduction of generic versions of the products at issue to the market prior to the expiration of the relevant patents. The 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 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, 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 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 U.S. Patent No. 10,828,310 ('310).

In July 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 Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively, Teva) 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 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 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<sup>®</sup> before expiration of United States Patent No. 10,617,668 relating to INVOKANA<sup>®</sup>. 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<sup>®</sup>, INVOKAMET<sup>®</sup> and/or, INVOKAMET XR<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> before the expiration of the relevant patents. The trial is scheduled to begin in August 2022.

#### OPSUMIT<sup>®</sup>

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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> before the expiration of the relevant patents.

#### INVEGA SUSTENNA<sup>®</sup>

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<sup>®</sup> before the expiration of United States Patent No. 9,439,906 ('906). Trial concluded in October 2020, and closing arguments were made in March 2021.

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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup>, if approved, would infringe 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> before the expiration of the relevant patents.

#### INVEGA TRINZA<sup>®</sup>

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<sup>®</sup> before expiration of United States Patent No. 10,143,693 relating to INVEGA TRINZA<sup>®</sup>. Janssen is seeking an order enjoining Mylan from marketing a generic version of INVEGA TRINZA<sup>®</sup> before the expiration of the relevant patent. Trial is scheduled to begin in October 2022.

#### IMBRUVICA<sup>®</sup>

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<sup>®</sup> 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<sup>®</sup>. JBI is the exclusive licensee of the asserted patents. The named defendants include the following generic companies: Cipla Limited and Cipla USA Inc. (collectively, Cipla); Sandoz Inc. and Lek Pharmaceuticals d.d. (collectively, Sandoz). In January 2019 and February 2019, Pharmacyclics and JBI amended their complaint against Sandoz and Cipla, respectively, to allege infringement of United States Patent Nos. 10,125,140 and 10,106,548. In May 2019, Pharmacyclics and JBI amended their complaint against Cipla to further allege infringement of United States Patent No. 10,016,435. In August 2019, Pharmacyclics and JBI amended their complaints against Cipla and Sandoz to further allege infringement of U.S. Patent Nos. 10,294,231 and 10,294,232. In August 2019, the Court granted a joint stipulation to stay the litigation against Cipla. In May 2021, JBI, Pharmacyclics and Cipla entered into a confidential settlement agreement.

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<sup>®</sup> 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<sup>®</sup> 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 March 2020, Pharmacyclics and JBI filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Alvogen asserting infringement of United States Patent No. 10,478,439. In October 2020, Pharmacyclics and JBI amended their complaint against Alvogen to further allege infringement of U.S. Patent No. 10,653,696. In April 2021, the court entered a joint stipulation dismissing the complaint against Alvogen.

#### UPTRAVI<sup>®</sup>

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 a number of generic companies

that filed ANDAs seeking approval to market generic versions of UPTRAVI® before expiration of Nippon Shinyaku's United States Patent Nos. 7,205,302; 8,791,122; and 9,284,280 relating to UPTRAVI®. Actelion is the exclusive licensee of the asserted patents. The defendants include Alembic Pharmaceuticals Limited and Alembic Pharmaceuticals Inc. (collectively, Alembic); and Zydus Pharmaceuticals (USA), Inc. and Zydus Worldwide DMCC (collectively, Zydus). In April 2021, the court entered a joint stipulation dismissing Alembic from suit.

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

## **GOVERNMENT PROCEEDINGS**

Like other companies in the pharmaceutical, consumer 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 AWP's in calculating provider reimbursement levels. The plaintiffs in these cases included three classes of private persons or entities that paid for any portion of the purchase of the drugs at issue based on AWP, and state government entities that made Medicaid payments for the drugs at issue based on AWP. Many of these cases, both federal actions and state actions removed to federal court, were consolidated for pre-trial purposes in a multi-district litigation in the United States District Court for the District of Massachusetts, where all claims against the J&J AWP Defendants were ultimately dismissed. The J&J AWP Defendants also prevailed in a case brought by the Commonwealth of Pennsylvania. Other AWP cases have been resolved through court order or settlement. The case brought by Illinois was settled after trial. In New Jersey, a putative class action based upon AWP allegations is pending against Centocor, Inc. and Ortho Biotech Inc. (both now Janssen Biotech, Inc.), Johnson & Johnson and ALZA Corporation. All other cases have been resolved.

### **Opioid Litigation**

Beginning in 2014 and continuing to the present, Johnson & Johnson and Janssen Pharmaceuticals, Inc. (JPI), along with other pharmaceutical companies, have been named in more than 3,200 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 more than 380 cases pending in various state courts. There are over 2,800 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 in Canada. In October 2019, an anti-trust complaint was filed by private plaintiffs in federal court in Tennessee and is pending transfer to the MDL. These actions allege a variety of claims related to opioid marketing practices, including false advertising, unfair competition, public nuisance, consumer fraud violations, deceptive acts and practices, false claims and unjust enrichment. The suits generally seek penalties and/or injunctive and monetary relief and, in some of the suits, the plaintiffs are seeking joint and several liability among the defendants. An adverse judgment in any of these lawsuits could result in the

imposition of large monetary penalties and significant damages including, punitive damages, cost of abatement, substantial fines, equitable remedies and other sanctions.

The trial in the matter filed by the Oklahoma Attorney General resulted in a judgment against Johnson & Johnson and JPI in the amount of \$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 is scheduled to be completed by August 2021.

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.

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 and would resolve opioid lawsuits filed and future claims by states, cities and counties. The Company has made progress towards negotiating a final settlement with a coalition of state Attorneys General and a committee of the counsel representing the states and their subdivisions. In July 2021, the Company announced that the terms of the agreement have been finalized and up to 20% of the all-in settlement is expected to be paid within the next 18 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 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. In July 2020, the Court ordered the relators to complete discovery by August 2020; the Relators have requested an extension of the August 2020 deadline that DePuy opposed and additional discovery-related motions have been filed by both parties since. In March 2021, DePuy filed its motion to strike and dismiss the relators' second amended complaint; all briefing on the motion is complete and the motion is pending. In March 2021, the District Court issued an order stating that if DePuy's motion to strike and dismiss is denied, the court will hold a conference at which a limited period for remaining discovery will be established.

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 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 produced documents to Arizona, North Carolina, and Texas in February 2021. 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 October 2020, JJCI moved to dismiss the complaint.

In December 2013, Janssen Ortho LLC (Janssen Ortho) sued the United States in the United States Court of International Trade (the Classification Litigation) seeking a determination that darunavir ethanolate (the active pharmaceutical ingredient in PREZISTA®) is exempt from duties upon importation into the United States. In August 2014, United States Customs and Border Protection (US CBP) issued a Penalty Notice against Janssen Ortho LLC (Janssen Ortho), assessing penalties for the alleged improper classification of darunavir ethanolate (the active pharmaceutical ingredient in PREZISTA®) in connection

with its importation into the United States. In February 2020, the Court in the Classification Litigation ruled that darunavir ethanolate is eligible for duty free treatment. In April 2020, the United States appealed that ruling to the United States Court of Appeals for the Federal Circuit. In August 2020, US CBP formally rejected Janssen's Supplemental Petition challenging the penalties assessment and demanded payment of the mitigated penalty. In October 2020, US CBP agreed to not refer the matter to the Office of Chief Counsel, pending resolution of the related Classification Litigation. In April 2021, the Federal Circuit denied the United States' appeal in the Classification Litigation. In June 2021, the US CBP cancelled its penalty claim.

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.

In August 2015, two third-party payors filed a purported class action in the United States District Court for the Eastern District of Louisiana against Janssen Research & Development, LLC, Janssen Ortho LLC, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Johnson & Johnson (as well as certain Bayer entities), alleging that the defendants improperly marketed and promoted XARELTO® as safer and more effective than less expensive alternative medications while failing to fully disclose its risks. The complaint seeks damages. In November 2020, Defendants moved to dismiss the complaint. In July 2021, the Court granted the motion to dismiss.

In September 2017, Pfizer, Inc. (Pfizer) filed an antitrust complaint against Johnson & Johnson and Janssen Biotech, Inc. (collectively, Janssen) in United States District Court for the Eastern District of Pennsylvania. Pfizer alleges that Janssen has violated federal antitrust laws through its contracting strategies for REMICADE®. The complaint seeks damages and injunctive relief. In July 2021, Pfizer withdrew its claims with prejudice.

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. 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 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. Oral argument on the motion to dismiss is scheduled for September 2021. 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 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. In addition, in July 2021, a putative class action was filed in British Columbia, Canada, similarly challenging the non-disclosure of benzene contamination of certain Neutrogena and Aveeno sunscreen products.

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 second quarter of 2021, the Company recorded a pre-tax charge of \$108 million, which is included on the following lines of the Consolidated Statement of Earnings, \$56 million in restructuring, \$20 million in cost of products sold and \$32 million in other (income) expense, net. In the first fiscal six months of 2021, the Company recorded a pre-tax charge of \$212 million, which is included on the following lines of the Consolidated Statement of Earnings, \$109 million in restructuring, \$47 million in cost of products sold and \$56 million in other (income) expense, net. Total project costs of approximately \$1.5 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 second quarter of 2021:

(Dollars in Millions)	Severance	Asset Write-offs	Other <sup>(2)</sup>	Total
Reserve balance, January 3, 2021	\$ 135	—	9	144
Current year activity:				
Charges	—	26	186	212
Cash payments	(12)	—	(181)	(193)
Settled non cash	—	(26)		(26)
Reserve balance, July 4, 2021 <sup>(1)</sup>	\$ 123	—	14	137

<sup>(1)</sup> 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.

<sup>(2)</sup> 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

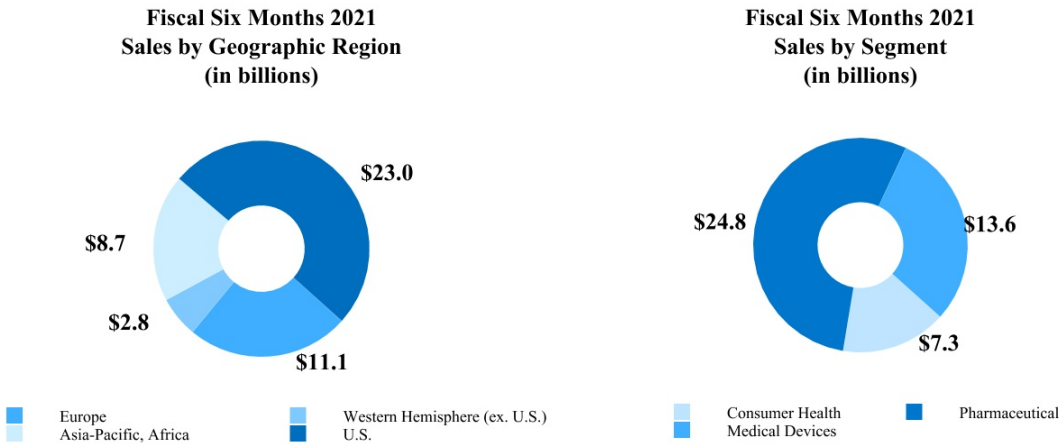
Sales to Customers

Analysis of Consolidated Sales

For the first fiscal six months of 2021, worldwide sales were \$45.6 billion, a total increase of 16.9%, including an operational increase of 13.7% as compared to 2020 first fiscal six months sales of \$39.0 billion. Currency fluctuations had a positive impact of 3.2% for the first fiscal six months of 2021. In the first fiscal six 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 \$23.0 billion in the first fiscal six months of 2021, which represented an increase of 13.8% as compared to the prior year. In the first fiscal six 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 \$22.6 billion, an increase of 20.3%, including an operational increase of 13.7%, and a positive currency impact of 6.6% as compared to the first fiscal six months sales of 2020. In the first fiscal six months of 2021, the net impact of acquisitions and divestitures on the international operational sales growth was a negative 1.1%.

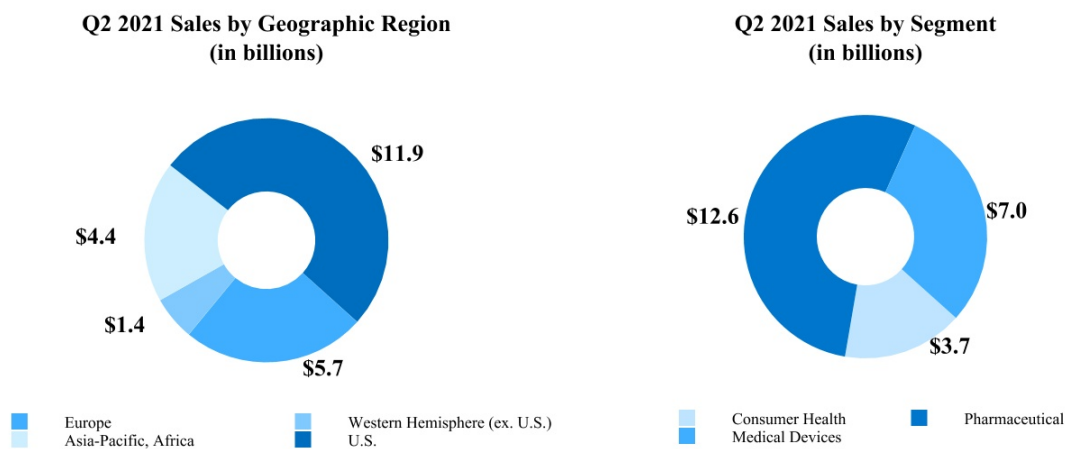
In the first fiscal six months of 2021, sales by companies in Europe achieved growth of 24.7%, which included an operational increase of 15.6% and a positive currency impact of 9.1%. Sales by companies in the Western Hemisphere, excluding the U.S., achieved growth of 5.9%, which included an operational increase of 5.4%, and a positive currency impact of 0.5%. Sales by companies in the Asia-Pacific, Africa region achieved growth of 20.2%, including an operational increase of 14.2% and a positive currency impact of 6.0%.



For the fiscal second quarter of 2021, worldwide sales were \$23.3 billion, a total increase of 27.1%, which included operational growth of 23.0% and a positive currency impact of 4.1% as compared to 2020 fiscal second quarter sales of \$18.3 billion. In the fiscal second quarter of 2021, the net impact of acquisitions and divestitures on worldwide operational sales growth was a negative 0.8%.

Sales by U.S. companies were \$11.9 billion in the fiscal second quarter of 2021, which represented an increase of 24.9% as compared to the prior year. In the fiscal second quarter of 2021, the net impact of acquisitions and divestitures on the U.S. operational sales growth was a negative 0.2%. Sales by international companies were \$11.4 billion, a total increase of 29.5%, which included operational growth of 20.9% and a positive currency impact of 8.6%. In the fiscal second quarter of 2021, the net impact of acquisitions and divestitures on the international operational sales growth was a negative 1.5%.

In the fiscal second quarter of 2021, sales by companies in Europe achieved growth of 39.5%, which included operational growth of 28.6% and a positive currency impact of 10.9%. Sales by companies in the Western Hemisphere, excluding the U.S., achieved growth of 20.6%, including operational growth of 12.7% and a positive currency impact of 7.9%. Sales by companies in the Asia-Pacific, Africa region achieved growth 21.0%, including operational growth of 14.8% and a positive currency impact of 6.2%.



Note: values may have been rounded

## Analysis of Sales by Business Segments

**Consumer Health**

Consumer Health segment sales in the first fiscal six months of 2021 were \$7.3 billion, an increase of 5.2% as compared to the same period a year ago, including operational growth of 2.7% and a positive currency impact of 2.5%. U.S. Consumer Health segment sales increased by 2.0%. International Consumer Health segment sales increased by 8.1%, including operational growth of 3.3% and a positive currency impact of 4.8%. In the first fiscal six months of 2021, the net impact of acquisitions and divestitures on the Consumer Health segment operational sales growth was a negative 0.6%.

## Major Consumer Health Franchise Sales — Fiscal Six Months Ended

(Dollars in Millions)	July 4, 2021	June 28, 2020	Total Change	Operations Change	Currency Change
OTC	\$ 2,482	\$ 2,497	(0.6) %	(3.9) %	3.3 %
Skin Health/Beauty	2,333	2,124	9.8	7.6	2.2
Oral Care	843	792	6.3	3.5	2.8
Baby Care	776	717	8.1	7.3	0.8
Women's Health	452	434	4.2	2.8	1.4
Wound Care/Other	393	356	10.2	8.0	2.2
<b>Total Consumer Health Sales</b>	<b>\$ 7,278</b>	<b>\$ 6,921</b>	<b>5.2 %</b>	<b>2.7 %</b>	<b>2.5 %</b>

Consumer Health segment sales in the fiscal second quarter of 2021 were \$3.7 billion, an increase of 13.3% as compared to the same period a year ago, including operational growth of 9.2% and a positive currency impact of 4.1%. U.S. Consumer Health segment sales increased by 12.4%. International Consumer Health segment sales increased by 14.1% including operational growth of 6.3% and a positive currency impact of 7.8%. In the fiscal second quarter of 2021, the net impact of acquisitions and divestitures on the Consumer Health segment operational sales growth was a negative 0.8%.

Subsequent to the quarter, the Company voluntarily recalled all lots of five NEUTROGENA® and AVEENO® aerosol sunscreen product lines due to low levels of benzene in some samples of the products. This recall did not have a material impact on the fiscal second quarter 2021 financial results and is not expected to have a material impact on the Company's overall results for the remainder of the year.

## Major Consumer Health Franchise Sales — Fiscal Second Quarter Ended

(Dollars in Millions)	July 4, 2021	June 28, 2020	Total Change	Operations Change	Currency Change
OTC	\$ 1,307	\$ 1,149	13.8 %	8.9 %	4.9 %
Skin Health/Beauty	1,170	1,007	16.2	12.9	3.3
Oral Care	426	397	7.0	2.5	4.5
Baby Care	387	356	8.6	5.0	3.6
Women's Health	230	202	13.9	9.0	4.9
Wound Care/Other	216	185	16.6	13.4	3.2
<b>Total Consumer Health Sales</b>	<b>\$ 3,735</b>	<b>\$ 3,296</b>	<b>13.3 %</b>	<b>9.2 %</b>	<b>4.1 %</b>

The OTC franchise achieved operational growth of 8.9% as compared to the prior year fiscal second quarter. Growth was driven by U.S. Allergy Care seasonal incidence and ZYRTEC® promotional campaigns, MOTRIN® recovery in China, and Digestive Health driven by PEPCID® and COVID-19 related health care professional recommendations for the hydration benefit offering (ORSL) in the Asia Pacific region.

The Skin Health/Beauty franchise achieved operational growth of 12.9% as compared to the prior year fiscal second quarter. Growth was primarily attributable to worldwide COVID-19 recovery in key markets and lapping of prior year low stocking levels at U.S. retailers as well as new product stocking primarily in NEUTROGENA® and AVEENO®. The growth was partially offset by competitive pressures. Growth outside the U.S. was partially offset by divestitures.

The Oral Care franchise achieved operational growth of 2.5% as compared to the prior year fiscal second quarter primarily due to sales of LISTERINE® mouthwash outside the U.S. related to an accelerating category and an increase in demand from continued successful promotional campaigns partially offset by divestitures.

The Baby Care franchise achieved operational growth of 5.0% as compared to the prior year fiscal second quarter. Growth outside the U.S. was primarily driven by strength in Asia Pacific eCommerce and successful promotional activities for JOHNSON'S® and AVEENO® baby products as compared to the prior year negative COVID-19 impacts. Growth in the U.S. was partially offset by comparisons to prior year COVID-19 demand surge.

The Women's Health franchise achieved operational growth of 9.0% as compared to the prior year fiscal second quarter primarily driven innovation launches and comparisons to prior year negative COVID-19 impact.

The Wound Care/Other franchise achieved operational growth of 13.4% as compared to the prior year fiscal second quarter. Growth was driven by category wide U.S. market growth with increased consumer behavior focus on preparedness and infection prevention, seasonal inventory builds and impacts from prior year de-stocking.

**Pharmaceutical**

Pharmaceutical segment sales in the first fiscal six months of 2021 were \$24.8 billion, an increase of 13.3% as compared to the same period a year ago, with an operational increase of 10.3% and a positive currency impact of 3.0%. U.S. Pharmaceutical sales increased 9.3% as compared to the same period a year ago. International Pharmaceutical sales increased by 18.3%, including operational growth of 11.4% and a positive currency impact of 6.9%. In the first fiscal six months of 2021, the net impact of acquisitions and divestitures on the Pharmaceutical segment operational sales growth was a negative 0.4%.

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

(Dollars in Millions)	July 4, 2021	June 28, 2020	Total Change	Operations Change	Currency Change
<b>Immunology</b>	<b>\$ 8,145</b>	<b>\$ 7,161</b>	<b>13.7 %</b>	<b>11.1 %</b>	<b>2.6 %</b>
REMICADE®	1,665	1,925	(13.5)	(15.1)	1.6
SIMPONI®/ SIMPONI ARIA®	1,146	1,075	6.6	3.8	2.8
STELARA®	4,422	3,516	25.8	22.7	3.1
TREMFYA®	897	638	40.6	37.3	3.3
Other Immunology	15	6	*	*	*
<b>Infectious Diseases</b>	<b>2,035</b>	<b>1,798</b>	<b>13.2</b>	<b>9.9</b>	<b>3.3</b>
COVID-19 vaccine	264	—	*	*	—
EDURANT®/rilpivirine	505	480	5.2	(2.1)	7.3
PREZISTA®/ PREZCOBIX®/ REZOLSTA®/ SYMTUZA®	1,051	1,089	(3.5)	(5.0)	1.5
Other Infectious Diseases	215	229	(6.1)	(9.7)	3.6
<b>Neuroscience</b>	<b>3,529</b>	<b>3,245</b>	<b>8.7</b>	<b>6.0</b>	<b>2.7</b>
CONCERTA®/methylphenidate	332	320	3.9	(0.3)	4.2
INVEGA SUSTENNA®/ XEPLION®/ INVEGA TRINZA®/ TREVICTA®	1,989	1,762	12.9	10.1	2.8
RISPERDAL CONSTA®	312	323	(3.3)	(6.0)	2.7
Other Neuroscience	896	841	6.5	4.5	2.0
<b>Oncology</b>	<b>7,105</b>	<b>5,804</b>	<b>22.4</b>	<b>17.9</b>	<b>4.5</b>
DARZALEX®	2,798	1,838	52.2	47.9	4.3
ERLEADA®	563	313	80.0	76.4	3.6
IMBRUVICA®	2,241	1,980	13.2	8.9	4.3
ZYTIGA®/ abiraterone acetate	1,201	1,258	(4.5)	(10.3)	5.8
Other Oncology <sup>(1)</sup>	302	416	(27.3)	(30.2)	2.9
<b>Pulmonary Hypertension</b>	<b>1,731</b>	<b>1,534</b>	<b>12.9</b>	<b>11.1</b>	<b>1.8</b>
OPSUMIT®	913	795	14.8	12.7	2.1
UPTRAVI®	618	532	16.2	15.0	1.2
Other Pulmonary Hypertension	200	207	(3.3)	(5.0)	1.7
<b>Cardiovascular / Metabolism / Other</b>	<b>2,253</b>	<b>2,344</b>	<b>(3.9)</b>	<b>(5.7)</b>	<b>1.8</b>
XARELTO®	1,158	1,086	6.6	6.6	—
INVOKANA®/ INVOKAMET®	310	354	(12.6)	(15.0)	2.4
PROCRI®/EPREX®	254	291	(12.8)	(15.7)	2.9
Other	532	614	(13.3)	(17.4)	4.1
<b>Total Pharmaceutical Sales</b>	<b>\$ 24,798</b>	<b>\$ 21,886</b>	<b>13.3 %</b>	<b>10.3 %</b>	<b>3.0 %</b>

\* Percentage greater than 100% or not meaningful

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

<sup>(1)</sup> Inclusive of VELCADE® which was previously disclosed separately



Pharmaceutical segment sales in the fiscal second quarter of 2021 were \$12.6 billion, an increase of 17.2% as compared to the same period a year ago, including an operational increase of 13.6% and a positive currency impact of 3.6%. U.S. Pharmaceutical sales increased 12.2% as compared to the same period a year ago. International Pharmaceutical sales increased by 23.7%, including operational growth of 15.4% and a positive currency impact of 8.3%. In the fiscal second quarter of 2021, the net impact of acquisitions and divestitures on the Pharmaceutical segment operational sales growth was a negative 0.5%. Adjustments to previous reserve estimates were approximately \$0.1 billion in both fiscal second quarters of 2021 and 2020.

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

(Dollars in Millions)	July 4, 2021	June 28, 2020	Total Change	Operations Change	Currency Change
<b>Immunology</b>	<b>\$ 4,231</b>	<b>\$ 3,523</b>	<b>20.1 %</b>	<b>17.0 %</b>	<b>3.1 %</b>
REMICADE®	888	935	(5.1)	(7.6)	2.5
SIMPONI®/ SIMPONI ARIA®	584	546	6.9	4.0	2.9
STELARA®	2,274	1,697	34.0	30.5	3.5
TREMFYA®	479	342	40.2	36.8	3.4
Other Immunology	7	3	*	*	*
<b>Infectious Diseases</b>	<b>1,028</b>	<b>878</b>	<b>17.1</b>	<b>12.8</b>	<b>4.3</b>
COVID-19 vaccine	164	—	*	*	—
EDURANT®/rilpivirine	262	256	2.3	(4.2)	6.5
PREZISTA®/ PREZCOBIX®/ REZOLSTA®/ SYMTUZA®	505	510	(1.0)	(3.9)	2.9
Other Infectious Diseases	98	113	(13.0)	(18.5)	5.5
<b>Neuroscience</b>	<b>1,808</b>	<b>1,587</b>	<b>13.9</b>	<b>10.6</b>	<b>3.3</b>
CONCERTA®/ methylphenidate	161	149	8.1	3.0	5.1
INVEGA SUSTENNA®/ XEPLION®/ INVEGA TRINZA®/ TREVICTA®	1,024	879	16.4	13.3	3.1
RISPERDAL CONSTA®	155	153	1.9	(1.3)	3.2
Other Neuroscience	468	406	15.1	12.0	3.1
<b>Oncology</b>	<b>3,535</b>	<b>2,791</b>	<b>26.7</b>	<b>21.5</b>	<b>5.2</b>
DARZALEX®	1,433	901	59.2	53.8	5.4
ERLEADA®	302	170	77.6	73.7	3.9
IMBRUVICA®	1,116	949	17.7	12.5	5.2
ZYTIGA®/ abiraterone acetate	563	568	(0.8)	(7.1)	6.3
Other Oncology <sup>(1)</sup>	120	204	(40.9)	(43.0)	2.1
<b>Pulmonary Hypertension</b>	<b>870</b>	<b>789</b>	<b>10.4</b>	<b>8.7</b>	<b>1.7</b>
OPSUMIT®	463	406	14.1	11.9	2.2
UPTRAVI®	313	282	11.0	9.8	1.2
Other Pulmonary Hypertension	95	101	(6.1)	(7.5)	1.4
<b>Cardiovascular / Metabolism / Other</b>	<b>1,126</b>	<b>1,184</b>	<b>(5.0)</b>	<b>(7.3)</b>	<b>2.3</b>
XARELTO®	569	559	1.8	1.8	—
INVOKANA®/ INVOKAMET®	160	179	(10.9)	(14.0)	3.1
PROCRI®/ EPREX®	127	136	(6.6)	(10.6)	4.0
Other	271	312	(13.0)	(18.4)	5.4
<b>Total Pharmaceutical Sales</b>	<b>\$ 12,599</b>	<b>\$ 10,752</b>	<b>17.2 %</b>	<b>13.6 %</b>	<b>3.6 %</b>

\* Percentage greater than 100% or not meaningful

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

<sup>(1)</sup> Inclusive of VELCADE® which was previously disclosed separately

Immunology products achieved operational growth of 17.0% 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 12.8% as compared to the same period a year ago. Growth was primarily driven by the contribution of the COVID-19 vaccine in the U.S and European Union. 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 10.6% 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 21.5% 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 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 8.7% 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 7.3% 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 PROCRT®/ EPREX® (epoetin alfa) due to biosimilar competition. Additionally, the growth of XARELTO® (rivaroxaban) was driven by demand partially offset by higher commercial access cost.

## Medical Devices

The Medical Devices segment sales in the first fiscal six months of 2021 were \$13.6 billion, an increase of 32.7% as compared to the same period a year ago, with an operational increase of 28.7% and a positive currency impact of 4.0%. U.S. Medical Devices sales increased 33.5%. International Medical Devices sales increased by 31.9%, including an operational increase of 24.5% and a positive currency impact of 7.4%. In the first fiscal six months of 2021, the net impact of acquisitions and divestitures on the Medical Devices segment operational sales growth was a negative 1.0% primarily due to the divestiture of the Advanced Sterilization Products (ASP) business.

### Major Medical Devices Franchise Sales — Fiscal Six Months Ended

(Dollars in Millions)	July 4, 2021	June 28, 2020	Total Change	Operations Change	Currency Change
<b>Surgery</b>	<b>\$ 4,894</b>	<b>\$ 3,651</b>	<b>34.0 %</b>	<b>29.3 %</b>	<b>4.7 %</b>
Advanced	2,286	1,723	32.6	27.8	4.8
General	2,608	1,928	35.3	30.7	4.6
<b>Orthopaedics</b>	<b>4,340</b>	<b>3,489</b>	<b>24.4</b>	<b>20.9</b>	<b>3.5</b>
Hips	749	563	33.0	29.2	3.8
Knees	667	517	28.9	25.2	3.7
Trauma	1,443	1,207	19.6	16.5	3.1
Spine, Sports & Other	1,482	1,202	23.2	19.6	3.6
<b>Vision</b>	<b>2,328</b>	<b>1,762</b>	<b>32.1</b>	<b>29.3</b>	<b>2.8</b>
Contact Lenses/Other	1,725	1,368	26.1	23.7	2.4
Surgical	602	394	52.8	48.6	4.2
<b>Interventional Solutions</b>	<b>1,995</b>	<b>1,317</b>	<b>51.5</b>	<b>46.5</b>	<b>5.0</b>
<b>Total Medical Devices Sales</b>	<b>\$ 13,557</b>	<b>\$ 10,220</b>	<b>32.7 %</b>	<b>28.7 %</b>	<b>4.0 %</b>

The Medical Devices segment sales in the fiscal second quarter of 2021 were \$7.0 billion, an increase of 62.7% as compared to the same period a year ago, which included operational growth of 57.2% and a positive currency impact of 5.5%. U.S. Medical Devices sales increased 77.2%. International Medical Devices sales increased by 51.6%, including operational growth of 41.9% and a positive currency impact of 9.7%. In the fiscal second quarter of 2021, the net impact of acquisitions and divestitures on the Medical Devices segment operational sales growth was a negative 1.5% 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.

## Major Medical Devices Franchise Sales — Fiscal Second Quarter Ended

(Dollars in Millions)	July 4, 2021	June 28, 2020	Total Change	Operations Change	Currency Change
<b>Surgery</b>	<b>\$ 2,522</b>	<b>\$ 1,551</b>	<b>62.6 %</b>	<b>56.0 %</b>	<b>6.6 %</b>
Advanced	1,168	775	50.5	44.3	6.2
General	1,354	775	74.7	67.8	6.9
<b>Orthopaedics</b>	<b>2,227</b>	<b>1,451</b>	<b>53.4</b>	<b>48.6</b>	<b>4.8</b>
Hips	392	226	73.7	68.1	5.6
Knees	350	174	*	94.6	6.4
Trauma	710	553	28.4	24.8	3.6
Spine, Sports & Other	776	499	55.3	50.2	5.1
<b>Vision</b>	<b>1,183</b>	<b>695</b>	<b>70.1</b>	<b>66.0</b>	<b>4.1</b>
Contact Lenses/Other	868	554	56.7	53.4	3.3
Surgical	314	141	*	*	*
<b>Interventional Solutions</b>	<b>1,046</b>	<b>590</b>	<b>77.4</b>	<b>71.3</b>	<b>6.1</b>
<b>Total Medical Devices Sales</b>	<b>\$ 6,978</b>	<b>\$ 4,288</b>	<b>62.7 %</b>	<b>57.2 %</b>	<b>5.5 %</b>

\* Percentage greater than 100% or not meaningful

The Surgery franchise achieved operational sales growth of 56.0% as compared to the prior year fiscal second quarter. The operational growth in Advanced Surgery was primarily driven by 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 from the initial onset of COVID-19 in the prior year and continued strength of the Suture portfolio, changes in U.S. inventory levels in Wound Closure and a prior year unfavorable one-time price adjustment in the U.S. partially offset by the impact of the ASP divestiture in the prior year.

The Orthopaedics franchise achieved operational sales growth of 48.6% as compared to the prior year fiscal second 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. The operational growth in Trauma was driven by global market recovery and uptake of new products. The operational growth in Spine, Sports & Other was driven by market recovery and uptake of new products.

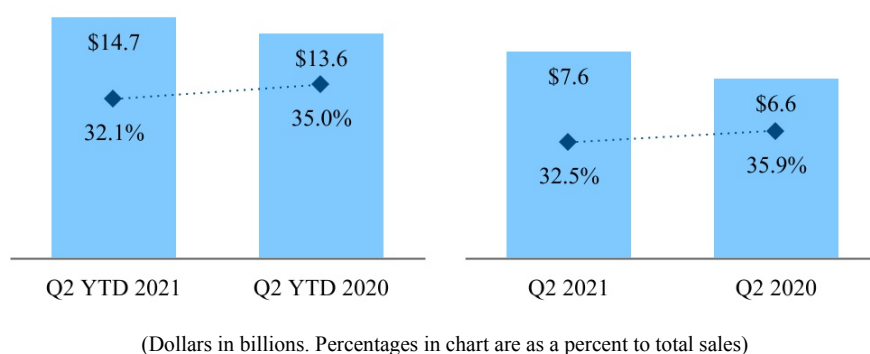
The Vision franchise achieved operational sales growth of 66.0% as compared to the prior year fiscal second quarter. The Contact Lenses/Other operational growth was due to market recovery, new products and channel inventory changes in the U.S. The Surgical operational growth was primarily due to market recovery and uptake of recently launched products.

The Interventional Solutions franchise achieved operational sales growth of 71.3% as compared to the prior year fiscal second 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 first fiscal six months of 2021 was \$14.1 billion representing 30.9% of sales as compared to \$10.4 billion in the first fiscal six months of 2020, representing 26.8% of sales.

Consolidated earnings before provision for taxes on income for the fiscal second quarter of 2021 was \$6.7 billion representing 28.6% of sales as compared to \$3.9 billion in the fiscal second quarter of 2020, representing 21.5% of sales.

**Cost of Products Sold****Fiscal Six months Q2 2021 versus Fiscal Six months Q2 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
- partially offset by:
- Segment mix with a higher percentage of sales coming from the Medical Devices business in the current year.

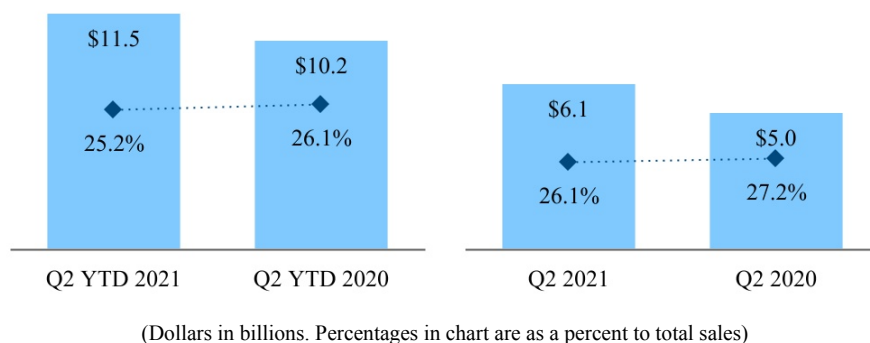
The intangible asset amortization expense included in cost of products sold for the first fiscal six months of 2021 and 2020 was \$2.4 billion and \$2.2 billion, respectively.

**Q2 2021 versus Q2 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
- partially offset by:
- Segment mix with a higher percentage of sales coming from the Medical Devices business in the current year

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

**Selling, Marketing and Administrative Expenses****Fiscal Six months Q2 2021 versus Fiscal Six months Q2 2020**

Selling, Marketing and Administrative Expenses decreased as a percent to sales driven by:

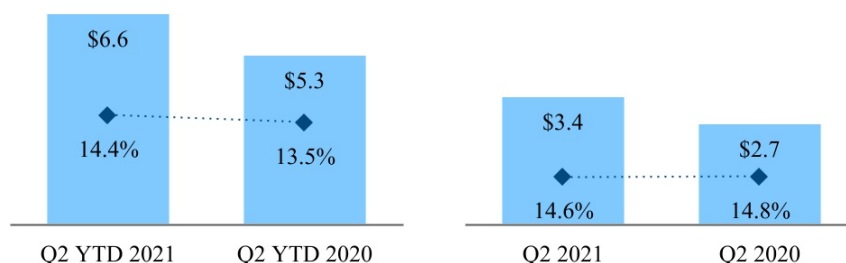
- Leveraging in the Medical Devices business resulting from the recovery of sales from the prior years impact of COVID-19
- partially offset by:
- Segment mix with a higher percentage of sales coming from the Medical Devices business in the current year

## Q2 2021 versus Q2 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

## **Research and Development Expense**



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

## Fiscal Six months Q2 2021 versus Fiscal Six months Q2 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

## Q2 2021 versus Q2 2020

Research and Development slightly decreased as a percent to sales driven by:

- Recovery of Medical Devices sales from the prior year's negative COVID-19 impact
- partially offset by:
- COVID-19 vaccine expenses, net of governmental reimbursements
  - Portfolio progression in the Pharmaceutical business

## **Interest (Income) Expense**

Interest (Income) Expense in the first fiscal six months of 2021 was a net interest expense of \$76 million as compared to income of \$16 million in the same period a year ago. Interest (Income) Expense in the fiscal second quarter of 2021 was a net interest expense of \$28 million as compared to \$26 million in the same period a year ago. In both the fiscal six months and fiscal second quarter the higher interest expense was primarily due to reduced interest income resulting from lower rates of interest earned on cash balances and a higher average debt balance. The balance of cash, cash equivalents and current marketable securities was \$25.3 billion at the end of the fiscal second quarter of 2021 as compared to \$19.1 billion at the end of the fiscal second quarter of 2020. The Company's debt position was \$33.5 billion as of July 4, 2021 as compared to \$30.4 billion the same period a year ago.

## **Other (Income) Expense, Net\***

## Fiscal Six months Q2 2021 versus Fiscal Six months Q2 2020

Other (income) expense, net for the first fiscal six months of 2020 was favorable by \$0.7 billion as compared to the prior year primarily due to the following:

## Fiscal Six Months

*(Dollars in Billions)(Income)/Expense*

	2021	2020	Change
Acquisition, Integration and Divestiture Related <sup>(1)</sup>	\$ (0.5)	(0.9)	0.4
Unrealized (gains)/losses on securities	(0.2)	(0.2)	0.0
Litigation related	0.0	0.7	(0.7)
Restructuring related	0.1	0.1	0.0
Employee benefit plan related	(0.3)	(0.2)	(0.1)
Other	(0.5)	(0.2)	(0.3)
Total Other (Income) Expense, Net	<u>\$ (1.4)</u>	<u>(0.7)</u>	<u>(0.7)</u>

Q2 2021 versus Q2 2020

Other (income) expense, net for the fiscal second quarter of 2021 was favorable by \$0.5 billion as compared to the prior year primarily due to the following:

## Fiscal Second Quarter

*(Dollars in Billions)(Income)/Expense*

	2021	2020	Change
Unrealized (gains)/losses on securities	\$ (0.2)	(0.5)	0.3
Litigation related	0.0	0.6	(0.6)
Employee benefit plan related	(0.1)	(0.1)	0.0
Other	(0.2)	0.0	(0.2)
Total Other (Income) Expense, Net	<u>\$ (0.5)</u>	<u>0.0</u>	<u>(0.5)</u>

<sup>(1)</sup> Primarily related to divestiture gains of two pharmaceutical brands outside the U.S. in the fiscal six 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 six 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 six months ended were as follows:

(Dollars in Millions)	Income Before Tax		Segment Sales		Percent of Segment Sales	
	July 4, 2021	June 28, 2020	July 4, 2021	June 28, 2020	July 4, 2021	June 28, 2020
Consumer Health	\$ 1,592	\$ 802	\$ 7,278	\$ 6,921	21.9 %	11.6 %
Pharmaceutical	9,579	8,348	24,798	21,886	38.6	38.1
Medical Devices	3,375	1,671	13,557	10,220	24.9	16.4
Segment earnings before tax	14,546	10,821	45,633	39,027	31.9	27.7
Less: Expenses not allocated to segments <sup>(1)</sup>	455	372				
Worldwide income before tax	<u>\$ 14,091</u>	<u>\$ 10,449</u>	<u>\$ 45,633</u>	<u>\$ 39,027</u>	<u>30.9 %</u>	<u>26.8 %</u>

<sup>(1)</sup> 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 first fiscal six months of 2021 was 21.9% versus 11.6% for the same period a year ago. The increase in the income before tax as a percent of sales in the first fiscal six months of 2021 as compared to the prior year was primarily driven by the following:

- Lower litigation expense
  - Supply chain efficiencies
- partially offset by:
- Increased brand marketing expense

The Pharmaceutical segment income before tax as a percent of sales in the first fiscal six months of 2021 was 38.6% versus 38.1% for the same period a year ago. The increase in the income before tax as a percent of sales for the first fiscal six months of 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 six months of 2021
- 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 first fiscal six months of 2021 was 24.9% versus 16.4% for the same period a year ago. The increase in the income before tax as a percent of sales for the first fiscal six months of 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 \$1.0 billion in the fiscal six months of 2020 related to the timing of certain developmental milestones associated with the Auris Health acquisition

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

(Dollars in Millions)	Income Before Tax		Segment Sales		Percent of Segment Sales	
	July 4, 2021	June 28, 2020	July 4, 2021	June 28, 2020	July 4, 2021	June 28, 2020
Consumer Health	\$ 804	\$ 32	\$ 3,735	\$ 3,296	21.5 %	1.0 %
Pharmaceutical	4,356	4,514	12,599	10,752	34.6	42.0
Medical Devices	1,746	(354)	6,978	4,288	25.0	(8.3)
Segment earnings before tax	6,906	4,192	23,312	18,336	29.6	22.9
Less: Expenses not allocated to segments <sup>(1)</sup>	244	252				
Worldwide income before tax	<u>\$ 6,662</u>	<u>\$ 3,940</u>	<u>\$ 23,312</u>	<u>\$ 18,336</u>	<u>28.6 %</u>	<u>21.5 %</u>

<sup>(1)</sup> Amounts not allocated to segments include interest (income) expense and general corporate (income) expense.



## Consumer Health Segment

The Consumer Health segment income before tax as a percent of sales in the fiscal second quarter of 2021 was 21.5% versus 1.0% for the same period a year ago. The increase in the income before tax as a percent of sales in the fiscal second quarter of 2021 as compared to the prior year was primarily driven by the following:

- Lower litigation expense
- Supply chain efficiencies

partially offset by:

- Increased brand marketing expense

## Pharmaceutical Segment

The Pharmaceutical segment income before tax as a percent of sales in the fiscal second quarter of 2021 was 34.6% versus 42.0% for the same period a year ago. The decrease in the income before tax as a percent of sales for the fiscal second quarter of 2021 as compared to the prior year was primarily driven by the following:

- Lower unrealized gains on securities (\$0.2 billion in 2021 vs. \$0.5 billion in 2020)
- Research & Development investment in the COVID-19 vaccine net of governmental reimbursements and general portfolio progression

## Medical Devices Segment

The Medical Devices segment income before tax as a percent of sales in the fiscal second quarter of 2021 was 25.0% versus a negative 8.3% for the same period a year ago. The increase in the income before tax as a percent of sales for the fiscal second quarter 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

## 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 second quarter of 2021, the Company recorded a pre-tax charge of \$108 million, which is included on the following lines of the Consolidated Statement of Earnings, \$56 million in restructuring, \$20 million in cost of products sold and \$32 million in other (income) expense, net. In the fiscal second quarter of 2020, the Company recorded a pre-tax charge of \$115 million, which is included on the following lines of the Consolidated Statement of Earnings, \$61 million in restructuring, \$22 million in cost of products sold and \$32 million in other (income) expense, net. In the first fiscal six months of 2021, the Company recorded a pre-tax charge of \$212 million, which is included on the following lines of the Consolidated Statement of Earnings, \$109 million in restructuring, \$47 million in cost of products sold and \$56 million in other (income) expense, net. In the first fiscal six months of 2020, the Company recorded a pre-tax charge of \$233 million, which is included on the following lines of the Consolidated Statement of Earnings, \$119 million in restructuring, \$37 million in cost of products sold and \$77 million in other (income) expense, net. Restructuring charges of approximately \$1.5 billion have been recorded since the restructuring was announced.

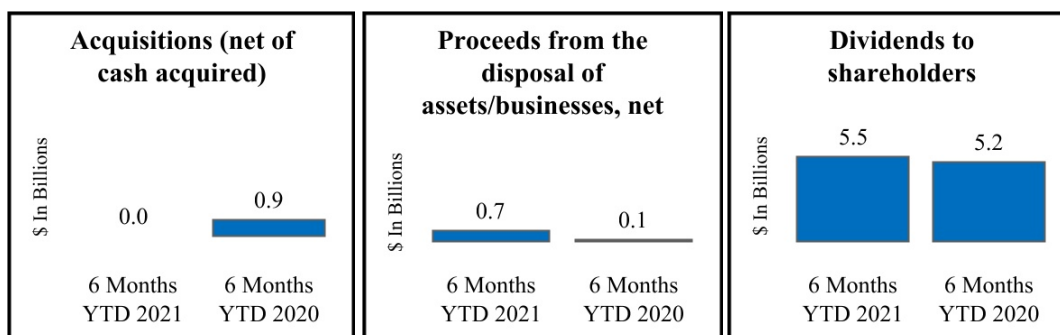
See Note 12 to the Consolidated Financial Statements for additional details related to the restructuring.

## Provision for Taxes on Income

For discussion related to the first fiscal six 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 4.4% 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 \$14.3 billion at the end of the fiscal second 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 \$0.3 billion increase were:

(Dollars In Billions)	
\$	14.0 Q4 2020 Cash and cash equivalents balance
	9.4 cash generated from operating activities
	(0.6) net cash used by investing activities
	(8.4) net cash used by financing activities
	(0.1) effect of exchange rate and rounding
\$	14.3 Q2 2021 Cash and cash equivalents balance

In addition, the Company had \$11.0 billion in marketable securities at the end of the fiscal second quarter of 2021 and \$11.2 billion at the end of fiscal year 2020.

Cash flow from operations of \$9.4 billion was the result of:

(Dollars In Billions)	
\$	12.5 Net Earnings
	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
	3.1 accounts receivable allowances
	(5.2) a decrease in accounts payable and accrued liabilities and other current and non-current liabilities
	(2.4) an increase in accounts receivable and inventories
	1.4 a decrease other current and non-current assets
\$	9.4 Cash Flow from operations

Investing activities use of \$0.6 billion of cash was primarily used for:

(Dollars In Billions)	
\$	(1.5) additions to property, plant and equipment
	0.7 proceeds from the disposal of assets/businesses, net
	0.2 net sales of investments
	0.4 credit support agreements activity, net
	(0.4) Other (primarily licenses and milestones)
\$	(0.6) Net cash used for investing activities

Financing activities use of \$8.4 billion of cash was primarily used for:

(Dollars In Billions)	
\$	(5.5) dividends to shareholders
	(2.1) repurchase of common stock
	(1.6) net repayment of short and long term debt
	0.5 proceeds from stock options exercised/employee withholding tax on stock awards, net
	0.1 credit support agreements activity, net
	0.2 other and rounding
\$	(8.4) Net cash used for financing activities

The Company has access to substantial sources of funds at numerous banks worldwide. In September 2020, the Company secured a new 364-day Credit Facility. Total credit available to the Company approximates \$10 billion, which expires on September 9, 2021. Interest charged on borrowings under the credit line agreement is based on either bids provided by banks, the prime rate, London Interbank Offered Rates (LIBOR), Secured Overnight Financing Rate (SOFR) Swap Curve or other applicable market rates as allowed under the terms of the agreement, plus applicable margins. Commitment fees under the agreement are not material.

In the fiscal second quarter of 2021, the Company's notes payable and long-term debt was in excess of cash, cash equivalents and marketable securities. As of July 4, 2021, the net debt position was \$8.2 billion as compared to the prior year of \$11.3 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 \$1.3 billion in contractual supply commitments associated with its development of the COVID-19 vaccine and the agreement to settle opioid litigation. In the fiscal second quarter of 2021, the Company paid \$2.5 billion including interest which related to talc litigation. 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.

In the fiscal second quarter of 2021, the Company paid approximately \$1.5 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 \$0.7 billion primarily related to the normal estimated payment for the fiscal first and second quarters of 2021.

## Dividends

On April 20, 2021, the Board of Directors declared a regular cash dividend of \$1.06 per share, payable on June 8, 2021 to shareholders of record as of May 25, 2021.

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. 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 and contractually obligated to be paid to these contract manufacturing organizations of approximately \$1.3 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 July 4, 2021, and for the first fiscal six 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 first fiscal six 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 second 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 second quarter.

Fiscal Month Period	Total Number of Shares Purchased <sup>(1)</sup>	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
April 5, 2021 through May 2, 2021	910,000	163.15		—
May 3, 2021 through May 30, 2021	2,131,600	167.83		—
May 31, 2021 through July 4, 2021	750,000	166.21		—
Total	3,791,600			

<sup>(1)</sup> During the fiscal second quarter of 2021, the Company repurchased an aggregate of 3,791,600 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.

Date: July 29, 2021

JOHNSON & JOHNSON  
(Registrant)

By /s/ J. J. WOLK

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J. J. WOLK

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

Date: July 29, 2021

By /s/ R. J. DECKER Jr.

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R. J. DECKER Jr.

Controller (Principal Accounting Officer)



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 July 4, 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

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Alex Gorsky  
Chief Executive Officer

Date: July 29, 2021

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 July 4, 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

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Joseph J. Wolk  
Chief Financial Officer

Date: July 29, 2021

**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 July 4, 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: July 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.

**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 July 4, 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: July 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.