# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# **FORM 10-Q**

<b>☑</b> Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934					
	for the quarte	erly period	ended April 3, 2022		
		or			
			on 13 or 15(d) of the Securities Exchange Act of sition period from	1934	
	Commi	ssion file nu	ımber 1-3215		
			Johnson specified in its charter)		
	New Jersey		22-1024240		
	(State or other jurisdiction of incorporation or organization)		(I.R.S. Employer Identification No.)		
	New Bru	nswick, Nev	ohnson Plaza w Jersey 08933 executive offices)		
	Registrant's telephone no	ımber, inclu	ding area code (732) 524-0400		
during th	cate by check mark whether the registrant (1) has filed all report he preceding 12 months (or for such shorter period that the regi- ments for the past 90 days. $\square$ Yes $\square$ No				
	cate by check mark whether the registrant has submitted electron S-T during the preceding 12 months (or for such shorter per				
emerging	cate by check mark whether the registrant is a large accelerated g growth company. See the definitions of "large accelerated file 12b-2 of the Exchange Act.				
	Large accelerated filer	✓	Accelerated filer		
	Non-accelerated filer Emerging growth company		Smaller reporting company		
	n emerging growth company, indicated by check mark if the re-			or complying	
Indic	cate by check mark whether the registrant is a shell company (a	s defined in	Rule 12b-2 of the Exchange Act). ☐ Yes ☑ No		

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, Par Value \$1.00	JNJ	New York Stock Exchange
0.650% 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 April 22, 2022, 2,631,401,804 shares of Common Stock, \$1.00 par value, were outstanding.

# JOHNSON & JOHNSON AND SUBSIDIARIES

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#### CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

#### Risks Related to Product Development, Market Success and Competition

- Challenges and uncertainties inherent in innovation and development of new and improved products and technologies on which the Company's
  continued growth and success depend, including uncertainty of clinical outcomes, additional analysis of existing clinical data, obtaining regulatory
  approvals, health plan coverage and customer access, and initial and continued commercial success;
- Challenges to the Company's ability to obtain and protect adequate patent and other intellectual property rights for new and existing products and technologies in the United States and other important markets;
- The impact of patent expirations, typically followed by the introduction of competing generic, biosimilar or other products 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;
- 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;
- The 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;
- The impact of an adverse judgment or settlement and the adequacy of reserves related to legal proceedings, including patent litigation, product liability, personal injury claims, securities class actions, government investigations, employment and other legal proceedings;

- Increased scrutiny of the healthcare 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 healthcare products; access to, and reimbursement and pricing for, healthcare 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, increasing audit scrutiny by tax authorities around the world and exposures to
  additional tax liabilities potentially in excess of existing reserves; and
- The 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, Healthcare Market Trends and the Planned Separation of the Company's Consumer Health Business

- Pricing pressures resulting from trends toward healthcare cost containment, including the continued consolidation among healthcare providers and
  other market participants, trends toward managed care, the shift toward governments increasingly becoming the primary payers of healthcare
  expenses, significant new entrants to the healthcare 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 healthcare 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;
- 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;
- The Company's ability to consummate the planned separation of the Company's Consumer Health business on a timely basis or at all;
- The Company's ability to successfully separate the Company's Consumer Health business and realize the anticipated benefits from the planned separation; and
- The New Consumer Health Company's ability to succeed as a standalone publicly traded company.

#### 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;
- The 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 novel coronavirus (COVID-19) pandemic;
- Changes to global climate, extreme weather and natural disasters that could affect demand for the Company's products and services, cause disruptions in manufacturing and distribution networks, alter the availability of goods and services within the supply chain, and affect the overall design and integrity of the Company's products and operations; and

The impact of armed conflicts and terrorist attacks in the United States and other parts of the world, including social and economic disruptions and
instability of financial and other markets.

#### Risks Related to Supply Chain and Operations

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

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 2, 2022, for a description of certain risks that could, among other things, cause the Company's actual results to differ materially from those expressed in its forward-looking statements. Investors should understand that it is not possible to predict or identify all such factors and should not consider the risks described above to be a complete statement of all potential risks and uncertainties. The Company does not undertake to publicly update any forward-looking statement that may be made from time to time, whether as a result of new information or future events or developments.

# Part I — FINANCIAL INFORMATION

# Item 1 — FINANCIAL STATEMENTS

# JOHNSON & JOHNSON AND SUBSIDIARIES CONSOLIDATED BALANCE SHEETS

(Unaudited; Dollars in Millions Except Share and Per Share Data)

(Chadarea, Bonars in Millions Except Share and Fer Share Bar	)		
ASSETS		April 3, 2022	January 2, 2022
Current assets:			
Cash and cash equivalents	\$	10,463	14,487
Marketable securities	Ψ	19,925	17,121
Accounts receivable, trade, less allowances for doubtful accounts and credit losses \$234 (2021, \$230)		15,594	15,283
Inventories (Note 2)		10,990	10,387
Prepaid expenses and other		3,452	3,701
Total current assets		60,424	60,979
Property, plant and equipment at cost		47,702	47,679
Less: accumulated depreciation		(29,001)	(28,717)
Property, plant and equipment, net		18,701	18,962
Intangible assets, net (Note 3)		44,420	46,392
Goodwill (Note 3)		34,935	35,246
Deferred taxes on income (Note 5)		9,936	10,223
Other assets		9,939	10,216
Total assets	\$	178,355	182,018
LIABILITIES AND SHAREHOLDERS' EQUITY		,	,
Current liabilities:			
Loans and notes payable	\$	4,297	3,766
Accounts payable	ψ	9,309	11,055
Accrued liabilities		13,006	13,612
Accrued rebates, returns and promotions		12,972	12,095
Accrued compensation and employee related obligations		2,098	3,586
Accrued taxes on income (Note 5)		1,708	1,112
Total current liabilities		43,390	45,226
Long-term debt (Note 4)		28,851	29,985
Deferred taxes on income (Note 5)		6,424	7,487
Employee related obligations (Note 6)		8,739	8,898
Long-term taxes payable (Note 5)		5,745	5,713
Other liabilities		10,497	10,686
Total liabilities	\$	103,646	107,995
Commitments and Contingencies (Note 11)	Ψ	105,010	107,775
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)	•	(13,757)	(13,058)
Retained earnings		124,380	123,060
Less: common stock held in treasury, at cost (490,459,000 and 490,878,000 shares)		39,034	39,099
Total shareholders' equity		74,709	74,023
Total liabilities and shareholders' equity	\$	178,355	182,018
	•	3	- ,

See Notes to Consolidated Financial Statements

# JOHNSON & JOHNSON AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF EARNINGS

(Unaudited; Dollars & Shares in Millions Except Per Share Amounts)

	Fiscal First Quarter Ended				
		April 3, 2022	Percent to Sales	April 4, 2021	Percent to Sales
Sales to customers (Note 9)	\$	23,426	100.0 % \$	22,321	100.0 %
Cost of products sold		7,598	32.4	7,063	31.7
Gross profit		15,828	67.6	15,258	68.3
Selling, marketing and administrative expenses		5,938	25.4	5,432	24.3
Research and development expense		3,462	14.8	3,178	14.2
In-process research and development		610	2.6	_	_
Interest income		(22)	(0.1)	(15)	(0.1)
Interest expense, net of portion capitalized		10	0.0	63	0.3
Other (income) expense, net		(102)	(0.4)	(882)	(3.9)
Restructuring (Note 12)		70	0.3	53	0.2
Earnings before provision for taxes on income		5,862	25.0	7,429	33.3
Provision for taxes on income (Note 5)		713	3.0	1,232	5.5
NET EARNINGS	\$	5,149	22.0 % \$	6,197	27.8 %
NET EARNINGS PER SHARE (Note 8)					
Basic	\$	1.96	\$	2.35	
Diluted	\$	1.93	\$	2.32	
AVG. SHARES OUTSTANDING					
Basic		2,629.2		2,631.6	
Diluted		2,666.5		2,672.7	

See Notes to Consolidated Financial Statements

# JOHNSON & JOHNSON AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(Unaudited; Dollars in Millions)

Fiscal First Quarter Ended

	Fiscal First Qua	irter Ended
	April 3, 2022	April 4, 2021
Net earnings	\$ 5,149	6,197
Other comprehensive income (loss), net of tax		
Foreign currency translation	(554)	276
Securities:		
Unrealized holding gain (loss) arising during period	(13)	_
Reclassifications to earnings	_	_
Net change	(13)	_
Employee benefit plans:		
Prior service cost amortization during period	(53)	(41)
Gain (loss) amortization during period	217	274
Net change	164	233
Derivatives & hedges:		
Unrealized gain (loss) arising during period	(195)	(522)
Reclassifications to earnings	(101)	(73)
Net change	(296)	(595)
Other comprehensive income (loss)	(699)	(86)
Comprehensive income	\$ 4,450	6,111

### See Notes to Consolidated Financial Statements

The tax effects in other comprehensive income for the fiscal first quarter were as follows for 2022 and 2021, respectively: Foreign Currency Translation: \$145 million and \$319 million; Securities: \$3 million in 2022; Employee Benefit Plans: \$19 million and \$66 million; Derivatives & Hedges: \$78 million and \$157 million.

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

Fiscal First Quarter Ended April 3, 2022

	Total	Retained Earnings	Accumulated Other Comprehensive Income	Common Stock Issued Amount	Treasury Stock Amount
Balance, January 2, 2022	\$ 74,023	123,060	(13,058)	3,120	(39,099)
Net earnings	5,149	5,149	_	_	_
Cash dividends paid (\$1.06 per share)	(2,787)	(2,787)	_	_	_
Employee compensation and stock option plans	600	(1,042)	_	_	1,642
Repurchase of common stock	(1,577)	_	_	_	(1,577)
Other comprehensive income (loss), net of tax	(699)	_	(699)	_	_
Balance, April 3, 2022	\$ 74,709	124,380	(13,757)	3,120	(39,034)

# Fiscal First Quarter Ended April 4, 2021

	Total	Retained Earnings	Accumulated Other Comprehensive Income	Common Stock Issued Amount	Treasury Stock Amount
Balance, January 3, 2021	\$ 63,278	113,890	(15,242)	3,120	(38,490)
Net earnings	6,197	6,197	_	_	_
Cash dividends paid (\$1.01 per share)	(2,659)	(2,659)	_	_	_
Employee compensation and stock option plans	542	(920)	_	_	1,462
Repurchase of common stock	(1,438)	_	_	_	(1,438)
Other comprehensive income (loss), net of tax	(86)	_	(86)	_	_
Balance, April 4, 2021	\$ 65,834	116,508	(15,328)	3,120	(38,466)

See Notes to Consolidated Financial Statements

# JOHNSON & JOHNSON AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited; Dollars in Millions)

	Fiscal Three Months Er	
	April 3, 2022	April 4, 2021
CASH FLOWS FROM OPERATING ACTIVITIES	2022	2021
Net earnings	\$ 5,149	6,197
Adjustments to reconcile net earnings to cash flows from operating activities:	,	,
Depreciation and amortization of property and intangibles	1,769	1,894
Stock based compensation	278	307
Asset write-downs	610	14
Net gain on sale of assets/businesses	(168)	(580)
Deferred tax provision	(926)	(730)
Credit losses and accounts receivable allowances	6	(13)
Changes in assets and liabilities, net of effects from acquisitions and divestitures:		
Increase in accounts receivable	(427)	(1,604)
Increase in inventories	(600)	(695)
Decrease in accounts payable and accrued liabilities	(2,817)	(2,336)
Decrease in other current and non-current assets	995	2,522
Increase/(Decrease) in other current and non-current liabilities	110	(902)
NET CASH FLOWS FROM OPERATING ACTIVITIES	3,979	4,074
CASH FLOWS FROM INVESTING ACTIVITIES		
Additions to property, plant and equipment	(607)	(677)
Proceeds from the disposal of assets/businesses, net (Note 10)	248	603
Acquisitions, net of cash acquired (Note 10)	(252)	_
Purchases of investments	(9,018)	(5,994)
Sales of investments	6,303	5,233
Credit support agreements activity, net	(249)	751
Other (primarily licenses and milestones)	(59)	(101)
NET CASH USED BY INVESTING ACTIVITIES	(3,634)	(185)
CASH FLOWS FROM FINANCING ACTIVITIES		
Dividends to shareholders	(2,787)	(2,659)
Repurchase of common stock	(1,577)	(1,438)
Proceeds from short-term debt	3,019	23
Repayment of short-term debt	(856)	(475)
Proceeds from long-term debt, net of issuance costs	_	1
Repayment of long-term debt	(2,132)	(1,001)
Proceeds from the exercise of stock options/employee withholding tax on stock awards, net	321	236
Credit support agreements activity, net	(235)	212
Other	(138)	(24)
NET CASH USED BY FINANCING ACTIVITIES	(4,385)	(5,125)
Effect of exchange rate changes on cash and cash equivalents	16	(78)
Decrease in cash and cash equivalents	(4,024)	(1,314)
Cash and Cash equivalents, beginning of period	14,487	13,985
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 10,463	12,671
Acquisitions		
Fair value of assets acquired	\$ 255	_
Fair value of liabilities assumed and noncontrolling interests	(3)	
Net cash paid for acquisitions	\$ 252	_

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 2, 2022. 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, inflation, 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 April 3, 2022 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 April 3, 2022, 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 2, 2022. There were no new material accounting standards issued in the fiscal first quarter of 2022 that impacted the Company.

#### **Recently Adopted Accounting Standards**

There were no new material accounting standards adopted in the fiscal first quarter of 2022.

#### Reclassification

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

#### NOTE 2 — INVENTORIES

(Dollars in Millions)	April 3, 2022	January 2, 2022
Raw materials and supplies	\$ 1,679	1,592
Goods in process	2,629	2,287
Finished goods	6,682	6,508
Total inventories	\$ 10,990	10,387

#### 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 2021. 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)	April 3, 2022	January 2, 2022	
Intangible assets with definite lives:			
Patents and trademarks — gross	\$ 37,960	38,572	
Less accumulated amortization	(20,492)	(20,088)	
Patents and trademarks — net	17,468	18,484	
Customer relationships and other intangibles — gross	22,910	23,011	
Less accumulated amortization	(12,147)	(11,925)	
Customer relationships and other intangibles — net <sup>(1)</sup>	10,763	11,086	
Intangible assets with indefinite lives:			
Trademarks	6,947	6,985	
Purchased in-process research and development <sup>(2)</sup>	9,242	9,837	
Total intangible assets with indefinite lives	16,189	16,822	
Total intangible assets — net	\$ 44,420	46,392	

<sup>&</sup>lt;sup>(1)</sup>The majority is comprised of customer relationships

Goodwill as of April 3, 2022 was allocated by segment of business as follows:

(Dollars in Millions)	Con	sumer Health	Pharmaceutical	MedTech	Total
Goodwill at January 2, 2022	\$	9,810	10,580	14,856	35,246
Goodwill, related to acquisitions		_	_	73	73
Currency translation/Other		(195)	(170)	(19)	(384)
Goodwill at April 3, 2022	\$	9,615	10,410	14,910	34,935

The weighted average amortization period for patents and trademarks is 12 years. The weighted average amortization period for customer relationships and other intangible assets is 21 years. The amortization expense of amortizable intangible assets included in cost of products sold was \$1.1 billion and \$1.2 billion for the fiscal first quarters ended April 3, 2022 and April 4, 2021, 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:

(I	Dollars in Millions)				
	<u>2022</u>	<u>2023</u>	<u>2024</u>	<u>2025</u>	<u>2026</u>
	\$4,600	4,600	4,400	3,600	3,000

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

<sup>&</sup>lt;sup>(2)</sup>In the fiscal first quarter of 2022, the Company recorded an intangible asset impairment charge of approximately \$0.6 billion related to an in-process research and development asset, bermekimab (JnJ-77474462), an investigational drug for the treatment of Atopic Dermatitis (AD) and Hidradenitis Suppurativa (HS). Additional information regarding efficacy of the AD indication became available which led the Company to the decision to terminate the development of bermekimab for AD. The Company acquired all rights to bermekimab from XBiotech, Inc.in the fiscal year 2020.

#### 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 April 3, 2022, the cumulative amount of cash collateral paid by the Company under the CSA amounted to \$1.1 billion net, related to net investment and cash flow hedges. On an ongoing basis, the Company monitors counter-party credit ratings. The Company considers credit non-performance risk to be low, because the Company primarily enters into agreements with commercial institutions that have at least an investment grade credit rating. Refer to the table on significant financial assets and liabilities measured at fair value contained in this footnote for receivables and payables with these commercial institutions. As of April 3, 2022, the Company had notional amounts outstanding for forward foreign exchange contracts, cross currency interest rate swaps and interest rate swaps of \$42.5 billion, \$37.4 billion and \$10.0 billion respectively. As of January 2, 2022, the Company had notional amounts outstanding for forward foreign exchange contracts, cross currency interest rate swaps of \$45.8 billion, \$37.4 billion and \$10.0 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 April 3, 2022, the balance of deferred net loss on derivatives included in accumulated other comprehensive income was \$632 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 first quarters ended in 2022 and 2021, net of tax:

			April 3, 202	.2				April 4, 202	1	
(Dollars in Millions)	Sales	Cost of Products Sold	R&D Expense	Interest (Income) Expense	Other (Income) Expense	Sales	Cost of Products Sold	R&D Expense	Interest (Income) Expense	Other (Income) Expense
The effects of fair value, net investment and cash flow hedging:	Saics	Solu	Expense	Expense	Expense	Saics	Solu	Lapense	Expense	Expense
Gain (Loss) on fair value hedging relationship:										
Interest rate swaps contracts:										
Hedged items	\$	_	_	(531)	_	_		_	_	_
Derivatives designated as hedging instruments	_	_	_	531	_	_	_	_	_	_
Gain (Loss) on net investment hedging relationship:										
Cross currency interest rate swaps contracts:										
Amount of gain or (loss) recognized in income on derivative amount excluded from effectiveness testing	_	_	_	45	_	_	_	_	40	_
Amount of gain or (loss) recognized in AOCI	_	_	_	45	_	_	_	_	40	_
Gain (Loss) on cash flow hedging relationship:										
Forward foreign exchange contracts:										
Amount of gain or (loss) reclassified from AOCI into income	(17)	(52)	23	_	(18)	17	34	(113)	_	3
Amount of gain or (loss) recognized in AOCI	22	(94)	33	_	(73)	(3)	(193)	(76)	_	17
Cross currency interest rate swaps contracts:										
Amount of gain or (loss) reclassified from AOCI into income	_	_	_	120	_	_		_	92	_
Amount of gain or (loss) recognized in AOCI	\$ —	_	_	(128)	_	_	_	_	(307)	_

As of April 3, 2022, and January 2, 2022, the following amounts were recorded on the Consolidated Balance Sheet related to cumulative basis adjustment for fair value hedges

Line item in the Consolidated Balance Sheet in which the hedged item is included	Carrying Amount of th	ne Hedged Liability	Cumulative Amount of Fai (Loss) Included in the Carryin Liabili	ng Amount of the Hedged
(Dollars in Millions)	April 3, 2022	January 2, 2022	April 3, 2022	January 2, 2022
Long-term Debt	9,313	9,793	(694)	(142)

The following table is the effect of derivatives not designated as hedging instruments for the fiscal first quarters ended 2022 and 2021:

		Recognize Income on De	
(Dollars in Millions)	Location of Gain /(Loss) Recognized in Income on Derivative	Fiscal First Qua	urter Ended
Derivatives Not Designated as Hedging Instruments		April 3, 2022	April 4, 2021
Foreign Exchange Contracts	Other (income) expense	\$ 29	(16)

Gain/(Loss)

The following table is the effect of net investment hedges for the fiscal first quarters ended in 2022 and 2021:

		Gain/(I Recogni: Accumu OC	zed Ín ılated	Location of Gain or (Loss) Reclassified from Accumulated Other Comprehensive Income Into Income	Gain/(Loss) Reclassified From Accumulated OCI Into Income		
(Dollars in Millions)		April 3, 2022	April 4, 2021		April 3, 20	22	April 4, 2021
Debt	\$	68	209	Interest (income) expense		—	_
Cross Currency interest rate swaps	\$	560	361	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)	Jani	uary 2, 2022			April 3, 2022	
	Car	rying Value	Changes in Fair Value Reflected in Net Income (1)	Sales/ Purchases/Other (2)	Carrying Value	Non Current Other Assets
Equity Investments with readily determinable value	\$	1,884	(402)	(30)	1,452	1,452
Equity Investments without readily determinable value	\$	500	(5)	10	505	505

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

For equity investments without readily determinable market values, there was a decrease of \$5 million in the fair value reflected in net income as a result of impairments.

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.

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

The Company's significant financial assets and liabilities measured at fair value as of April 3, 2022 and January 2, 2022 were as follows:

	A	pril 3, 2022			<b>January 2, 2022</b>
(Dollars in Millions)	Level 1	Level 2	Level 3	Total	Total <sup>(1)</sup>
Derivatives designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts	\$ _	742	_	742	540
Interest rate contracts (2)	_	975	_	975	796
Total	_	1,717	_	1,717	1,336
Liabilities:					
Forward foreign exchange contracts	_	1,058	_	1,058	881
Interest rate contracts (2)	_	1,652	_	1,652	979
Total	_	2,710	_	2,710	1,860
Derivatives not designated as hedging instruments:					
Assets:					
Forward foreign exchange contracts	_	36	_	36	24
Liabilities:					
Forward foreign exchange contracts	_	68	_	68	28
Other Investments:					
Equity investments (3)	1,452	_	_	1,452	1,884
Debt securities (4)	_	19,583	_	19,583	19,727
Other Liabilities					
Contingent consideration (5)	\$ _	_	486	486	533

Gross to Net Derivative Reconciliation		April 3, 2022	<b>January 2, 2022</b>
(Dollars in Millions)			
Total Gross Assets	\$	1,753	1,360
Credit Support Agreement (CSA)		(1,655)	(1,285)
Total Net Asset		98	75
Total Gross Liabilities		2,778	1,888
Credit Support Agreement (CSA)		(2,709)	(1,855)
Total Net Liabilities	\$	69	33

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

	April 3, 2022	April 4, 2021	
(Dollars in Millions)			
Beginning Balance	\$ 533	\$	633
Changes in estimated fair value (6)	(47)		15
Additions	_		_
Payments	_		(48)
Ending Balance	\$ 486	\$	600

<sup>(1) 2021</sup> assets and liabilities are all classified as Level 2 with the exception of equity investments of \$1,884 million, which are classified as Level 1 and contingent consideration of \$533 million, classified as Level 3.

The Company's cash, cash equivalents and current marketable securities as of April 3, 2022 comprised:

(Dollars in Millions)	Carrying Amount	Gain/( Loss)	Estimated Fair Value	Cash & Cash Equivalents	Current Marketable Securities
Cash	\$ 3,128	_	3,128	3,128	_
Non-U.S. sovereign securities <sup>(1)</sup>	329	_	329	_	329
U.S. reverse repurchase agreements	1,449	_	1,449	1,449	_
Corporate debt securities <sup>(1)</sup>	3,557	(6)	3,551	540	3,017
Money market funds	1,579	_	1,579	1,579	_
Time deposits <sup>(1)</sup>	763	_	763	763	_
Subtotal	10,805	(6)	10,799	7,459	3,346
		Unrealized Loss			
U.S. Gov't securities	19,354	(19)	19,335	2,968	16,367
Other sovereign securities	3	_	3	_	3
Corporate debt securities	246	(1)	245	36	209
Subtotal available for sale debt <sup>(2)</sup>	\$ 19,603	(20)	19,583	3,004	16,579
Total cash, cash equivalents and current marketable securities	\$ 30,408	(26)	30,382	10,463	19,925

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

<sup>(2)</sup> Includes cross currency interest rate swaps and interest rate swaps.

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

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

<sup>5)</sup> Includes \$469 million and \$520 million, classified as non-current other liabilities as of April 3, 2022 and January 2, 2022, respectively. Includes \$17 million and \$13 million classified as current liabilities as of April 3, 2022 and January 2, 2022, respectively.

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

<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 2, 2022 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 April 3, 2022 are as follows:

(Dollars in Millions)	•	Cost Basis	Fair Value
Due within one year	\$	19,585	19,564
Due after one year through five years		19	19
Due after five years through ten years		_	_
Total debt securities	\$	19,604	19,583

Financial Instruments not measured at Fair Value:

The following financial liabilities are held at carrying amount on the consolidated balance sheet as of April 3, 2022:

(Dollars in Millions)	Carrying Amount	Estimated Fair Value
Financial Liabilities		
Current Debt	\$ 4,297	4,298
Non-Current Debt		
6.73% Debentures due 2023	250	266
3.375% Notes due 2023	802	820
0.650% Notes due 2024 (750MM Euro 1.1311)	824	829
5.50% Notes due 2024 (500 MM GBP 1.3485)	654	713
2.625% Notes due 2025	749	762
0.55% Notes due 2025	950	886
2.45% Notes due 2026	1,995	1,981
2.95% Notes due 2027	930	934
0.95% Notes due 2027	1,436	1,307
2.90% Notes due 2028	1,496	1,489
1.150% Notes due 2028 (750MM Euro 1.1311)	826	829
6.95% Notes due 2029	298	379
1.30% Notes due 2030	1,672	1,486
4.95% Debentures due 2033	498	590
4.375% Notes due 2033	855	959
1.650% Notes due 2035 (1.5B Euro 1.1311)	1,654	1,687
3.55% Notes due 2036	917	947
5.95% Notes due 2037	993	1,288
3.625% Notes due 2037	1,416	1,463
3.40% Notes due 2038	992	999
5.85% Debentures due 2038	697	901
4.50% Debentures due 2040	540	617
2.10% Notes due 2040	914	777
4.85% Notes due 2041	297	342
4.50% Notes due 2043	496	565
3.70% Notes due 2046	1,975	2,097
3.75% Notes due 2047	906	969
3.50% Notes due 2048	743	766
2.25% Notes due 2050	914	759
2.45% Notes due 2060	1,155	942
Other	7	7
Total Non-Current Debt	\$ 28,851	29,356

The weighted average effective interest rate on non-current debt is 3.04%.

The excess of the estimated fair value over the carrying value of debt was \$3.2 billion at January 2, 2022.

The current debt balance as of April 3, 2022 includes \$3.8\$ billion of commercial paper which has a weighted average interest rate of 0.37% and a weighted average maturity of approximately three months.

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

#### NOTE 5 — INCOME TAXES

The worldwide effective income tax rates for the fiscal first quarters of 2022 and 2021 were 12.2% and 16.6%, respectively. This decrease in the consolidated tax rate is primarily due to lower income in higher tax jurisdictions, primarily in the U.S., compared to the same period in the prior year. This lower income in the first fiscal quarter of 2022 was caused by a mark to market adjustment to the Company's investment portfolio and the impairment of the bermekimab AD IPR&D (for further information see Note 3 of the Consolidated Financial Statements), both at the U.S. statutory rate. The impact of the income mix was partially offset by incremental tax costs directly related to the planned separation of the Company's Consumer Health business.

The Company also had tax benefits received from stock-based compensation that were either exercised or vested during each of the fiscal first quarters. Additionally, the Company's effective tax rate benefited from the impact of certain provisions of the Tax Cuts and Jobs Act of 2017 that became effective in fiscal year 2022.

As of April 3, 2022, the Company had approximately \$3.3 billion of liabilities from unrecognized tax benefits. The Company conducts business and files tax returns in numerous countries and currently has tax audits in progress in a number of jurisdictions. With respect to the United States, the IRS has completed its audit for the tax years through 2012 and is currently auditing tax years 2013 through 2016. In other major jurisdictions where the Company conducts business, the years that remain open to tax audit go back to the year 2008. The Company believes it is possible that tax audits may be completed over the next twelve months by taxing authorities in some jurisdictions outside of the United States. However, the Company is not able to provide a reasonably reliable estimate of the timing of any other future tax payments relating to uncertain tax positions.

#### NOTE 6 — PENSIONS AND OTHER BENEFIT PLANS

#### Components of Net Periodic Benefit Cost

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

	Fiscal First Quarter En				
		Retireme	ent Plans	Other Ben	efit Plans
(Dollars in Millions)	Apr	il 3, 2022	April 4, 2021	April 3, 2022	April 4, 2021
Service cost	\$	321	353	80	77
Interest cost		230	193	26	20
Expected return on plan assets		(699)	(680)	(2)	(2)
Amortization of prior service cost/(credit)		(46)	(45)	(1)	(8)
Recognized actuarial losses		162	314	30	38
Curtailments and settlements		1	1	_	_
Net periodic benefit cost/(credit)	\$	(31)	136	133	125

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, including Cost of products sold, Research and development expense, and Selling, marketing and administrative expenses. 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 three months ended April 3, 2022, the Company contributed \$29 million and \$5 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:

		Foreign	Gain/(Loss)	Employee	Gain/(Loss)	Total Accumulated
		Currency	On	Benefit	On Derivatives	Other Comprehensive
(Dollars in Millions)	7	Translation	Securities	Plans	& Hedges	Income (Loss)
January 2, 2022	\$	(10,017)	(3)	(2,702)	(336)	(13,058)
Net change		(554)	(13)	164	(296)	(699)
April 3, 2022	\$	(10,571)	(16)	(2,538)	(632)	(13,757)

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

Details on reclassifications out of Accumulated Other Comprehensive Income:

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

Employee Benefit Plans - reclassifications are included in net periodic benefit cost. See Note 6 for additional details.

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

### NOTE 8 — EARNINGS PER SHARE

The following is a reconciliation of basic net earnings per share to diluted net earnings per share:

		Fiscal First Q	uarter Ended
(Shares in Millions)	Ap	oril 3, 2022	April 4, 2021
Basic net earnings per share	\$	1.96	2.35
Average shares outstanding — basic		2,629.2	2,631.6
Potential shares exercisable under stock option plans		140.1	128.4
Less: shares which could be repurchased under treasury stock method		(102.8)	(87.3)
Average shares outstanding — diluted		2,666.5	2,672.7
Diluted net earnings per share	\$	1.93	2.32

The diluted net earnings per share calculation for the fiscal first quarter ended April 3, 2022 included all shares related to stock options, as the exercise price of all options was less than the average market value of the Company's stock.

The diluted net earnings per share calculation for the fiscal first quarter ended April 4, 2021 excluded 9 million shares related to stock options, as the exercise price of these options was greater than the average market value of the Company's stock.

# NOTE 9 — SEGMENTS OF BUSINESS AND GEOGRAPHIC AREAS

### SALES BY SEGMENT OF BUSINESS

	Fis	cal First Quarter Ended	
(Dollars in Millions)	April 3, 2022	April 4, 2021	Percent Change
CONSUMER HEALTH			
$OTC^{(1)}$			
U.S.	\$ 670	599	11.8 %
International	791	673	17.5
Worldwide	1,461	1,273	14.8
Skin Health/Beauty			
U.S.	544	634	(14.2)
International	468	529	(11.6)
Worldwide	1,012	1,163	(13.0)
Oral Care			
U.S.	143	163	(12.6)
International	223	254	(12.0)
Worldwide	366	417	(12.2)
Baby Care			
U.S.	85	96	(11.5)
International	270	293	(7.7)
Worldwide	355	389	(8.6)
Women's Health			
U.S.	3	3	7.2
International	224	219	2.5
Worldwide	228	222	2.6
Wound Care/Other			
U.S.	112	115	(3.3)
International	52	61	(15.3)
Worldwide	164	177	(7.4)
TOTAL CONSUMER HEALTH			
U.S.	1,557	1,611	(3.4)
International	2,029	2,030	0.0
Worldwide	3,586	3,641	(1.5)

PHARMACEUTICAL			
[mmunology			
U.S.	2,501	2,413	3.7
International	1,617	1,501	7.7
Worldwide	4,119	3,914	5.2
REMICADE			
U.S.	358	489	(26.8)
U.S. Exports	80	57	40.5
International	225	232	(2.6)
Worldwide	663	777	(14.7)
SIMPONI / SIMPONI ARIA			
U.S.	287	255	12.5
International	283	307	(7.6)
Worldwide	571	562	1.5
<u>STELARA</u>			
U.S.	1,379	1,331	3.6
International	909	817	11.2
Worldwide	2,288	2,148	6.5
<u>TREMFYA</u>			
U.S.	391	274	42.7
International	199	143	38.8
Worldwide	590	418	41.3
OTHER IMMUNOLOGY			
U.S.	6	7	(3.2)
International	0	2	*
Worldwide	6	8	(22.0)
infectious Diseases			
U.S.	461	512	(10.0)
International	836	485	72.3
Worldwide	1,297	998	30.0
COVID-19 VACCINE			
U.S.	75	100	(24.9)
International	382	0	*
Worldwide	457	100	*
EDURANT / rilpivirine			
U.S.	9	10	(12.6)
International	239	233	2.5
Worldwide PREZISTA / PREZCOBIX / REZOLSTA / SYMTUZA	248	243	1.8
U.S.	369	380	(3.1)
International	132	166	(20.3)
Worldwide	501	546	(8.3)
			()

OTHER INFECTIOUS DISEASES <sup>(1)</sup>			
U.S.	8	21	(62.5
International	83	87	(3.8)
Worldwide	91	108	(15
euroscience			
U.S.	843	771	9.
International	898	943	(4.
Worldwide	1,741	1,715	1.
CONCERTA / methylphenidate	,	,	
U.S.	35	47	(26.
International	122	123	(1.
Worldwide	157	171	(8.
<u>INVEGA SUSTENNA / XEPLION / INVEGA TRINZA /</u> REVICTA			· ·
U.S.	661	589	12.
International	387	376	3.
Worldwide	1,048	965	8.
RISPERDAL CONSTA			
U.S.	63	67	(6.
International	66	89	(26.
Worldwide	129	157	(17.
OTHER NEUROSCIENCE(1)			
U.S.	84	67	25.
International	323	355	(8.
Worldwide	408	422	(3.
ncology			
U.S.	1,582	1,377	14.
International	2,369	2,193	8.
Worldwide	3,950	3,570	10.
DARZALEX			
U.S.	953	691	37.
International	903	674	34.
Worldwide	1,856	1,365	36.
<u>ERLEADA</u>			
U.S.	206	171	20.
International	194	90	*
Worldwide	400	261	53.
IMBRUVICA IMBRUVICA	250	444	(1.6
U.S.	370	444	(16.
International	668	680	(1.
Worldwide	1,038	1,125	(7.
ZYTIGA / abiraterone acetate	10	50	(62
U.S.	19	50	(62.
International	520	588	(11.
Worldwide	539	638	(15.

OTHER ONCOLOGY			
U.S.	34	21	63.1
International	84	161	(47.7)
Worldwide	118	182	(35.1)
Pulmonary Hypertension			
U.S.	572	573	(0.2)
International	279	288	(2.9)
Worldwide	852	861	(1.1)
<u>OPSUMIT</u>			
U.S.	273	272	0.5
International	170	179	(4.8)
Worldwide	443	450	(1.6)
<u>UPTRAVI</u>			
U.S.	269	259	3.9
International	56	46	20.9
Worldwide	325	305	6.5
OTHER PULMONARY HYPERTENSION			
U.S.	30	42	(29.0)
International	53	63	(15.2)
Worldwide	83	105	(20.8)
Cardiovascular / Metabolism / Other			
U.S.	672	799	(15.8)
International	238	245	(3.0)
Worldwide	910	1,044	(12.8)
XARELTO			
U.S.	508	589	(13.8)
International	_	_	_
Worldwide	508	589	(13.8)
INVOKANA / INVOKAMET			
U.S.	60	87	(30.7)
International	68	63	7.5
Worldwide	128	150	(14.6)
OTHER <sup>(1,2)</sup>			
U.S.	104	122	(14.9)
International	170	182	(6.6)
Worldwide	274	305	(10.0)
FOTAL PHARMACEUTICAL			
U.S.	6,632	6,446	2.9
International	6,237	5,655	10.3
Worldwide	12,869	12,101	6.3
	,,-	,	3.5

MEDTECH <sup>(3)</sup>			
Interventional Solutions			
U.S.	494	434	13.8
International	597	514	16.2
Worldwide	1,092	949	15.1
Orthopaedics			
U.S.	1,289	1,249	3.2
International	899	864	4.1
Worldwide	2,188	2,113	3.5
<u>HIPS</u>			
U.S.	225	209	7.3
International	164	146	12.2
Worldwide	389	356	9.3
KNEES			
U.S.	201	185	8.6
International	138	132	4.1
Worldwide	339	317	6.7
<u>TRAUMA</u>			
U.S.	475	450	5.5
International	273	282	(3.3)
Worldwide	748	733	2.1
SPINE, SPORTS & OTHER			
U.S.	387	404	(4.1)
International	324	303	7.0
Worldwide	712	707	0.6
Surgery			
U.S.	921	898	2.5
International	1,513	1,474	2.7
Worldwide	2,434	2,372	2.6
<u>ADVANCED</u>			
U.S.	417	405	3.0
International	729	713	2.2
Worldwide	1,146	1,118	2.5
<u>GENERAL</u>			
U.S.	504	493	2.1
International	784	761	3.1
Worldwide	1,288	1,254	2.7
Vision			
U.S.	521	472	10.4
International	736	673	9.4
Worldwide	1,257	1,145	9.8
CONTACT LENSES / OTHER	,		
U.S.	400	371	7.7
		371 486 857	7.7 5.1 6.2

SURGICAL			
U.S.	121	101	20.2
International	226	187	20.5
Worldwide	347	288	20.4
TOTAL MEDTECH			
U.S.	3,225	3,054	5.6
International	3,746	3,525	6.3
Worldwide	6,971	6,579	5.9
WORLDWIDE			
U.S.	11,414	11,111	2.7
International	12,012	11,210	7.2
Worldwide	\$ 23,426	22,321	5.0 %

<sup>\*</sup>Percentage greater than 100% or not meaningful

#### EARNINGS BEFORE PROVISION FOR TAXES BY SEGMENT\*

	Fiscal First Quarter Ended			
(Dollars in Millions)		April 3, 2022	April 4, 2021	Percent Change
Consumer Health (1)	\$	686	842	(18.5)%
Pharmaceutical <sup>(2)</sup>		3,924	5,169	(24.1)
MedTech <sup>(3)</sup>		1,477	1,629	(9.3)
Segment earnings before provision for taxes		6,087	7,640	(20.3)
Less: Expense not allocated to segments (4)		123	211	
Less: Consumer Health separation costs		102	_	
Worldwide income before tax	\$	5,862	7,429	(21.1)%

<sup>\*</sup>Fiscal first quarter 2021 earnings before provision for taxes has been reclassified as certain international OTC products, primarily in China, were reclassified from the Pharmaceutical segment to the Consumer Health segment based on operational changes

- Divestiture gains of \$0.6 billion in the fiscal first quarter of 2021 related to two brands outside the U.S.
- Intangible amortization expense of \$0.8 billion and \$0.9 billion in the fiscal first quarter of 2022 and 2021, respectively
- In the fiscal first quarter of 2022, the Company recorded an intangible asset impairment charge of approximately \$0.6 billion related to an in-process research and development asset, bermekimab (JnJ-77474462), an investigational drug for the treatment of Atopic Dermatitis (AD) and Hidradenitis Suppurativa (HS). Additional information regarding efficacy of the AD indication became available which led the Company to the decision to terminate the development of bermekimab for AD.
- A loss of \$0.4 billion related to the change in the fair value of securities in the fiscal first quarter of 2022

In fiscal 2021 and 2020, the Company entered into a series of contract manufacturing arrangements for vaccine production with third party contract manufacturing organizations. These arrangements provide the Company with future supplemental commercial capacity for vaccine production and potentially transferable rights to such production if capacity is not required. Amounts paid for services to be delivered and contractually obligated to be paid to these contract manufacturing organizations of approximately \$0.9 billion are reflected in the prepaid expenses and other, other assets, accrued liabilities and other liabilities

<sup>(1)</sup> In the fiscal first quarter of 2021, approximately \$0.1 billion of certain international OTC products, primarily in China, were reclassified from the Pharmaceutical segment to the Consumer Health segment based on operational changes

<sup>(2)</sup> Inclusive of PROCRIT / EPREX which was previously disclosed separately

<sup>(3)</sup> Previously referred to as Medical Devices

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

<sup>•</sup> Intangible amortization expense of \$0.1 billion in both the fiscal first quarter of 2022 and 2021

<sup>(2)</sup> Pharmaceutical includes:

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 the global demand for the COVID-19 vaccine and its related supply.

# (3) MedTech includes:

- A restructuring related charge of \$0.1 billion in both the fiscal first quarter of 2022 and 2021
- Intangible amortization expense of \$0.3 billion in both the fiscal first quarter of 2022 and 2021

#### SALES BY GEOGRAPHIC AREA

	Fiscal First Quarter Ended				
(Dollars in Millions)	April 3, 2022	April 4, 2021	Percent Change		
United States	\$ 11,414	11,111	2.7 %		
Europe	6,024	5,414	11.3		
Western Hemisphere, excluding U.S.	1,482	1,424	4.1		
Asia-Pacific, Africa	4,506	4,372	3.1		
Total	\$ 23,426	22,321	5.0 %		

#### NOTE 10— ACQUISITIONS AND DIVESTITURES

There were no material acquisitions in the fiscal first quarter of 2022.

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.

#### NOTE 11 — LEGAL PROCEEDINGS

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

The Company records accruals for loss contingencies associated with these legal matters when it is probable that a liability will be incurred, and the amount of the loss can be reasonably estimated. As of April 3, 2022, 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.

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

#### 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 JOHNSON'S Baby Powder; INVOKANA; and ETHICON PHYSIOMESH Flexible Composite Mesh. As of April 3, 2022, in the United States there were approximately 230 plaintiffs with direct claims in pending lawsuits regarding injuries allegedly due to the DePuy ASR XL Acetabular System and DePuy ASR Hip Resurfacing System; 3,900 with respect to the PINNACLE Acetabular Cup System; 9,800 with respect to pelvic meshes; 8,600 with respect to RISPERDAL; 4,300 with respect to XARELTO; 40,400 with respect to body powders containing talc; 80 with respect to INVOKANA; and 4,800 with respect to ETHICON PHYSIOMESH Flexible Composite Mesh. The number of pending lawsuits is expected to fluctuate as certain lawsuits are settled or dismissed and additional lawsuits are filed.

In August 2010, DePuy Orthopaedics, Inc. (DePuy) announced a worldwide voluntary recall of its ASR XL Acetabular System and DePuy ASR Hip Resurfacing System (ASR Hip) used in hip replacement surgery. Claims for personal injury have been made against DePuy and Johnson & Johnson. 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 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 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 2013 and prior to February 15, 2017. This settlement program has resolved more than 10,000 claims, thereby bringing to resolution significant ASR Hip litigation activity in the United States. However, lawsuits in the United States remain, and the settlement program does not address litigation outside of the United States. In Australia, a class action settlement was reached that resolved the claims of the majority of ASR Hip patients in that country. In Canada, the Company has reached agreements to settle the class actions filed in that country. The Company continues to receive information with respect to potential additional costs associated with this recall on a worldwide basis. The Company has established accruals for the costs associated with the United States settlement program and 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 the 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 the High Court heard oral argument on the application in November 2021. Special leave was refused. While this brings an end to the appellate process, there will now be an individual case assessment process for the remaining group member claims. In March 2022, the Court appointed a barrister to prepare a written report and recommendation on the form and mechanism of the individual case assessment process, due by August 2022, with a court hearing on those findings later that month. 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 parties in the Israeli class action are currently finalizing the terms of the settlement. A motion to approve the settlement is expected to be filed with the Court by May 2022. The Company has established accruals with respect to product liability litigation associated with Ethicon's pelvic mesh product

Following a June 2016 worldwide market withdrawal of ETHICON PHYSIOMESH Flexible Composite Mesh (Physiomesh), claims for personal injury have been made against Ethicon, Inc. (Ethicon) and Johnson & Johnson alleging personal injury arising out of the use of this hernia mesh device. Cases filed in federal courts in the United States have been organized as a multi-district litigation (MDL) in the United States District Court for the Northern District of Georgia. A multi-county litigation (MCL) also has been formed in New Jersey state court and assigned to Atlantic County for cases pending in New Jersey. In addition to the matters in the MDL and MCL, there are additional lawsuits pending in the United States District Court for the Southern District of Ohio, which are part of the MDL for polypropylene mesh devices manufactured by C.R. Bard, Inc., one multi-plaintiff lawsuit pending in Oklahoma state court and lawsuits pending outside the United States. In May 2021, Ethicon and lead counsel for the plaintiffs entered into a term sheet to resolve approximately 3,600 Physiomesh cases (covering approximately 4,300 plaintiffs) pending in the MDL and MCL at that time. A master settlement agreement (MSA) was entered into in September 2021 and includes 3,729 cases in the MDL and MCL. All deadlines and trial settings in those proceedings are currently stayed pending the completion of the settlement agreement. The deadline for issuance of Individual Allocation amounts by the Special Master was March 2022. Plaintiffs requested an extension of the deadline. Post-settlement cases in the Physiomesh MDL and MCL are subject to docket control orders requiring early expert reports and discovery requirements. As of April 2022, there are approximately 105 active cases subject to these orders which are being reviewed and evaluated.

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 United States, and in jurisdictions outside the United States. Discovery is underway in the MCL proceedings.

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

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

Claims for personal injury have been made against Janssen Pharmaceuticals, Inc. and Johnson & Johnson arising out of the use of RISPERDAL, and related compounds, indicated for the treatment of schizophrenia, acute manic or mixed episodes associated with bipolar I disorder and irritability associated with autism. Lawsuits primarily have been filed in state courts in Pennsylvania, California, and Missouri. Other actions are pending in various courts in the United States and Canada. Product liability lawsuits continue to be filed, and the Company continues to receive information with respect to potential costs and the anticipated number of cases. The Company has successfully defended a number of these cases but there have been verdicts against the Company, including a verdict in October 2019 of \$8.0 billion of punitive damages related to one plaintiff, which the trial judge reduced to \$6.8 million in January 2020. In September 2021, the Company entered into a settlement in principle with the counsel representing plaintiffs in this matter and in substantially all of the outstanding cases in the United States. The costs associated with this and other settlements are reflected in the Company's accruals.

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

A significant number of personal injury claims alleging that talc causes cancer were made against Johnson & Johnson Consumer Inc. and Johnson & Johnson arising out of the use of body powders containing talc, primarily JOHNSON'S Baby Powder. The number of these personal injury lawsuits, filed in state and federal courts in the United States as well as outside of the United States, continued to increase.

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 settled cases.

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

In October 2021, notwithstanding the Company's confidence in the safety of its talc products, the Debtor filed a voluntary petition with the United States Bankruptcy Court for the Western District of North Carolina, Charlotte Division, seeking relief under chapter 11 of the Bankruptcy Code (the LTL Bankruptcy Case). As a result of the LTL Bankruptcy Case, the North Carolina Bankruptcy Court entered a temporary restraining order staying all litigation against LTL and Old JJCI. On November 15, 2021, the North Carolina Bankruptcy Court confirmed the scope of the stay, issuing a Preliminary Injunction (PI) prohibiting and enjoining the commencement and prosecution of talc-related claims against LTL, Old JJCI, New JJCI, Johnson & Johnson, other of their corporate affiliates, identified retailers, insurance companies, and certain other parties (the Protected Parties). The LTL Bankruptcy Case was transferred to the United States Bankruptcy Court for the District of New Jersey in November 2021, and that court extended the PI through the end of February 2022. Claimants filed motions to dismiss the LTL Bankruptcy Case and, following a multiple day hearing, the New Jersey Bankruptcy Court denied those motions by order issued in March 2022. The New Jersey Bankruptcy Court simultaneously issued another order extending the stay as to the Protected Parties. The claimants subsequently filed notices of appeal as to the denial of the motions to dismiss and the extension of the stay, and also asked the New Jersey Bankruptcy Court for leave to pursue direct appeals to the Third Circuit Court of Appeals, which was granted. In April 2022, claimants filed a request with Third Circuit Court of Appeals to hear the case, and LTL filed its opposition to the request. While the New Jersey Bankruptcy Court's order effectively stays all of the Company's talc-related personal injury litigation, LTL has agreed to lift the stay on a small number of appeals where appeal bonds have been filed.

The Company has agreed to provide funding to LTL for the payment of amounts the New Jersey Bankruptcy Court determines are owed by LTL and the establishment of a \$2 billion trust in furtherance of this purpose. The Company has established a reserve for approximately \$2 billion in connection with the aforementioned trust. After and as a result of the filing of the LTL Bankruptcy Case, the Company de-consolidated LTL, which is a related party. The impact of the de-consolidation is not material to the Company. The parties have not yet reached a resolution of all talc matters in the LTL Bankruptcy Case, and the Company is unable to estimate the possible loss or range of loss beyond the amount accrued.

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 petition under chapter 11 of the United States Code (the Bankruptcy Code) in the United States Bankruptcy Court for the District of Delaware (Imerys Bankruptcy). The Imerys Bankruptcy relates to Imerys's potential liability for personal injury from exposure to talcum powder sold by Imerys. In its

bankruptcy, Imerys alleges it has claims against the Company for indemnification and rights to joint insurance proceeds. In May 2020, Imerys, its parent Imerys S.A., the Tort Claimants' Committee (TCC), and the Future Claimants' Representative (FCR) (collectively, the Plan Proponents) filed their Plan of Reorganization (the Plan) and the Disclosure Statement related thereto. The Plan Proponents have since filed numerous amendments to the Plan and Disclosure Statement. A hearing on the Plan Proponent's Disclosure Statement was held in January 2021, and the Court entered an order approving the Disclosure Statement, allowing Imerys to proceed with soliciting votes on the Plan. In March 2021, the Company voted to reject the Plan and opted out of the consensual releases in the Plan. In April 2021, the Plan Proponents announced the Plan had received the requisite number of accepting votes to confirm the Plan. The Company challenged certain improprieties with respect to portions of the vote and sought to disqualify those votes. In October 2021, the Bankruptcy Court issued a ruling deeming thousands of votes as withdrawn as improperly voted. In October 2021, Imerys cancelled the confirmation hearing on the Plan. Imerys, the TCC, the FCR, and certain of Imerys's insurers (the Mediation Parties) have since agreed to engage in mediation.

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

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

In February 2021, several of the Company's insurers involved in coverage litigation in New Jersey State Court (the Coverage Action) filed a motion in the Imerys Bankruptcy Court proceeding seeking a determination that the automatic stay does not apply to the Coverage Action and, in the alternative, seeking relief from the automatic stay to allow them to continue to litigate their claims in the Coverage Action. In March 2021, the Company filed a limited response and reservation of rights with respect to the motion. The Court entered an agreed order modifying the stay to allow the litigation in the Coverage Action to continue. In October 2021, LTL filed a Notice of Bankruptcy Filing and Stay of Proceedings clarifying that the automatic stay arising upon the filing of the LTL Bankruptcy Case should apply to the Coverage Action. In March 2022, the New Jersey Bankruptcy Court ruled that the stay applied to the Coverage Action.

In February 2018, a securities class action lawsuit was filed against Johnson & Johnson and certain named officers in the United States District Court for the District of New Jersey, alleging that Johnson & Johnson violated the federal securities laws by failing to disclose alleged asbestos contamination in body powders containing talc, primarily JOHNSON'S Baby Powder, and that purchasers of Johnson & Johnson's shares suffered losses as a result. Plaintiff is seeking damages. In April 2019, the Company moved to dismiss the complaint and briefing on the motion was complete as of August 2019. In December 2019, the Court denied, in part, the motion to dismiss. In March 2020, the Company answered the complaint. In April 2021, briefing on Plaintiffs' motion for class certification was completed. In July 2021, the Company filed a notice of supplemental authority in opposition to Plaintiff's motion for class certification, and Plaintiff filed a response. In December 2021, the Company filed a motion to supplement the class certification record, and in January 2022, Plaintiff responded. In March 2022, LTL asked the New Jersey Bankruptcy Court to stay the securities class action.

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. In February 2022, the Court granted Johnson & Johnson's cross motion to dismiss.

In October 2019, December 2019, and January 2020, four shareholders filed four separate derivative lawsuits against Johnson & Johnson as the nominal defendant and its current directors and certain officers as defendants in the United States District Court for the District of New Jersey, alleging a breach of fiduciary duties related to the alleged asbestos contamination in body powders containing talc, primarily JOHNSON'S Baby Powder, and that Johnson & Johnson has suffered damages as a result of those alleged breaches. In February 2020, the four cases were consolidated into a single action under the caption *In re Johnson* 

& Johnson Talc Stockholder Derivative Litigation. In July 2020, a report was delivered to the Company's Board of Directors by independent counsel retained by the Board to investigate the allegations in the derivative lawsuits and in a series of shareholder letters that the Board received raising similar issues and demanding that suit be brought against certain Directors. Four of the shareholders who sent demands are plaintiffs in the In re Johnson & Johnson Talc Stockholder Derivative Litigation. The independent counsel recommended that the Company reject the shareholder demands and take the steps that are necessary or appropriate to secure dismissal of the derivative lawsuits. The Board unanimously adopted the recommendations of the independent counsel's report. In October 2020, the shareholders filed a consolidated complaint, and in January 2021, Johnson & Johnson moved to dismiss the consolidated complaint. In March 2021, Plaintiffs filed a motion for discovery. The Court temporarily terminated Johnson & Johnson's motion to dismiss pending a decision on Plaintiff's motion for discovery. In November 2021, at the Court's request, the parties submitted supplemental briefing on Plaintiff's motion for discovery.

In January 2019, two ERISA class action lawsuits were filed by participants in the Johnson & Johnson Savings Plan against Johnson & Johnson, its Pension and Benefits Committee, and certain named officers in the United States District Court for the District of New Jersey, alleging that the defendants breached their fiduciary duties by offering Johnson & Johnson stock as a Johnson & Johnson Savings Plan investment option when it was imprudent to do so because of failures to disclose alleged asbestos contamination in body powders containing talc, primarily JOHNSON'S Baby Powder. Plaintiffs are seeking damages and injunctive relief. In September 2019, Defendants filed a motion to dismiss. In April 2020, the Court granted Defendants' motion but granted leave to amend. In June 2020, Plaintiffs filed an amended complaint, and in July 2020, Defendants moved to dismiss the amended complaint. As of October 2020, briefing on Defendants' motion was complete. In February 2021, the Court granted Defendants' motion, and granted Plaintiffs leave to amend. In April 2021, Plaintiffs informed the Court that they did not intend to file an amended complaint, and the Court dismissed the case with prejudice. In May 2021, Plaintiffs filed a notice of appeal with the Third Circuit. In July 2021, Plaintiffs filed their opening brief in the Third Circuit and in September 2021, Defendants filed their response brief, and in October 2021, Plaintiffs filed their reply brief. In January 2022, the Third Circuit heard oral argument.

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. Plaintiffs filed their opening brief in July 2021. The company filed its responsive brief in October 2021. In October 2021, Notice of Suggestion of Bankruptcy was filed with the Ninth Circuit. A bankruptcy stay was imposed in December 2021, and the Court held the reply deadline in abeyance. In February 2022, the Bankruptcy Court issued an order extending the stay.

In addition, the Company has received inquiries, subpoenas, and requests to produce documents regarding talc matters and the LTL Bankruptcy Case from various governmental authorities. The Company has produced documents and responded to inquiries, 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.

#### MedTech

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. In March 2022, the U.S. Court of Appeals for the Federal Circuit affirmed the finding of invalidity of the '601 patent. In March 2021, the USPTO ruled that the challenged claims of the '447 and '906 patents are not invalid. Auris has appealed that decision. Auris filed a request for reexamination of the '276 patent in November 2021, and in January 2022, the USPTO granted the reexamination request. Trial is scheduled to begin in January 2023.

In August 2019, RSB Spine LLC (RSB Spine) filed a patent infringement suit against DePuy Synthes, Inc. in the 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. Trial is scheduled to begin in December 2022.

In October 2020, Rasmussen Instruments, LLC (Rasmussen) filed a patent infringement suit against DePuy Synthes Products, Inc., DePuy Synthes Sales, Inc. and Medical Device Business Services, Inc. (collectively, DePuy) in the United States District Court for the District of Massachusetts. Rasmussen alleges that DePuy willfully infringes U.S. Patent Nos. 9,492,180 and 10,517,583 ('583) by making and selling the Attune Balanced Sizer. In April 2021, Rasmussen sought permission to amend its infringement contentions to allege that DePuy also willfully infringes the '583 patent by making and selling the Attune Balancing Blocks. Rasmussen seeks treble damages for willful infringement. Trial concluded in March 2022, with the jury returning a verdict in favor of Rasmussen, finding willful infringement of the '180 patent, and awarding damages in the amount of \$20 million. DePuy is challenging the verdict in its post-trial motions.

# **Pharmaceutical**

Litigation Against Filers of Abbreviated New Drug Applications (ANDAs)

The following summarizes lawsuits the Company's subsidiaries have brought against generic companies that have filed ANDAs with the U.S. 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. 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. In the event the Company's subsidiaries are not successful in an action, or the automatic statutory stay of the ANDAs expires before the United States District Court rulings are obtained, the generic companies involved would have the ability, upon approval of the U.S. FDA, to introduce generic versions of their products to the market, resulting in the potential for substantial market share and revenue

losses for the applicable products, and which may result in a non-cash impairment charge in any associated intangible asset. In addition, from time to time, the Company's subsidiaries may settle these types of actions and such settlements can involve the introduction of generic versions of the products at issue to the market prior to the expiration of the relevant patents.

## **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.

#### XARELTO

Beginning in March 2021, Janssen Pharmaceuticals, Inc. (JPI) and Bayer Pharma AG and Bayer AG (collectively, Bayer) filed patent infringement lawsuits in the United States District Court for the District of Delaware against a number of generic companies who filed ANDAs seeking approval to market generic versions of XARELTO (2.5 mg) before expiration of U.S. Patent No. 10,828,310 ('310). The following generic drug companies are named defendants: Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd.; Lupin Limited and Lupin Pharmaceuticals, Inc.; Taro Pharmaceutical Industries Ltd. and Taro Pharmaceuticals U.S.A., Inc.; and Teva Pharmaceuticals USA, Inc. In October 2021, the court consolidated the Delaware lawsuits for all purposes, including trial. Trial for the consolidated Delaware lawsuits is scheduled to begin in May 2023.

In July 2021, JPI and Bayer filed a patent infringement lawsuit in the United States District Court for the Northern District of West Virginia against Mylan Pharmaceuticals Inc. and Mylan Inc. which filed an ANDA seeking approval to market a generic version of XARELTO (2.5 mg) before expiration of the '310 patent. In August 2021, JPI and Bayer filed a motion before the United States Judicial Panel on Multidistrict Litigation (the MDL panel) to transfer this lawsuit to the United States District Court for the District of Delaware for coordinated and consolidated pretrial proceedings. In December 2021, the MDL panel granted the motion. No trial date has been set in this lawsuit.

In February 2022, JPI and Bayer filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Micro Labs Ltd. and Micro Labs USA Inc. (collectively, Micro) which filed an ANDA seeking approval to market a generic version of XARELTO (2.5 mg) before expiration of the '310 patent. In March 2022, the case against Micro was consolidated for all purposes, including trial, with the consolidated Delaware lawsuits.

In each of these lawsuits, JPI and Bayer are seeking an order enjoining defendants from marketing their generic version of XARELTO (2.5 mg) before the expiration of the '310 patent.

In February 2022, Mylan Pharmaceuticals Inc. filed a Petition for Inter Parties Review with the United States Patent and Trademark Office, seeking to invalidate the '310 patent.

In April 2022, Janssen Pharmaceuticals, Inc. (JPI), Bayer Intellectual Property GmbH and Bayer AG filed a patent infringement lawsuit in the United States District Court for the District of New Jersey against Changzhou Pharmaceutical Factory, which filed an ANDA seeking approval to market generic a version of XARELTO (10 mg, 15 mg, and 20 mg) before expiration of U.S. Patent No. 9,539,218 ('218). In this lawsuit, JPI, Bayer Intellectual Property GmbH and Bayer AG are seeking an order enjoining Changzhou from marketing its generic version of XARELTO (10 mg, 15 mg, and 20 mg) before the expiration of the '218 patent.

### INVOKANA/INVOKAMET/INVOKAMET XR

In October 2019, Janssen Pharmaceuticals, Inc., Janssen Research & Development, LLC, Cilag GmbH International and Janssen Pharmaceutica NV (collectively, Janssen) and Mitsubishi Tanabe Pharma Corporation (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 MTPC's United States Patent No. 7,943,788 ('788) relating to INVOKAMET. In this lawsuit, Janssen and MTPC are seeking an order enjoining DRL from marketing its generic version of INVOKAMET before the 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 MTPC's United States Patent

Nos. 7,943,582 ('582) and/or 8,513,202 ('202) relating to INVOKAMET XR. In February 2022, the case was dismissed by stipulation.

In October 2020, Janssen Inc., Janssen Pharmaceutica NV and MTPC initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Sandoz Canada Inc. (Sandoz) in Canada in response to Sandoz's filing of an ANDS seeking approval to market a generic version of INVOKANA before the expiration of the Canadian Patent Nos. 2,799,204, 2,534,024 and 2,671,357. Janssen Inc., Janssen Pharmaceutica NV and MTPC are seeking an order enjoining Sandoz from marketing its generic version of INVOKANA before the expiration of the relevant patents. The trial is scheduled to begin in August 2022. In February 2022, the case was discontinued.

## **OPSUMIT**

In May 2020, Janssen Inc. (Janssen) and Actelion Pharmaceuticals Ltd (Actelion) initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Sandoz Canada Inc. (Sandoz) in Canada in response to Sandoz's filing of an ANDS seeking approval to market a generic version of OPSUMIT 10 mg, before the expiration of Canadian Patent No. 2,659,770 ('770). Trial against Sandoz concluded in February 2022.

In May 2020, Janssen and Actelion initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Apotex Inc. (Apotex) in Canada in response to Apotex's filing of an ANDS seeking approval to market a generic version of OPSUMIT 10 mg, before the expiration of the '770 patent. Trial against Apotex concluded in March 2022.

In July 2020, Janssen and Actelion initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against JAMP Pharma Corporation (JAMP) in Canada in response to JAMP's filing of an ANDS seeking approval to market a generic version of OPSUMIT 10 mg before the expiration of the '770 patent and Canadian Patent No. 2,621,273 ('273). In April 2022, the parties entered a confidential settlement agreement, and the case was discontinued

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

#### INVEGA SUSTENNA

In January 2018, Janssen Pharmaceutica NV and Janssen Pharmaceuticals, Inc. (collectively, Janssen) initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Teva Pharmaceuticals USA, Inc. (Teva), which filed an ANDA seeking approval to market a generic version of INVEGA SUSTENNA before the expiration of United States Patent No. 9,439,906 ('906). Trial concluded in October 2020. In October 2021, the court issued a decision in Janssen's favor. Teva has appealed the decision.

In August 2019, Janssen initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Mylan Laboratories Limited (Mylan), which filed an ANDA seeking approval to market a generic version of INVEGA SUSTENNA before the expiration of the '906 patent. Pursuant to an agreement by the parties, judgment in favor of Janssen was entered in December 2021. Mylan appealed.

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

In November 2021, Janssen initiated a patent infringement lawsuit in the United States District Court for the District of Delaware against Tolmar, Inc., Tolmar Therapeutics, Inc., Tolmar Pharmaceuticals, Inc. and Tolmar Holding, Inc. (collectively, Tolmar), which filed an ANDA seeking approval to market a generic version of INVEGA SUSTENNA before the expiration of the '906 patent. A trial is scheduled to begin in October 2023.

In February 2022, Janssen initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Accord Healthcare, Inc., Accord Healthcare, Ltd. and Intas Pharmaceuticals, Ltd. (collectively, Accord), who filed an ANDA seeking approval to market a generic version of INVEGA SUSTENNA before the expiration of the '906 patent.

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

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

In November 2020, Janssen Canada initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Pharmascience Inc. in response to Pharmascience Inc.'s filing of an ANDS seeking approval to market a generic version of INVEGA SUSTENNA before the expiration of the '335 patent. A summary trial on the issue of infringement took place in November 2021. In January 2022, the Court issued a decision in favor of Janssen on the issue of infringement. Pharmascience filed an appeal. In March 2022, Janssen Canada initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Pharmascience in response to Pharmascience's filing of an ANDS seeking approval to market a generic version of an additional strength of INVEGA SUSTENNA before the expiration of the '335 patent. The action has been consolidated with the November 2020 action for trial, which is scheduled to begin in July 2022.

In January 2021, Janssen Canada initiated a Statement of Claim under Section 6 of the Patented Medicines (Notice of Compliance) Regulations against Apotex Inc. (Apotex) in response to Apotex's filing of an ANDS seeking approval to market a generic version of INVEGA SUSTENNA before the expiration of the '335 patent. A summary trial on the issue of infringement took place in December 2021. In January 2022, the Court issued a decision in favor of Janssen on the issue of infringement. Apotex appealed.

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

#### INVEGA TRINZA

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

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

In October 2021, Janssen initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Mylan. Mylan filed an ANDA seeking approval to market generic versions of INVEGA TRINZA (273 mg and 410 mg) before expiration of the '693 patent.

In January 2022, the court consolidated the three cases into the case filed in September 2020. In each of these consolidated cases, Janssen is seeking an order enjoining Mylan from marketing its generic versions of INVEGA TRINZA before expiration of the '693 patent.

## **IMBRUVICA**

In March 2019, Pharmacyclics LLC (Pharmacyclics) and Janssen Biotech, Inc. (JBI) filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Alvogen Pine Brook LLC and Natco Pharma Ltd. (collectively, Alvogen), which filed an ANDA seeking approval to market generic versions of IMBRUVICA tablets, asserting infringement of United States Patent Nos. 7,514,444; 8,003,309; 8,476,284; 8,497,277; 8,697,711; 8,753,403; 8,754,090; 8,754,091; 8,952,015; 8,957,079; 9,181,257; 9,296,753; 9,655,857; 9,725,455; 10,010,507; 10,106,548; and 10,125,140. In June 2019, Pharmacyclics and JBI amended their complaint against Alvogen to further allege infringement of United States Patent No. 10,213,386.

Trial against Alvogen took place in October 2020. In August 2021, the District Court issued a decision in favor of Pharmacyclics and Janssen finding the asserted claims against Alvogen to be infringed and not invalid. Alvogen has appealed that decision.

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

#### **SYMTUZA**

In November 2021, Janssen Products, L.P. and Janssen Sciences Ireland Unlimited Company (collectively, Janssen) and Gilead Sciences, Inc. and Gilead Sciences Ireland UC (collectively, Gilead) initiated a patent infringement lawsuit in the United States District Court for the District of Delaware against Lupin Limited, Lupin Pharmaceuticals, Inc., MSN Laboratories Private Ltd., MSN Life Sciences Private Ltd., and MSN Pharmaceuticals Inc. (collectively, Lupin), which filed an ANDA seeking approval to market a generic version of SYMTUZA before the expiration of United States Patent Nos. 10,039,718 (the '718 patent) and 10,786,518 (the '518 patent). Janssen is seeking an order enjoining Lupin from marketing its generic version of SYMTUZA before the expiration of the '718 and '518 patents.

#### Other Litigation

In November 2021, Janssen Pharmaceutica N.V. (Janssen) provided to Alkermes Pharma Ireland Limited, Elan Pharma International Limited, and Elan Drug Delivery, Inc. three-months' notice of termination of a License Agreement by and among Elan Pharmaceutical Research Corp., d/b/a Nanosystems, Elan Pharma International Limited and Janssen, executed in March, 1999. In November 2021, Janssen also provided to Alkermes Pharma Ireland Limited three-months' notice of termination of a License Agreement between Elan Pharma International Limited and Janssen executed in July 2003. In April 2022, in responses to these notices, Alkermes Pharma Ireland Limited (Alkermes) initiated arbitration in the International Institute for Conflict Prevention and Resolution.

#### **GOVERNMENT PROCEEDINGS**

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

# Average Wholesale Price (AWP) Litigation

Johnson & Johnson and several of its pharmaceutical subsidiaries (the J&J AWP Defendants), along with numerous other pharmaceutical companies, were named as defendants in a series of lawsuits in state and federal courts involving allegations that the pricing and marketing of certain pharmaceutical products amounted to fraudulent and otherwise actionable conduct because, among other things, the companies allegedly reported an inflated Average Wholesale Price (AWP) for the drugs at issue. Payors alleged that they used those AWPs in calculating provider reimbursement levels. The plaintiffs in these cases included three classes of private persons or entities that paid for any portion of the purchase of the drugs at issue based on AWP, and state government entities that made Medicaid payments for the drugs at issue based on AWP. Many of these cases, both federal actions and state actions removed to federal court, were consolidated for pre-trial purposes in a multi-district litigation in the United States District Court for the District of Massachusetts, where all claims against the J&J AWP Defendants were ultimately dismissed. The J&J AWP Defendants also prevailed in a case brought by the Commonwealth of Pennsylvania. Other AWP cases have been resolved through court order or settlement. The case brought by Illinois was settled after trial. In New Jersey, a putative class action based upon AWP allegations is pending against Centocor, Inc. and Ortho Biotech Inc. (both now Janssen Biotech, Inc.), Johnson & Johnson and ALZA Corporation. All other cases have been resolved.

## Opioid Litigation

Beginning in 2014 and continuing to the present, Johnson & Johnson and Janssen Pharmaceuticals, Inc. (JPI), along with other pharmaceutical companies, have been named in close to 3,500 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, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming. The Government of Puerto Rico filed suit in Superior Court of San Juan.

Johnson & Johnson, JPI and other pharmaceutical companies had 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 2019, 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 appealed the judgment, and in November 2021, the Oklahoma Supreme Court reversed the trial court's judgment and directed entry of judgment for Defendants. In October 2019 Johnson & Johnson and JPI announced a settlement of the first case set for trial in the MDL with two counties in Ohio. In April 2021, three California counties and the City of Oakland commenced a trial in California state court against Johnson & Johnson and JPI, and other affiliates, as well as three other pharmaceutical manufacturers. The trial concluded in October 2021, and in December 2021, the Court entered a final trial judgment in favor of Defendants on all claims. In February 2022, Plaintiffs' motion to set aside and vacate the judgment was denied. Plaintiffs appealed the judgment, but later filed a request to dismiss the appeal after electing to participate in the national settlement agreement.

In October 2019, the Company announced a proposed agreement in principle that would include the Company paying \$4 billion as settlement of these matters that had not been tried or settled. 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 is not an admission of liability or wrong-doing. In July 2021, the Company announced that the terms of the agreement to settle the state and subdivision claims had been finalized and up to one-third of the all-in settlement is expected to be paid within the next 12 months, depending upon the level of participation by the states and their subdivisions. The terms provided 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. Based on expected participation, the Company committed in advance to proceed with the settlement in five of the participating states (New York, Texas, Florida, Nevada, and New Mexico) and with tribal governments. By late February 2022, 45 states, five territories, the District of Columbia, and the vast majority of eligible subdivisions had elected to participate in the settlement, and the Company confirmed that the level of participation was sufficient to proceed with the agreement as to all participants. The agreement was effective in April 2022 and initial payments are set for July 2022. In April 2022, the Company entered into settlement agreements with the states of Alabama and West Virginia and their participating subdivisions.

There are approximately 100 cases remaining post-settlement in various state courts. There are approximately 1,000 remaining federal cases coordinated in a federal Multi-District Litigation (MDL) pending in the U.S. District Court for the Northern District of Ohio. In addition, the Province of British Columbia filed suit against Johnson & Johnson and its Canadian affiliate Janssen Inc., and many other industry members, in Canada, and is seeking to have that action certified as an opt in class action on behalf of other provincial/territorial and the federal governments in Canada. Additional proposed class actions have been filed in Canada against Johnson & Johnson and Janssen Inc., and many other industry members, by and on behalf of people who used opioids (for personal injuries), municipalities and First Nations bands. In October 2019, an antitrust 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.

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.

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. A series of additional derivative complaints making similar allegations against the same and similar defendants were filed in New Jersey state and federal courts in 2019 and 2020. By 2022, all but two state court cases had been voluntarily dismissed. In February 2022, the state court granted Johnson & Johnson's motion to dismiss one of the two cases, and the shareholder that brought the second case filed a notice of dismissal. The shareholder whose complaint was dismissed filed a motion for reconsideration.

## 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. In March 2021, DePuy filed its motion to strike and dismiss the relators' second amended complaint; the District Court denied DePuy's motion to strike and dismiss in July 2021. DePuy filed a motion for reconsideration of the District Court's July 2021 ruling. In November 2021, the District Court granted DePuy's motion for reconsideration and dismissed the case with prejudice. The District Court's order was unsealed in December 2021. The Relators filed several post-dismissal motions, including a January 2022 omnibus motion for reconsideration, which the District Court denied. Following the District Court's order dismissing the case with prejudice, DePuy filed a December 2021 motion seeking the recovery of attorneys' fees and costs, which the District Court denied except as to costs. The Relators have appealed the District Court's dismissal of the case to the First Circui

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. Janssen's motion to dismiss was denied in December 2021.

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. In October 2019, Johnson & Johnson and Ethicon settled the multi-state investigation with 41 other states and the District of Columbia. 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. Trial in the Kentucky matter is scheduled for May 2023. The California case started trial in July 2019 and concluded in September 2019. 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 appealed the penalty judgment. In April 2022, the Court of Appeals reduced the judgment to \$302 million, but otherwise denied the appeal. The Company is pursuing an appeal to the Supreme Court of California.

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 & Johnson & Johnson & Johnson Consumer Inc.) (collectively, JJCI). The complaint alleges that JJCI 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. Johnson & Johnson and JJCI moved for summary judgment on the grounds that the State's claim was barred by preemption, which the trial court denied. 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. Briefing and oral argument were completed. Thereafter, the Court rejected the interlocutory appeal in April 2021 and remanded the matter to the trial court. In August 2021, JJCI filed a Petition for Writ of Certiorari in the United States Supreme Court as to the Mississippi Supreme Court's ruling of April 2021. In December 2021 the United States Supreme Court denied the Petition for Writ of Certiorari. After the Mississippi Supreme Court remanded the matter to the trial court, the State moved for a trial setting. JJCI objected to any trial setting and in January 2022, the Court granted plaintiff's motion for trial setting and directed the parties to consult with the Court administrator to secure a trial date. In February 2022, the trial court set the case for trial to begin in February 2023. However, given the efforts to resolve talc-related claims in the LTL Bankruptcy Case, the Company and the State agreed to a temporary stay of discovery until May 2022.

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. In March 2022, the New Mexico court denied the Company's motion to compel the State of New Mexico to engage in discovery of state agencies and denied the Company's request for interlocutory appeal of that decision. The Company then filed a Petition for Writ of Superintending Control and a Request for a Stay to the New Mexico Supreme Court on the issue of the State of New Mexico's discovery obligations. In April 2022, in view of the efforts to resolve talc-related claims in the LTL Bankruptcy Case, the Company and the State agreed to a 60-day stay of all matters except for the pending writ before the New Mexico Supreme Court.

Forty-two states and the District of Columbia have commenced a joint investigation into the Company's marketing of its talcum powder products. At this time, the multi-state group has not asserted any claims against the Company. Five states have issued Civil Investigative Demands seeking documents and other information. The Company has produced documents to Arizona, North Carolina, Texas, and Washington and entered into confidentiality agreements. The Company has not received any follow up requests from those states. In March 2022, each of the forty-two states (including Mississippi and New Mexico) agreed to enter into negotiations to determine if they would resolve their claims through the LTL Bankruptcy Case.

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. The Court denied summary judgment on all claims in December 2021. *Daubert* motions were granted in part and denied in part in January 2022, and the case is proceeding to trial.

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 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. This case was settled in March 2022, subject to Court approval.

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. This case was settled in February 2022, subject to Court approval.

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. This case was settled in January 2022.

In June 2019, the United States Federal Trade Commission (FTC) issued a Civil Investigative Demand to Johnson & Johnson and Janssen Biotech, Inc. (collectively, Janssen) 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 February 2022, the United States Federal Trade Commission (FTC) issued Civil Investigative Demands to Johnson & Johnson and Janssen Biotech, Inc. (collectively, Janssen) in connection with its investigation of whether advertising practices for REMICADE violate federal law. Janssen has produced documents and information responsive to the Civil Investigative Demands.

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 2022, the United States Court of Appeals for the District of Columbia Circuit reversed the District Court's decision. In February 2022, defendants petitioned for rehearing en banc.

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 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. In December 2021, several insurance companies and other payers filed individual "Opt-Out" complaints containing allegations similar to the original complaint. 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. In December 2021, BWI filed a motion for summary judgment. In March 2022, the Court granted BWI's motion for summary judgment.

In November 2019, Johnson & Johnson received a demand for indemnification from Pfizer Inc. (Pfizer), pursuant to the 2006 Stock and Asset Purchase Agreement between the Company and Pfizer. Also in November 2019, Johnson & Johnson Inc. received notice reserving rights to claim indemnification from Sanofi Consumer Health, Inc. (Sanofi), pursuant to the 2016 Asset Purchase Agreement between Johnson & Johnson Inc. and Sanofi. In January 2020, Johnson & Johnson received a demand for indemnification from Boehringer Ingelheim Pharmaceuticals, Inc. (Boehringer Ingelheim), 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. The Company and Johnson & Johnson Inc. have also been named in putative class actions filed in Canada with similar allegations regarding ZANTAC or ranitidine use. Johnson & Johnson Inc. was also named as a defendant along with other manufacturers in various personal injury actions in Canada related to ZANTAC products. Johnson & Johnson Inc. has provided Sanofi notice reserving rights to claim indemnification pursuant to the 2016 Asset Purchase Agreement related to the class actions and personal injury actions.

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 2021, the Court granted in part and denied in part defendants' motion to dismiss certain causes of action. All claims against the individual defendants were dismissed. The trial is scheduled for February 2023.

Beginning in May 2021, multiple putative class actions were filed in state and federal courts (California, Florida, New York, and New Jersey) against various Johnson & Johnson entities alleging violations of state consumer fraud statutes based on nondisclosure of alleged benzene contamination of certain Neutrogena and Aveeno sunscreen products and the affirmative promotion of those products as "safe"; and, in at least one case, alleging a strict liability manufacturing defect and failure to warn claims, asserting that the named plaintiffs suffered unspecified injuries as a result of alleged exposure to benzene. The Judicial Panel on Multi-District Litigation has consolidated all pending actions, except one product liability case and one case pending in New Jersey state court, in the United States District Court for the Southern District of Florida, Fort Lauderdale Division. In October 2021, the Company reached an agreement in principle for the settlement of a nationwide class, encompassing the claims of the consolidated actions, subject to approval by the Florida federal Court. In March 2022, the Court granted preliminary approval of the settlement.

Johnson & Johnson (subsequently substituted by Johnson & Johnson Consumer Inc. (JJCI)) along with more than 120 other companies, is a defendant in a cost recovery and contribution action brought by Occidental Chemical Corporation in June 2018 in the United States District Court for the District of New Jersey, related to the clean-up of a section of the Lower Passaic River in New Jersey.

Johnson & Johnson or its subsidiaries are also parties to various 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 first quarter of 2022, the Company recorded a net pre-tax charge of \$72 million, which is included on the following lines of the Consolidated Statement of Earnings, \$70 million in restructuring, \$16 million in cost of products sold and income of \$14 million (from property sales) in other (income) expense, net. Total project costs of approximately \$1.8 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 the end of 2022. The Company expects to record pre-tax restructuring charges of approximately \$2.1 billion to \$2.3 billion by the completion of the program in December 2022. 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 first quarter of 2022:

(Dollars in Millions)	Se	verance Asset V	Write-offs/Sales	Other <sup>(2)</sup>	Total
Reserve balance, January 2, 2022	\$	112	_	25	137
Current year activity:					
Charges		_	(23)	95	72
Cash settlements		(10)	35 (3)	(107)	(82)
Settled non cash		_	(12)	_	(12)
Reserve balance, April 3, 2022 <sup>(1)</sup>	\$	102	<u>—</u>	13	115

<sup>(1)</sup> Cash outlays for severance are expected to be substantially paid out by the completion of the program in December 2022.

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.

<sup>(2)</sup> Other includes project expense such as salaries for employees supporting these initiatives and consulting expenses.

<sup>(3)</sup> Represents gain on sale of assets

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

## RESULTS OF OPERATIONS

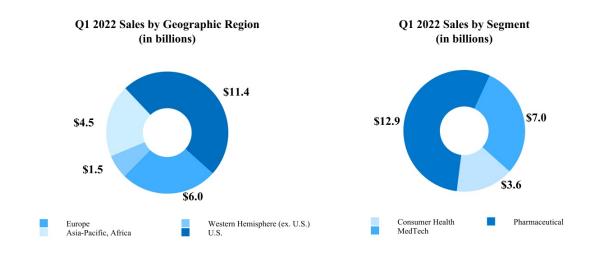
Sales to Customers

#### Analysis of Consolidated Sales

For the fiscal first quarter of 2022, worldwide sales were \$23.4 billion, a total increase of 5.0%, which included operational growth of 7.7% and a negative currency impact of 2.7% as compared to 2021 fiscal first quarter sales of \$22.3 billion. In the fiscal first quarter of 2022, the net impact of acquisitions and divestitures on worldwide operational sales growth was a negative 0.2%.

Sales by U.S. companies were \$11.4 billion in the fiscal first quarter of 2022, which represented an increase of 2.7% as compared to the prior year. In the fiscal first quarter of 2022, the net impact of acquisitions and divestitures on the U.S. operational sales growth was a negative 0.1%. Sales by international companies were \$12.0 billion, a total increase of 7.2%, which included operational growth of 12.6% and a negative currency impact of 5.4%. In the fiscal first quarter of 2022, the net impact of acquisitions and divestitures on the international operational sales growth was a negative 0.3%.

In the fiscal first quarter of 2022, sales by companies in Europe achieved growth of 11.3%, which included operational growth of 19.5% and a negative currency impact of 8.2%. Sales by companies in the Western Hemisphere, excluding the U.S., achieved growth of 4.1%, including operational growth of 5.1% and a negative currency impact of 1.0%. Sales by companies in the Asia-Pacific, Africa region achieved growth 3.1%, including operational growth of 6.6% and a negative currency impact of 3.5%.



Note: values may have been rounded

## Analysis of Sales by Business Segments

#### **Consumer Health**

Consumer Health segment sales in the fiscal first quarter of 2022 were \$3.6 billion, a decrease of 1.5% as compared to the same period a year ago, including operational growth of 0.8% offset by a negative currency impact of 2.3%. U.S. Consumer Health segment sales decreased by 3.4%. International Consumer Health segment sales were flat including operational growth of 4.1% and a negative currency impact of 4.1%. In the fiscal first quarter of 2022, the net impact of acquisitions and divestitures on the Consumer Health segment operational sales growth was a negative 0.8% primarily due to the DR. CI:LABO - Sedona divestiture in Asia Pacific.

Major Consumer Health Franchise Sales\* — Fiscal First Quarter Ended

(Dollars in Millions)	Aŗ	oril 3, 2022	April 4, 2021	Total Change	Operations Change	Currency Change
$OTC^{(1)}$	\$	1,461	\$ 1,273	14.8 %	17.1 %	(2.3) %
Skin Health/Beauty		1,012	1,163	(13.0)	(11.0)	(2.0)
Oral Care		366	417	(12.2)	(10.2)	(2.0)
Baby Care		355	389	(8.6)	(6.4)	(2.2)
Women's Health		228	222	2.6	8.3	(5.7)
Wound Care/Other		164	177	(7.4)	(7.2)	(0.2)
<b>Total Consumer Health Sales</b>	\$	3,586	\$ 3,641	(1.5)%	0.8 %	(2.3)%

<sup>\*</sup>Certain prior year amounts have been reclassified to conform to current year presentation

The OTC franchise achieved operational growth of 17.1% as compared to the prior year fiscal first quarter. Growth was driven by upper respiratory products, TYLENOL and MOTRIN and IMODIUM and PEPCID products in digestive health.

The Skin Health/Beauty franchise experienced an operational decline of 11.0% as compared to the prior year fiscal first quarter. The decline was driven by external supply constraints, the DR. CI:LABO - Sedona divestiture in Asia Pacific and competitive pressures. The decline was partially offset by U.S. category recovery and strength in the Latin America and Asia Pacific regions.

The Oral Care franchise experienced an operational decline of 10.2% as compared to the prior year fiscal first quarter. The decline was primarily driven by strategic SKU rationalization in the U.S. and lapping prior year COVID-19 related increased demand outside the U.S.

The Baby Care franchise experienced an operational decline of 6.4% as compared to the prior year fiscal first quarter. The decline was driven by supply constraints in the U.S. and EMEA.

The Women's Health franchise achieved operational growth of 8.3% as compared to the prior year fiscal first quarter primarily driven by growth in EMEA due to increased stocking and LATAM due to price increases.

The Wound Care/Other franchise experienced an operational decline of 7.2% as compared to the prior year fiscal first quarter primarily driven by the professional tape divestiture along with comparison to prior year COVID-19 recovery for NEOSPORIN in the U.S. and BAND-AID® Brand Adhesive Bandages outside the U.S. This decline was partially offset by growth of U.S. BAND-AID® Brand Adhesive Bandages.

In November 2021, the Company announced its intention to separate the Company's Consumer Health business, with the intention to create a new, publicly traded company. The Company is targeting completion of the planned separation in 18 to 24 months after the initial announcement.

<sup>(1)</sup> In the fiscal first quarter of 2021, approximately \$0.1 billion of certain international OTC products, primarily in China, were reclassified from the Pharmaceutical segment to the Consumer Health segment based on operational changes

## Pharmaceutical

Pharmaceutical segment sales in the fiscal first quarter of 2022 were \$12.9 billion, an increase of 6.3% as compared to the same period a year ago, including an operational increase of 9.3% and a negative currency impact of 3.0%. U.S. Pharmaceutical sales increased 2.9% as compared to the same period a year ago. International Pharmaceutical sales increased by 10.3%, including operational growth of 16.7% and a negative currency impact of 6.4%. In the fiscal first quarter of 2022, the net impact of acquisitions and divestitures on the Pharmaceutical segment operational sales growth was negligible. Adjustments to previous sales reserve estimates were negligible in the fiscal first quarter of 2022 and approximately \$0.2 billion in the fiscal first quarter of 2021.

Major Pharmaceutical Therapeutic Area Sales\*\* — Fiscal First Quarter Ended

(Dollars in Millions)	A	April 3, 2022	April 4, 2021	Total Change	Operations Change	Currency Change
Immunology	\$	4,119	\$ 3,914	5.2 %	7.5 %	(2.3)%
REMICADE		663	777	(14.7)	(14.2)	(0.5)
SIMPONI/ SIMPONI ARIA		571	562	1.5	4.7	(3.2)
STELARA		2,288	2,148	6.5	9.0	(2.5)
TREMFYA		590	418	41.3	44.5	(3.2)
Other Immunology		6	8	(22.0)	(22.0)	0.0
Infectious Diseases		1,297	998	30.0	33.1	(3.1)
COVID-19 VACCINE		457	100	*	*	*
EDURANT/rilpivirine		248	243	1.8	9.6	(7.8)
PREZISTA/ PREZCOBIX/ REZOLSTA/ SYMTUZA		501	546	(8.3)	(6.9)	(1.4)
Other Infectious Diseases <sup>(2)</sup>		91	108	(15.3)	(11.0)	(4.3)
Neuroscience		1,741	1,715	1.5	5.0	(3.5)
CONCERTA/ methylphenidate		157	171	(8.3)	(4.8)	(3.5)
INVEGA SUSTENNA/ XEPLION/ INVEGA TRINZA/ TREVICTA		1,048	965	8.6	11.3	(2.7)
RISPERDAL CONSTA		129	157	(17.6)	(13.9)	(3.7)
Other Neuroscience <sup>(2)</sup>		408	422	(3.5)	1.7	(5.2)
Oncology		3,950	3,570	10.6	14.9	(4.3)
DARZALEX		1,856	1,365	36.0	40.3	(4.3)
ERLEADA		400	261	53.0	57.5	(4.5)
IMBRUVICA		1,038	1,125	(7.7)	(3.9)	(3.8)
ZYTIGA/ abiraterone acetate		539	638	(15.6)	(10.1)	(5.5)
Other Oncology		118	182	(35.1)	(32.3)	(2.8)
Pulmonary Hypertension		852	861	(1.1)	1.2	(2.3)
OPSUMIT		443	450	(1.6)	1.1	(2.7)
UPTRAVI		325	305	6.5	7.7	(1.2)
Other Pulmonary Hypertension		83	105	(20.8)	(16.8)	(4.0)
Cardiovascular / Metabolism / Other		910	1,044	(12.8)	(11.9)	(0.9)
XARELTO		508	589	(13.8)	(13.8)	
INVOKANA/ INVOKAMET		128	150	(14.6)	(13.1)	(1.5)
Other <sup>(1,2)</sup>		274	 305	(10.0)	(7.5)	(2.5)
Total Pharmaceutical Sales	\$	12,869	\$ 12,101	6.3 %	9.3 %	(3.0)%

<sup>\*</sup> Percentage greater than 100% or not meaningful

<sup>\*\*</sup>Certain prior year amounts have been reclassified to conform to current year presentation

<sup>(1)</sup> Inclusive of PROCRIT / EPREX which was previously disclosed separately

<sup>(2)</sup>In the fiscal first quarter of 2021, approximately \$0.1 billion of certain international OTC products, primarily in China, were reclassified from the Pharmaceutical segment to the Consumer Health segment based on operational changes

Immunology products achieved operational growth of 7.5% as compared to the same period a year ago driven by continued strong uptake of STELARA (ustekinumab) in Crohn's disease and Ulcerative Colitis partially offset by share declines in Psoriasis and Psoriatic Arthritis and strength of TREMFYA (guselkumab) in Psoriasis and uptake in Psoriatic Arthritis. 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.

The latest expiring United States patent for STELARA (ustekinumab) will expire in September 2023. STELARA (ustekinumab) U.S. sales in fiscal 2021 were approximately \$5.9 billion. The expiration of a product patent or loss of market exclusivity is likely to result in a reduction in sales.

Infectious disease products achieved operational growth of 33.1% as compared to the same period a year ago. Growth was primarily driven by the contribution of the COVID-19 vaccine. This was partially offset by lower sales of PREZISTA and PREZCOBIX/REZOLSTA (darunavir/cobicistat) due to increased competition and loss of exclusivity of PREZISTA in certain countries outside the U.S.

Neuroscience products achieved operational sales growth of 5.0% 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 patient mix, new patient starts and persistence of treatment as well as the launch of INVEGA HAFYERA.

Oncology products achieved operational sales growth of 14.9% as compared to the same period a year ago. Contributors to the growth were strong sales of DARZALEX (daratumumab) driven by share gains in all regions, continued strong market growth, and solid uptake of the subcutaneous formulation; the continued global launch uptake of ERLEADA (apalutamide) and IMBRUVICA (ibrutinib) growth in all regions outside the U.S. In the U.S. IMBRUVICA (ibrutinib) declined due to competitive pressures from novel oral agents.

Pulmonary Hypertension achieved operational sales growth of 1.2% as compared to the same period a year ago. Sales growth of OPSUMIT (macitentan) and UPTRAVI (selexipag) were due to demand and share gains partially offset by COVID-19 related market constraints as well as entrants in Other Pulmonary Hypertension.

Cardiovascular / Metabolism / Other products experienced an operational decline of 11.9% as compared to the same period a year ago. The decline was primarily attributable to lower sales of XARELTO due to a one-time favorable prior period pricing adjustment in the fiscal first quarter of 2021 and INVOKANA/INVOKAMET (canagliflozin) due to continued share erosion.

Starting in the second quarter of fiscal 2022, the Company updated its policy so that no end customer will be permitted to direct delivery of product to a location other than the billing location. The updated policy will impact contract pharmacy transactions involving non-grantee 340B covered entities for most of the Company's drugs, subject to multiple exceptions. Both grantee and non-grantee covered entities can maintain unlimited contract pharmacy arrangements under policy exceptions. The Company will continue to offer 340B discounts to covered entities on all of its covered outpatient drugs, and it believes its policy will improve its ability to identify inappropriate duplicate discounts and diversion prohibited by the 340B statute. The 340B Drug Pricing Program is a U.S. federal government program requiring drug manufacturers to provide significant discounts on covered outpatient drugs to covered entities. This policy update could have potential discount and volume implications going forward.

#### MedTech\*

The MedTech segment sales in the fiscal first quarter of 2022 were \$7.0 billion, an increase of 5.9% as compared to the same period a year ago, which included operational growth of 8.5% and a negative currency impact of 2.6%. U.S. MedTech sales increased 5.6%. International MedTech sales increased by 6.3%, including operational growth of 11.1% and a negative currency impact of 4.8%. In the fiscal first quarter of 2022, the net impact of acquisitions and divestitures on the MedTech segment operational sales growth was a negative 0.1%.

Major MedTech Franchise Sales — Fiscal First Quarter Ended

(Dollars in Millions)	Apı	April 3, 2022		ril 4, 2021	Total Change	Operations Change	Currency Change
Surgery	\$	2,434	\$	2,372	2.6 %	5.0 %	(2.4)%
Advanced		1,146		1,118	2.5	4.5	(2.0)
General		1,288		1,254	2.7	5.5	(2.8)
Orthopaedics		2,188		2,113	3.5	5.6	(2.1)
Hips		389		356	9.3	11.3	(2.0)
Knees		339		317	6.7	8.8	(2.1)
Trauma		748		733	2.1	4.2	(2.1)
Spine, Sports & Other		712		707	0.6	2.7	(2.1)
Vision		1,257		1,145	9.8	13.9	(4.1)
Contact Lenses/Other		910		857	6.2	10.6	(4.4)
Surgical		347		288	20.4	23.8	(3.4)
Interventional Solutions		1,092		949	15.1	17.4	(2.3)
<b>Total MedTech Sales</b>	\$	6,971	\$	6,579	5.9 %	8.5 %	(2.6)%

<sup>\*</sup>Previously referred to as Medical Devices

The Surgery franchise achieved operational sales growth of 5.0% as compared to the prior year fiscal first quarter. The operational growth in Advanced Surgery was primarily driven by Endocutter and Biosurgery products attributable to market recovery, market expansion and the success of new products. Growth of Endocutter products was offset by COVID-19 market slow down in the Asia Pacific region and competitive pressures in the U.S. Energy products growth was flat to the prior year fiscal first quarter with market recovery and new product penetration mostly offset by COVID-19 market slow downs in Asia Pacific. The operational growth in General Surgery was primarily driven by market recovery, strength of the Suture portfolio, and technology penetration.

The Orthopaedics franchise achieved operational sales growth of 5.6% as compared to the prior year fiscal first quarter. The operational growth in hips reflects the market recovery, continued strength of the portfolio including the ACTIS stem and enabling technologies – KINCISE and VELYS Hip Navigation and momentum in the U.S. Ambulatory Surgery Center channel. The operational growth in knees was primarily driven by market recovery and uptake of new products and momentum in the U.S. Ambulatory Surgery Center channel. 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 recovery across most specialties, new products in Sports, Spine & VELYS Digital Solutions and a prior year China distribution channel change. Growth was partially offset by market softness and competitive pressures in Spine.

The Vision franchise achieved operational sales growth of 13.9% as compared to the prior year fiscal first quarter. The Contact Lenses/Other operational growth was due to market recovery, new products and the U.S. benefit related to a current year forward buy ahead of a list price increase. The growth was partially offset by the negative impact from prior year stocking. 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 17.4% as compared to the prior year fiscal first quarter driven by the market recovery, success of new products and commercial strategies.

## ANALYSIS OF CONSOLIDATED EARNINGS BEFORE PROVISION FOR TAXES ON INCOME

Consolidated earnings before provision for taxes on income for the fiscal first quarter of 2022 was \$5.9 billion representing 25.0% of sales as compared to \$7.4 billion in the fiscal first quarter of 2021, representing 33.3% of sales.

## **Cost of Products Sold**



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

## Q1 2022 versus Q1 2021

Cost of products increased as a percent to sales driven by:

- Unfavorable volume/mix in the MedTech segment
- Commodity inflation in the Consumer Health segment

The intangible asset amortization expense included in cost of products sold for the fiscal first quarters of 2022 and 2021 was \$1.1 billion and \$1.2 billion, respectively.

## Selling, Marketing and Administrative Expenses



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

# Q1 2022 versus Q1 2021

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

• Higher brand marketing expenses in the Pharmaceutical and Consumer Health businesses

### Research and Development Expense



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

#### Q1 2022 versus Q1 2021

Research and Development increased as a percent to sales driven by:

• General portfolio progression in the Pharmaceutical business

### In-Process Research and Development (IPR&D)

In the fiscal first quarter of 2022, the Company recorded an intangible asset impairment charge of approximately \$0.6 billion related to an in-process research and development asset, bermekimab (JnJ-77474462), an investigational drug for the treatment of Atopic Dermatitis (AD) and Hidradenitis Suppurativa (HS). Additional information regarding efficacy of the AD indication became available which led the Company to the decision to terminate the development of bermekimab for AD. The Company acquired all rights to bermekimab from XBiotech, Inc. in the fiscal year 2020.

#### **Interest (Income) Expense**

Interest (Income) Expense in the fiscal first quarter of 2022 was a net interest income of \$12 million as compared to interest expense of \$48 million in the same period a year ago primarily due to the benefit from net investment hedging, a higher average cash balance and a lower average debt balance. The balance of cash, cash equivalents and current marketable securities was \$30.4 billion at the end of the fiscal first quarter of 2022 as compared to \$24.6 billion at the end of the fiscal first quarter of 2021. The Company's debt position was \$33.1 billion as of April 3, 2022 as compared to \$33.6 billion the same period a year ago.

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

# Q1 2022 versus Q1 2021

Other (income) expense, net for the fiscal first quarter of 2022 was unfavorable by \$0.8 billion as compared to the prior year primarily due to the following:

Fiscal First Quarter						
(Dollars in Billions)(Income)/Expense	2	2022	202	21	(	Change
Changes in the fair value of securities	\$	0.4		0.0		0.4
Acquisition, integration and divestiture related <sup>(1)</sup>		0.0		(0.5)		0.5
Consumer Health separation costs		0.1		0.0		0.1
Employee benefit plan related		(0.3)		(0.2)		(0.1)
Other		(0.3)		(0.2)		(0.1)
Total Other (Income) Expense, Net	\$	(0.1)	\$	(0.9)	\$	0.8

<sup>(1)</sup> Primarily related to divestiture gains of two pharmaceutical brands outside the U.S. in the fiscal first quarter of 2021.

<sup>\*</sup>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), changes in the fair value of securities, gains and losses on divestitures, gains and losses on sale of assets, 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 (loss) before tax by segment of business for the fiscal first quarters were as follows:

	Income Before Tax			Segment Sales				Percent of Segment Sales		
(Dollars in Millions)	April	3, 2022	Apri	14, 2021	Αŗ	oril 3, 2022	Ap	oril 4, 2021	April 3, 2022	April 4, 2021
Consumer Health	\$	686	\$	842	\$	3,586	\$	3,641	19.1 %	23.1 %
Pharmaceutical		3,924		5,169		12,869		12,101	30.5	42.7
MedTech		1,477		1,629		6,971		6,579	21.2	24.8
Segment earnings before tax		6,087		7,640		23,426		22,321	26.0	34.2
Less: Expenses not allocated to segments (1)		123		211						
Less: Consumer Health separation costs		102		_						
Worldwide income before tax	\$	5,862	\$	7,429	\$	23,426	\$	22,321	25.0 %	33.3 %

<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/(loss) before tax as a percent of sales in the fiscal first quarter of 2022 was 19.1% versus 23.1% for the same period a year ago. The decrease in the income before tax as a percent of sales in the fiscal first quarter of 2022 as compared to the prior year was primarily driven by the following:

- An increase in brand marketing expenses
- Commodity inflation

# **Pharmaceutical Segment**

The Pharmaceutical segment income before tax as a percent of sales in the fiscal first quarter of 2022 was 30.5% versus 42.7% for the same period a year ago. The decrease in the income before tax as a percent of sales for the fiscal first quarter of 2021 as compared to the prior year was primarily driven by the following:

- An IPR&D charge of \$0.6 billion in 2022 related to bermekimab (JnJ-77474462), an investigational drug for the treatment of AD and Hidradenitis Suppurativa (HS)
- Divestiture gains of \$0.6 billion in 2021.
- Net mark-to-market loss related to the change in the fair value of securities (\$0.4 billion in 2022 vs. \$0.0 billion in 2021)
- Increased Research & Development investment for general portfolio progression
- Higher brand marketing expenses

#### MedTech Segment

The MedTech segment income before tax as a percent of sales in the fiscal first quarter of 2022 was 21.2% versus 24.8% for the same period a year ago. The decrease in the income before tax as a percent of sales for the fiscal first quarter was primarily driven by the following:

• Product mix within the MedTech franchises

#### 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 the end of 2022. The Company expects to record pre-tax restructuring charges of approximately \$2.1 to \$2.3 billion by the completion of the program in December 2022. In the fiscal first quarter of 2022, the Company recorded a net pre-tax charge of \$72 million, which is included on the following lines of the Consolidated Statement of Earnings, \$70 million in restructuring, \$16 million in cost of products sold and income of \$14 million (from property sales) in other (income) expense, net. In the fiscal first quarter of 2021, the Company recorded a pre-tax charge of \$104 million, which is included on the following lines of the Consolidated Statement of Earnings, \$53 million in restructuring, \$27 million in cost of products sold and \$24 million in other (income) expense, net. Restructuring charges of approximately \$1.8 billion have been recorded since the restructuring was announced.

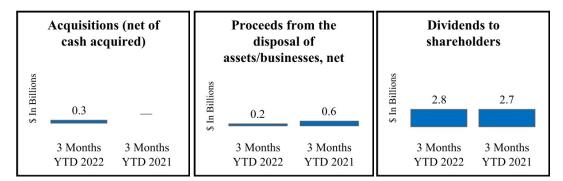
See Note 12 to the Consolidated Financial Statements for additional details related to the restructuring.

#### **Provision for Taxes on Income**

The worldwide effective income tax rate was 12.2% in 2022 and 16.6% in 2021. During fiscal year 2022, the Company is expected to incur significant additional international tax costs related to the legal separation of the Consumer Health businesses.

For discussion related to the fiscal first quarter of 2022 provision for taxes refer to Note 5 to the Consolidated Financial Statements.

#### LIQUIDITY AND CAPITAL RESOURCES



#### Cash Flows

Cash and cash equivalents were \$10.5 billion at the end of the fiscal first quarter of 2022 as compared with \$14.5 billion at the end of fiscal year 2021. The primary sources and uses of cash that contributed to the \$4.0 billion decrease were:

(Dollars In Billions)		
\$	14.5 Q4 2021 Cash and cash equivalents balance	
	4.0 cash generated from operating activities	
	(3.6) net cash used by investing activities	
	(4.4) net cash used by financing activities	
\$	10.5 Q1 2022 Cash and cash equivalents balance	

In addition, the Company had \$19.9 billion in marketable securities at the end of the fiscal first quarter of 2022 and \$17.1 billion at the end of fiscal year 2021.

Cash flow from operations of \$4.0 billion was the result of:

(Dollars In Billions)	
\$	5.1 Net Earnings
	non-cash expenses and other adjustments primarily for depreciation and amortization, stock-based compensation, asset write-downs and credit losses and accounts receivable allowances partially offset by the deferred tax provision and net 1.6 gain on sale of assets/businesses
	(1.0) an increase in accounts receivable and inventories
	(2.8) a decrease in accounts payable and accrued liabilities
	1.0 a decrease in other current and non-current assets
	0.1 an increase in other current and non-current liabilities
\$	4.0 Cash Flow from operations

Investing activities use of \$3.6 billion of cash was primarily used for:

(Dollars In Billions		
\$	(0.6) additions to property, plant and equipment	
	0.2 proceeds from the disposal of assets/businesses, net	
	(0.3) acquisitions, net of cash acquired and other	
	(2.7) net purchases of investments	
	(0.2) credit support agreements activity, net	
\$	(3.6) Net cash used for investing activities	

Financing activities use of \$4.4 billion of cash was primarily used for:

(Dollars In Billions)	
\$	(2.8) dividends to shareholders
	(1.6) repurchase of common stock
	0.0 net repayment of short and long term debt
	0.3 proceeds from stock options exercised/employee withholding tax on stock awards, net
	(0.2) credit support agreements activity, net
	(0.1) other and rounding
\$	(4.4) Net cash used for financing activities

The Company has access to substantial sources of funds at numerous banks worldwide. In September 2021, the Company secured a new 364-day Credit Facility. Total credit available to the Company approximates \$10 billion, which expires on September 8, 2022. Interest charged on borrowings under the credit line agreement is based on either Term Secured Overnight Financing Rate (SOFR) Reference Rate or other applicable market rates as allowed under the terms of the agreement, plus applicable margins. Commitment fees under the agreement are not material.

In the fiscal first quarter of 2022, the Company's notes payable and long-term debt was in excess of cash, cash equivalents and marketable securities. As of April 3, 2022, the net debt position was \$2.8 billion as compared to the prior year of \$9.0 billion. Considering recent market conditions and the on-going COVID-19 crisis, the Company has re-evaluated its operating cash flows and liquidity profile and does not foresee any significant incremental risk. The Company anticipates that operating cash flows, the ability to raise funds from external sources, borrowing capacity from existing committed credit facilities and access

to the commercial paper markets will continue to provide sufficient resources to fund operating needs, including the Company's approximate \$0.9 billion in contractual supply commitments associated with its development of the COVID-19 vaccine, the agreement to settle opioid litigation for \$5 billion and the establishment of the \$2 billion trust for tale related liabilities (See Note 11 to the Consolidated Financial Statements for additional details). In addition, the Company monitors the global capital markets on an ongoing basis and from time to time may raise capital when market conditions are favorable. Subsequent to April 3, 2022, the Company paid approximately \$1.0 billion to the U.S. Treasury including \$0.8 billion related to the current installment due on foreign undistributed earnings as part of the TCJA charge (see Note 1 to the Consolidated Financial Statements in the Company's Annual Report on Form 10-K for the fiscal year ended January 2, 2022) and \$0.2 billion primarily related to the normal estimated payment for the fiscal first quarter of 2022.

#### Dividends

On January 4, 2022, the Board of Directors declared a regular cash dividend of \$1.06 per share, payable on March 8, 2022 to shareholders of record as of February 22, 2022.

On April 19, 2022, the Board of Directors declared a regular cash dividend of \$1.13 per share, payable on June 7, 2022 to shareholders of record as of May 24, 2022. 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 2021 and 2020, the Company entered into a series of contract manufacturing arrangements for vaccine production with third party contract manufacturing organizations. These arrangements provide the Company with future supplemental commercial capacity for vaccine production and potentially transferable rights to such production if capacity is not required. Amounts paid for services to be delivered and contractually obligated to be paid to these contract manufacturing organizations of approximately \$0.9 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 the global demand for the Covid-19 vaccine and its related supply.

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.

#### Russia-Ukraine War

Although the long-term implications of Russia's invasion of Ukraine are difficult to predict at this time, the financial impact of the conflict in the fiscal first quarter of 2022, including accounts receivable or inventory reserves, was not material. As of both the 2021 fiscal year ending January 2, 2022, and the fiscal first quarter ending April 3, 2022, the business of the Company's Ukraine subsidiaries represented less than 1% of the Company's consolidated assets and revenues. As of both the 2021 fiscal year ending January 2, 2022, and the fiscal first quarter ending April 3, 2022, the business of the Company's Russian subsidiaries represented less than 1% of the Company's consolidated assets and represented 1% of revenues.

The Company continued to supply its products throughout the first quarter as patients rely on many of the products for healthcare purposes. However, in early March, the Company took steps to suspend all advertising, enrollment in clinical trials, and any additional investment in Russia. Additionally, at the end of March, the Company made the decision to suspend supply of personal care products in Russia.

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%. Beginning in the fiscal second quarter of 2022, the Company will account for operations in Turkey as highly inflationary, as the prior three-year cumulative inflation rate surpassed 100%. This will 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.

Governments around the world consider various proposals to make changes to tax laws, which may include increasing or decreasing existing statutory tax rates. In connection with various government initiatives, companies are required to disclose more information to tax authorities on operations around the world, which may lead to greater audit scrutiny of profits earned in other countries. 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 healthcare products and services, including delaying medical procedures, rationing prescription medications, reducing the frequency of physician visits and foregoing healthcare insurance coverage, as a result of the current global economic downturn, 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 2, 2022.

#### 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. Joaquin Duato, Chief Executive Officer; Chairman, Executive Committee and Joseph J. Wolk, Executive Vice President, Chief Financial Officer, reviewed and participated in this evaluation. Based on this evaluation, Messrs. Duato 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 first quarter of 2022. 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 first 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
January 3, 2022 through January 30, 2022	918,500	170.99		_
January 31, 2022 through February 27, 2022	4,728,073	168.98		_
February 28, 2022 through April 3, 2022	3,596,956	172.58		_
Total	9,243,529			

<sup>(1)</sup> During the fiscal first quarter of 2022, the Company repurchased an aggregate of 9,243,529 shares of Johnson & Johnson Common Stock in open-market transactions, all of which were purchased as part of a systematic plan to meet the needs of the Company's compensation programs.

#### Item 6 — EXHIBITS

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

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

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

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

#### Exhibit 101:

EX-101.INS Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded

within the Inline XBRL document

EX-101.SCH Inline XBRL Taxonomy Extension Schema

EX-101.CAL Inline XBRL Taxonomy Extension Calculation Linkbase
EX-101.LAB Inline XBRL Taxonomy Extension Label Linkbase
EX-101.PRE Inline XBRL Taxonomy Extension Presentation Linkbase
EX-101.DEF Inline XBRL Taxonomy Extension Definition Document

Exhibit 104: Cover Page Interactive Data File—the cover page interactive data file does not appear in the Interactive Data File because its

XBRL tags are embedded within the Inline XBRL document.

# SIGNATURES

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

JOHNSON & JOHNSON

(Registrant)

Date: April 29, 2022 By /s/ J. J. WOLK

J. J. WOLK

Executive Vice President, Chief Financial Officer (Principal Financial

Officer)

Date: April 29, 2022 By /s/ R. J. DECKER Jr.

R. J. DECKER Jr.

Controller (Principal Accounting Officer)

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

- I, Joaquin Duato, certify that:
- 1. I have reviewed this Quarterly Report on Form 10-Q for the quarterly period ended April 3, 2022 (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/ Joaquin Duato

Joaquin Duato
Chief Executive Officer

Date: April 29, 2022

# 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 April 3, 2022 (the "report") of Johnson & Johnson (the "Company");
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;
- 4. The Company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f) and 15d-15(f)) for the Company and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the Company's most recent fiscal quarter (the Company's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and
- 5. The Company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

/s/ Joseph J. Wolk

Joseph J. Wolk
Chief Financial Officer

Date: April 29, 2022

## CERTIFICATION OF CHIEF EXECUTIVE OFFICER

## PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT

The undersigned, Joaquin Duato, 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 April 3, 2022 (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/ Joaquin Duato
Joaquin Duato
Chief Executive Officer

Dated: April 29, 2022

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 April 3, 2022 (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: April 29, 2022

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.