Merck & Co., Inc.

Background

By the year ended December 31, 2001, Merck & Co., Inc. ("Merck") had a well-established wonder drug that was a once-a-day treatment for arthritis pain: Vioxx. Here is an excerpt from the 10-K[1] for that year:

> Vioxx, Merck's ***second largest-selling product***, continued its strong growth in 2001 and was the product leader within the COX-2 class for new prescription volume growth in the United States. ***It exceeded the $2 billion sales mark faster than any other product in Merck's history.*** Pain relief and gastrointestinal safety continue to be the primary needs in the arthritis and pain market. Vioxx is now available in 68 markets around the world as a once-a-day treatment for osteoarthritis, acute pain and dysmenorrhea and, in some countries outside the United States, rheumatoid arthritis. Physicians are responding favorably to the Company's pain studies in which Vioxx 50 mg was compared to acetaminophen in combination with either codeine 60 mg or oxycodone 5 mg, which are commonly prescribed narcotics. In addition, an initiative with U.S. hospitals resulted in a favorable formulary status for Vioxx at more than 3,000 major hospitals. In November 2001, Vioxx was approved for symptomatic relief in the treatment of adult rheumatoid arthritis in all EU member states through the mutual recognition procedure. In December 2001, Vioxx, under the trade names Ceoxx or Vioxx Acute, was also approved for relief of acute pain and pain from dysmenorrhea in 13 member states of the EU. (Emphasis added.)

More good news from the 10-K for 2002:

> Vioxx , Merck's once-a-day coxib, remains the largest and most prescribed arthritis pain medication across many markets worldwide, including Europe, Canada and Latin America. For the year, *Vioxx* sales grew 8% over 2001, achieving $2.5 billion in sales. Excluding the estimated impact of wholesaler buying patterns, the year-on-year growth of *Vioxx* approximated 1%. In 2003, worldwide sales of coxibs, *Vioxx* and *Arcoxia* , are expected to approximate $2.6 billion to $2.8 billion.

This great trend continued. From the 10-K for 2003:

> Worldwide sales of *Vioxx* , Merck's first once-a-day coxib, grew 2% over 2002, achieving $2.5 billion in sales in 2003. Although U.S. mail-order- adjusted prescription levels for *Vioxx* decreased by approximately 8% in 2003, *Vioxx* remains the most widely available coxib on managed care formularies in the United States. *Vioxx* is the only coxib in the United States that offers 24-hour pain relief in a once-daily tablet for all indications, with more than 91 million prescriptions written in the United States since its introduction in 1999. Outside the United States, *Vioxx* is the best-selling arthritis and pain medicine.

But then came trouble. From the 2004 10-K:

> On September 30, 2004, the Company announced a voluntary worldwide withdrawal of *Vioxx*, its arthritis and acute pain medication. The Company's decision, which was effective immediately, was based on new three-year data from a prospective, randomized, placebo-controlled clinical trial, APPROVe (Adenomatous Polyp Prevention on *Vioxx*).

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> The Company estimates that there were 105 million U.S. prescriptions written for Vioxx from May 1999 through August 2004. Based on this estimate, the Company estimates that the number of patients who have taken Vioxx in the United States since its 1999 launch is approximately 20 million. The number of patients outside the United States who have taken Vioxx is undetermined at this time.

[1] 10-K accessed May 5, 2019 at: http://d1lge852tjjqow.cloudfront.net/CIK-0000310158/0527bfdb-9529-44df-8da3-c85d7751c0ab.pdf

Attached find excerpts from the financial statements of Merck & Co., Inc. for periods around the initiation of civil litigation related to Vioxx. Rely on the excerpts to answer the following questions:

1. When does Merck record a contingency such as a possible loss from litigation?
2. When does Merck record legal defense costs that it expects to incur?
3. Is there a difference in your answers to 1 and 2? How much did Merck record for legal defense costs for Vioxx litigation? How much did Merck record for possible judgments against Merck in the Vioxx litigation?

Consolidated Statement of Income

Merck & Co., Inc. and Subsidiaries
Years Ended December 31
($ in millions except per share amounts)

	2004	2003	2002
Sales	**$ 22,938.6**	$ 22,485.9	$ 21,445.8
Costs, Expenses and Other			
Materials and production	**4,959.8**	4,436.9	4,004.9
Marketing and administrative	**7,346.3**	6,394.9	5,652.2
Research and development	**4,010.2**	3,279.9	2,677.2
Equity income from affiliates	**(1,008.2)**	(474.2)	(644.7)
Other (income) expense, net	**(344.0)**	(203.2)	104.5
	14,964.1	13,434.3	11,794.1
Income from Continuing Operations Before Taxes	**7,974.5**	9,051.6	9,651.7
Taxes on Income	**2,161.1**	2,462.0	2,856.9
Income from Continuing Operations	**5,813.4**	6,589.6	6,794.8
Income from Discontinued Operations, Net of Taxes	**—**	241.3	354.7
Net Income	**$ 5,813.4**	$ 6,830.9	$ 7,149.5
Basic Earnings per Common Share			
Continuing Operations	**$ 2.62**	$ 2.95	$ 3.01
Discontinued Operations	**—**	.11	.16
Net Income	**$ 2.62**	$ 3.05*	$ 3.17
Earnings per Common Share Assuming Dilution			
Continuing Operations	**$ 2.61**	$ 2.92	$ 2.98
Discontinued Operations	**—**	.11	.16
Net Income	**$ 2.61**	$ 3.03	$ 3.14

**Amount does not add as a result of rounding.*

Consolidated Balance Sheet

Merck & Co., Inc. and Subsidiaries
December 31
($ in millions)

	2004	2003
Assets		
Current Assets		
Cash and cash equivalents	**$ 2,878.8**	$ 1,201.0
Short-term investments	**4,211.1**	2,972.0
Accounts receivable	**3,627.7**	4,023.6
Inventories	**1,898.7**	2,554.7
Prepaid expenses and taxes	**858.9**	775.9
Total current assets	**13,475.2**	11,527.2
Investments	**6,727.1**	7,941.2
Property, Plant and Equipment (at cost)		
Land	**366.6**	356.7
Buildings	**8,874.3**	8,016.9
Machinery, equipment and office furnishings	**11,926.1**	11,018.2
Construction in progress	**1,641.6**	1,901.9
	22,808.6	21,293.7
Less allowance for depreciation	**8,094.9**	7,124.7
	14,713.7	14,169.0
Goodwill	**1,085.7**	1,085.4
Other Intangibles, Net	**679.2**	864.0
Other Assets	**5,891.9**	5,000.7
	$ 42,572.8	$ 40,587.5

Liabilities and Stockholders' Equity		
Current Liabilities		
Loans payable and current portion of long-term debt	**$ 2,181.2**	$ 1,700.0
Trade accounts payable	**421.4**	735.2
Accrued and other current liabilities	**5,288.1**	3,772.8
Income taxes payable	**3,012.3**	2,538.9
Dividends payable	**841.1**	822.7
Total current liabilities	**11,744.1**	9,569.6
Long-Term Debt	**4,691.5**	5,096.0
Deferred Income Taxes and Noncurrent Liabilities	**6,442.1**	6,430.3
Minority Interests	**2,406.9**	3,915.2
Stockholders' Equity		
Common stock, one cent par value		
Authorized - 5,400,000,000 shares		
Issued - 2,976,230,393 shares	**29.8**	29.8
Other paid-in capital	**6,869.8**	6,956.6
Retained earnings	**36,626.3**	34,142.0
Accumulated other comprehensive (loss) income	**(45.9)**	65.5
	43,480.0	41,193.9
Less treasury stock, at cost		
767,591,491 shares - 2004		
754,466,884 shares - 2003	**26,191.8**	25,617.5
Total stockholders' equity	**17,288.2**	15,576.4
	$ 42,572.8	$ 40,587.5

The accompanying notes are an integral part of this consolidated financial statement.

Consolidated Statement of Cash Flows

Merck & Co., Inc. and Subsidiaries
Years Ended December 31
($ in millions)

	2004	2003	2002
Cash Flows from Operating Activities of Continuing Operations			
Net income	**$ 5,813.4**	$ 6,830.9	$ 7,149.5
Less: Income from discontinued operations, net of taxes	**—**	(241.3)	(354.7)
Income from continuing operations	**5,813.4**	6,589.6	6,794.8
Adjustments to reconcile income from continuing operations to net cash provided by operating activities of continuing operations:			
Depreciation and amortization	**1,450.7**	1,314.2	1,231.2
Deferred income taxes	**48.9**	131.7	387.5
Other	**(35.4)**	(98.1)	(116.9)
Net changes in assets and liabilities:			
Accounts receivable	**173.1**	320.9	130.2
Inventories	**331.9**	(435.3)	(41.5)
Trade accounts payable	**(323.8)**	(21.6)	325.4
Accrued and other current liabilities	**1,382.3**	505.4	97.0
Income taxes payable	**453.9**	494.1	459.9
Noncurrent liabilities	**(445.4)**	(255.3)	(359.9)
Other	**(50.5)**	(119.1)	(197.1)
Net Cash Provided by Operating Activities of Continuing Operations	**8,799.1**	8,426.5	8,710.6
Cash Flows from Investing Activities of Continuing Operations			
Capital expenditures	**(1,726.1)**	(1,915.9)	(2,128.1)
Purchase of securities, subsidiaries and other investments	**(82,256.4)**	(61,586.9)	(37,443.6)
Proceeds from sale of securities, subsidiaries and other investments	**82,363.8**	60,823.4	35,807.4
Acquisitions of Banyu shares	**(12.8)**	(1,527.8)	—
Other	**(6.6)**	(25.0)	(3.7)
Net Cash Used by Investing Activities of Continuing Operations	**(1,638.1)**	(4,232.2)	(3,768.0)
Cash Flows from Financing Activities of Continuing Operations			
Net change in short-term borrowings	**(252.4)**	(2,347.2)	(508.4)
Proceeds from issuance of debt	**405.1**	1,300.3	2,618.5
Payments on debt	**(37.3)**	(736.2)	(2,504.9)
Redemption of preferred units of subsidiary	**(1,500.0)**	—	—
Purchase of treasury stock	**(974.6)**	(2,034.1)	(2,091.3)
Dividends paid to stockholders	**(3,310.7)**	(3,250.4)	(3,191.6)
Proceeds from exercise of stock options	**240.3**	388.2	318.3
Other	**(161.8)**	(148.5)	(172.5)
Net Cash Used by Financing Activities of Continuing Operations	**(5,591.4)**	(6,827.9)	(5,531.9)
Effect of Exchange Rate Changes on Cash and Cash Equivalents	**108.2**	155.7	113.2

Discontinued Operations			
Net cash provided by Medco Health	—	248.0	575.1
Dividend received from Medco Health, net of intercompany settlements and cash transferred	—	1,187.9	—
Net Cash Provided by Discontinued Operations	—	1,435.9	575.1
Net Increase (Decrease) in Cash and Cash Equivalents	**1,677.8**	(1,042.0)	99.0
Cash and Cash Equivalents at Beginning of Year	**1,201.0**	2,243.0	2,144.0
Cash and Cash Equivalents at End of Year	**$ 2,878.8**	$ 1,201.0	$ 2,243.0

The accompanying notes are an integral part of this consolidated financial statement.

Notes to Consolidated Financial Statements (Excerpts)

1. Nature of Operations

Merck is a global research-driven pharmaceutical company that discovers, develops, manufactures and markets a broad range of innovative products to improve human and animal health, directly and through its joint ventures. The Company's products include therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders.

2. Summary of Accounting Policies

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Legal Defense Costs — Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable.

Use of Estimates — The consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States (GAAP) and, accordingly, include certain amounts that are based on management's best estimates and judgments. Estimates are used in determining such items as provisions for sales discounts and returns, depreciable and amortizable lives, recoverability of inventories produced in preparation for product launches, amounts recorded for contingencies, environmental liabilities and other reserves, pension and other postretirement benefit plan assumptions, and taxes on income. Because of the uncertainty inherent in such estimates, actual results may differ from these estimates.

3. Voluntary Product Withdrawal

On September 30, 2004, the Company announced a voluntary worldwide withdrawal of *Vioxx*, its arthritis and acute pain medication. The Company's decision, which was effective immediately, was based on new three-year data from a prospective, randomized, placebo-controlled clinical trial, APPROVe (Adenomatous Polyp Prevention on *Vioxx*).

In connection with the withdrawal, the Company recorded an unfavorable adjustment to net income of $552.6 million, or $.25 per share. The adjustment to pre-tax income was $726.2 million. Of this amount, $491.6 million related to estimated customer returns of product previously sold and was recorded as a reduction of Sales, $93.2 million related to write-offs of inventory held by the Company and was recorded in Materials and production expense, and $141.4 million related to estimated costs to undertake the withdrawal of the product and was recorded in Marketing and administrative expense. The tax benefit of this adjustment was $173.6 million, which reflects the geographical mix of *Vioxx* returns and the cost of the withdrawal. The adjustment did not include charges for future legal defense costs. (See Note 11.) At December 31, 2004, $173.8 million of the remaining accrued balance was reported in Accrued and other current liabilities and $235.0 million was reported as a reduction to Accounts receivable.

…

11. Contingencies and Environmental Liabilities

The Company is involved in various claims and legal proceedings of a nature considered normal to its business, including product liability, intellectual property and commercial litigation, as well as additional matters such as antitrust actions. The Company records accruals for contingencies when it is probable that a liability has been incurred and the amount can be reasonably estimated. These accruals are adjusted periodically as assessments change or additional information becomes available. For product liability claims, a portion of the overall accrual is actuarially determined and considers such factors as past experience, number of claims reported and estimates of claims incurred but not yet reported. Individually significant contingent losses are accrued when probable and reasonably estimable. Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and

reasonably estimable.

The Company's decision to obtain insurance coverage is dependent on market conditions, including cost and availability, existing at the time such decisions are made. As a result of a number of factors, product liability insurance has become less available while the cost has increased significantly. The Company has evaluated its risks and has determined that the cost of obtaining product liability insurance outweighs the likely benefits of the coverage that is available and as such, has no insurance for certain product liabilities effective August 1, 2004, including liability for products first sold after that date. The Company will continue to evaluate its insurance needs and the costs, availability and benefits of product liability insurance in the future.

Vioxx Litigation

Product Liability Lawsuits

As previously disclosed, federal and state product liability lawsuits involving individual claims, as well as several putative class actions have been filed against the Company with respect to *Vioxx*. As of January 31, 2005 the Company has been served or is aware that it has been named as a defendant in approximately 850 lawsuits, which include approximately 2,425 plaintiff groups alleging personal injuries resulting from the use of *Vioxx*. Certain of these lawsuits include allegations regarding gastrointestinal bleeding, cardiovascular events, thrombotic events or kidney damage. The Company has also been named as a defendant in approximately 90 putative class actions alleging personal injuries or seeking (i) medical monitoring as a result of the putative class members' use of *Vioxx*, (ii) disgorgement of certain profits under common law unjust enrichment theories, and/or (iii) various remedies under state consumer fraud and fair business practice statutes, including recovering the cost of *Vioxx* purchased by individuals and third-party payors such as union health plans (all of the actions discussed in this paragraph are collectively referred to as the "*Vioxx* Product Liability Lawsuits"). The actions filed in the state courts of California and New Jersey, respectively, have been transferred to a single judge in each state for coordinated proceedings. In addition, the Company filed a motion with the Judicial Panel on Multidistrict Litigation (the "JPML") seeking to transfer to a single federal judge and coordinate for pre-trial purposes all federal cases alleging personal injury and/or economic loss relating to the purchase or use of *Vioxx*; several plaintiffs in certain *Vioxx* Product Liability Lawsuits pending in federal court have made similar requests. On February 16, 2005, the JPML granted the motions to transfer all *Vioxx* Product Liability Lawsuits pending in federal courts nationwide into one Multidistrict Litigation ("MDL") for coordinated pre-trial proceedings. The MDL has been transferred to the United States District Court for the Eastern District for Louisiana before District Judge Eldon E. Fallon.

Shareholder Lawsuits

As previously disclosed, in addition to the *Vioxx* Product Liability Lawsuits, a number of purported class action lawsuits were filed in late 2003 and early 2004 by several shareholders in the United States District Court for the Eastern District of Louisiana naming as defendants the Company and several current or former officers and directors of the Company. These cases have been consolidated. After the announcement of the withdrawal of *Vioxx*, the Company was named as a defendant in additional purported securities class action lawsuits filed in federal courts in New Jersey, Pennsylvania, and Louisiana. These actions allege that the defendants made false and misleading statements regarding *Vioxx* in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, including with respect to the withdrawal of *Vioxx*, and seek unspecified compensatory damages and the costs of suit, including attorneys' fees. Plaintiffs request certification of a class of purchasers of Company stock during various periods between May 21, 1999 and October 29, 2004. In addition, two shareholders filed an individual securities action in the United States District Court for the Central District of Illinois seeking compensatory damages and costs. Certain complaints include allegations under Sections 11, 12 and 15 of the Securities Act of 1933 that certain officers and directors made incomplete and misleading statements in a registration statement and certain prospectuses filed in connection with the Merck Stock Investment Plan, a dividend reinvestment plan (all of the actions discussed in this paragraph are collectively referred to as the "*Vioxx* Securities Lawsuits"). Several plaintiffs have dismissed their complaints without prejudice. As of January 31, 2005, a total of 14 *Vioxx* Securities Lawsuits were pending in various federal courts.

As previously disclosed, in March 2004, two shareholder derivative actions were filed in the United States District Court for the Eastern District of Louisiana naming the Company as a nominal defendant and certain members of the Board (past and present), together with certain executive officers, as defendants. The complaints arise out of substantially the same factual allegations that are made in the *Vioxx* Securities Lawsuits. The derivative suits, which are purportedly brought to assert rights of the Company, assert claims against the Board members and officers for breach of fiduciary duty, waste of corporate assets, unjust enrichment, abuse of control and gross mismanagement. After the withdrawal of *Vioxx*, additional shareholder derivative actions were filed in the New Jersey Superior Court for Hunterdon County and in the United States District Court for the District of New Jersey against the Company and certain officers and members of the Board (past and present) (all of the actions discussed in this paragraph are collectively referred to as the "*Vioxx* Derivative Lawsuits"). Two of the *Vioxx* Derivative Lawsuits include allegations that certain directors made false and misleading statements in connection with certain Proxy Statements filed with the SEC in violation of Section 14(a) of the Securities Act of 1933. As of January 31, 2005, a total of seven *Vioxx* Derivative Lawsuits were pending.

On October 29, 2004, two individual shareholders made a demand on the Board to take legal action against Mr. Raymond Gilmartin, Chairman, President and Chief Executive Officer and other individuals for allegedly causing damage to the Company with

respect to the allegedly improper marketing of *Vioxx*. In response to that demand letter, the Board of Directors determined at its November 23, 2004 meeting that the Board would take the shareholders' request under consideration and it remains under consideration.

In addition to these shareholder actions, since the announcement of the withdrawal of *Vioxx*, putative class actions have been filed against the Company in the United States District Court for the Eastern District of Louisiana and in the United States District Court for the District of New Jersey (the "*Vioxx* ERISA Lawsuits" and, together with the *Vioxx* Securities Lawsuits and the *Vioxx* Derivative Lawsuits, the "*Vioxx* Shareholder Lawsuits") on behalf of certain of the Company's current and former employees who are participants in certain of the Company's retirement plans asserting claims under the Employee Retirement Income Security Act ("ERISA"). The lawsuits make similar allegations to the allegations contained in the *Vioxx* Securities Lawsuits. As of January 31, 2005, a total of eleven *Vioxx* ERISA Lawsuits were pending.

In October 2004, the plaintiff in one of the *Vioxx* ERISA Lawsuits filed a motion with the JPML to transfer to a single federal judge and coordinate for pretrial purposes all of the *Vioxx* ERISA Lawsuits. In November 2004, the Company responded to that motion and filed its own motion seeking coordination of all of the *Vioxx* Shareholder Lawsuits. The hearing on those motions was held on January 27, 2005.

International Lawsuits

In addition to the lawsuits discussed above, the Company has been named as a defendant in actions in various countries in Europe, Australia, Canada, Brazil and Israel related to *Vioxx*.

Additional Lawsuits

Based on media reports and other sources, the Company anticipates that additional *Vioxx* Product Liability Lawsuits and *Vioxx* Shareholder Lawsuits (collectively, the "*Vioxx* Lawsuits") will be filed against it and/or certain of its current and former officers and directors in the future.

Insurance

The Company has product liability insurance for claims brought in the *Vioxx* Product Liability Lawsuits of up to approximately $630 million after deductibles and co-insurance. This insurance provides coverage for legal defense costs and potential damage amounts that have been or will be incurred in connection with the *Vioxx* Product Liability Lawsuits. The Company believes that this insurance coverage extends to additional *Vioxx* Product Liability Lawsuits that may be filed in the future. Certain of the Company's insurers have reserved their rights to take a contrary position with respect to certain coverage and there could be disputes with insurers about coverage matters. The Company currently believes that it has at least approximately $190 million of Directors and Officers insurance coverage for the *Vioxx* Securities Lawsuits and *Vioxx* Derivative Lawsuits, and at least approximately $275 million of insurance coverage for the *Vioxx* ERISA Lawsuits. Additional insurance coverage for these claims may also be available under upper level excess policies that provide coverage for a variety of risks. There may be disputes with insurers about the availability of some or all of this insurance coverage. At this time, the Company believes it is reasonably possible its insurance coverage with respect to the *Vioxx* Lawsuits will not be adequate to cover its defense costs and any losses.

Investigations

In November 2004, the Company was advised by the staff of the Securities and Exchange Commission ("SEC") that it was commencing an informal inquiry concerning *Vioxx*. On January 28, 2005, the Company announced that it received notice that the SEC issued a formal notice of investigation. Also, the Company received a subpoena from the U.S. Department of Justice requesting information related to the Company's research, marketing and selling activities with respect to *Vioxx* in a federal health care investigation under criminal statutes. There are also ongoing investigations by certain Congressional committees. Also, the District Attorney's Office in Munich, Germany notified the Company's subsidiary in Germany that it received complaints and commenced an investigation in order to determine whether any criminal charges should be brought in Germany concerning *Vioxx* (together with the previously mentioned investigations, the "*Vioxx* Investigations"). The Company will cooperate with all of the *Vioxx* Investigations. The Company cannot predict the outcome of these inquiries; however, they could result in a potential civil disposition from the SEC and/or potential civil or criminal dispositions from the Justice Department.

Reserves

The Company currently anticipates that one or more of the *Vioxx* Product Liability Lawsuits may go to trial in the first half of 2005. The Company cannot predict the timing of any trials with respect to the *Vioxx* Shareholder Lawsuits. The Company believes that it has meritorious defenses to the *Vioxx* Lawsuits and will vigorously defend against them. In view of the inherent difficulty of predicting the outcome of litigation, particularly where there are many claimants and the claimants seek indeterminate damages, the Company is unable to predict the outcome of these matters, and at this time cannot reasonably estimate the possible loss or range of loss with respect to the *Vioxx* Lawsuits. The Company has not established any reserves for any potential liability relating to the *Vioxx* Lawsuits or the *Vioxx* Investigations (collectively the "*Vioxx* Litigation"). The Company has established a reserve of $675 million solely for its future legal defense costs related to the *Vioxx* Litigation. This reserve is based on certain assumptions and is the minimum amount that

the Company believes at this time it can reasonably estimate will be spent over a multi-year period. The Company significantly increased the reserve when it had the ability to reasonably estimate its future legal defense costs for the *Vioxx* Litigation. Some of the significant factors that were considered in the establishment of the reserve for the *Vioxx* Litigation were as follows: the actual costs incurred by the Company up to that time; the development of the Company's legal defense strategy and structure in light of the expanded scope of the *Vioxx* Litigation; the number of cases being brought against the Company; and the anticipated timing, progression, and related costs of pre-trial activities and trials in the *Vioxx* Product Liability Lawsuits. The Company will continue to monitor its legal defense costs and review the adequacy of the associated reserves. Unfavorable outcomes in the *Vioxx* Lawsuits or resulting from the *Vioxx* Investigations could have a material adverse effect on the Company's financial position, liquidity and results of operations.