

MERCK & CO INC  
Form 10-K  
February 27, 2009

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**As filed with the Securities and Exchange Commission on February 27, 2009**

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

**FORM 10-K**

**(MARK ONE)**

- b**      **Annual Report Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934**  
For the Fiscal Year Ended December 31, 2008
- or
- o**      **Transition Report Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934**  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_

**Commission File No. 1-3305**

**Merck & Co., Inc.**  
One Merck Drive  
Whitehouse Station, N. J. 08889-0100  
(908) 423-1000

*Incorporated in New Jersey*

*I.R.S. Employer  
Identification No. 22-1109110*

**Securities Registered pursuant to Section 12(b) of the Act:**

<i>Title of Each Class</i>	<i>Name of Each Exchange on which Registered</i>
Common Stock (\$0.01 par value)	New York Stock Exchange

Number of shares of Common Stock (\$0.01 par value) outstanding as of January 30, 2009: 2,107,712,364.

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Aggregate market value of Common Stock (\$0.01 par value) held by non-affiliates on June 30, 2008 based on closing price on June 30, 2008: \$80,729,000,000.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. **Yes**  **No**

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. **Yes**  **No**

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer       Accelerated filer       Non-accelerated filer       Smaller reporting company   
(Do not check if a smaller reporting company)

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

**Documents Incorporated by Reference:**

<i>Document</i>	<i>Part of Form 10-K</i>
Proxy Statement for the Annual Meeting of Stockholders to be held April 28, 2009, to be filed with the Securities and Exchange Commission within 120 days after the close of the fiscal year covered by this report	Part III

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Merck & Co., Inc. ( Merck or the Company ) 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. The Company's operations are principally managed on a products basis and are comprised of two reportable segments: the Pharmaceutical segment and the Vaccines and Infectious Diseases segment. The Pharmaceutical segment includes human health pharmaceutical products marketed either directly by Merck or through joint ventures. These products consist of therapeutic and preventive agents, sold by prescription, for the treatment of human disorders. Merck sells these human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions. The Vaccines and Infectious Diseases segment includes human health vaccine and infectious disease products marketed either directly by Merck or, in the case of vaccines, also through a joint venture. Vaccine products consist of preventative pediatric, adolescent and adult vaccines, primarily administered at physician offices. Merck sells these human health vaccines primarily to physicians, wholesalers, physician distributors and government entities. Infectious disease products consist of therapeutic agents for the treatment of infection sold primarily to drug wholesalers and retailers, hospitals and government agencies. The Company's professional representatives communicate the effectiveness, safety and value of its pharmaceutical and vaccine products to health care professionals in private practice, group practices and managed care organizations.

For financial information and other information about the Pharmaceutical segment and the Vaccines and Infectious Diseases segment, see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations and Item 8. Financial Statements and Supplementary Data below.

*Overview* During 2008, the Company continued to address business challenges in the midst of an evolving pharmaceutical industry environment. Revenue declined by 1% in 2008 driven largely by lower sales of *Fosamax* (alendronate sodium) for the treatment and prevention of osteoporosis. *Fosamax* and *Fosamax Plus D* (alendronate sodium/cholecalciferol) lost market exclusivity for substantially all formulations in the United States in February 2008 and April 2008, respectively, and as a result the Company is experiencing a significant decline in sales in the United States within the *Fosamax* franchise. Also contributing to the decline were lower sales of *Zocor* (simvastatin), the Company's statin for modifying cholesterol which lost U.S. market exclusivity in 2006. Partially offsetting these declines were higher sales of *Januvia* (sitagliptin phosphate) and *Janumet* (sitagliptin phosphate and metformin hydrochloride) for the treatment of type 2 diabetes and *Isentress* (raltegravir), an antiretroviral therapy for the treatment of HIV infection.

To address the business and industry challenges that Merck faces, the Company remains focused on innovation and customer value in order to drive the growth of its business and help position Merck for future success.

The Company has made significant progress with re-engineering its operations through research and development initiatives, the roll-out of a new commercial model and the continuation of Merck's supply strategy. These activities should enable the Company to optimize its product portfolio and invest in growth opportunities, such as emerging markets, Merck BioVentures and business development.

Merck continues its efforts to diversify the Company's scientific portfolio both through internal programs and external research collaborations. The Company is focused on developing novel, best-in-class or follow-on treatments for patients in primary care, specialty care, and hospital settings. Additionally, Merck Research Laboratories is pursuing a

portfolio of treatment modalities that not only includes small molecules and vaccines, but also biologics, peptides and RNA interference ( RNAi ). Further, Merck is moving to diversify its portfolio by creating a new division, Merck BioVentures, which leverages a unique technology platform for both follow-on and novel biologics.

The Company has numerous active clinical programs across the Company s major research franchises: bone, respiratory, immunology and endocrine; cardiovascular; diabetes and obesity; infectious diseases; neuroscience; oncology and vaccines. The Company currently has nine candidates in Phase III clinical development and

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anticipates submitting two New Drug Applications ( NDA ) with the U.S. Food and Drug Administration ( FDA ) with respect to two of the candidates in 2009: MK-0974, telcagepant, an investigational compound for the treatment of migraines, and MK-7418, rolofylline, an investigational compound for the treatment of acute heart failure. In addition, the Company anticipates submitting an NDA in 2009 for MK-0653C, ezetimibe combined with atorvastatin, an investigational medication for the treatment of dyslipidemia being developed by the Merck/Schering-Plough joint venture. Also, the Company anticipates regulatory action in 2009 on two supplemental filings that have been submitted to the FDA: one for *Gardasil*, Merck's HPV vaccine, for use in males; and one for *Isentress*, a first-in-class integrase inhibitor for the treatment of HIV-1 infection, for an expanded indication for use in treatment-naïve patients.

On the commercial side, the Company is rolling out a more customer-centric selling model that is designed to provide a competitive advantage, help build trust with customers, and improve patient outcomes. The strategy employs the use of new marketing technologies to complement a new, more customer-centered approach; and moves away from the traditional frequency-based sales and marketing approach; it also creates efficiencies by eliminating redundancies in core functions and across the sales organization.

On the manufacturing side, Merck has made significant progress in the three years since it began re-engineering to create a lean, flexible, cost-effective capability. The Company continues to address its manufacturing issues and it is working to build additional capacity in vaccines and biologics, as well as to support Merck's expansion into emerging markets. To assist this goal, the Company is shifting investments from developed markets into emerging markets commensurate with the size and strategic importance of the opportunity.

In October 2008, the Company announced a global restructuring program (the 2008 Restructuring Program ) to reduce its cost structure, increase efficiency, and enhance competitiveness. As discussed above, Merck is rolling out a new, more customer-centric selling model. Additionally, the Company will make greater use of outside technology resources, centralize common sales and marketing activities, and consolidate and streamline its operations. Merck's manufacturing division will further focus its capabilities on core products and outsource non-core manufacturing. Also, Merck is expanding its access to worldwide external science through a basic research global operating strategy, which is designed to provide a sustainable pipeline and is focused on translating basic research productivity into late-stage clinical success. To increase efficiencies, basic research operations will consolidate work in support of a given therapeutic area into one of four locations. This will provide a more efficient use of research facilities and result in the closure of three basic research sites located in Tsukuba, Japan; Pomezia, Italy; and Seattle by the end of 2009. As part of the 2008 Restructuring Program, the Company expects to eliminate approximately 7,200 positions—6,800 active employees and 400 vacancies—across all areas of the Company worldwide by the end of 2011, approximately 1,750 of which the Company eliminated in 2008. About 40% of the total reductions will occur in the United States. As part of the 2008 Restructuring Program, the Company is streamlining management layers by reducing its total number of senior and mid-level executives globally by approximately 25%. The Company, however, continues to hire new employees as the business requires. The 2008 Restructuring Program is expected to be completed by the end of 2011 with the total pretax costs estimated to be \$1.6 billion to \$2.0 billion. In 2008, the Company recorded pretax restructuring costs of \$921.3 million related to the 2008 Restructuring Program. The Company estimates that two-thirds of the cumulative pretax costs will result in future cash outlays, primarily from employee separation expense. Approximately one-third of the cumulative pretax costs are non-cash, relating primarily to the accelerated depreciation of facilities to be closed or divested. Merck expects the 2008 Restructuring Program to yield cumulative pretax savings of \$3.8 billion to \$4.2 billion from 2008 to 2013.

During 2008, in connection with certain transactions with AstraZeneca LP ( AZLP ), the Company recorded an aggregate pretax gain of \$2.2 billion which is included in Other (income) expense, net and received net proceeds from AZLP of \$2.6 billion. See Note 8 to the consolidated financial statements for further information.



Earnings per common share ( EPS ) assuming dilution for 2008 were \$3.64, including the impact of the gain on distribution from AZLP of \$0.66 per share and restructuring costs of \$(0.44) per share. In addition, EPS in 2008 reflects the favorable impact of certain tax items. All of these items are discussed more fully in the notes to the consolidated financial statements.

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<i>(\$ in millions)</i>	2008	2007	2006
<i>Pharmaceutical:</i>			
Singular	\$ 4,336.9	\$ 4,266.3	\$ 3,579.0
Cozaar/Hyzaar	3,557.7	3,350.1	3,163.1
Fosamax	1,552.7	3,049.0	3,134.4
Januvia	1,397.1	667.5	42.9
Cosopt/Trusopt	781.2	786.8	697.1
Zocor	660.1	876.5	2,802.7
Maxalt	529.2	467.3	406.4
Propecia	429.1	405.4	351.8
Arcoxia	377.3	329.1	265.4
Vasotec/Vaseretic	356.7	494.6	547.2
Janumet	351.1	86.4	-
Proscar	323.5	411.0	618.5
Emend	263.8	204.2	130.8
Other pharmaceutical <sup>(2)</sup>	2,278.9	2,422.9	2,780.5
Vaccine and infectious disease product sales included in the Pharmaceutical segment <sup>(3)</sup>	2,187.6	1,800.5	1,315.8
Pharmaceutical segment revenues	19,382.9	19,617.6	19,835.6
<i>Vaccines<sup>(4)</sup> and Infectious Diseases:</i>			
Gardasil	1,402.8	1,480.6	234.8
ProQuad/M-M-R II/Varivax	1,268.5	1,347.1	820.1
RotaTeq	664.5	524.7	163.4
Zostavax	312.4	236.0	38.6
Hepatitis vaccines	148.3	279.9	248.5
Other vaccines	354.6	409.9	354.0
Primaxin	760.4	763.5	704.8
Candidas	596.4	536.9	529.8
Isentress	361.1	41.3	-
Crixivan/Stocrin	275.1	310.2	327.3
Invanz	265.0	190.2	139.2
Other infectious disease	15.5	1.7	-
Vaccine and infectious disease product sales included in the Pharmaceutical segment <sup>(3)</sup>	(2,187.6)	(1,800.5)	(1,315.8)
Vaccines and Infectious Diseases segment revenues	4,237.0	4,321.5	2,244.7

Other segment revenues <sup>(5)</sup>	<b>81.8</b>	162.0	162.1
Total segment revenues	<b>23,701.7</b>	24,101.1	22,242.4
Other <sup>(6)</sup>	<b>148.6</b>	96.6	393.6
	<b>\$ 23,850.3</b>	\$ 24,197.7	\$ 22,636.0

(1) Presented net of discounts and returns.

(2) Other pharmaceutical primarily includes sales of other human pharmaceutical products and revenue from the Company's relationship with AZLP primarily relating to sales of Nexium, as well as Prilosec. Revenue from AZLP was \$1.6 billion, \$1.7 billion and \$1.8 billion in 2008, 2007 and 2006, respectively. In 2006, other pharmaceutical also reflected certain supply sales, including supply sales associated with the Company's arrangement with Dr. Reddy's Laboratories for the sale of generic simvastatin.

(3) Sales of vaccine and infectious disease products by non-U.S. subsidiaries are included in the Pharmaceutical segment.

(4) These amounts do not reflect sales of vaccines sold in most major European markets through the Company's joint venture, Sanofi Pasteur MSD, the results of which are reflected in Equity income from affiliates. These amounts do, however, reflect supply sales to Sanofi Pasteur MSD.

(5) Includes other non-reportable human and animal health segments.

(6) Other revenues are primarily comprised of miscellaneous corporate revenue, sales related to divested products or businesses and other supply sales not included in segment results.

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The Company's pharmaceutical products include therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. Among these are *Singulair* (montelukast sodium), a leukotriene receptor antagonist for the chronic treatment of asthma and for the relief of symptoms of allergic rhinitis; *Cozaar* (losartan potassium), *Hyzaar* (losartan potassium and hydrochlorothiazide), *Vasotec* (enalapril maleate) and *Vaseretic* (enalapril maleate-hydrochlorothiazide), the Company's most significant hypertension and/or heart failure products; *Fosamax* and *Fosamax Plus D*, Merck's osteoporosis products for the treatment and, in the case of *Fosamax*, prevention of osteoporosis; *Januvia* and *Janumet* for the treatment of type 2 diabetes; *Cosopt* (dorzolamide hydrochloride and timolol maleate ophthalmic solution) and *Trusopt* (dorzolamide hydrochloride ophthalmic solution), Merck's largest-selling ophthalmological products; *Zocor*, Merck's statin for modifying cholesterol; *Maxalt* (rizatriptan benzoate), an acute migraine product; *Propecia* (finasteride), a product for the treatment of male pattern hair loss; *Arcoxia* (etoricoxib) for the treatment of arthritis and pain; *Proscar* (finasteride), a urology product for the treatment of symptomatic benign prostate enlargement; and *Emend* (aprepitant) for the prevention of chemotherapy-induced and post-operative nausea and vomiting.

The Company's vaccine and infectious disease products include *Gardasil*, a vaccine to help prevent cervical, vulvar and vaginal cancers, precancerous or dysplastic lesions, and genital warts caused by HPV types 6, 11, 16 and 18; *Varivax* (Varicella Virus Vaccine Live), a vaccine to help prevent chickenpox; *ProQuad* (Measles, Mumps, Rubella and Varicella Virus Vaccine Live), a pediatric combination vaccine against measles, mumps, rubella and varicella; *M-M-R II* (Measles, Mumps and Rubella Virus Vaccine Live), a vaccine against measles, mumps and rubella; *RotaTeq* (Rotavirus Vaccine Live, Oral, Pentavalent), a vaccine to help protect against rotavirus gastroenteritis in infants and children; *Zostavax* (Zoster Vaccine Live), a vaccine to help prevent shingles (herpes zoster); *Primaxin* (imipenem and cilastatin sodium) and *Cancidas* (caspofungin acetate), anti-bacterial/anti-fungal products; *Isentress*, *Crixivan* (indinavir sulfate) and *Stocrin* (efavirenz), antiretroviral therapies for the treatment of HIV infection; and *Invanz* (ertapenem sodium) for the treatment of infection. For a further discussion of sales of the Company's products, see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations below.

**U.S. Product Approvals** On January 25, 2008, the FDA approved *Emend* (fosaprepitant dimeglumine) for Injection, 115 mg, for the prevention of chemotherapy-induced nausea and vomiting. *Emend* for Injection provides a new option for day one, as a substitute for *Emend* (125 mg) taken orally, as part of the recommended three-day regimen. Prior to the FDA decision, the European Union (EU) on January 11, 2008 granted marketing approval for *Emend* for Injection, known as *Ivemend* in the EU, an action that applies to all 27 EU member countries as well as Norway and Iceland.

On August 5, 2008, Merck announced that the FDA approved an expanded label for *Cancidas*, which makes it the first and only echinocandin therapy approved in the United States for the treatment of pediatric patients aged three months to 17 years with indicated fungal infections.

On September 12, 2008, the FDA approved *Gardasil* for the prevention of vulvar and vaginal cancers caused by HPV types 16 and 18. The approval is based on data from a combined analysis of three studies that demonstrated the efficacy and safety of *Gardasil* in more than 15,000 patients.

**Vioxx U.S. Product Liability Settlement** On September 30, 2004, Merck 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*).

On November 9, 2007, the Company announced that it had entered into an agreement (the Settlement Agreement) with the law firms that comprise the executive committee of the Plaintiffs' Steering Committee of the federal multidistrict *Vioxx* litigation as well as representatives of plaintiffs' counsel in the Texas, New Jersey and California

state coordinated proceedings to resolve state and federal myocardial infarction ( MI ) and ischemic stroke ( IS ) claims filed as of that date in the United States. The Settlement Agreement, which also applies to tolled claims, was signed by the parties after several meetings with three of the four judges overseeing the coordination of more than 95% of the current claims in the *Vioxx* litigation. The Settlement Agreement applies only to U.S. legal residents and those who allege that their MI or IS occurred in the United States.

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As of October 30, 2008, the deadline for enrollment in the Settlement Program (as defined below), more than 48,100 of the approximately 48,325 individuals who were eligible for the Settlement Program and whose claims were not 1) dismissed, 2) expected to be dismissed in the near future, or 3) tolled claims that appear to have been abandoned had submitted some or all of the materials required for enrollment in the Settlement Program. This represents approximately 99.8% of the eligible MI and IS claims previously registered with the Settlement Program. Under the terms of the Settlement Agreement, Merck could exercise a right to walk away from the Settlement Agreement if the thresholds and other requirements were not met. The Company waived that right as of August 4, 2008. The waiver of that right triggered Merck's obligation to pay a fixed total of \$4.85 billion. Payments will be made in installments into the settlement funds. The first payment of \$500 million was made in August 2008 and an additional payment of \$250 million was made in October 2008. Additional payments will be made on a periodic basis going forward, when and as needed to fund payments of claims and administrative expenses.

*Joint Ventures* The Company has a number of joint ventures relating to its Pharmaceutical and Vaccines and Infectious Diseases segments.

*Pharmaceutical*

In 2000, the Company and Schering-Plough Corporation ( Schering-Plough ) entered into agreements to create separate equally-owned partnerships to develop and market in the United States new prescription medicines in the cholesterol-management and respiratory therapeutic areas. In December 2001, the cholesterol-management partnership agreements were expanded to include all the countries of the world, excluding Japan. In October 2002, *Zetia* (ezetimibe) (marketed as *Ezetrol* outside the United States), the first in a new class of cholesterol-lowering agents, was launched in the United States. In July 2004, *Vytorin* (marketed as *Inegy* outside the United States), a combination product containing the active ingredients of both *Zetia* and *Zocor*, was approved in the United States.

As previously disclosed, in January 2008, the Company announced the results of the Effect of Combination Ezetimibe and High-Dose Simvastatin vs. Simvastatin Alone on the Atherosclerotic Process in Patients with Heterozygous Familial Hypercholesterolemia ( ENHANCE ) clinical trial, an imaging trial in 720 patients with heterozygous familial hypercholesterolemia, a rare genetic condition that causes very high levels of LDL bad cholesterol and greatly increases the risk for premature coronary artery disease. As previously reported, despite the fact that ezetimibe/simvastatin 10/80 mg (*Vytorin*) significantly lowered LDL bad cholesterol more than simvastatin 80 mg alone, there was no significant difference between treatment with ezetimibe/simvastatin and simvastatin alone on the pre-specified primary endpoint, a change in the thickness of carotid artery walls over two years as measured by ultrasound. There also were no significant differences between treatment with ezetimibe/simvastatin and simvastatin on the four pre-specified key secondary endpoints: percent of patients manifesting regression in the average carotid artery intima-media thickness ( CA IMT ); proportion of patients developing new carotid artery plaques >1.3 mm; changes in the average maximum CA IMT; and changes in the average CA IMT plus in the average common femoral artery IMT. In ENHANCE, when compared to simvastatin alone, ezetimibe/simvastatin significantly lowered LDL bad cholesterol, as well as triglycerides and C-reactive protein ( CRP ). Ezetimibe/simvastatin is not indicated for the reduction of CRP. In the ENHANCE study, the overall safety profile of ezetimibe/simvastatin was generally consistent with the product label. The ENHANCE study was not designed nor powered to evaluate cardiovascular clinical events. The Improved Reduction in High-Risk Subjects Presenting with Acute Coronary Syndrome ( IMPROVE-IT ) trial is underway and is designed to provide cardiovascular outcomes data for ezetimibe/simvastatin in patients with acute coronary syndrome. No incremental benefit of ezetimibe/simvastatin on cardiovascular morbidity and mortality over and above that demonstrated for simvastatin has been established. In March 2008, the results of ENHANCE were reported at the annual Scientific Session of the American College of Cardiology.

On July 21, 2008, efficacy and safety results from the Simvastatin and Ezetimibe in Aortic Stenosis ( SEAS ) study were announced. SEAS was designed to evaluate whether intensive lipid lowering with *Vytorin* 10/40 mg would reduce the need for aortic valve replacement and the risk of cardiovascular morbidity and mortality versus placebo in

patients with asymptomatic mild to moderate aortic stenosis who had no indication for statin therapy. *Vytorin* failed to meet its primary end point for the reduction of major cardiovascular events. There also was no significant difference in the key secondary end point of aortic valve events; however, there was a reduction in the group of patients taking *Vytorin* compared to placebo in the key secondary end point of ischemic cardiovascular

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events. *Vytorin* is not indicated for the treatment of aortic stenosis. No incremental benefit of *Vytorin* on cardiovascular morbidity and mortality over and above that demonstrated for simvastatin has been established. In the study, patients in the group who took *Vytorin* 10/40 mg had a higher incidence of cancer than the group who took placebo. There was also a nonsignificant increase in deaths from cancer in patients in the group who took *Vytorin* versus those who took placebo. Cancer and cancer deaths were distributed across all major organ systems. The Company believes the cancer finding in SEAS is likely to be an anomaly that, taken in light of all the available data, does not support an association with *Vytorin*. In August 2008, the FDA announced that it was investigating the results from the SEAS trial. In this announcement, the FDA also cited interim data from two large ongoing cardiovascular trials of *Vytorin* – the Study of Heart and Renal Protection ( SHARP ) and the IMPROVE-IT clinical trials – in which there was no increased risk of cancer with the combination of simvastatin plus ezetimibe. The SHARP trial is expected to be completed in 2010. The IMPROVE-IT trial is scheduled for completion around 2012. The FDA determined that, as of that time, these findings in the SEAS trial plus the interim data from ongoing trials should not prompt patients to stop taking *Vytorin* or any other cholesterol lowering drug.

The Company, through Merck/Schering-Plough Pharmaceuticals (the MSP Partnership ), is committed to working with regulatory agencies to further evaluate the available data and interpretations of those data; however, the Company does not believe that changes in the clinical use of *Vytorin* are warranted.

As previously disclosed, the Company and its joint venture partner, Schering-Plough, have received several letters addressed to both companies from the House Committee on Energy and Commerce, its Subcommittee on Oversight and Investigations ( O&I ), and the Ranking Minority Member of the Senate Finance Committee, collectively seeking a combination of witness interviews, documents and information on a variety of issues related to the ENHANCE clinical trial, the sale and promotion of *Vytorin*, as well as sales of stock by corporate officers. In addition, since August 2008, the companies have received three additional letters from O&I, including one dated February 19, 2009, seeking certain information and documents related to the SEAS clinical trial. As previously disclosed, the companies have each received subpoenas from the New York and New Jersey State Attorneys General Offices and a letter from the Connecticut Attorney General seeking similar information and documents. In addition, the Company has received five Civil Investigative Demands ( CIDs ) from a multistate group of 35 State Attorneys General who are jointly investigating whether the companies violated state consumer protection laws when marketing *Vytorin*. Finally, in September 2008, the Company received a letter from the Civil Division of the Department of Justice ( DOJ ) informing it that the DOJ is investigating whether the companies' conduct relating to the promotion of *Vytorin* caused false claims to be submitted to federal health care programs. The Company is cooperating with these investigations and working with Schering-Plough to respond to the inquiries. In addition, the Company has become aware of or been served with approximately 145 civil class action lawsuits alleging common law and state consumer fraud claims in connection with the MSP Partnership's sale and promotion of *Vytorin* and *Zetia*. Certain of those lawsuits allege personal injuries and/or seek medical monitoring. These actions, which have been filed in or transferred to federal court, are coordinated in a multidistrict litigation in the U.S. District Court for the District Court of New Jersey before District Judge Dennis M. Cavanaugh. The parties are presently engaged in motions practice and briefing. Also, as previously disclosed, on April 3, 2008, a Merck shareholder filed a putative class action lawsuit in federal court in the Eastern District of Pennsylvania alleging that Merck and its Chairman, President and Chief Executive Officer, Richard T. Clark, violated the federal securities laws. On April 22, 2008, a member of a Company Employee Retirement Income Security Act ( ERISA ) plan filed a putative class action lawsuit against the Company and certain of its officers and directors alleging they breached their fiduciary duties under ERISA.

In 1982, the Company entered into an agreement with Astra AB ( Astra ) to develop and market Astra products in the United States. In 1994, the Company and Astra formed an equally owned joint venture that developed and marketed most of Astra's new prescription medicines in the United States including *Prilosec* (omeprazole), the first in a class of medications known as proton pump inhibitors, which slows the production of acid from the cells of the stomach lining.



In 1998, the Company and Astra restructured the joint venture whereby the Company acquired Astra's interest in the joint venture, renamed KBI Inc. ( KBI ), and contributed KBI's operating assets to a new U.S. limited partnership named Astra Pharmaceuticals, L.P. (the Partnership ), in exchange for a 1% limited partner interest. Astra contributed the net assets of its wholly owned subsidiary, Astra USA, Inc., to the Partnership in exchange for a

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99% general partner interest. The Partnership, renamed AstraZeneca LP ( AZLP ) upon Astra s 1999 merger with Zeneca Group Plc (the AstraZeneca merger ), became the exclusive distributor of the products for which KBI retained rights.

The Company earns certain Partnership returns as well as ongoing revenue based on sales of current and future KBI products. The Partnership returns include a priority return provided for in the Partnership Agreement, variable returns based, in part, upon sales of certain former Astra USA, Inc. products, and a preferential return representing the Company s share of undistributed Partnership GAAP earnings. The AstraZeneca merger triggered a partial redemption in March 2008 of Merck s interest in certain AZLP product rights. Upon this redemption, Merck received \$4.3 billion from AZLP. This amount was based primarily on a multiple of Merck s average annual variable returns derived from sales of the former Astra USA, Inc. products for the three years prior to the redemption (the Limited Partner Share of Agreed Value ). Merck recorded a \$1.5 billion pretax gain on the partial redemption in 2008. The partial redemption of Merck s interest in the product rights did not result in a change in Merck s 1% limited partner interest. As described in Item 7. Management s Discussion and Analysis below, after certain adjustments, the Company recorded an aggregate pretax gain of \$2.2 billion.

In conjunction with the 1998 restructuring, Astra purchased an option (the Asset Option ) for a payment of \$443.0 million, which was recorded as deferred income, to buy Merck s interest in the KBI products, excluding the gastrointestinal medicines *Nexium* (esomeprazole) and *Prilosec* (the Non-PPI Products ). The Asset Option is exercisable in the first half of 2010 at an exercise price equal to the net present value as of March 31, 2008 of projected future pretax revenue to be received by the Company from the Non-PPI Products (the Appraised Value ). Merck also had the right to require Astra to purchase such interest in 2008 at the Appraised Value. In February 2008, the Company advised AZLP that it would not exercise the Asset Option, thus the \$443.0 million remains deferred. In addition, in 1998, the Company granted Astra an option (the Shares Option ) to buy Merck s common stock interest in KBI and, therefore, Merck s interest in *Nexium* and *Prilosec*, exercisable two years after Astra s exercise of the Asset Option. Astra can also exercise the Shares Option in 2017 or if combined annual sales of the two products fall below a minimum amount provided, in each case, only so long as AstraZeneca s Asset Option has been exercised in 2010. The exercise price for the Shares Option is based on the net present value of estimated future net sales of *Nexium* and *Prilosec* as determined at the time of exercise, subject to certain true-up mechanisms.

In 1989, the Company formed a joint venture with Johnson & Johnson to develop and market a broad range of nonprescription medicines for U.S. consumers. This 50% owned joint venture also includes Canada. Significant joint venture products are *Pepcid AC* (famotidine), an over-the-counter form of the Company s ulcer medication *Pepcid* (famotidine), as well as *Pepcid Complete*, an over-the-counter product which combines the Company s ulcer medication with antacids (calcium carbonate and magnesium hydroxide).

*Vaccines*

In 1994, the Company and Pasteur Mérieux Connaught (now Sanofi Pasteur S.A.) formed a joint venture to market human vaccines in Europe and to collaborate in the development of combination vaccines for distribution in the then existing EU and the European Free Trade Association. The Company and Sanofi Pasteur contributed, among other things, their European vaccine businesses for equal shares in the joint venture, known as Pasteur Mérieux MSD, S.N.C. (now Sanofi Pasteur MSD, S.N.C.). The joint venture maintains a presence, directly or through affiliates or branches in Belgium, Italy, Germany, Spain, France, Austria, Ireland, Sweden, Portugal, the Netherlands, Switzerland and the United Kingdom, and through distributors in the rest of its territory.

*Other*

In 1997, the Company and Rhône-Poulenc S.A. (now Sanofi-Aventis S.A.) combined their respective animal health businesses to form Merial Limited ( Merial ), a fully integrated animal health company, which is a stand-alone joint venture, 50% owned by each party. Merial provides a comprehensive range of pharmaceuticals and vaccines to

enhance the health, well-being and performance of a wide range of animal species.

*Competition* The markets in which the Company conducts its business are highly competitive and often highly regulated. Global efforts toward health care cost containment continue to exert pressure on product pricing and access.

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Such competition involves an intensive search for technological innovations and the ability to market these innovations effectively. With its long-standing emphasis on research and development, the Company is well prepared to compete in the search for technological innovations. Additional resources to meet competition include quality control, flexibility to meet customer specifications, an efficient distribution system and a strong technical information service. The Company is active in acquiring and marketing products through joint ventures and licenses and has been refining its sales and marketing efforts to further address changing industry conditions. To enhance its product portfolio, the Company also continues to pursue external alliances. However, the introduction of new products and processes by competitors may result in price reductions and product replacements, even for products protected by patents. For example, the number of compounds available to treat diseases typically increases over time and has resulted in slowing the growth in sales of certain of the Company's products.

Legislation enacted in all states in the United States, particularly in the area of human pharmaceutical products, allows, encourages or, in a few instances, in the absence of specific instructions from the prescribing physician, mandates the use of generic products (those containing the same active chemical as an innovator's product) rather than brand-name products. Governmental and other pressures toward the dispensing of generic products have significantly reduced the sales of certain of the Company's products no longer protected by patents, such as *Zocor*, which lost market exclusivity in the U.S. in 2006 and the Company experienced a significant decline in *Zocor* sales thereafter. *Fosamax* and *Fosamax Plus D* lost marketing exclusivity in the United States in 2008. As a result of these events, the Company is experiencing significant declines in *Fosamax* and *Fosamax Plus D* U.S. sales. Also, *Trusopt* and *Cosopt* lost market exclusivity in the United States in October 2008 and as a result the Company is experiencing a significant decline in sales of these products.

*Distribution* The Company sells its human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions. Human health vaccines are sold primarily to physicians, wholesalers, physician distributors and government entities. The Company's professional representatives communicate the effectiveness, safety and value of the Company's pharmaceutical and vaccine products to health care professionals in private practice, group practices and managed care organizations.

*Raw Materials* Raw materials and supplies, which are generally available from multiple sources, are purchased worldwide and are normally available in quantities adequate to meet the needs of the Company's Pharmaceutical and Vaccines and Infectious Diseases segments.

*Government Regulation and Investigation* The pharmaceutical industry is subject to global regulation by regional, country, state and local agencies. Of particular importance is the FDA in the United States, which administers requirements covering the testing, approval, safety, effectiveness, manufacturing, labeling and marketing of prescription pharmaceuticals. In many cases, the FDA requirements have increased the amount of time and money necessary to develop new products and bring them to market in the United States. In 1997, the Food and Drug Administration Modernization Act (the FDA Modernization Act) was passed and was the culmination of a comprehensive legislative reform effort designed to streamline regulatory procedures within the FDA and to improve the regulation of drugs, medical devices and food. The legislation was principally designed to ensure the timely availability of safe and effective drugs and biologics by expediting the premarket review process for new products. A key provision of the legislation is the re-authorization of the Prescription Drug User Fee Act of 1992, which permits the continued collection of user fees from prescription drug manufacturers to augment FDA resources earmarked for the review of human drug applications. This helps provide the resources necessary to ensure the prompt approval of safe and effective new drugs.

In the United States, the government expanded health care access by enacting the Medicare Prescription Drug Improvement and Modernization Act of 2003, which was signed into law in December 2003. Prescription drug

coverage began on January 1, 2006. This legislation supports the Company's goal of improving access to medicines by expanding insurance coverage, while preserving market-based incentives for pharmaceutical innovation. At the same time, the legislation will ensure that prescription drug costs will be controlled by competitive pressures and by encouraging the appropriate use of medicines. The U.S. Congress has considered, and may consider again, proposals to increase the government's role in pharmaceutical pricing in the Medicare program.

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These proposals may include removing the current legal prohibition against the Secretary of the Health and Human Services intervening in price negotiations between Medicare drug benefit program plans and pharmaceutical companies. They may also include mandating the payment of rebates for some or all of the pharmaceutical utilization in Medicare drug benefit plans. In addition, Congress may again consider proposals to allow, under certain conditions, the importation of medicines from other countries.

For many years, the pharmaceutical industry has been under federal and state oversight with the approval process for new drugs, drug safety, advertising and promotion, drug purchasing and reimbursement programs and formularies variously under review. The Company believes that it will continue to be able to conduct its operations, including the introduction of new drugs to the market, in this regulatory environment. One type of federal initiative to contain federal health care spending is the prospective or capitated payment system, first implemented to reduce the rate of growth in Medicare reimbursement to hospitals. Such a system establishes in advance a flat rate for reimbursement for health care for those patients for whom the payor is fiscally responsible. This type of payment system and other cost containment systems are now widely used by public and private payors and have caused hospitals, health maintenance organizations and other customers of the Company to be more cost-conscious in their treatment decisions, including decisions regarding the medicines to be made available to their patients. The Company continues to work with private and federal employers to slow increases in health care costs. Further, the Company's efforts to demonstrate that its medicines can help save costs in other areas have encouraged the use of the Company's medicines and have helped offset the effects of increasing cost pressures.

Also, federal and state governments have pursued methods to directly reduce the cost of drugs and vaccines for which they pay. For example, federal laws require the Company to pay specified rebates for medicines reimbursed by Medicaid, to provide discounts for outpatient medicines purchased by certain Public Health Service entities and disproportionate share hospitals (hospitals meeting certain criteria), and to provide minimum discounts of 24% off of a defined non-federal average manufacturer price for purchases by certain components of the federal government such as the Department of Veterans Affairs and the Department of Defense.

Initiatives in some states seek rebates beyond the minimum required by Medicaid legislation, in some cases for patients beyond those who are eligible for Medicaid. Under the Federal Vaccines for Children entitlement program, the U.S. Centers for Disease Control and Prevention ( CDC ) funds and purchases recommended pediatric vaccines at a public sector price for the immunization of Medicaid-eligible, uninsured, Native American and certain underinsured children. The Company was awarded a CDC contract in 2008 for the supply of pediatric vaccines for the Vaccines for Children program. As of January 1, 2006, patients previously eligible for Medicaid who are also Medicare beneficiaries (65 years and older or disabled) left the state-administered Medicaid system to be covered by the new Medicare prescription drug benefit.

Outside the United States, the Company encounters similar regulatory and legislative issues in most of the countries where it does business. There, too, the primary thrust of governmental inquiry and action is toward determining drug safety and effectiveness, often with mechanisms for controlling the prices of or reimbursement for prescription drugs and the profits of prescription drug companies. The EU has adopted directives concerning the classification, labeling, advertising, wholesale distribution and approval for marketing of medicinal products for human use. The Company's policies and procedures are already consistent with the substance of these directives; consequently, it is believed that they will not have any material effect on the Company's business.

In addition, certain countries within the EU, recognizing the economic importance of the research-based pharmaceutical industry and the value of innovative medicines to society, are working with industry representatives to improve the competitive climate through a variety of means including market deregulation.

In January 2008, the European Commission ( EC ) launched a sector inquiry in the pharmaceutical markets under the rules of EU competition law. As part of its inquiry, the Company s offices in Germany were inspected by the authorities in January 2008. The Preliminary Report of the EC was issued on November 28, 2008, in which the EC stated that it had confirmed its original hypothesis that competition in the pharmaceutical sector may be restricted or distorted, as indicated by a decline in innovation measured by the number of novel medicines reaching the market, and by alleged instances of delayed market entry of generic medicines. The public consultation period with respect to the Preliminary Report expired on January 31, 2009, and the EC has issued further inquiries in respect of the subject of the investigation. The EC has not alleged that the Company or any of its subsidiaries have

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engaged in any unlawful practices. The final report is planned for later in 2009. The Company is cooperating with the EC in this sector inquiry.

The Company is subject to the jurisdiction of various regulatory agencies and is, therefore, subject to potential administrative actions. Such actions may include seizures of products and other civil and criminal sanctions. Under certain circumstances, the Company on its own may deem it advisable to initiate product recalls. The Company believes that it should be able to compete effectively within this environment.

The Company is subject to a number of privacy and data protection laws and regulations globally. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues with the potential to affect directly the Company's business, including recently enacted laws in a majority of U.S. states requiring security breach notification.

*Patents, Trademarks and Licenses* Patent protection is considered, in the aggregate, to be of material importance in the Company's marketing of human health products in the United States and in most major foreign markets. Patents may cover products *per se*, pharmaceutical formulations, processes for or intermediates useful in the manufacture of products or the uses of products. Protection for individual products extends for varying periods in accordance with the legal life of patents in the various countries. The protection afforded, which may also vary from country to country, depends upon the type of patent and its scope of coverage.

The FDA Modernization Act includes a Pediatric Exclusivity Provision that may provide an additional six months of market exclusivity in the United States for indications of new or currently marketed drugs if certain agreed upon pediatric studies are completed by the applicant. These exclusivity provisions were re-authorized by the Prescription Drug User Fee Act passed in September 2007. Current U.S. patent law provides additional patent term under Patent Term Restoration for periods when the patented product was under regulatory review before the FDA.

Patent portfolios developed for products introduced by the Company normally provide market exclusivity. The Company has the following key U.S. patent protection (including Patent Term Restoration and Pediatric Exclusivity) for major marketed products:

<b>Product</b>	<b>Year of Expiration (in U.S.)</b>
<i>Cancidas</i>	2015
<i>Comvax</i>	2020
<i>Cozaar</i>	2010
<i>Crixivan</i>	2012 (compound)/2018 (formulation)
<i>Emend</i>	2015
<i>Gardasil</i>	2026
<i>Hyzaar</i>	2010
<i>Invanz</i>	2016 (compound)/2017 (composition)
<i>Isentress</i>	2023
<i>Januvia/Janumet</i>	2022 (compound)/2026 (salt)
<i>Maxalt</i>	2012 (compound)/2014 (other)
<i>Primaxin</i>	2009
<i>Propecia</i>	2013
<i>Recombivax</i>	2020
<i>RotaTeq</i>	2019 (with pending Patent Term Restoration)
<i>Singulair</i>	2012



<i>Zetia/Vytorin</i>	2017 (ezetimibe component in both products)
<i>Zolinza</i>	2015
<i>Zostavax</i>	2016

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A basic patent is also in effect for Sustiva/*Stocrin*. Bristol-Myers Squibb Company, under an exclusive license from the Company, sells Sustiva in the United States, Canada and certain European countries. The Company markets *Stocrin* in other countries throughout the world.

While the expiration of a product patent normally results in a loss of market exclusivity for the covered pharmaceutical product, commercial benefits may continue to be derived from: (i) later-granted patents on processes and intermediates related to the most economical method of manufacture of the active ingredient of such product; (ii) patents relating to the use of such product; (iii) patents relating to novel compositions and formulations; and (iv) in the United States and certain other countries, market exclusivity that may be available under relevant law. The effect of product patent expiration on pharmaceutical products also depends upon many other factors such as the nature of the market and the position of the product in it, the growth of the market, the complexities and economics of the process for manufacture of the active ingredient of the product and the requirements of new drug provisions of the Federal Food, Drug and Cosmetic Act or similar laws and regulations in other countries.

Additions to market exclusivity are sought in the United States and other countries through all relevant laws, including laws increasing patent life. Some of the benefits of increases in patent life have been partially offset by a general increase in the number of incentives for and use of generic products. Additionally, improvements in intellectual property laws are sought in the United States and other countries through reform of patent and other relevant laws and implementation of international treaties.

For further information with respect to the Company's patents, see [Patent Litigation](#) and [Risk Factors](#) below.

Worldwide, all of the Company's important products are sold under trademarks that are considered in the aggregate to be of material importance. Trademark protection continues in some countries as long as used; in other countries, as long as registered. Registration is for fixed terms and can be renewed indefinitely.

Royalties received during 2008 on patent and know-how licenses and other rights amounted to \$209.3 million. The Company also paid royalties amounting to \$1.318 billion in 2008 under patent and know-how licenses it holds.

## **Research and Development**

The Company's business is characterized by the introduction of new products or new uses for existing products through a strong research and development program. Approximately 11,000 people are employed in the Company's research activities. Research and development expenses were \$4.8 billion in 2008, \$4.9 billion in 2007 and \$4.8 billion in 2006. The Company maintains its ongoing commitment to research over a broad range of therapeutic areas and clinical development in support of new products.

The Company maintains a number of long-term exploratory and fundamental research programs in biology and chemistry as well as research programs directed toward product development. Merck's research and development model is designed to increase productivity and improve the probability of success by prioritizing the Company's research and development resources on disease areas of unmet medical needs, scientific opportunity and commercial opportunity. Merck is managing its research and development portfolio across diverse approaches to discovery and development by balancing investments appropriately on novel, innovative targets with the potential to have a major impact on human health, on developing best-in-class approaches, and on delivering maximum value of the Company's new medicines and vaccines through new indications and new formulations. Another important component of Merck's science-based diversification is based on expanding the Company's portfolio of modalities to include not only small molecules and vaccines, but also biologics, peptides and RNAi. Further, Merck is moving to diversify its portfolio by creating a new division, Merck BioVentures, which leverages a unique platform for both follow-on and novel biologics. The Company will continue to pursue appropriate external licensing opportunities.

During 2008, the Company began implementing a new model for its basic research global operating strategy. The new model will align franchise and function through clear roles and responsibilities, align resources

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with disease area priorities and balance capacity across discovery phases and allow the Company to act upon those programs with the highest probability of success. Additionally, the strategy is designed to expand the Company's access to worldwide external science and incorporate external research as a key component of the Company's early discovery pipeline in order to translate basic research productivity into late-stage clinical success.

In the development of human health products, industry practice and government regulations in the United States and most foreign countries provide for the determination of effectiveness and safety of new chemical compounds through preclinical tests and controlled clinical evaluation. Before a new drug or vaccine may be marketed in the United States, recorded data on preclinical and clinical experience are included in the NDA for a drug or the Biologics License Application (BLA) for a vaccine submitted to the FDA for the required approval.

Once the Company's scientists discover a new small molecule compound that they believe has promise to treat a medical condition, the Company commences preclinical testing with that compound. Preclinical testing includes laboratory testing and animal safety studies to gather data on chemistry, pharmacology and toxicology. Pending acceptable preclinical data, the Company will initiate clinical testing in accordance with established regulatory requirements. The clinical testing begins with Phase I studies, which are designed to assess safety, tolerability, pharmacokinetics, and preliminary pharmacodynamic activity of the compound in humans. If favorable, additional, larger Phase II studies are initiated to determine the efficacy of the compound in the affected population, define appropriate dosing for the compound, as well as identify any adverse effects that could limit the compound's usefulness. If data from the Phase II trials are satisfactory, the Company commences large-scale Phase III trials to confirm the compound's efficacy and safety. Upon completion of those trials, if satisfactory, the Company submits regulatory filings with the appropriate regulatory agencies around the world to have the product candidate approved for marketing. There can be no assurance that a compound that is the result of any particular program will obtain the regulatory approvals necessary for it to be marketed.

Vaccine development follows the same general pathway as for drugs. Preclinical testing focuses on the vaccine's safety and ability to elicit a protective immune response (immunogenicity). Pre-marketing vaccine clinical trials are typically done in three phases. Initial Phase I clinical studies are conducted in normal subjects to evaluate the safety, tolerability and immunogenicity of the vaccine candidate. Phase II studies are dose-ranging studies and may enroll hundreds of subjects. Finally, Phase III trials typically enroll thousands of individuals and provide the necessary data on effectiveness and safety. If successful, the Company submits regulatory filings with the appropriate regulatory agencies. Also during this stage, the proposed manufacturing facility undergoes a pre-approval inspection during which production of the vaccine as it is in progress is examined in detail.

In the United States, the FDA review process begins once a complete NDA is submitted and received by the FDA. Pursuant to the Prescription Drug User Fee Act, the FDA review period targets for NDAs or supplemental NDAs is either six months, for priority review, or ten months, for a standard review. Within 60 days after receipt of an NDA, the FDA determines if the application is sufficiently complete to permit a substantive review. The FDA also assesses, at that time, whether the application will be granted a priority review or standard review. Once the review timelines are defined, the FDA will generally act upon the application within those timelines, unless a major amendment has been submitted (either at the Company's own initiative or the FDA's request) to the pending application. If this occurs, the FDA may extend the review period to allow for review of the new information, but by no more than 180 days. Extensions to the review period are communicated to the Company. The FDA can act on an application by issuing an approval letter or a complete response letter.

The Company anticipates filing an NDA with the FDA in 2009 for MK-0974, telcagepant, an investigational oral calcitonin gene-related peptide receptor antagonist, which represents a new mechanism for the treatment of migraine and has demonstrated efficacy comparable to zolmitriptan, an effective triptan, in the Phase III clinical program.

The Company also anticipates filing an NDA with the FDA in 2009 for MK-7418, rolofylline, a potential first-in-class selective adenosine A1 antagonist, which is a Phase III investigational drug being evaluated for the treatment of acute heart failure.

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Additionally, the Company anticipates filing an NDA with the FDA in 2009 for MK-0653C, ezetimibe combined with atorvastatin, an investigational medication for the treatment of dyslipidemia being developed by the Merck/Schering-Plough joint venture.

The Company also anticipates regulatory action in 2009 on two supplemental filings that have been submitted to the FDA: one for *Gardasil*, Merck's HPV vaccine, for use in males; and one for *Isentress*, a first-in-class integrase inhibitor for the treatment of HIV-1 infection, for an expanded indication for use in treatment-naïve patients.

In January 2009, the Company received a second complete response letter from FDA regarding the supplemental BLA ( sBLA ) for the use of *Gardasil* in women ages 27 through 45. The agency has completed its review of the response that Merck provided in July 2008 and has recommended that Merck submit additional data when the 48 month study has been completed. The initial sBLA included data collected through an average of 24 months from enrollment into the study, which is when the number of pre-specified endpoints had been met. Following a review of the final results of the study, Merck anticipates providing a response to the agency in the fourth quarter of 2009. The letter does not affect current indications for *Gardasil* in females ages 9 through 26 nor does the letter relate to the sBLA that was submitted in December 2008 for the use of *Gardasil* in males.

In February 2009, data on several Phase III *Isentress* studies were presented at the 16<sup>th</sup> Conference on Retroviruses and Opportunistic Infections in Montreal, Canada. In new subgroup analyses of a Phase III study (STARTMRK) that compared *Isentress* to efavirenz (one of the leading antiretrovirals prescribed for previously untreated (treatment-naïve) HIV-infected patients), *Isentress* was found to be as effective as efavirenz at suppressing viral load and provided improvements in immune system function across a broad spectrum of patient subpopulations through 48 weeks. The use of *Isentress* in previously untreated HIV-infected patients is an investigational use of the drug. Both medicines were taken in combination with tenofovir/emtricitabine. In addition, results from two Phase III studies (SWITCHMRK-1 and -2) evaluating the effect of switching patients whose HIV is controlled on a lopinavir/ritonavir-based regimen to a regimen containing *Isentress* tablets showed that *Isentress* significantly improved total cholesterol, triglycerides and non-HDL-cholesterol. The study also showed that *Isentress* did not demonstrate non-inferior virologic efficacy at maintaining viral load suppression. As a result of the viral load findings in these trials, Merck discontinued these two studies.

Merck currently has nine products in Phase III development (including MK-0974 and MK-7418 discussed above):

MK-8669, deforolimus, is a novel mTor (mammalian target of rapamycin) inhibitor being evaluated for the treatment of cancer. The drug candidate is being jointly developed and commercialized with ARIAD Pharmaceuticals, Inc., under an agreement reached in 2007. A Phase III study (SUCCEED) in patients with metastatic soft-tissue or bone sarcomas is under way. The Company continues to anticipate filing an NDA with the FDA in 2010.

V503 is a nine-valent HPV vaccine in development to expand protection against cancer-causing HPV types. The Phase III clinical program is underway and Merck anticipates filing a BLA with the FDA in 2012.

MK-0822, odanacatib, is a highly selective inhibitor of the cathepsin K enzyme, which is being evaluated for the treatment of osteoporosis. The Phase III program is ongoing. Merck continues to anticipate filing an NDA with the FDA in 2012.

MK-0524A is a drug candidate that combines extended-release ( ER ) niacin and a novel flushing inhibitor, laropiprant. MK-0524A has demonstrated the ability to lower LDL-cholesterol ( LDL-C ), raise HDL-cholesterol ( HDL-C ) and lower triglycerides with significantly less flushing than traditional extended release niacin alone. High LDL-C, low HDL-C and elevated triglycerides are risk factors associated with heart attacks and strokes. In April 2008, Merck received a non-approvable action letter from the FDA in response to its NDA for MK-0524A. At a meeting to the

discuss the letter, the FDA stated that additional efficacy and safety data were required and suggested that the Company wait for the results of the Treatment of HDL to Reduce the Incidence of Vascular Events ( HPS2-THRIVE ) cardiovascular outcomes study, which is expected to be completed in January 2012. Merck anticipates filing an NDA with the FDA for MK-0524A in 2012.

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In July 2008, the Company announced that *Tredaptive* (also known as MK-0524A) was approved for marketing in the 27 countries of the EU, Iceland and Norway. *Tredaptive* is approved for the treatment of dyslipidemia, particularly in patients with combined mixed dyslipidemia (characterized by elevated levels of LDL-C and triglycerides and low HDL-C) and in patients with primary hypercholesterolemia (heterozygous familial and non-familial). *Tredaptive* should be used in patients in combination with statins, when the cholesterol lowering effects of statin monotherapy is inadequate. *Tredaptive* can be used as monotherapy only in patients in whom statins are considered inappropriate or not tolerated. The launch of *Tredaptive* in Europe and other markets has been delayed due to a manufacturing-related issue. Merck is committed to quickly resolving the issue and to making *Tredaptive* available in Europe as soon as possible. In other countries around the world, Merck continues to pursue regulatory approvals for MK-0524A.

MK-0524B is a drug candidate that combines the novel approach to raising HDL-C and lowering triglycerides from ER niacin combined with laropiprant with the proven benefits of simvastatin in one combination product. Merck will not seek approval for MK-0524B in the United States until it files its complete response relating to MK-0524A.

MK-0859, anacetrapib, is an inhibitor of the cholesteryl ester transfer protein that has shown promise in lipid management by raising HDL-C and reducing LDL-C without raising blood pressure. A Phase III study was initiated in 2008 and enrollment in a cardiovascular outcomes study is planned to begin in 2010. The Company anticipates filing an NDA with the FDA beyond 2014.

MK-0431C combines *Januvia* with pioglitazone, another type 2 diabetes therapy. The Company anticipates filing an NDA with the FDA in 2011.

In October 2008, Merck announced it will not seek regulatory approval for taranabant, an investigational medicine, to treat obesity and has discontinued its Phase III clinical development program for taranabant for obesity. Available Phase III data showed that both efficacy and adverse events were dose related, with greater efficacy and more adverse events in the higher doses. Therefore, after careful consideration, the Company determined that the overall profile of taranabant did not support further development for obesity.

In December 2008, the Company terminated its collaboration with Dynavax Technologies Corporation ( Dynavax ) for the development of V270, an investigational hepatitis B vaccine, which was entered into in 2007. In October 2008, Merck and Dynavax received notification from the FDA regarding the two companies' response to the agency's request for safety information relating to the clinical hold on the two Investigational New Drug ( IND ) Applications for V270. In issuing the clinical hold in March 2008, the FDA requested a review of clinical and safety data including all available information about a single case of Wegener's granulomatosis, an uncommon disease in which the blood vessels are inflamed, reported in a Phase III clinical trial. Dynavax and Merck had previously provided a response to the FDA in September 2008. In its October 2008 correspondence, the FDA advised the companies that the balance of risk versus potential benefit no longer favored continued clinical evaluation of V270 in healthy adults and children.

The Company's clinical pipeline includes candidates in multiple disease areas, including anemia, atherosclerosis, cancer, diabetes, heart failure, hypertension, infectious diseases, migraine, neurodegenerative diseases, psychiatric diseases, osteoporosis, pain, and respiratory disease. The Company supplements its internal research with an aggressive licensing and external alliance strategy focused on the entire spectrum of collaborations from early research to late-stage compounds, as well as new technologies. The Company completed a number of transactions in 2008, including research collaborations, preclinical and clinical compounds, and technology transactions across a broad range of therapeutic categories.

In September 2008, Merck and Japan Tobacco Inc. ( JT ) signed a worldwide licensing agreement to develop and commercialize JTT-305, an investigational oral osteoanabolic (bone growth stimulating) agent for the treatment of osteoporosis, a disease which reduces bone density and strength and results in an increased risk of bone fractures.



JTT-305 is an investigational oral calcium sensing receptor antagonist that is currently being evaluated by JT in Phase II clinical trials in Japan for its effect on increasing bone density and is in Phase I clinical trials outside of Japan. Under the terms of the agreement, Merck gained worldwide rights, except for Japan, to develop and commercialize JTT-305 and certain other related compounds. JT received an upfront payment of \$85 million, which

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the Company recorded as Research and development expense, and is eligible to receive additional cash payments upon achievement of certain milestones associated with the development and approval of a drug candidate covered by this agreement. JT will also be eligible to receive royalties from sales of any drug candidates that receive marketing approval. The license agreement between Merck and JT will remain in effect until expiration of all royalty and milestone obligations, and may be terminated in the event of an uncured material breach by the other party. The agreement may also be terminated by Merck without cause before initial commercial sale of JTT-305 by giving six months prior notice to JT, and thereafter by giving one year prior notice thereof to JT. The license agreement may also be terminated immediately by Merck if Merck determines due to safety and/or efficacy concerns based on available scientific evidence to cease development of JTT-305 and/or to withdraw JTT-305 from the market on a permanent basis.

In February 2009, Merck entered into a definitive agreement with Insmed Inc. ( Insmed ) to purchase Insmed's portfolio of follow-on biologic therapeutic candidates and its commercial manufacturing facilities located in Boulder, Colorado. Under the terms of the agreement, Merck will pay Insmed an aggregate of \$130 million in cash to acquire all rights to the Boulder facilities and Insmed's pipeline of follow-on biologic candidates. Insmed's follow-on biologics portfolio includes two clinical candidates: INS-19, an investigational recombinant granulocyte-colony stimulating factor ( G-CSF ) that will be evaluated for its ability to prevent infections in patients with cancer receiving chemotherapy, and INS-20, a pegylated recombinant G-CSF designed to allow for less frequent dosing. The agreement provides for initial payments of up to \$10 million for INS-19 and INS-20. Merck will pay Insmed the remaining balance upon closing of the transaction, which is expected by the end of the first quarter of 2009, without any further milestone or royalty obligations.

The chart below reflects the Company's current research pipeline as of February 15, 2009. Candidates shown in Phase III include specific products. Candidates shown in Phase I and II include the most advanced compound with a specific mechanism in a given therapeutic area. Small molecules and biologics are given MK-number designations and vaccine candidates are given V-number designations. Back-up compounds, regardless of their phase of development, additional indications in the same therapeutic area and additional claims, line extensions or formulations for in-line products are not shown. All clinical programs in Merck BioVentures division are included.

**Phase I****Alzheimer's Disease**

V950

**Anemia**

MK-2578

**Cancer**

MK-0752

MK-1775

MK-2206

MK-4101

MK-4827

MK-5108

MK-8033

V934/V935

**Cardiovascular**

MK-1597

MK-3614

MK-8984

**Phase I**

**Diabetes**

MK-4074

**Infectious Disease**

MK-3281

**Neurologic**

MK-5395

**Neutropenia**

INS-19

INS-20

**Psychiatric Disease**

MK-0594

MK-8368

MK-8998

**Respiratory Disease**

MK-5932

**Phase II**

**Atherosclerosis**

MK-1903

MK-6213

**Cancer**

MK-0646

**Diabetes**

MK-0893

MK-0941

MK-8245

**Infectious Disease**

MK-7009

V419

V710

**Insomnia**

MK-4305

**Neurologic**

MK-0249

**Osteoporosis**

MK-5442 (JTT-305)

**Psychiatric Disease**

MK-5757

**Respiratory Disease**

MK-0476C

MK-0633

**Sarcopenia**

MK-2866

**Phase III**

**Acute Heart Failure**

MK-7418

(rolofylline)

**Atherosclerosis**

MK-0524A

(extended-release

niacin/laropiprant)

MK-0524B

(extended-release  
niacin/laropiprant/  
simvastatin)

MK-0859

(anacetrapib)

**Cancer**

MK-8669

(deforolimus;  
AP23573)

**Diabetes**

MK-0431C

**HPV**

V503

**Migraine**

MK-0974

(telcagepant)

**Osteoporosis**

MK-0822

(odanacatib)

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All product or service marks appearing in type form different from that of the surrounding text are trademarks or service marks owned by or licensed to Merck, its subsidiaries or affiliates (including *Zetia* and *Vytorin*, trademarks owned by entities of the Merck/Schering-Plough partnership), except as noted. *Cozaar* and *Hyzaar* are registered trademarks of E.I. du Pont de Nemours and Company, Wilmington, DE and *Prilosec* and *Nexium* are trademarks of the AstraZeneca group. The U.S. trademarks for *Vasotec* and *Vaseretic* are owned by Biovail Laboratories Incorporated.

## **Employees**

As of December 31, 2008, the Company had approximately 55,200 employees worldwide, with approximately 28,800 employed in the United States, including Puerto Rico. Approximately 21% of worldwide employees of the Company are represented by various collective bargaining groups.

In October 2008, the Company announced a global restructuring program (the 2008 Restructuring Program) to reduce its cost structure, increase efficiency, and enhance competitiveness. As part of the 2008 Restructuring Program, the Company expects to eliminate approximately 7,200 positions—6,800 active employees and 400 vacancies—across all areas of the Company worldwide by the end of 2011. About 40% of the total reductions will occur in the United States. As part of the 2008 Restructuring Program, the Company is streamlining management layers by reducing its total number of senior and mid-level executives globally by approximately 25%. Merck will rollout a new, more customer-centric selling model designed to provide Merck with a meaningful competitive advantage and help physicians, patients and payers improve patient outcomes. The Company also will make greater use of outside technology resources, centralize common sales and marketing activities, and consolidate and streamline its operations. Merck's manufacturing division will further focus its capabilities on core products and outsource non-core manufacturing. In addition, Merck is expanding its access to worldwide external science through a basic research global operating strategy, which is designed to provide a sustainable pipeline and is focused on translating basic research productivity into late-stage clinical success. To increase efficiencies, basic research operations will consolidate work in support of a given therapeutic area into one of four locations. This will provide a more efficient use of research facilities and result in the closure of three basic research sites in Tsukuba, Japan; Pomezia, Italy; and Seattle by the end of 2009.

## **Environmental Matters**

The Company believes that it is in compliance in all material respects with applicable environmental laws and regulations. In 2008, the Company incurred capital expenditures of approximately \$18.7 million for environmental protection facilities. The Company is also remediating environmental contamination resulting from past industrial activity at certain of its sites. Expenditures for remediation and environmental liabilities were \$34.5 million in 2008, \$19.5 million in 2007, \$12.6 million in 2006, and are estimated at \$47.1 million for the years 2009 through 2013. These amounts do not consider potential recoveries from other parties. The Company has taken an active role in identifying and providing for these costs and, in management's opinion, the liabilities for all environmental matters which are probable and reasonably estimable have been accrued and totaled \$89.5 million at December 31, 2008. Although it is not possible to predict with certainty the outcome of these environmental matters, or the ultimate costs of remediation, management does not believe that any reasonably possible expenditures that may be incurred in excess of the liabilities accrued should exceed \$70.0 million in the aggregate. Management also does not believe that these expenditures should have a material adverse effect on the Company's financial position, results of operations, liquidity or capital resources for any year.

## **Geographic Area Information**

The Company's operations outside the United States are conducted primarily through subsidiaries. Sales worldwide by subsidiaries outside the United States were 44% of sales in 2008 and 39% of sales in 2007 and 2006.

The Company's worldwide business is subject to risks of currency fluctuations, governmental actions and other governmental proceedings abroad. The Company does not regard these risks as a deterrent to further expansion of its operations abroad. However, the Company closely reviews its methods of operations and adopts strategies responsive to changing economic and political conditions.

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In recent years, the Company has been expanding its operations in countries located in Latin America, the Middle East, Africa, Eastern Europe and Asia Pacific where changes in government policies and economic conditions are making it possible for the Company to earn fair returns. Business in these developing areas, while sometimes less stable, offers important opportunities for growth over time.

Financial information about geographic areas of the Company's business is discussed in Item 8. Financial Statements and Supplementary Data below.

## **Available Information**

The Company's Internet website address is [www.merck.com](http://www.merck.com). The Company will make available, free of charge at the Investor Information portion of its website, its Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and all amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after such reports are electronically filed with, or furnished to, the Securities and Exchange Commission (SEC).

The Company's corporate governance guidelines and the charters of the Board of Directors' six standing committees are available on the Company's website at [www.merck.com/about/corporategovernance](http://www.merck.com/about/corporategovernance) and all such information is available in print to any stockholder who requests it from the Company.

## **Item 1A. Risk Factors.**

You should carefully consider all of the information set forth in this Form 10-K, including the following risk factors, before deciding to invest in any of the Company's securities. The risks below are not the only ones the Company faces. Additional risks not currently known to the Company or that the Company presently deems immaterial may also impair its business operations. The Company's business, financial condition, results of operations or prospects could be materially adversely affected by any of these risks. This Form 10-K also contains forward-looking statements that involve risks and uncertainties. The Company's results could materially differ from those anticipated in these forward-looking statements as a result of certain factors, including the risks it faces as described below and elsewhere. See Cautionary Factors that May Affect Future Results below.

### **The Company faces significant litigation related to *Vioxx*.**

On September 30, 2004, the Company voluntarily withdrew *Vioxx*, its arthritis and acute pain medication, from the market worldwide. As of December 31, 2008, approximately 10,800 product liability lawsuits, involving approximately 26,800 plaintiff groups, alleging personal injuries resulting from the use of *Vioxx*, have been filed against the Company in state and federal courts in the United States. The Company is also a defendant in approximately 242 purported class actions related to the use of *Vioxx*. (All of these suits are referred to as the *Vioxx* Product Liability Lawsuits.) As discussed above, on November 9, 2007, the Company announced that it had entered into an agreement (the Settlement Agreement) with the law firms that comprise the executive committee of the Plaintiffs' Steering Committee of the federal multidistrict *Vioxx* litigation as well as representatives of plaintiffs counsel in the Texas, New Jersey and California state coordinated proceedings to resolve state and federal MI and IS claims filed as of that date in the United States. The Settlement Agreement, which also applies to tolled claims, was signed by the parties after several meetings with three of the four judges overseeing the coordination of more than 95% of the current claims in the *Vioxx* product liability litigation. The Settlement Agreement applies only to U.S. legal residents and those who allege that their MI or IS occurred in the United States.

As of October 30, 2008, the deadline for enrollment in the Settlement Program, more than 48,100 of the approximately 48,325 individuals who were eligible for the Settlement Program and whose claims were not

1) dismissed, 2) expected to be dismissed in the near future, or 3) tolled claims that appear to have been abandoned had submitted some or all of the materials required for enrollment in the Settlement Program. This represents approximately 99.8% of the eligible MI and IS claims previously registered with the Settlement Program. Under the terms of the Settlement Agreement, Merck could exercise a right to walk away from the Settlement Agreement if the thresholds and other requirements were not met. The Company waived that right as of August 4, 2008. The waiver of that right triggered Merck's obligation to pay a fixed total of \$4.85 billion. Payments will be made in installments into the settlement funds. The first payment of \$500 million was made in August 2008 and an additional payment of



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\$250 million was made in October 2008. Additional payments will be made on a periodic basis going forward, when and as needed to fund payments of claims and administrative expenses.

Of the plaintiff groups described above, most are currently in the *Vioxx* Settlement Program. As of December 31, 2008, 70 plaintiff groups who were otherwise eligible for the Settlement Program have not participated and their claims remained pending against Merck. In addition, the claims of 1,400 plaintiff groups who are not eligible for the program remained pending against Merck. A number of the 1,400 plaintiff groups are subject to motions to dismiss for failure to comply with court-ordered deadlines. Since December 31, 2008, hundreds of these plaintiff groups have since been dismissed.

Claims of certain individual third-party payors remain pending in the New Jersey court, and counsel purporting to represent a large number of third-party payors has threatened to file numerous additional such actions. Discovery is currently ongoing in these cases, and a status conference with the court took place in January 2009 to discuss scheduling issues, including the selection of early trial pool cases.

There are also pending in various U.S. courts putative class actions purportedly brought on behalf of individual purchasers or users of *Vioxx* and claiming either reimbursement of alleged economic loss or an entitlement to medical monitoring. All of these cases are at early procedural stages, and no class has been certified. In New Jersey, the trial court dismissed the complaint in the case of Sinclair, a purported statewide medical monitoring class. The Appellate Division reversed the dismissal, and the issue was appealed to the New Jersey Supreme Court. That court heard argument on October 22, 2007. On June 4, 2008, the New Jersey Supreme Court reversed the Appellate Division and dismissed this action.

In addition to the *Vioxx* Product Liability Lawsuits, various purported class actions and individual lawsuits have been brought against the Company and several current and former officers and directors of the Company alleging that the Company made false and misleading statements regarding *Vioxx* in violation of the federal and state securities laws (all of these suits are referred to as the *Vioxx* Securities Lawsuits ). On April 12, 2007, Judge Chesler granted defendants' motion to dismiss the complaint with prejudice. Plaintiffs appealed Judge Chesler's decision to the United States Court of Appeals for the Third Circuit. On September 9, 2008, the Third Circuit issued an opinion reversing Judge Chesler's order and remanding the case to the District Court. On September 23, 2008, Merck filed a petition seeking rehearing *en banc*, which was denied. The case was remanded to the District Court in October 2008, and Plaintiffs have filed their Consolidated and Fifth Amended Class Action Complaint. In addition, various putative class actions have been brought against the Company and several current and former employees, officers, and directors of the Company alleging violations of ERISA. (All of these suits are referred to as the *Vioxx* ERISA Lawsuits .) In addition, shareholder derivative suits that were previously filed and dismissed are now on appeal and several shareholders have filed demands with the Company asserting claims against the Board members and Company officers. (All of these suits and demands are referred to as the *Vioxx* Derivative Lawsuits and, together with the *Vioxx* Securities Lawsuits and the *Vioxx* ERISA Lawsuits, the *Vioxx* Shareholder Lawsuits .) The Company has also been named as a defendant in actions in various countries outside the United States. (All of these suits are referred to as the *Vioxx* Foreign Lawsuits .) The Company has also been sued by ten states, five counties and New York City with respect to the marketing of *Vioxx*. The Company anticipates that additional lawsuits relating to *Vioxx* may be filed against it and/or certain of its current and former officers and directors in the future.

The SEC is conducting a formal investigation of the Company concerning *Vioxx*. The DOJ has issued a subpoena requesting information relating to the Company's research, marketing and selling activities with respect to *Vioxx* in a federal health care investigation under criminal statutes. This investigation includes subpoenas for witnesses to appear before a grand jury. There are also ongoing investigations by local authorities in Europe. The Company is cooperating with authorities in all of these investigations. (All of these investigations are referred to as the *Vioxx* Investigations .) The Company cannot predict the outcome of any of these investigations; however, they could result in potential civil

and/or criminal liability.

Juries have now decided in favor of the Company twelve times and in plaintiffs' favor five times. One Merck verdict was set aside by the court and has not been retried. Another Merck verdict was set aside and retried, leading to one of the five plaintiffs' verdicts. There have been two unresolved mistrials. With respect to the five plaintiffs' verdicts, Merck filed an appeal or sought judicial review in each of those cases. In one of those five, an

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intermediate appellate court overturned the trial verdict and directed that judgment be entered for Merck, and in another, an intermediate appellate court overturned the trial verdict, entering judgment for Merck on one claim and ordering a new trial on the remaining claims. The *Vioxx* product liability litigation is discussed more fully in Item 3. Legal Proceedings below.

The outcomes of these *Vioxx* Product Liability trials should not be interpreted to indicate any trend or what outcome may be likely in future *Vioxx* trials.

A trial in a representative action in Australia is scheduled to commence on March 30, 2009, in the Federal Court of Australia. The named plaintiff, who alleges he suffered a MI, seeks to represent others in Australia who ingested *Vioxx* and suffered a MI, thrombotic stroke, unstable angina, transient ischemic attack or peripheral vascular disease. On November 24, 2008, the Company filed a motion for an order that the proceeding no longer continue as a representative proceeding. During a hearing on December 5, 2008, the court dismissed that motion and, on January 9, 2009, issued its reasons for that decision. On February 17, 2009, the Company's motion for leave to appeal that decision was denied and the parties were directed to prepare proposed lists of issues to be tried.

The Company currently anticipates that two U.S. *Vioxx* Product Liability Lawsuits will be tried in 2009. Except with respect to the product liability trial scheduled to be held in Australia, the Company cannot predict the timing of any other trials related to the *Vioxx* Litigation. The Company believes that it has meritorious defenses to the *Vioxx* Product Liability Lawsuits, *Vioxx* Shareholder Lawsuits and *Vioxx* Foreign Lawsuits (collectively, the *Vioxx* Lawsuits) and will vigorously defend against them. The Company's insurance coverage with respect to the *Vioxx* Lawsuits will not be adequate to cover its defense costs and any losses.

During 2008, the Company spent approximately \$305 million in the aggregate in legal defense costs worldwide related to (i) the *Vioxx* Product Liability Lawsuits, (ii) the *Vioxx* Shareholder Lawsuits, (iii) the *Vioxx* Foreign Lawsuits, and (iv) the *Vioxx* Investigations (collectively, the *Vioxx* Litigation). In the fourth quarter of 2008, the Company recorded a charge of \$62 million to add to the reserve solely for its future legal defense costs related to the *Vioxx* Litigation which was \$522 million at December 31, 2007 and \$279 million at December 31, 2008. In addition, in 2007, the Company recorded a pretax charge of \$4.85 billion equal to the aggregate amount to be paid to the qualifying claimants in the Settlement Program. During 2008, the Company paid \$750 million into the settlement funds for the Settlement Program. Thus, the Company's total reserve for the *Vioxx* Litigation at December 31, 2008 was \$4.379 billion (the *Vioxx* Reserve). The amount of the *Vioxx* Reserve allocated to defense costs is based on certain assumptions, described below under Legal Proceedings, and is the best estimate of the minimum amount that the Company believes will be incurred in connection with the remaining aspects of the *Vioxx* Litigation, however, events such as additional trials in the *Vioxx* Litigation and other events that could arise in the course of the *Vioxx* Litigation could affect the ultimate amount of defense costs to be incurred by the Company.

The Company is not currently able to estimate any additional amount of damages that it may be required to pay in connection with the *Vioxx* Lawsuits or *Vioxx* Investigations. These proceedings are still expected to continue for years and the Company has very little information as to the course the proceedings will take. In view of the inherent difficulty of predicting the outcome of litigation, particularly where there are many claimants and the claimants seek unspecified 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 not included in the Settlement Program. The Company has not established any reserves for any potential liability relating to the *Vioxx* Lawsuits not included in the Settlement Program or the *Vioxx* Investigations.

A series of unfavorable outcomes in the *Vioxx* Lawsuits or the *Vioxx* Investigations, resulting in the payment of substantial damages or fines or resulting in criminal penalties, in excess of the *Vioxx* Reserve, could have a material adverse effect on the Company's business, cash flow, results of operations, financial position and prospects.

**Certain of the Company's major products are going to lose patent protection in the near future and, when that occurs, the Company expects a significant decline in sales of those products.**

The Company depends upon patents to provide it with exclusive marketing rights for its products for some period of time. As product patents for several of the Company's products have recently expired, or are about to expire, in the United States and in other countries, the Company faces strong competition from lower price generic

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drugs. Loss of patent protection for one of the Company's products typically leads to a rapid loss of sales for that product, as lower priced generic versions of that drug become available. In the case of products that contribute significantly to the Company's sales, the loss of patent protection can have a material adverse effect on the Company's business, cash flow, results of operations, financial position and prospects.

*Fosamax* and *Fosamax Plus D* lost marketing exclusivity in the United States in 2008. As a result of these events, the Company is experiencing significant declines in *Fosamax* and *Fosamax Plus D* U.S. sales. Sales of *Fosamax* outside the United States have already been adversely affected by the availability of generic alendronate sodium products in some markets, including the United Kingdom, Canada and Germany. Also, *Trusopt* and *Cosopt* lost market exclusivity in the United States in October 2008 and as a result the Company is experiencing a significant decline in sales of these products.

The patent that provides U.S. market exclusivity for *Primaxin* expires in September 2009. After such time, the Company expects a significant decline in U.S. sales of *Primaxin*. In addition, *Cozaar* and *Hyzaar* will each lose patent protection in the United States in April 2010. The Company expects significant declines in U.S. sales of these products after that time.

A chart listing the U.S. patent protection for the Company's major marketed products is set forth above in Item 1. Business Patents, Trademarks and Licenses.

**The Company's research and development efforts may not succeed in developing commercially successful products and the Company may not be able to acquire commercially successful products in other ways; in consequence, the Company may not be able to replace sales of successful products that have lost patent protection.**

Like other major pharmaceutical companies, in order to remain competitive, the Company must continue to launch new products each year. Declines in sales of products such as *Zocor* and *Fosamax* after the loss of marketing exclusivity mean that the Company's future success is dependent on its pipeline of new products, including new products which it develops through joint ventures and products which it is able to obtain through license or acquisition. To accomplish this, the Company commits substantial effort, funds and other resources to research and development, both through its own dedicated resources, and through various collaborations with third parties. To support its research and development efforts the Company must make ongoing, substantial expenditures, without any assurance that the efforts it is funding will result in a commercially successful product. The Company must also commit substantial efforts, funds and other resources to recruiting and retaining high quality scientists and other personnel with pharmaceutical research and development expertise.

For a description of the research and development process, see Research and Development above. Each phase of testing is highly regulated, and during each phase there is a substantial risk that the Company will encounter serious obstacles or will not achieve its goals, and accordingly the Company may abandon a product in which it has invested substantial amounts of time and money. Some of the risks encountered in the research and development process include the following: pre-clinical testing of a new compound may yield disappointing results; clinical trials of a new drug may not be successful; a new drug may not be effective or may have harmful side effects; a new drug may not be approved by the FDA for its intended use; it may not be possible to obtain a patent for a new drug; or sales of a new product may be disappointing.

The Company cannot state with certainty when or whether any of its products now under development will be approved or launched; whether it will be able to develop, license or otherwise acquire compounds, product candidates or products; or whether any products, once launched, will be commercially successful. The Company must maintain a continuous flow of successful new products and successful new indications or brand extensions for existing products

sufficient both to cover its substantial research and development costs and to replace sales that are lost as profitable products, such as *Zocor* and *Fosamax*, lose patent protection or are displaced by competing products or therapies. Failure to do so in the short term or long term would have a material adverse effect on the Company's business, results of operations, cash flow, financial position and prospects.

**Table of Contents****Issues concerning *Vytorin* and the ENHANCE and SEAS clinical trials have had an adverse effect on sales of *Vytorin* and *Zetia* in the U.S.**

The Company and Schering-Plough sell *Vytorin* and *Zetia* through their joint venture company, the MSP Partnership. On January 14, 2008, the MSP Partnership announced the primary endpoint and other results of the ENHANCE trial. ENHANCE was a surrogate endpoint trial conducted in 720 patients with Heterozygous Familial Hypercholesterolemia, a rare condition that affects approximately 0.2% of the population. The primary endpoint was the mean change in the intima-media thickness measured at three sites in the carotid arteries (the right and left common carotid, internal carotid and carotid bulb) between patients treated with ezetimibe/simvastatin 10/80 mg versus patients treated with simvastatin 80 mg alone over a two year period. There was no statistically significant difference between treatment groups on the primary endpoint. There was also no statistically significant difference between the treatment groups for each of the components of the primary endpoint, including the common carotid artery.

As previously disclosed, the Company and its joint venture partner, Schering-Plough, have received several letters addressed to both companies from the House Committee on Energy and Commerce, its Subcommittee on Oversight and Investigations ( O&I ), and the Ranking Minority Member of the Senate Finance Committee, collectively seeking a combination of witness interviews, documents and information on a variety of issues related to the ENHANCE clinical trial, the sale and promotion of *Vytorin*, as well as sales of stock by corporate officers. In addition, since August 2008, the companies have received three additional letters from O&I, including one dated February 19, 2009, seeking certain information and documents related to the SEAS clinical trial, which is described in more detail below. The companies have each received subpoenas from the New York and New Jersey State Attorneys General Offices and a letter from the Connecticut Attorney General seeking similar information and documents. In addition, the Company has received five Civil Investigative Demands ( CIDs ) from a multistate group of 35 State Attorneys General who are jointly investigating whether the companies violated state consumer protection laws when marketing *Vytorin*. Finally, in September 2008, the Company received a letter from the Civil Division of the DOJ informing it that the DOJ is investigating whether the companies' conduct relating to the promotion of *Vytorin* caused false claims to be submitted to federal health care programs. The Company is cooperating with these investigations and working with Schering-Plough to respond to the inquiries. In addition, the Company has become aware of or been served with approximately 145 civil class action lawsuits alleging common law and state consumer fraud claims in connection with the MSP Partnership's sale and promotion of *Vytorin* and *Zetia*. Certain of those lawsuits allege personal injuries and/or seek medical monitoring. Also, as previously disclosed, on April 3, 2008, a Merck shareholder filed a putative class action lawsuit in federal court in the Eastern District of Pennsylvania alleging that Merck and its Chairman, President and Chief Executive Officer, Richard T. Clark, violated the federal securities laws. On April 22, 2008, a member of a Merck ERISA plan filed a putative class action lawsuit against the Company and certain of its officers and directors alleging they breached their fiduciary duties under ERISA.

In January 2009, the FDA announced that it had completed its review of the final clinical study report of ENHANCE. The FDA stated that the results from ENHANCE did not change its position that an elevated LDL cholesterol is a risk factor for cardiovascular disease and that lowering LDL cholesterol reduces the risk for cardiovascular disease. The FDA also stated that, based on current available data, patients should not stop taking *Vytorin* or other cholesterol lowering medications and should talk to their doctor if they have any questions about *Vytorin*, *Zetia*, or the ENHANCE trial.

In July 2008, efficacy and safety results from the SEAS study were announced. SEAS was designed to evaluate whether intensive lipid lowering with *Vytorin* would reduce the need for aortic valve replacement and the risk of cardiovascular morbidity and mortality versus placebo in patients with asymptomatic mild to moderate aortic stenosis who had no indication for statin therapy. *Vytorin* failed to meet its primary end point for the reduction of major cardiovascular events. There also was no significant difference in the key secondary end point of aortic valve events;

however, there was a reduction in the group of patients taking *Vytorin* compared to placebo in the key secondary end point of ischemic cardiovascular events. In the study, patients in the group who took *Vytorin* had a higher incidence of cancer than the group who took placebo. There was also a nonsignificant increase in deaths from



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cancer in patients in the group who took *Vytorin* versus those who took placebo. Cancer and cancer deaths were distributed across all major organ systems.

In August 2008, the FDA announced that it was investigating the results from the SEAS trial. In this announcement, the FDA also cited interim data from two large ongoing cardiovascular trials of *Vytorin* – the Study of Heart and Renal Protection ( SHARP ) and the IMPROVE-IT clinical trials – in which there was no increased risk of cancer with the combination of simvastatin plus ezetimibe. The SHARP trial is expected to be completed in 2010. The IMPROVE-IT trial is scheduled for completion around 2012. The FDA determined that, as of that time, these findings in the SEAS trial plus the interim data from ongoing trials should not prompt patients to stop taking *Vytorin* or any other cholesterol lowering drug.

Following the announcements of the ENHANCE and SEAS clinical trial results, sales of *Vytorin* and *Zetia* declined in 2008 in the U.S. These issues concerning the ENHANCE and SEAS clinical trials have had an adverse effect on the MSP Partnership's sales of *Vytorin* and *Zetia* and could continue to have an adverse effect on such sales. If sales of such products are materially adversely affected, the Company's business, cash flow, results of operations, financial position and prospects could also be materially adversely affected. In addition, unfavorable outcomes resulting from the government investigations or the litigation concerning the sale and promotion of these products could have a material adverse effect on the Company's business, cash flow, results of operations, financial position and prospects.

### **The Company's products, including products in development, can not be marketed unless the Company obtains and maintains regulatory approval.**

The Company's activities, including research, preclinical testing, clinical trials and manufacturing and marketing its products, are subject to extensive regulation by numerous federal, state and local governmental authorities in the United States, including the FDA, and by foreign regulatory authorities, including the European Commission. In the United States, the FDA is of particular importance to the Company, as it administers requirements covering the testing, approval, safety, effectiveness, manufacturing, labeling and marketing of prescription pharmaceuticals. In many cases, the FDA requirements have increased the amount of time and money necessary to develop new products and bring them to market in the United States. Regulation outside the United States also is primarily focused on drug safety and effectiveness and, in many cases, cost reduction. The FDA and foreign regulatory authorities have substantial discretion to require additional testing, to delay or withhold registration and marketing approval and to mandate product withdrawals.

Even if the Company is successful in developing new products, it will not be able to market any of those products unless and until it has obtained all required regulatory approvals in each jurisdiction where it proposes to market the new products. Once obtained, the Company must maintain approval as long as it plans to market its new products in each jurisdiction where approval is required. The Company's failure to obtain approval, significant delays in the approval process, or its failure to maintain approval in any jurisdiction will prevent it from selling the new products in that jurisdiction until approval is obtained, if ever. The Company would not be able to realize revenues for those new products in any jurisdiction where it does not have approval.

### **The Company is dependent on its patent rights, and if its patent rights are invalidated or circumvented, its business would be adversely affected.**

Patent protection is considered, in the aggregate, to be of material importance in the Company's marketing of human health products in the United States and in most major foreign markets. Patents covering products that it has introduced normally provide market exclusivity, which is important for the successful marketing and sale of its products. The Company seeks patents covering each of its products in each of the markets where it intends to sell the products and where meaningful patent protection is available.

Even if the Company succeeds in obtaining patents covering its products, third parties or government authorities may challenge or seek to invalidate or circumvent its patents and patent applications. It is important for the Company's business to defend successfully the patent rights that provide market exclusivity for its products. The Company is often involved in patent disputes relating to challenges to its patents or infringement and similar claims against the Company. The Company aggressively defends its important patents both within and outside the United States, including by filing claims of infringement against other parties. See Item 3. Legal Proceedings Patent

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Litigation below. In particular, manufacturers of generic pharmaceutical products from time to time file Abbreviated New Drug Applications ( ANDA ) with the FDA seeking to market generic forms of the Company's products prior to the expiration of relevant patents owned by the Company. The Company normally responds by vigorously defending its patent, including by filing lawsuits alleging patent infringement. Patent litigation and other challenges to the Company's patents are costly and unpredictable and may deprive the Company of market exclusivity for a patented product or, in some cases, third party patents may prevent the Company from marketing and selling a product in a particular geographic area.

As discussed below in Item 3. Legal Proceedings Patent Litigation, the Company has received a notice from Teva Pharmaceuticals, Inc. ( Teva ), a generic company, indicating that it had filed an ANDA for montelukast and that it is challenging the U.S. patent that is listed for *Singulair*. On April 2, 2007, the Company filed a patent infringement action against Teva. The lawsuit automatically stays FDA approval of Teva's ANDA until August 2009 or until an adverse court decision, if any, whichever may occur earlier. A trial in this matter commenced on February 23, 2009.

If one or more important products lose patent protection in profitable markets, sales of those products are likely to decline significantly as a result of generic versions of those products becoming available. The Company's results of operations may be adversely affected by the lost sales unless and until the Company has successfully launched commercially successful replacement products.

### **The Company faces intense competition from lower-cost generic products.**

In general, the Company faces increasing competition from lower-cost generic products. The patent rights that protect its products are of varying strengths and durations. In addition, in some countries, patent protection is significantly weaker than in the United States or the EU. In the United States, political pressure to reduce spending on prescription drugs has led to legislation which encourages the use of generic products. Although it is the Company's policy to actively protect its patent rights, generic challenges to the Company's products can arise at any time, and it may not be able to prevent the emergence of generic competition for its products.

Loss of patent protection for a product typically is followed promptly by generic substitutes, reducing the Company's sales of that product. Availability of generic substitutes for the Company's drugs may adversely affect its results of operations and cash flow. In addition, proposals emerge from time to time in the United States and other countries for legislation to further encourage the early and rapid approval of generic drugs. Any such proposal that is enacted into law could worsen this substantial negative effect on the Company's sales and, potentially, its business, cash flow, results of operations, financial position and prospects.

### **The Company faces intense competition from new products.**

The Company's products face intense competition from competitors' products. This competition may increase as new products enter the market. In such an event, the competitors' products may be safer or more effective or more effectively marketed and sold than the Company's products. Alternatively, in the case of generic competition, they may be equally safe and effective products which are sold at a substantially lower price than the Company's products. As a result, if the Company fails to maintain its competitive position, this could have a material adverse effect on its business, cash flow, results of operations, financial position and prospects.

### **The Company faces pricing pressure with respect to its products.**

The Company's products are subject to increasing price pressures and other restrictions worldwide, including in the United States. In the United States, these include (i) practices of managed care groups and institutional and governmental purchasers and (ii) U.S. federal laws and regulations related to Medicare and Medicaid, including the

Medicare Prescription Drug Improvement and Modernization Act of 2003 (the 2003 Act ). The 2003 Act included a prescription drug benefit for individuals which first went into effect on January 1, 2006. The increased purchasing power of entities that negotiate on behalf of Medicare beneficiaries could result in further pricing pressures.

Outside the United States, numerous major markets have pervasive government involvement in funding healthcare, and in that regard, fix the pricing and reimbursement of pharmaceutical and vaccine products.

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Consequently, in those markets, the Company is subject to government decision making and budgetary actions with respect to its products.

The Company expects pricing pressures to increase in the future.

### **The Company is experiencing difficulties and delays in the manufacturing of certain of its products.**

As previously disclosed, the Company has experienced difficulties in manufacturing certain of its vaccines and other products. The Company is working on these issues, but there can be no assurance of when or if these issues will be finally resolved.

In addition to the difficulties that the Company is experiencing currently, the Company may experience difficulties and delays inherent in manufacturing its products, such as (i) failure of the Company or any of its vendors or suppliers to comply with Current Good Manufacturing Practices and other applicable regulations and quality assurance guidelines that could lead to manufacturing shutdowns, product shortages and delays in product manufacturing; (ii) construction delays related to the construction of new facilities or the expansion of existing facilities, including those intended to support future demand for the Company's products; and (iii) other manufacturing or distribution problems including changes in manufacturing production sites and limits to manufacturing capacity due to regulatory requirements, changes in types of products produced, or physical limitations that could impact continuous supply. Manufacturing difficulties can result in product shortages, leading to lost sales.

### **Pharmaceutical products can develop unexpected safety or efficacy concerns.**

Unexpected safety or efficacy concerns can arise with respect to marketed products, whether or not scientifically justified, leading to product recalls, withdrawals, or declining sales, as well as product liability, consumer fraud and/or other claims.

### **The Company has no product liability insurance for products first sold after August 1, 2004.**

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.

### **Changes in laws and regulations could adversely affect the Company's business.**

All aspects of the Company's business, including research and development, manufacturing, marketing, pricing, sales, litigation and intellectual property rights, are subject to extensive legislation and regulation. Changes in applicable federal and state laws and agency regulations could have a material adverse effect on the Company's business.

### **The recent financial crisis and current uncertainty in global economic conditions could negatively affect the Company's operating results.**

The current financial crisis and uncertainty in global economic conditions have resulted in substantial volatility in the credit markets and a low level of liquidity in many financial markets. These conditions may result in a further slowdown to the global economy that could affect the Company's business by reducing the prices that drug wholesalers and retailers, hospitals, government agencies and managed health care providers may be able or willing to pay for the Company's products or by reducing the demand for the Company's products, which could in turn negatively impact the Company's sales and revenue generation and result in a material adverse effect on the Company's business,

cash flow, results of operations, financial position and prospects.

**Reliance on third party relationships and outsourcing arrangements could adversely affect the Company's business.**

The Company depends on third parties, including suppliers, alliances with other pharmaceutical and biotechnology companies and third party service providers, for key aspects of its business including development, manufacture and commercialization of its products and support for its information technology systems. Failure of these third parties to meet their contractual, regulatory and other obligations to the Company or the development of factors that materially disrupt the relationships between the Company and these third parties, could have a material adverse effect on the Company's business.

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**The Company is increasingly dependent on sophisticated information technology and infrastructure.**

The Company is increasingly dependent on sophisticated information technology and infrastructure. Any significant breakdown, intrusion, interruption or corruption of these systems or data breaches could have a material adverse effect on our business. In addition, the Company currently is proceeding with a multi-year implementation of an enterprise wide resource planning system, which includes modification to the design, operation and documentation of its internal controls over financial reporting, and intends to implement the resource planning system in the U.S. in 2009. Any material problems in the implementation could have a material adverse effect on the Company's business.

**Cautionary Factors that May Affect Future Results**

(Cautionary Statements Under the Private Securities Litigation Reform Act of 1995)

This report, including the Annual Report, and other written reports and oral statements made from time to time by the Company may contain so-called forward-looking statements, all of which are based on management's current expectations and are subject to risks and uncertainties which may cause results to differ materially from those set forth in the statements. One can identify these forward-looking statements by their use of words such as expects, plans, will, estimates, forecasts, projects and other words of similar meaning. One can also identify them by the fact that they do not relate strictly to historical or current facts. These statements are likely to address the Company's growth strategy, financial results, product development, product approvals, product potential, and development programs. One must carefully consider any such statement and should understand that many factors could cause actual results to differ materially from the Company's forward-looking statements. These factors include inaccurate assumptions and a broad variety of other risks and uncertainties, including some that are known and some that are not. No forward-looking statement can be guaranteed and actual future results may vary materially. The Company does not assume the obligation to update any forward-looking statement. The Company cautions you not to place undue reliance on these forward-looking statements. Although it is not possible to predict or identify all such factors, they may include the following:

Significant litigation related to *Vioxx*.

Competition from generic products as the Company's products lose patent protection.

Increased brand competition in therapeutic areas important to the Company's long-term business performance.

The difficulties and uncertainties inherent in new product development. The outcome of the lengthy and complex process of new product development is inherently uncertain. A drug candidate can fail at any stage of the process and one or more late-stage product candidates could fail to receive regulatory approval. New product candidates may appear promising in development but fail to reach the market because of efficacy or safety concerns, the inability to obtain necessary regulatory approvals, the difficulty or excessive cost to manufacture and/or the infringement of patents or intellectual property rights of others. Furthermore, the sales of new products may prove to be disappointing and fail to reach anticipated levels.

Pricing pressures, both in the United States and abroad, including rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and health care reform, pharmaceutical reimbursement and pricing in general.

Changes in government laws and regulations and the enforcement thereof affecting the Company's business.

Efficacy or safety concerns with respect to marketed products, whether or not scientifically justified, leading to product recalls, withdrawals or declining sales.

Legal factors, including product liability claims, antitrust litigation and governmental investigations, including tax disputes, environmental concerns and patent disputes with branded and generic competitors, any of which could preclude commercialization of products or negatively affect the profitability of existing products.

Lost market opportunity resulting from delays and uncertainties in the approval process of the FDA and foreign regulatory authorities.



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Increased focus on privacy issues in countries around the world, including the United States and the EU. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues with the potential to affect directly the Company's business, including recently enacted laws in a majority of U.S. states requiring security breach notification.

Changes in tax laws including changes related to the taxation of foreign earnings.

Changes in accounting pronouncements promulgated by standard-setting or regulatory bodies, including the Financial Accounting Standards Board and the SEC, that are adverse to the Company.

Economic factors over which the Company has no control, including changes in inflation, interest rates and foreign currency exchange rates.

This list should not be considered an exhaustive statement of all potential risks and uncertainties. See Risk Factors above.

### **Item 1B. Unresolved Staff Comments.**

None

### **Item 2. Properties.**

The Company's corporate headquarters is located in Whitehouse Station, New Jersey. The Company's U.S. commercial operations are headquartered in Upper Gwynedd, Pennsylvania. The Company's U.S. pharmaceutical business is conducted through divisional headquarters located in Upper Gwynedd and Whitehouse Station, New Jersey. The Company's vaccines business is conducted through divisional headquarters located in West Point, Pennsylvania. Principal research facilities for human health products are located in Rahway, New Jersey and West Point. The Company also has production facilities for human health products at seven locations in the United States and Puerto Rico. Outside the United States, through subsidiaries, the Company owns or has an interest in manufacturing plants or other properties in Australia, Canada, Japan, Singapore, South Africa, and other countries in Western Europe, Central and South America, and Asia.

Capital expenditures for 2008 were \$1.3 billion compared with \$1.0 billion for 2007. In the United States, these amounted to \$946.6 million for 2008 and \$788.0 million for 2007. Abroad, such expenditures amounted to \$351.7 million for 2008 and \$223.0 million for 2007.

The Company and its subsidiaries own their principal facilities and manufacturing plants under titles which they consider to be satisfactory. The Company considers that its properties are in good operating condition and that its machinery and equipment have been well maintained. Plants for the manufacture of products are suitable for their intended purposes and have capacities and projected capacities adequate for current and projected needs for existing Company products. Some capacity of the plants is being converted, with any needed modification, to the requirements of newly introduced and future products.

### **Item 3. Legal Proceedings.**

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.

## **Vioxx Litigation**

### *Product Liability Lawsuits*

As previously disclosed, individual and putative class actions have been filed against the Company in state and federal courts alleging personal injury and/or economic loss with respect to the purchase or use of *Vioxx*. All such actions filed in federal court are coordinated in a multidistrict litigation in the U.S. District Court for the Eastern District of Louisiana (the MDL ) before District Judge Eldon E. Fallon. A number of such actions filed in state court are coordinated in separate coordinated proceedings in state courts in New Jersey, California and Texas,

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and the counties of Philadelphia, Pennsylvania and Washoe and Clark Counties, Nevada. As of December 31, 2008, the Company had been served or was aware that it had been named as a defendant in approximately 10,800 lawsuits, which include approximately 26,800 plaintiff groups, alleging personal injuries resulting from the use of *Vioxx*, and in approximately 242 putative class actions alleging personal injuries and/or economic loss. (All of the actions discussed in this paragraph and in *Other Lawsuits* below are collectively referred to as the *Vioxx* Product Liability Lawsuits.) Of these lawsuits, approximately 8,850 lawsuits representing approximately 22,050 plaintiff groups are or are slated to be in the federal MDL and approximately 165 lawsuits representing approximately 165 plaintiff groups are included in a coordinated proceeding in New Jersey Superior Court before Judge Carol E. Higbee.

Of the plaintiff groups described above, most are currently in the *Vioxx* Settlement Program, described below. As of December 31, 2008, 70 plaintiff groups who were otherwise eligible for the Settlement Program have not participated and their claims remained pending against Merck. In addition, the claims of 1,400 plaintiff groups who are not eligible for the Settlement Program remained pending against Merck. A number of the 1,400 plaintiff groups are subject to motions to dismiss for failure to comply with court-ordered deadlines. Since December 31, 2008, hundreds of these plaintiff groups have since been dismissed.

In addition to the *Vioxx* Product Liability Lawsuits discussed above, the claims of over 27,400 plaintiffs had been dismissed as of December 31, 2008. Of these, there have been over 4,925 plaintiffs whose claims were dismissed with prejudice (i.e., they cannot be brought again) either by plaintiffs themselves or by the courts. Over 22,475 additional plaintiffs have had their claims dismissed without prejudice (i.e., subject to the applicable statute of limitations, they can be brought again). Of these, approximately 13,750 plaintiff groups represent plaintiffs who had lawsuits pending in the New Jersey Superior Court at the time of the Settlement Agreement described below and who enrolled in the program established by the Settlement Agreement (the *Settlement Program*), Judge Higbee has dismissed these cases without prejudice for administrative reasons.

On November 9, 2007, Merck announced that it had entered into an agreement (the *Settlement Agreement*) with the law firms that comprise the executive committee of the Plaintiffs Steering Committee (PSC) of the federal *Vioxx* MDL as well as representatives of plaintiffs counsel in the Texas, New Jersey and California state coordinated proceedings to resolve state and federal MI and IS claims filed as of that date in the United States. The Settlement Agreement, which also applies to tolled claims, was signed by the parties after several meetings with three of the four judges overseeing the coordination of more than 95% of the U.S. *Vioxx* Product Liability Lawsuits. The Settlement Agreement applies only to U.S. legal residents and those who allege that their MI or IS occurred in the United States.

The entire Settlement Agreement, including accompanying exhibits, may be found at [www.merck.com](http://www.merck.com). The Company has included this website address only as an inactive textual reference and does not intend it to be an active link to its website nor does it incorporate by reference the information contained therein. Under the Settlement Agreement, Merck will pay a fixed aggregate amount of \$4.85 billion into two funds (\$4.0 billion for MI claims and \$850 million for IS claims) for qualifying claims that enter into the Settlement Program. Individual claimants will be examined by administrators of the Settlement Program to determine qualification based on objective, documented facts provided by claimants, including records sufficient for a scientific evaluation of independent risk factors. The conditions in the Settlement Agreement also require claimants to pass three gates: an injury gate, a duration gate, and a proximity gate (each as defined in the Settlement Agreement).

The Settlement Agreement provides that Merck does not admit causation or fault. The Settlement Agreement provided that Merck's payment obligations would be triggered only if, among other conditions, (1) law firms on the federal and state PSCs and firms that have tried cases in the coordinated proceedings elect to recommend enrollment in the program to 100% of their clients who allege either MI or IS, and (2) by June 30, 2008, plaintiffs enroll in the Settlement Program at least 85% of each of all currently pending and tolled (i) MI claims, (ii) IS claims, (iii) eligible MI and IS claims together which involve death, and (iv) eligible MI and IS claims together which allege more than

12 months of use. Under the terms of the Settlement Agreement, Merck could exercise a right to walk away from the Settlement Agreement if the thresholds and other requirements were not met. The Company waived that right as of August 4, 2008. The waiver of that right triggered Merck's obligation to pay a fixed total of \$4.85 billion. Payments will be made in installments into the settlement funds. The first payment of

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\$500 million was made in August 2008 and an additional payment of \$250 million was made in October 2008. Interim payments have been made to certain plaintiffs who alleged that they suffered an MI and the Company anticipates that interim payments to IS claimants will begin shortly. Additional payments will be made on a periodic basis going forward, when and as needed to fund payments of claims and administrative expenses.

Merck's total payment for both funds of \$4.85 billion is a fixed amount to be allocated among qualifying claimants based on their individual evaluation. The distribution of interim payments to qualified claimants began in August 2008 and will continue on a rolling basis until all claimants who qualify for an interim payment are paid. Final payments will be made after the examination of all of the eligible claims has been completed.

After the Settlement Agreement was announced on November 9, 2007, judges in the Federal MDL, California, Texas and New Jersey State Coordinated Proceedings entered a series of orders. The orders: (1) temporarily stayed their respective litigations; (2) required plaintiffs to register their claims by January 15, 2008; (3) required plaintiffs with cases pending as of November 9, 2007 to preserve and produce records and serve expert reports; and (4) required plaintiffs who file thereafter to make similar productions on an accelerated schedule. The Clark County, Nevada and Washoe County, Nevada coordinated proceedings were also generally stayed.

As of October 30, 2008, the deadline for enrollment in the Settlement Program, more than 48,100 of the approximately 48,325 individuals who were eligible for the Settlement Program and whose claims were not 1) dismissed, 2) expected to be dismissed in the near future, or 3) tolled claims that appear to have been abandoned had submitted some or all of the materials required for enrollment in the Settlement Program. This represents approximately 99.8% of the eligible MI and IS claims previously registered with the Settlement Program.

On April 14, 2008 and June 3, 2008, two groups of various private insurance companies and health plans filed suit against BrownGreer, the claims administrator for the Settlement Program (the Claims Administrator), and U.S. Bancorp, escrow agent for the Settlement Program (the AvMed and Greater New York Benefit Fund suits). The private insurance companies and health plans claim to have paid healthcare costs on behalf of some of the enrolling claimants and seek to enjoin the Claims Administrator from paying enrolled claimants until their claims for reimbursement from the enrolled claimants are resolved. Each group sought temporary restraining orders and preliminary injunctions. Judge Fallon denied these requests. In AvMed, the defendants moved to sever the claims of the named plaintiffs and, in Greater New York Benefit Fund, to strike the class allegations. Judge Fallon granted these motions. AvMed appealed both of these decisions. The Fifth Circuit heard argument on AvMed's appeal on November 4, 2008. On November 17, 2008, the Court of Appeals affirmed the district court's ruling that denied the two motions for preliminary injunctive relief. Greater New York Benefit Fund has served a notice of appeal. On January 22, 2009, the PSC and counsel for certain private insurers announced that they reached a settlement agreement. The agreement provides a program for resolution of liens asserted by private insurers against payments received by certain claimants who have enrolled in the Settlement Program. The agreement can be terminated by the private insurers if fewer than 90% of eligible claimants participate. The plaintiffs in the AvMed and Greater New York Benefit Fund lawsuits have agreed to participate in the settlement.

There are two U.S. *Vioxx* Product Liability Lawsuits currently scheduled for trial in 2009. The Company maintains a list of such trials at its website at [www.merck.com](http://www.merck.com), which it will periodically update as appropriate. The Company has included its website address only as an inactive textual reference and does not intend it to be an active link to its website nor does it incorporate by reference the information contained therein.

The Company has previously disclosed the outcomes of several *Vioxx* Product Liability Lawsuits that were tried prior to 2008.

Juries have now decided in favor of the Company twelve times and in plaintiffs' favor five times. One Merck verdict was set aside by the court and has not been retried. Another Merck verdict was set aside and retried, leading to one of the five plaintiffs' verdicts. There have been two unresolved mistrials. With respect to the five plaintiffs' verdicts, Merck filed an appeal or sought judicial review in each of those cases. In one of those five, an intermediate appellate court overturned the trial verdict and directed that judgment be entered for Merck, and in another, an intermediate appellate court overturned the trial verdict, entering judgment for Merck on one claim and ordering a new trial on the remaining claims.

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All but the following three cases that went to trial are now resolved: *McDarby v. Merck*, *Ernst v. Merck*, and *Garza v. Merck*.

The first, *McDarby*, was originally tried along with a second plaintiff, *Cona*, in April 2006, in Superior Court of New Jersey, Law Division, Atlantic County. The jury returned a split verdict. The jury determined that *Vioxx* did not substantially contribute to the heart attack of Mr. *Cona*, but did substantially contribute to the heart attack of Mr. *McDarby*. The jury also concluded that, in each case, Merck violated New Jersey's consumer fraud statute, which allows plaintiffs to receive their expenses for purchasing the drug, trebled, as well as reasonable attorneys' fees. The jury awarded \$4.5 million in compensatory damages to Mr. *McDarby* and his wife, who also was a plaintiff in that case, as well as punitive damages of \$9 million. On June 8, 2007, Judge Higbee denied Merck's motion for a new trial. On June 15, 2007, Judge Higbee awarded approximately \$4 million in the aggregate in attorneys' fees and costs. The Company has appealed the judgments in both cases and the Appellate Division held oral argument on both cases on January 16, 2008. On May 29, 2008, the New Jersey Appellate Division vacated the consumer fraud awards in both cases on the grounds that the Product Liability Act provides the sole remedy for personal injury claims. The Appellate Division also vacated the *McDarby* punitive damage award on the ground of federal preemption and vacated the attorneys' fees and costs awarded under the Consumer Fraud Act in both cases. The Court upheld the *McDarby* compensatory award. The Company has filed with the Supreme Court of New Jersey a petition to appeal those parts of the trial court's rulings that the Appellate Division affirmed. Plaintiffs filed a cross-petition to appeal those parts of the trial court's rulings that the Appellate Division reversed. On October 8, 2008, the Supreme Court of New Jersey granted Merck's petition for certification of appeal, limited solely to the issue of whether the Federal Food, Drug and Cosmetic Act preempts state law tort claims predicated on the alleged inadequacy of warnings contained in *Vioxx* labeling that was approved by the FDA. The court denied the plaintiff's cross-petition. On December 4, 2008, the New Jersey Supreme Court granted Merck's motion to stay the appeal pending the issuance of a decision from United States Supreme Court in *Wyeth v. Levine*.

As previously reported, in September 2006, Merck filed a notice of appeal of the August 2005 jury verdict in favor of the plaintiff in the Texas state court case, *Ernst v. Merck*. On May 29, 2008, the Texas Court of Appeals reversed the trial court's judgment and issued a judgment in favor of Merck. The Court of Appeals found the evidence to be legally insufficient on the issue of causation. Plaintiffs have filed a motion for rehearing *en banc* in the Court of Appeals. Merck filed a response in October 2008. In January 2009, plaintiffs filed a reply in support of their rehearing motion.

As previously reported, in April 2006, in *Garza v. Merck*, a jury in state court in Rio Grande City, Texas returned a verdict in favor of the family of decedent Leonel Garza. The jury awarded a total of \$7 million in compensatory damages to Mr. Garza's widow and three sons. The jury also purported to award \$25 million in punitive damages even though under Texas law, in this case, potential punitive damages were capped at \$750,000. On May 14, 2008, the San Antonio Court of Appeals reversed the judgment and rendered a judgment in favor of Merck. On December 10, 2008, the Court of Appeals, on rehearing, vacated its prior ruling and issued a replacement. In the new ruling, the Court ordered a take-nothing judgment for Merck on the design defect claim, but reversed and remanded for a new trial as to the strict liability claim because of juror misconduct. On January 26, 2009, Merck filed a petition for review with the Texas Supreme Court.

Merck voluntarily withdrew *Vioxx* from the market on September 30, 2004. Most states have statutes of limitations for product liability claims of no more than three years, which require that claims must be filed within no more than three years after the plaintiffs learned or could have learned of their potential cause of action. As a result, some may view September 30, 2007 as a significant deadline for filing *Vioxx* cases. It is important to note, however, that the law regarding statutes of limitations can be complex and variable, depending on the facts and applicable law. Some states have longer statutes of limitations. There are also arguments that the statutes of limitations began running before September 30, 2004. New Jersey Superior Court Judge Higbee and Federal District Court Judge Fallon have issued orders in cases from New Jersey and eight other jurisdictions ruling that the statutory period for making *Vioxx*

personal injury claims has passed. Judge Higbee's order was issued on October 15, 2007 and Judge Fallon's was issued on November 8, 2007.



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### *Other Lawsuits*

As previously disclosed, on July 29, 2005, a New Jersey state trial court certified a nationwide class of third-party payors (such as unions and health insurance plans) that paid in whole or in part for the *Vioxx* used by their plan members or insureds. The named plaintiff in that case sought recovery of certain *Vioxx* purchase costs (plus penalties) based on allegations that the purported class members paid more for *Vioxx* than they would have had they known of the product's alleged risks. On March 31, 2006, the New Jersey Superior Court, Appellate Division, affirmed the class certification order. On September 6, 2007, the New Jersey Supreme Court reversed the certification of a nationwide class action of third-party payors, finding that the suit does not meet the requirements for a class action. Claims of certain individual third-party payors remain pending in the New Jersey court, and counsel purporting to represent a large number of third-party payors have filed additional such actions. Judge Higbee lifted the stay in these cases and the cases are currently in the discovery phase. A status conference with the court took place in January 2009 to discuss scheduling issues in these cases, including the selection of early trial pool cases.

The New Jersey Superior Court heard argument on plaintiffs' motion for class certification in *Martin-Kleinman v. Merck*, which is a putative consumer class action, on December 5, 2008.

There are also pending in various U.S. courts putative class actions purportedly brought on behalf of individual purchasers or users of *Vioxx* and claiming either reimbursement of alleged economic loss or an entitlement to medical monitoring. The majority of these cases are at early procedural stages. On June 12, 2008, a Missouri state court certified a class of Missouri plaintiffs seeking reimbursement for out-of-pocket costs relating to *Vioxx*. The plaintiffs do not allege any personal injuries from taking *Vioxx*. The Company filed a petition for interlocutory review on June 23, 2008, which was granted on July 30, 2008. Briefing is now complete. During the pendency of the appeal, discovery is proceeding in the lower court. On February 3, 2009, Judge Fallon dismissed the master personal injury/wrongful death class action master complaint and the medical monitoring class action master complaint in the MDL.

Plaintiffs also have filed a class action in California state court seeking class certification of California third-party payors and end-users. The parties are engaged in class certification discovery and briefing. The court heard oral argument on the class certification issue on February 19, 2009.

The Company has also been named as a defendant in eighteen separate lawsuits brought by Attorneys General of ten states, five counties, the City of New York, and private citizens (whom have brought *qui tam* and taxpayer derivative suits). One of the lawsuits brought by the counties is a class action filed by Santa Clara County, California on behalf of all similarly situated California counties. These actions allege that the Company misrepresented the safety of *Vioxx* and seek (i) recovery of the cost of *Vioxx* purchased or reimbursed by the state and its agencies; (ii) reimbursement of all sums paid by the state and its agencies for medical services for the treatment of persons injured by *Vioxx*; (iii) damages under various common law theories; and/or (iv) remedies under various state statutory theories, including state consumer fraud and/or fair business practices or Medicaid fraud statutes, including civil penalties.

With the exception of a case filed by the Texas Attorney General (which remains in Texas state court and is currently scheduled for trial in November 2009), a case filed by the Michigan Attorney General (which was ordered remanded to state court in January 2009), a case recently filed by the Pennsylvania Attorney General (which has been removed to federal court but is the subject of a pending motion to remand), and one case which has not been removed to federal court, the rest of the actions described in the above paragraph have been transferred to the federal MDL and are in the discovery phase.

### *Shareholder Lawsuits*

As previously disclosed, in addition to the *Vioxx* Product Liability Lawsuits, the Company and various current and former officers and directors are defendants in various putative class actions and individual lawsuits under the federal

securities laws and state securities laws (the *Vioxx* Securities Lawsuits ). All of the *Vioxx* Securities Lawsuits pending in federal court have been transferred by the Judicial Panel on Multidistrict Litigation (the *JPML* ) to the United States District Court for the District of New Jersey before District Judge Stanley R. Chesler for inclusion in a nationwide MDL (the *Shareholder MDL* ). Judge Chesler has consolidated the *Vioxx*

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Securities Lawsuits for all purposes. The putative class action, which requested damages on behalf of purchasers of Company stock between May 21, 1999 and October 29, 2004, alleged 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, and sought unspecified compensatory damages and the costs of suit, including attorneys' fees. The complaint also asserted claims under Section 20A of the Securities and Exchange Act against certain defendants relating to their sales of Merck stock and under Sections 11, 12 and 15 of the Securities Act of 1933 against certain defendants based on statements in a registration statement and certain prospectuses filed in connection with the Merck Stock Investment Plan, a dividend reinvestment plan. On April 12, 2007, Judge Chesler granted defendants' motion to dismiss the complaint with prejudice. Plaintiffs appealed Judge Chesler's decision to the United States Court of Appeals for the Third Circuit. On September 9, 2008, the Third Circuit issued an opinion reversing Judge Chesler's order and remanding the case to the District Court. On September 23, 2008, Merck filed a petition seeking rehearing *en banc*, which was denied. The case was remanded to the District Court in October 2008, and plaintiffs have filed their Consolidated and Fifth Amended Class Action Complaint. Merck filed a petition for a writ of certiorari with the United States Supreme Court on January 15, 2009. Merck expects to file a motion to dismiss the Fifth Amended Class Action Complaint.

In October 2005, a Dutch pension fund filed a complaint in the District of New Jersey alleging violations of federal securities laws as well as violations of state law against the Company and certain officers. Pursuant to the Case Management Order governing the Shareholder MDL, the case, which is based on the same allegations as the *Vioxx* Securities Lawsuits, was consolidated with the *Vioxx* Securities Lawsuits. Defendants' motion to dismiss the pension fund's complaint was filed on August 3, 2007. In September 2007, the Dutch pension fund filed an amended complaint rather than responding to defendants' motion to dismiss. In addition in 2007, six new complaints were filed in the District of New Jersey on behalf of various foreign institutional investors also alleging violations of federal securities laws as well as violations of state law against the Company and certain officers. Defendants are not required to respond to these complaints until after Judge Chesler resolves any motion to dismiss in the consolidated securities action.

As previously disclosed, various shareholder derivative actions filed in federal court were transferred to the Shareholder MDL and consolidated for all purposes by Judge Chesler (the *Vioxx* Derivative Lawsuits). On May 5, 2006, Judge Chesler granted defendants' motion to dismiss and denied plaintiffs' request for leave to amend their complaint. Plaintiffs appealed, arguing that Judge Chesler erred in denying plaintiffs' leave to amend their complaint with materials acquired during discovery. On July 18, 2007, the United States Court of Appeals for the Third Circuit reversed the District Court's decision on the grounds that Judge Chesler should have allowed plaintiffs to make use of the discovery material to try to establish demand futility, and remanded the case for the District Court's consideration of whether, even with the additional materials, plaintiffs' request to amend their complaint would still be futile. Plaintiffs filed their brief in support of their request for leave to amend their complaint in November 2007. The Court denied the motion in June 2008 and closed the case. Plaintiffs have appealed Judge Chesler's decision to the United States Court of Appeals for the Third Circuit.

In addition, as previously disclosed, various putative class actions filed in federal court under the Employee Retirement Income Security Act (ERISA) against the Company and certain current and former officers and directors (the *Vioxx* ERISA Lawsuits) and, together with the *Vioxx* Securities Lawsuits and the *Vioxx* Derivative Lawsuits, the *Vioxx* Shareholder Lawsuits) have been transferred to the Shareholder MDL and consolidated for all purposes. The consolidated complaint asserts claims on behalf of certain of the Company's current and former employees who are participants in certain of the Company's retirement plans for breach of fiduciary duty. The lawsuits make similar allegations to the allegations contained in the *Vioxx* Securities Lawsuits. On July 11, 2006, Judge Chesler granted in part and denied in part defendants' motion to dismiss the ERISA complaint. In October 2007, plaintiffs moved for certification of a class of individuals who were participants in and beneficiaries of the Company's retirement savings plans at any time between October 1, 1998 and September 30, 2004 and whose plan accounts included investments in

the Merck Common Stock Fund and/or Merck common stock. On February 9, 2009, the Court denied the motion for certification of a class as to one count and granted the motion as to the remaining counts. The Court also limited the class to those individuals who were participants in and beneficiaries of the Company's retirement savings plans who suffered a loss due to their investments in Merck stock through the plans and who did not execute a settlement releasing their claims. On October 6, 2008, defendants filed

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a motion for judgment on the pleadings seeking dismissal of the complaint. On December 24, 2008, plaintiffs filed a motion for partial summary judgment against certain individual defendants. Both motions are pending. Discovery is ongoing in this litigation.

As previously disclosed, on October 29, 2004, two individual shareholders made a demand on the Company's Board to take legal action against Mr. Raymond Gilmartin, former 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 December 2004, the Special Committee of the Board of Directors retained the Honorable John S. Martin, Jr. of Debevoise & Plimpton LLP to conduct an independent investigation of, among other things, the allegations set forth in the demand. Judge Martin's report was made public in September 2006. Based on the Special Committee's recommendation made after careful consideration of the Martin report and the impact that derivative litigation would have on the Company, the Board rejected the demand. On October 11, 2007, the shareholders filed a lawsuit in state court in Atlantic County, New Jersey against current and former executives and directors of the Company alleging that the Board's rejection of their demand was unreasonable and improper, and that the defendants breached various duties to the Company in allowing *Vioxx* to be marketed. The current and former executive and director defendants filed motions to dismiss the complaint in June 2008. On October 30, 2008, proceedings in the case were stayed through March 1, 2009. On November 21, 2008, the pending motions to dismiss were denied without prejudice.

*International Lawsuits*

As previously disclosed, in addition to the lawsuits discussed above, the Company has been named as a defendant in litigation relating to *Vioxx* in various countries (collectively, the *Vioxx* Foreign Lawsuits) in Europe, as well as Canada, Brazil, Argentina, Australia, Turkey, and Israel.

On May 30, 2008, the provincial court of Queen's Bench in Saskatchewan, Canada entered an order certifying a class of *Vioxx* users in Canada, except those in Quebec. The class includes individual purchasers who allege inducement to purchase by unfair marketing practices; individuals who allege *Vioxx* was not of acceptable quality, defective or not fit for the purpose of managing pain associated with approved indications; or ingestors who claim *Vioxx* caused or exacerbated a cardiovascular or gastrointestinal condition. On June 17, 2008, the Court of Appeal for Saskatchewan granted the Company leave to appeal the certification order. That appeal was argued before that court, and the court has reserved decision. On July 28, 2008, the Superior Court in Ontario denied the Company's motion to stay class proceedings in Ontario, which had been based on the earlier certification order entered in Saskatchewan, and decided to certify an overlapping class of *Vioxx* users in Canada, except those in Quebec and Saskatchewan, who allege negligence and an entitlement to elect to waive the tort. On November 24, 2008, the Ontario Divisional Court granted the Company's motion for leave to appeal the Superior Court's decision denying the stay of the Ontario class proceedings and denied the Company's motion to appeal the certification order. The Company's appeal was heard by the Ontario Divisional Court in February 2009. On February 13, 2009, the Divisional Court declined to set aside the order denying the stay. The Company intends to seek leave to appeal from the Ontario Court of Appeal. Earlier, in November 2006, the Superior court in Quebec authorized the institution of a class action on behalf of all individuals who, in Quebec, consumed *Vioxx* and suffered damages arising out of its ingestion. As of December 31, 2008, the plaintiffs have not instituted an action based upon that authorization.

A trial in a representative action in Australia is scheduled to commence on March 30, 2009, in the Federal Court of Australia. The named plaintiff, who alleges he suffered an MI, seeks to represent others in Australia who ingested *Vioxx* and suffered an MI, thrombotic stroke, unstable angina, transient ischemic attack or peripheral vascular disease. On November 24, 2008, the Company filed a motion for an order that the proceeding no longer continue as a representative proceeding. During a hearing on December 5, 2008, the court dismissed that motion and, on January 9, 2009, issued its reasons for that decision. On February 17, 2009, the Company's motion for leave to appeal that decision was denied and the parties were directed to prepare proposed lists of issues to be tried.



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### *Additional Lawsuits*

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

### *Insurance*

As previously disclosed, the Company has product liability insurance for claims brought in the *Vioxx* Product Liability Lawsuits with stated upper limits of approximately \$630 million after deductibles and co-insurance. This insurance provides coverage for legal defense costs and potential damage amounts in connection with the *Vioxx* Product Liability Lawsuits. Through an arbitration proceeding and negotiated settlements, the Company received an aggregate of approximately \$590 million in product liability insurance proceeds relating to the *Vioxx* Product Liability Lawsuits, plus approximately \$45 million in fees and interest payments. The Company has no additional insurance for the *Vioxx* Product Liability Lawsuits. The Company's insurance coverage with respect to the *Vioxx* Lawsuits will not be adequate to cover its defense costs and losses.

The Company has Directors and Officers insurance coverage applicable to the *Vioxx* Securities Lawsuits and *Vioxx* Derivative Lawsuits with stated upper limits of approximately \$190 million. The Company has Fiduciary and other insurance for the *Vioxx* ERISA Lawsuits with stated upper limits of approximately \$275 million. As a result of the arbitration, additional insurance coverage for these claims should also be available, if needed, under upper-level excess policies that provide coverage for a variety of risks. There are disputes with the insurers about the availability of some or all of the Company's insurance coverage for these claims and there are likely to be additional disputes. The amounts actually recovered under the policies discussed in this paragraph may be less than the stated upper limits.

### *Investigations*

As previously disclosed, in November 2004, the Company was advised by the staff of the 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 has received subpoenas from the DOJ 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. This investigation includes subpoenas for witnesses to appear before a grand jury. In addition, as previously disclosed, investigations are being conducted by local authorities in certain cities in Europe in order to determine whether any criminal charges should be brought concerning *Vioxx*. The Company is cooperating with these governmental entities in their respective investigations (the *Vioxx* Investigations ). The Company cannot predict the outcome of these inquiries; however, they could result in potential civil and/or criminal dispositions.

As previously disclosed, on May 20, 2008, the Company reached civil settlements with Attorneys General from 29 states and the District of Columbia to fully resolve previously disclosed investigations under state consumer protection laws related to past activities for *Vioxx*. As part of the civil resolution of these investigations, Merck paid a total of \$58 million to be divided among the 29 states and the District of Columbia. The agreement also includes compliance measures that supplement policies and procedures previously established by the Company.

In addition, the Company received a subpoena in September 2006 from the State of California Attorney General seeking documents and information related to the placement of *Vioxx* on California's Medi-Cal formulary. The Company is cooperating with the Attorney General in responding to the subpoena.

### *Reserves*

As discussed above, on November 9, 2007, Merck entered into the Settlement Agreement with the law firms that comprise the executive committee of the PSC of the federal *Vioxx* MDL as well as representatives of plaintiffs' counsel in the Texas, New Jersey and California state coordinated proceedings to resolve state and federal MI and IS claims

filed as of that date in the United States. The Settlement Agreement, which also applies to tolled claims, was signed by the parties after several meetings with three of the four judges overseeing the coordination of more than 95% of the current claims in the *Vioxx* Litigation. The Settlement Agreement applies only to U.S. legal residents and those who allege that their MI or IS occurred in the United States. In 2007, as a result of entering into



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the Settlement Agreement, the Company recorded a pretax charge of \$4.85 billion which represents the fixed aggregate amount to be paid to plaintiffs qualifying for payment under the Settlement Program.

The Company currently anticipates that two U.S. *Vioxx* Product Liability Lawsuits will be tried in 2009. Except with respect to the product liability trial scheduled to be held in Australia, the Company cannot predict the timing of any other trials related to the *Vioxx* Litigation. 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 not included in the Settlement Program. The Company has not established any reserves for any potential liability relating to the *Vioxx* Lawsuits not included in the Settlement Program or the *Vioxx* Investigations. In each of those cases the Company believes it has strong points to raise on appeal and therefore that unfavorable outcomes in such cases are not probable. Unfavorable outcomes in the *Vioxx* Litigation could have a material adverse effect on the Company's financial position, liquidity and results of operations.

Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable. As of December 31, 2007, the Company had an aggregate reserve of approximately \$5.372 billion (the *Vioxx* Reserve) for the Settlement Program and the Company's future legal defense costs related to the *Vioxx* Litigation.

During 2008, the Company spent approximately \$305 million in the aggregate, in legal defense costs worldwide related to (i) the *Vioxx* Product Liability Lawsuits, (ii) the *Vioxx* Shareholder Lawsuits, (iii) the *Vioxx* Foreign Lawsuits, and (iv) the *Vioxx* Investigations (collectively, the *Vioxx* Litigation). In the fourth quarter, the Company recorded a charge of \$62 million solely for its future legal defense costs related to the *Vioxx* Litigation. In addition, in the fourth quarter the Company paid an additional \$250 million into the settlement funds in connection with the Settlement Program after having paid \$500 million into the settlement funds in the third quarter. Consequently, as of December 31, 2008, the aggregate amount of the *Vioxx* Reserve was approximately \$4.379 billion. In addition to the *Vioxx* Reserve solely for its future legal defense costs, the Company considered the same factors that it considered when it previously established reserves for the *Vioxx* Litigation. Some of the significant factors considered in the review of the *Vioxx* Reserve were as follows: the actual costs incurred by the Company; the development of the Company's legal defense strategy and structure in light of the scope of the *Vioxx* Litigation, including the Settlement Agreement and the expectation that certain lawsuits will continue to be pending; the number of cases being brought against the Company; the costs and outcomes of completed trials and the most current information regarding anticipated timing, progression, and related costs of pre-trial activities and trials in the *Vioxx* Litigation. The amount of the *Vioxx* Reserve as of December 31, 2008, allocated solely to defense costs represents the Company's best estimate of the minimum amount of defense costs to be incurred in connection with the remaining aspects of the *Vioxx* Litigation; however, events such as additional trials in the *Vioxx* Litigation and other events that could arise in the course of the *Vioxx* Litigation could affect the ultimate amount of defense costs to be incurred by the Company.

The Company will continue to monitor its legal defense costs and review the adequacy of the associated reserves and may determine to increase the *Vioxx* Reserve at any time in the future if, based upon the factors set forth, it believes it would be appropriate to do so.

## **Other Product Liability Litigation**

As previously disclosed, the Company is a defendant in product liability lawsuits in the United States involving *Fosamax* (the *Fosamax* Litigation). As of December 31, 2008, approximately 779 cases, which include approximately 1,158 plaintiff groups had been filed and were pending against Merck in either federal or state court, including one case which seeks class action certification, as well as damages and/or medical monitoring. In these actions, plaintiffs

allege, among other things, that they have suffered osteonecrosis of the jaw, generally subsequent to invasive dental procedures, such as tooth extraction or dental implants and/or delayed healing, in association with the use of *Fosamax*. On August 16, 2006, the JPML ordered that the *Fosamax* product liability cases pending in federal courts nationwide should be transferred and consolidated into one multidistrict litigation (the *Fosamax* MDL ) for coordinated pre-trial proceedings. The *Fosamax* MDL has been transferred to Judge John Keenan in the

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United States District Court for the Southern District of New York. As a result of the JPML order, approximately 645 of the cases are before Judge Keenan. Judge Keenan has issued a Case Management Order (and various amendments thereto) setting forth a schedule governing the proceedings which focused primarily upon resolving the class action certification motions in 2007 and completing fact discovery in an initial group of 25 cases by October 1, 2008. Briefing and argument on plaintiffs' motions for certification of medical monitoring classes were completed in 2007 and Judge Keenan issued an order denying the motions on January 3, 2008. On January 28, 2008, Judge Keenan issued a further order dismissing with prejudice all class claims asserted in the first four class action lawsuits filed against Merck that sought personal injury damages and/or medical monitoring relief on a class wide basis. In October 2008, Judge Keenan issued an order requiring that *Daubert* motions be filed in May 2009 and scheduling trials in the first three cases in the MDL for August 2009, October 2009, and January 2010, respectively. A trial is scheduled in Alabama state court later in 2009.

In addition, in July 2008, an application was made by the Atlantic County Superior Court of New Jersey requesting that all of the *Fosamax* cases pending in New Jersey be considered for mass tort designation and centralized management before one judge in New Jersey. On October 6, 2008, the New Jersey Supreme Court ordered that all pending and future actions filed in New Jersey arising out of the use of *Fosamax* and seeking damages for existing dental and jaw-related injuries, including osteonecrosis of the jaw, but not solely seeking medical monitoring, be designated as a mass tort for centralized management purposes before Judge Higbee in Atlantic County Superior Court. As a result of the New Jersey Supreme Court's order, approximately 100 cases were coordinated as of December 31, 2008 before Judge Higbee, who is expected to begin setting various case management deadlines during the first quarter of 2009.

Discovery is ongoing in both the *Fosamax* MDL litigation as well as in various state court cases. The Company intends to defend against these lawsuits.

As of December 31, 2007, the Company had a remaining reserve of approximately \$27 million solely for its future legal defense costs for the *Fosamax* Litigation. During 2008, the Company spent approximately \$34 million and added \$40 million to its reserve. Consequently, as of December 31, 2008, the Company had a reserve of approximately \$33 million solely for its future legal defense costs for the *Fosamax* Litigation. Some of the significant factors considered in the establishment of the reserve for the *Fosamax* Litigation legal defense costs were as follows: the actual costs incurred by the Company thus far; the development of the Company's legal defense strategy and structure in light of the creation of the *Fosamax* MDL; the number of cases being brought against the Company; and the anticipated timing, progression, and related costs of pre-trial activities in the *Fosamax* Litigation. The Company will continue to monitor its legal defense costs and review the adequacy of the associated reserves. Due to the uncertain nature of litigation, the Company is unable to estimate its costs beyond the completion of the first three federal trials discussed above. The Company has not established any reserves for any potential liability relating to the *Fosamax* Litigation. Unfavorable outcomes in the *Fosamax* Litigation could have a material adverse effect on the Company's financial position, liquidity and results of operations.

**Commercial Litigation**

As previously disclosed, the Company was joined in ongoing litigation alleging manipulation by pharmaceutical manufacturers of Average Wholesale Prices (AWP), which are sometimes used in calculations that determine public and private sector reimbursement levels. In 2002, the JPML ordered the transfer and consolidation of all pending federal AWP cases to federal court in Boston, Massachusetts. Plaintiffs filed one consolidated class action complaint, which aggregated the claims previously filed in various federal district court actions and also expanded the number of manufacturers to include some which, like the Company, had not been defendants in any prior pending case. In May 2003, the court granted the Company's motion to dismiss the consolidated class action and dismissed the Company from the class action case. Subsequent to the Company's dismissal, the plaintiffs filed an amended consolidated class

action complaint, which did not name the Company as a defendant. The Company and many other pharmaceutical manufacturers are defendants in similar complaints pending in federal and state court brought individually by a number of counties in the State of New York. Fifty of the county cases have been consolidated in New York state court. The Company was dismissed from the Suffolk County case, which was the first of the New York county cases to be filed. In addition to the New York county cases, as of December 31, 2008, the Company was a defendant in state cases brought by the Attorneys General of eleven states,

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all of which are being defended. In February 2009, the Kansas Attorney General filed suit against Merck and several other manufacturers. Additionally, the Attorney General of Arizona voluntarily dismissed Merck from its case in February 2009. The court in the AWP cases pending in Hawaii listed Merck and others to be set for trial in mid-2010.

**Governmental Proceedings**

As previously disclosed, in February 2008, the Company announced that it entered into agreements with the government to settle federal and state civil cases alleging violations of the Medicaid Rebate Statute, as well as federal and state False Claims Acts in connection with certain nominal pricing programs and sales and marketing activities between 1994 and 2001. In connection with these settlements, as previously disclosed, Merck entered into a Corporate Integrity Agreement ( CIA ) with the U.S. Department of Health and Human Services Office of Inspector General ( HHS-OIG ) for a five-year term. The CIA requires, among other things, that Merck maintain its ethics training program and policies and procedures governing promotional practices and Medicaid price reporting. Further, as required by the CIA, Merck has retained an Independent Review Organization ( IRO ) to conduct a systems review of its promotional policies and procedures and to conduct, on a sample basis, transactional reviews of Merck's promotional programs and certain Medicaid pricing calculations. Merck is also required to provide regular reports and certifications to the HHS-OIG regarding its compliance with the CIA. The IRO is currently conducting the required reviews. Merck is scheduled to submit its first Annual Report to the HHS-OIG in May 2009.

**Vytorin/Zetia Litigation**

As previously disclosed, the Company and its joint venture partner, Schering-Plough, have received several letters addressed to both companies from the House Committee on Energy and Commerce, its Subcommittee on Oversight and Investigations ( O&I ), and the Ranking Minority Member of the Senate Finance Committee, collectively seeking a combination of witness interviews, documents and information on a variety of issues related to the ENHANCE clinical trial, the sale and promotion of *Vytorin*, as well as sales of stock by corporate officers. In addition, since August 2008, the companies have received three additional letters from O&I, including one dated February 19, 2009, seeking certain information and documents related to the SEAS clinical trial. As previously disclosed, the companies have each received subpoenas from the New York and New Jersey State Attorneys General Offices and a letter from the Connecticut Attorney General seeking similar information and documents. In addition, the Company has received five Civil Investigative Demands ( CIDs ) from a multistate group of 35 State Attorneys General who are jointly investigating whether the companies violated state consumer protection laws when marketing *Vytorin*. Finally, in September 2008, the Company received a letter from the Civil Division of the DOJ informing it that the DOJ is investigating whether the companies' conduct relating to the promotion of *Vytorin* caused false claims to be submitted to federal health care programs. The Company is cooperating with these investigations and working with Schering-Plough to respond to the inquiries. In addition, the Company has become aware of or been served with approximately 145 civil class action lawsuits alleging common law and state consumer fraud claims in connection with the MSP Partnership's sale and promotion of *Vytorin* and *Zetia*. Certain of those lawsuits allege personal injuries and/or seek medical monitoring. These actions, which have been filed in or transferred to federal court, are coordinated in a multidistrict litigation in the U.S. District Court for the District Court of New Jersey before District Judge Dennis M. Cavanaugh. The parties are presently engaged in motions practice and briefing.

Also, as previously disclosed, on April 3, 2008, a Merck shareholder filed a putative class action lawsuit in federal court in the Eastern District of Pennsylvania alleging that Merck and its Chairman, President and Chief Executive Officer, Richard T. Clark, violated the federal securities laws. This suit has since been withdrawn and re-filed in the District of New Jersey and has been consolidated with another federal securities lawsuit under the caption *In re Merck & Co., Inc. Vytorin Securities Litigation*. An amended consolidated complaint was filed on October 6, 2008 and names as defendants Merck; Merck/Schering-Plough Pharmaceuticals, LLC; and certain of the Company's officers and directors. Specifically, the complaint alleges that Merck delayed releasing unfavorable results of a clinical study

regarding the efficacy of *Vytorin* and that Merck made false and misleading statements about expected earnings, knowing that once the results of the *Vytorin* study were released, sales of *Vytorin* would decline and Merck's earnings would suffer. On April 22, 2008, a member of a Merck ERISA plan filed a putative

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class action lawsuit against the Company and certain of its officers and directors alleging they breached their fiduciary duties under ERISA. Since that time, there have been other similar ERISA lawsuits filed against the Company in the District of New Jersey, and all of those lawsuits have been consolidated under the caption *In re Merck & Co., Inc. Vytorin ERISA Litigation*. An amended consolidated complaint was filed on February 5, 2009, and names as defendants Merck and various members of Merck's Board of Directors and members of committees of Merck's Board of Directors. Plaintiffs allege that the ERISA plans' investment in Company stock was imprudent because the Company's earnings are dependent on the commercial success of its cholesterol drug *Vytorin* and that defendants knew or should have known that the results of a scientific study would cause the medical community to turn to less expensive drugs for cholesterol management. The Company intends to defend the lawsuits referred to in this section vigorously. Unfavorable outcomes resulting from the government investigations or the civil litigation could have a material adverse effect on the Company's financial position, liquidity and results of operations.

In November 2008, the individual shareholder who had previously delivered a letter to the Company's Board of Directors demanding that the Board take legal action against the responsible individuals to recover the amounts paid by the Company in 2007 to resolve certain governmental investigations delivered another letter to the Board demanding that the Board or a subcommittee thereof commence an investigation into the matters raised by various civil suits and governmental investigations relating to *Vytorin*.

**Vaccine Litigation**

As previously disclosed, the Company is a party to individual and class action product liability lawsuits and claims in the United States involving pediatric vaccines (e.g., hepatitis B vaccine) that contained thimerosal, a preservative used in vaccines. Merck has not distributed thimerosal-containing pediatric vaccines in the United States since the fall of 2001. As of December 31, 2008, there were approximately 230 thimerosal related lawsuits pending in which the Company is a defendant, although the vast majority of those lawsuits are not currently active. Other defendants include other vaccine manufacturers who produced pediatric vaccines containing thimerosal as well as manufacturers of thimerosal. In these actions, the plaintiffs allege, among other things, that they have suffered neurological injuries as a result of exposure to thimerosal from pediatric vaccines. There are no cases currently scheduled for trial. The Company will defend against these lawsuits; however, it is possible that unfavorable outcomes could have a material adverse effect on the Company's financial position, liquidity and results of operations.

The Company has been successful in having cases of this type either dismissed or stayed on the ground that the action is prohibited under the National Childhood Vaccine Injury Act (the Vaccine Act). The Vaccine Act prohibits any person from filing or maintaining a civil action (in state or federal court) seeking damages against a vaccine manufacturer for vaccine-related injuries unless a petition is first filed in the United States Court of Federal Claims (hereinafter the Vaccine Court). Under the Vaccine Act, before filing a civil action against a vaccine manufacturer, the petitioner must either (a) pursue his or her petition to conclusion in Vaccine Court and then timely file an election to proceed with a civil action in lieu of accepting the Vaccine Court's adjudication of the petition or (b) timely exercise a right to withdraw the petition prior to Vaccine Court adjudication in accordance with certain statutorily prescribed time periods. The Company is not a party to Vaccine Court proceedings because the petitions are brought against the United States Department of Health and Human Services.

The Company is aware that there are approximately 5,000 cases pending in the Vaccine Court involving allegations that thimerosal-containing vaccines and/or the *M-M-R II* vaccine cause autism spectrum disorders. Not all of the thimerosal-containing vaccines involved in the Vaccine Court proceeding are Company vaccines. The Company is the sole source of the *M-M-R II* vaccine domestically. The Special Masters presiding over the Vaccine Court proceedings held hearings in three test cases involving the theory that the combination of *M-M-R II* vaccine and thimerosal in vaccines causes autism spectrum disorders. On February 12, 2009, the Special Masters issued decisions in each of those cases, finding that the theory was unsupported by valid scientific evidence and that the petitioners in the three

cases were therefore not entitled to compensation. The Special Masters have held similar hearings in three different test cases involving the theory that thimerosal in vaccines alone causes autism spectrum disorders. Decisions have not been issued in this second set of test cases. The Special Masters had previously indicated that they would hold similar hearings involving the theory that *M-M-R II* alone causes autism spectrum disorders, but they have stated that they no longer intend to do so. The Vaccine Court has indicated that it intends to



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use the evidence presented at these test case hearings to guide the adjudication of the remaining autism spectrum disorder cases.

**Patent Litigation**

From time to time, generic manufacturers of pharmaceutical products file ANDAs with the FDA seeking to market generic forms of the Company's products prior to the expiration of relevant patents owned by the Company. Generic pharmaceutical manufacturers have submitted ANDAs to the FDA seeking to market in the United States a generic form of *Fosamax*, *Nexium*, *Singulair*, *Primaxin* and *Emend* prior to the expiration of the Company's (and AstraZeneca's in the case of *Nexium*) patents concerning these products. In addition, an ANDA has been submitted to the FDA seeking to market in the United States a generic form of *Zetia* prior to the expiration of Schering-Plough's patent concerning that product. The generic companies' ANDAs generally include allegations of non-infringement, invalidity and unenforceability of the patents. The Company has filed patent infringement suits in federal court against companies filing ANDAs for generic alendronate (*Fosamax*), montelukast (*Singulair*), imipenem/cilastatin (*Primaxin*) and AstraZeneca and the Company have filed patent infringement suits in federal court against companies filing ANDAs for generic esomeprazole (*Nexium*). Also, the Company and Schering-Plough have filed a patent infringement suit in federal court against companies filing ANDAs for generic ezetimibe (*Zetia*). Similar patent challenges exist in certain foreign jurisdictions. The Company intends to vigorously defend its patents, which it believes are valid, against infringement by generic companies attempting to market products prior to the expiration dates of such patents. As with any litigation, there can be no assurance of the outcomes, which, if adverse, could result in significantly shortened periods of exclusivity for these products.

In February 2007, Schering-Plough received a notice from a generic company indicating that it had filed an ANDA for *Zetia* and that it is challenging the U.S. patents that are listed for *Zetia*. Merck and Schering-Plough market *Zetia* through a joint venture, MSP Singapore Company LLC. On March 22, 2007, Schering-Plough and MSP Singapore Company LLC filed a patent infringement suit against Glenmark Pharmaceuticals Inc., USA and its parent corporation (Glenmark). The lawsuit automatically stays FDA approval of Glenmark's ANDA until October 2010 or until an adverse court decision, if any, whichever may occur earlier.

As previously disclosed, in January 2007, the Company received a letter from Ranbaxy Laboratories Ltd. (Ranbaxy) stating that it had filed an ANDA seeking approval of a generic version of Merck's *Primaxin* (imipenem/cilastatin). The lawsuit asserted infringement on Merck's patent which is due to expire on September 15, 2009. In July 2008, Merck and Ranbaxy entered into an agreement pursuant to which Ranbaxy can begin to market in the United States a generic form of imipenem/cilastatin on September 1, 2009.

As previously disclosed, in February 2007, the Company received a notice from Teva, a generic company, indicating that it had filed an ANDA for montelukast and that it is challenging the U.S. patent that is listed for *Singulair*. On April 2, 2007, the Company filed a patent infringement action against Teva. The lawsuit automatically stays FDA approval of Teva's ANDA until August 2009 or until an adverse court decision, if any, whichever may occur earlier. A trial in this matter commenced on February 23, 2009.

As previously disclosed, in January 2005, the U.S. Court of Appeals for the Federal Circuit in Washington, DC found the Company's patent claims for once-weekly administration of *Fosamax* to be invalid. The Company exhausted all options to appeal this decision in 2005. Based on the Court of Appeals' decision, *Fosamax* and *Fosamax Plus D* lost marketing exclusivity in the United States in 2008. As a result of these events, the Company is experiencing significant declines in *Fosamax* and *Fosamax Plus D* U.S. sales. Similarly, in most major foreign markets the basic use patent covering alendronate expired in 2008 and generic products are being sold.

In May 2005, the Federal Court of Canada Trial Division issued a decision refusing to bar the approval of generic alendronate on the grounds that Merck's patent for weekly alendronate was likely invalid. This decision cannot be appealed and generic alendronate was launched in Canada in June 2005. In July 2005, Merck was sued in the Federal Court of Canada by Apotex Corp. ( Apotex ) seeking damages for lost sales of generic weekly alendronate due to the patent proceeding. In October 2008, the Federal Court of Canada issued a decision awarding Apotex its lost profits for its generic alendronate product for the period of time that it was held off the market due to Merck's lawsuit. The Company has appealed this decision.

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As previously disclosed, in September 2004, the Company appealed a decision of the Opposition Division of the European Patent Office ( EPO ) that revoked the Company's patent in Europe that covers the once-weekly administration of alendronate. On March 14, 2006, the Board of Appeal of the EPO upheld the decision of the Opposition Division revoking the patent. On March 28, 2007, the EPO issued another patent in Europe to the Company that covers the once-weekly administration of alendronate. Under its terms, this new patent is effective until July 2018. The Company has sued multiple parties in European countries asserting its European patent covering once-weekly dosing of *Fosamax*. Oppositions have been filed in the EPO against this patent. A hearing in that proceeding is scheduled for March 2009.

In addition, as previously disclosed, in Japan after a proceeding was filed challenging the validity of the Company's Japanese patent for the once-weekly administration of alendronate, the patent office invalidated the patent. The decision is under appeal.

In October 2008, the U.S. patent for dorzolamide, covering both *Trusopt* and *Cosopt*, expired, after which the Company experienced a significant decline in U.S. sales of these products. The Company is involved in litigation proceedings of the corresponding patents in Canada and Great Britain.

The Company and AstraZeneca received notice in October 2005 that Ranbaxy had filed an ANDA for esomeprazole magnesium. The ANDA contains Paragraph IV challenges to patents on *Nexium*. In November 2005, the Company and AstraZeneca sued Ranbaxy in the United States District Court in New Jersey. As previously disclosed, AstraZeneca, Merck and Ranbaxy have entered into a settlement agreement which provides that Ranbaxy will not bring its generic esomeprazole product to market in the United States until May 27, 2014. The Company and AstraZeneca each received a CID from the United States Federal Trade Commission (the FTC ) in July 2008 regarding the settlement agreement with Ranbaxy. The Company is cooperating with the FTC in responding to this CID.

The Company and AstraZeneca received notice in January 2006 that IVAX Pharmaceuticals, Inc. ( IVAX ), subsequently acquired by Teva, had filed an ANDA for esomeprazole magnesium. The ANDA contains Paragraph IV challenges to patents on *Nexium*. In March 2006, the Company and AstraZeneca sued Teva in the United States District Court in New Jersey. In January 2008, the Company and AstraZeneca sued Dr. Reddy's Laboratories ( Dr. Reddy's ) in the District Court in New Jersey based on Dr. Reddy's filing of an ANDA for esomeprazole magnesium. A trial has been scheduled for January 2010 with respect to both IVAX's and Dr. Reddy's ANDAs. In addition, the Company and AstraZeneca received notice in December 2008 that Sandoz Inc. ( Sandoz ) had filed an ANDA for esomeprazole magnesium. The ANDA contains Paragraph IV challenges to patents on *Nexium*. In January 2009, the Company and AstraZeneca sued Sandoz in the District Court in New Jersey based on Sandoz's filing of an ANDA for esomeprazole magnesium.

In January 2009, the Company received notice that an ANDA was filed with the FDA for aprepitant which contained a Paragraph IV challenge to patents on *Emend*. The Company is evaluating the information provided with the notice to determine what action should be taken.

In Europe, the Company is aware of various companies seeking registration for generic losartan (the active ingredient for *Cozaar*). The Company has patent rights to losartan via license from E.I. du Pont de Nemours and Company ( du Pont ). The Company and du Pont have filed patent infringement proceedings against various companies in Portugal, Spain, Norway and Austria.

## **Other Litigation**

In February 2008, an individual shareholder delivered a letter to the Company's Board of Directors demanding that the Board take legal action against the responsible individuals to recover the amounts paid by the Company in 2007 to

resolve certain governmental investigations.

As previously disclosed, prior to the spin-off of Medco Health Solutions, Inc. ( Medco Health ), the Company and Medco Health agreed to settle, on a class action basis, a series of lawsuits asserting violations of ERISA (the Gruer Cases ). The Company, Medco Health and certain plaintiffs counsel filed the settlement agreement with the federal District Court in New York, where cases commenced by a number of plaintiffs, including participants in a number of pharmaceutical benefit plans for which Medco Health is the pharmacy benefit manager,

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as well as trustees of such plans, have been consolidated. Medco Health and the Company agreed to the proposed settlement in order to avoid the significant cost and distraction of prolonged litigation. The proposed class settlement has been agreed to by plaintiffs in five of the cases filed against Medco Health and the Company. Under the proposed settlement, the Company and Medco Health have agreed to pay a total of \$42.5 million, and Medco Health has agreed to modify certain business practices or to continue certain specified business practices for a period of five years. The financial compensation is intended to benefit members of the settlement class, which includes ERISA plans for which Medco Health administered a pharmacy benefit at any time since December 17, 1994. The District Court held hearings to hear objections to the fairness of the proposed settlement and approved the settlement in 2004, but has not yet determined the number of class member plans that have properly elected not to participate in the settlement. The settlement becomes final only if and when all appeals have been resolved. Certain class member plans have indicated that they will not participate in the settlement. Cases initiated by three such plans and two individuals remain pending in the Southern District of New York. Plaintiffs in these cases have asserted claims based on ERISA as well as other federal and state laws that are the same as or similar to the claims that had been asserted by settling class members in the Gruer Cases. The Company and Medco Health are named as defendants in these cases.

Three notices of appeal were filed and the appellate court heard oral argument in May 2005. In December 2005, the appellate court issued a decision vacating the District Court's judgment and remanding the cases to the District Court to allow the District Court to resolve certain jurisdictional issues. A hearing was held to address such issues in February 2006. The District Court issued a ruling in August 2006 resolving such jurisdictional issues in favor of the settling plaintiffs. The class members and the other party that had previously appealed the District Court's judgment renewed their appeals. In October 2007, the renewed appeals were affirmed in part and vacated in part by the federal court of appeals. The appeals court remanded the class settlement for further proceedings in the District Court.

The District Court preliminarily approved the amended settlement in May 2008. However, plaintiffs that had initially opted out of the settlement class filed objections to the settlement. The District Court ordered briefing on the objections and heard argument in October 2008. The District Court has not yet issued its ruling on those objections.

After the spin-off of Medco Health, Medco Health assumed substantially all of the liability exposure for the matters discussed in the foregoing three paragraphs. These cases are being defended by Medco Health.

There are various other legal proceedings, principally product liability and intellectual property suits involving the Company, which are pending. While it is not feasible to predict the outcome of such proceedings or the proceedings discussed in this Item, in the opinion of the Company, all such proceedings are either adequately covered by insurance or, if not so covered, should not ultimately result in any liability that would have a material adverse effect on the financial position, liquidity or results of operations of the Company, other than proceedings for which a separate assessment is provided in this Item.

## **Environmental Matters**

The Company is a party to a number of proceedings brought under the Comprehensive Environmental Response, Compensation and Liability Act, commonly known as Superfund, and other federal and state equivalents. These proceedings seek to require the operators of hazardous waste disposal facilities, transporters of waste to the sites and generators of hazardous waste disposed of at the sites to clean up the sites or to reimburse the government for cleanup costs. The Company has been made a party to these proceedings as an alleged generator of waste disposed of at the sites. In each case, the government alleges that the defendants are jointly and severally liable for the cleanup costs. Although joint and several liability is alleged, these proceedings are frequently resolved so that the allocation of cleanup costs among the parties more nearly reflects the relative contributions of the parties to the site situation. The Company's potential liability varies greatly from site to site. For some sites the potential liability is *de minimis* and for others the costs of cleanup have not yet been determined. While it is not feasible to predict the outcome of many of

these proceedings brought by federal or state agencies or private litigants, in the opinion of the Company, such proceedings should not ultimately result in any liability which would have a material adverse effect on the financial position, results of operations, liquidity or capital resources of the Company. The

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Company has taken an active role in identifying and providing for these costs and such amounts do not include any reduction for anticipated recoveries of cleanup costs from former site owners or operators or other recalcitrant potentially responsible parties.

As previously disclosed, approximately 2,200 plaintiffs have filed an amended complaint against Merck and 12 other defendants in United States District Court, Eastern District of California asserting claims under the Clean Water Act, the Resource Conservation and Recovery Act, as well as negligence and nuisance. The suit seeks damages for personal injury, diminution of property value, medical monitoring and other alleged real and personal property damage associated with groundwater and soil contamination found at the site of a former Merck subsidiary in Merced, California. The Company intends to defend itself against these claims.

**Item 4. Submission of Matters to a Vote of Security Holders.**

Not applicable.

**Executive Officers of the Registrant (ages as of February 1, 2009)**

RICHARD T. CLARK Age 62

April, 2007 Chairman, President and Chief Executive Officer

May, 2005 Chief Executive Officer and President

June, 2003 President, Merck Manufacturing Division responsible for the Company's manufacturing, information services and operational excellence organizations worldwide

ADELE D. AMBROSE Age 52

December, 2007 Vice President and Chief Communications Officer responsible for the Global Communications organization

April, 2005 On sabbatical

Prior to April 2005, Ms. Ambrose was Executive Vice President, Public Relations & Investor Communications at AT&T Wireless (wireless services provider from September 2001 to April 2005)

JOHN CANAN Age 52

January, 2008 Senior Vice President and Controller responsible for the Corporate Controller's Group

September, 2006 Vice President, Controller responsible for the Corporate Controller's Group

June, 2003 Vice President, Corporate Audit & Assurance Services

CELIA A. COLBERT Age 52

January, 2008 Senior Vice President, Secretary (since September, 1993) and Assistant General Counsel (since November, 1993) Responsible for Corporate Secretary function and Corporate Staff Legal Groups, functional responsibility for Office of Ethics and Compliance.

WILLIE A. DEESE Age 53

January, 2008 Executive Vice President and President, Merck Manufacturing Division ( MMD ) responsible for the Company s global manufacturing, procurement, and distribuion and logistics functions

May, 2005 President, MMD responsible for the Company s global manufacturing, procurement, and operational excellence functions



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January, 2004 Senior Vice President, Global Procurement

KENNETH C. FRAZIER Age 54

August, 2007 Executive Vice President and President, Global Human Health responsible for the Company's marketing and sales organizations worldwide, including the global pharmaceutical and vaccine franchises

November, 2006 Executive Vice President and General Counsel responsible for legal and public affairs functions and The Merck Company Foundation (a not-for-profit charitable organization affiliated with the Company)

December, 1999 Senior Vice President and General Counsel responsible for legal and public affairs functions and The Merck Company Foundation (a not-for-profit charitable organization affiliated with the Company)

MIRIAN M. GRADDICK-WEIR Age 54

January, 2008 Executive Vice President, Human Resources responsible for the Global Human Resources organization

September, 2006 Senior Vice President, Human Resources

Prior to September 2006, Dr. Graddick-Weir was Executive Vice President of Human Resources and Employee Communications at AT&T (communications services provider), and has held several other senior Human Resources leadership positions at AT&T for more than 20 years.

PETER N. KELLOGG Age 52

August, 2007 Executive Vice President and Chief Financial Officer responsible for the Company's worldwide financial organization, investor relations, corporate development and licensing, and the Company's joint venture relationships

Prior to August, 2007, Mr. Kellogg was Executive Vice President, Finance and Chief Financial Officer of Biogen Idec (biotechnology company) since November 2003, from the merger of Biogen, Inc. and IDEC Pharmaceuticals Corporation. Mr. Kellogg was formerly Executive Vice President, Finance and Chief Financial Officer of Biogen, Inc. after serving as Vice President, Finance and Chief Financial Officer since July 2000

PETER S. KIM Age 50

January, 2008 Executive Vice President and President, Merck Research Laboratories (since January, 2003) responsible for the Company's research and development efforts worldwide

BRUCE N. KUHLIK Age 52

January, 2008 Executive Vice President and General Counsel responsible for legal, communications, and public policy functions and The Merck Company Foundation (a not-for-profit charitable organization affiliated with the Company)

May, 2005 Vice President and Associate General Counsel primary responsibility for the Company's *Vioxx* litigation defense

Prior to May 2005, Mr. Kuhlik was Senior Vice President and General Counsel for the Pharmaceutical Research and Manufacturers of America since October, 2002

MARK E. MCDONOUGH Age 44

February, 2007 Vice President and Treasurer responsible for the Company's treasury function

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January, 2004 Assistant Treasurer, Global Capital Markets responsible for managing the Company's investment and financing portfolios and the treasury share repurchase program

MARGARET G. MCGLYNN Age 49

August, 2007 President, Merck Vaccines and Infectious Diseases global responsibilities for the vaccines business and infectious diseases franchise including the Company's Sanofi-Pasteur joint venture

August, 2005 President, Merck Vaccines global responsibilities for the vaccines business including the Company's Sanofi-Pasteur joint venture

January, 2003 President, U.S. Human Health responsible for one of the two prescription drug divisions (hospital and specialty product franchises) comprising U.S. Human Health ( USHH ), and the Managed Care Group of USHH

STEFAN OSCHMANN Age 51

September, 2006 President, Europe, Middle East, Africa & Canada responsible for the Company's business operations in Europe, Middle East, Africa and Canada

October, 2005 Senior Vice President, Worldwide Human Health Marketing

January, 2001 Managing Director, MSD Germany, a subsidiary of the Company

J. CHRIS SCALET Age 50

January, 2008 Executive Vice President, Global Services, and Chief Information Officer ( CIO ) responsible for Global Shared Services across the human resources, finance, site services and information services function; and the enterprise business process redesign initiative

January, 2006 Senior Vice President, Global Services, and CIO responsible for Global Shared Services across the human resources, finance, site services and information services function; and the enterprise business process redesign initiative

March, 2003 Senior Vice President, Information Services, and CIO responsible for all areas of information technology and services including application development, technical support, voice and data communications, and computer operations worldwide

ADAM H. SCHECHTER Age 44

August, 2007 President, Global Pharmaceuticals global responsibilities for the Company's atherosclerosis/cardiovascular, diabetes/obesity, oncology, specialty/neuroscience, respiratory, bone, arthritis and analgesia franchises as well as commercial responsibility in the United States for the Company's portfolio of prescription medicines

July, 2006 President, U.S. Human Health commercial responsibility in the United States for the Company's portfolio of prescription medicines

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October, 2005 General Manager, U.S. Human Health responsible for the Neuro-Psychiatry, Osteoporosis, Migraine, Respiratory, and New Products franchises

February, 2004 Vice President/General Manager, Merck/Schering-Plough Pharmaceuticals U.S. Joint Venture

All officers listed above serve at the pleasure of the Board of Directors. None of these officers was elected pursuant to any arrangement or understanding between the officer and the Board.

Table of Contents**PART II****Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.**

The principal market for trading of the Company's Common Stock is the New York Stock Exchange ( NYSE ) under the symbol MRK. The Common Stock market price information set forth in the table below is based on historical NYSE market prices.

The following table also sets forth, for the calendar periods indicated, the dividend per share information.

**Cash Dividends Paid per Common Share**

	Year	4th Q	3rd Q	2nd Q	1st Q
<b>2008</b>	<b>\$ 1.52</b>	<b>\$ 0.38</b>	<b>\$ 0.38</b>	<b>\$ 0.38</b>	<b>\$ 0.38</b>
2007	\$ 1.52	\$ 0.38	\$ 0.38	\$ 0.38	\$ 0.38

**Common Stock Market Prices**

<b>2008</b>	4th Q	3rd Q	2nd Q	1st Q
<b>High</b>	<b>\$ 32.46</b>	<b>\$ 38.90</b>	<b>\$ 42.24</b>	<b>\$ 61.18</b>
<b>Low</b>	<b>\$ 22.82</b>	<b>\$ 30.34</b>	<b>\$ 34.49</b>	<b>\$ 36.82</b>
2007				
High	\$ 61.62	\$ 53.81	\$ 55.14	\$ 46.55
Low	\$ 51.44	\$ 48.11	\$ 44.52	\$ 42.35

As of January 31, 2009, there were approximately 165,169 stockholders of record.

**Equity Compensation Plan Information**

The following table summarizes information about the options, warrants and rights and other equity compensation under the Company's equity plans as of the close of business on December 31, 2008. The table does not include information about tax qualified plans such as the Merck & Co., Inc. Employee Savings and Security Plan.

**Number of  
securities**

<b>Plan Category</b>	<b>Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)</b>	<b>Weighted-average exercise price of outstanding options, warrants and rights (b)</b>	<b>remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)</b>
Equity compensation plans approved by security holders <sup>(1)</sup>	247,047,953 <sup>(2)</sup>	\$ 51.57	126,830,385
Equity compensation plans not approved by security holders <sup>(3)</sup>	-	-	-
<b>Total</b>	<b>247,047,953</b>	<b>\$ 51.57</b>	<b>126,830,385</b>

<sup>(1)</sup> Includes options to purchase shares of Company Common Stock and other rights under the following stockholder-approved plans: the 1996 Incentive Stock Plan, the 2001 Incentive Stock Plan, the 2004 Incentive Stock Plan, the 2007 Incentive Stock Plan, the 1996 Non-Employee Directors Stock Option Plan, the 2001 Non-Employee Directors Stock Option Plan and the 2006 Non-Employee Directors Stock Option Plan.

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- (2) *Excludes approximately 6,292,164 shares of restricted stock units and 3,242,796 performance share units (assuming maximum payouts) under the 2004 and 2007 Incentive Stock Plans. Also excludes 268,723 shares of phantom stock deferred under the Merck & Co., Inc. Deferral Program. As of December 31, 2006, no additional shares were reserved under the Deferral Program. Beginning January 1, 2007, one-tenth of 1 percent of the outstanding shares of Merck Common Stock on the last business day of the preceding calendar year plus any shares authorized under the Deferral Program but not issued are reserved for future issuance (2,643,159 as of December 31, 2008). The actual amount of shares to be issued prospectively equals the amount participants elect to defer from payouts under the Company's various incentive programs, such as the Executive Incentive Plan, into phantom stock, increased by the amount of dividends that would be paid on an equivalent number of shares of Merck Common Stock, divided by the market price of Merck Common Stock.*
- (3) *The table does not include information for equity compensation plans and options and other warrants and rights assumed by the Company in connection with mergers and acquisitions and pursuant to which there remain outstanding options or other warrants or rights (collectively, Assumed Plans), which include the following: Medco Containment Services, Inc. 1991 Class C Non-Qualified Stock Option Plan; SIBIA Neurosciences, Inc. 1996 Equity and Incentive Stock Option Plan; Provantage Health Services, Inc. 1999 Stock Incentive Plan; Rosetta Inpharmatics, Inc. 1997 and 2000 Employee Stock Option Plans. A total of 603,316 shares of Merck Common Stock may be purchased under the Assumed Plans, at a weighted average exercise price of \$22.59. No further grants may be made under any Assumed Plans.*

**Table of Contents****Performance Graph**

The following graph compares the cumulative total stockholder return (stock price appreciation plus reinvested dividends) on the Company's Common Stock with the cumulative total return (including reinvested dividends) of the Dow Jones US Pharmaceutical Index ( DJUSPR ), formerly referred to as the Dow Jones Pharmaceutical Index - United States Owned Companies, and the Standard & Poor's 500 Index ( S&P 500 Index ) for the five years ended December 31, 2008. Amounts below have been rounded to the nearest dollar or percent.

**Comparison of Five-Year Cumulative Total Return\***

Merck & Co., Inc., Dow Jones US Pharmaceutical Index and S&P 500 Index

				<b>End of Period Value</b>		<b>2008/2003 CAGR**</b>
MERCK				\$ 81		-4%
DJUSPR				88		-2
S&P 500				90		-2
	2003	2004	2005	2006	2007	2008
MERCK	100.00	72.36	75.30	107.42	147.54	80.69
DJUSPR	100.00	91.72	90.20	103.18	107.79	88.23
S&P 500	100.00	110.87	116.31	134.66	142.05	89.51

\* Assumes that the value of the investment in Company Common Stock and each index was \$100 on December 31, 2003 and that all dividends were reinvested.

\*\* Compound Annual Growth Rate



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Issuer purchases of equity securities for the three month period ended December 31, 2008 are as follows:

**Issuer Purchases of Equity Securities**

<b>Period</b>	<b>Total</b>		<b>Total Number of</b>	<b>(\$ in millions)</b>
	<b>Number</b>	<b>Average</b>	<b>Shares Purchased</b>	<b>Approx. Dollar Value</b>
	<b>of Shares</b>	<b>Price Paid</b>	<b>as Part of</b>	<b>of Shares That May</b>
	<b>Purchased</b>	<b>Per Share</b>	<b>Publicly Announced</b>	<b>Yet</b>
			<b>Plans or Programs<sup>(1)</sup></b>	<b>Be Purchased Under</b>
				<b>the</b>
				<b>Plans or Programs<sup>(1)</sup></b>
October 1				
October 31, 2008	7,241,000	\$28.95	7,241,000	\$ 2,372.7
November 1				
November 30, 2008	0	N/A	0	\$ 2,372.7
December 1				
December 31, 2008	0	N/A	0	\$ 2,372.7
Total	7,241,000	\$28.95	7,241,000	\$ 2,372.7

<sup>(1)</sup> *These share repurchases were made as part of a plan announced in July 2002 to purchase \$10 billion in Merck shares.*

**Table of Contents****Item 6. Selected Financial Data.**

The following selected financial data should be read in conjunction with Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations and consolidated financial statements and notes thereto contained in Item 8. Financial Statements and Supplementary Data of this report.

Merck & Co., Inc. and Subsidiaries  
(\$ in millions except per share amounts)

	2008 <sup>(1)</sup>	2007 <sup>(2)</sup>	2006 <sup>(3)</sup>	2005 <sup>(4)</sup>	2004 <sup>(5)</sup>
<b>Results for Year:</b>					
Sales	\$23,850.3	\$24,197.7	\$22,636.0	\$22,011.9	\$22,972.8
Materials and production costs	5,582.5	6,140.7	6,001.1	5,149.6	4,965.7
Marketing and administrative expenses	7,377.0	7,556.7	8,165.4	7,155.5	7,238.7
Research and development expenses	4,805.3	4,882.8	4,782.9	3,848.0	4,010.2
Restructuring costs	1,032.5	327.1	142.3	322.2	107.6
Equity income from affiliates	(2,560.6)	(2,976.5)	(2,294.4)	(1,717.1)	(1,008.2)
U.S. Vioxx Settlement Agreement charge	-	4,850.0	-	-	-
Other (income) expense, net	(2,194.2)	46.2	(382.7)	(110.2)	(344.0)
Income before taxes	9,807.8	3,370.7	6,221.4	7,363.9	8,002.8
Taxes on income	1,999.4	95.3	1,787.6	2,732.6	2,172.7
Net income	7,808.4	3,275.4	4,433.8	4,631.3	5,830.1
Basic earnings per common share	\$3.66	\$1.51	\$2.04	\$2.11	\$2.63
Earnings per common share assuming dilution	\$3.64	\$1.49	\$2.03	\$2.10	\$2.62
Cash dividends declared	3,250.4	3,310.7	3,318.7	3,338.7	3,329.1
Cash dividends paid per common share	\$1.52	\$1.52	\$1.52	\$1.52	\$1.49
Capital expenditures	1,298.3	1,011.0	980.2	1,402.7	1,726.1
Depreciation	1,445.1	1,752.4	2,098.1	1,544.2	1,258.7
<b>Year-End Position:</b>					
Working capital	\$4,986.2	\$2,787.2	\$2,507.5	\$7,806.9	\$1,688.8
Property, plant and equipment, net	11,999.6	12,346.0	13,194.1	14,398.2	14,713.7
Total assets	47,195.7	48,350.7	44,569.8	44,845.8	42,572.8
Long-term debt	3,943.3	3,915.8	5,551.0	5,125.6	4,691.5
Stockholders' equity	18,758.3	18,184.7	17,559.7	17,977.7	17,349.3

**Financial Ratios:**

Income as a % of sales	<b>32.7%</b>	13.5%	19.6%	21.0%	25.4%
Net income as a % of average total assets	<b>16.3%</b>	7.0%	9.9%	10.6%	14.0%

**Year-End Statistics:**

Average common shares outstanding (millions)	<b>2,135.8</b>	2,170.5	2,177.6	2,197.0	2,219.0
Average common shares outstanding assuming dilution (millions)	<b>2,145.3</b>	2,192.9	2,187.7	2,200.4	2,226.4
Number of stockholders of record	<b>165,700</b>	173,000	184,200	198,200	216,100
Number of employees	<b>55,200</b>	59,800	60,000	61,500	62,600

- (1) Amounts for 2008 include a gain on distribution from AstraZeneca LP, a gain related to the sale of the Company's remaining worldwide rights to Aggrastat, the favorable impact of certain tax items, the impact of restructuring actions, additional legal defense costs and an expense for a contribution to the Merck Company Foundation.
- (2) Amounts for 2007 include the impact of the U.S. Vioxx Settlement Agreement charge, restructuring actions, a civil governmental investigations charge, an insurance arbitration settlement gain, acquired research expense resulting from an acquisition, additional Vioxx legal defense costs, gains on sales of assets and product divestitures, as well as a net gain on the settlements of certain patent disputes.
- (3) Amounts for 2006 include the impact of restructuring actions, acquired research expenses resulting from acquisitions, additional Vioxx legal defense costs and the adoption of a new accounting standard requiring the expensing of stock options.
- (4) Amounts for 2005 include the impact of the net tax charge primarily associated with the American Jobs Creation Act repatriation, restructuring actions and additional Vioxx legal defense costs.
- (5) Amounts for 2004 include the impact of the withdrawal of Vioxx, Vioxx legal defense costs and restructuring actions.

**Table of Contents****Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.****Description of Merck's Business**

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. The Company's operations are principally managed on a products basis and are comprised of two reportable segments: the Pharmaceutical segment and the Vaccines and Infectious Diseases segment. The Pharmaceutical segment includes human health pharmaceutical products marketed either directly by Merck or through joint ventures. These products consist of therapeutic and preventive agents, sold by prescription, for the treatment of human disorders. Merck sells these human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions. The Vaccines and Infectious Diseases segment includes human health vaccine and infectious disease products marketed either directly by Merck or, in the case of vaccines, also through a joint venture. Vaccine products consist of preventative pediatric, adolescent and adult vaccines, primarily administered at physician offices. Merck sells these human health vaccines primarily to physicians, wholesalers, physician distributors and government entities. Infectious disease products consist of therapeutic agents for the treatment of infection sold primarily to drug wholesalers and retailers, hospitals and government agencies. The Company's professional representatives communicate the effectiveness, safety and value of its pharmaceutical and vaccine products to health care professionals in private practice, group practices and managed care organizations.

**Overview**

During 2008, the Company continued to address business challenges in the midst of an evolving pharmaceutical industry environment. Revenue declined by 1% in 2008 driven largely by lower sales of *Fosamax* for the treatment and prevention of osteoporosis. *Fosamax* and *Fosamax Plus D* lost market exclusivity for substantially all formulations in the United States in February 2008 and April 2008, respectively, and as a result the Company is experiencing a significant decline in sales in the United States within the *Fosamax* franchise. Also contributing to the decline were lower sales of *Zocor*, the Company's statin for modifying cholesterol which lost U.S. market exclusivity in 2006. Partially offsetting these declines were higher sales of *Januvia* and *Janumet* for the treatment of type 2 diabetes and *Isentress*, an antiretroviral therapy for the treatment of HIV infection.

To address the business and industry challenges that Merck faces, the Company remains focused on innovation and customer value in order to drive the growth of its business and help position Merck for future success.

The Company has made significant progress with re-engineering its operations through research and development initiatives, the roll-out of a new commercial model and the continuation of Merck's supply strategy. These activities should enable the Company to optimize its product portfolio and invest in growth opportunities, such as emerging markets, Merck BioVentures and business development.

Merck continues its efforts to diversify the Company's scientific portfolio both through internal programs and external research collaborations. The Company is focused on developing novel, best-in-class or follow-on treatments for patients in primary care, specialty care, and hospital settings. Additionally, Merck Research Laboratories is pursuing a portfolio of treatment modalities that not only includes small molecules and vaccines, but also biologics, peptides and RNA interference (RNAi). Further, Merck is moving to diversify its portfolio by creating a new division, Merck BioVentures, which leverages a unique technology platform for both follow-on and novel biologics.

The Company has numerous active clinical programs across the Company's major research franchises: bone, respiratory, immunology and endocrine; cardiovascular; diabetes and obesity; infectious diseases; neuroscience; oncology and vaccines. The Company currently has nine candidates in Phase III clinical development and anticipates submitting two New Drug Applications ( NDA ) with the U.S. Food and Drug Administration ( FDA ) with respect to two of the candidates in 2009: MK-0974, telcagepant, an investigational compound for the treatment of migraines, and MK-7418, rolofylline, an investigational compound for the treatment of acute heart failure. In addition, the Company anticipates submitting an NDA in 2009 for MK-0653C, ezetimibe combined with

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atorvastatin, an investigational medication for the treatment of dyslipidemia being developed by the Merck/Schering-Plough joint venture. Also, the Company anticipates regulatory action in 2009 on two supplemental filings that have been submitted to the FDA: one for *Gardasil*, Merck's HPV vaccine, for use in males; and one for *Isentress*, a first-in-class integrase inhibitor for the treatment of HIV-1 infection, for an expanded indication for use in treatment-naïve patients.

On the commercial side, the Company is rolling out a more customer-centric selling model that is designed to provide a competitive advantage, help build trust with customers, and improve patient outcomes. The strategy employs the use of new marketing technologies to complement a new, more customer-centered approach; and moves away from the traditional frequency-based sales and marketing approach; it also creates efficiencies by eliminating redundancies in core functions and across the sales organization.

On the manufacturing side, Merck has made significant progress in the three years since it began re-engineering to create a lean, flexible, cost-effective capability. The Company continues to address its manufacturing issues and it is working to build additional capacity in vaccines and biologics, as well as to support Merck's expansion into emerging markets. To assist this goal, the Company is shifting investments from developed markets into emerging markets commensurate with the size and strategic importance of the opportunity.

In October 2008, the Company announced a global restructuring program (the 2008 Restructuring Program) to reduce its cost structure, increase efficiency, and enhance competitiveness. As discussed above, Merck is rolling out a new, more customer-centric selling model. Additionally, the Company will make greater use of outside technology resources, centralize common sales and marketing activities, and consolidate and streamline its operations. Merck's manufacturing division will further focus its capabilities on core products and outsource non-core manufacturing. Also, Merck is expanding its access to worldwide external science through a basic research global operating strategy, which is designed to provide a sustainable pipeline and is focused on translating basic research productivity into late-stage clinical success. To increase efficiencies, basic research operations will consolidate work in support of a given therapeutic area into one of four locations. This will provide a more efficient use of research facilities and result in the closure of three basic research sites located in Tsukuba, Japan; Pomezia, Italy; and Seattle by the end of 2009. As part of the 2008 Restructuring Program, the Company expects to eliminate approximately 7,200 positions (6,800 active employees and 400 vacancies) across all areas of the Company worldwide by the end of 2011, approximately 1,750 of which the Company eliminated in 2008. About 40% of the total reductions will occur in the United States. As part of the 2008 Restructuring Program, the Company is streamlining management layers by reducing its total number of senior and mid-level executives globally by approximately 25%. The Company, however, continues to hire new employees as the business requires. The 2008 Restructuring Program is expected to be completed by the end of 2011 with the total pretax costs estimated to be \$1.6 billion to \$2.0 billion. In 2008, the Company recorded pretax restructuring costs of \$921.3 million related to the 2008 Restructuring Program. The Company estimates that two-thirds of the cumulative pretax costs will result in future cash outlays, primarily from employee separation expense. Approximately one-third of the cumulative pretax costs are non-cash, relating primarily to the accelerated depreciation of facilities to be closed or divested. Merck expects the 2008 Restructuring Program to yield cumulative pretax savings of \$3.8 billion to \$4.2 billion from 2008 to 2013.

During 2008, in connection with certain transactions with AstraZeneca LP (AZLP), the Company recorded an aggregate pretax gain of \$2.2 billion which is included in Other (income) expense, net and received net proceeds from AZLP of \$2.6 billion. See Note 8 to the consolidated financial statements for further information.

Earnings per common share (EPS) assuming dilution for 2008 were \$3.64, including the impact of the gain on distribution from AZLP of \$0.66 per share and restructuring costs of \$(0.44) per share. In addition, EPS in 2008 reflects the favorable impact of certain tax items. All of these items are discussed more fully in the notes to the consolidated financial statements.

**Competition and the Health Care Environment**

The markets in which the Company conducts its business are highly competitive and often highly regulated. Global efforts toward health care cost containment continue to exert pressure on product pricing and access.

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In the United States, the government expanded health care access by enacting the Medicare Prescription Drug Improvement and Modernization Act of 2003, which was signed into law in December 2003. Prescription drug coverage began on January 1, 2006. This legislation supports the Company's goal of improving access to medicines by expanding insurance coverage, while preserving market-based incentives for pharmaceutical innovation. At the same time, the legislation will ensure that prescription drug costs will be controlled by competitive pressures and by encouraging the appropriate use of medicines. The U.S. Congress has considered, and may consider again, proposals to increase the government's role in pharmaceutical pricing in the Medicare program. These proposals may include removing the current legal prohibition against the Secretary of the Health and Human Services intervening in price negotiations between Medicare drug benefit program plans and pharmaceutical companies. They may also include mandating the payment of rebates for some or all of the pharmaceutical utilization in Medicare drug benefit plans. In addition, Congress may again consider proposals to allow, under certain conditions, the importation of medicines from other countries.

In addressing cost-containment pressure, the Company has made a continuing effort to demonstrate that its medicines provide value to patients and those who pay for health care. In addition, pricing flexibility across the Company's product portfolio has encouraged growing use of its medicines and mitigated the effects of increasing cost pressures.

Outside the United States, in difficult environments encumbered by government cost-containment actions, the Company has worked in partnership with payers to encourage them to allocate scarce resources to optimize health care outcomes, limiting the potentially detrimental effects of government policies on sales growth and access to innovative medicines and vaccines, and to support the discovery and development of innovative products to benefit patients. The Company also is working with governments in many emerging markets in Eastern Europe, Latin America and Asia to encourage them to increase their investments in health and thereby improve their citizens' access to medicines. In addition, certain countries within the EU, recognizing the economic importance of the research-based pharmaceutical industry and the value of innovative medicines to society, are working with industry representatives to improve the competitive climate through a variety of means including market deregulation.

In order to advance the related policy debate, the EC launched the High Level Pharmaceutical Forum ( HLPF ) during the period 2005 through 2008. The initiative aimed at improving the prospects of the research-based pharmaceutical industry in Europe and thus the health prospects of all patients who will benefit from innovative therapies. Through an active dialogue among all stakeholders in the health care system (from payers to patients), this initiative was an attempt to tackle key policy issues in Europe: (i) promoting greater pricing flexibility for medicines; (ii) ensuring that health authorities apply best practices for the evaluation of the relative effectiveness of medicines; and (iii) improving greater access to information on medicines for patients in Europe. The Company was actively engaged with the EC and other stakeholders and was broadly in agreement with the recommendations from the HLPF.

In January 2008, the EC launched a sector inquiry in the pharmaceutical markets under the rules of EU competition law. As part of this inquiry, the Company's offices in Germany were inspected by the authorities beginning in January 2008. The Preliminary Report of the EC was issued on November 28, 2008, in which the EC stated it had confirmed its original hypothesis that competition in the pharmaceutical sector may be restricted or distorted, as indicated by a decline in innovation measured by the number of novel medicines reaching the market, and by alleged instances of delayed market entry of generic medicines. The public consultation period with respect to the Preliminary Report expired on January 31, 2009, and the EC has issued further inquiries in respect of the subject of the investigation. The EC has not alleged that the Company or any of its subsidiaries have engaged in any unlawful practices. The final report is planned for later in 2009. The Company is cooperating with the EC in this sector inquiry.

The Company is committed to improving access to medicines and enhancing the quality of life for people around the world. The African Comprehensive HIV/AIDS Partnerships in Botswana, a partnership between the government of Botswana, the Bill & Melinda Gates Foundation and The Merck Company Foundation/Merck & Co., Inc., is



supporting Botswana's response to HIV/AIDS through a comprehensive and sustainable approach to HIV prevention, care, treatment and support.

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To further catalyze access to HIV medicines in developing countries, under price reduction guidelines that the Company announced in 2001, Merck makes no profit on the sale of its current HIV/AIDS medicines in the world's poorest countries and those hardest hit by the pandemic, and offers its HIV/AIDS medicines at significantly reduced prices to medium-income countries. In February 2007, Merck announced that it had again reduced the price of *Stocrin* in the least developed countries of the world and those hardest hit by the pandemic. By the end of 2008, approximately 725,000 people living with HIV and AIDS in 125 developing countries and territories were estimated to be on treatment with antiretroviral regimens containing *Crixivan*, *Stocrin* or *Atripla*. Through these and other actions, Merck is working independently and with partners in the public and private sectors alike to focus on the most critical barriers to access to medicines in the developing world: the need for sustainable financing, increased international assistance and additional investments in education, training and health infrastructure and capacity in developing countries.

In October 2008, Merck announced that *RotaTeq* has been awarded pre-qualification status by the World Health Organization (WHO). WHO pre-qualification allows for expanded access to *RotaTeq* and provides a greater opportunity to help protect millions of infants from rotavirus gastroenteritis. Because *RotaTeq* is pre-qualified by the WHO, the vaccine is eligible for procurement by the Pan American Health Organization, UNICEF and other United Nations agencies for use in national vaccination programs. *RotaTeq* is the only ready-to-use oral liquid rotavirus vaccine to receive WHO pre-qualification. Merck has committed to providing *RotaTeq* to the Global Alliance for Vaccines and Immunization-eligible countries at prices at which it does not profit.

The Company is subject to a number of privacy and data protection laws and regulations globally. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues with the potential to affect directly the Company's business, including recently enacted laws in a majority of U.S. states requiring security breach notification.

Although no one can predict the outcome of these and other legislative, regulatory and advocacy initiatives, the Company is well positioned to respond to the evolving health care environment and market forces.

The Company anticipates that the worldwide trend toward cost-containment will continue, resulting in ongoing pressures on health care budgets. As the Company continues to successfully launch new products, contribute to health care debates and monitor reforms, its new products, policies and strategies should enable it to maintain a strong position in the changing economic environment.

**Acquisitions**

In September 2007, Merck completed the acquisition of NovaCardia, Inc. (NovaCardia) for \$366.4 million which was paid through the issuance of Merck common stock. NovaCardia is a clinical-stage pharmaceutical company focused on cardiovascular disease. This acquisition added rolofylline (MK-7418), NovaCardia's investigational Phase III compound for acute heart failure, to Merck's pipeline. In connection with the acquisition, the Company recorded a charge of \$325.1 million for acquired research associated with rolofylline as at the acquisition date, technological feasibility had not been established and no alternative future use existed. The charge was not deductible for tax purposes. The ongoing activity with respect to the future development of rolofylline continues and the costs have not been and are not expected to be material to the Company's research and development expenses.

In December 2006, Merck completed the acquisition of Sirna Therapeutics, Inc. (Sirna) for approximately \$1.1 billion. Sirna is a biotechnology company that is developing a new class of medicines based on RNAi technology, which could significantly alter the treatment of disease. In connection with the acquisition, the Company recorded a charge of \$466.2 million for acquired research associated with Sirna's compounds currently under development, which related to the development of treatments for both the hepatitis B and hepatitis C viruses, which

were in preclinical development, as well as licensing agreements held by Sirna. The charge was not deductible for tax purposes. The ongoing activity with respect to each of these compounds under development continues and the costs have not been and are not expected to be material to the Company's research and development expenses. The acquisition of Sirna has increased Merck's ability to use RNAi technology to turn off a targeted gene in a human cell, potentially rendering inoperative a gene responsible for triggering a specific disease.

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In June 2006, Merck acquired GlycoFi, Inc. ( GlycoFi ) a privately-held biotechnology company in the field of yeast glycoengineering, which is the addition of specific carbohydrate modifications to the proteins in yeast, and optimization of biologic drug molecules, for \$373 million in cash (\$400 million purchase price net of \$25 million of shares already owned and net transaction costs). The Company recorded a \$296.3 million charge for acquired research in connection with the acquisition which was not deductible for tax purposes. In May 2006, Merck acquired Abmaxis, Inc. ( Abmaxis ) a privately-held biopharmaceutical company dedicated to the discovery and optimization of monoclonal antibody products for human therapeutics and diagnostics, for \$80 million in cash. Substantially all of the purchase price was allocated to an intangible asset relating to Abmaxis' technology platform. While each of the acquisitions has independent scientific merits, the combination of the GlycoFi and Abmaxis platforms is potentially synergistic, giving Merck the ability to operate across the entire spectrum of therapeutic antibody discovery, development and commercialization.

See Note 4 to the consolidated financial statements for further discussion of these acquisitions.

**Operating Results***Sales*

Worldwide sales totaled \$23.9 billion for 2008, a decline of 1% compared with 2007, primarily attributable to a 4% volume decrease, partially offset by a 3% favorable effect from foreign exchange. The revenue decline over 2007 largely reflects lower sales of *Fosamax* for the treatment and prevention of osteoporosis. *Fosamax* and *Fosamax Plus D* lost market exclusivity for substantially all formulations in the United States in February 2008 and April 2008, respectively. Also contributing to the decline were lower sales of *Zocor*, the Company's statin for modifying cholesterol which lost U.S. market exclusivity in 2006, lower sales of *Vasotec/Vaseretic* for the treatment of hypertension and/or heart failure which lost patent protection in certain foreign markets and lower sales of certain vaccines, including hepatitis and Haemophilus influenzae type b ( HIB ) vaccines. Partially offsetting these declines were higher sales of *Januvia* and *Janumet* for the treatment of type 2 diabetes, *Isentress*, an antiretroviral therapy for the treatment of HIV infection, *Cozaar/Hyzaar* for the treatment of hypertension, *RotaTeq*, a vaccine to help protect against rotavirus gastroenteritis in infants and children, and *Singulair*, a medicine indicated for the chronic treatment of asthma and the relief of symptoms of allergic rhinitis.

Domestic sales declined 9% compared with 2007, while foreign sales rose 10%. Foreign sales represented 44% of total sales in 2008. The domestic sales decline was largely driven by lower sales of *Fosamax* and *Fosamax Plus D*, vaccines and *Singulair*, partially offset by higher sales of *Januvia*, *Janumet* and *Isentress*. Foreign sales growth reflects the strong performance of *Januvia*, *Janumet*, *Singulair*, *Cozaar/Hyzaar* and *Isentress*, partially offset by lower sales of *Vasotec/Vaseretic* and *Zocor*.

Worldwide sales for 2007 increased 7% in total compared with 2006 reflecting a 4% volume increase, a 2% favorable effect from foreign exchange and a less than 1% favorable effect from price changes. Sales growth was primarily driven by growth of the Company's vaccines, including *Gardasil*, a vaccine to help prevent cervical, vulvar and vaginal cancers, precancerous or dysplastic lesions, and genital warts caused by HPV types 6, 11, 16 and 18, *Varivax*, a vaccine to help prevent chickenpox, *RotaTeq* and *Zostavax*, a vaccine to help prevent shingles (herpes zoster). Also contributing to sales growth during this period was strong performance of *Singulair*, higher sales of *Januvia* and sales of *Janumet*, as well as increased sales of *Cozaar/Hyzaar*. Sales growth was partially offset by lower sales of *Zocor* and *Proscar*, a urology product for the treatment of symptomatic benign prostate enlargement. Merck's U.S. market exclusivity for *Proscar* expired in June 2006. Also offsetting sales growth in 2007 were lower revenues from the Company's relationship with AZLP and lower sales of *Fosamax* and *Fosamax Plus D*. Foreign sales represented 39% of total sales for 2007.



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<i>(\$ in millions)</i>	<b>2008</b>	2007	2006
<i>Pharmaceutical:</i>			
Singulair	\$ <b>4,336.9</b>	\$ 4,266.3	\$ 3,579.0
Cozaar/Hyzaar	<b>3,557.7</b>	3,350.1	3,163.1
Fosamax	<b>1,552.7</b>	3,049.0	3,134.4
Januvia	<b>1,397.1</b>	667.5	42.9
Cosopt/Trusopt	<b>781.2</b>	786.8	697.1
Zocor	<b>660.1</b>	876.5	2,802.7
Maxalt	<b>529.2</b>	467.3	406.4
Propecia	<b>429.1</b>	405.4	351.8
Arcoxia	<b>377.3</b>	329.1	265.4
Vasotec/Vaseretic	<b>356.7</b>	494.6	547.2
Janumet	<b>351.1</b>	86.4	-
Proscar	<b>323.5</b>	411.0	618.5
Emend	<b>263.8</b>	204.2	130.8
Other pharmaceutical <sup>(2)</sup>	<b>2,278.9</b>	2,422.9	2,780.5
Vaccine and infectious disease product sales included in the Pharmaceutical segment <sup>(3)</sup>	<b>2,187.6</b>	1,800.5	1,315.8
 Pharmaceutical segment revenues	 <b>19,382.9</b>	 19,617.6	 19,835.6
 <i>Vaccines<sup>(4)</sup> and Infectious Diseases:</i>			
Gardasil	<b>1,402.8</b>	1,480.6	234.8
ProQuad/M-M-R II/Varivax	<b>1,268.5</b>	1,347.1	820.1
RotaTeq	<b>664.5</b>	524.7	163.4
Zostavax	<b>312.4</b>	236.0	38.6
Hepatitis vaccines	<b>148.3</b>	279.9	248.5
Other vaccines	<b>354.6</b>	409.9	354.0
Primaxin	<b>760.4</b>	763.5	704.8
Candidas	<b>596.4</b>	536.9	529.8
Isentress	<b>361.1</b>	41.3	-
Crixivan/Stocrin	<b>275.1</b>	310.2	327.3
Invanz	<b>265.0</b>	190.2	139.2
Other infectious disease	<b>15.5</b>	1.7	-
Vaccine and infectious disease product sales included in the Pharmaceutical segment <sup>(3)</sup>	<b>(2,187.6)</b>	(1,800.5)	(1,315.8)
 Vaccines and Infectious Diseases segment revenues	 <b>4,237.0</b>	 4,321.5	 2,244.7
 Other segment revenues <sup>(5)</sup>	 <b>81.8</b>	 162.0	 162.1

Total segment revenues	<b>23,701.7</b>	24,101.1	22,242.4
Other <sup>(6)</sup>	<b>148.6</b>	96.6	393.6
	<b>\$ 23,850.3</b>	\$ 24,197.7	\$ 22,636.0

(1) *Presented net of discounts and returns.*

(2) *Other pharmaceutical primarily includes sales of other human pharmaceutical products and revenue from the Company's relationship with AZLP primarily relating to sales of Nexium, as well as Prilosec. Revenue from AZLP was \$1.6 billion, \$1.7 billion and \$1.8 billion in 2008, 2007 and 2006, respectively. In 2006, other pharmaceutical also reflects certain supply sales, including supply sales associated with the Company's arrangement with Dr. Reddy's Laboratories for the sale of generic simvastatin.*

(3) *Sales of vaccine and infectious disease products by non-U.S. subsidiaries are included in the Pharmaceutical segment.*

(4) *These amounts do not reflect sales of vaccines sold in most major European markets through the Company's joint venture, Sanofi Pasteur MSD, the results of which are reflected in Equity income from affiliates. These amounts do, however, reflect supply sales to Sanofi Pasteur MSD.*

(5) *Includes other non-reportable human and animal health segments.*

(6) *Other revenues are primarily comprised of miscellaneous corporate revenues, sales related to divested products or businesses and other supply sales not included in segment results.*

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The Company's pharmaceutical products include therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. Among these are *Singulair*, a leukotriene receptor antagonist for the chronic treatment of asthma and for the relief of symptoms of allergic rhinitis; *Cozaar*, *Hyzaar*, *Vasotec* and *Vaseretic*, the Company's most significant hypertension and/or heart failure products; *Fosamax* and *Fosamax Plus D* (marketed as *Fosavance* throughout the European Union ( EU ) and as *Fosamac* in Japan), for the treatment and, in the case of *Fosamax*, prevention of osteoporosis; *Januvia* and *Janumet*, for the treatment of type 2 diabetes; *Cosopt* and *Trusopt*, Merck's largest-selling ophthalmological products; *Zocor*, Merck's statin for modifying cholesterol; *Maxalt*, an acute migraine product; *Propecia*, a product for the treatment of male pattern hair loss; *Arcoxia*, for the treatment of arthritis and pain; *Proscar*, a urology product for the treatment of symptomatic benign prostate enlargement; and *Emend*, for the prevention of chemotherapy-induced and post-operative nausea and vomiting.

The Company's vaccine and infectious disease products include *Gardasil*, a vaccine to help prevent cervical, vulvar and vaginal cancers, precancerous or dysplastic lesions, and genital warts caused by HPV types 6, 11, 16 and 18; *Varivax*, a vaccine to help prevent chickenpox; *ProQuad*, a pediatric combination vaccine against measles, mumps, rubella and varicella; *M-M-R II*, a vaccine against measles, mumps and rubella; *RotaTeq*, a vaccine to help protect against rotavirus gastroenteritis in infants and children; *Zostavax*, a vaccine to help prevent shingles (herpes zoster); *Primaxin* and *Candidas*, anti-bacterial/anti-fungal products; *Isentress*, *Crixivan* and *Stocrin*, antiretroviral therapies for the treatment of HIV infection; and *Invanz* for the treatment of infection.

*Pharmaceutical Segment Revenues*

Sales of the Pharmaceutical segment declined 1% in 2008 primarily due to declines in *Fosamax*, *Zocor* and *Vasotec/Vaseretic*, partially offset by growth in *Januvia*, *Janumet* and *Cozaar/Hyzaar*. Sales of the Pharmaceutical segment declined 1% in 2007 primarily due to lower sales of *Zocor* and *Proscar* post patent expiration, partially offset by increases in *Singulair*, *Cozaar/Hyzaar*, *Januvia* and sales of *Janumet*.

Worldwide sales of *Singulair* grew 2% reaching \$4.3 billion in 2008 and rose 19% to \$4.3 billion in 2007, reflecting the continued demand for asthma and seasonal and perennial allergic rhinitis medications. Sales performance in 2008 benefited from higher sales outside the United States, including volume growth in Europe and Japan and the positive effect of foreign exchange. Sales in the United States declined reflecting the impact of the switch of a competing allergic rhinitis product to over-the-counter status in the United States in early 2008, the timing and public reaction to the FDA early communication regarding a very limited number of post-marketing adverse event reports which created uncertainty in the marketplace, and smaller spring and fall allergy seasons. *Singulair* continues to be the number one prescribed product in the U.S. respiratory market.

Global sales of *Cozaar*, and its companion agent *Hyzaar* (a combination of *Cozaar* and hydrochlorothiazide), increased 6% to \$3.6 billion in 2008 and grew 6% to \$3.4 billion in 2007. The increase in 2008 was driven by strong performance of *Hyzaar* in Japan (marketed as *Preminent*), as well as by the positive effect of foreign exchange. *Cozaar* and *Hyzaar* are among the leading medicines in the angiotensin receptor blocker class. *Cozaar* and *Hyzaar* will each lose patent protection in the United States in April 2010. The Company expects significant declines in U.S. sales of these products after that time.

Worldwide sales of *Fosamax* and *Fosamax Plus D* declined 49% in 2008 to \$1.6 billion and decreased 3% in 2007 to \$3.0 billion. Since substantially all formulations of these medicines have lost U.S. market exclusivity, the Company is experiencing significant declines in sales in the United States within the *Fosamax* franchise and the Company expects such declines to continue.

Global sales of *Januvia*, Merck's dipeptidyl peptidase-4 ( DPP-4 ) inhibitor, were \$1.4 billion in 2008, \$667.5 million in 2007 and \$42.9 million in 2006. *Januvia* was approved by the FDA in October 2006 and by the EC in March 2007.



*Januvia* continues to be the second leading branded oral anti-diabetic agent in terms of new prescription share in the United States. DPP-4 inhibitors represent a class of prescription medications that improve blood sugar control in patients with type 2 diabetes by enhancing a natural body system called the incretin system, which helps to regulate glucose by affecting the beta cells and alpha cells in the pancreas.

In November 2008, new data presented at the 61st Annual Scientific Meeting of the Gerontological Society of America showed *Januvia* significantly reduced blood sugar levels in elderly patients with type 2 diabetes and was not associated with hypoglycemia (low blood sugar). In this study of 206 patients aged 65 to 96 years, there

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were no reports of hypoglycemia in either the *Januvia* or the placebo groups. Advanced age contributes to the risk of hypoglycemia.

Worldwide sales of *Janumet*, Merck's oral antihyperglycemic agent that combines sitagliptin (Merck's DPP-4 inhibitor, *Januvia*) with metformin in a single tablet to target all three key defects of type 2 diabetes, were \$351.1 million in 2008 compared with \$86.4 million in 2007. *Janumet*, launched in the United States in April 2007, was approved, as an adjunct to diet and exercise, to improve blood sugar control in adult patients with type 2 diabetes who are not adequately controlled on metformin or sitagliptin alone, or in patients already being treated with the combination of sitagliptin and metformin. In February 2008, Merck received FDA approval to market *Janumet* as an initial treatment for type 2 diabetes when treatment with both sitagliptin and metformin is appropriate. In July 2008, *Janumet* was approved for marketing in the EU, Iceland and Norway.

Other products experiencing growth in 2008 include *Maxalt* to treat acute migraine pain, *Emend* for the prevention of chemotherapy-induced and post-operative nausea and vomiting, *Arcoxia* for the treatment of arthritis and pain, and *Propecia* for male pattern hair loss.

Worldwide sales of *Zocor* declined 25% in 2008 and 69% in 2007. *Zocor* lost U.S. market exclusivity in June 2006 and has also lost market exclusivity in many international markets.

In February 2006, the Company entered into an agreement with Dr. Reddy's Laboratories (Dr. Reddy's) that authorized the sale of generic simvastatin. Under the terms of the agreement, the Company was reimbursed on a cost-plus basis by Dr. Reddy's for supplying finished goods and received a share of the net profits recorded by Dr. Reddy's. In 2006, Merck recorded \$208.9 million of revenue associated with the Dr. Reddy's arrangement for simvastatin.

*Proscar* lost market exclusivity in the United States in June 2006. Merck's sales of *Proscar* declined 21% in 2008 and 34% in 2007. The basic patent for *Proscar* also covers *Propecia*, however, *Propecia* is protected by additional patents which expire in October 2013.

The patent that provided U.S. market exclusivity for *Cosopt* and *Trusopt* expired in October 2008 and, as a result, the Company is experiencing significant declines in U.S. sales of these products.

The patent that provides U.S. market exclusivity for *Primaxin* expires in September 2009. After such time, the Company expects a significant decline in U.S. sales of this product.

During 2008, the Company divested its remaining ownership of *Aggrastat* in foreign markets to Iroko Pharmaceuticals.

Also during 2008, the Company and AZLP entered into an agreement with Ranbaxy Laboratories Ltd. (Ranbaxy) to settle patent litigation with respect to esomeprazole (*Nexium*) which provides that Ranbaxy will not bring its generic esomeprazole product to market in the United States until May 27, 2014. The Company faces other challenges with respect to outstanding patent infringement matters for esomeprazole (see Note 10 to the consolidated financial statements).

In February 2009, the Company formally notified the European Medicines Agency of its decision to withdraw the application for Marketing Authorization for vorinostat, a histone deacetylase inhibitor, for treatment of patients with advanced stage, refractory cutaneous T-cell lymphoma (CTCL). Vorinostat, which is marketed as *Zolinza* in the United States, was granted orphan drug designation by the EC for the treatment of CTCL in 2004.

*Vaccines and Infectious Diseases Segment Revenues*

Sales of the Vaccines and Infectious Diseases segment were \$4.2 billion in 2008, \$4.3 billion in 2007 and \$2.2 billion in 2006. The decline in 2008 was primarily due to lower sales of *Gardasil*, hepatitis vaccines, other viral vaccines, which include *Varivax*, *M-M-R II* and *ProQuad*, HIB vaccines and lower sales of *Primaxin*. These declines were partially offset by growth in *Isentress*, *RotaTeq* and *Zostavax*. The increase in 2007 was primarily driven by the strong performance of *Gardasil*, as well as by *Varivax*, *RotaTeq* and *Zostavax*.

The following discussion of vaccine and infectious disease products includes total vaccine and infectious disease product sales, the majority of which are included in the Vaccines and Infectious Diseases segment and the remainder, representing sales of these products by non-U.S. subsidiaries, are included in the Pharmaceutical

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segment. These amounts do not reflect sales of vaccines sold in most major European markets through Sanofi Pasteur MSD ( SPMSD ), the Company's joint venture with Sanofi Pasteur, the results of which are reflected in Equity income from affiliates (see Selected Joint Venture and Affiliate Information below). Supply sales to SPMSD, however, are reflected in Vaccines and Infectious Diseases segment revenues.

Worldwide sales of the Company's cervical cancer vaccine *Gardasil*, as recorded by Merck, were \$1.4 billion in 2008, \$1.5 billion in 2007 and \$234.8 million in 2006. *Gardasil* was approved by the FDA in June 2006 and is the world's top-selling HPV vaccine and only HPV vaccine available for use in the United States. In September 2008, the FDA approved *Gardasil* for the prevention of vulvar and vaginal cancers caused by HPV types 16 and 18. *Gardasil* currently is indicated for girls and women 9 through 26 years of age for the prevention of cervical, vulvar and vaginal cancers, precancerous or dysplastic lesions, and genital warts caused by HPV types 6, 11, 16 and 18. Sales performance in 2008 reflects lower sales domestically, partially offset by growth outside the United States. Sales growth outside the United States was aided by the adoption of school-based programs in all Canadian provinces. The decline in the United States was affected by two factors. First, because of strong launch uptake, a significant portion of the 11 to 18 year old eligible population has already been vaccinated. As a result, despite continued strong vaccination rates in this population, the number of total vaccinations has declined. Secondly, the number of total vaccinations in the 19 to 26 year old age group has declined as compared with 2007. Sales in 2007 include initial purchases by many states through the U.S. Centers for Disease Control and Prevention ( CDC ) Vaccines for Children program. The Company is a party to certain third party license agreements with respect to *Gardasil* (including a cross-license and settlement agreement with GlaxoSmithKline). As a result of these agreements, the Company pays royalties on worldwide *Gardasil* sales of approximately 24% to 26% in the aggregate, which are included in Materials and production costs.

In January 2009, the FDA issued a second complete response letter regarding the supplemental biologics license application ( sBLA ) for the use of *Gardasil* in women ages 27 through 45. The agency completed its review of the response that Merck provided in July 2008 to the FDA's first complete response letter issued in June 2008 and has recommended that Merck submit additional data when the 48 month study has been completed. The initial sBLA included data collected through an average of 24 months from enrollment into the study, which is when the number of pre-specified endpoints had been met. Following a review of the final results of the study, Merck anticipates providing a response to the FDA in the fourth quarter of 2009. The letter does not affect current indications for *Gardasil* in females ages 9 through 26 nor does the letter relate to the sBLA that was submitted in December 2008 for the use of *Gardasil* in males.

In November 2008, data presented at the European Research Organization on Genital Infection and Neoplasia International Multidisciplinary Conference showed that *Gardasil* prevented 90% of external genital lesions caused by HPV types 6, 11, 16 and 18 in a pivotal Phase III study in men aged 16 to 26. These are the only data evaluating efficacy of any HPV vaccine in preventing disease in males. The initial planned analysis of this study, an analysis of male study participants aged 16 to 26 who had not been infected with at least one of the four HPV types before the start of the study through one month after receiving their third dose of the vaccine or placebo, has been completed. This analysis was predetermined in the study protocol to be conducted after at least 32 cases of external genital lesions were observed. The study is ongoing, and additional data will be submitted to global regulatory agencies once available. Merck submitted an sBLA for *Gardasil* in December 2008 which has been accepted by the FDA for the use of *Gardasil* in boys and men ages 9 to 26 for the prevention of external genital lesions caused by HPV types 6, 11, 16 and 18. Other regulatory submissions around the world will occur as planned.

*RotaTeq* achieved worldwide sales as recorded by Merck of \$664.5 million in 2008, \$524.7 million in 2007 and \$163.4 million in 2006. The increases in 2008 and 2007 were primarily driven by the continued uptake in the United States and successful launches around the world. The FDA approved *RotaTeq* in February 2006. Sales in 2008 included purchases of \$54 million in 2008 and \$78 million in 2007 to support the CDC stockpile. The Company

anticipates that domestic sales in 2009 will be impacted by the recent launch of a competing product.

As previously disclosed, the Company has resolved an issue related to the bulk manufacturing process for the Company's varicella zoster virus (VZV)-containing vaccines. The Company is manufacturing bulk varicella and is producing doses of *Varivax* and *Zostavax*. The Company has received regulatory approvals in the United States and certain other markets to increase its manufacturing capacity for VZV-containing vaccines. The Company is working to ensure adequate market supply and continued sufficient inventory of *Varivax* and to clear back orders

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and build stable supply and inventory for *Zostavax*. *ProQuad*, one of the VZV-containing vaccines, is currently not available for ordering; however, orders have been transitioned, as appropriate, to *M-M-R II* and *Varivax*. Total sales as recorded by Merck for *ProQuad* were \$9.5 million in 2008, \$264.4 million in 2007 and \$234.8 million in 2006. Merck anticipates that *ProQuad* will not return to the U.S. market in 2009.

Merck's sales of *Varivax* were \$924.6 million in 2008, \$854.9 million in 2007 and \$327.9 million in 2006. *Varivax* is the only vaccine available in the United States to help protect against chickenpox due to the unavailability of *ProQuad*. In 2007, *Varivax* benefited from the Advisory Committee on Immunization Practices June 2006 second dose recommendation. Merck's sales of *M-M-R II* were \$334.4 million in 2008, \$227.8 million in 2007 and \$257.3 million in 2006. Sales of *Varivax* and *M-M-R II* were affected by the unavailability of *ProQuad*. Combined sales of *ProQuad*, *M-M-R II* and *Varivax* declined in 2008 compared with 2007.

Sales of *Zostavax* recorded by Merck were \$312.4 million in 2008, \$236.0 million in 2007 and \$38.6 million in 2006. Sales in 2008 and 2007 were impacted by bulk vaccine supply issues that caused delays in the fulfillment of customer orders. The Company cleared the majority of backorders in December 2008. The Company expects to clear backorders that remained at the end of the year in the first quarter of 2009 and to return to normal shipping times in mid-2009. Once the backorders are resolved, the Company expects to have adequate supply to meet anticipated customer demand for the remainder of 2009. The Company currently anticipates launching *Zostavax* outside the United States after 2009. *Zostavax* was approved by the FDA as well as by regulatory authorities in Australia and the EU in May 2006. The vaccine is the first and only medical option for the prevention of shingles.

The Company has been working to resolve manufacturing issues related to its HIB-containing vaccines, *PedvaxHIB* and *Comvax* since December 2007. The Company has resolved the original issue related to equipment sterilization, but has identified other unrelated manufacturing process changes that will require a regulatory filing. Merck anticipates that *PedvaxHIB* and *Comvax* will return to the U.S. market in mid-to-late 2009. Timing of product availability outside the United States is dependent upon local regulatory requirements.

The pediatric formulation of *Vaqta*, a vaccine against hepatitis A, became available again in December of 2008 and the Company anticipates the adult formulation may be available in the second half of 2009. Outside of the United States, the supply of *Vaqta* is limited and availability will vary by region. In addition, doses of the adult and dialysis formulations of the Company's hepatitis B vaccine, *Recombivax HB*, will be depleted during the first quarter of 2009 after which time they will be unavailable in the United States for the remainder of the year. The pediatric/adolescent formulation of *Recombivax HB* is expected to experience intermittent backorders in the United States throughout 2009. Merck expects supplies of the pediatric/adolescent formulation of *Recombivax HB* to be limited throughout 2009 and the Company does not expect to return to full supply of the pediatric/adolescent formulation of *Recombivax HB* until some time in 2010.

Sales of *Isentress* were \$361.1 million in 2008 and \$41.3 million in 2007. In October 2007, the FDA granted *Isentress* accelerated approval for use in combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment-experienced adult patients who have evidence of viral replication and HIV-1 strains resistant to multiple antiretroviral agents. *Isentress* is the first medicine to be approved in the class of antiretroviral drugs called integrase inhibitors. *Isentress* works by inhibiting the insertion of HIV DNA into human DNA by the integrase enzyme. Inhibiting integrase from performing this essential function limits the ability of the virus to replicate and infect new cells. In January 2009, the FDA granted traditional approval to *Isentress* following review of the 48 week data from the BENCHMRK 1 & 2 clinical trials.

Merck is also conducting Phase III clinical trials of *Isentress* in the treatment-naïve (previously untreated) HIV population. In December 2008, Merck announced that the FDA had accepted the supplemental New Drug Application (sNDA) filing for *Isentress* tablets for standard review. The Company is seeking U.S. marketing approval of *Isentress*

in combination with other HIV medicines for treatment in adult patients who are previously untreated (naïve) for HIV. Merck expects FDA action in July 2009.

In February 2009, data on several Phase III *Isentress* studies were presented at the 16th Conference on Retroviruses and Opportunistic Infections in Montreal, Canada. In new subgroup analyses of a Phase III study (STARTMRK) that compared *Isentress* to efavirenz (one of the leading antiretrovirals prescribed for previously untreated (treatment-naïve) HIV-infected patients), *Isentress* was found to be as effective as efavirenz at

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suppressing viral load and provided improvements in immune system function across a broad spectrum of patient subpopulations through 48 weeks. The use of *Isentress* in previously untreated HIV-infected patients is an investigational use of the drug. Both medicines were taken in combination with tenofovir/emtricitabine. In addition, results from two Phase III studies (SWITCHMRK-1 and -2) evaluating the effect of switching patients whose HIV is controlled on a lopinavir/ritonavir-based regimen to a regimen containing *Isentress* tablets showed that *Isentress* significantly improved total cholesterol, triglycerides and non-HDL-cholesterol. The study also showed that *Isentress* did not demonstrate non-inferior virologic efficacy at maintaining viral load suppression. As a result of the viral load findings in these trials, Merck discontinued these two studies.

Other Vaccines and Infectious Diseases segment products experiencing growth in 2008 include *Invanz* for the treatment of infection and *Candidas*, an anti-fungal product.

In 2008, the FDA approved an expanded label for *Candidas*, which makes it the first and only echinocandin therapy approved in the United States for the treatment of pediatric patients aged three months to 17 years with indicated fungal infections.

**Costs, Expenses and Other**

(\$ in millions)	2008	Change	2007	Change	2006
Materials and production	\$ 5,582.5	-9%	\$ 6,140.7	2%	\$ 6,001.1
Marketing and administrative	7,377.0	-2%	7,556.7	-7%	8,165.4
Research and development	4,805.3	-2%	4,882.8	2%	4,782.9
Restructuring costs	1,032.5	*	327.1	*	142.3
Equity income from affiliates	(2,560.6)	-14%	(2,976.5)	30%	(2,294.4)
U.S. <i>Vioxx</i> Settlement Agreement charge	-	*	4,850.0	-	-
Other (income) expense, net	(2,194.2)	*	46.2	*	(382.7)
	\$ 14,042.5	-33%	\$ 20,827.0	27%	\$ 16,414.6

\* 100% or greater.

**Materials and Production**

In 2008, materials and production costs declined 9% compared with a 1% decline in sales primarily reflecting lower restructuring costs. Included in materials and production costs in 2008 were \$123.2 million of restructuring costs related to both the 2008 and 2005 Restructuring Programs comprised of \$88.7 million of accelerated depreciation associated with the planned sale or closure of certain of the Company's manufacturing facilities and \$34.5 million of other costs, primarily asset write-offs. This compares with restructuring costs of \$483.1 million in 2007 representing \$460.6 million of accelerated depreciation and \$22.5 million of asset impairments. (See Note 3 to the consolidated financial statements.)

In 2007, materials and production costs increased primarily due to an increase in sales. This increase was partially offset by lower costs related to the 2005 Restructuring Program which were \$483.1 million in 2007 compared with \$736.4 million in 2006.



Gross margin was 76.6% in 2008 compared with 74.6% in 2007 and 73.5% in 2006. The restructuring charges noted above had an unfavorable impact of 0.5 percentage points in 2008, 2.0 percentage points in 2007 and 3.3 percentage points in 2006. Gross margin in 2008 reflects changes in product mix, including the decline in *Fosamax* and *Fosamax Plus D* sales as a result of the loss of U.S. market exclusivity in 2008, and manufacturing efficiencies. Gross margin in 2007 reflects a slight unfavorable impact from changes in product mix and the positive impact of manufacturing efficiencies. Gross margin in 2006 reflects the unfavorable impact of changes in product mix, including the decline in *Zocor* sales as a result of the loss of U.S. market exclusivity in June 2006.

*Marketing and Administrative*

Marketing and administrative expenses declined 2% in 2008 and 7% in 2007. Marketing and administrative expenses in 2008, 2007 and 2006 included \$62 million, \$280 million and \$673 million, respectively, of

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additional reserves solely for future *Vioxx* legal defense costs. Expenses in 2008 and 2006 also reflect \$40 million and \$48 million, respectively, of additional reserves solely for future legal defense costs for *Fosamax* litigation. In addition, marketing and administrative expenses for 2007 included a \$455 million gain from an insurance arbitration award related to *Vioxx* product liability litigation coverage. (See Note 10 to the consolidated financial statements for more information on *Vioxx*-related and *Fosamax*-related matters). In addition to lower expenses for future legal defense costs, the decline in marketing and administrative expenses in 2008 and 2007 also reflect the Company's efforts to reduce its cost base. The Company has incurred separation costs associated with sales force reductions that are reflected in Restructuring costs as discussed below.

*Research and Development*

Research and development expenses declined 2% in 2008 compared with 2007. Expenses in 2008 reflect \$128.4 million of costs related to the closure or sale of research facilities in connection with the 2008 Restructuring Program, substantially all of which represent accelerated depreciation. Expenses in 2007 reflect \$325.1 million of acquired research expense related to the NovaCardia acquisition. Research and development expenses in 2008 compared with 2007 reflect an increase in development spending in support of the continued advancement of the research pipeline.

Research and development expenses increased 2% in 2007 compared with 2006 reflecting significant growth in the number of compounds entering clinical trials from internal projects as well as integration of late stage acquisitions. Research and development expenses in 2007 included \$325.1 million of acquired research expense related to the NovaCardia acquisition compared with acquired research expense of \$762.5 million in 2006 related to the acquisitions of Sirna and GlycoFi. In addition, research and development expenses for 2006 reflected accelerated depreciation costs of \$56.5 million related to the closure of research facilities in connection with the 2005 Restructuring Program.

During 2008, the Company continued the advancement of drug candidates through the pipeline. The Company's research pipeline chart is included in Item 1. Business Research and Development above.

On January 25, 2008, the FDA approved *Emend* (fosaprepitant dimeglumine) for Injection, 115 mg, for the prevention of chemotherapy-induced nausea and vomiting. *Emend* for Injection provides a new option for day one, as a substitute for *Emend* (125 mg) taken orally, as part of the recommended three-day regimen. Prior to the FDA decision, the EU on January 11, 2008 granted marketing approval for *Emend* for Injection, known as *Ivemend* in the EU, an action that applies to all 27 EU member countries as well as Norway and Iceland.

The Company currently has nine drug candidates in Phase III development and anticipates making NDA filings with respect to two of the candidates in 2009 as noted below. Additionally, the Company anticipates filing an NDA with the FDA in 2009 for MK-0653C, an investigational medication combining ezetimibe with atorvastatin for the treatment of dyslipidemia being developed by the Merck/Schering-Plough joint venture.

The Company continues to anticipate filing an NDA with the FDA in 2009 for MK-7418, rolofylline, a potential first-in-class selective adenosine A1 antagonist, which is an investigational drug being evaluated for the treatment of acute heart failure. In March 2008, the results of a Phase III pilot dose-ranging study of patients hospitalized with acute heart failure syndrome and renal impairment treated with rolofylline were presented at the annual Scientific Session of the American College of Cardiology. Rolofylline administered with intravenous ( IV ) loop diuretics was associated with improved dyspnea (shortness of breath) and preserved renal function compared to treatment with placebo and IV diuretics. In addition, in a post-hoc analysis, treatment with rolofylline was associated with a trend towards reduced 60-day mortality or hospital re-admission for cardiovascular or renal causes. Rolofylline increases renal blood flow and urine production by blocking adenosine-mediated vasoconstriction of the afferent arterioles of the kidneys and inhibiting salt and water reabsorption by the kidney. In this small pilot study, the rates of adverse events seen across treatment groups were similar. The confirmatory Phase III studies with rolofylline 30 mg are

underway.

The Company also continues to anticipate filing an NDA with the FDA in 2009 for MK-0974, telcagepant, an investigational oral calcitonin gene-related peptide receptor ( CGRP ) antagonist, which represents a new mechanism for the treatment of migraine. In September 2008, Merck announced that in a Phase III clinical trial telcagepant significantly relieved moderate-to-severe migraine attacks, including migraine pain and migraine-

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associated symptoms, compared to placebo. The data were presented in London, England at the European Headache/Migraine Trust International Congress. The reported findings are from a worldwide, multicenter, randomized, placebo-controlled clinical trial in adult patients with acute migraine. Also in June 2008, Merck presented data at the American Headache Society annual meeting from a Phase III clinical trial which showed telcagepant significantly improved relief of migraine pain and migraine-associated symptoms two hours after dosing compared to placebo. In addition, the efficacy results for telcagepant 300 mg were similar to the highest recommended dose of zolmitriptan, an approved migraine therapy, with a lower incidence of adverse events associated with telcagepant in this study. This trial is part of an ongoing Phase III program evaluating telcagepant. There were no reports of serious adverse events in the telcagepant or zolmitriptan treatment arms. Telcagepant is an antagonist of the receptor for CGRP, a potent neuropeptide thought to play a central role in the underlying pathophysiology of migraine.

MK-8669, deforolimus, is a novel mTor (mammalian target of rapamycin) inhibitor being evaluated for the treatment of cancer. The drug candidate is being jointly developed and commercialized with ARIAD Pharmaceuticals, Inc., under an agreement reached in 2007. A Phase III study (SUCCEED) in patients with metastatic soft-tissue or bone sarcomas is underway. The Company continues to anticipate filing an NDA with the FDA in 2010.

MK-0431C combines *Januvia* (sitagliptin) with pioglitazone, another type 2 diabetes therapy. The Company anticipates filing an NDA with the FDA in 2011.

V503 is a nine-valent HPV vaccine in development to expand protection against cancer-causing HPV types. The Phase III clinical program is underway and Merck anticipates filing a biologics license application ( BLA ) with the FDA in 2012.

MK-0822, odanacatib, is a highly selective inhibitor of the cathepsin K enzyme, which is being evaluated for the treatment of osteoporosis. Osteoporosis is a disease which reduces bone density and strength and results in an increased risk of bone fractures. The cathepsin K enzyme is believed to play a central role in osteoclastic bone resorption, particularly in the degradation of the protein component of bone. Inhibition of cathepsin K is a novel approach to the treatment of osteoporosis that differs from those of currently approved treatments. In September 2008, two-year data from a Phase IIB study of odanacatib were reported at the 30th Annual Meeting of the American Society for Bone and Mineral Research which demonstrated dose-dependent increases in bone mineral density ( BMD ) at the total hip, lumbar spine and femoral neck fracture sites and decreased indices of bone resorption compared to placebo in postmenopausal women with low BMD. The multi-center, double-blind, randomized, placebo-controlled study evaluated doses of 3, 10, 25 or 50 mg of odanacatib administered orally, once-weekly and without regard to the timing of meals or the patient's physical position in postmenopausal women with low BMD for 24 months. The number of patients experiencing a drug-related adverse experience was similar between the 50 mg odanacatib group and placebo. The effect of odanacatib 50 mg on vertebral, hip and non-vertebral fractures is currently being evaluated in a large, global Phase III study. Merck continues to anticipate filing an NDA with the FDA in 2012.

MK-0524A is a drug candidate that combines extended-release ( ER ) niacin and a novel flushing inhibitor, laropiprant. MK-0524A has demonstrated the ability to lower LDL-cholesterol ( LDL-C or bad cholesterol), raise HDL-cholesterol ( HDL-C or good cholesterol) and lower triglycerides with significantly less flushing than traditional extended release niacin alone. High LDL-C, low HDL-C and elevated triglycerides are risk factors associated with heart attacks and strokes. In April 2008, Merck received a non-approvable action letter from the FDA in response to its NDA for MK-0524A. At a meeting to discuss the letter, the FDA stated that additional efficacy and safety data were required and suggested that the Company wait for the results of the Treatment of HDL to Reduce the Incidence of Vascular Events ( HPS2-THRIVE ) cardiovascular outcomes study, which is expected to be completed in January 2012. Merck anticipates filing an NDA with the FDA for MK-0524A in 2012. In July 2008, the Company announced that *Tredaptive* (also known as MK-0524A) was approved for marketing in the 27 countries of the EU, Iceland and

Norway. *Tredaptive* is approved for the treatment of dyslipidemia, particularly in patients with combined mixed dyslipidemia (characterized by elevated levels of LDL-C and triglycerides and low HDL-C) and in patients with primary hypercholesterolemia (heterozygous familial and non-familial). *Tredaptive* should be used in patients in combination with statins, when the cholesterol lowering

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effects of statin monotherapy is inadequate. *Tredaptive* can be used as monotherapy only in patients in whom statins are considered inappropriate or not tolerated. The launch of *Tredaptive* in Europe and other markets has been delayed due to a manufacturing-related issue. Merck is committed to quickly resolving the issue and to making *Tredaptive* available in Europe as soon as possible. In other countries around the world, Merck continues to pursue regulatory approvals for MK-0524A.

MK-0524B is a drug candidate that combines the novel approach to raising HDL-C and lowering triglycerides from ER niacin combined with laropiprant with the proven benefits of simvastatin in one combination product. Merck will not seek approval for MK-0524B in the United States until it files its complete response relating to MK-0524A.

MK-0859, anacetrapib, is an inhibitor of the cholesteryl ester transfer protein that has shown promise in lipid management by raising HDL-C and reducing LDL-C without raising blood pressure. A Phase III study was initiated in 2008 and enrollment in a cardiovascular outcomes study is planned to begin in 2010. The Company anticipates filing an NDA with the FDA beyond 2014.

In December 2008, the Company terminated its collaboration with Dynavax Technologies Corporation ( Dynavax ) for the development of V270, an investigational hepatitis B vaccine, which was entered into in 2007. In October 2008, Merck and Dynavax received notification from the FDA regarding the two companies' response to the agency's request for safety information relating to the clinical hold on the two Investigational New Drug ( IND ) Applications for V270. In issuing the clinical hold in March 2008, the FDA requested a review of clinical and safety data including all available information about a single case of Wegener's granulomatosis, an uncommon disease in which the blood vessels are inflamed, reported in a Phase III clinical trial. Dynavax and Merck had previously provided a response to the FDA in September 2008. In its October 2008 correspondence, the FDA advised the companies that the balance of risk versus potential benefit no longer favored continued clinical evaluation of V270 in healthy adults and children.

In October 2008, Merck announced it will not seek regulatory approval for taranabant, an investigational medicine, to treat obesity and has discontinued its Phase III clinical development program for taranabant for obesity. Available Phase III data showed that both efficacy and adverse events were dose related, with greater efficacy and more adverse events in the higher doses. Therefore, after careful consideration, the Company determined that the overall profile of taranabant did not support further development for obesity.

Merck continues to remain focused on augmenting its internal efforts by capitalizing on growth opportunities that will drive both near- and long-term growth. During 2008, the Company completed transactions across a broad range of therapeutic categories, as well as early-stage technology transactions. Merck is actively monitoring the landscape for growth opportunities that meet the Company's strategic criteria. Highlights from these activities include:

In February 2009, Merck entered into a definitive agreement with Insmid Inc. ( Insmid ) to purchase Insmid's portfolio of follow-on biologic therapeutic candidates and its commercial manufacturing facilities located in Boulder, Colorado. Under the terms of the agreement, Merck will pay Insmid an aggregate of \$130 million in cash to acquire all rights to the Boulder facilities and Insmid's pipeline of follow-on biologic candidates. Insmid's follow-on biologics portfolio includes two clinical candidates: INS-19, an investigational recombinant granulocyte-colony stimulating factor ( G-CSF ) that will be evaluated for its ability to prevent infections in patients with cancer receiving chemotherapy, and INS-20, a pegylated recombinant G-CSF designed to allow for less frequent dosing. The agreement provides for initial payments of up to \$10 million for INS-19 and INS-20. Merck will pay Insmid the remaining balance upon closing of the transaction, which is expected by the end of the first quarter of 2009, without any further milestone or royalty obligations.

In September 2008, Merck and Japan Tobacco Inc. ( JT ) signed a worldwide licensing agreement to develop and commercialize JTT-305, an investigational oral osteoanabolic (bone growth stimulating) agent for the treatment of

osteoporosis. JTT-305 is an investigational oral calcium sensing receptor antagonist that is currently being evaluated by JT in Phase II clinical trials in Japan for its effect on increasing bone density and is in Phase I clinical trials outside of Japan. Under the terms of the agreement, Merck gained worldwide rights, except for Japan,

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to develop and commercialize JTT-305 and certain other related compounds. JT received an upfront payment of \$85 million, which the Company recorded as Research and development expense, and is eligible to receive additional cash payments upon achievement of certain milestones associated with the development and approval of a drug candidate covered by the agreement. JT will also be eligible to receive royalties from sales of any drug candidates that receive marketing approval.

The Company maintains a number of long-term exploratory and fundamental research programs in biology and chemistry as well as research programs directed toward product development. Merck's research and development model is designed to increase productivity and improve the probability of success by prioritizing the Company's research and development resources on disease areas of unmet medical needs, scientific opportunity and commercial opportunity. Merck is managing its research and development portfolio across diverse approaches to discovery and development by balancing investments appropriately on novel, innovative targets with the potential to have a major impact on human health, on developing best-in-class approaches, and on delivering maximum value of its new medicines and vaccines through new indications and new formulations. Another important component of Merck's science-based diversification is based on expanding the Company's portfolio of modalities to include not only small molecules and vaccines, but also biologics, peptides and RNAi. Further, Merck is moving to diversify its portfolio by creating a new division, Merck BioVentures, which leverages a unique platform for both follow-on and novel biologics. The Company will continue to pursue appropriate external licensing opportunities.

During 2008, the Company began implementing a new model for its basic research global operating strategy. The new model will align franchise and function through clear roles and responsibilities, align resources with disease area priorities and balance capacity across discovery phases and allow the Company to act upon those programs with the highest probability of success. Additionally, the strategy is designed to expand the Company's access to worldwide external science and incorporate external research as a key component of the Company's early discovery pipeline in order to translate basic research productivity into late-stage clinical success.

The Company's clinical pipeline includes candidates in multiple disease areas, including anemia, atherosclerosis, cancer, diabetes, heart failure, hypertension, infectious diseases, migraine, neurodegenerative diseases, psychiatric diseases, osteoporosis, pain, and respiratory disease. The Company supplements its internal research with an aggressive licensing and external alliance strategy focused on the entire spectrum of collaborations from early research to late-stage compounds, as well as new technologies. A chart reflecting the Company's current research pipeline as of February 15, 2009 is set forth in Item 1. Business Research and Development above.

*Share-Based Compensation*

The Company recognizes share-based compensation expense pursuant to Financial Accounting Standards Board (FASB) Statement No. 123R, *Share-Based Payment* (FAS 123R), which requires all share-based payments to employees be expensed over the requisite service period based on the grant-date fair value of the awards. Total pretax share-based compensation expense was \$348.0 million in 2008, \$330.2 million in 2007 and \$312.5 million in 2006. At December 31, 2008, there was \$444.1 million of total pretax unrecognized compensation expense related to nonvested stock option, restricted stock unit and performance share unit awards which will be recognized over a weighted average period of 2.0 years. For segment reporting, share-based compensation costs are unallocated expenses.

*Restructuring Costs*

Restructuring costs were \$1.0 billion, \$327.1 million and \$142.3 million for 2008, 2007 and 2006, respectively. Of the restructuring costs recorded in 2008, \$735.5 million related to the 2008 Restructuring Program and the remainder were associated with the 2005 Restructuring Program. In 2008, 2007 and 2006, Merck incurred separation costs of \$957.3 million (of which \$684.9 million related to the 2008 Restructuring Program), \$251.4 million and \$113.7 million, respectively, associated with actual headcount reductions, as well as headcount reductions that were probable and could be reasonably estimated. The Company eliminated 5,800 positions in 2008 (of which 1,750 related



to the 2008 Restructuring Program), 2,400 positions in 2007 and 3,700 positions in 2006. These position eliminations are comprised of actual headcount reductions, and the elimination of contractors and vacant positions. Also included in restructuring costs are curtailment, settlement and termination charges on the

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Company's pension and other postretirement benefit plans and shutdown costs. For segment reporting, restructuring costs are unallocated expenses.

*Equity Income from Affiliates*

Equity income from affiliates reflects the performance of the Company's joint ventures and partnerships. In 2008, the decline in equity income from affiliates reflects decreased equity income from the Merck/Schering-Plough partnership and lower partnership returns from AZLP, partially offset by higher equity income from Merial Limited (Merial) and SPMSD. The decrease in equity income from the Merck/Schering-Plough joint venture is the result of lower revenues of *Vytorin* and *Zetia* following the announcements of the ENHANCE and SEAS clinical trial results. In addition, as a result of the termination of the respiratory joint venture, the Company was obligated to Schering-Plough Corporation (Schering-Plough) in the amount of \$105 million as specified in the joint venture agreements. This resulted in a charge of \$43 million in the second quarter of 2008 which was included in equity income from affiliates. The remaining amount is being amortized over the remaining patent life of *Zetia* through 2016. The lower partnership returns from AZLP are primarily attributable to the first quarter 2008 partial redemption of Merck's interest in certain AZLP product rights, which resulted in a reduction of the priority return and the variable returns which were based, in part, upon sales of certain former Astra USA, Inc. products. The higher equity income from Merial primarily reflects higher sales of biological products. The increase in equity income from SPMSD is largely attributable to higher sales of *Gardasil* in joint venture territories outside of the United States. In 2007 and 2006, the increase in equity income from affiliates primarily reflects the successful performance of *Vytorin* and *Zetia* through the Merck/Schering-Plough partnership. See Selected Joint Venture and Affiliate Information below.

*U.S. Vioxx Settlement Agreement Charge*

On November 9, 2007, Merck entered into an agreement (the Settlement Agreement) with the law firms that comprise the executive committee of the Plaintiffs' Steering Committee of the federal multidistrict *Vioxx* litigation as well as representatives of plaintiffs' counsel in state coordinated proceedings to resolve state and federal myocardial infarction (MI) and ischemic stroke (IS) claims already filed against the Company in the United States. Under the Settlement Agreement, the Company will pay an aggregate fixed amount of \$4.85 billion into two funds for qualifying claims consisting of \$4.0 billion for qualifying MI claims and \$850 million for qualifying IS claims that enter into the resolution process (Settlement Program), of which \$750 million was paid into such funds in 2008. As a consequence of the Settlement Agreement, the Company recorded a pretax charge of \$4.85 billion in 2007. (See Note 10 to the consolidated financial statements).

*Other (Income) Expense, Net*

The change in Other (income) expense, net during 2008 was primarily due to an aggregate gain in 2008 from AZLP of \$2.2 billion (see Note 8 to the consolidated financial statements), the impact of a \$671 million charge in 2007 related to the resolution of certain civil governmental investigations, and a 2008 gain of \$249 million related to the sale of the Company's remaining worldwide rights to *Aggrastat*, partially offset by a \$300 million expense in 2008 for a contribution to the Merck Company Foundation, an increase in exchange losses of \$202 million, higher recognized losses of \$153 million, net, in the Company's investment portfolio and a \$58 million charge related to the resolution of an investigation into whether the Company violated consumer protection laws with respect to the sales and marketing of *Vioxx* (see Note 10 to the consolidated financial statements). The fluctuation in exchange losses (gains) in 2008 from 2007 is primarily due to the higher cost of foreign currency contracts due to lower U.S. interest rates and unfavorable impacts of period-to-period changes in foreign currency exchange rates on net long or net short foreign currency positions, considering both net monetary assets and related foreign currency contracts. The change in Other (income) expense, net during 2007 as compared with 2006 primarily reflects a \$671 million charge in 2007 related to the resolution of certain civil governmental investigations partially offset by

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the favorable impact of gains on sales of assets and product divestitures, as well as a net gain on the settlements of certain patent disputes.

*Segment Profits*

(\$ in millions)	2008	2007	2006
Pharmaceutical segment profits	\$ <b>12,400.4</b>	\$ 13,430.6	\$ 12,476.5
Vaccines and infectious diseases segment profits	<b>2,798.9</b>	2,625.0	1,253.1
Other segment profits	<b>419.3</b>	452.7	380.7
Other	<b>(5,810.8)</b>	(13,137.6)	(7,888.9)
Income before income taxes	<b>\$ 9,807.8</b>	\$ 3,370.7	\$ 6,221.4

Segment profits are comprised of segment revenues less certain elements of materials and production costs and operating expenses, including components of equity income (loss) from affiliates and depreciation and amortization expenses. For internal management reporting presented to the chief operating decision maker, the Company does not allocate the vast majority of indirect production costs, research and development expenses and general and administrative expenses, as well as the cost of financing these activities. Separate divisions maintain responsibility for monitoring and managing these costs, including depreciation related to fixed assets utilized by these divisions and, therefore, they are not included in segment profits. Also excluded from the determination of segment profits are the gain on distribution from AZLP, the U.S. *Vioxx* Settlement Agreement charge, taxes paid at the joint venture level and a portion of equity income. Additionally, segment profits do not reflect other expenses from corporate and manufacturing cost centers and other miscellaneous income (expense). These unallocated items are reflected in Other in the above table. Also included in other are miscellaneous corporate profits, operating profits related to divested products or businesses, other supply sales and adjustments to eliminate the effect of double counting certain items of income and expense.

Pharmaceutical segment profits decreased 8% in 2008 largely driven by lower sales of *Fosamax* and *Fosamax Plus D*, *Zocor* and decreased equity income from the Merck/Schering-Plough joint venture and from AZLP. Pharmaceutical segment profits increased 8% in 2007 reflecting higher equity income, primarily driven by the strong performance of the Merck/Schering-Plough partnership, partially offset by the loss of U.S. market exclusivity for *Zocor* and *Proscar*.

Vaccine and Infectious Diseases segment profits increased 7% in 2008 primarily driven by the continued successful rollout of *Isentress* and the strong performance of *RotaTeq*, as well as higher equity income from SPMSD. Vaccine and Infectious Diseases segment profits more than doubled in 2007 as compared with 2006 driven by the launch of three new vaccines in the latter part of 2006 and the successful performance of *Varivax*.

*Taxes on Income*

The Company's effective income tax rate was 20.4% in 2008, 2.8% in 2007 and 28.7% in 2006. The 2008 effective tax rate reflects a net favorable impact as compared with the statutory rate of approximately 3 percentage points, which includes favorable impacts relating to tax settlements that resulted in a reduction of the Company's liability for unrecognized tax benefits of approximately \$200 million, the realization of foreign tax credits and the favorable tax impact of foreign exchange rate changes during the fourth quarter, particularly the strengthening of the Japanese yen against the US dollar, partially offset by an unfavorable impact resulting from the AZLP gain being fully taxable in the United States at a combined federal and state tax rate of approximately 36.3%. In the first quarter of 2008, the

Company decided to distribute certain prior years' foreign earnings to the United States which will result in a utilization of foreign tax credits. These foreign tax credits arose as a result of tax payments made outside of the United States in prior years that became realizable in the first quarter based on a change in the Company's decision to distribute these foreign earnings. The 2007 effective tax rate reflects the reduction of domestic pretax income primarily resulting from the U.S. *Vioxx* Settlement Agreement charge and the related change in mix of domestic and foreign pretax income.

**Table of Contents****Net Income and Earnings per Share**

(\$ in millions except per share amounts)	<b>2008</b>	<b>Change</b>	2007	<b>Change</b>	2006
Net income	\$ <b>7,808.4</b>	*	\$ 3,275.4	-26%	\$ 4,433.8
As a % of sales	<b>32.7%</b>		13.5%		19.6%
As a % of average total assets	<b>16.3%</b>		7.0%		9.9%
Earnings per common share assuming dilution	\$ <b>3.64</b>	*	\$ 1.49	-27%	\$ 2.03

\* 100% or greater.

**Net Income and Earnings per Common Share**

Net income was \$7.8 billion in 2008 compared with \$3.3 billion in 2007 and \$4.4 billion in 2006. Earnings per common share assuming dilution were \$3.64 in 2008 compared with \$1.49 in 2007 and \$2.03 in 2006. The increases in net income and earnings per share in 2008 as compared with 2007 are primarily attributable to the gain on distribution from AZLP in 2008 and the impacts in 2007 of the U.S. *Vioxx* Settlement Agreement and civil governmental investigations charges. In addition, the increases reflect the positive impact of certain tax items, lower acquired research costs and lower expenses for legal defense costs, partially offset by higher restructuring costs and lower equity earnings in 2008, as well as the recognition in 2007 of an insurance arbitration gain. The declines in net income and earnings per share in 2007 as compared with 2006 reflect the impact of the U.S. *Vioxx* Settlement Agreement charge and civil governmental investigations charge in 2007, partially offset by lower expenses for legal defense costs, a gain from an insurance arbitration award related to *Vioxx* product liability litigation coverage, lower acquired research costs and the favorable impact of gains on sales of assets and product divestitures, as well as a net gain on the settlements of certain patent disputes. Net income and EPS in 2007 as compared with 2006 also reflect revenue growth of vaccines, *Singulair* and *Januvia*, as well as higher equity income from affiliates. Net income as a percentage of sales was 32.7% in 2008, 13.5% in 2007 and 19.6% in 2006. The changes in the percentage of sales ratio reflect the same factors discussed above. Net income as a percentage of average total assets was 16.3% in 2008, 7.0% in 2007 and 9.9% in 2006.

**Selected Joint Venture and Affiliate Information**

To expand its research base and realize synergies from combining capabilities, opportunities and assets, in previous years the Company formed a number of joint ventures. (See Note 8 to the consolidated financial statements.)

**Merck/Schering-Plough Partnership**

In 2000, the Company and Schering-Plough (collectively, the Partners) entered into agreements to create separate equally-owned partnerships to develop and market in the United States new prescription medicines in the cholesterol-management and respiratory therapeutic areas. These agreements generally provide for equal sharing of development costs and for co-promotion of approved products by each company. In 2001, the cholesterol-management partnership agreements were expanded to include all the countries of the world, excluding Japan. In 2002, ezetimibe, the first in a new class of cholesterol-lowering agents, was launched in the United States as *Zetia* (marketed as *Ezetrol* outside the United States). In 2004, a combination product containing the active ingredients of both *Zetia* and *Zocor* was approved in the United States as *Vytorin* (marketed as *Inegy* outside the United States). *Vytorin* is the only combination tablet cholesterol treatment to provide LDL cholesterol lowering through the dual inhibition of cholesterol production and absorption.

The cholesterol agreements provide for the sharing of operating income generated by the Merck/Schering-Plough cholesterol partnership (the MSP Partnership) based upon percentages that vary by product, sales level and country. In the U.S. market, the Partners share profits on *Zetia* and *Vytorin* sales equally, with the exception of the first

\$300 million of annual *Zetia* sales, on which Schering-Plough receives a greater share of profits. Operating income includes expenses that the Partners have contractually agreed to share, such as a portion of manufacturing costs, specifically identified promotion costs (including direct-to-consumer advertising and direct and identifiable out-of-pocket promotion) and other agreed upon costs for specific services such as on-going clinical research, market support, market research, market expansion, as well as a specialty sales force and physician education programs. Expenses incurred in support of the MSP Partnership but not shared between the

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Partners, such as marketing and administrative expenses (including certain sales force costs), as well as certain manufacturing costs, are not included in Equity income from affiliates. However, these costs are reflected in the overall results of the Company. Certain research and development expenses are generally shared equally by the Partners, after adjusting for earned milestones.

Sales of joint venture products were as follows:

(\$ in millions)	2008	2007	2006
Vytorin	\$ 2,360.0	\$ 2,779.1	\$ 1,955.3
Zetia	2,201.1	2,407.1	1,928.8
	<b>\$ 4,561.1</b>	<b>\$ 5,186.2</b>	<b>\$ 3,884.1</b>

Global sales of *Vytorin* declined 15% in 2008 and grew 42% in 2007. Global sales of *Zetia* decreased 9% in 2008 and increased 25% in 2007. Following the announcements of the ENHANCE and SEAS clinical trial results (which are discussed below), sales of *Vytorin* and *Zetia* declined in 2008.

As previously disclosed, in January 2008, the Company announced the results of the Effect of Combination Ezetimibe and High-Dose Simvastatin vs. Simvastatin Alone on the Atherosclerotic Process in Patients with Heterozygous Familial Hypercholesterolemia ( ENHANCE ) clinical trial, an imaging trial in 720 patients with heterozygous familial hypercholesterolemia, a rare genetic condition that causes very high levels of LDL bad cholesterol and greatly increases the risk for premature coronary artery disease. As previously reported, despite the fact that ezetimibe/simvastatin 10/80 mg (*Vytorin*) significantly lowered LDL bad cholesterol more than simvastatin 80 mg alone, there was no significant difference between treatment with ezetimibe/simvastatin and simvastatin alone on the pre-specified primary endpoint, a change in the thickness of carotid artery walls over two years as measured by ultrasound. There also were no significant differences between treatment with ezetimibe/simvastatin and simvastatin on the four pre-specified key secondary endpoints: percent of patients manifesting regression in the average carotid artery intima-media thickness ( CA IMT ); proportion of patients developing new carotid artery plaques >1.3 mm; changes in the average maximum CA IMT; and changes in the average CA IMT plus in the average common femoral artery IMT. In ENHANCE, when compared to simvastatin alone, ezetimibe/simvastatin significantly lowered LDL bad cholesterol, as well as triglycerides and C-reactive protein ( CRP ). Ezetimibe/simvastatin is not indicated for the reduction of CRP. In the ENHANCE study, the overall safety profile of ezetimibe/simvastatin was generally consistent with the product label. The ENHANCE study was not designed nor powered to evaluate cardiovascular clinical events. The Improved Reduction in High-Risk Subjects Presenting with Acute Coronary Syndrome ( IMPROVE-IT ) trial is underway and is designed to provide cardiovascular outcomes data for ezetimibe/simvastatin in patients with acute coronary syndrome. No incremental benefit of ezetimibe/simvastatin on cardiovascular morbidity and mortality over and above that demonstrated for simvastatin has been established. In March 2008, the results of ENHANCE were reported at the annual Scientific Session of the American College of Cardiology.

On July 21, 2008, efficacy and safety results from the Simvastatin and Ezetimibe in Aortic Stenosis ( SEAS ) study were announced. SEAS was designed to evaluate whether intensive lipid lowering with *Vytorin* 10/40 mg would reduce the need for aortic valve replacement and the risk of cardiovascular morbidity and mortality versus placebo in patients with asymptomatic mild to moderate aortic stenosis who had no indication for statin therapy. *Vytorin* failed to meet its primary end point for the reduction of major cardiovascular events. There also was no significant difference in the key secondary end point of aortic valve events; however, there was a reduction in the group of patients taking

*Vytorin* compared to placebo in the key secondary end point of ischemic cardiovascular events. *Vytorin* is not indicated for the treatment of aortic stenosis. No incremental benefit of *Vytorin* on cardiovascular morbidity and mortality over and above that demonstrated for simvastatin has been established. In the study, patients in the group who took *Vytorin* 10/40 mg had a higher incidence of cancer than the group who took placebo. There was also a nonsignificant increase in deaths from cancer in patients in the group who took *Vytorin* versus those who took placebo. Cancer and cancer deaths were distributed across all major organ systems. The Company believes the cancer finding in SEAS is likely to be an anomaly that, taken in light of all the available data, does not support an association with *Vytorin*. In August 2008, the FDA announced that it was investigating the results from the SEAS trial. In this announcement, the FDA also cited interim data from two large ongoing



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cardiovascular trials of *Vytorin* the Study of Heart and Renal Protection ( SHARP ) and the IMPROVE-IT clinical trials in which there was no increased risk of cancer with the combination of simvastatin plus ezetimibe. The SHARP trial is expected to be completed in 2010. The IMPROVE-IT trial is scheduled for completion around 2012. The FDA determined that, as of that time, these findings in the SEAS trial plus the interim data from ongoing trials should not prompt patients to stop taking *Vytorin* or any other cholesterol lowering drug.

The Company, through the MSP Partnership, is committed to working with regulatory agencies to further evaluate the available data and interpretations of those data; however, the Company does not believe that changes in the clinical use of *Vytorin* are warranted.

See Note 10 to the consolidated financial statements for information with respect to litigation involving the Partners and the MSP Partnership related to the sale and promotion of *Zetia* and *Vytorin*.

The respiratory therapeutic agreements provided for the joint development and marketing in the United States by the Partners of a once-daily, fixed-combination tablet containing the active ingredients montelukast sodium and loratadine. Montelukast sodium, a leukotriene receptor antagonist, is sold by Merck as *Singulair* and loratadine, an antihistamine, is sold by Schering-Plough as Claritin, both of which are indicated for the relief of symptoms of allergic rhinitis. During 2008, the Partners received a not-approvable letter from the FDA for the proposed fixed combination of loratadine/montelukast and subsequently announced the withdrawal of the NDA for the combination tablet. The companies also terminated the respiratory joint venture. This action had no impact on the business of the cholesterol joint venture. As a result of the termination of the respiratory joint venture, the Company was obligated to Schering-Plough in the amount of \$105 million as specified in the joint venture agreements. This resulted in a charge of \$43 million during the second quarter of 2008 which was included in Equity income from affiliates. The remaining amount is being amortized over the remaining patent life of *Zetia* through 2016.

The results from the Company's interest in the MSP Partnership are recorded in Equity income from affiliates. Merck recognized equity income of \$1.5 billion in 2008, \$1.8 billion in 2007 and \$1.2 billion in 2006.

The financial statements of the MSP Partnership are included in Item 15. (a) (2) Financial Statement Schedules below.

*AstraZeneca LP*

In 1982, Merck entered into an agreement with Astra AB ( Astra ) to develop and market Astra's products under a royalty-bearing license. In 1993, the Company's total sales of Astra products reached a level that triggered the first step in the establishment of a joint venture business carried on by Astra Merck Inc. ( AMI ), in which Merck and Astra each owned a 50% share. This joint venture, formed in 1994, developed and marketed most of Astra's new prescription medicines in the United States including *Prilosec*, the first of a class of medications known as proton pump inhibitors, which slows the production of acid from the cells of the stomach lining.

In 1998, Merck and Astra completed the restructuring of the ownership and operations of the joint venture whereby the Company acquired Astra's interest in AMI, renamed KBI Inc. ( KBI ), and contributed KBI's operating assets to a new U.S. limited partnership, Astra Pharmaceuticals L.P. (the Partnership ), in exchange for a 1% limited partner interest. Astra contributed the net assets of its wholly owned subsidiary, Astra USA, Inc., to the Partnership in exchange for a 99% general partner interest. The Partnership, renamed AstraZeneca LP ( AZLP ) upon Astra's 1999 merger with Zeneca Group Plc (the AstraZeneca merger ), became the exclusive distributor of the products for which KBI retained rights.

While maintaining a 1% limited partner interest in AZLP, Merck has consent and protective rights intended to preserve its business and economic interests, including restrictions on the power of the general partner to make certain distributions or dispositions. Furthermore, in limited events of default, additional rights will be granted to the

Company, including powers to direct the actions of, or remove and replace, the Partnership's chief executive officer and chief financial officer. Merck earns ongoing revenue based on sales of current and future KBI products and such revenue was \$1.6 billion, \$1.7 billion and \$1.8 billion in 2008, 2007 and 2006, respectively, primarily relating to sales of *Nexium*, as well as *Prilosec*. In addition, Merck earns certain Partnership returns, which are recorded in Equity income from affiliates. Such returns include a priority return provided for in the Partnership

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Agreement, variable returns based, in part, upon sales of certain former Astra USA, Inc. products, and a preferential return representing Merck's share of undistributed AZLP GAAP earnings. These returns aggregated \$598.4 million, \$820.1 million and \$783.7 million in 2008, 2007 and 2006, respectively. The AstraZeneca merger triggered a partial redemption in March 2008 of Merck's interest in certain AZLP product rights. Upon this redemption, Merck received \$4.3 billion from AZLP. This amount was based primarily on a multiple of Merck's average annual variable returns derived from sales of the former Astra USA, Inc. products for the three years prior to the redemption (the Limited Partner Share of Agreed Value). Merck recorded a \$1.5 billion pretax gain on the partial redemption in 2008. The partial redemption of Merck's interest in the product rights did not result in a change in Merck's 1% limited partner interest.

In conjunction with the 1998 restructuring, Astra purchased an option (the Asset Option) for a payment of \$443.0 million, which was recorded as deferred income, to buy Merck's interest in the KBI products, excluding the gastrointestinal medicines *Nexium* and *Prilosec* (the Non-PPI Products). The Asset Option is exercisable in the first half of 2010 at an exercise price equal to the net present value as of March 31, 2008 of projected future pretax revenue to be received by the Company from the Non-PPI Products (the Appraised Value). Merck also had the right to require Astra to purchase such interest in 2008 at the Appraised Value. In February 2008, the Company advised AZLP that it would not exercise the Asset Option, thus the \$443.0 million remains deferred. In addition, in 1998, the Company granted Astra an option (the Shares Option) to buy Merck's common stock interest in KBI and, therefore, Merck's interest in *Nexium* and *Prilosec*, exercisable two years after Astra's exercise of the Asset Option. Astra can also exercise the Shares Option in 2017 or if combined annual sales of the two products fall below a minimum amount provided, in each case, only so long as AstraZeneca's Asset Option has been exercised in 2010. The exercise price for the Shares Option is based on the net present value of estimated future net sales of *Nexium* and *Prilosec* as determined at the time of exercise, subject to certain true-up mechanisms.

The AstraZeneca merger constituted a Trigger Event under the KBI restructuring agreements. As a result of the merger, in exchange for Merck's relinquishment of rights to future Astra products with no existing or pending U.S. patents at the time of the merger, Astra paid \$967.4 million (the Advance Payment). The Advance Payment was deferred as it remained subject to a true-up calculation (the True-Up Amount) that was directly dependent on the fair market value in March 2008 of the Astra product rights retained by the Company. The calculated True-Up Amount of \$243.7 million was returned to AZLP in March 2008 and Merck recognized a pretax gain of \$723.7 million related to the residual Advance Payment balance.

Under the provisions of the KBI restructuring agreements, because a Trigger Event has occurred, the sum of the Limited Partner Share of Agreed Value, the Appraised Value and the True-Up Amount was guaranteed to be a minimum of \$4.7 billion. Distribution of the Limited Partner Share of Agreed Value less payment of the True-Up Amount resulted in cash receipts to Merck of \$4.0 billion and an aggregate pretax gain of \$2.2 billion which is included in Other (income) expense, net. AstraZeneca's purchase of Merck's interest in the Non-PPI Products is contingent upon the exercise of the Asset Option by AstraZeneca in 2010 and, therefore, payment of the Appraised Value may or may not occur. Also, in March 2008, the \$1.38 billion outstanding loan from Astra plus interest through the redemption date was settled. As a result of these transactions, the Company received net proceeds from AZLP of \$2.6 billion.

*Merial Limited*

In 1997, Merck and Rhône-Poulenc S.A. (now Sanofi-Aventis S.A.) combined their animal health businesses to form Merial Limited (Merial), a fully integrated animal health company, which is a stand-alone joint venture, 50% owned by each party. Merial provides a comprehensive range of pharmaceuticals and vaccines to enhance the health, well-being and performance of a wide range of animal species.



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Sales of joint venture products were as follows:

(\$ in millions)	2008	2007	2006
Fipronil products	\$ 1,053.0	\$ 1,033.3	\$ 886.9
Biological products	789.7	674.9	600.7
Avermectin products	511.8	478.4	468.7
Other products	288.2	262.2	238.4
	\$ 2,642.7	\$ 2,448.8	\$ 2,194.7

*Sanofi Pasteur MSD*

In 1994, Merck and Pasteur Merieux Connaught (now Sanofi Pasteur S.A.) established a 50% owned joint venture to market vaccines in Europe and to collaborate in the development of combination vaccines for distribution in Europe.

In 2006, Merck launched three new vaccines that have been approved for use in the EU and are being or will be marketed by SPMSD in certain Western European countries: *Gardasil* to help prevent cervical, vulvar and vaginal cancers, precancerous or dysplastic lesions, and genital warts caused by HPV types 6, 11, 16 and 18; *RotaTeq* to help protect against rotavirus gastroenteritis in infants and children; and *Zostavax* to help prevent shingles (herpes zoster) in individuals 60 years of age or older.

Sales of joint venture products were as follows:

(\$ in millions)	2008	2007	2006
Gardasil	\$ 865.3	\$ 476.0	\$ 7.5
Viral vaccines	105.1	86.8	100.1
Hepatitis vaccines	72.6	72.9	70.9
Other vaccines	841.8	802.3	735.4
	\$ 1,884.8	\$ 1,438.0	\$ 913.9

*Johnson & Johnson<sup>o</sup>Merck Consumer Pharmaceuticals Company*

In 1989, Merck formed a joint venture with Johnson & Johnson to develop and market a broad range of nonprescription medicines for U.S. consumers. This 50% owned joint venture was subsequently expanded into Canada. Significant joint venture products are *Pepcid AC*, an over-the-counter form of the Company's ulcer medication *Pepcid*, as well as *Pepcid Complete*, an over-the-counter product which combines the Company's ulcer medication with antacids.

Sales of joint venture products were as follows:

(\$ in millions)	2008	2007	2006
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Gastrointestinal products	\$	<b>210.7</b>	\$	218.5	\$	250.9
Other products		<b>1.4</b>		1.2		1.7
	\$	<b>212.1</b>	\$	219.7	\$	252.6

### Capital Expenditures

Capital expenditures were \$1.3 billion in 2008, \$1.0 billion in 2007 and \$980.2 million in 2006. Expenditures in the United States were \$946.6 million in 2008, \$788.0 million in 2007 and \$714.7 million in 2006. Expenditures during 2008 included \$650.3 million for production facilities, \$177.1 million for research and development facilities, \$18.7 million for environmental projects, and \$452.2 million for administrative, safety and general site projects, of which approximately 35% represents capital investments related to a multi-year initiative to standardize the Company's information systems. Capital expenditures for 2009 are estimated to be \$1.6 billion.

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Depreciation expense was \$1.4 billion in 2008, \$1.8 billion in 2007 and \$2.1 billion in 2006, of which \$1.0 billion, \$1.4 billion and \$1.5 billion, respectively, applied to locations in the United States. Total depreciation expense in 2008, 2007 and 2006 included accelerated depreciation of \$216.7 million, \$460.6 million and \$763.8 million, respectively, associated with the 2008 and 2005 Restructuring Programs (see Note 3 to the consolidated financial statements).

**Analysis of Liquidity and Capital Resources**

Merck's strong financial profile enables the Company to fully fund research and development, focus on external alliances, support in-line products and maximize upcoming launches while providing significant cash returns to shareholders.

**Selected Data**

<i>(\$ in millions)</i>	<b>2008</b>	2007	2006
Working capital	<b>\$ 4,986.2</b>	\$ 2,787.2	\$ 2,507.5
Total debt to total liabilities and equity	<b>13.2%</b>	11.9%	15.3%
Cash provided by operations to total debt	<b>1.1:1</b>	1.2:1	1.0:1

Cash provided by operating activities, which was \$6.6 billion in 2008, \$7.0 billion in 2007 and \$6.8 billion in 2006, continues to be the Company's primary source of funds to finance capital expenditures, treasury stock purchases and dividends paid to stockholders. Cash provided by operating activities in 2008 reflects \$2.1 billion received in connection with a partial redemption of the Company's partnership interest in AZLP discussed above, representing a distribution of the Company's accumulated earnings on its investment in AZLP since inception. Cash provided by operating activities in 2008 was also impacted by a \$675 million payment made in connection with the previously disclosed resolution of investigations of civil claims by federal and state authorities relating to certain past marketing and selling activities and \$750 million of payments into the *Vioxx* settlement funds. Cash provided by operating activities for 2007 reflects the payment made under a previously disclosed settlement with the Internal Revenue Service ( IRS ).

Cash used by investing activities in 2008 was \$1.8 billion compared with \$2.8 billion in 2007. The lower use of cash by investing activities primarily reflects a distribution from AZLP in 2008 representing a return of the Company's investment in AZLP and a \$1.1 billion payment in 2007 in connection with the December 2006 acquisition of Sirna Therapeutics, Inc., partially offset by higher net purchases of securities and other investments, higher capital expenditures and an increase in restricted assets. Cash used in financing activities was \$5.5 billion in 2008 compared with \$4.9 billion in 2007 reflecting higher purchases of treasury stock, lower proceeds from the exercise stock options and higher payments on debt in connection with the settlement of a note due to Astra, partially offset by a net increase in short-term borrowings.

At December 31, 2008, the total of worldwide cash and investments was \$12.0 billion, including \$5.5 billion of cash, cash equivalents and short-term investments, and \$6.5 billion of long-term investments. In addition, the Company has \$6.3 billion of cash and investments restricted under certain collateral arrangements as discussed below.

Working capital levels are more than adequate to meet the operating requirements of the Company. The increase in working capital was primarily attributable to net cash receipts from AZLP as discussed above in Selected Joint

Venture and Affiliate Information. The ratios of total debt to total liabilities and equity and cash provided by operations to total debt reflect the strength of the Company's operating cash flows and the ability of the Company to cover its contractual obligations.

In August 2008, the Company executed a \$4.1 billion letter of credit agreement with a financial institution, which satisfied certain conditions set forth in the U.S. *Vioxx* Settlement Agreement (see Note 10 to the consolidated financial statements). The Company pledged collateral to the financial institution of approximately \$5.1 billion pursuant to the terms of the letter of credit agreement. Although the amount of assets pledged as collateral is set by the letter of credit agreement and such assets are held in custody by a third party, the assets are



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managed by the Company. The Company considers the assets pledged under the letter of credit agreement to be restricted. As a result, \$2.1 billion and \$1.4 billion of cash and investments, respectively, were classified as restricted current assets and \$1.6 billion of investments were classified as restricted non-current assets. The letter of credit amount and required collateral balances will decline as payments (after the first \$750 million) under the Settlement Agreement are made. As of December 31, 2008, \$3.8 billion was recorded within Deferred income taxes and other current assets and \$1.3 billion was classified as Other assets.

Additionally, during 2008, the Company paid \$750 million into the *Vioxx* settlement funds pursuant to the Settlement Agreement.

As previously disclosed, the IRS has completed its examination of the Company's tax returns for the years 1993 to 2001. As a result of the examination, the Company made an aggregate payment of \$2.79 billion in February 2007. This payment was offset by (i) a tax refund of \$165 million received in 2007 for amounts previously paid for these matters and (ii) a federal tax benefit of approximately \$360 million related to interest included in the payment, resulting in a net cash cost to the Company of approximately \$2.3 billion in 2007. The impact for years subsequent to 2001 for items reviewed as part of the examination was included in the payment although those years remain open in all other respects. The closing of the IRS examination did not have a material impact on the Company's results of operations in 2007 as these amounts had been previously accrued for.

As previously disclosed, in October 2006, the CRA issued the Company a notice of reassessment containing adjustments related to certain intercompany pricing matters. In February 2009, Merck and the CRA negotiated a settlement agreement in regard to these matters. The settlement calls for Merck to pay additional tax of approximately \$300 million (U.S. dollars) and interest of approximately \$360 million (U.S. dollars) with no additional amounts or penalties due on this assessment. In accordance with FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* — an interpretation of FASB Statement No. 109 (FIN 48), the settlement will be accounted for in the first quarter of 2009. The Company had previously established reserves for these matters. A significant portion of the taxes paid is expected to be creditable for U.S. tax purposes. The resolution of these matters will not have a material effect on the Company's financial position or liquidity, other than with respect to the associated collateral as discussed below.

In addition, in July 2007 and November 2008, the CRA proposed additional adjustments for 1999 and 2000, respectively, relating to other intercompany pricing matters. The adjustments would increase Canadian tax due by approximately \$260 million (U.S. dollars) plus \$240 million (U.S. dollars) of interest. It is possible that the CRA will propose similar adjustments for later years. The Company disagrees with the positions taken by the CRA and believes they are without merit. The Company intends to contest the assessments through the CRA appeals process and the courts if necessary. Management believes that resolution of these matters will not have a material effect on the Company's financial position or liquidity.

In connection with the appeals process, during 2007, the Company pledged collateral to two financial institutions, one of which provided a guarantee to the CRA and the other to the Quebec Ministry of Revenue representing a portion of the tax and interest assessed. The collateral is included in Deferred income taxes and other current assets and Other Assets in the Consolidated Balance Sheet and totaled approximately \$1.2 billion and \$1.4 billion at December 31, 2008 and 2007, respectively. The guarantees will be reduced and the related collateral released following payments to the CRA and Quebec Ministry of Revenue, causing the restricted amounts to be reclassified to cash and investments as appropriate on the Consolidated Balance Sheet.

The IRS is examining the Company's 2002 to 2005 federal income tax returns. In addition, various state and foreign tax examinations are in progress. Tax years that remain subject to examination by major tax jurisdictions include Germany from 1999, Italy from 2000 and Japan from 2002.



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The Company's contractual obligations as of December 31, 2008 are as follows:

**Payments Due by Period**

(\$ in millions)	Total	2009	2010 - 2011	2012 -2013	Thereafter
Purchase obligations	\$ 1,243.6	\$ 557.7	\$ 365.1	\$ 246.5	\$ 74.3
Loans payable and current portion of long-term debt	2,297.1	2,297.1	-	-	-
Long-term debt	3,943.3	-	553.6	541.1	2,848.6
U.S. Vioxx Settlement Agreement <sup>(1)</sup>	4,100.0	4,100.0	-	-	-
Unrecognized tax benefits <sup>(2)</sup>	1,203.8	1,203.8	-	-	-
Operating leases	376.2	103.0	139.3	77.7	56.2
	\$ 13,164.0	\$ 8,261.6	\$ 1,058.0	\$ 865.3	\$ 2,979.1

<sup>(1)</sup> *Timing of payments under the U.S. Vioxx Settlement Agreement may vary depending on the timing of the claims assessment process.*

<sup>(2)</sup> *As of December 31, 2008, the Company's Consolidated Balance Sheet reflects liabilities for unrecognized tax benefits, interest and penalties of \$5.35 billion, including \$1.20 billion reflected as a current liability, largely reflecting amounts related to the settlement with the Canadian Revenue Agency as discussed above. Due to the high degree of uncertainty regarding the timing of future cash outflows of liabilities for unrecognized tax benefits beyond one year, a reasonable estimate of the period of cash settlement for years beyond 2009 can not be made.*

Purchase obligations consist primarily of goods and services that are enforceable and legally binding and include obligations for minimum inventory contracts, research and development and advertising. Amounts reflected for research and development obligations do not include contingent milestone payments. Loans payable and current portion of long-term debt also reflects \$322.2 million of long-dated notes that are subject to repayment at the option of the holders on an annual basis. Required funding obligations for 2009 relating to the Company's pension and other postretirement benefit plans are not expected to be material. However, the Company currently anticipates contributing \$600.0 million and \$60.0 million, respectively, to its pension plans and other postretirement benefit plans during 2009.

In December 2008, the Company's existing shelf registration filed with the Securities and Exchange Commission (SEC) expired. The Company intends to file a new shelf registration in 2009.

In April 2008, the Company extended the maturity date of its \$1.5 billion, 5-year revolving credit facility from April 2012 to April 2013. The facility provides backup liquidity for the Company's commercial paper borrowing facility and is for general corporate purposes. The Company has not drawn funding from this facility.

The Company's long-term credit ratings assigned by Moody's Investors Service and Standard & Poor's are Aa3 with a stable outlook and AA- with a stable outlook, respectively. These ratings continue to allow access to the capital markets and flexibility in obtaining funds on competitive terms. The Company continues to maintain a conservative financial profile. Total cash and investments of \$12.0 billion exceed the sum of loans payable and long-term debt of

\$6.2 billion. The Company places its cash and investments in instruments that meet high credit quality standards, as specified in its investment policy guidelines. These guidelines also limit the amount of credit exposure to any one issuer. Despite this strong financial profile, certain contingent events, if realized, which are discussed in Note 10 to the consolidated financial statements, could have a material adverse impact on the Company's liquidity and capital resources. The Company does not participate in any off-balance sheet arrangements involving unconsolidated subsidiaries that provide financing or potentially expose the Company to unrecorded financial obligations.

In July 2002, the Board of Directors approved purchases over time of up to \$10.0 billion of Merck shares. Total treasury stock purchased under this program in 2008 was \$2.7 billion. As of December 31, 2008, \$2.4 billion remains under the 2002 stock repurchase authorization approved by the Merck Board of Directors.

**Table of Contents****Financial Instruments Market Risk Disclosures***Foreign Currency Risk Management*

While the U.S. dollar is the functional currency of the Company's foreign subsidiaries, a significant portion of the Company's revenues are denominated in foreign currencies. Merck relies on sustained cash flows generated from foreign sources to support its long-term commitment to U.S. dollar-based research and development. To the extent the dollar value of cash flows is diminished as a result of a strengthening dollar, the Company's ability to fund research and other dollar-based strategic initiatives at a consistent level may be impaired. The Company has established revenue hedging and balance sheet risk management programs to protect against volatility of future foreign currency cash flows and changes in fair value caused by volatility in foreign exchange rates.

The objective of the revenue hedging program is to reduce the potential for longer-term unfavorable changes in foreign exchange to decrease the U.S. dollar value of future cash flows derived from foreign currency denominated sales, primarily the euro and Japanese yen. To achieve this objective, the Company will partially hedge anticipated third-party sales that are expected to occur over its planning cycle, typically no more than three years into the future. The Company will layer in hedges over time, increasing the portion of sales hedged as it gets closer to the expected date of the transaction, such that it is probable the hedged transaction will occur. The portion of sales hedged is based on assessments of cost-benefit profiles that consider natural offsetting exposures, revenue and exchange rate volatilities and correlations, and the cost of hedging instruments. The hedged anticipated sales are a specified component of a portfolio of similarly denominated foreign currency-based sales transactions, each of which responds to the hedged risk in the same manner. Merck manages its anticipated transaction exposure principally with purchased local currency put options, which provide the Company with a right, but not an obligation, to sell foreign currencies in the future at a predetermined price. If the U.S. dollar strengthens relative to the currency of the hedged anticipated sales, total changes in the options' cash flows offset the decline in the expected future U.S. dollar cash flows of the hedged foreign currency sales. Conversely, if the U.S. dollar weakens, the options' value reduces to zero, but the Company benefits from the increase in the value of the anticipated foreign currency cash flows. While a weaker U.S. dollar would result in a net benefit, the market value of the Company's hedges would have declined by \$194.7 million and \$69.5 million, respectively, from a uniform 10% weakening of the U.S. dollar at December 31, 2008 and 2007. The market value was determined using a foreign exchange option pricing model and holding all factors except exchange rates constant. Because Merck principally uses purchased local currency put options, a uniform weakening of the U.S. dollar will yield the largest overall potential loss in the market value of these options. The sensitivity measurement assumes that a change in one foreign currency relative to the U.S. dollar would not affect other foreign currencies relative to the U.S. dollar. Although not predictive in nature, the Company believes that a 10% threshold reflects reasonably possible near-term changes in Merck's major foreign currency exposures relative to the U.S. dollar. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

The primary objective of the balance sheet risk management program is to protect the U.S. dollar value of foreign currency denominated net monetary assets from the effects of volatility in foreign exchange that might occur prior to their conversion to U.S. dollars. Merck principally utilizes forward exchange contracts, which enable the Company to buy and sell foreign currencies in the future at fixed exchange rates and economically offset the consequences of changes in foreign exchange on the amount of U.S. dollar cash flows derived from the net assets. Merck routinely enters into contracts to offset the effects of exchange on exposures denominated in developed country currencies, primarily the euro and Japanese yen. For exposures in developing country currencies, the Company will enter into forward contracts to partially offset the effects of exchange on exposures when it is deemed economical to do so based on a cost-benefit analysis that considers the magnitude of the exposure, the volatility of the exchange rate and the cost of the hedging instrument. The Company will also minimize the effect of exchange on monetary assets and liabilities by managing operating activities and net asset positions at the local level. The Company uses forward contracts to hedge the changes in fair value of certain foreign currency denominated available-for-sale securities attributable to

fluctuations in foreign currency exchange rates. A sensitivity analysis to changes in the value of the U.S. dollar on foreign currency denominated derivatives, investments and monetary assets and liabilities indicated that if the U.S. dollar uniformly weakened by 10% against all currency exposures of the Company at December 31, 2008 and 2007, Income before taxes would have declined by \$15.8 million and

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\$24.6 million, respectively. Because Merck is in a net short position relative to its major foreign currencies after consideration of forward contracts, a uniform weakening of the U.S. dollar will yield the largest overall potential net loss in earnings due to exchange. This measurement assumes that a change in one foreign currency relative to the U.S. dollar would not affect other foreign currencies relative to the U.S. dollar. Although not predictive in nature, the Company believes that a 10% threshold reflects reasonably possible near-term changes in Merck's major foreign currency exposures relative to the U.S. dollar. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

***Interest Rate Risk Management***

In addition to the revenue hedging and balance sheet risk management programs, the Company may use interest rate swap contracts on certain investing and borrowing transactions to manage its net exposure to interest rate changes and to reduce its overall cost of borrowing. The Company does not use leveraged swaps and, in general, does not leverage any of its investment activities that would put principal capital at risk. At December 31, 2008, the Company was a party to two pay-floating, receive-fixed interest rate swap contracts maturing in 2011 with notional amounts of \$125 million each designated as fair value hedges of fixed-rate notes in which the notional amounts match the amount of the hedged fixed-rate notes. The swaps effectively convert the fixed-rate obligations to floating-rate instruments. In 2008, the Company terminated four interest rate swap contracts with notional amounts of \$250 million each, and terminated one interest rate swap contract with a notional amount of \$500 million. These swaps had effectively converted its \$1.0 billion, 4.75% fixed-rate notes due 2015 and its \$500 million, 4.375% fixed-rate notes due 2013 to variable rate debt. As a result of the swap terminations, the Company received \$128.3 million in cash, excluding accrued interest which was not material. The corresponding gains related to the basis adjustment of the debt associated with the terminated swap contracts were deferred and are being amortized as a reduction of interest expense over the remaining term of the notes. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

The Company's investment portfolio includes cash equivalents and short-term investments, the market values of which are not significantly impacted by changes in interest rates. The market value of the Company's medium- to long-term fixed-rate investments is modestly impacted by changes in U.S. interest rates. Changes in medium- to long-term U.S. interest rates have a more significant impact on the market value of the Company's fixed-rate borrowings, which generally have longer maturities. A sensitivity analysis to measure potential changes in the market value of the Company's investments, debt and related swap contracts from a change in interest rates indicated that a one percentage point increase in interest rates at December 31, 2008 and 2007 would have positively impacted the net aggregate market value of these instruments by \$98.9 million and \$62.1 million, respectively. A one percentage point decrease at December 31, 2008 and 2007 would have negatively impacted the net aggregate market value by \$156.3 million and \$114.6 million, respectively. The fair value of the Company's debt was determined using pricing models reflecting one percentage point shifts in the appropriate yield curves. The fair values of the Company's investments were determined using a combination of pricing and duration models.

**Critical Accounting Policies and Other Matters**

The Company's consolidated financial statements 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, share-based compensation assumptions, amounts recorded in connection with acquisitions, restructuring costs, impairments of long-lived assets and investments, and taxes on income. Because of the uncertainty inherent in such estimates, actual results may differ from these estimates. Application of the following accounting policies result in accounting estimates having the potential for the most significant impact on the financial statements.

*Revenue Recognition*

Revenues from sales of products are recognized at the time of delivery and when title and risk of loss passes to the customer. Recognition of revenue also requires reasonable assurance of collection of sales proceeds and completion of all performance obligations. Domestically, sales discounts are issued to customers as direct



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discounts at the point-of-sale or indirectly through an intermediary wholesaler, known as chargebacks, or indirectly in the form of rebates. Additionally, sales are generally made with a limited right of return under certain conditions. Revenues are recorded net of provisions for sales discounts and returns, which are established at the time of sale.

The provision for aggregate indirect customer discounts covers chargebacks and rebates. Chargebacks are discounts that occur when a contracted customer purchases directly through an intermediary wholesaler. The contracted customer generally purchases product at its contracted price plus a mark-up from the wholesaler. The wholesaler, in turn, charges the Company back for the difference between the price initially paid by the wholesaler and the contract price paid to the wholesaler by the customer. The provision for chargebacks is based on expected sell-through levels by the Company's wholesale customers to contracted customers, as well as estimated wholesaler inventory levels. Rebates are amounts owed based upon definitive contractual agreements or legal requirements with private sector and public sector (Medicaid and Medicare Part D) benefit providers, after the final dispensing of the product by a pharmacy to a benefit plan participant. The provision is based on expected payments, which are driven by patient usage and contract performance by the benefit provider customers.

The Company assumes a first-in, first-out movement of inventory within the supply chain for purposes of estimating its aggregate indirect customer discount accrual. In addition, the Company uses historical customer segment mix, adjusted for other known events, in order to estimate the expected provision. Amounts accrued for aggregate indirect customer discounts are evaluated on a quarterly basis through comparison of information provided by the wholesalers and other customers to the amounts accrued. Adjustments are recorded when trends or significant events indicate that a change in the estimated provision is appropriate.

The Company continually monitors its provision for aggregate indirect customer discounts. There were no material adjustments to estimates associated with the aggregate indirect customer discount provision in 2008, 2007 or 2006.

Summarized information about changes in the aggregate indirect customer discount accrual is as follows:

<i>(\$ in millions)</i>	<b>2008</b>		2007	
Balance, January 1	\$	<b>699.4</b>	\$	757.1
Current provision		<b>2,037.5</b>		2,109.7
Adjustments to prior years		<b>(13.7)</b>		(14.1)
Payments		<b>(2,106.9)</b>		(2,153.3)
Balance, December 31	\$	<b>616.3</b>	\$	699.4

Accruals for chargebacks are reflected as a direct reduction to accounts receivable and accruals for rebates as current liabilities. The accrued balances relative to these provisions included in Accounts receivable and Accrued and other current liabilities were \$55.6 million and \$560.7 million, respectively, at December 31, 2008, and \$82.5 million and \$616.9 million, respectively, at December 31, 2007.

The Company maintains a returns policy that allows its customers to return product within a specified period prior to and subsequent to the expiration date (generally, six months before and twelve months after product expiration). The estimate of the provision for returns is based upon historical experience with actual returns. Additionally, the Company considers factors such as levels of inventory in the distribution channel, product dating and expiration period, whether products have been discontinued, entrance in the market of additional generic competition, changes in

formularies or launch of over-the-counter products, among others. The product returns provision, as well as actual returns, were less than 1.0% of net sales in 2008, 2007 and 2006.

Through its distribution program with U.S. wholesalers, the Company encourages wholesalers to align purchases with underlying demand and maintain inventories below specified levels. The terms of the program allow the wholesalers to earn fees upon providing visibility into their inventory levels as well as by achieving certain performance parameters, such as, inventory management, customer service levels, reducing shortage claims and reducing product returns. Information provided through the wholesaler distribution program includes items such as sales trends, inventory on-hand, on-order quantity and product returns.

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Wholesalers generally provide only the above mentioned data to the Company, as there is no regulatory requirement to report lot level information to manufacturers, which is the level of information needed to determine the remaining shelf life and original sale date of inventory. Given current wholesaler inventory levels, which are generally less than a month, the Company believes that collection of order lot information across all wholesale customers would have limited use in estimating sales discounts and returns.

*Inventories Produced in Preparation for Product Launches*

The Company capitalizes inventories produced in preparation for product launches sufficient to support initial market demand. Typically, capitalization of such inventory does not begin until the related product candidates are in Phase III clinical trials and are considered to have a high probability of regulatory approval. The Company monitors the status of each respective product within the regulatory approval process; however, the Company generally does not disclose specific timing for regulatory approval. If the Company is aware of any specific risks or contingencies other than the normal regulatory approval process or if there are any specific issues identified during the research process relating to safety, efficacy, manufacturing, marketing or labeling, the related inventory would generally not be capitalized. Expiry dates of the inventory are impacted by the stage of completion. The Company manages the levels of inventory at each stage to optimize the shelf life of the inventory in relation to anticipated market demand in order to avoid product expiry issues. For inventories that are capitalized, anticipated future sales and shelf lives support the realization of the inventory value as the inventory shelf life is sufficient to meet initial product launch requirements. Inventories produced in preparation for product launches capitalized at December 31, 2008 and 2007 were not significant.

*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. (See Note 10 to the consolidated financial statements.) 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. As of December 31, 2007, the Company had an aggregate reserve of approximately \$5.372 billion (the *Vioxx* Reserve ) for the Settlement Program and the Company's future legal defense costs worldwide related to (i) the *Vioxx* Product Liability Lawsuits, (ii) the *Vioxx* Shareholder Lawsuits, (iii) the *Vioxx* Foreign Lawsuits, and (iv) the *Vioxx* Investigations (collectively, the *Vioxx* Litigation ) (see Note 10 to the consolidated financial statements). During 2008, the Company spent approximately \$305 million in the aggregate in legal defense costs worldwide related to the *Vioxx* Litigation. In the fourth quarter of 2008, the Company recorded a charge of \$62 million solely for its future legal defense costs related to the *Vioxx* Litigation. In addition, in the fourth quarter of 2008, the Company paid an additional \$250 million into the settlement funds in connection with the Settlement Program after having paid \$500 million into the settlement funds in the third quarter of 2008. Consequently, as of December 31, 2008, the aggregate amount of the *Vioxx* Reserve was approximately \$4.379 billion. In addition to the *Vioxx* Reserve solely for its future legal defense costs, the Company considered the same factors that it considered when it previously established reserves for the *Vioxx* Litigation. Some of the significant factors considered in the review of the *Vioxx* Reserve were as follows: the actual costs incurred by the Company; the development of the Company's legal defense strategy and structure in light of the scope of the *Vioxx* Litigation, including the Settlement Agreement and the expectation that certain lawsuits will continue to be pending; the number of cases being brought against the Company; the costs and outcomes of completed trials and the most current information regarding anticipated timing, progression, and related costs of pre-trial activities and trials in the *Vioxx* Litigation. The amount of

the *Vioxx* Reserve as of December 31, 2008 allocated solely to defense costs represents the Company's best estimate of the minimum amount of defense costs to be incurred in connection with the remaining aspects of the *Vioxx* Litigation; however, events such as additional trials in the *Vioxx* Litigation and other events that could arise in the course of the *Vioxx* Litigation could affect the ultimate amount of defense

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costs to be incurred by the Company. The Company will continue to monitor its legal defense costs and review the adequacy of the associated reserves and may determine to increase the *Vioxx* Reserve at any time in the future if, based upon the factors set forth, it believes it would be appropriate to do so.

The Company currently anticipates that two U.S. *Vioxx* Product Liability Lawsuits will be tried in 2009. Except with respect to a product liability trial scheduled to be held in Australia, the Company cannot predict the timing of any other trials related to the *Vioxx* Litigation. 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 not included in the Settlement Program. The Company has not established any reserves for any potential liability relating to the *Vioxx* Lawsuits not included in the Settlement Program or the *Vioxx* Investigations. In each of those cases the Company believes it has strong points to raise on appeal and therefore that unfavorable outcomes in such cases are not probable. Unfavorable outcomes in the *Vioxx* Litigation could have a material adverse effect on the Company's financial position, liquidity and results of operations.

As of December 31, 2007, the Company had a remaining reserve of approximately \$27 million solely for its future legal defense costs for the *Fosamax* Litigation. During 2008, the Company spent approximately \$34 million and added \$40 million to its reserve. Consequently, as of December 31, 2008, the Company had a reserve of approximately \$33 million solely for its future legal defense costs for the *Fosamax* Litigation. Some of the significant factors considered in the establishment of the reserve for the *Fosamax* Litigation legal defense costs were as follows: the actual costs incurred by the Company thus far; the development of the Company's legal defense strategy and structure in light of the creation of the *Fosamax* multidistrict litigation; the number of cases being brought against the Company; and the anticipated timing, progression, and related costs of pre-trial activities in the *Fosamax* Litigation. The Company will continue to monitor its legal defense costs and review the adequacy of the associated reserves. Due to the uncertain nature of litigation, the Company is unable to estimate its costs beyond the completion of the first three federal trials discussed in Note 10 to the consolidated financial statements. The Company has not established any reserves for any potential liability relating to the *Fosamax* Litigation. Unfavorable outcomes in the *Fosamax* Litigation could have a material adverse effect on the Company's financial position, liquidity and results of operations.

The Company is a party to a number of proceedings brought under the Comprehensive Environmental Response, Compensation and Liability Act, commonly known as Superfund, and other federal and state equivalents. When a legitimate claim for contribution is asserted, a liability is initially accrued based upon the estimated transaction costs to manage the site. Accruals are adjusted as site investigations, feasibility studies and related cost assessments of remedial techniques are completed, and as the extent to which other potentially responsible parties who may be jointly and severally liable can be expected to contribute is determined.

The Company is also remediating environmental contamination resulting from past industrial activity at certain of its sites and takes an active role in identifying and providing for these costs. A worldwide survey was initially performed to assess all sites for potential contamination resulting from past industrial activities. Where assessment indicated that physical investigation was warranted, such investigation was performed, providing a better evaluation of the need for remedial action. Where such need was identified, remedial action was then initiated. Estimates of the extent of contamination at each site were initially made at the pre-investigation stage and liabilities for the potential cost of remediation were accrued at that time. As more definitive information became available during the course of investigations and/or remedial efforts at each site, estimates were refined and accruals were adjusted accordingly. These estimates and related accruals continue to be refined annually.

The Company believes that it is in compliance in all material respects with applicable environmental laws and regulations. Expenditures for remediation and environmental liabilities were \$34.5 million in 2008, and are estimated

at \$47.1 million for the years 2009 through 2013. In management's opinion, the liabilities for all environmental matters that are probable and reasonably estimable have been accrued and totaled \$89.5 million and \$109.6 million at December 31, 2008 and December 31, 2007, respectively. These liabilities are undiscounted, do not consider potential recoveries from other parties and will be paid out over the periods of remediation for the

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applicable sites, which are expected to occur primarily over the next 15 years. Although it is not possible to predict with certainty the outcome of these matters, or the ultimate costs of remediation, management does not believe that any reasonably possible expenditures that may be incurred in excess of the liabilities accrued should exceed \$70.0 million in the aggregate. Management also does not believe that these expenditures should result in a material adverse effect on the Company's financial position, results of operations, liquidity or capital resources for any year.

*Share-Based Compensation*

The Company recognizes compensation cost in accordance with FAS 123R, which requires all share-based payments to employees, including grants of stock options, to be expensed over the requisite service period based on the grant date fair value of the awards. The Company determines the fair value of certain share-based awards using the Black-Scholes option-pricing model which uses both historical and current market data to estimate the fair value. This method incorporates various assumptions such as the risk-free interest rate, expected volatility, expected dividend yield and expected life of the options.

*Pensions and Other Postretirement Benefit Plans*

Net pension and other postretirement benefit cost totaled \$376.6 million in 2008, \$489.3 million in 2007 and \$563.7 million in 2006. The decrease of \$112.7 million in 2008 is primarily due to the lower amortization of actuarial net losses and higher expected return on plan assets which were partially offset by an increase in termination benefits attributable to the Company's restructuring actions. Pension and other postretirement benefit plan information for financial reporting purposes is calculated using actuarial assumptions including a discount rate for plan benefit obligations and an expected rate of return on plan assets.

The Company reassesses its benefit plan assumptions on a regular basis. For both the pension and other postretirement benefit plans, the discount rate is evaluated on measurement dates and modified to reflect the prevailing market rate of a portfolio of high-quality fixed-income debt instruments that would provide the future cash flows needed to pay the benefits included in the benefit obligation as they come due. At December 31, 2008, the discount rates for the Company's U.S. pension plans and U.S. other postretirement benefit plans ranged from 6.0% to 6.40% compared with a range of 5.75% to 6.50% at December 31, 2007.

The expected rate of return for both the pension and other postretirement benefit plans represents the average rate of return to be earned on plan assets over the period the benefits included in the benefit obligation are to be paid. In developing the expected rate of return, the Company considers long-term compound annualized returns of historical market data as well as actual returns on the Company's plan assets. Using this reference information, the Company develops forward-looking return expectations for each asset category and a weighted average expected long-term rate of return for a target portfolio allocated across these investment categories. The expected portfolio performance reflects the contribution of active management as appropriate. As a result of this analysis, for 2009, the Company's expected rate of return of 8.75% remained unchanged from 2008 for its U.S. pension and other postretirement benefit plans.

The target investment portfolio of the Company's U.S. pension and other postretirement benefit plans is allocated 45% to 60% in U.S. equities, 20% to 30% in international equities, 15% to 25% in fixed-income investments, and up to 8% in cash and other investments. The portfolio's equity weighting is consistent with the long-term nature of the plans benefit obligation. The expected annual standard deviation of returns of the target portfolio, which approximates 13%, reflects both the equity allocation and the diversification benefits among the asset classes in which the portfolio invests. The actual return on plan assets for pension and other postretirement benefit plans reflects the allocation to global equity markets which delivered significant negative returns during 2008.

Actuarial assumptions are based upon management's best estimates and judgment. A reasonably possible change of plus (minus) 25 basis points in the discount rate assumption, with other assumptions held constant, would have an

estimated \$35.2 million favorable (unfavorable) impact on its U.S. net pension and postretirement benefit cost. A reasonably possible change of plus (minus) 25 basis points in the expected rate of return assumption, with other assumptions held constant, would have an estimated \$13.0 million favorable (unfavorable) impact on its U.S. net pension and postretirement benefit cost. The Company does not expect to have a minimum pension funding



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requirement under the Internal Revenue Code during 2009. The preceding hypothetical changes in the discount rate and expected rate of return assumptions would not impact the Company's funding requirements.

Net loss amounts, which reflect experience differentials primarily relating to differences between expected and actual returns on plan assets as well as the effects of changes in actuarial assumptions, are recorded as a component of Accumulated other comprehensive income. Expected returns for pension plans are based on a calculated market-related value of assets. Under this methodology, asset gains/losses resulting from actual returns that differ from the Company's expected returns are recognized in the market-related value of assets ratably over a five-year period. Also, net loss amounts in Accumulated other comprehensive income in excess of certain thresholds are amortized into net pension and other postretirement benefit cost over the average remaining service life of employees. Amortization of net losses for the Company's U.S. plans at December 31, 2008 is expected to increase net pension and other postretirement benefit cost by approximately \$130 million annually from 2009 through 2013.

*Acquisitions*

The Company accounts for acquired businesses using the purchase method of accounting in accordance with FAS 141, *Business Combinations*, which requires that the assets acquired and liabilities assumed be recorded at the date of acquisition at their respective fair values. Any excess of the purchase price over the estimated fair values of net assets acquired is recorded as goodwill. If the Company determines the acquired company is a development stage company which has not commenced its planned principal operations, the acquisition will be accounted for as an acquisition of assets rather than as a business combination and, therefore, goodwill would not be recorded. The fair value of intangible assets, including acquired research, is based on significant judgments made by management, and accordingly, for significant items, the Company typically obtains assistance from third party valuation specialists. Amounts are allocated to acquired research and expensed at the date of acquisition if technological feasibility has not been established and no alternative future use exists. For projects which can be used immediately in the research process that have alternative future uses, the Company capitalizes these intangible assets and amortizes them over an appropriate useful life. The valuations and useful life assumptions are based on information available near the acquisition date and are based on expectations and assumptions that are deemed reasonable by management. The judgments made in determining estimated fair values assigned to assets acquired and liabilities assumed, as well as asset lives, can materially impact the Company's results of operations.

For intangible assets, including acquired research, the Company typically uses the income approach, which estimates fair value based on each project's projected cash flows. Future cash flows are predominately based on a net income forecast of each project, consistent with historical pricing, margins and expense levels of similar products. Revenues are estimated based on relevant market size and growth factors, expected industry trends, individual project life cycles, and the life of each research project's underlying patent, if any. Expected revenues are then adjusted for the probability of technical and marketing success and the resulting cash flows are discounted at a risk-adjusted discount rate.

On January 1, 2009, the Company adopted FASB Statement No. 141R, *Business Combinations* ( FAS 141R ), which changes the way assets and liabilities are recognized in purchase accounting on a prospective basis. See *Recently Issued Accounting Standards* below.

*Restructuring Costs*

The Company has recorded restructuring costs in connection with its global restructuring programs designed to reduce the Company's cost structure, increase efficiency and enhance competitiveness. As a result, the Company has made estimates and judgments regarding its future plans, including future termination benefits and other exit costs to be incurred when the restructuring actions take place. In connection with these actions, management also assesses the recoverability of long-lived assets employed in the business. In certain instances, asset lives have been shortened based on changes in the expected useful lives of the affected assets. Severance and other related costs are reflected

within Restructuring costs. Asset-related charges are reflected within Materials and production costs and Research and development expenses depending upon the nature of the asset.

**Table of Contents***Impairments of Long-Lived Assets*

The Company assesses changes in economic conditions and makes assumptions regarding estimated future cash flows in evaluating the value of the Company's property, plant and equipment, goodwill and other intangible assets.

The Company periodically evaluates whether current facts or circumstances indicate that the carrying values of its long-lived assets to be held and used are recoverable in accordance with FASB Statement No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. If such circumstances are determined to exist, an estimate of the undiscounted future cash flows of these assets, or appropriate asset groupings, is compared to the carrying value to determine whether an impairment exists. If the asset is determined to be impaired, the loss is measured based on the difference between the asset's fair value and its carrying value. If quoted market prices are not available, the Company will estimate fair value using a discounted value of estimated future cash flows approach.

The Company tests its goodwill for impairment at least annually in accordance with FASB Statement No. 142, *Goodwill and Other Intangible Assets*, using a fair value based test. Goodwill represents the excess of acquisition costs over the fair value of net assets of businesses purchased and is assigned to reporting units within the Company's segments. Other acquired intangibles are recorded at cost. When events or circumstances warrant a review, the Company will assess recoverability from future operations of other intangibles using undiscounted cash flows derived from the lowest appropriate asset groupings, generally the subsidiary level. Impairments are recognized in operating results to the extent that carrying values exceed fair value, which is determined based on the net present value of estimated cash flows.

*Impairments of Investments*

The Company reviews its investments for impairments based on the determination of whether the decline in market value of the investment below the carrying value is other than temporary. The Company considers available evidence in evaluating potential impairments of its investments, including the duration and extent to which fair value is less than cost and the Company's ability and intent to hold the investments.

*Fair Value Measurements*

On January 1, 2008, the Company adopted FASB Statement No. 157, *Fair Value Measurements* ( FAS 157 ) which clarifies the definition of fair value, establishes a framework for measuring fair value, and expands the disclosures on fair value measurements. FAS 157 establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. FAS 157 describes three levels of inputs that may be used to measure fair value (see Note 5 to the consolidated financial statements). At December 31, 2008, the Company's Level 3 assets of \$96.6 million primarily include mortgage-backed and asset-backed securities, as well as certain corporate notes and bonds for which there was a decrease in the observability of market pricing for these investments. On January 1, 2008, the Company had \$1,273.1 million invested in a short-term fixed income fund (the Fund ). Due to market liquidity conditions, cash redemptions from the Fund were restricted. As a result of this restriction on cash redemptions, the Company did not consider the Fund to be traded in an active market with observable pricing on January 1, 2008 and these amounts were categorized as Level 3. On January 7, 2008, the Company elected to be redeemed-in-kind from the Fund and received its share of the underlying securities of the Fund. As a result, \$1,099.7 million of the underlying securities were transferred out of Level 3 as it was determined these securities had observable markets. As of December 31, 2008, \$96.6 million of the investment securities associated with the redemption-in-kind remained classified in Level 3 (approximately 0.9% of the Company's investment securities) as the securities contained at least one significant input which was unobservable (all of which were pledged under certain collateral arrangements (see Note 15 to the consolidated financial statements)). These securities account for the entire balance of the Company's Level 3 assets at December 31, 2008. These securities were valued primarily using pricing models for which management understands the methodologies. These models incorporate transaction details such as contractual terms, maturity, timing and amount of future cash inflows, as well as assumptions about liquidity and credit valuation adjustments of marketplace participants at

December 31, 2008.

**Table of Contents***Taxes on Income*

The Company's effective tax rate is based on pretax income, statutory tax rates and tax planning opportunities available in the various jurisdictions in which the Company operates. An estimated effective tax rate for a year is applied to the Company's quarterly operating results. In the event that there is a significant unusual or one-time item recognized, or expected to be recognized, in the Company's quarterly operating results, the tax attributable to that item would be separately calculated and recorded at the same time as the unusual or one-time item. The Company considers the resolution of prior year tax matters to be such items. Significant judgment is required in determining the Company's tax provision and in evaluating its tax positions. The recognition and measurement of a tax position is based on management's best judgment given the facts, circumstances and information available at the reporting date. In accordance with FIN 48, the Company evaluates tax positions to determine whether the benefits of tax positions are more likely than not of being sustained upon audit based on the technical merits of the tax position. For tax positions that are more likely than not of being sustained upon audit, the Company recognizes the largest amount of the benefit that is greater than 50% likely of being realized upon ultimate settlement in the financial statements. For tax positions that are not more likely than not of being sustained upon audit, the Company does not recognize any portion of the benefit in the financial statements. If the more likely than not threshold is not met in the period for which a tax position is taken, the Company may subsequently recognize the benefit of that tax position if the tax matter is effectively settled, the statute of limitations expires, or if the more likely than not threshold is met in a subsequent period. (See Note 15 to the consolidated financial statements.)

Tax regulations require items to be included in the tax return at different times than the items are reflected in the financial statements. Timing differences create deferred tax assets and liabilities. Deferred tax assets generally represent items that can be used as a tax deduction or credit in the tax return in future years for which the Company has already recorded the tax benefit in the financial statements. The Company establishes valuation allowances for its deferred tax assets when the amount of expected future taxable income is not likely to support the use of the deduction or credit. Deferred tax liabilities generally represent tax expense recognized in the financial statements for which payment has been deferred or expense for which the Company has already taken a deduction on the tax return, but has not yet recognized as expense in the financial statements. At December 31, 2008, foreign earnings of \$22.0 billion have been retained indefinitely by subsidiary companies for reinvestment, therefore no provision has been made for income taxes that would be payable upon the distribution of such earnings.

**Recently Issued Accounting Standards**

In December 2007, the FASB issued FAS 141R which expands the scope of acquisition accounting to all transactions under which control of a business is obtained. This standard requires an acquirer to recognize the assets acquired and liabilities assumed at the acquisition date fair values with limited exceptions. Additionally, FAS 141R requires that contingent consideration as well as contingent assets and liabilities be recorded at fair value on the acquisition date, that acquired in-process research and development be capitalized and recorded as intangible assets at the acquisition date, and also requires transaction costs and costs to restructure the acquired company be expensed. FAS 141R is effective, on a prospective basis, January 1, 2009 and future transactions will be accounted for under this standard.

In December 2007, the FASB issued Statement No. 160, *Noncontrolling Interests in Consolidated Financial Statements – an amendment of ARB No. 51* ( FAS 160 ) which provides guidance for the accounting, reporting and disclosure of noncontrolling interests and requires, among other things, that noncontrolling interests be recorded as equity in the consolidated financial statements. FAS 160 is effective, on a prospective basis, January 1, 2009 with the exception of the presentation and disclosure requirements of FAS 160 which must be applied retrospectively. The adoption of this standard will result in the reclassification of \$2.4 billion of Minority Interests (now referred to as noncontrolling interests) to a separate component of Stockholders' Equity on the Consolidated Balance Sheet. Additionally, net income attributable to noncontrolling interests will be shown separately from parent net income in the Consolidated Statement of Income.

In December 2007, the FASB ratified the consensus reached by the Emerging Issues Task Force ( EITF ) on Issue No. 07-1, *Accounting for Collaborative Arrangements* ( EITF 07-1 ). EITF 07-1, which is effective January 1, 2009, is applied retrospectively to all prior periods presented for all collaborative arrangements existing as of the effective date. EITF 07-1 defines collaborative arrangements and establishes reporting requirements for

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transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. The effect of adoption of EITF 07-1 is not expected to be material to the Company's financial position or results of operations.

In March 2008, the FASB issued Statement No. 161, *Disclosures about Derivative Instruments and Hedging Activities* ( FAS 161 ), which is effective January 1, 2009. FAS 161 requires enhanced disclosures about derivative instruments and hedging activities to allow for a better understanding of their effects on an entity's financial position, financial performance, and cash flows. Among other things, FAS 161 requires disclosure of the fair values of derivative instruments and associated gains and losses in a tabular format. Since FAS 161 requires only additional disclosures about the Company's derivatives and hedging activities, the adoption of FAS 161 will not affect the Company's financial position or results of operations.

In June 2008, the FASB issued Staff Position EITF 03-6-1, *Determining Whether Instruments Granted in Share-Based Payment Transactions are Participating Securities* ( FSP EITF 03-6-1 ), which is effective January 1, 2009. FSP EITF 03-6-1 clarifies that share-based payment awards that entitle holders to receive nonforfeitable dividends before they vest will be considered participating securities and therefore included in the basic earnings per share calculation. The effect of adoption of FSP EITF 03-6-1 is not expected to be material to the Company's results of operations.

In November 2008, the FASB issued EITF 08-6, *Equity Method Investment Accounting Considerations* ( EITF 08-6 ). EITF 08-6 clarifies the accounting for certain transactions and impairment considerations involving equity method investments. EITF 08-6 is effective January 1, 2009, and will be applied on a prospective basis to future transactions.

In November 2008, the FASB issued EITF 08-7, *Accounting for Defensive Intangible Assets* ( EITF 08-7 ). EITF 08-7 clarifies that a defensive intangible asset should be accounted for as a separate unit of accounting and should be assigned a useful life that reflects the entity's consumption of the expected benefits related to the asset. EITF 08-7 is effective January 1, 2009, and will be applied on a prospective basis to future transactions.

In December 2008, the FASB issued Staff Position FAS 132(R)-1, *Employers' Disclosures about Postretirement Benefit Plan Assets* ( FSP FAS 132(R)-1 ), which is effective December 31, 2009. FSP FAS 132(R)-1 amends FASB Statement No. 132R, *Employers' Disclosures about Pensions and other Postretirement Benefits*, to provide guidance on an employer's disclosures about plan assets of a defined pension or other postretirement plan. FSP FAS 132(R)-1 requires disclosures about plan assets including how investment allocation decisions are made, the major categories of plan assets, the inputs and valuation techniques used to measure the fair value of plan assets, the effect of fair value measurements using significant unobservable inputs (Level 3) on changes in plan assets for the period, and significant concentrations of risk within plan assets. Since FSP FAS 132(R)-1 requires only additional disclosures about the Company's pension and other postretirement plan assets, the adoption of FSP FAS 132(R)-1 will not affect the Company's financial position or results of operations.

## **Cautionary Factors That May Affect Future Results**

This report and other written reports and oral statements made from time to time by the Company may contain so-called forward-looking statements, all of which are based on management's current expectations and are subject to risks and uncertainties which may cause results to differ materially from those set forth in the statements. One can identify these forward-looking statements by their use of words such as expects, plans, will, estimates, forecasts, projects and other words of similar meaning. One can also identify them by the fact that they do not relate strictly to historical or current facts. These statements are likely to address the Company's growth strategy, financial results, product development, product approvals, product potential and development programs. One must carefully consider any such statement and should understand that many factors could cause actual results to differ materially from the Company's forward-looking statements. These factors include inaccurate assumptions and a broad variety of other

risks and uncertainties, including some that are known and some that are not. No forward-looking statement can be guaranteed and actual future results may vary materially.



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The Company does not assume the obligation to update any forward-looking statement. One should carefully evaluate such statements in light of factors, including risk factors, described in the Company's filings with the Securities and Exchange Commission, especially on Forms 10-K, 10-Q and 8-K. In Item 1A. Risk Factors of this annual report on Form 10-K the Company discusses in more detail various important risk factors that could cause actual results to differ from expected or historic results. The Company notes these factors for investors as permitted by the Private Securities Litigation Reform Act of 1995. One should understand that it is not possible to predict or identify all such factors. Consequently, the reader should not consider any such list to be a complete statement of all potential risks or uncertainties.

**Item 7A. Quantitative and Qualitative Disclosures about Market Risk.**

The information required by this Item is incorporated by reference to the discussion under Financial Instruments Market Risk Disclosures in Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

**Table of Contents****Item 8. Financial Statements and Supplementary Data.****(a) Financial Statements**

The consolidated balance sheet of Merck & Co., Inc. and subsidiaries as of December 31, 2008 and 2007, and the related consolidated statements of income, of retained earnings, of comprehensive income and of cash flows for each of the three years in the period ended December 31, 2008, the Notes to Consolidated Financial Statements, and the report dated February 26, 2009 of PricewaterhouseCoopers LLP, independent registered public accounting firm, are as follows:

**Consolidated Statement of Income**

Merck &amp; Co., Inc. and Subsidiaries

*Years Ended December 31**(\$ in millions except per share amounts)*

	<b>2008</b>	2007	2006
Sales	<b>\$23,850.3</b>	\$24,197.7	\$22,636.0
Costs, Expenses and Other			
Materials and production	<b>5,582.5</b>	6,140.7	6,001.1
Marketing and administrative	<b>7,377.0</b>	7,556.7	8,165.4
Research and development	<b>4,805.3</b>	4,882.8	4,782.9
Restructuring costs	<b>1,032.5</b>	327.1	142.3
Equity income from affiliates	<b>(2,560.6)</b>	(2,976.5)	(2,294.4)
U.S. <i>Vioxx</i> Settlement Agreement charge	-	4,850.0	-
Other (income) expense, net	<b>(2,194.2)</b>	46.2	(382.7)
	<b>14,042.5</b>	20,827.0	16,414.6
Income Before Taxes	<b>9,807.8</b>	3,370.7	6,221.4
Taxes on Income	<b>1,999.4</b>	95.3	1,787.6
Net Income	<b>\$7,808.4</b>	\$3,275.4	\$4,433.8
Basic Earnings per Common Share	<b>\$3.66</b>	\$1.51	\$2.04
Earnings per Common Share Assuming Dilution	<b>\$3.64</b>	\$1.49	\$2.03

**Consolidated Statement of Retained Earnings**

Merck &amp; Co., Inc. and Subsidiaries

*Years Ended December 31*

(\$ in millions)

	<b>2008</b>	2007	2006
Balance, January 1	<b>\$ 39,140.8</b>	\$ 39,095.1	\$ 37,980.0
Cumulative Effect of Adoption of FIN 48	-	81.0	-
Net Income	<b>7,808.4</b>	3,275.4	4,433.8
Dividends Declared on Common Stock	<b>(3,250.4)</b>	(3,310.7)	(3,318.7)
Balance, December 31	<b>\$ 43,698.8</b>	\$ 39,140.8	\$ 39,095.1

**Consolidated Statement of Comprehensive Income**

Merck &amp; Co., Inc. and Subsidiaries

Years Ended December 31

(\$ in millions)

	<b>2008</b>	2007	2006
Net Income	<b>\$ 7,808.4</b>	\$ 3,275.4	\$ 4,433.8
Other Comprehensive (Loss) Income			
Net unrealized gain (loss) on derivatives, net of tax and net income realization	<b>151.6</b>	(4.4)	(50.9)
Net unrealized (loss) gain on investments, net of tax and net income realization	<b>(80.5)</b>	58.0	26.1
Benefit plan net (loss) gain and prior service cost (credit), net of tax and amortization	<b>(1,761.7)</b>	240.3	-
Minimum pension liability, net of tax	-	-	22.5
Cumulative translation adjustment relating to equity investees, net of tax	<b>(37.2)</b>	44.3	18.9
	<b>(1,727.8)</b>	338.2	16.6
Comprehensive Income	<b>\$ 6,080.6</b>	\$ 3,613.6	\$ 4,450.4

*The accompanying notes are an integral part of these consolidated financial statements.*

**Table of Contents****Consolidated Balance Sheet**

Merck &amp; Co., Inc. and Subsidiaries

December 31

(\$ in millions)

	2008	2007
<b>Assets</b>		
Current Assets		
Cash and cash equivalents	\$ 4,368.3	\$ 5,336.1
Short-term investments	1,118.1	2,894.7
Accounts receivable (including non-trade receivables of \$871.2 in 2008 and \$906.0 in 2007)	3,778.9	3,636.2
Inventories (excludes inventories of \$395.0 in 2008 and \$345.2 in 2007 classified in Other assets - see Note 6)	2,283.3	1,881.0
Deferred income taxes and other current assets	7,756.3	1,297.4
 Total current assets	 19,304.9	 15,045.4
 Investments	 6,491.3	 7,159.2
 Property, Plant and Equipment (at cost)		
Land	386.1	405.8
Buildings	9,767.4	10,048.0
Machinery, equipment and office furnishings	13,103.7	13,553.7
Construction in progress	871.0	795.6
	24,128.2	24,803.1
Less allowance for depreciation	12,128.6	12,457.1
	11,999.6	12,346.0
 Goodwill	 1,438.7	 1,454.8
 Other Intangibles, Net	 525.4	 713.2
 Other Assets	 7,435.8	 11,632.1

	<b>\$ 47,195.7</b>	\$ 48,350.7
<b>Liabilities and Stockholders Equity</b>		
Current Liabilities		
Loans payable and current portion of long-term debt	<b>\$ 2,297.1</b>	\$ 1,823.6
Trade accounts payable	<b>617.6</b>	624.5
Accrued and other current liabilities	<b>9,174.1</b>	8,534.9
Income taxes payable	<b>1,426.4</b>	444.1
Dividends payable	<b>803.5</b>	831.1
Total current liabilities	<b>14,318.7</b>	12,258.2
Long-Term Debt	<b>3,943.3</b>	3,915.8
Deferred Income Taxes and Noncurrent Liabilities	<b>7,766.6</b>	11,585.3
Minority Interests	<b>2,408.8</b>	2,406.7
Stockholders Equity		
Common stock, one cent par value		
Authorized 5,400,000,000 shares		
Issued 2,983,508,675 shares 2008 and 2007	<b>29.8</b>	29.8
Other paid-in capital	<b>8,319.1</b>	8,014.9
Retained earnings	<b>43,698.8</b>	39,140.8
Accumulated other comprehensive loss	<b>(2,553.9)</b>	(826.1)
	<b>49,493.8</b>	46,359.4
Less treasury stock, at cost		
875,818,333 shares 2008		
811,005,791 shares 2007	<b>30,735.5</b>	28,174.7
Total stockholders equity	<b>18,758.3</b>	18,184.7
	<b>\$ 47,195.7</b>	\$ 48,350.7

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

**Table of Contents****Consolidated Statement of Cash Flows**

Merck &amp; Co., Inc. and Subsidiaries

Years Ended December 31

(\$ in millions)

	2008	2007	2006
<b>Cash Flows from Operating Activities</b>			
Net income	\$ 7,808.4	\$ 3,275.4	\$ 4,433.8
Adjustments to reconcile net income to net cash provided by operating activities:			
Gain on distribution from AstraZeneca LP	(2,222.7)	-	-
Equity income from affiliates	(2,560.6)	(2,976.5)	(2,294.4)
Dividends and distributions from equity affiliates	4,289.6	2,485.6	1,931.9
U.S. <i>Vioxx</i> Settlement Agreement charge	-	4,850.0	-
Depreciation and amortization	1,631.2	1,988.2	2,268.4
Deferred income taxes	530.1	(1,781.9)	(530.2)
Share-based compensation	348.0	330.2	312.5
Acquired research	-	325.1	762.5
Taxes paid for Internal Revenue Service settlement	-	(2,788.1)	-
Other	731.7	(64.7)	18.1
Net changes in assets and liabilities:			
Accounts receivable	(889.4)	(290.7)	(709.3)
Inventories	(452.1)	(40.7)	226.5
Trade accounts payable	-	117.7	16.4
Accrued and other current liabilities	(1,710.9)	451.1	461.6
Income taxes payable	(465.3)	987.2	(138.2)
Noncurrent liabilities	(108.0)	26.2	(125.6)
Other	(358.3)	105.1	131.2
<b>Net Cash Provided by Operating Activities</b>	<b>6,571.7</b>	<b>6,999.2</b>	<b>6,765.2</b>
<b>Cash Flows from Investing Activities</b>			
Capital expenditures	(1,298.3)	(1,011.0)	(980.2)
Purchases of securities and other investments	(11,967.3)	(10,132.7)	(19,591.3)
Proceeds from sales of securities and other investments	11,065.8	10,860.2	16,143.8
Acquisitions of subsidiaries, net of cash acquired	-	(1,135.9)	(404.9)
Distribution from AstraZeneca LP	1,899.3	-	-
Increase in restricted assets	(1,629.7)	(1,401.1)	(48.1)
Other	95.8	10.5	(3.0)
<b>Net Cash Used by Investing Activities</b>	<b>(1,834.4)</b>	<b>(2,810.0)</b>	<b>(4,883.7)</b>

**Cash Flows from Financing Activities**

Net change in short-term borrowings	<b>1,859.9</b>	11.4	(1,522.8)
Proceeds from issuance of debt	-	-	755.1
Payments on debt	<b>(1,392.0)</b>	(1,195.3)	(506.2)
Purchases of treasury stock	<b>(2,725.0)</b>	(1,429.7)	(1,002.3)
Dividends paid to stockholders	<b>(3,278.5)</b>	(3,307.3)	(3,322.6)
Proceeds from exercise of stock options	<b>102.3</b>	898.6	369.9
Other	<b>(89.2)</b>	156.2	(375.3)
Net Cash Used by Financing Activities	<b>(5,522.5)</b>	(4,866.1)	(5,604.2)
Effect of Exchange Rate Changes on Cash and Cash Equivalents	<b>(182.6)</b>	98.3	52.1
Net Decrease in Cash and Cash Equivalents	<b>(967.8)</b>	(578.6)	(3,670.6)
Cash and Cash Equivalents at Beginning of Year	<b>5,336.1</b>	5,914.7	9,585.3
Cash and Cash Equivalents at End of Year	<b>\$ 4,368.3</b>	\$ 5,336.1	\$ 5,914.7

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

**Table of Contents****Notes to Consolidated Financial Statements**

Merck &amp; Co., Inc. and Subsidiaries

(\$ in millions except per share amounts)

**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. The Company's operations are principally managed on a products basis and are comprised of two reportable segments: the Pharmaceutical segment and the Vaccines and Infectious Diseases segment. The Pharmaceutical segment includes human health pharmaceutical products marketed either directly by Merck or through joint ventures. These products consist of therapeutic and preventive agents, sold by prescription, for the treatment of human disorders. Merck sells these human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions. The Vaccines and Infectious Diseases segment includes human health vaccine and infectious disease products marketed either directly by Merck or, in the case of vaccines, also through a joint venture. Vaccine products consist of preventive pediatric, adolescent and adult vaccines, primarily administered at physician offices. Merck sells these human health vaccines primarily to physicians, wholesalers, physician distributors and government entities. Infectious disease products consist of therapeutic agents for the treatment of infection sold primarily to drug wholesalers and retailers, hospitals and government agencies. The Company's professional representatives communicate the effectiveness, safety and value of its pharmaceutical and vaccine products to health care professionals in private practice, group practices and managed care organizations.

**2. Summary of Accounting Policies**

*Principles of Consolidation* The consolidated financial statements include the accounts of the Company and all of its subsidiaries in which a controlling interest is maintained. Intercompany balances and transactions are eliminated. Controlling interest is determined by majority ownership interest and the absence of substantive third-party participating rights or, in the case of variable interest entities, by majority exposure to expected losses, residual returns or both. For those consolidated subsidiaries where Merck ownership is less than 100%, the outside stockholders interests are shown as Minority interests. Investments in affiliates over which the Company has significant influence but not a controlling interest, such as interests in entities owned equally by the Company and a third party that are under shared control, are carried on the equity basis.

*Foreign Currency Translation* The U.S. dollar is the functional currency for the Company's foreign subsidiaries.

*Cash Equivalents* Cash equivalents are comprised of certain highly liquid investments with original maturities of less than three months.

*Inventories* Inventories are valued at the lower of cost or market. The cost of substantially all domestic inventories is determined using the last-in, first-out ( LIFO ) method for both book and tax purposes. The cost of all other inventories is determined using the first-in, first-out ( FIFO ) method. Inventories consist of currently marketed products and certain products awaiting regulatory approval. In evaluating the recoverability of inventories produced in preparation for product launches, the Company considers the probability that revenue will be obtained from the future sale of the related inventory together with the status of the product within the regulatory approval process.

*Investments* Investments in marketable debt and equity securities classified as available-for-sale are reported at fair value. On January 1, 2008, the Company adopted Financial Accounting Standards Board ( FASB ) Statement No. 157, *Fair Value Measurements* ( FAS 157 ), which clarifies the definition of fair value, establishes a framework for



measuring fair value and expands the disclosures on fair value measurements. FAS 157 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. FAS 157 also establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.

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Fair value of the Company's investments is determined using quoted market prices in active markets for identical assets or liabilities or quoted prices for similar assets or liabilities or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. For declines in fair value that are considered other-than-temporary, impairment losses are charged to Other (income) expense, net. Declines in fair value that are considered temporary, to the extent not hedged, are reported net of tax in Accumulated other comprehensive income ( AOCI ). The Company considers available evidence in evaluating potential impairment of its investments, including the duration and extent to which fair value is less than cost and the Company's ability and intent to hold the investment. Realized gains and losses are included in Other (income) expense, net.

*Revenue Recognition* Revenues from sales of products are recognized at the time of delivery and when title and risk of loss passes to the customer. Recognition of revenue also requires reasonable assurance of collection of sales proceeds and completion of all performance obligations. Domestically, sales discounts are issued to customers as direct discounts at the point-of-sale or indirectly through an intermediary wholesaler, known as chargebacks, or indirectly in the form of rebates. Additionally, sales are generally made with a limited right of return under certain conditions. Revenues are recorded net of provisions for sales discounts and returns, which are established at the time of sale. Accruals for chargebacks are reflected as a direct reduction to accounts receivable and accruals for rebates are recorded as current liabilities. The accrued balances relative to these provisions included in Accounts receivable and Accrued and other current liabilities were \$55.6 million and \$560.7 million, respectively, at December 31, 2008 and \$82.5 million and \$616.9 million, respectively, at December 31, 2007.

The Company recognizes revenue from the sales of vaccines to the Federal government for placement into stockpiles related to the Pediatric Vaccine Stockpile in accordance with Securities and Exchange Commission ( SEC ) Interpretation, *Commission Guidance Regarding Accounting for Sales of Vaccines and BioTerror Countermeasures to the Federal Government for Placement into the Pediatric Vaccine Stockpile or the Strategic National Stockpile*.

*Depreciation* Depreciation is provided over the estimated useful lives of the assets, principally using the straight-line method. For tax purposes, accelerated methods are used. The estimated useful lives primarily range from 10 to 50 years for Buildings, and from 3 to 15 years for Machinery, equipment and office furnishings.

*Software Capitalization* The Company capitalizes certain costs incurred in connection with obtaining or developing internal-use software including external direct costs of material and services, and payroll costs for employees directly involved with the software development in accordance with Statement of Position 98-1, *Accounting for the Costs of Computer Software Developed or Obtained for Internal Use*. Capitalized software costs are included in Property, plant and equipment and amortized beginning when the asset is substantially ready for use. Capitalized software costs associated with the Company's multi-year implementation of an enterprise-wide resource planning system are being amortized over 7 to 10 years. At December 31, 2008 and 2007, the Company had approximately \$330 million and \$200 million, respectively, of remaining unamortized capitalized software costs associated with this initiative. All other capitalized software costs are being amortized over periods ranging from 3 to 5 years. Costs incurred during the preliminary project stage and post-implementation stage, as well as maintenance and training costs, are expensed as incurred.

*Acquisitions* The Company accounts for acquired businesses using the purchase method of accounting in accordance with FASB Statement No. 141, *Business Combinations*, which requires that the assets acquired and liabilities assumed be recorded at the date of acquisition at their respective fair values. Any excess of the purchase price over the estimated fair values of net assets acquired is recorded as goodwill. If the Company determines the acquired company is a development stage company which has not commenced its planned principal operations, the acquisition will be accounted for as an acquisition of assets rather than as a business combination and, therefore, goodwill would not be recorded. In accordance with FASB Interpretation No. 4, *Applicability of FASB Statement No. 2 to Business Combinations Accounted for by the Purchase Method*, the Company allocates amounts to acquired research which are

expensed at the date of acquisition if technological feasibility has not been established and no alternative future use exists. For projects which can be used immediately in the research process that have alternative future uses, the Company capitalizes these intangible assets and amortizes them over an appropriate useful life. The operating results of the acquired business are reflected in the Company's consolidated financial

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statements and results of operations as of the date of acquisition. On January 1, 2009, the Company adopted FASB Statement No. 141R, *Business Combinations*, which changes the way assets and liabilities are recognized in purchase accounting on a prospective basis. See *Recently Issued Accounting Standards* below.

*Goodwill and Other Intangibles* Goodwill represents the excess of acquisition costs over the fair value of net assets of businesses purchased. Goodwill is assigned to reporting units within the Company's segments and evaluated for impairment on at least an annual basis, using a fair value based test. Other acquired intangibles are recorded at cost and are amortized on a straight-line basis over their estimated useful lives ranging from 3 to 20 years (see Note 7). When events or circumstances warrant a review, the Company will assess recoverability from future operations of other intangibles using undiscounted cash flows derived from the lowest appropriate asset groupings, generally the subsidiary level. Impairments are recognized in operating results to the extent that carrying value exceeds fair value, which is determined based on the net present value of estimated future cash flows.

*Research and Development* Research and development is expensed as incurred. Upfront and milestone payments due to third parties in connection with research and development collaborations prior to regulatory approval are expensed as incurred. Payments due to third parties upon or subsequent to regulatory approval are capitalized and amortized over the shorter of the remaining license or product patent life. On January 1, 2008, the Company adopted Emerging Issues Task Force (EITF) Issue No. 07-3, *Accounting for Advance Payments for Goods or Services Received for Use in Future Research and Development Activities*, which requires that nonrefundable advance payments for goods and services that will be used in future research and development activities be expensed when the activity has been performed or when the goods have been received rather than when the payment is made. See *Recently Issued Accounting Standards* below.

*Share-Based Compensation* The Company expenses all share-based payments to employees, including grants of stock options, over the requisite service period based on the grant-date fair value of the awards.

*Restructuring Costs* The Company records restructuring activities, including costs for one-time termination benefits, in accordance with FASB Statement No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*. Employee termination benefits covered by existing benefit arrangements are recorded in accordance with FASB Statement No. 112, *Employers' Accounting for Postemployment Benefits – an amendment of FASB Statement No. 5 and 43* and FASB Statement No. 88, *Employers' Accounting for Settlements and Curtailments of Defined Benefit Pension Plans for Termination Benefits*. Employee termination costs are recorded when actions are probable and estimable. Asset impairment costs are recorded in accordance with FASB Statement No. 144, *Accounting for the Impairment and Disposal of Long-Lived Assets*.

*Contingencies and Legal Defense Costs* The Company records accruals for contingencies and legal defense costs expected to be incurred in connection with a loss contingency when it is probable that a liability has been incurred and the amount can be reasonably estimated in accordance with FASB Statement No. 5, *Accounting for Contingencies*.

*Taxes on Income* Deferred taxes are recognized for the future tax effects of temporary differences between financial and income tax reporting based on enacted tax laws and rates. The Company evaluates tax positions to determine whether the benefits of tax positions are more likely than not of being sustained upon audit based on the technical merits of the tax position. For tax positions that are more likely than not of being sustained upon audit, the Company recognizes the largest amount of the benefit that is greater than 50% likely of being realized upon ultimate settlement in the financial statements. For tax positions that are not more likely than not of being sustained upon audit, the Company does not recognize any portion of the benefit in the financial statements.

*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, share-based compensation assumptions, amounts recorded in connection with acquisitions, restructuring costs, impairments of long-lived assets and investments, and

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taxes on income. Because of the uncertainty inherent in such estimates, actual results may differ from these estimates.

*Reclassifications* Certain reclassifications have been made to prior year amounts to conform with the current year presentation.

*Recently Adopted Accounting Standards* In 2008, the Company adopted FASB Statement No. 157, *Fair Value Measurements* ( FAS 157 ), Statement No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities including an amendment of FASB Statement No. 115* ( FAS 159 ), Statement No. 162, *The Hierarchy of Generally Accepted Accounting Principles* ( FAS 162 ), EITF Issue No. 07-3, *Accounting for Advance Payments for Goods or Services Received for Use in Future Research and Development Activities* ( EITF 07-3 ) and FASB Staff Position FAS 140-4 and FIN 46(R)-8, *Disclosures by Public Entities (Enterprises) about Transfers of Financial Assets and Interests in Variable Interest Entities* ( FSP FAS 140-4 and FIN 46(R)-8 ).

On January 1, 2008, the Company adopted FAS 157, which clarifies the definition of fair value, establishes a framework for measuring fair value, and expands the disclosures on fair value measurements. In February 2008, the FASB issued Staff Position 157-2, *Effective Date of FASB Statement No. 157* ( FSP 157-2 ), that deferred the effective date of FAS 157 for one year for nonfinancial assets and liabilities recorded at fair value on a non-recurring basis. The effect of adoption of FAS 157 for financial assets and liabilities recognized at fair value on a recurring basis did not have a material impact on the Company's financial position and results of operations (see Note 5). The effect of adoption of FSP 157-2 on the Company's financial position and results of operations is not expected to be material. In October 2008, the FASB issued Staff Position 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active* ( FSP 157-3 ), which clarifies the application of FAS 157 in a market that is not active. FSP 157-3 was effective upon issuance and the effect of adoption on the Company's financial position and results of operations was not material.

On January 1, 2008, the Company adopted FAS 159, which permits companies to make an irrevocable election to measure certain financial assets and financial liabilities at fair value. Unrealized gains and losses on items for which the fair value option has been elected are reported in earnings at each subsequent reporting date. The Company did not elect the fair value option under FAS 159 for any of its financial assets or liabilities upon adoption or in any subsequent period.

In the fourth quarter of 2008, the Company adopted FAS 162, which identifies the sources of accounting principles and the framework for selecting the principles used (order of authority) in the preparation of financial statements that are presented in conformity with generally accepted accounting standards in the United States. The effect of adoption of FAS 162 on the Company's financial statements was not material.

On January 1, 2008, the Company adopted EITF 07-03, which is being applied prospectively for new contracts. EITF 07-3 addresses nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities. EITF 07-3 requires that these payments be deferred and capitalized and recognized as an expense as the related goods are delivered or the related services are performed. The effect of adoption of EITF 07-3 on the Company's financial position and results of operations was not material.

On December 31, 2008, the Company adopted FSP FAS 140-4 and FIN 46(R)-8 which amends FASB Statement No. 140, *Accounting for Transfers and Servicing of Financial Assets and Extinguishment of Liabilities*, to require additional disclosures about transfers of financial assets. FSP FAS 140-4 and FIN 46(R)-8 also amends FASB Interpretation No. 46R, *Consolidation of Variable Interest Entities*, to include additional disclosures about a public entity's involvement with variable interest entities. The effect of adoption of FSP FAS 140-4 and FIN 46(R)-8 had no impact on the Company's disclosures.

*Recently Issued Accounting Standards* The FASB recently issued Statement No. 141R, *Business Combinations* ( FAS 141R ), Statement No. 160, *Noncontrolling Interests in Consolidated Financial Statements – an amendment of ARB No. 51* ( FAS 160 ), Statement No. 161, *Disclosures about Derivative Instruments and Hedging Activities* ( FAS 161 ), Staff Position EITF 03-6-1, *Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities* ( FSP EITF 03-6-1 ), Staff Position FAS 132(R)-1, *Employers’ Disclosures about Postretirement Benefit Plan Assets* ( FSP FAS 132(R)-1 ), and ratified the consensus reached by the EITF on Issue No. 07-1, *Accounting for Collaborative Arrangements* ( EITF 07-1 ), Issue No. 08-6,

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*Equity Method Investment Accounting Considerations* ( EITF 08-6 ) and Issue No. 08-7, *Accounting for Defensive Intangible Assets* ( EITF 08-7 ).

FAS 141R expands the scope of acquisition accounting to all transactions under which control of a business is obtained. This standard requires an acquirer to recognize the assets acquired and liabilities assumed at the acquisition date fair values with limited exceptions. Additionally, FAS 141R requires that contingent consideration as well as contingent assets and liabilities be recorded at fair value on the acquisition date, that acquired in-process research and development be capitalized and recorded as intangible assets at the acquisition date, and also requires transaction costs and costs to restructure the acquired company be expensed. FAS 141R is effective, on a prospective basis, January 1, 2009 and future transactions will be accounted for under this standard.

FAS 160 provides guidance for the accounting, reporting and disclosure of noncontrolling interests and requires, among other things, that noncontrolling interests be recorded as equity in the consolidated financial statements. FAS 160 is effective, on a prospective basis, January 1, 2009 with the exception of the presentation and disclosure requirements of FAS 160 which must be applied retrospectively. The adoption of this standard will result in the reclassification of \$2.4 billion of Minority Interests (now referred to as noncontrolling interests) to a separate component of Stockholders' Equity on the Consolidated Balance Sheet. Additionally, net income attributable to noncontrolling interests will be shown separately from parent net income in the Consolidated Statement of Income.

FAS 161, which is effective January 1, 2009, requires enhanced disclosures about derivative instruments and hedging activities to allow for a better understanding of their effects on an entity's financial position, financial performance, and cash flows. Among other things, FAS 161 requires disclosure of the fair values of derivative instruments and associated gains and losses in a tabular format. Since FAS 161 requires only additional disclosures about the Company's derivatives and hedging activities, the adoption of FAS 161 will not affect the Company's financial position or results of operations.

FSP EITF 03-6-1, which is effective January 1, 2009, clarifies that share-based payment awards that entitle holders to receive nonforfeitable dividends before they vest will be considered participating securities and therefore included in the basic earnings per share calculation. The effect of adoption of FSP EITF 03-6-1 is not expected to be material to the Company's results of operations.

FSP FAS 132(R)-1, which is effective December 31, 2009, amends FASB Statement No. 132R, *Employers' Disclosures about Pensions and other Postretirement Benefits*, to provide guidance on an employer's disclosures about plan assets of a defined pension or other postretirement plan. FSP FAS 132(R)-1 requires disclosures about plan assets including how investment allocation decisions are made, the major categories of plan assets, the inputs and valuation techniques used to measure the fair value of plan assets, the effect of fair value measurements using significant unobservable inputs (Level 3) on changes in plan assets for the period, and significant concentrations of risk within plan assets. Since FSP FAS 132(R)-1 requires only additional disclosures about the Company's pension and other postretirement plan assets, the adoption of FSP FAS 132(R)-1 will not affect the Company's financial position or results of operations.

EITF 07-1, which is effective January 1, 2009, is applied retrospectively to all prior periods presented for all collaborative arrangements existing as of the effective date. EITF 07-1 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. The effect of adoption of EITF 07-1 is not expected to be material to the Company's financial position or results of operations.

EITF 08-6, which is effective January 1, 2009, clarifies the accounting for certain transactions and impairment considerations involving equity method investments and will be applied on a prospective basis to future transactions.



EITF 08-7, which is effective January 1, 2009, clarifies that a defensive intangible asset should be accounted for as a separate unit of accounting and should be assigned a useful life that reflects the entity's consumption of the expected benefits related to the asset. EITF 08-7 will be applied on a prospective basis to future transactions.

**Table of Contents****3. Restructuring***2008 Global Restructuring Program*

In October 2008, the Company announced a global restructuring program (the 2008 Restructuring Program) to reduce its cost structure, increase efficiency, and enhance competitiveness. As part of the 2008 Restructuring Program, the Company expects to eliminate approximately 7,200 positions (6,800 active employees and 400 vacancies) across all areas of the Company worldwide by the end of 2011. During 2008, the Company eliminated approximately 1,750 positions in connection with this program, comprised of employee separations and the elimination of contractors and vacant positions. About 40% of the total reductions will occur in the United States. As part of the 2008 Restructuring Program, the Company is streamlining management layers by reducing its total number of senior and mid-level executives globally by approximately 25%. The Company, however, continues to hire new employees as the business requires. Merck is rolling out a new, more customer-centric selling model designed to provide Merck with a meaningful competitive advantage and help physicians, patients and payers improve patient outcomes. The Company also will make greater use of outside technology resources, centralize common sales and marketing activities, and consolidate and streamline its operations. Merck's manufacturing division will further focus its capabilities on core products and outsource non-core manufacturing. Also, Merck is expanding its access to worldwide external science through a basic research global operating strategy, which is designed to provide a sustainable pipeline and is focused on translating basic research productivity into late-stage clinical success. To increase efficiencies, basic research operations will consolidate work in support of a given therapeutic area into one of four locations. This will provide a more efficient use of research facilities and result in the closure of three basic research sites located in Tsukuba, Japan; Pomezia, Italy; and Seattle by the end of 2009.

Separation costs are accounted for under FAS 112 and FAS 146. In connection with the 2008 Restructuring Program, separation costs under the Company's existing severance programs worldwide were accounted for under FAS 112 and recorded in the third quarter of 2008 to the extent such costs were probable and estimable. The Company commenced accruing costs related to one-time termination benefits offered to employees under the 2008 Restructuring Program in the fourth quarter of 2008 as that is when the necessary criteria under FAS 146 were met. The Company recorded pretax restructuring costs of \$921.3 million related to the 2008 Restructuring Program in 2008. The 2008 Restructuring Program is expected to be completed by the end of 2011 with the total pretax costs estimated to be \$1.6 billion to \$2.0 billion. The Company estimates that two-thirds of the cumulative pretax costs will result in future cash outlays, primarily from employee separation expense. Approximately one-third of the cumulative pretax costs are non-cash, relating primarily to the accelerated depreciation of facilities to be closed or divested.

*2005 Global Restructuring Program*

In November 2005, the Company announced a global restructuring program (the 2005 Restructuring Program) designed to reduce the Company's cost structure, increase efficiency and enhance competitiveness. As part of the 2005 Restructuring Program, Merck has sold or closed five manufacturing sites and two preclinical sites and since inception eliminated 11,250 positions company-wide comprised of employee separations and the elimination of contractors and vacant positions. The Company has also sold or closed certain other facilities and sold related assets in connection with the 2005 Restructuring Program. Since inception through December 31, 2008, the Company has recorded total pretax accumulated costs of \$2.5 billion associated with the 2005 Restructuring Program, which is substantially complete.

For segment reporting, restructuring charges are unallocated expenses.

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The following table summarizes the charges related to restructuring activities by type of cost:

<i>Year Ended December 31, 2008</i>	Separation Costs	Accelerated Depreciation	Other	Total
<b>2008 Restructuring Program</b>				
<b>Materials and production</b>	\$ -	\$ 33.7	\$ 25.0	\$ 58.7
<b>Research and development</b>	-	127.1	-	127.1
<b>Restructuring costs</b>	<b>684.9</b>	-	<b>50.6</b>	<b>735.5</b>
	<b>684.9</b>	<b>160.8</b>	<b>75.6</b>	<b>921.3</b>
<b>2005 Restructuring Program</b>				
<b>Materials and production</b>	-	55.0	9.5	64.5
<b>Research and development</b>	-	0.9	0.4	1.3
<b>Restructuring costs</b>	<b>272.4</b>	-	<b>24.6</b>	<b>297.0</b>
	<b>272.4</b>	<b>55.9</b>	<b>34.5</b>	<b>362.8</b>
	<b>\$ 957.3</b>	<b>\$ 216.7</b>	<b>\$ 110.1</b>	<b>\$ 1,284.1</b>
<i>Year Ended December 31, 2007</i>				
Materials and production	\$ -	\$ 460.6	\$ 22.5	\$ 483.1
Research and development	-	-	(0.1)	(0.1)
Restructuring costs	251.4	-	75.7	327.1
	\$ 251.4	\$ 460.6	\$ 98.1	\$ 810.1
<i>Year Ended December 31, 2006</i>				
Materials and production	\$ -	\$ 707.3	\$ 29.1	\$ 736.4
Research and development	-	56.5	0.3	56.8
Restructuring costs	113.7	-	28.6	142.3
	\$ 113.7	\$ 763.8	\$ 58.0	\$ 935.5

Separation costs are associated with actual headcount reductions, as well as those headcount reductions which were probable and could be reasonably estimated. Approximately 5,800 positions, 2,400 positions and 3,700 positions were

eliminated in 2008, 2007 and 2006, respectively. Of the positions eliminated in 2008 approximately 1,750 related to the 2008 Restructuring Program and 4,050 related to the 2005 Restructuring Program. These position eliminations are comprised of actual headcount reductions, and the elimination of contractors and vacant positions.

Accelerated depreciation costs primarily relate to manufacturing and research facilities to be sold or closed as part of the programs. All of the sites have and will continue to operate up through the respective closure dates, and since future cash flows were sufficient to recover the respective book values, Merck was required to accelerate depreciation of the site assets rather than write them off immediately. The site assets include manufacturing and research facilities and equipment.

Other activity in 2008, 2007 and 2006 includes \$29.4 million, \$39.4 million and \$25.0 million, respectively, associated with certain fixed assets that were no longer to be used in the business as a result of these restructuring actions and were therefore written off. Additionally, other activity includes \$68.4 million, \$18.9 million and \$34.2 million in 2008, 2007 and 2006, respectively, related to curtailment, settlement and termination charges on the Company's pension and other postretirement benefit plans (see Note 13). Other activity also includes shut-down costs, and in 2008 and 2006, pretax gains of \$61.5 million and \$40.7 million, respectively, resulting from the sales of facilities and related assets in connection with restructuring activities.

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The following table summarizes the charges and spending relating to restructuring activities:

	Separation Costs	Accelerated Depreciation	Other	Total
<b>2008 Restructuring Program</b>				
<b>Restructuring reserves as of January 1, 2008</b>	\$ -	\$ -	\$ -	\$ -
<b>Expense</b>	<b>684.9</b>	<b>160.8</b>	<b>75.6</b>	<b>921.3</b>
<b>(Payments) receipts, net</b>	<b>(77.2)</b>	<b>-</b>	<b>(37.3)</b>	<b>(114.5)</b>
<b>Non-cash activity</b>	<b>-</b>	<b>(160.8)</b>	<b>(38.3)</b>	<b>(199.1)</b>
<b>Restructuring reserves as of December 31, 2008<sup>(1)</sup></b>	<b>\$ 607.7</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ 607.7</b>
<b>2005 Restructuring Program</b>				
Restructuring reserves as of January 1, 2007	\$ 177.7	\$ -	\$ -	\$ 177.7
Expense	251.4	460.6	98.1	810.1
(Payments) receipts, net	(197.6)	-	(59.9)	(257.5)
Non-cash activity	-	(460.6)	(38.2)	(498.8)
Restructuring reserves as of December 31, 2007	\$ 231.5	\$ -	\$ -	\$ 231.5
Expense	\$ 272.4	\$ 55.9	\$ 34.5	\$ 362.8
(Payments) receipts, net	(389.1)	-	(23.2) <sup>(2)</sup>	(412.3)
Non-cash activity	-	(55.9)	(11.3)	(67.2)
<b>Restructuring reserves as of December 31, 2008<sup>(1)</sup></b>	<b>\$ 114.8</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ 114.8</b>

<sup>(1)</sup> The cash outlays associated with the restructuring reserve for the 2008 Restructuring Program are expected to be completed by the end of 2011. The cash outlays associated with the remaining restructuring reserve for the 2005 Restructuring Program are expected to be largely completed by the end of 2009.

<sup>(2)</sup> Includes proceeds from the sales of facilities in connection with the 2005 Restructuring Program.

#### 4. Research Collaborations, Acquisitions and License Agreements

Merck continues its strategy of establishing strong external alliances to complement its substantial internal research capabilities, including research collaborations, acquisitions, licensing pre-clinical and clinical compounds and technology transfers to drive both near- and long-term growth.

In February 2009, Merck entered into a definitive agreement with Insmid Inc. ( Insmid ) to purchase Insmid's portfolio of follow-on biologic therapeutic candidates and its commercial manufacturing facilities located in Boulder, Colorado. Under the terms of the agreement, Merck will pay Insmid an aggregate of \$130 million in cash to acquire all rights to the Boulder facilities and Insmid's pipeline of follow-on biologic candidates. Insmid's follow-on biologics portfolio includes two clinical candidates: INS-19, an investigational recombinant granulocyte-colony stimulating factor

( G-CSF ) that will be evaluated for its ability to prevent infections in patients with cancer receiving chemotherapy and INS-20, a pegylated recombinant G-CSF designed to allow for less frequent dosing. The agreement provides for initial payments of up to \$10 million for INS-19 and INS-20. Merck will pay Insmed the remaining balance upon closing of the transaction, which is expected by the end of the first quarter of 2009, without any further milestone or royalty obligations.

In September 2008, Merck and Japan Tobacco Inc. ( JT ) signed a worldwide licensing agreement to develop and commercialize JTT-305, an investigational oral osteoanabolic (bone growth stimulating) agent for the treatment of osteoporosis, a disease which reduces bone density and strength and results in an increased risk of bone fractures. JTT-305 is an investigational oral calcium sensing receptor antagonist that is currently being evaluated by JT in Phase II clinical trials in Japan for its effect on increasing bone density and is in Phase I clinical trials outside of Japan. Under the terms of the agreement, Merck gained worldwide rights, except for Japan, to develop and commercialize JTT-305 and certain other related compounds. JT received an upfront payment of \$85 million, which the Company recorded as Research and development expense, and is eligible to receive additional cash payments

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upon achievement of certain milestones associated with the development and approval of a drug candidate covered by this agreement. JT will also be eligible to receive royalties from sales of any drug candidates that receive marketing approval. The license agreement between Merck and JT will remain in effect until expiration of all royalty and milestone obligations, and may be terminated in the event of an uncured material breach by the other party. The agreement may also be terminated by Merck without cause before initial commercial sale of JTT-305 by giving six months prior notice to JT, and thereafter by giving one year prior notice thereof to JT. The license agreement may also be terminated immediately by Merck if Merck determines due to safety and/or efficacy concerns based on available scientific evidence to cease development of JTT-305 and/or to withdraw JTT-305 from the market on a permanent basis.

In September 2008, the Company terminated its collaboration with FoxHollow Technologies, Inc. ( FoxHollow ) for atherosclerotic plaque analysis. The collaboration was entered into in 2005 and expanded in 2006 whereby Merck acquired an equity interest in FoxHollow.

In December 2008, the Company terminated its collaboration with Dynavax Technologies Corporation for the development of V270, an investigational hepatitis B vaccine, which was entered into in 2007.

In September 2007, Merck completed the acquisition of NovaCardia, Inc. ( NovaCardia ), a privately held clinical-stage pharmaceutical company focused on cardiovascular disease. This acquisition added rolofylline (MK-7418), NovaCardia's investigational Phase III compound for acute heart failure, to Merck's pipeline. Merck acquired all of the outstanding equity of NovaCardia for a total purchase price of \$366.4 million (including \$16.4 million of cash and investments on hand at closing), which was paid through the issuance of 7.3 million shares of Merck common stock to the former NovaCardia shareholders based on Merck's average closing stock price for the five days prior to closing of the acquisition. In connection with the acquisition, the Company recorded a charge of \$325.1 million for acquired research associated with rolofylline as at the acquisition date, technological feasibility had not been established and no alternative future use existed. The charge, which is not deductible for tax purposes, was recorded in Research and development expense and was determined based upon the present value of expected future cash flows resulting from this technology adjusted for the probability of its technical and marketing success utilizing an income approach reflecting an appropriate risk-adjusted discount rate of 22.0%. The ongoing activity with respect to the future development of rolofylline continues and the costs have not been and are not expected to be material to the Company's research and development expenses. The remaining purchase price was allocated to cash and investments of \$16.4 million, a deferred tax asset relating to a net operating loss carryforward of \$23.9 million and other net assets of \$1.0 million. Because NovaCardia was a development stage company that had not commenced its planned principal operations, the transaction was accounted for as an acquisition of assets rather than as a business combination and, therefore, goodwill was not recorded. NovaCardia's results of operations have been included in the Company's consolidated financial results since the acquisition date.

Also in 2007, Merck and GTx, Inc. ( GTx ) entered into an agreement providing for a research and development and global strategic collaboration for selective androgen receptor modulators ( SARMs ), a new class of drugs with the potential to treat age-related muscle loss (sarcopenia) as well as other musculoskeletal conditions. Also in 2007, Merck and ARIAD Pharmaceuticals, Inc. ( ARIAD ) entered into a global collaboration to jointly develop and commercialize deforolimus (MK-8669), ARIAD's novel mTOR inhibitor, for use in cancer. These collaborations generally continue in effect until the expiration of all royalty and milestone payment obligations. These collaborations may generally be terminated in the event of insolvency or a material uncured breach by either party. Additionally, the collaboration agreement between Merck and GTx may be terminated by Merck upon ninety days notice to GTx at any time after December 18, 2009. The collaboration agreement between Merck and ARIAD may be terminated by Merck upon the failure of MK-8669 to meet certain developmental and safety requirements or in the event Merck concludes it is not advisable to continue the development of MK-8669 for use in a cancer indication. In addition, Merck may terminate the ARIAD collaboration agreement on or after the third anniversary of the effective date by providing at

least 12 months prior written notice. Upon termination of the ARIAD collaboration agreement, depending upon the circumstances, the parties have varying rights and obligations with respect to the continued development and commercialization of MK-8669 and continuing royalty obligations.

On December 29, 2006, Merck completed the acquisition of Sirna Therapeutics, Inc. ( Sirna ) for \$13 per share in cash, for a total value of approximately \$1.1 billion, which included the purchase of all outstanding Sirna



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shares, warrants and stock options. The aggregate purchase price of \$1.1 billion was paid on January 3, 2007. Sirna was a publicly-held biotechnology company that is developing a new class of medicines based on RNA interference ( RNAi ) technology, which could significantly alter the treatment of disease. RNAi-based therapeutics selectively catalyze the destruction of the RNA transcribed from an individual gene. The acquisition of Sirna has increased Merck's ability to use RNAi technology to turn off a targeted gene in a human cell, potentially rendering inoperative a gene responsible for triggering a specific disease. The transaction was accounted for under the purchase method of accounting, in which the assets acquired and the liabilities assumed from Sirna at the date of acquisition were recorded at their respective fair values as of the acquisition date in the Company's consolidated financial statements. The determination of fair values requires management to make significant estimates and assumptions. The excess of the purchase price over the fair value of the acquired net assets was recorded as goodwill of \$369.2 million. The goodwill was fully allocated to the Pharmaceutical segment and is not deductible for tax purposes. Also, the Company recorded a charge of \$466.2 million for acquired research associated with Sirna's compounds currently under development, for which, at the acquisition date, technological feasibility had not been established and no alternative future use existed. The acquired research charge related to the development of treatments for both the hepatitis B and hepatitis C viruses, which were in preclinical development, as well as licensing agreements held by Sirna. The charge, which is not deductible for tax purposes, was recorded in Research and development expense and was determined based upon the present value of expected future cash flows of new product candidates resulting from this technology adjusted for the probability of its technical and marketing success utilizing an income approach reflecting appropriate risk-adjusted discount rates of 27.0% to 30.0%. The ongoing activity with respect to each of these compounds under development continues and the costs have not been and are not expected to be material to the Company's research and development expenses. The allocation of the purchase price also resulted in the recognition of an intangible asset of \$357.8 million and a related deferred tax liability of \$146.3 million, as well as other assets and liabilities - net of \$89.3 million. The intangible asset relates to Sirna's developed technology that can be used immediately in the research and development process and has alternative future uses. This intangible asset is being amortized to Research and development expense on a straight-line basis over a seven year useful life. Pro forma financial information is not required because Sirna's historical financial results are not significant when compared with the Company's financial results. The transaction closed on December 29, 2006, and accordingly, Sirna's operating results were included in the Company's results of operations beginning January 1, 2007.

In June 2006, the Company acquired all of the outstanding equity of GlycoFi, Inc. ( GlycoFi ) for approximately \$373 million in cash (\$400 million purchase price net of \$25 million in shares already owned and net transaction costs). GlycoFi was a privately-held biotechnology company in the field of yeast glycoengineering, which is the addition of specific carbohydrate modifications to the proteins in yeast, and optimization of biologic drug molecules. GlycoFi's technology platform is used in the development of glycoproteins, as well as the optimization of a glycoprotein target. In connection with the acquisition, the Company recorded a charge of \$296.3 million for acquired research associated with GlycoFi's technology platform to be used in the research and development process, for which, at the acquisition date, technological feasibility had not been established and no alternative future use existed. This charge is not deductible for tax purposes. The technology is currently being utilized in Merck's pipeline of biologics. The charge was recorded in Research and development expense and was determined based upon the present value of expected future cash flows of new product candidates resulting from this technology adjusted for the probability of its technical and marketing success utilizing an income approach reflecting the appropriate risk-adjusted discount rate. The Company also recorded a \$99.4 million intangible asset (\$57.6 million net of deferred taxes) related to GlycoFi's developed technology that can be used immediately in the research and development process and has alternative future uses. This intangible asset is being amortized to Research and development expense on a straight-line basis over a five year useful life. The remaining net assets acquired in this transaction were not material. Because GlycoFi was a development stage company that had not commenced its planned principal operations, the transaction was accounted for as an acquisition of assets rather than as a business combination and, therefore, goodwill was not recorded. GlycoFi's results of operations have been included with the Company's consolidated financial results since the acquisition date.

In May 2006, the Company acquired all of the equity of Abmaxis, Inc. ( Abmaxis ) for approximately \$80 million in cash. Abmaxis was a privately-held biopharmaceutical company dedicated to the discovery and optimization of monoclonal antibody ( MAb ) products for human therapeutics and diagnostics. Abmaxis developed and validated a breakthrough antibody engineering technology platform, Abmaxis *in-silico*

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Immunization, which has alternative future uses to the Company with no significant technological or engineering risks at the date of acquisition. In connection with the acquisition, the Company allocated substantially all of the purchase price to Abmaxis' technology platform and recorded an intangible asset of \$135.3 million (\$78.5 million net of deferred taxes). This intangible asset is being amortized to Research and development expense on a straight-line basis over a five year useful life. The remaining net assets acquired in this transaction were not material. Because Abmaxis was a development stage company that had not commenced its planned principal operations, the transaction was accounted for as an acquisition of assets rather than as a business combination and, therefore, goodwill was not recorded. Abmaxis' results of operations have been included with the Company's consolidated financial results since the acquisition date.

Also in 2006, Merck and Idera Pharmaceuticals ( Idera ) formed a broad collaboration to research, develop and commercialize Idera's Toll-like Receptor agonists for use in combination with Merck's therapeutic and prophylactic vaccines under development for oncology, infectious diseases and Alzheimer's disease. Additionally in 2006, Merck and Ambrilia Biopharma Inc. ( Ambrilia ), a biopharmaceutical company developing innovative therapeutics in the fields of cancer and infectious diseases, announced they entered into an exclusive licensing agreement granting Merck the worldwide rights to Ambrilia's HIV/AIDS protease inhibitor program. Also in 2006, Neuromed Pharmaceuticals Ltd. and Merck signed a research collaboration and license agreement to research, develop and commercialize novel compounds for the treatment of pain and other neurological disorders.

**5. Financial Instruments and Fair Value***Foreign Currency Risk Management*

While the U.S. dollar is the functional currency of the Company's foreign subsidiaries, a significant portion of the Company's revenues are denominated in foreign currencies. Merck relies on sustained cash flows generated from foreign sources to support its long-term commitment to U.S. dollar-based research and development. To the extent the dollar value of cash flows is diminished as a result of a strengthening dollar, the Company's ability to fund research and other dollar-based strategic initiatives at a consistent level may be impaired. The Company has established revenue hedging and balance sheet risk management programs to protect against volatility of future foreign currency cash flows and changes in fair value caused by volatility in foreign exchange rates.

The objective of the revenue hedging program is to reduce the potential for longer-term unfavorable changes in foreign exchange to decrease the U.S. dollar value of future cash flows derived from foreign currency denominated sales, primarily the euro and Japanese yen. To achieve this objective, the Company will partially hedge anticipated third-party sales that are expected to occur over its planning cycle, typically no more than three years into the future. The Company will layer in hedges over time, increasing the portion of sales hedged as it gets closer to the expected date of the transaction, such that it is probable that the hedged transaction will occur. The portion of sales hedged is based on assessments of cost-benefit profiles that consider natural offsetting exposures, revenue and exchange rate volatilities and correlations, and the cost of hedging instruments. The hedged anticipated sales are a specified component of a portfolio of similarly denominated foreign currency-based sales transactions, each of which responds to the hedged risk in the same manner. Merck manages its anticipated transaction exposure principally with purchased local currency put options, which provide the Company with a right, but not an obligation, to sell foreign currencies in the future at a predetermined price. If the U.S. dollar strengthens relative to the currency of the hedged anticipated sales, total changes in the options' cash flows offset the decline in the expected future U.S. dollar cash flows of the hedged foreign currency sales. Conversely, if the U.S. dollar weakens, the options' value reduces to zero, but the Company benefits from the increase in the value of the anticipated foreign currency cash flows.

The designated hedge relationship is based on total changes in the options' cash flows. Accordingly, the entire fair value change in the options is deferred in AOCI and reclassified into Sales when the hedged anticipated revenue is recognized. The hedge relationship is highly effective and hedge ineffectiveness is *de minimis*. The fair values of

purchased currency options are reported in Accounts receivable or Other assets. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

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The primary objective of the balance sheet risk management program is to protect the U.S. dollar value of foreign currency denominated net monetary assets from the effects of volatility in foreign exchange that might occur prior to their conversion to U.S. dollars. Merck principally utilizes forward exchange contracts, which enable the Company to buy and sell foreign currencies in the future at fixed exchange rates and economically offset the consequences of changes in foreign exchange on the amount of U.S. dollar cash flows derived from the net assets. Merck routinely enters into contracts to offset the effects of exchange on exposures denominated in developed country currencies, primarily the euro and Japanese yen. For exposures in developing country currencies, the Company will enter into forward contracts to partially offset the effects of exchange on exposures when it is deemed economical to do so based on a cost-benefit analysis that considers the magnitude of the exposure, the volatility of the exchange rate and the cost of the hedging instrument. The Company will also minimize the effect of exchange on monetary assets and liabilities by managing operating activities and net asset positions at the local level.

Foreign currency denominated monetary assets and liabilities are remeasured at spot rates in effect on the balance sheet date with the effects of changes in spot rates reported in Other (income) expense, net. The forward contracts are not designated as hedges and are marked to market through Other (income) expense, net. Accordingly, fair value changes in the forward contracts help mitigate the changes in the value of the remeasured assets and liabilities attributable to changes in foreign currency exchange rates, except to the extent of the spot-forward differences. These differences are not significant due to the short-term nature of the contracts, which typically have average maturities at inception of less than one year.

The Company uses forward contracts to hedge the changes in fair value of certain foreign currency denominated available-for-sale securities attributable to fluctuations in foreign currency exchange rates. Changes in the fair value of the hedged securities due to fluctuations in spot rates are offset in Other (income) expense, net, by the fair value changes in the forward contracts attributable to spot rate fluctuations. Hedge ineffectiveness was not material during 2008, 2007 or 2006. Changes in the contracts' fair value due to spot-forward differences are excluded from the designated hedge relationship and recognized in Other (income) expense, net. These amounts were not significant for the years ended December 31, 2008, 2007 or 2006.

The fair values of forward exchange contracts are reported in the following four balance sheet line items: Accounts receivable (current portion of gain position), Other assets (non-current portion of gain position), Accrued and other current liabilities (current portion of loss position), or Deferred income taxes and noncurrent liabilities (non-current portion of loss position). The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

*Interest Rate Risk Management*

The Company may use interest rate swap contracts on certain investing and borrowing transactions to manage its net exposure to interest rate changes and to reduce its overall cost of borrowing. The Company does not use leveraged swaps and, in general, does not leverage any of its investment activities that would put principal capital at risk.

At December 31, 2008, the Company was a party to two pay-floating, receive-fixed interest rate swap contracts maturing in 2011 with notional amounts of \$125 million each designated as fair value hedges of fixed-rate notes in which the notional amounts match the amount of the hedged fixed-rate notes. The swaps effectively convert the fixed-rate obligations to floating-rate instruments. The fair value changes in the notes are offset in interest expense by the fair value changes in the swap contracts. The fair values of these contracts are reported in Accounts receivable, Other assets, Accrued and other current liabilities, or Deferred income taxes and noncurrent liabilities. During 2008, the Company terminated four interest rate swap contracts with notional amounts of \$250 million each, and terminated one interest rate swap contract with a notional amount of \$500 million. These swaps had effectively converted its \$1.0 billion, 4.75% fixed-rate notes due 2015 and its \$500 million, 4.375% fixed-rate notes due 2013 to variable rate debt. As a result of the swap terminations, the Company received \$128.3 million in cash, excluding accrued interest

which was not material. The corresponding gains related to the basis adjustment of the debt associated with the terminated swap contracts were deferred and are being amortized as a reduction of interest expense over the remaining term of the notes. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

**Table of Contents***Fair Value Measurements*

On January 1, 2008, the Company adopted FAS 157, which clarifies the definition of fair value, establishes a framework for measuring fair value, and expands the disclosures on fair value measurements. In February 2008, the FASB issued FSP 157-2 that deferred the effective date of FAS 157 for one year for nonfinancial assets and liabilities recorded at fair value on a non-recurring basis. In October 2008, the FASB issued FSP 157-3, which clarifies the application of FAS 157 in a market that is not active. FAS 157 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. FAS 157 also establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. FAS 157 describes three levels of inputs that may be used to measure fair value:

*Level 1* Quoted prices in active markets for identical assets or liabilities. The Company's Level 1 assets include equity securities that are traded in an active exchange market.

*Level 2* Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. The Company's Level 2 assets and liabilities primarily include debt securities with quoted prices that are traded less frequently than exchange-traded instruments, corporate notes and bonds, U.S. and foreign government and agency securities, certain mortgage-backed and asset-backed securities, municipal securities, and derivative contracts whose values are determined using pricing models with inputs that are observable in the market or can be derived principally from or corroborated by observable market data.

*Level 3* Unobservable inputs that are supported by little or no market activity and that are financial instruments whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation. The Company's Level 3 assets mainly include mortgage-backed and asset-backed securities, as well as certain corporate notes and bonds with limited market activity. At December 31, 2008, \$96.6 million, or approximately 0.9%, of the Company's investment securities were categorized as Level 3 fair value assets (all of which were pledged under certain collateral arrangements (see Note 15)). All of the assets classified as Level 3 at December 31, 2008 were acquired when the Company elected to be redeemed-in-kind from a short-term fixed income fund that restricted cash redemptions as described below.

If the inputs used to measure the financial assets and liabilities fall within more than one level described above, the categorization is based on the lowest level input that is significant to the fair value measurement of the instrument.

**Table of Contents***Financial Assets and Liabilities Measured at Fair Value on a Recurring Basis*

Financial assets and liabilities measured at fair value on a recurring basis are summarized below:

	2008					2007	
	Fair Value Measurements Using					Carrying Value	Fair Value
(\$ in millions)	Carrying Value	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Inputs (Level 2)	Other Significant Inputs (Level 3)	Total		
		<b>Assets</b>					
<i>Investments</i>							
Corporate notes and bonds	\$ 3,093.2	\$ -	\$ 3,093.2	\$ -	\$ 3,093.2	\$ 5,465.0	\$ 5,465.0
U.S. government and agency securities	2,885.7	-	2,885.7	-	2,885.7	1,748.4	1,748.4
Mortgage-backed securities <sup>(1)</sup>	723.9	-	723.9	-	723.9	760.0	760.0
Municipal securities	-	-	-	-	-	744.6	744.6
Foreign government bonds	319.4	-	319.4	-	319.4	269.9	269.9
Asset-backed securities <sup>(1)</sup>	306.7	-	306.7	-	306.7	313.2	313.2
Equity securities	144.7	71.1	73.6	-	144.7	150.8	150.8
Commercial paper	133.0	-	133.0	-	133.0	258.1	258.1
Other debt securities	2.8	-	2.8	-	2.8	343.9	343.9
Total Investments	\$ 7,609.4	\$ 71.1	\$ 7,538.3	\$ -	\$ 7,609.4	\$ 10,053.9	\$ 10,053.9
Other assets <sup>(2)</sup>	\$ 2,974.5	\$ -	\$ 2,877.9	\$ 96.6	\$ 2,974.5	\$ 958.6	\$ 958.6
<i>Derivative assets<sup>(3)</sup></i>							
Purchased currency options	\$ 451.3	\$ -	\$ 451.3	\$ -	\$ 451.3	\$ 59.9	\$ 59.9
Forward exchange contracts	73.2	-	73.2	-	73.2	62.1	62.1
Interest rate swaps	23.9	-	23.9	-	23.9	108.0	108.0
Total Derivative Assets	\$ 548.4	\$ -	\$ 548.4	\$ -	\$ 548.4	\$ 230.0	\$ 230.0
<b>Liabilities</b>							
<i>Derivative liabilities<sup>(3)</sup></i>							
Written currency options	\$ 1.9	\$ -	\$ 1.9	\$ -	\$ 1.9	\$ 8.8	\$ 8.8
Forward exchange contracts	273.1	-	273.1	-	273.1	35.8	35.8
Total Derivative Liabilities	\$ 275.0	\$ -	\$ 275.0	\$ -	\$ 275.0	\$ 44.6	\$ 44.6

<sup>(1)</sup> Mortgage-backed securities represent AAA rated securities issued or unconditionally guaranteed as to payment of principal and interest by U.S. government agencies. Substantially all of the asset-backed securities are highly-rated (Standard & Poor's rating of AAA and Moody's Investors Service rating of Aaa), secured primarily by credit card, auto loan, and home equity receivables, with weighted-average lives of primarily 5 years or less.



- (2) *Other assets represent a portion of the pledged collateral discussed below and in Note 15. Level 2 Other assets are comprised of \$987.4 million of corporate notes and bonds, \$792.5 million of municipal securities, \$357.3 million of commercial paper, \$276.0 million of mortgage-backed securities, \$240.1 million of U.S. government and agency securities and \$224.6 million of asset-backed securities.*
- (3) *The fair value determination of derivatives includes an assessment of the credit risk of counterparties to the derivatives and the Company's own credit risk, the effects of which were not significant.*

*Level 3 Valuation Techniques*

Financial assets are considered Level 3 when their fair values are determined using pricing models, discounted cash flow methodologies or similar techniques and at least one significant model assumption or input is unobservable. Level 3 financial assets also include certain investment securities for which there is limited market activity such that the determination of fair value requires significant judgment or estimation. The Company's Level 3 investment securities at December 31, 2008, primarily include mortgage-backed and asset-backed securities, as well as certain corporate notes and bonds for which there was a decrease in the observability of market pricing for these investments. These securities were valued primarily using pricing models for which management understands the methodologies. These models incorporate transaction details such as contractual terms, maturity, timing and amount of future cash inflows, as well as assumptions about liquidity and credit valuation adjustments of marketplace participants at December 31, 2008.

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The table below provides a summary of the changes in fair value, including net transfers in and/or out, of all financial assets measured at fair value on a recurring basis using significant unobservable inputs (Level 3) during 2008:

(\$ in millions)	Beginning Balance January 1	Net Transfers (Out) of Level 3 <sup>(1)</sup>	Purchases, Sales, Settlements, Net Earnings <sup>(2)</sup>	Total Realized and Unrealized Losses		Ending Balance December 31	Losses Recorded in Earnings for Level 3 Assets Still Held at December 31
				Included in:	Compre- hensive Income		
Other assets	\$ 958.6	\$ (684.5)	\$ (132.8)	\$ (43.6)	\$ (1.1)	\$ 96.6	\$ (44.3)
Other debt securities	314.5	(314.5)	-	-	-	-	-
Total	\$ 1,273.1	\$ (999.0)	\$ (132.8)	\$ (43.6)	\$ (1.1)	\$ 96.6	\$ (44.3)

<sup>(1)</sup> Transfers in and out of Level 3 are deemed to occur at the beginning of the quarter in which the transaction takes place.

<sup>(2)</sup> Amounts are recorded in Other (income) expense, net, in the Consolidated Statement of Income.

On January 1, 2008, the Company had \$1,273.1 million invested in a short-term fixed income fund (the Fund). Due to market liquidity conditions, cash redemptions from the Fund were restricted. As a result of this restriction on cash redemptions, the Company did not consider the Fund to be traded in an active market with observable pricing on January 1, 2008 and these amounts were categorized as Level 3. On January 7, 2008, the Company elected to be redeemed-in-kind from the Fund and received its share of the underlying securities of the Fund. As a result, \$1,099.7 million of the underlying securities were transferred out of Level 3 as it was determined that these securities had observable markets. On December 31, 2008, \$96.6 million of the investment securities associated with the redemption-in-kind were classified in Level 3 as the securities contained at least one significant input which was unobservable. These securities account for the entire balance of the Company's Level 3 assets at December 31, 2008.

**Financial Instruments not Measured at Fair Value**

Some of the Company's financial instruments are not measured at fair value on a recurring basis but are recorded at amounts that approximate fair value due to their liquid or short-term nature, such as cash and cash equivalents, receivables and payables.

The estimated fair value of the Company's loans payable and long-term debt (including current portion) at December 31, 2008 was \$6,294.8 million compared with a carrying value of \$6,240.4 million and at December 31, 2007 estimated fair value was \$5,815.1 million compared with a carrying amount of \$5,739.4 million. Fair value was estimated using quoted dealer prices.

A summary of the December 31 gross unrealized gains and losses on the Company's available-for-sale investments, including those pledged as collateral, recorded in AOCI is as follows:

	2008		2007	
	Gains <sup>(1)</sup>	Losses <sup>(1)</sup>	Gains	Losses
Corporate notes and bonds	\$ 31.6	\$ (65.3)	\$ 28.4	\$ (20.7)
U.S. government and agency securities	67.4	(3.2)	32.2	(0.1)
Mortgage-backed securities	12.5	(5.0)	8.9	-
Municipal securities	28.4	(0.3)	13.3	(0.2)
Asset-backed securities	0.6	(20.7)	1.8	(1.4)
Foreign government bonds	13.5	-	0.7	(0.6)
Other debt securities	1.5	(3.4)	14.5	-
Equity securities	17.7	(3.1)	97.0	(5.5)
	\$ 173.2	\$ (101.0)	\$ 196.8	\$ (28.5)

<sup>(1)</sup> At December 31, 2008, gross unrealized gains and gross unrealized losses related to amounts pledged as collateral (see below and Note 15) were \$36.1 million and \$(30.3) million, respectively.

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The amount of gross unrealized losses at December 31, 2008 that were in a continuous loss position for more than 12 months was *de minimis*. Available-for-sale debt securities maturing within one year totaled \$1.1 billion at December 31, 2008. Of the remaining debt securities, \$5.6 billion mature within five years.

*Letter of Credit*

In August 2008, the Company executed a \$4.1 billion letter of credit agreement with a financial institution, which satisfied certain conditions set forth in the U.S. *Vioxx* Settlement Agreement (see Note 10). The Company pledged collateral to the financial institution of approximately \$5.1 billion pursuant to the terms of the letter of credit agreement. Although the amount of assets pledged as collateral is set by the letter of credit agreement and such assets are held in custody by a third party, the assets are managed by the Company. The Company considers the assets pledged under the letter of credit agreement to be restricted. As a result, \$2.1 billion and \$1.4 billion of cash and investments, respectively, were classified as restricted current assets and \$1.6 billion of investments were classified as restricted non-current assets. The letter of credit amount and required collateral balances will decline as payments (after the first \$750 million) under the Settlement Agreement are made. As of December 31, 2008, \$3.8 billion was recorded within Deferred income taxes and other current assets and \$1.3 billion was classified as Other assets.

*Concentrations of Credit Risk*

On an ongoing basis, the Company monitors concentrations of credit risk associated with corporate issuers of securities and financial institutions with which it conducts business. Credit exposure limits are established to limit a concentration with any single issuer or institution. Cash and investments are placed in instruments that meet high credit quality standards, as specified in the Company's investment policy guidelines.

The Company's four largest U.S. customers, McKesson Corporation, Cardinal Health, Inc., AmerisourceBergen Corporation and Medco Health Solutions, Inc., represented, in aggregate, approximately one-seventh of accounts receivable at December 31, 2008. The Company monitors the creditworthiness of its customers to which it grants credit terms in the normal course of business. Bad debts have been minimal. The Company does not normally require collateral or other security to support credit sales.

**6. Inventories**

Inventories at December 31 consisted of:

	2008	2007
Finished goods	\$ 432.6	\$ 382.9
Raw materials and work in process	2,147.1	1,732.2
Supplies	98.6	111.1
Total (approximates current cost)	2,678.3	2,226.2
Reduction to LIFO costs	-	-
	\$ 2,678.3	\$ 2,226.2
Recognized as:		
Inventories	\$ 2,283.3	\$ 1,881.0
Other assets	395.0	345.2

Inventories valued under the LIFO method comprised approximately 56% and 57% of inventories at December 31, 2008 and 2007, respectively. Amounts recognized as Other assets are comprised entirely of raw materials and work in

process inventories, the majority of which are noncurrent vaccine inventories.

**Table of Contents****7. Other Intangibles**

Other intangibles at December 31 consisted of:

	<b>2008</b>	2007
Patents and product rights	<b>\$ 1,656.4</b>	\$ 1,656.3
Other	<b>779.2</b>	781.0
Total acquired cost	<b>2,435.6</b>	2,437.3
Patents and product rights	<b>\$ 1,528.5</b>	\$ 1,449.4
Other	<b>381.7</b>	274.7
Total accumulated amortization	<b>1,910.2</b>	1,724.1
	<b>\$ 525.4</b>	\$ 713.2

Other reflects intangibles, primarily technology rights, recorded in connection with the acquisitions of Sirna, GlycoFi and Abmaxis (see Note 4). Aggregate amortization expense was \$186.1 million in 2008, \$235.8 million in 2007 and \$170.3 million in 2006. The estimated aggregate amortization expense for each of the next five years is as follows: 2009, \$133.5 million; 2010, \$130.8 million; 2011, \$104.3 million; 2012, \$85.3 million; 2013, \$62.9 million.

**8. Joint Ventures and Other Equity Method Affiliates**

Equity income from affiliates reflects the performance of the Company's joint ventures and other equity method affiliates and was comprised of the following:

<i>Years Ended December 31</i>	<b>2008</b>	2007	2006
Merck/Schering-Plough	<b>\$ 1,536.3</b>	\$ 1,830.8	\$ 1,218.6
AstraZeneca LP	<b>598.4</b>	820.1	783.7
Other <sup>(1)</sup>	<b>425.9</b>	325.6	292.1
	<b>\$ 2,560.6</b>	\$ 2,976.5	\$ 2,294.4

<sup>(1)</sup> Primarily reflects results from Merial Limited, Sanofi Pasteur MSD and Johnson & Johnson's Merck Consumer Pharmaceuticals Company.

***Merck/Schering-Plough***

In 2000, the Company and Schering-Plough Corporation ( Schering-Plough ) (collectively the Partners ) entered into agreements to create separate equally-owned partnerships to develop and market in the United States new prescription medicines in the cholesterol-management and respiratory therapeutic areas. These agreements generally provide for equal sharing of development costs and for co-promotion of approved products by each company. In 2001, the cholesterol-management partnership agreements were expanded to include all the countries of the world, excluding Japan. In 2002, ezetimibe, the first in a new class of cholesterol-lowering agents, was launched in the United States as *Zetia* (marketed as *Ezetrol* outside the United States). In 2004, a combination product containing the active ingredients of both *Zetia* and *Zocor*, was approved in the United States as *Vytorin* (marketed as *Inegy* outside of the United States).

The cholesterol agreements provide for the sharing of operating income generated by the Merck/Schering-Plough cholesterol partnership (the MSP Partnership ) based upon percentages that vary by product, sales level and country. In the U.S. market, the Partners share profits on *Zetia* and *Vytorin* sales equally, with the exception of the first \$300 million of annual *Zetia* sales on which Schering-Plough receives a greater share of profits. Operating income includes expenses that the Partners have contractually agreed to share, such as a portion of manufacturing costs, specifically identified promotion costs (including direct-to-consumer advertising and direct and identifiable out-of-pocket promotion) and other agreed upon costs for specific services such as on-going clinical research, market support, market research, market expansion, as well as a specialty sales force and physician education programs. Expenses incurred in support of the MSP Partnership but not shared between the Partners, such as marketing and administrative expenses (including certain sales force costs), as well as certain manufacturing costs, are not included in Equity income from affiliates. However, these costs are reflected in the

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overall results of the Company. Certain research and development expenses are generally shared equally by the Partners, after adjusting for earned milestones.

See Note 10 for information with respect to litigation involving the MSP Partnership and the Partners related to the sale and promotion of *Zetia* and *Vytorin*.

The respiratory therapeutic agreements provided for the joint development and marketing in the United States by the Partners of a once-daily, fixed-combination tablet containing the active ingredients montelukast sodium and loratadine. Montelukast sodium, a leukotriene receptor antagonist, is sold by Merck as *Singulair* and loratadine, an antihistamine, is sold by Schering-Plough as Claritin, both of which are indicated for the relief of symptoms of allergic rhinitis. During 2008, the Partners received a not-approvable letter from the U.S. Food and Drug Administration ( FDA ) for the proposed fixed combination of loratadine/montelukast and subsequently announced the withdrawal of the New Drug Application for the combination tablet. The companies also terminated the respiratory joint venture. This action had no impact on the business of the cholesterol joint venture. As a result of the termination of the respiratory joint venture, the Company was obligated to Schering-Plough in the amount of \$105 million as specified in the joint venture agreements. This resulted in a charge of \$43 million during the second quarter of 2008 which was included in Equity income from affiliates. The remaining amount is being amortized over the remaining patent life of *Zetia* through 2016.

Summarized financial information for the MSP Partnership is as follows:

<i>Years Ended December 31</i>	<b>2008</b>	2007	2006
Sales	<b>\$ 4,561.1</b>	\$ 5,186.2	\$ 3,884.1
Vytorin	<b>2,360.0</b>	2,779.1	1,955.3
Zetia	<b>2,201.1</b>	2,407.1	1,928.8
Materials and production costs	<b>176.3</b>	216.0	179.0
Other expense, net	<b>1,230.1</b>	1,307.2	1,217.1
Income before taxes	<b>\$ 3,154.7</b>	\$ 3,663.0	\$ 2,488.0
Merck's share of income before taxes <sup>(1)</sup>	<b>\$ 1,489.5</b>	\$ 1,832.5	\$ 1,214.5

<i>December 31</i>	<b>2008</b>	2007
Total assets <sup>(2)</sup>	<b>\$ 608.0</b>	\$1,014.0
Total liabilities <sup>(2)</sup>	<b>488.0</b>	656.0

<sup>(1)</sup> Merck's share of the MSP Partnership's income before taxes differs from the equity income recognized from the MSP Partnership primarily due to the timing of recognition of certain transactions between the Company and the MSP Partnership, including the \$105 million milestone payment discussed above and other milestone payments.

<sup>(2)</sup> Amounts are comprised almost entirely of current balances.

**AstraZeneca LP**

In 1982, Merck entered into an agreement with Astra AB ( Astra ) to develop and market Astra's products under a royalty-bearing license. In 1993, the Company's total sales of Astra products reached a level that triggered the first step



in the establishment of a joint venture business carried on by Astra Merck Inc. ( AMI ), in which Merck and Astra each owned a 50% share. This joint venture, formed in 1994, developed and marketed most of Astra's new prescription medicines in the United States including *Prilosec*, the first of a class of medications known as proton pump inhibitors, which slows the production of acid from the cells of the stomach lining.

In 1998, Merck and Astra completed the restructuring of the ownership and operations of the joint venture whereby the Company acquired Astra's interest in AMI, renamed KBI Inc. ( KBI ), and contributed KBI's operating assets to a new U.S. limited partnership, Astra Pharmaceuticals L.P. (the Partnership ), in exchange for a 1% limited partner interest. Astra contributed the net assets of its wholly owned subsidiary, Astra USA, Inc., to the Partnership in exchange for a 99% general partner interest. The Partnership, renamed AstraZeneca LP ( AZLP ) upon Astra's 1999 merger with Zeneca Group Plc (the AstraZeneca merger ), became the exclusive distributor of the products for which KBI retained rights.

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While maintaining a 1% limited partner interest in AZLP, Merck has consent and protective rights intended to preserve its business and economic interests, including restrictions on the power of the general partner to make certain distributions or dispositions. Furthermore, in limited events of default, additional rights will be granted to the Company, including powers to direct the actions of, or remove and replace, the Partnership's chief executive officer and chief financial officer. Merck earns ongoing revenue based on sales of current and future KBI products and such revenue was \$1.6 billion, \$1.7 billion and \$1.8 billion in 2008, 2007 and 2006, respectively, primarily relating to sales of *Nexium*, as well as *Prilosec*. In addition, Merck earns certain Partnership returns which are recorded in Equity income from affiliates as reflected in the table above. Such returns include a priority return provided for in the Partnership Agreement, variable returns based, in part, upon sales of certain former Astra USA, Inc. products, and a preferential return representing Merck's share of undistributed AZLP GAAP earnings. The AstraZeneca merger triggered a partial redemption in March 2008 of Merck's interest in certain AZLP product rights. Upon this redemption, Merck received \$4.3 billion from AZLP. This amount was based primarily on a multiple of Merck's average annual variable returns derived from sales of the former Astra USA, Inc. products for the three years prior to the redemption (the Limited Partner Share of Agreed Value). Merck recorded a \$1.5 billion pretax gain on the partial redemption in 2008. The partial redemption of Merck's interest in the product rights did not result in a change in Merck's 1% limited partner interest.

In conjunction with the 1998 restructuring, Astra purchased an option (the Asset Option) for a payment of \$443.0 million, which was recorded as deferred income, to buy Merck's interest in the KBI products, excluding the gastrointestinal medicines *Nexium* and *Prilosec* (the Non-PPI Products). The Asset Option is exercisable in the first half of 2010 at an exercise price equal to the net present value as of March 31, 2008 of projected future pretax revenue to be received by the Company from the Non-PPI Products (the Appraised Value). Merck also had the right to require Astra to purchase such interest in 2008 at the Appraised Value. In February 2008, the Company advised AZLP that it would not exercise the Asset Option, thus the \$443.0 million remains deferred. In addition, in 1998 the Company granted Astra an option (the Shares Option) to buy Merck's common stock interest in KBI, and, therefore, Merck's interest in *Nexium* and *Prilosec*, exercisable two years after Astra's exercise of the Asset Option. Astra can also exercise the Shares Option in 2017 or if combined annual sales of the two products fall below a minimum amount provided, in each case, only so long as AstraZeneca's Asset Option has been exercised in 2010. The exercise price for the Shares Option is based on the net present value of estimated future net sales of *Nexium* and *Prilosec* as determined at the time of exercise, subject to certain true-up mechanisms.

The AstraZeneca merger constituted a Trigger Event under the KBI restructuring agreements. As a result of the merger, in exchange for Merck's relinquishment of rights to future Astra products with no existing or pending U.S. patents at the time of the merger, Astra paid \$967.4 million (the Advance Payment). The Advance Payment was deferred as it remained subject to a true-up calculation (the True-Up Amount) that was directly dependent on the fair market value in March 2008 of the Astra product rights retained by the Company. The calculated True-Up Amount of \$243.7 million was returned to AZLP in March 2008 and Merck recognized a pretax gain of \$723.7 million related to the residual Advance Payment balance.

Under the provisions of the KBI restructuring agreements, because a Trigger Event has occurred, the sum of the Limited Partner Share of Agreed Value, the Appraised Value and the True-Up Amount was guaranteed to be a minimum of \$4.7 billion. Distribution of the Limited Partner Share of Agreed Value less payment of the True-Up Amount resulted in cash receipts to Merck of \$4.0 billion and an aggregate pretax gain of \$2.2 billion which is included in Other (income) expense, net. AstraZeneca's purchase of Merck's interest in the Non-PPI Products is contingent upon the exercise of the Asset Option by AstraZeneca in 2010 and, therefore, payment of the Appraised Value may or may not occur. Also, in March 2008, the \$1.38 billion outstanding loan from Astra plus interest through the redemption date was settled. As a result of these transactions, the Company received net proceeds from AZLP of \$2.6 billion.



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Summarized financial information for AZLP is as follows:

<i>Years Ended December 31</i>	<b>2008</b>	2007	2006
Sales	\$ <b>5,450.4</b>	\$ 6,345.4	\$ 6,753.0
Materials and production costs	<b>2,682.4</b>	3,364.0	3,940.4
Other expense, net	<b>1,408.1</b>	1,090.1	1,131.6
Income before taxes	<b>1,359.9</b>	1,891.3	1,681.0

<i>December 31</i>	<b>2008</b>	2007
Current assets	\$ <b>2,023.9</b>	\$ 5,360.7
Noncurrent assets	<b>359.0</b>	437.0
Total liabilities (all current)	<b>3,054.4</b>	2,231.1

In connection with the 1998 restructuring of AMI, the Company assumed a \$2.4 billion par value preferred stock obligation with a dividend rate of 5% per annum, which is carried by KBI and included in Minority interests. While a small portion of the preferred stock carried by KBI is convertible into KBI common shares, none of the preferred securities are convertible into the Company's common shares and, therefore, are not included as common shares issuable for purposes of computing Earnings per common share assuming dilution (see Note 16).

*Merial Limited*

In 1997, Merck and Rhône-Poulenc S.A. (now Sanofi-Aventis S.A.) combined their animal health businesses to form Merial Limited ( Merial ), a fully integrated animal health company, which is a stand-alone joint venture, 50% owned by each party. Merial provides a comprehensive range of pharmaceuticals and vaccines to enhance the health, well-being and performance of a wide range of animal species. Merial sales were \$2.6 billion for 2008, \$2.4 billion for 2007 and \$2.2 billion for 2006.

*Sanofi Pasteur MSD*

In 1994, Merck and Pasteur Mérieux Connaught (now Sanofi Pasteur S.A.) established an equally-owned joint venture to market vaccines in Europe and to collaborate in the development of combination vaccines for distribution in Europe. Joint venture vaccine sales were \$1.9 billion for 2008, \$1.4 billion for 2007 and \$913.9 million for 2006.

*Johnson & Johnson<sup>o</sup>Merck Consumer Pharmaceuticals Company*

In 1989, Merck formed a joint venture with Johnson & Johnson to develop and market a broad range of nonprescription medicines for U.S. consumers. This 50% owned venture was subsequently expanded into Canada. Significant joint venture products are *Pepcid AC*, an over-the-counter form of the Company's ulcer medication *Pepcid*, as well as *Pepcid Complete*, an over-the-counter product which combines the Company's ulcer medication with antacids. Sales of products marketed by the joint venture were \$212.1 million for 2008, \$219.7 million for 2007 and \$252.6 million for 2006.

Investments in affiliates accounted for using the equity method, including the above joint ventures, totaled \$1.4 billion at December 31, 2008 and \$3.9 billion at December 31, 2007. These amounts are reported in Other assets. Amounts due from the above joint ventures included in Accounts receivable were \$623.4 million at December 31, 2008 and

\$637.4 million at December 31, 2007.

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Summarized information for those affiliates (excluding the MSP Partnership and AZLP disclosed separately above) is as follows:

<i>Years Ended December 31</i>	<b>2008</b>	2007	2006
Sales	<b>\$ 4,860.4</b>	\$ 4,218.6	\$ 3,640.7
Materials and production costs	<b>1,553.6</b>	1,346.9	1,189.3
Other expense, net	<b>2,297.9</b>	1,995.2	1,693.3
Income before taxes	<b>1,008.9</b>	876.5	758.1
<i>December 31</i>	<b>2008</b>	2007	
Current assets	<b>\$ 1,935.8</b>	\$2,113.2	
Noncurrent assets	<b>1,174.4</b>	1,139.5	
Current liabilities	<b>1,152.6</b>	1,295.8	