

Merck & Co. Inc.
Form 10-K
February 28, 2012
[Table of Contents](#)

As filed with the Securities and Exchange Commission on February 28, 2012

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D. C. 20549

FORM 10-K

(MARK ONE)

☒ **Annual Report Pursuant to Section 13 or 15(d)**
of the Securities Exchange Act of 1934

For the Fiscal Year Ended December 31, 2011

or

☐ **Transition Report Pursuant to Section 13 or 15(d)**
of the Securities Exchange Act of 1934

For the transition period from _____ to _____

Commission File No. 1-6571

Merck & Co., Inc.

One Merck Drive

Edgar Filing: Merck & Co. Inc. - Form 10-K

Whitehouse Station, N. J. 08889-0100

(908) 423-1000

Incorporated in New Jersey

I.R.S. Employer

Identification No. 22-1918501

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

Name of Each Exchange

Title of Each Class

on which Registered

Common Stock (\$0.50 par value)

New York Stock Exchange

Number of shares of Common Stock (\$0.50 par value) outstanding as of January 31, 2012: 3,044,008,396.

Aggregate market value of Common Stock (\$0.50 par value) held by non-affiliates on June 30, 2011 based on closing price on June 30, 2011: \$108,759,000,000.

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 whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). **Yes** ☐ **No** ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405) 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:

Document

Part of Form 10-K
Part III

Proxy Statement for the Annual Meeting of

Shareholders to be held May 22, 2012, to be filed with the

Securities and Exchange Commission within 120 days after the

Edgar Filing: Merck & Co. Inc. - Form 10-K

close of the fiscal year covered by this report

Table of Contents

Table of Contents

| | Page |
|---|-------------|
| Part I | |
| Item 1. <u>Business</u> | 1 |
| Item 1A. <u>Risk Factors</u> | 21 |
| <u>Cautionary Factors that May Affect Future Results</u> | 33 |
| Item 1B. <u>Unresolved Staff Comments</u> | 34 |
| Item 2. <u>Properties</u> | 34 |
| Item 3. <u>Legal Proceedings</u> | 34 |
| Item 4. <u>Mine Safety Disclosures</u> | 34 |
| <u>Executive Officers of the Registrant</u> | 34 |
| Part II | |
| Item 5. <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u> | 38 |
| Item 6. <u>Selected Financial Data</u> | 41 |
| Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u> | 42 |
| Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u> | 82 |
| Item 8. <u>Financial Statements and Supplementary Data</u> | 83 |
| (a) <u>Financial Statements</u> | 83 |
| <u>Notes to Consolidated Financial Statements</u> | 87 |
| <u>Report of Independent Registered Public Accounting Firm</u> | 147 |
| (b) <u>Supplementary Data</u> | 148 |
| Item 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u> | 149 |
| Item 9A. <u>Controls and Procedures</u> | 149 |
| <u>Management's Report</u> | 149 |
| Item 9B. <u>Other Information</u> | 150 |
| Part III | |
| Item 10. <u>Directors, Executive Officers and Corporate Governance</u> | 151 |
| Item 11. <u>Executive Compensation</u> | 151 |
| Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u> | 151 |
| Item 13. <u>Certain Relationships and Related Transactions, and Director Independence</u> | 151 |
| Item 14. <u>Principal Accountant Fees and Services</u> | 152 |
| Part IV | |
| Item 15. <u>Exhibits and Financial Statement Schedules</u> | 152 |
| <u>Signatures</u> | 158 |
| <u>Consent of Independent Registered Public Accounting Firm</u> | 159 |

Table of Contents

PART I

Item 1. Business.

Merck & Co., Inc. (Merck or the Company) is a global health care company that delivers innovative health solutions through its prescription medicines, vaccines, biologic therapies, animal health, and consumer care products, which it markets directly and through its joint ventures. The Company's operations are principally managed on a products basis and are comprised of four operating segments, which are the Pharmaceutical, Animal Health, Consumer Care and Alliances segments, and one reportable segment, which is the Pharmaceutical segment. The Pharmaceutical segment includes human health pharmaceutical and vaccine products marketed either directly by the Company or through joint ventures. Human health pharmaceutical products consist of therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. The Company 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. Vaccine products consist of preventive pediatric, adolescent and adult vaccines, primarily administered at physician offices. The Company sells these human health vaccines primarily to physicians, wholesalers, physician distributors and government entities. The Company also has animal health operations that discover, develop, manufacture and market animal health products, including vaccines, which the Company sells to veterinarians, distributors and animal producers. Additionally, the Company has consumer care operations that develop, manufacture and market over-the-counter, foot care and sun care products, which are sold through wholesale and retail drug, food chain and mass merchandiser outlets.

For financial information and other information about the Pharmaceutical 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.

All product or service marks appearing in type form different from that of the surrounding text are trademarks or service marks owned, licensed to, promoted or distributed by Merck, its subsidiaries or affiliates, except as noted. All other trademarks or services marks are those of their respective owners.

Overview

During 2011, the Company focused on accelerating revenue growth, reducing costs to drive efficiencies, allocating resources to drive future growth by making strategic investments in product launches, as well as in the emerging markets, and advancing and augmenting its research and development pipeline.

Worldwide sales totaled \$48.0 billion in 2011, an increase of 4% compared with \$46.0 billion in 2010. Foreign exchange favorably affected global sales performance by 2%. The revenue increase was driven largely by growth in *Januvia* (sitagliptin) and *Janumet* (sitagliptin/metformin hydrochloride HCl), treatments for type 2 diabetes, *Singulair* (montelukast sodium), a medicine for the chronic treatment of asthma and the relief of symptoms of allergic rhinitis, *Isentress* (raltegravir), an antiretroviral therapy for use in combination therapy for the treatment of HIV-1 infection, *Gardasil* [human papillomavirus quadrivalent (types 6, 11, 16 and 18) vaccine, recombinant], a vaccine to help prevent certain diseases caused by four types of human papillomavirus (HPV), *Simponi* (golimumab), a treatment for inflammatory diseases, *RotaTeq* [Rotavirus Vaccine, Live, Oral, Pentavalent], a vaccine to help protect against rotavirus gastroenteritis in infants and children, *Zetia* (ezetimibe), a cholesterol absorption inhibitor, *Pneumovax* [pneumococcal vaccine polyvalent], a vaccine to help prevent pneumococcal disease, and *Bridion* (sugammadex), for the reversal of certain muscle relaxants used during surgery. In addition, revenue in 2011 benefited from higher sales of the Company's animal health products and from the launch of *Victrelis* (boceprevir), a treatment for chronic hepatitis C. These increases were partially offset by lower sales of *Cozaar* (losartan potassium) and *Hyzaar* (losartan potassium and hydrochlorothiazide), treatments for hypertension, which lost patent protection in the United States in April 2010 and in a number of major European markets in March 2010, as well as by lower sales of Caelyx, Subutex and Suboxone as the Company no longer has marketing rights to these products. Revenue was also negatively affected by lower sales of *Vytorin* (ezetimibe/simvastatin), a cholesterol modifying medicine, *Temodar* (temozolomide), a treatment for certain types of brain tumors, *ProQuad* [Measles, Mumps, Rubella and Varicella Virus Vaccine Live], a pediatric combination vaccine to help protect against measles, mumps, rubella and varicella, and *Varivax* [Varicella Virus Vaccine Live], a vaccine to help

Table of Contents

prevent chickenpox (varicella). In addition, as discussed below, the ongoing implementation of certain provisions of U.S. health care reform legislation during 2011 resulted in further increases in Medicaid rebates and other impacts that reduced revenues. Additionally, many countries in the European Union (the "EU") have undertaken austerity measures aimed at reducing costs in health care and have implemented pricing actions that negatively impacted sales in 2011.

In April 2011, Merck and Johnson & Johnson ("J&J") reached an agreement to amend the agreement governing the distribution rights to *Remicade* (infliximab) and *Simponi*. This agreement concluded the arbitration proceeding J&J initiated in May 2009. Under the terms of the amended distribution agreement, Merck relinquished marketing rights for *Remicade* and *Simponi* to J&J in territories including Canada, Central and South America, the Middle East, Africa and Asia Pacific effective July 1, 2011. Merck retained exclusive marketing rights throughout Europe, Russia and Turkey (the "Retained Territories"). The Retained Territories represented approximately 70% of Merck's 2010 revenue of \$2.8 billion from *Remicade* and *Simponi*. In addition, beginning July 1, 2011, all profits derived from Merck's exclusive distribution of the two products in the Retained Territories are being equally divided between Merck and J&J. J&J also received a one-time payment from Merck of \$500 million in April 2011.

During 2011, the Company continued the advancement of drug candidates through its pipeline. *Victrelis*, the Company's innovative oral medicine for the treatment of chronic hepatitis C, was approved by the U.S. Food and Drug Administration (the "FDA") and the European Commission (the "EC"). The FDA also approved *Juvisync* (sitagliptin and simvastatin), a new treatment for type 2 diabetes that combines the active ingredient in the glucose-lowering medication *Januvia* with the cholesterol-lowering medication *Zocor* (simvastatin). In addition, the EC approved *Zoely* (NOMAC/E2), a monophasic combined oral contraceptive tablet for use by women to prevent pregnancy. Cubicin, an antibacterial agent with activity against methicillin-resistant *Staphylococcus aureus* ("MRSA"), for which the Company has licensed development and distribution rights in Japan, was approved for use in that country.

In February 2012, the FDA approved *Janumet XR* (sitagliptin and metformin HCl extended-release), a new treatment for type 2 diabetes that combines sitagliptin, which is the active component of *Januvia*, with extended-release metformin in a once-daily formulation; *Cosopt PF* (dorzolamide hydrochloride-timolol maleate ophthalmic solution) 2.0%/0.5%, Merck's preservative-free formulation of *Cosopt*, indicated for the reduction of elevated intraocular pressure in appropriate patients with open-angle glaucoma or ocular hypertension; and *Zioptan* (tafluprost ophthalmic solution), a preservative-free prostaglandin analogue ophthalmic solution.

The Company also received additional indications for several of its existing products. During 2011, the FDA approved an expanded age indication for *Zostavax* [Zoster Vaccine Live], a vaccine to help prevent shingles (herpes zoster), to include adults ages 50 to 59. In addition, the FDA approved *Sylatron* (peginterferon alfa-2b) for Injection for the adjuvant treatment of melanoma in patients with microscopic or gross nodal involvement. Also, *Simponi* received an indication in the EU for use in combination with methotrexate in adults with severe, active and progressive rheumatoid arthritis not previously treated with methotrexate, having been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function. In January 2012, the FDA approved the use of *ISENTRESS*, in combination with other antiretroviral medicines, for the treatment of HIV-1 infection in pediatric patients two years of age and older and weighing at least 10 kg.

The Company currently has two candidates under review with the FDA: MK-8669, ridaforolimus, for the treatment of metastatic soft-tissue or bone sarcomas in patients who had a favorable response to chemotherapy and MK-0653C, *Zetia* combined with atorvastatin for the treatment of primary or mixed hyperlipidemia. MK-8669 is also under review in the EU.

The Company currently has 19 candidates in Phase III development and anticipates filing a New Drug Application ("NDA") with the FDA with respect to certain of these candidates in 2012 including MK-4305, suvorexant, an investigational treatment for insomnia; MK-8616, *Bridion*, a medication for the reversal of certain muscle relaxants used during surgery; and V503, a nine-valent HPV vaccine. The Company also anticipates filings in 2013 for, among others, MK-0822, odanacatib, an investigational treatment for osteoporosis, and MK-0524A, *Tredaptive* (extended-release niacin/laropiprant/simvastatin), which is under development for the treatment of atherosclerosis.

Merck continues to pursue opportunities that have the potential to drive both near- and long-term growth. During 2011, the Company completed a variety of transactions including the acquisition of Inspire

Table of Contents

Pharmaceuticals, Inc., a specialty pharmaceutical company focused on developing and commercializing ophthalmic products. Additionally, the Company entered into transactions designed to strengthen its presence in emerging markets in the longer term.

Merck continues to realize cost savings across all areas of the Company. These savings result from various actions, including the Merger Restructuring Program discussed below, previously announced ongoing cost reduction activities, as well as from non-restructuring-related activities. As of the end of 2011, the Company has realized approximately \$2.9 billion in annual net cost savings from these activities since the merger of legacy Merck & Co., Inc. and Schering-Plough Corporation (Schering-Plough) on November 3, 2009 (the Merger).

In July 2011, the Company announced the latest phase of its global restructuring program (the Merger Restructuring Program) that was initiated in conjunction with the integration of the legacy Merck and legacy Schering-Plough businesses. This Merger Restructuring Program is intended to optimize the cost structure of the combined company. As part of this latest phase, the Company expects to reduce its workforce measured at the time of the Merger by an additional 12% to 13% across the Company worldwide. A majority of the workforce reductions in this phase of the Merger Restructuring Program relate to manufacturing (including Animal Health), administrative and headquarters organizations. Previously announced workforce reductions of approximately 17% in earlier phases of the program primarily reflect the elimination of positions in sales, administrative and headquarters organizations, as well as from the sale or closure of certain manufacturing and research and development sites and the consolidation of office facilities. The Company will continue to hire employees in strategic growth areas of the business as necessary. The Company will continue to pursue productivity efficiencies and evaluate its manufacturing supply chain capabilities on an ongoing basis which may result in future restructuring actions. The Company recorded total pretax restructuring costs of \$1.8 billion in 2011, \$1.8 billion in 2010 and \$1.5 billion in 2009 related to this program. The restructuring actions under the Merger Restructuring Program are expected to be substantially completed by the end of 2013, with the exception of certain actions, principally manufacturing-related, which are expected to be substantially completed by 2015, with the total cumulative pretax costs estimated to be approximately \$5.8 billion to \$6.6 billion. The Company estimates that approximately two-thirds of the cumulative pretax costs relate to cash outlays, primarily related to 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. The Company expects the Merger Restructuring Program to yield annual savings by the end of 2013 of approximately \$3.5 billion to \$4.0 billion and annual savings upon completion of the program of approximately \$4.0 billion to \$4.6 billion.

During 2011, the Company continued to be affected by the U.S. health care reform legislation that was enacted in 2010 as additional provisions went into effect. Beginning in 2011, the law requires pharmaceutical manufacturers to pay a 50% discount to Medicare Part D beneficiaries when they are in the Medicare Part D coverage gap (i.e., the so-called donut hole). Approximately \$150 million was recorded as a reduction to revenue in 2011 related to the estimated impact of this provision of health care reform. Also, the Company recorded \$162 million of expenses for the annual health care reform fee, which the Company was required to pay beginning in 2011. The law also increased mandated Medicaid rebates, which reduced revenues by approximately \$179 million and \$170 million in 2011 and 2010, respectively.

Effective December 1, 2011, Richard T. Clark, chairman, retired from the Company and the Merck Board of Directors. Kenneth C. Frazier, Merck's president and chief executive officer, was elected by the Board to serve as chairman following Mr. Clark's retirement.

In November 2011, Merck's Board of Directors raised the Company's quarterly dividend to \$0.42 per share from \$0.38 per share.

Earnings per common share assuming dilution attributable to common shareholders (EPS) for 2011 were \$2.02, which reflect a net unfavorable impact resulting from acquisition-related costs, restructuring costs, as well as the charge related to the settlement of the arbitration proceeding with J&J discussed above, partially offset by the favorable impact of certain tax items and gains on the disposition of the Company's interest in the Johnson & Johnson[®]Merck Consumer Pharmaceuticals Company joint venture and the sale of certain manufacturing facilities and related assets. Non-GAAP EPS in 2011 were \$3.77 excluding these items (see Non-GAAP Income and Non-GAAP EPS below).

Table of Contents**Product Sales**

Sales⁽¹⁾ of the Company's products were as follows:

| <i>Years Ended December 31</i> | 2011 | 2010 | 2009 |
|--|-------------|-------------|-------------|
| Pharmaceutical: | | | |
| <i>Cardiovascular</i> | | | |
| Zetia | \$ 2,428 | \$ 2,297 | \$ 403 |
| Vytorin | 1,882 | 2,014 | 441 |
| Integrilin | 230 | 266 | 46 |
| <i>Diabetes and Obesity</i> | | | |
| Januvia | 3,324 | 2,385 | 1,922 |
| Janumet | 1,363 | 954 | 658 |
| <i>Diversified Brands</i> | | | |
| Cozaar/Hyzaar | 1,663 | 2,104 | 3,561 |
| Zocor | 456 | 468 | 558 |
| Propecia | 447 | 447 | 440 |
| Claritin Rx | 314 | 296 | 71 |
| Remeron | 241 | 223 | 38 |
| Vasotec/Vaseretic | 231 | 255 | 311 |
| Proscar | 223 | 216 | 291 |
| <i>Infectious Disease</i> | | | |
| Isentress | 1,359 | 1,090 | 752 |
| PegIntron | 657 | 737 | 149 |
| Cancidas | 640 | 611 | 617 |
| Primaxin | 515 | 610 | 689 |
| Invanz | 406 | 362 | 293 |
| Avelox | 322 | 316 | 66 |
| Noxafil | 230 | 198 | 34 |
| Crixivan/Stocrin | 192 | 206 | 206 |
| Rebetol | 174 | 221 | 36 |
| Victrelis | 140 | | |
| <i>Neurosciences and Ophthalmology</i> | | | |
| Maxalt | 639 | 550 | 575 |
| Cosopt/Trusopt | 477 | 484 | 503 |
| <i>Oncology</i> | | | |
| Temodar | 935 | 1,065 | 188 |
| Emend | 419 | 378 | 317 |
| Intron A | 194 | 209 | 38 |
| <i>Respiratory and Immunology</i> | | | |
| Singular | 5,479 | 4,987 | 4,660 |
| Remicade | 2,667 | 2,714 | 431 |
| Nasonex | 1,286 | 1,219 | 165 |
| Clarinex | 621 | 623 | 101 |
| Arcoxia | 431 | 398 | 358 |
| Simponi | 264 | 97 | 4 |
| Asmanex | 206 | 208 | 37 |
| Proventil | 155 | 210 | 26 |
| Dulera | 96 | 8 | |
| <i>Vaccines⁽²⁾</i> | | | |
| Gardasil | 1,209 | 988 | 1,118 |
| ProQuad/M-M-R II/Varivax | 1,202 | 1,378 | 1,369 |
| RotaTeq | 651 | 519 | 522 |
| Pneumovax | 498 | 376 | 346 |
| Zostavax | 332 | 243 | 277 |
| <i>Women's Health and Endocrine</i> | | | |
| Fosamax | 855 | 926 | 1,100 |
| NuvaRing | 623 | 559 | 88 |
| Follistim AQ | 530 | 528 | 96 |
| Implanon | 294 | 236 | 37 |
| Cerazette | 268 | 209 | 35 |
| Other pharmaceutical ⁽³⁾ | 3,521 | 3,879 | 1,263 |

Edgar Filing: Merck & Co. Inc. - Form 10-K

| | | | |
|------------------------------------|------------------|-----------|-----------|
| Total Pharmaceutical segment sales | 41,289 | 39,267 | 25,236 |
| Other segment sales ⁽⁴⁾ | 6,327 | 6,059 | 2,114 |
| Total segment sales | 47,616 | 45,326 | 27,350 |
| Other ⁽⁵⁾ | 431 | 661 | 78 |
| | \$ 48,047 | \$ 45,987 | \$ 27,428 |

⁽¹⁾ Sales of legacy Schering-Plough products in 2009 are included only for the post-Merger period. In addition, prior to the Merger, substantially all sales of Zetia and Vytorin were recognized by the MSP Partnership and the results of Merck's interest in the MSP Partnership were recorded in Equity income from affiliates. As a result of the Merger, the MSP Partnership became wholly owned by the Company; accordingly, all sales of MSP Partnership products after the Merger are reflected in the table above. Sales of Zetia and Vytorin in 2009 reflect Merck's sales of these products in Latin America which was not part of the MSP Partnership, as well as sales of these products for the post-Merger period in 2009.

⁽²⁾ 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.

⁽³⁾ Other pharmaceutical primarily reflects sales of other human health pharmaceutical products, including products within the franchises not listed separately.

⁽⁴⁾ Reflects other non-reportable segments, including Animal Health and Consumer Care, and revenue from the Company's relationship with AZLP primarily relating to sales of Nexium, as well as Prilosec. Revenue from AZLP was \$1.2 billion, \$1.3 billion and \$1.4 billion in 2011, 2010 and 2009, respectively.

⁽⁵⁾ Other revenues are primarily comprised of miscellaneous corporate revenues, third-party manufacturing sales, sales related to divested products or businesses and other supply sales not included in segment results.

Table of Contents

Pharmaceutical

The Company's pharmaceutical products include therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. Certain of the products within the Company's franchises are as follows:

Cardiovascular: *Zetia* (marketed as *Ezetrol* outside the United States); *Vytorin* (marketed as *Inegy* outside the United States); and *Integrilin* (eptifibatide) Injection, a treatment for patients with acute coronary syndrome.

Diabetes and Obesity: *Januvia* and *Janumet* for the treatment of type 2 diabetes.

Diversified Brands: *Cozaar*; *Hyzaar*; *Zocor*; *Propecia* (finasteride), a product for the treatment of male pattern hair loss; *Claritin Rx* (loratadine) for treatment of seasonal outdoor allergies and year-round indoor allergies; *Remeron* (mirtazapine), an antidepressant; *Vasotec* (enalapril maleate) and *Vaseretic* (enalapril maleate-hydrochlorothiazide), hypertension and/or heart failure products; and *Proscar* (finasteride), a urology product for the treatment of symptomatic benign prostate enlargement.

Infectious Disease: *Isentress*; *PegIntron* (peginterferon alpha-2b), a treatment for chronic hepatitis C; *Cancidas* (caspofungin acetate), an anti-fungal product; *Primaxin* (imipenem and cilastatin sodium), an anti-bacterial product; *Invanz* (ertapenem sodium) for the treatment of certain infections; *Avelox* (moxifloxacin), which the Company only markets in the United States, a broad-spectrum fluoroquinolone antibiotic for certain respiratory and skin infections; *Noxafil* (posaconazole) for the prevention of invasive fungal infections; *Crixivan* (indinavir sulfate) and *Stocrin* (efavirenz), antiretroviral therapies for the treatment of HIV infection; *Rebetol* (ribavirin, USP) Capsules and Oral Solution for use in combination with *PegIntron* or *Intron A* (interferon alpha-2b, recombinant) for treating chronic hepatitis C; and *Victrelis*.

Neurosciences and Ophthalmology: *Maxalt* (rizatriptan benzoate), a product for acute treatment of migraine; and *Cosopt* and *Trusopt* (dorzolamide hydrochloride ophthalmic solution), ophthalmic products.

Oncology: *Temodar* (marketed as *Temodal* outside the United States); *Emend* (aprepitant) for the prevention of chemotherapy-induced and post-operative nausea and vomiting; and *Intron A* for Injection, marketed for chronic hepatitis B and C and numerous anticancer indications worldwide, including as adjuvant therapy for malignant melanoma.

Respiratory and Immunology: *Singulair*; *Remicade*; *Nasonex* (mometasone furoate monohydrate), an inhaled nasal corticosteroid for the treatment of nasal allergy symptoms; *Clarinx* (desloratadine), a non-sedating antihistamine; *Arcoxia* (etoricoxib) for the treatment of arthritis and pain; *Simponi*; *Asmanex Twisthaler* (mometasone furoate inhalation powder), an oral dry-powder corticosteroid inhaler for first-line maintenance treatment of asthma in patients 4 and older; *Proventil HFA* (albuterol sulfate) inhalation aerosol for the relief of bronchospasm in patients 12 years or older; and *Dulera* Inhalation Aerosol (mometasone furoate/formoterol fumarate dihydrate), a fixed-dose combination asthma treatment in patients 12 years of age or older.

Vaccines: *Gardasil*; *ProQuad*; *M-M-R II* [Measles, Mumps and Rubella Virus Vaccine Live], a vaccine to help prevent measles, mumps and rubella; *Varivax*; *RotaTeq*; *Pneumovax*; and *Zostavax*, a vaccine to help prevent shingles (herpes zoster) in patients aged 50 and older.

Women's Health and Endocrine: *Fosamax* (alendronate sodium) for the treatment and prevention of osteoporosis; *NuvaRing* (etonogestrel/ethinyl estradiol vaginal ring), a vaginal contraceptive ring; *Follistim AQ* (follicle stimulating hormone injection), a biological fertility treatment; *Implanon* (etonogestrel implant), a single-rod subdermal contraceptive implant; and *Cerazette* (desogestrel), a progestin only oral contraceptive.

Animal Health

The Animal Health segment discovers, develops, manufactures and markets animal health products, including vaccines. Principal marketed products in this segment include:

Livestock Products: *Nuflor* antibiotic range for use in cattle and swine; *Bovilis/Vista* vaccine lines for infectious diseases in cattle; *Banamine* bovine and swine anti-inflammatory; *Estrumate* for the treatment of fertility disorders in cattle; *Regumate/Matrix* fertility management for swine and horses; *Resflor* combination broad-spectrum antibiotic and non-steroidal anti-inflammatory drug for bovine respiratory disease; *Zilmax* and *Revalor* to

Table of Contents

improve production efficiencies in beef cattle; *M+Pac* swine pneumonia vaccine; and *Porcilis* vaccine line for infectious diseases in swine.

Poultry Products: *Nobilis/Innovax*, vaccine lines for poultry; and *Paracox* and *Coccivac* coccidiosis vaccines.

Companion Animal Products: *Nobivac/Continuum* vaccine lines for flexible dog and cat vaccination; *Otomax/Mometamax/Posatex* ear ointments for acute and chronic otitis; *Caninsulin/Vetsulin* diabetes mellitus treatment for dogs and cats; *Panacur/Safeguard* broad-spectrum anthelmintic (de-wormer) for use in many animals; and *Scalibor/Exspot* for protecting against bites from fleas, ticks, mosquitoes and sandflies.

Aquaculture Products: *Slice* parasiticide for sea lice in salmon; *Aquavac/Norvax* vaccines against bacterial and viral disease in fish; *Compact PD* vaccine for salmon; and *Aquaflor* antibiotic for farm-raised fish.

Consumer Care

The Consumer Care segment develops, manufactures and markets over-the-counter, foot care and sun care products. Principal products in this segment include:

Over-the-Counter Products: *Claritin* non-drowsy antihistamines; *MiraLAX* treatment for occasional constipation; *Coricidin HBP* decongestant-free cold/flu medicine for people with high blood pressure; *Afrin* nasal decongestant spray; and *Zegerid OTC* treatment for frequent heartburn.

Foot Care: *Dr. Scholl's* foot care products; *Lotrimin* topical antifungal products; and *Tinactin* topical antifungal products and foot and sneaker odor/wetness products.

Sun Care: *Coppertone* sun care lotions, sprays and dry oils.

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.

Product Approvals

In February 2012, the FDA approved *Zioptan* (tafluprost), a preservative-free prostaglandin analog ophthalmic solution for reducing elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension. Merck has exclusive commercial rights to tafluprost in Western Europe (excluding Germany), North America, South America, Africa, the Middle East, India and Australia. *Zioptan* is marketed as *Saflutan* in certain markets outside the United States.

Also, in February 2012, the FDA approved *Janumet XR*, a new treatment for type 2 diabetes that combines sitagliptin, which is the active component of *Januvia*, with extended-release metformin. *Janumet XR* provides a convenient once-daily treatment option for health care providers and patients who need help to control their blood sugar.

In addition, in February 2012, the FDA approved *Cosopt PF*, Merck's preservative-free formulation of *Cosopt* ophthalmic solution, indicated for the reduction of elevated intraocular pressure in appropriate patients with open-angle glaucoma or ocular hypertension.

In October 2011, the FDA approved *Juvisync*, a new treatment for type 2 diabetes that combines the glucose-lowering medication sitagliptin with the cholesterol-lowering medication *Zocor*. *Juvisync* is the first treatment option for health care providers to help patients who need the blood sugar-lowering benefits of a DPP-4 inhibitor and the cholesterol-lowering benefits of simvastatin, with the convenience of a single tablet once daily.

In August 2011, *Zoely*, an oral contraceptive, was granted marketing authorization by the EC for use by women to prevent pregnancy. *Zoely* is a combined oral contraceptive tablet containing a unique monophasic combination of two hormones: norgestrel acetate, a highly selective progesterone-derived progestin, and 17-beta estradiol, an estrogen that is similar to the one naturally present in a woman's body. The marketing authorization of *Zoely* applies to all 27 EU member states plus Iceland, Liechtenstein and Norway. Teva Pharmaceutical Industries Ltd. holds exclusive marketing rights for *Zoely* in France, Italy, Belgium and Spain.

Table of Contents

In May 2011, the FDA approved *Victrelis*, the Company's innovative oral medicine for the treatment of chronic hepatitis C. *Victrelis* is approved for the treatment of chronic hepatitis C genotype 1 infection, in combination with peginterferon alfa and ribavirin, in adult patients (18 years of age and older) with compensated liver disease, including cirrhosis, who are previously untreated or who have failed previous interferon and ribavirin therapy. *Victrelis* is an antiviral agent designed to interfere with the ability of the hepatitis C virus to replicate by inhibiting a key viral enzyme. In July 2011, the EC approved *Victrelis*. The EC's decision grants a single marketing authorization that is valid in the 27 countries that are members of the EU, as well as unified labeling applicable to Iceland, Liechtenstein and Norway. In addition to the United States, *Victrelis* has been launched in 19 markets including France, Germany, Canada and Brazil.

Joint Ventures

AstraZeneca LP

In 1982, Merck entered into an agreement with Astra AB (Astra) to develop and market Astra products in the United States. In 1994, Merck 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, Merck and Astra restructured the joint venture whereby Merck 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 99% general partner interest. The Partnership, renamed AstraZeneca LP (AZLP) upon Astra's 1999 merger with Zeneca Group Plc, 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, a preferential return representing the Company's share of undistributed Partnership AZLP generally accepted accounting principles (GAAP) earnings, and a variable return related to the Company's 1% limited partner interest.

In conjunction with the 1998 restructuring discussed above, Astra purchased an option (the Asset Option) for a payment of \$443 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). In April 2010, AstraZeneca exercised the Asset Option. Merck received \$647 million from AstraZeneca representing the net present value as of March 31, 2008 of projected future pretax revenue to be received by Merck from the Non-PPI Products, which was recorded as a reduction to the Company's investment in AZLP. The Company recognized the \$443 million of deferred income in 2010 as a component of *Other (income) expense, net*. In addition, in 1998, Merck granted Astra an option (the Shares Option) to buy Merck's common stock interest in KBI and, through it, Merck's interest in Nexium and Prilosec, exercisable in 2012. The exercise price for the Shares Option will be primarily based on the net present value of projected future pretax revenue to be received by Merck from Nexium and Prilosec as determined at the time of exercise, subject to certain true-up mechanisms. The Company believes that it is likely that AstraZeneca will exercise the Shares Option.

Sanofi Pasteur MSD

In 1994, Merck 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. Merck 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.

Table of Contents

Licenses

In 1998, a subsidiary of Schering-Plough entered into a licensing agreement with Centocor Ortho Biotech Inc. (Centocor), a J&J company, to market *Remicade*, which is prescribed for the treatment of inflammatory diseases. In 2005, Schering-Plough's subsidiary exercised an option under its contract with Centocor for license rights to develop and commercialize *Simponi*, a fully human monoclonal antibody. The Company had exclusive marketing rights to both products outside the United States, Japan and certain other Asian markets. In December 2007, Schering-Plough and Centocor revised their distribution agreement regarding the development, commercialization and distribution of both *Remicade* and *Simponi*, extending the Company's rights to exclusively market *Remicade* to match the duration of the Company's exclusive marketing rights for *Simponi*. In addition, Schering-Plough and Centocor agreed to share certain development costs relating to *Simponi*'s auto-injector delivery system. On October 6, 2009, the EC approved *Simponi* as a treatment for rheumatoid arthritis and other immune system disorders in two presentations—a novel auto-injector and a prefilled syringe. As a result, the Company's marketing rights for both products extend for 15 years from the first commercial sale of *Simponi* in the EU following the receipt of pricing and reimbursement approval within the EU.

In April 2011, Merck and J&J reached an agreement to amend the agreement governing the distribution rights to *Remicade* and *Simponi*. This agreement concluded the arbitration proceeding J&J initiated in May 2009. Under the terms of the amended distribution agreement, Merck relinquished marketing rights for *Remicade* and *Simponi* to J&J in territories including Canada, Central and South America, the Middle East, Africa and Asia Pacific effective July 1, 2011. Merck retained exclusive marketing rights throughout Europe, Russia and Turkey (the Retained Territories). In addition, beginning July 1, 2011, all profits derived from Merck's exclusive distribution of the two products in the Retained Territories are being equally divided between Merck and J&J. Under the prior terms of the distribution agreement, the contribution income (profit) split, which was at 58% to Merck and 42% percent to J&J, would have declined for Merck and increased for J&J each year until 2014, when it would have been equally divided. J&J also received a one-time payment from Merck of \$500 million in April 2011.

Competition and the Health Care Environment

Competition

The markets in which the Company conducts its business and the pharmaceutical industry are highly competitive and highly regulated. The Company's competitors include other worldwide research-based pharmaceutical companies, smaller research companies with more limited therapeutic focus, and generic drug and consumer health care manufacturers. The Company's operations may be affected by technological advances of competitors, industry consolidation, patents granted to competitors, competitive combination products, new products of competitors, the generic availability of competitors' branded products, new information from clinical trials of marketed products or post-marketing surveillance and generic competition as the Company's products mature. In addition, patent positions are increasingly being challenged by competitors, and the outcome can be highly uncertain. An adverse result in a patent dispute can preclude commercialization of products or negatively affect sales of existing products and could result in the recognition of an impairment charge with respect to certain products. Competitive pressures have intensified as pressures in the industry have grown. The effect on operations of competitive factors and patent disputes cannot be predicted.

Pharmaceutical competition involves a rigorous 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 positioned to compete in the search for technological innovations. Additional resources required to meet market challenges 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 external alliances, such as joint ventures and licenses, and has been refining its sales and marketing efforts to further address changing industry conditions. However, the introduction of new products and processes by competitors may result in price reductions and product displacements, even for products protected by patents. For example, the number of compounds available to treat a particular disease typically increases over time and can result in slowed sales growth for the Company's products in that therapeutic category.

Table of Contents

The highly competitive animal health business is affected by several factors including regulatory and legislative issues, scientific and technological advances, product innovation, the quality and price of the Company's products, effective promotional efforts and the frequent introduction of generic products by competitors.

The Company's consumer care operations face competition from other consumer health care businesses as well as retailers who carry their own private label brands. The Company's competitive position is affected by several factors, including regulatory and legislative issues, scientific and technological advances, the quality and price of the Company's products, promotional efforts and the growth of lower cost private label brands.

Health Care Environment

Global efforts toward health care cost containment continue to exert pressure on product pricing and market access. In the United States, federal and state governments for many years also have pursued methods to 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 and to provide discounts for outpatient medicines purchased by certain Public Health Service entities and disproportionate share hospitals (hospitals meeting certain criteria). Under the Federal Vaccines for Children entitlement program, the U.S. Centers for Disease Control and Prevention funds and purchases recommended pediatric vaccines at a public sector price for the immunization of Medicaid-eligible, uninsured, Native American and certain underinsured children. Merck is contracted to provide its pediatric vaccines to this program.

Against this backdrop, the United States enacted major health care reform legislation in 2010, which began to be implemented in 2011. Various insurance market reforms advanced in 2011 and will continue through full implementation in 2014. The new law is expected to expand access to health care to more than 32 million Americans by the end of the decade who did not previously have regular access to health care. With respect to the effect of the law on the pharmaceutical industry, the law increased the mandated Medicaid rebate from 15.1% to 23.1%, expanded the rebate to Medicaid managed care utilization, and increased the types of entities eligible for the federal 340B drug discount program. The law also requires pharmaceutical manufacturers to pay a 50% discount to Medicare Part D beneficiaries when they are in the Medicare Part D coverage gap (i.e., the so-called "donut hole"). Also, pharmaceutical manufacturers are now required to pay an annual health care reform fee. The total annual industry fee was \$2.5 billion in 2011 and will be \$2.8 billion in 2012. The fee is assessed on each company in proportion to its share of sales to certain government programs, such as Medicare and Medicaid.

The Company also faces increasing pricing pressure globally from managed care organizations, government agencies and programs that could negatively affect the Company's sales and profit margins. 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 and the Patient Protection and Affordable Care Act. Changes to the health care system enacted as part of health care reform in the United States, as well as increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, could result in further pricing pressures.

In addition, in the effort to contain the U.S. federal deficit, the pharmaceutical industry could be considered a potential source of savings via legislative proposals that have been debated but not enacted in prior years. These types of revenue generating or cost saving proposals include direct price controls in the Medicare prescription drug program (Part D). In addition, Congress may again consider proposals to allow, under certain conditions, the importation of medicines from other countries. It remains very uncertain as to what proposals, if any, may be included as part of future federal budget deficit reduction proposals that would directly or indirectly affect the Company.

In 2011 and 2010, global efforts toward health care cost containment were intense in several European countries. Many countries have announced austerity measures, which include the implementation of pricing actions to reduce prices of generic and patented drugs. While the Company is taking steps to mitigate the impact in the EU, the austerity measures have negatively affected the Company's revenue performance in 2011 and 2010 and the Company anticipates the austerity measures will continue to negatively affect revenue performance in 2012.

Additionally, the global economic downturn and the sovereign debt issues in certain European countries, among other factors, have adversely impacted foreign receivables in certain European countries. While the

Table of Contents

Company continues to receive payment on these receivables, these conditions have resulted in an increase in the average length of time it takes to collect accounts receivable outstanding thereby adversely affecting cash flows.

The full impact of U.S. health care reform, as well as continuing budget pressures on governments around the world, cannot be predicted at this time.

In addressing cost containment pressures, the Company continues to attempt to demonstrate that its medicines provide value to patients and to those who pay for health care. In markets with historically low rates of government health care spending, the Company encourages those governments to increase their investments in order to improve their citizens' access to appropriate health care, including medicines.

Operating conditions have become more challenging under the global pressures of competition, industry regulation and cost containment efforts. Although no one can predict the effect of these and other factors on the Company's business, the Company continually takes measures to evaluate, adapt and improve the organization and its business practices to better meet customer needs and believes that it is well positioned to respond to the evolving health care environment and market forces.

Government Regulation

The pharmaceutical industry is subject to regulation by regional, country, state and local agencies around the world. Governmental regulation and legislation tend to focus on standards and processes for determining drug safety and effectiveness, as well as conditions for sale or reimbursement, especially related to the pricing of products.

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 and practices have increased the amount of time and resources necessary to develop new products and bring them to market in the United States.

The EU has adopted directives and other legislation concerning the classification, labeling, advertising, wholesale distribution, integrity of the supply chain, enhanced pharmacovigilance monitoring and approval for marketing of medicinal products for human use. These provide mandatory standards throughout the EU, which may be supplemented or implemented with additional regulations by the EU member states. 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.

The Company believes that it will continue to be able to conduct its operations, including launching new drugs into the market, in this regulatory environment.

Access to Medicines

As a global health care company, Merck's primary role is to discover and develop innovative medicines and vaccines. The Company also recognizes that it has an important role to play in helping to improve access to its products around the world. The Company's efforts in this regard are wide-ranging. For example, the Company has been recognized for pricing many of its products through a differential pricing framework, taking into consideration such factors as a country's level of economic development and public health need. In addition, the Merck Patient Assistance Program provides medicines and adult vaccines for free to people who do not have prescription drug or health insurance coverage and who, without the Company's assistance, cannot afford their Merck medicine and vaccines.

Building on the Company's own efforts, Merck has undertaken collaborations with many stakeholders to improve access to medicines and enhance the quality of life for people around the world.

For example, in 2011, Merck announced that it would launch Merck for Mothers, a long-term effort with global health partners to create a world where no woman has to die from preventable complications of pregnancy and childbirth. The launch includes a 10-year, \$500 million initiative that applies Merck's scientific and business expertise to making proven solutions more widely available, developing new technologies and improving public awareness, policy efforts and private sector engagement for maternal mortality.

Merck has also in the past provided funds to The Merck Company Foundation, an independent organization, which has partnered with a variety of organizations dedicated to improving global health. One of these

Table of Contents

partnerships is The African Comprehensive HIV/AIDS Partnership in Botswana, a collaboration with the government of Botswana and the Bill & Melinda Gates Foundation, that was renewed in 2010 and supports Botswana's response to HIV/AIDS through a comprehensive and sustainable approach to HIV prevention, care, treatment, and support.

Privacy and Data Protection

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. There has been increased attention to privacy and data protection issues in both developed and emerging markets with the potential to affect directly the Company's business, including recently enacted laws and regulations in the United States, Europe, Asia and Latin America and increased enforcement activity in the United States and other developed markets.

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, hospitals and managed care organizations. The Company sells its animal health products to veterinarians, distributors and animal producers. The Company's over-the-counter, foot care and sun care products are sold through wholesale and retail drug, food chain and mass merchandiser outlets.

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 business.

Patents, Trademarks and Licenses

Patent protection is considered, in the aggregate, to be of material importance in the Company's marketing of its 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 Food and Drug Administration Modernization Act (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 by the FDA.

Table of Contents

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:

| Product | Year of Expiration (in the U.S.)⁽¹⁾ |
|--|---|
| <i>Maxalt</i> ⁽²⁾ | 2012 |
| <i>Singulair</i> | 2012 |
| <i>Cancidas</i> | 2013 (compound)/2015 (composition) |
| <i>Propecia</i> ⁽³⁾ | 2013 (formulation/use) |
| <i>Asmanex</i> | 2014 (use)/2018 (formulation) |
| <i>Avelox</i> ⁽⁴⁾ | 2014 |
| <i>Dulera</i> | 2014 (use)/2020 (combination) |
| <i>Integrilin</i> | 2014 (compound)/2015 (use/formulation) |
| <i>Nasonex</i> | 2014 (use/formulation)/2018(formulation) |
| <i>Temodar</i> ⁽⁵⁾ | 2014 |
| <i>Emend</i> | 2015 |
| <i>Follistim AQ</i> | 2015 |
| <i>PegIntron</i> | 2015 (conjugates)/2020 (Mature IFN-alpha) |
| <i>Invanz</i> | 2016 (compound)/2017 (composition) |
| <i>Zostavax</i> | 2016 (use) |
| <i>Zetia</i> ⁽⁶⁾ / <i>Vytorin</i> | 2017 |
| <i>Zioptan</i> ⁽⁷⁾ | 2017 |
| <i>NuvaRing</i> | 2018 (delivery system) |
| <i>Noxafil</i> | 2019 |
| <i>RotaTeq</i> | 2019 |
| <i>Clarinet</i> ⁽⁸⁾ | 2020 (formulation) |
| <i>Comvax</i> | 2020 (method of making/vectors) |
| <i>Intron A</i> | 2020 |
| <i>Recombivax</i> | 2020 (method of making/vectors) |
| <i>Saphris/Sycrest</i> | 2020 (use/formulation) (with pending Patent Term Restoration) |
| <i>Januvia/Janumet/Juvisync/Janumet XR</i> | 2022 (compound)/2026 (salt) |
| <i>Isentress</i> | 2023 |
| <i>Victrelis</i> | 2024 (with pending Patent Term Restoration) |
| <i>Gardasil</i> | 2026 (method of making/use/product by process) |

⁽¹⁾ Compound patent unless otherwise noted.

⁽²⁾ The Company has determined that it will not enforce an additional patent that was set to expire in 2014.

⁽³⁾ By agreement, one generic manufacturer has been given the right to enter the market in January 2013 and another has been given the right to enter in July 2013.

⁽⁴⁾ By agreement, a generic manufacturer may launch a generic in the U.S. as early as February 2014. Six months Pediatric Exclusivity may extend this date to August 2014.

⁽⁵⁾ By agreement, a generic manufacturer may launch a generic in the U.S. in August 2013.

⁽⁶⁾ By agreement, a generic manufacturer may launch a generic version of Zetia in the U.S. in December 2016.

Edgar Filing: Merck & Co. Inc. - Form 10-K

⁽⁷⁾ *An application for Patent Term Restoration of the Zioptan compound patent will be filed within the prescribed time limits. The Company expects five years of Patent Term Restoration.*

⁽⁸⁾ *By virtue of litigation settlements, certain generic manufacturers have been given the right to enter the U.S. market in 2012.*

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.

Table of Contents

The patent that provides U.S. market exclusivity for *Singulair*, the Company's largest selling product, expires in August 2012. The Company expects that within the two years following patent expiration, it will lose substantially all U.S. sales of *Singulair*, with most of those declines coming in the first full year following patent expiration. Also, the patent that provides market exclusivity for *Singulair* will expire in a number of major European markets in February 2013 and the Company expects sales of *Singulair* in those markets will decline significantly thereafter. The patent that provides market exclusivity for *Singulair* in Japan will expire in 2016. In addition, the patent that provides U.S. market exclusivity for *Maxalt* will expire in December 2012. Also, the patent that provides market exclusivity for *Maxalt* will expire in a number of major European markets in February 2013. The Company anticipates that sales in the United States and in these European markets will decline significantly after these patent expiries.

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.

The Company has the following key U.S. patent protection for drug candidates under review:

Currently Anticipated**Under Review****Year of Expiration (in the U.S.)⁽¹⁾⁽²⁾⁽³⁾⁽⁴⁾**

MK-0653C (ezetimibe/atorvastatin)

2017

MK-8669 (ridaforolimus)

2023

The Company also has the following key U.S. patent protection for drug candidates in Phase III development:

Currently Anticipated**Phase III Drug Candidate****Year of Expiration (in the U.S.)⁽¹⁾⁽²⁾⁽³⁾⁽⁴⁾**

MK-7243 (grass pollen)

N/A⁽⁵⁾

MK-3641 (ragweed)

N/A⁽⁵⁾

MK-0524A (extended-release niacin/laropiprant)

2023

MK-0524B (extended-release niacin/laropiprant/simvastatin)

2023

MK-0859 (anacetrapib)

2027

MK-6621 (vernakalant i.v.)

2020

MK-3415A (*Clostridium difficile* infection)

2026

MK-8175A (NOMAC/E2)

2017 (use)

MK-0431E (sitagliptin/atorvastatin)

2022 (compound)/2026 (salt)

MK-8962 (corifollitropin alfa for injection)

2018 (formulation)

MK-7009 (vaniprevir)

2027

V212 (inactivated varicella zoster virus (VZV) vaccine)

2016 (method of use)

V503 (HPV vaccine (9 valent))

2024 (compound)/2026 (method of making/use)

MK-4305 (suvorexant)

2029

MK-8616 (*Bridion*)

2021

MK-0822 (odanacatib)

2024

MK-3814 (preladenant)

2021

V419 (pediatric hexavalent combination vaccine)

2020 (method of making/vectors)

MK-5348 (vorapaxar)

2024

⁽¹⁾ Compound patent unless otherwise noted.

⁽²⁾ Subject to any future patent term restoration of up to five years and six month pediatric market exclusivity, either or both of which may be available.

Edgar Filing: Merck & Co. Inc. - Form 10-K

- ⁽³⁾ *Depending on the circumstances surrounding any final regulatory approval of the compound, there may be other listed patents or patent applications pending that could have relevance to the product as finally approved; the relevance of any such application would depend upon the claims that ultimately may be granted and the nature of the final regulatory approval of the product.*
- ⁽⁴⁾ *Regulatory exclusivity tied to the protection of clinical data is complementary to patent protection and, in many cases, may provide more efficacious or longer lasting marketing exclusivity than a compound's patent estate. In the United States, the data protection generally runs 5 years from first marketing approval of a new chemical entity, extended to 7 years for an orphan drug indication and 12 years from first marketing approval of a biological product.*
- ⁽⁵⁾ *Twelve years of data exclusivity from first marketing approval is expected.*

Table of Contents

For further information with respect to the Company's patents, see Item 1A. Risk Factors and Item 8. Financial Statements and Supplementary Data, Note 12. Contingencies and Environmental Liabilities 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.

Royalty income in 2011 on patent and know-how licenses and other rights amounted to \$367 million. Merck also incurred royalty expenses amounting to \$1.3 billion in 2011 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 14,100 people are employed in the Company's research activities. Research and development expenses were \$8.5 billion in 2011, \$11.1 billion in 2010, and \$5.8 billion in 2009 (which included restructuring costs in all years, as well as \$587 million and \$2.4 billion of in-process research and development impairment charges in 2011 and 2010, respectively). 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. The Company'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 approved medicines and vaccines through new indications and new formulations. Another important component of the Company'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, small proteins, antibodies) and RNAi. Further, Merck has moved to diversify its portfolio through its Merck BioVentures division, which has the potential to harness the market opportunity presented by biological medicine patent expiries by delivering high quality follow-on biologic products to enhance access for patients worldwide. The Company supplements its internal research with a 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's clinical pipeline includes candidates in multiple disease areas, including atherosclerosis, cancer, cardiovascular diseases, diabetes, infectious diseases, inflammatory/autoimmune diseases, insomnia, neurodegenerative diseases, ophthalmics, osteoporosis, respiratory diseases and women's health.

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 or biologic submitted to the FDA for the required approval.

Once the Company's scientists discover a new small molecule compound or biologics molecule 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, immunogenicity 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

Table of Contents

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. Finally, Phase III trials 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 three months. Extensions to the review period are communicated to the Company. The FDA can act on an application either by issuing an approval letter, or by issuing a Complete Response Letter stating that the application will not be approved in its present form and describing all deficiencies that the FDA has identified. Should the Company wish to pursue an application after receiving a Complete Response Letter, it can resubmit the application with information that addresses the questions or issues identified by the FDA in order to support approval. Resubmissions are subject to review period targets, which vary depending on the underlying submission type and the content of the resubmission.

Research and Development Update

The Company currently has two candidates under regulatory review in the United States and internationally.

MK-8669, ridaforolimus, is an investigational oral mTOR (mammalian target of rapamycin) inhibitor under development for the treatment of metastatic soft-tissue or bone sarcomas in patients who had a favorable response to chemotherapy that was accepted for standard review by the FDA in September 2011. In August 2011, the European Medicines Agency (EMA) accepted the marketing authorization application for ridaforolimus. As part of an exclusive license agreement with ARIAD Pharmaceuticals, Inc. (ARIAD), Merck is responsible for the development and worldwide commercialization of ridaforolimus. ARIAD has an option to co-promote ridaforolimus for sarcoma in the United States subject to execution of a co-promotion agreement.

MK-0653C, *Zetia* combined with atorvastatin was accepted for standard review by the FDA for the treatment of primary or mixed hyperlipidemia. In response to notice of the Company's filing, Pfizer Inc. (Pfizer) filed a patent infringement lawsuit in U.S. District Court against the Company asserting certain Pfizer patent rights in respect of atorvastatin. This lawsuit has the potential to bar FDA approval of the Company's NDA for up to 30 months (until January 6, 2014) subject to being shortened or lengthened by a court decision, or shortened by an agreement between the parties.

In addition to the candidates under regulatory review, the Company has 19 drug candidates in Phase III development targeting a broad range of diseases. The Company plans to file five major products for approval between 2012 and 2013, including: suvorexant (insomnia), *Bridion* (reversal of neuromuscular blockade), V503 (cervical cancer vaccine), odanacatib (osteoporosis) and *Tredaptive* (atherosclerosis).

MK-4305, suvorexant, is an investigational dual orexin receptor antagonist, a potential new approach to the treatment of insomnia. Orexins are neuropeptides (chemical messengers) that are released by specialized

Table of Contents

neurons in the hypothalamus region of the brain and are believed to be an important regulator of the brain's sleep-wake process. In February 2012, Merck announced that based on the positive results of two pivotal Phase III efficacy trials for suvorexant, the Company anticipates filing an NDA for MK-4305 with the FDA in 2012.

MK-8616, *Bridion*, is a medication for the reversal of certain muscle relaxants used during surgery. *Bridion* is currently approved and has been launched in many countries outside of the United States. Prior to the Merger, Schering-Plough received a Not-Approvable Letter from the FDA for *Bridion*. The Company has conducted additional clinical trials to address the FDA's comments and plans to file an NDA for *Bridion* with the FDA in 2012.

V503 is a nine-valent HPV vaccine in development to help protect against certain HPV-related diseases. V503 incorporates antigens against five additional cancer-causing HPV types as compared with *Gardasil*. The Phase III clinical program, which includes an event-driven clinical trial, is ongoing and Merck continues to anticipate filing a BLA for V503 with the FDA in 2012.

MK-0822, odanacatib, is an oral, once-weekly investigational treatment for osteoporosis in post-menopausal women. Osteoporosis is a disease that reduces bone density and strength and results in an increased risk of bone fractures. Odanacatib is a cathepsin K inhibitor that selectively inhibits the cathepsin K enzyme. Cathepsin K is known to play a central role in the function of osteoclasts, which are cells that break down existing bone tissue, particularly the protein components of bone. Inhibition of cathepsin K is a novel approach to the treatment of osteoporosis. Odanacatib continues to be studied to determine its safety and potential effects on hip, vertebral and non-vertebral fractures in an event-driven Phase III clinical trial. The Company anticipates filing an NDA for MK-0822 with the FDA in 2013.

MK-0524A is a drug candidate that combines extended-release 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 Not-Approvable 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 Merck wait for the results of the HPS2-THRIVE (Treatment of HDL to Reduce the Incidence of Vascular Events) event-driven cardiovascular outcomes study, which is expected to be completed in 2012. The Company anticipates filing an NDA with the FDA for MK-0524A in 2013. MK-0524A has been approved in more than 60 countries outside the United States 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) and is marketed as *Tredaptive* (or as *Cordaptive* in certain countries). *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.

MK-8962, *Elonva*, corifollitropin alpha injection, which has been approved in the EU for controlled ovarian stimulation in combination with a GnRH antagonist for the development of multiple follicles in women participating in an assisted reproductive technology program, is currently in Phase III development in the United States. Based on feedback from the FDA, additional data from an ongoing Phase III trial will be required at the time of filing. Merck now anticipates filing an NDA for *Elonva* with the FDA in 2013.

MK-6621, vernakalant i.v., is an investigational candidate for the treatment of atrial fibrillation which is being marketed as *Brinavess* in the EU. Merck acquired exclusive rights to develop and commercialize vernakalant i.v., as well as exclusive worldwide rights to oral formulations of vernakalant. Prior to Merck's acquisition of the rights to vernakalant i.v. in Canada, Mexico and the United States, the program was placed on clinical hold by the FDA and the Phase III, ACT V trial was suspended in 2010. ACT V has now been terminated. In the United States, the program remains on hold. The Company plans to have further discussions with the FDA.

MK-8175A, NOMAC/E2, which is being marketed as *Zoely* in the EU, is an oral contraceptive for use by women to prevent pregnancy. NOMAC/E2 is a combined oral contraceptive tablet containing a unique monophasic combination of two hormones: norgestrel acetate, a highly selective, progesterone-derived progestin, and 17-beta

Table of Contents

estradiol, an estrogen that is similar to the one naturally present in a woman's body. In November 2011, Merck received a Complete Response Letter from the FDA for NOMAC/E2. The Company is planning to conduct an additional clinical study requested by the FDA and update the application in the future.

MK-5348, vorapaxar, is a thrombin receptor antagonist being developed for the prevention of thrombosis, or clot formation, and the reduction of cardiovascular events. Vorapaxar has been evaluated in two major clinical outcomes studies in different patient groups: TRACER (Thrombin Receptor Antagonist for Clinical Event Reduction in Acute Coronary Syndrome), a clinical outcomes trial in patients with acute coronary syndrome, and TRA-2P (Thrombin Receptor Antagonist in Secondary Prevention of atherothrombotic ischemic events), a secondary prevention study in patients with a previous heart attack or ischemic stroke, or with documented peripheral vascular disease. In February 2012, Merck announced the top-line results of the TRA-2P study. TRA-2P showed that the addition of vorapaxar to standard of care significantly reduced the risk of the protocol-specified primary endpoint of the composite of cardiovascular death, heart attack (myocardial infarction), stroke or urgent coronary revascularization compared to standard of care. There was a significant increase in bleeding, including intracranial hemorrhage, among patients taking vorapaxar in addition to standard of care, although there was a lower risk of intracranial hemorrhage in patients without a history of stroke. The full results of TRA-2P will be presented at the American College of Cardiology Scientific Sessions in March 2012. In November 2011, researchers presented results from the TRACER outcomes study at the American Heart Association Scientific Sessions, and the results have been published. TRACER did not achieve its primary endpoint. In January 2011, Merck and the external study investigators announced that the combined Data and Safety Monitoring Board (DSMB) for the two clinical trials had reviewed the available safety and efficacy data and recommended that patients in the TRACER trial discontinue study drug and investigators close out the study. Merck will review the data from both TRA-2P and TRACER with the investigators and other outside experts to help better understand the profile of this investigational medicine in specific patient populations and to determine next steps, including potential regulatory filings.

MK-0524B is a drug candidate that combines the novel approach to raising HDL-C and lowering triglycerides from extended-release niacin combined with laropiprant with the proven benefits of simvastatin in one combination product. Merck anticipates filing an NDA for MK-0524B with the FDA in 2014.

MK-7243 is an investigational allergy immunotherapy sublingual tablet (AIT) in Phase III development for grass pollen allergy for which the Company has North American rights. AIT is a dissolvable oral tablet that is designed to prevent allergy symptoms by inducing a protective immune response against allergies, thereby treating the underlying cause of the disease. Merck is investigating AIT for the treatment of grass pollen allergic rhinoconjunctivitis in both children and adults. The Company anticipates filing an NDA for MK-7243 with the FDA in 2013.

MK-3641, an AIT for ragweed allergy, is also in Phase III development for the North American market. The Company anticipates filing an NDA for MK-3641 with the FDA in 2013.

MK-3814, preladenant, is a selective adenosine 2a receptor antagonist in Phase III development for treatment of Parkinson's disease. The Company anticipates filing an NDA for preladenant with the FDA in 2014.

MK-3415A, an investigational candidate for the treatment of *Clostridium difficile* infection, is a combination of two monoclonal antibodies used to treat patients with a single infusion. The Company anticipates filing an NDA for MK-3415A with the FDA in 2014.

V212 is an inactivated varicella-zoster virus vaccine in development for the prevention of herpes zoster. The Company is enrolling two Phase III trials, one in autologous hematopoietic cell transplant patients and the other in patients with solid tumor malignancies undergoing chemotherapy and hematological malignancies. The Company anticipates filing a BLA first with the autologous hematopoietic cell transplant data in 2014 and filing for the second indication in cancer patients at a later date.

V419 is an investigational hexavalent pediatric combination vaccine, which contains components of current vaccines, designed to help protect against six potentially serious diseases: diphtheria, tetanus, whooping cough (*Bordetella pertussis*), polio (poliovirus types 1, 2, and 3), invasive disease caused by *Haemophilus influenzae* type b, and hepatitis B that is being developed in collaboration with Sanofi-Pasteur. The Company anticipates filing a BLA for V419 with the FDA in 2014.

Table of Contents

MK-0431E combines *Januvia* and atorvastatin in a single tablet and is being developed for the treatment of diabetes and atherosclerosis. The Company anticipates filing an NDA for MK-0431E with the FDA in 2014.

MK-7009, vaniprevir, is an investigational, oral twice daily protease inhibitor for the treatment of chronic hepatitis C virus. The drug is in Phase III trials in Japan. The Company anticipates filing a new drug application for MK-7009 in Japan in 2014.

MK-0859, anacetrapib, is an investigational inhibitor of the cholesteryl ester transfer protein (CETP) that is being investigated in lipid management to raise HDL-C and reduce LDL-C. Based on the results from the Phase III DEFINE (Determining the Efficacy and Tolerability of CETP INhibition with AnacEtrapib) safety study of 1,623 patients with coronary heart disease or coronary heart disease risk equivalents, the Company initiated a large, event-driven cardiovascular clinical outcomes trial REVEAL (Randomized EValuation of the Effects of Anacetrapib Through Lipid-modification) involving patients with preexisting vascular disease. The Company continues to anticipate filing an NDA for anacetrapib with the FDA beyond 2015.

In 2011, Merck discontinued the clinical development program for telcagepant, the Company's investigational calcitonin gene-related peptide receptor antagonist for the treatment of acute migraine. The decision was based on an assessment of data across the clinical program. The Company also discontinued the clinical development program for MK-0431C, a combination of sitagliptin and pioglitazone, for the treatment of diabetes based on a review of the regulatory and commercial prospects for the combination drug candidate.

In 2012, Merck discontinued the clinical development program in the EU for MK-0887A, *Zenhale*, a fixed dose combination of two previously approved drugs for the treatment of asthma: mometasone furoate and formoterol fumarate dehydrate, which is marketed in the United States as *Dulera* Inhalation Aerosol.

Table of Contents

The chart below reflects the Company's research pipeline as of February 21, 2012. Candidates shown in Phase III include specific products and the date such candidate entered into Phase III development. Candidates shown in Phase II include the most advanced compound with a specific mechanism or, if listed compounds have the same mechanism, they are each currently intended for commercialization in a given therapeutic area. Small molecules and biologics are given MK-number designations and vaccine candidates are given V-number designations. Candidates in Phase I, additional indications in the same therapeutic area and additional claims, line extensions or formulations for in-line products are not shown.

| Phase II | Phase III (Phase III entry date) | Under Review |
|---------------------------------------|--|--|
| Allergy | Allergy | Atherosclerosis |
| MK-8237, Immunotherapy ⁽¹⁾ | MK-7243, Grass pollen ⁽¹⁾ (March 2008) | MK-0653C (ezetimibe/atorvastatin) (U.S.) |
| | MK-3641, Ragweed ⁽¹⁾ (September 2009) | Sarcoma |
| Cancer | | |
| MK-0646 (dalotuzumab) | Atherosclerosis | MK-8669 (ridaforolimus) (U.S.) (EU) |
| MK-1775 | MK-0524A (extended-release niacin/laropiprant) (U.S.) (December 2005) | |
| MK-2206 | MK-0524B (extended-release niacin/laropiprant/simvastatin) (July 2007) | |
| MK-7965 (dinaciclib) | MK-0859 (anacetrapib) (May 2008) | |
| Contraception, Medicated IUS | | Footnotes: |
| MK-8342 | Atrial Fibrillation | ⁽¹⁾ North American rights only. |
| | MK-6621 (vernakalant i.v.) (U.S.) (August 2003) ⁽²⁾ | ⁽²⁾ Prior to Merck's acquisition of rights to vernakalant i.v. in Canada, Mexico and the United States, the program was placed on clinical hold by the FDA in 2010. The suspended Phase III trial, ACT V has now been terminated. The program remains on hold in the United States. The Company plans to have further discussions with the FDA. |
| Diabetes Mellitus | Clostridium difficile Infection | ⁽³⁾ For development in Japan only. |
| MK-3102 | MK-3415A (November 2011) | ⁽⁴⁾ In November 2011, Merck received a Complete Response Letter from the FDA for NOMAC/E2 (MK-8175A). The Company is planning to conduct an additional clinical study requested by the FDA and update the application in the future. |
| Hepatitis C | Contraception | |
| MK-5172 | MK-8175A (NOMAC/E2) ⁽⁴⁾ (U.S.) (June 2006) | |
| Insomnia | Diabetes and Atherosclerosis | |
| MK-3697 | | |
| MK-6096 | MK-0431E (sitagliptin/atorvastatin) (October 2011) | |

Edgar Filing: Merck & Co. Inc. - Form 10-K

Overactive Bladder

MK-4618

Fertility

MK-8962 (corifollitropin alfa for injection) (U.S.) (July 2006)

Pneumoconjugate Vaccine

V114

Hepatitis C

MK-7009 (vaniprevir)⁽³⁾ (June 2011)

Psoriasis

MK-3222

Herpes Zoster

V212 (inactivated VZV vaccine) (December 2010)

HPV-Related Cancers

V503 (HPV vaccine (9 valent)) (September 2008)

Insomnia

MK-4305 (suvorexant) (December 2009)

Neuromuscular Blockade Reversal

MK-8616 (*Bridion*) (U.S.) (November 2005)

Osteoporosis

MK-0822 (odanacatib) (September 2007)

Parkinson's Disease

MK-3814 (preladenant) (July 2010)

Pediatric Hexavalent Combination Vaccine

V419 (April 2011)

Thrombosis

Edgar Filing: Merck & Co. Inc. - Form 10-K

MK-5348 (vorapaxar) (September 2007)

Employees

As of December 31, 2011, the Company had approximately 86,000 employees worldwide, with approximately 33,100 employed in the United States, including Puerto Rico. Approximately 31% of worldwide employees of the Company are represented by various collective bargaining groups.

In February 2010, the Company commenced actions under the Merger Restructuring Program in conjunction with the integration of the legacy Merck and legacy Schering-Plough businesses. This Merger Restructuring Program is intended to optimize the cost structure of the combined company. Additional actions under the program continued during 2010. In July 2011, the Company announced the latest phase of the Merger Restructuring Program during which the Company expects to reduce its workforce measured at the time of the

Table of Contents

Merger by an additional 12% to 13% across the Company worldwide. A majority of the workforce reductions in this phase of the Merger Restructuring Program relate to manufacturing (including Animal Health), administrative and headquarters organizations. Previously announced workforce reductions of approximately 17% in earlier phases of the program primarily reflect the elimination of positions in sales, administrative and headquarters organizations, as well as from the sale or closure of certain manufacturing and research and development sites and the consolidation of office facilities. Since inception of the Merger Restructuring Program through December 31, 2011, Merck has eliminated approximately 18,430 positions comprised of employee separations, as well as the elimination of contractors and more than 2,500 positions that were vacant at the time of the Merger.

In October 2008, Merck 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 the Company worldwide. Since inception of the 2008 Restructuring Program through December 31, 2011, Merck has eliminated approximately 6,250 positions comprised of employee separations and the elimination of contractors and vacant positions.

Prior to the Merger, Schering-Plough commenced a Productivity Transformation Program, which was designed to reduce and avoid costs and increase productivity. The position eliminations associated with this program are largely complete.

Environmental Matters

The Company believes that there are no compliance issues associated with applicable environmental laws and regulations that would have a material adverse effect on the Company. The Company is also remediating environmental contamination resulting from past industrial activity at certain of its sites. Expenditures for remediation and environmental liabilities were \$25 million in 2011, \$16 million in 2010 and \$17 million in 2009, and are estimated at \$93 million in the aggregate for the years 2012 through 2016. 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 \$171 million at December 31, 2011. 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 \$133 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.

Merck believes that climate change could present risks to its business. Some of the potential impacts of climate change to its business include increased operating costs due to additional regulatory requirements, physical risks to the Company's facilities, water limitations and disruptions to its supply chain. These potential risks are integrated into the Company's business planning including investment in reducing energy, water use and greenhouse gas emissions. The Company does not believe these risks are material to its business at this time.

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 57% of sales in 2011, 56% of sales in 2010 and 47% of sales in 2009. The increase in proportion of sales outside the United States in 2010 was primarily due to the inclusion of results of Schering-Plough following the close of the Merger.

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.

Merck has expanded its operations in countries located in Latin America, the Middle East, Africa, Eastern Europe and Asia Pacific. Business in these developing areas, while sometimes less stable, offers important opportunities for growth over time.

Table of Contents

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. The Company will make available, free of charge at the Investors' 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/leadership and all such information is available in print to any stockholder who requests it from the Company.

Item 1A. Risk Factors.

Investors 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 described below and elsewhere. See "Cautionary Factors that May Affect Future Results" below.

Certain of the Company's major products are going to lose patent protection in the near future, including *Singulair* in 2012, 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 in the United States and in other countries, the Company faces strong competition from lower priced generic 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. The patent that provides U.S. market exclusivity for *Singulair*, which is the Company's largest selling product with U.S. sales of approximately \$3.5 billion in 2011, expires in August 2012. The Company expects that within the two years following patent expiration, it will lose substantially all U.S. sales of *Singulair*, with most of those declines coming in the first full year following patent expiration. Also, the patent that provides market exclusivity for *Singulair* will expire in a number of major European markets in February 2013 and the Company expects sales of *Singulair* in those markets will decline significantly thereafter. In addition, the patent that provides U.S. market exclusivity for *Maxalt* will expire in December 2012. Also, the patent that provides market exclusivity for *Maxalt* will expire in a number of major European markets in February 2013. The Company anticipates that sales in the United States, which were approximately \$450 million in 2011, and in these European markets will decline significantly after these patent expiries. In addition, as previously disclosed, in 2012, AstraZeneca has the right to exercise its option to acquire the Company's interest in a subsidiary and, through it, the Company's interest in Nexium and Prilosec and the Company believes that it is likely that AstraZeneca will exercise its option.

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 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

Table of Contents

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 8. Financial Statements and Supplementary Data, Note 12. Contingencies and Environmental Liabilities below. In particular, manufacturers of generic pharmaceutical products from time to time file Abbreviated New Drug Applications 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. A trial relating to the Company's U.S. patent for *Nasonex* is expected to take place in 2012. 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.

Additionally, certain foreign governments have indicated that compulsory licenses to patents may be granted in the case of national emergencies, which could diminish or eliminate sales and profits from those regions and negatively affect the Company's results of operations. Further, recent court decisions relating to other companies' U.S. patents, potential U.S. legislation relating to patent reform, as well as regulatory initiatives may result in further erosion of intellectual property protection.

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 and, in the case of certain products, such a loss could result in a material non-cash impairment charge. 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.

Key Company products generate a significant amount of the Company's profits and cash flows, and any events that adversely affect the markets for its leading products could have a material and negative impact on results of operations and cash flows.

The Company's ability to generate profits and operating cash flow depends largely upon the continued profitability of the Company's key products, such as *Singulair*, *Januvia*, *Remicade*, *Zetia*, *Vytorin*, *Janumet*, *Isentress*, *Nasonex*, *Gardasil*, and *Temodar*. As a result of the Company's dependence on key products, any event that adversely affects any of these products or the markets for any of these products could have a significant impact on results of operations and cash flows. These events could include loss of patent protection, increased costs associated with manufacturing, generic or over-the-counter availability of the Company's product or a competitive product, the discovery of previously unknown side effects, increased competition from the introduction of new, more effective treatments and discontinuation or removal from the market of the product for any reason. If any of these events had a material adverse effect on the sales of certain products, such an event could result in a material non-cash impairment charge.

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. Expected declines in sales of products, such as *Singulair* and *Maxalt*, after the loss of market exclusivity mean that the Company's future success is dependent on its pipeline of new products, including new products which it may develop through joint ventures and products which it is able to obtain through

Table of Contents

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. There is a high rate of failure inherent in the research to develop new drugs to treat diseases. As a result, there is a high risk that funds invested by the Company in research programs will not generate financial returns. This risk profile is compounded by the fact that this research has a long investment cycle. To bring a pharmaceutical compound from the discovery phase to market may take a decade or more and failure can occur at any point in the process, including later in the process after significant funds have been invested.

For a description of the research and development process, see Item 1. **Business** **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, therefore, the Company may abandon a product in which it has invested substantial amounts of time and resources. 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 *Singular* and *Maxalt* in 2012, 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.

The Company's success is dependent on the successful development and marketing of new products, which are subject to substantial risks.

Products that appear promising in development may fail to reach market for numerous reasons, including the following:

findings of ineffectiveness, superior safety or efficacy of competing products, or harmful side effects in clinical or pre-clinical testing;

failure to receive the necessary regulatory approvals, including delays in the approval of new products and new indications, and increasing uncertainties about the time required to obtain regulatory approvals and the benefit/risk standards applied by regulatory agencies in determining whether to grant approvals;

lack of economic feasibility due to manufacturing costs or other factors; and

preclusion from commercialization by the proprietary rights of others.

In the future, if certain pipeline programs are cancelled or if the Company believes that their commercial prospects have been reduced, the Company may recognize material non-cash impairment charges for those programs that were measured at fair value and capitalized in connection with the Merger. These non-cash impairment charges, which the Company anticipates would be excluded from the Company's non-GAAP earnings, could be material to the Company's future GAAP earnings. For example, the Company recognized a non-cash impairment charge of \$1.7 billion in 2010 with respect to vorapaxar, which is a legacy Schering-Plough pipeline program.

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 in the EU. In the United States, the FDA is of particular importance to the Company, as it administers

Edgar Filing: Merck & Co. Inc. - Form 10-K

requirements covering the testing, approval, safety, effectiveness, manufacturing, labeling and marketing of prescription pharmaceuticals. In

Table of Contents

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 otherwise preclude distribution and sale of product.

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.

Developments following regulatory approval may adversely affect sales of the Company's products.

Even after a product reaches market, certain developments following regulatory approval, including results in post-marketing Phase IV trials or other studies, may decrease demand for the Company's products, including the following:

the re-review of products that are already marketed;

new scientific information and evolution of scientific theories;

the recall or loss of marketing approval of products that are already marketed;

changing government standards or public expectations regarding safety, efficacy or labeling changes; and

greater scrutiny in advertising and promotion.

In the past several years, clinical trials and post-marketing surveillance of certain marketed drugs of the Company and of competitors within the industry have raised concerns that have led to recalls, withdrawals or adverse labeling of marketed products. Clinical trials and post-marketing surveillance of certain marketed drugs also have raised concerns among some prescribers and patients relating to the safety or efficacy of pharmaceutical products in general that have negatively affected the sales of such products. In addition, increased scrutiny of the outcomes of clinical trials has led to increased volatility in market reaction. Further, these matters often attract litigation and, even where the basis for the litigation is groundless, considerable resources may be needed to respond.

In addition, following the wake of product withdrawals and other significant safety issues, health authorities such as the FDA, the EMA and Japan's Pharmaceutical and Medical Device Agency have increased their focus on safety when assessing the benefit/risk balance of drugs. Some health authorities appear to have become more cautious when making decisions about approvability of new products or indications and are re-reviewing select products that are already marketed, adding further to the uncertainties in the regulatory processes. There is also greater regulatory scrutiny, especially in the United States, on advertising and promotion and, in particular, direct-to-consumer advertising.

If previously unknown side effects are discovered or if there is an increase in negative publicity regarding known side effects of any of the Company's products, it could significantly reduce demand for the product or require the Company to take actions that could negatively affect sales, including removing the product from the market, restricting its distribution or applying for labeling changes. Further, in the current environment in which all pharmaceutical companies operate, the Company is at risk for product liability and consumer protection claims and civil and criminal governmental actions related to its products, research and/or marketing activities.

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

Edgar Filing: Merck & Co. Inc. - Form 10-K

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

Table of Contents

protection is significantly weaker than in the United States or in 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 competitors' products which, in addition to other factors, could in certain circumstances lead to non-cash impairment charges.

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, including the generic availability of competitors' branded products, they may be equally safe and effective products that 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. In addition, if legacy Schering-Plough products that were measured at fair value and capitalized in connection with the Merger, such as *Saphris*, or former Merck/Schering Plough Partnership products, *Vytorin* or *Zetia*, experience difficulties in the market that negatively impact product cash flows, the Company may recognize material non-cash impairment charges with respect to the value of those products. These non-cash impairment charges, which the Company anticipates would be excluded from the Company's non-GAAP earnings, could be material to the Company's future GAAP earnings.

The Company faces pricing pressure with respect to its products.

The Company faces increasing pricing pressure globally from managed care organizations, government agencies and programs that could negatively affect the Company's sales and profit margins. 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 and the Patient Protection and Affordable Care Act. Changes to the health care system enacted as part of health care reform in the United States, as well as increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, could result in further pricing pressures. In addition, the Company faces the risk of litigation with the government over its pricing calculations.

Outside the United States, numerous major markets have pervasive government involvement in funding health care and, in that regard, fix the pricing and reimbursement of pharmaceutical and vaccine products. 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 health care industry will continue to be subject to increasing regulation and political action.

The Company believes that the health care industry will continue to be subject to increasing regulation as well as political and legal action, as future proposals to reform the health care system are considered by Congress and state legislatures. In 2010, major health care reform was adopted into law in the United States.

Important market reforms have begun and will continue through full implementation in 2014. The new law is expected to expand access to health care to more than 32 million Americans by the end of the decade. In 2011, Merck incurred additional costs as a result of the new law, including increased Medicaid rebates and other impacts that reduced revenues. In 2010, the minimum rebate to states participating in the Medicaid program

Table of Contents

increased from 15.1% to 23.1% on the Company's branded prescription drugs; the Medicaid rebate was extended to Medicaid Managed Care Organizations; and eligibility for the federal 340B drug discount program was extended to rural referral centers, sole community hospitals, critical access hospitals, certain free standing cancer hospitals, and certain additional children's hospitals.

In addition, the law requires drug manufacturers to pay a 50% discount to Medicare Part D beneficiaries when they are in the Medicare Part D coverage gap (i.e., the so-called "donut hole"). Also, beginning in 2011, the Company is now required to pay an annual health care reform fee, which is being assessed on all branded prescription drug manufacturers and importers. The fee is calculated based on the industry's total sales of branded prescription drugs to specified government programs. The percentage of a manufacturer's sales that are included is determined by a tiered scale based on the manufacturer's individual revenues. Each manufacturer's portion of the total annual fee is based on the manufacturer's proportion of the total includable sales in the prior year. The annual industry fee for 2011 was \$2.5 billion and the annual industry fee for 2012 is \$2.8 billion.

The Company cannot predict the likelihood of future changes in the health care industry in general, or the pharmaceutical industry in particular, or what impact they may have on the Company's results of operations, financial condition or business.

The current uncertainty in global economic conditions together with austerity measures being taken by certain governments could negatively affect the Company's operating results.

The current uncertainty in global economic 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 result in a material adverse effect on the Company's business, cash flow, results of operations, financial position and prospects.

While many of the Company's brands experienced positive growth trends in the EU during 2011, the environment in the EU and across Europe continues to be challenging. Many countries have announced austerity measures aimed at reducing costs in areas such as health care. The implementation of pricing actions varies by country and many have announced measures to reduce prices of generic and patented drugs. While the Company is taking steps to mitigate the immediate impact in the EU, the austerity measures negatively affected the Company's revenue performance in 2011 and the Company anticipates mid-single digit pricing pressures in 2012 across Europe. Furthermore, these European austerity measures could negatively affect the Company's revenue performance in 2012 more than the Company anticipates. Lastly, in 2012, the Company will be subject to biennial price reductions in Japan.

Furthermore, the Company believes the credit and economic conditions within Greece, Spain, Italy and Portugal, among other members of the EU, have deteriorated during 2011 and may continue to deteriorate in 2012. These conditions, as well as inherent variability of timing of cash receipts, have resulted in, and may continue to result in, an increase in the average length of time that it takes to collect on the accounts receivable outstanding in these countries and may also impact the likelihood of collecting 100% of outstanding accounts receivable. As of December 31, 2011, the Company's accounts receivable in Greece, Italy, Spain and Portugal totaled approximately \$1.6 billion. Of this amount, hospital and public sector receivables were approximately \$1.1 billion in the aggregate, of which approximately 8%, 36%, 47% and 9% related to Greece, Italy, Spain and Portugal, respectively. As of December 31, 2011, the Company's total accounts receivable outstanding for more than one year were approximately \$400 million, of which approximately 90% related to accounts receivable in Greece, Italy, Spain and Portugal, mostly comprised of hospital and public sector receivables.

If the conditions in Europe worsen and one or more countries in the euro zone exits the euro zone and reintroduces its legacy currency, the resulting economic and currency impacts in the affected markets and globally could have a material adverse effect on the Company's results.

Table of Contents

The Company has significant global operations, which expose it to additional risks, and any adverse event could have a material negative impact on the Company's results of operations.

The extent of the Company's operations outside the United States are significant. Risks inherent in conducting a global business include:

changes in medical reimbursement policies and programs and pricing restrictions in key markets;

multiple regulatory requirements that could restrict the Company's ability to manufacture and sell its products in key markets;

trade protection measures and import or export licensing requirements;

foreign exchange fluctuations;

diminished protection of intellectual property in some countries; and

possible nationalization and expropriation.

In addition, there may be changes to the Company's business and political position if there is instability, disruption or destruction in a significant geographic region, regardless of cause, including war, terrorism, riot, civil insurrection or social unrest; and natural or man-made disasters, including famine, flood, fire, earthquake, storm or disease.

The Company has experienced difficulties and delays in manufacturing of certain of its products.

As previously disclosed, Merck has, in the past, experienced difficulties in manufacturing certain of its vaccines and other products. Similarly, the Company has, in the past, experienced difficulties manufacturing certain of its animal health products and is currently experiencing difficulty manufacturing certain women's health products. The Company is working on its manufacturing 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.

The Company faces significant litigation related to Vioxx.

On September 30, 2004, Merck voluntarily withdrew *Vioxx*, its arthritis and acute pain medication, from the market worldwide. Although Merck has settled the major portion of the U.S. Product Liability litigation, the Company still faces material litigation arising from the voluntary withdrawal of *Vioxx*.

In addition to the *Vioxx* Product Liability lawsuits, various purported class actions and individual lawsuits have been brought against Merck and several current and former officers and directors of Merck alleging that Merck made false and misleading statements regarding *Vioxx* in violation of the federal securities laws and state laws (all of these suits are referred to as the *Vioxx* Securities Lawsuits). The *Vioxx* Securities Lawsuits have been transferred by the Judicial Panel on Multidistrict Litigation (the *JPML*) to the U.S. District Court for the District of New Jersey before District Judge Stanley R. Chesler for inclusion in a nationwide MDL (the *Shareholder MDL*), and have been consolidated for all

Edgar Filing: Merck & Co. Inc. - Form 10-K

purposes. The *Vioxx* Securities Lawsuits are discussed more fully in Item 8. Financial Statements and Supplementary Data, Note 12.

Contingencies and Environmental Liabilities below. Merck 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 .) Merck has also been sued by a number of states, one county and a private citizen as a *qui tam* lawsuit with respect to the marketing of *Vioxx*.

Table of Contents

As previously disclosed, the U.S. Department of Justice (DOJ) issued subpoenas requesting information relating to Merck s research, marketing and selling activities with respect to *Vioxx* in a federal health care investigation under criminal statutes. In 2010, the Company established a \$950 million reserve (the *Vioxx* Liability Reserve) in connection with the anticipated resolution of the DOJ s investigation.

On November 22, 2011, the Company announced that it had reached a resolution with federal and state authorities regarding this matter, pending Court approval. Under civil settlement agreements signed with the United States and individually with 44 states and the District of Columbia, Merck will pay approximately two-thirds of the reserved charge to resolve civil allegations related to *Vioxx*. As a result, the United States and the participating states have released Merck from civil liability related to the governments allegations regarding the sale and promotion of *Vioxx*. The Company also has agreed to plead guilty to one count of misdemeanor misbranding of *Vioxx* under the Federal Food, Drug, and Cosmetic Act by promoting the drug for the treatment of rheumatoid arthritis prior to the FDA s approval of that indication in April 2002. The Company will pay a fine of approximately one-third of the reserved amount to the federal government as part of the plea agreement. With regard to the non-participating states, Merck continues to face lawsuits filed by those states.

On December 16, 2011, the United States District Court for the District of Massachusetts conducted a hearing with regard to the resolution. During that hearing, the parties advised the Court as to the nature of the resolution and the core documents comprising the resolution. The Court scheduled a subsequent hearing for March 2012, during which the Court may issue a ruling concerning whether it accepts Merck s plea and the resolution.

The *Vioxx* litigation is discussed more fully in Item 8. Financial Statements and Supplementary Data, Note 12. Contingencies and Environmental Liabilities below. A trial in the Missouri state court action is scheduled to begin on May 12, 2012. 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* Securities 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.

The Company is not currently able to estimate any additional amounts that it may be required to pay in connection with the *Vioxx* Lawsuits. These proceedings are still expected to continue for years and the Company cannot predict 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 remaining *Vioxx* Lawsuits. The Company has not established any reserves for any potential liability relating to the remaining *Vioxx* Lawsuits other than the *Vioxx* Liability Reserve and a reserve related to the settlement of the Canadian *Vioxx* litigation discussed in Item 8. Financial Statements and Supplementary Data, Note 12. Contingencies and Environmental Liabilities below.

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

Issues concerning *Vytorin* and the ENHANCE clinical trial have had an adverse effect on sales of *Vytorin* and *Zetia* in the United States and results from ongoing trials could have an adverse effect on such sales.

The Company sells *Vytorin* and *Zetia*. As previously disclosed, in January 2008, the legacy companies announced the results of the 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. The 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

Table of Contents

cardiovascular morbidity and mortality over and above that demonstrated for simvastatin has been established. 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 elevated LDL cholesterol is a risk factor for cardiovascular disease and that lowering LDL cholesterol reduces the risk for cardiovascular disease. For a discussion concerning shareholder litigation arising out of the ENHANCE study, see Item 8. Financial Statements and Supplementary Data, Note 12. Contingencies and Environmental Liabilities below.

The IMPROVE-IT trial is scheduled for completion in 2013. In the IMPROVE-IT trial, a blinded interim efficacy analysis was conducted by the DSMB for the trial when approximately 50% of the endpoints were accrued. The DSMB recommended continuing the trial with no changes in the study protocol. Another blinded interim efficacy analysis is planned by the DSMB in the first quarter of 2012 when approximately 75% of the primary events have been accrued. If, based on the results of the interim analysis, the trial were to be halted because of concerns related to *Vytorin*, that could have a material adverse effect on sales of *Vytorin* and *Zetia*.

These issues concerning the ENHANCE clinical trial have had an adverse effect on sales of *Vytorin* and *Zetia* and could continue to have an adverse effect on such sales. If the results of the IMPROVE-IT trial fail to demonstrate an incremental benefit of ezetimibe/simvastatin on cardiovascular morbidity and mortality over and above that demonstrated for simvastatin, sales of *Zetia* and *Vytorin* could be materially adversely affected. 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 and the Company could be required to record a material non-cash impairment charge. In addition, unfavorable outcomes resulting from the shareholder litigation concerning the ENHANCE clinical trial results could have a material adverse effect on the Company's business, cash flow, results of operations, financial position and prospects.

The Company may fail to realize all of the anticipated cost savings, revenue enhancements and other benefits expected from the Merger, which could adversely affect the value of the Company's common stock.

The success of the Merger will depend, in part, on the Company's ability to successfully combine the businesses of Merck and Schering-Plough and realize the anticipated benefits and cost savings from the combination of the two companies. If the combined company is not able to achieve all of these objectives within the anticipated time frame, the value of the Company's common stock may be adversely affected.

It is possible that the integration process could result in the loss of key employees, result in the disruption of the Company's ongoing business or identify inconsistencies in standards, controls, procedures and policies that adversely affect our ability to maintain relationships with customers, suppliers, distributors, creditors, lessors, clinical trial investigators or managers or to achieve the anticipated benefits of the Merger.

Specifically, issues that must be addressed in integrating the operations of the two legacy companies in order to realize the anticipated benefits of the Merger include, among other things:

integrating the research and development, manufacturing, distribution, marketing and promotion activities and information technology systems of Merck and Schering-Plough;

conforming standards, controls, procedures and accounting and other policies, business cultures and compensation structures between the companies;

identifying and eliminating redundant and underperforming operations and assets; and

managing tax costs or inefficiencies associated with integrating the operations of the combined company.

Integration efforts between the two companies have and will continue to divert management attention and resources. The Company's integration efforts involve plans to close or sell certain facilities worldwide. Implementation of any such plans is subject to satisfaction of local legal requirements including, but not limited to, compliance with relevant information and consultation obligations, where applicable. These processes may result in delays or the failure of the Company to realize all of its anticipated synergies. An inability to realize the full extent of the anticipated benefits of the Merger, as well as any delays encountered in the integration process, could have an adverse effect on the Company's business and results of operations, which may affect the value of the shares of Company common stock.

Table of Contents

In addition, the actual integration may result in additional and unforeseen expenses, such as new information technology systems, and the anticipated benefits of the integration plan may not be realized. Actual cost and sales synergies may be lower than the Company expects and may take longer to achieve than anticipated. If the Company is not able to adequately address these challenges, it may be unable to successfully integrate the operations of the two legacy companies, or to realize the anticipated benefits of the integration of the two legacy companies.

Delays encountered in the integration process could have a material adverse effect on the revenues, expenses, operating results and financial condition of the Company. Although the Company expects significant benefits, such as increased cost savings, to result from the Merger, there can be no assurance that the Company will realize all of these anticipated benefits.

The Company may not be able to realize the expected benefits of its investments in emerging markets.

The Company has been taking steps to increase its presence in emerging markets. However, there is no guarantee that the Company's efforts to expand sales in emerging markets will succeed. Some countries within emerging markets may be especially vulnerable to periods of global financial instability or may have very limited resources to spend on health care. In order for the Company to successfully implement its emerging markets strategy, it must attract and retain qualified personnel. The Company may also be required to increase its reliance on third-party agents within less developed markets. In addition, many of these countries have currencies that fluctuate substantially and if such currencies devalue and we cannot offset the devaluations, the Company's financial performance within such countries could be adversely affected.

For all these reasons, sales within emerging markets carry significant risks. However, a failure to continue to expand the Company's business in emerging markets could have a material adverse effect on the business, financial condition or results of the Company's operations.

The Company is exposed to market risk from fluctuations in currency exchange rates and interest rates.

The Company operates in multiple jurisdictions and, as such, virtually all sales are denominated in currencies of the local jurisdiction. Additionally, the Company has entered and will enter into acquisition, licensing, borrowings or other financial transactions that may give rise to currency and interest rate exposure.

Since the Company cannot, with certainty, foresee and mitigate against such adverse fluctuations, fluctuations in currency exchange rates and interest rates could negatively affect the Company's results of operations, financial position and cash flows.

In order to mitigate against the adverse impact of these market fluctuations, the Company will from time to time enter into hedging agreements. While hedging agreements, such as currency options and interest rate swaps, may limit some of the exposure to exchange rate and interest rate fluctuations, such attempts to mitigate these risks may be costly and not always successful.

The Company is subject to evolving and complex tax laws, which may result in additional liabilities that may affect results of operations.

The Company is subject to evolving and complex tax laws in the jurisdictions in which it operates. Significant judgment is required for determining the Company's tax liabilities, and the Company's tax returns are periodically examined by various tax authorities. The Company believes that its accrual for tax contingencies is adequate for all open years based on past experience, interpretations of tax law, and judgments about potential actions by tax authorities; however, due to the complexity of tax contingencies, the ultimate resolution of any tax matters may result in payments greater or less than amounts accrued.

In February 2011, President Obama's administration re-proposed significant changes to the U.S. international tax laws, including changes that would tax companies on excess returns attributable to certain offshore intangible assets, limit U.S. tax deductions for expenses related to un-repatriated foreign-source income

Table of Contents

and modify the U.S. foreign tax credit rules. Other potentially significant changes to the U.S. international laws, including a move toward a territorial tax system, have been set out by various Congressional committees. The Company cannot determine whether these proposals will be enacted into law or what, if any, changes may be made to such proposals prior to their being enacted into law. If these or other changes to the U.S. international tax laws are enacted, they could have a significant impact on the financial results of the Company.

In addition, the Company may be impacted by changes in tax laws, including tax rate changes, changes to the laws related to the remittance of foreign earnings (deferral), or other limitations impacting the U.S. tax treatment of foreign earnings, new tax laws, and revised tax law interpretations in domestic and foreign jurisdictions.

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, including potential civil or criminal governmental actions.

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.

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.

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 for certain operations in the United States began in 2010 and will be further implemented for U.S. operations in 2012 and includes modification to the design, operation and documentation of its internal controls over financial reporting. The Company implemented the resource planning system in major European markets and Canada in 2011 and intends to implement it in additional markets in 2012. Any material problems in the implementation could have a material adverse effect on the Company's business.

Negative events in the animal health industry could have a negative impact on future results of operations.

Future sales of key animal health products could be adversely impacted by a number of risk factors including certain risks that are specific to the animal health business. For example, the outbreak of disease carried by animals, such as Bovine Spongiform Encephalopathy or mad cow disease, could lead to their widespread death and precautionary destruction as well as the reduced consumption and demand for animals, which could adversely impact the Company's results of operations. Also, the outbreak of any highly contagious diseases near the Company's main production sites could require the Company to immediately halt production of vaccines at such sites or force the Company to incur substantial expenses in procuring raw materials or vaccines elsewhere. Other risks specific to animal health include epidemics and pandemics, government procurement and pricing practices,

Table of Contents

weather and global agribusiness economic events. As the Animal Health segment of the Company's business becomes more significant, the impact of any such events on future results of operations would also become more significant.

Biologics carry unique risks and uncertainties, which could have a negative impact on future results of operations.

The successful development, testing, manufacturing and commercialization of biologics, particularly human and animal health vaccines, is a long, expensive and uncertain process. There are unique risks and uncertainties with biologics, including:

There may be limited access to and supply of normal and diseased tissue samples, cell lines, pathogens, bacteria, viral strains and other biological materials. In addition, government regulations in multiple jurisdictions, such as the United States and European countries within the EU, could result in restricted access to, or transport or use of, such materials. If the Company loses access to sufficient sources of such materials, or if tighter restrictions are imposed on the use of such materials, the Company may not be able to conduct research activities as planned and may incur additional development costs.

The development, manufacturing and marketing of biologics are subject to regulation by the FDA, the EMA and other regulatory bodies. These regulations are often more complex and extensive than the regulations applicable to other pharmaceutical products. For example, in the United States, a BLA, including both preclinical and clinical trial data and extensive data regarding the manufacturing procedures, is required for human vaccine candidates and FDA approval is required for the release of each manufactured commercial lot.

Manufacturing biologics, especially in large quantities, is often complex and may require the use of innovative technologies to handle living micro-organisms. Each lot of an approved biologic must undergo thorough testing for identity, strength, quality, purity and potency. Manufacturing biologics requires facilities specifically designed for and validated for this purpose, and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, the Company may be required to provide pre-clinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes.

Biologics are frequently costly to manufacture because production ingredients are derived from living animal or plant material, and most biologics cannot be made synthetically. In particular, keeping up with the demand for vaccines may be difficult due to the complexity of producing vaccines.

The use of biologically derived ingredients can lead to allegations of harm, including infections or allergic reactions, or closure of product facilities due to possible contamination. Any of these events could result in substantial costs.

Product liability insurance for products may be limited, cost prohibitive or unavailable.

As a result of a number of factors, product liability insurance has become less available while the cost has increased significantly. With respect to product liability, the Company self-insures substantially all of its risk, as the availability of commercial insurance has become more restrictive. 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 legacy Merck products first sold after that date. The Company will continually assess the most efficient means to address its risk; however, there can be no guarantee that insurance coverage will be obtained or, if obtained, will be sufficient to fully cover product liabilities that may arise.

Table of Contents

Cautionary Factors that May Affect Future Results

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

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 anticipates, expects, plans, will, estimates, forecasts, projects and other words of similar meaning. One can also identify them by the fact 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:

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, including laws governing intellectual property, 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.

Significant litigation related to *Vioxx*, and *Vytorin* and *Zetia*.

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.

Edgar Filing: Merck & Co. Inc. - Form 10-K

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

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 states in the United States requiring security breach notification.

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

Table of Contents

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. The Company's vaccines business is conducted through divisional headquarters located in West Point, Pennsylvania. As part of the Company's worldwide strategic plan, Merck's Animal Health global headquarters functions, currently located in Boxmeer, the Netherlands, will be centralized in New Jersey. Principal U.S. research facilities are located in Rahway, Kenilworth and Summit, New Jersey, West Point, Pennsylvania, Palo Alto, California, and Elkhorn, Nebraska (Animal Health). Principal research facilities outside the U.S. are located in the Netherlands. The Company also has production facilities for human health products at 15 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 were \$1.7 billion in each of 2011 and 2010. In the United States, these amounted to \$1.2 billion for 2011 and \$990 million for 2010. Abroad, such expenditures amounted to \$516 million for 2011 and \$687 million for 2010.

The Company and its subsidiaries own their principal facilities and manufacturing plants under titles that 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 information called for by this Item is incorporated herein by reference to Note 12. Contingencies and Environmental Liabilities included in Part II, Item 8. Financial Statements and Supplementary Data.

Item 4. Mine Safety Disclosures.

Not Applicable

Executive Officers of the Registrant (ages as of February 1, 2012)

At the time of the Merger, November 3, 2009, certain executive officers assumed their position in the newly merged company as noted below.

KENNETH C. FRAZIER Age 57

December 2011 Chairman, President and Chief Executive Officer, Merck & Co., Inc.

Edgar Filing: Merck & Co. Inc. - Form 10-K

January 2011 President and Chief Executive Officer, Merck & Co., Inc.

May 2010 President, Merck & Co., Inc. responsible for the Company's three largest worldwide divisions Global Human Health, Merck Manufacturing Division and Merck Research Laboratories

Table of Contents

November 2009 Executive Vice President and President, Global Human Health, Merck & Co., Inc. responsible for the Company's marketing and sales organizations worldwide, including the global pharmaceutical and vaccine franchises

August 2007 Executive Vice President and President, Global Human Health, Merck & Co., Inc. 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, Merck & Co., Inc. responsible for legal and public affairs functions and The Merck Company Foundation (a not-for-profit charitable organization affiliated with the Company)

ADELE D. AMBROSE Age 55

November 2009 Senior Vice President and Chief Communications Officer, Merck & Co., Inc. responsible for the Global Communications organization

December 2007 Vice President and Chief Communications Officer, Merck & Co., Inc. responsible for the Global Communications organization

RICHARD S. BOWLES III Age 60

November 2009 Executive Vice President and Chief Ethics & Compliance Officer, Merck & Co., Inc. responsible for the Company's compliance function, including Global Safety & Environment, Systems Assurance, Ethics and Privacy

Prior to November 2009, Dr. Bowles was Senior Vice President, Global Quality Operations, Schering-Plough Corporation since March 2001.

JOHN CANAN Age 55

November 2009 Senior Vice President Finance-Global Controller, Merck & Co., Inc. responsible for the Company's global controller's organization including all accounting, controls, external reporting and financial standards and policies

January 2008 Senior Vice President and Controller, Merck & Co., Inc. responsible for the Corporate Controller's Group

September 2006 Vice President, Controller, Merck & Co., Inc. responsible for the Corporate Controller's Group

WILLIE A. DEESE Age 56

November 2009 Executive Vice President and President, Merck Manufacturing Division, Merck & Co., Inc. responsible for the Company's global manufacturing, procurement, and distribution and logistics functions

January 2008 Executive Vice President and President, Merck Manufacturing Division, Merck & Co., Inc. responsible for the Company's global manufacturing, procurement, and distribution and logistics functions

May 2005 President, Merck Manufacturing Division, Merck & Co., Inc. responsible for the Company's global manufacturing, procurement, and operational excellence functions

RICHARD R. DELUCA, JR. Age 49

September 2011 Executive Vice President and President, Merck Animal Health, Merck & Co., Inc. responsible for the Merck Animal Health organization

Prior to September 2011, Mr. DeLuca was Chief Financial Officer, Becton Dickinson Biosciences (a medical technology company) since 2010 and President, Wyeth's Fort Dodge Animal Health division from 2007 to 2010. He also served as Chief Operating Officer, Fort Dodge from 2006 to 2007 and Executive Vice President and Chief Financial Officer from 2002 to 2006.

Table of Contents

CUONG VIET DO Age 45

October 2011 Executive Vice President and Chief Strategy Officer, Merck & Co., Inc. responsible for leading the formulation and execution of the Company's long term strategic plan

Prior to October 2011, Mr. Do was Senior Vice President, Corporate Strategy and Business Development, TE Connectivity (a global company that designs, manufactures and markets products for customers in a variety of industries) from 2009 to 2011 and Senior Vice President and Chief Strategy Officer, Lenovo (a personal technology company) from 2006 to 2009.

MIRIAN M. GRADDICK-WEIR Age 57

November 2009 Executive Vice President, Human Resources, Merck & Co., Inc. responsible for the Global Human Resources organization

January 2008 Executive Vice President, Human Resources, Merck & Co., Inc. responsible for the Global Human Resources organization

September 2006 Senior Vice President, Human Resources, Merck & Co., Inc.

BRIDGETTE P. HELLER Age 50

March 2010 Executive Vice President and President, Merck Consumer Care, Merck & Co., Inc. responsible for the Merck Consumer Care organization

Prior to March 2010, Ms. Heller was President, Johnson & Johnson's Baby Global Business Unit from 2007 to 2010 and President for Global Baby, Kids and Wound Care from 2005 to 2007.

PETER N. KELLOGG Age 55

November 2009 Executive Vice President and Chief Financial Officer, Merck & Co., Inc. responsible for the Company's worldwide financial organization, investor relations, corporate development and licensing, and the Company's joint venture relationships

August 2007 Executive Vice President and Chief Financial Officer, Merck & Co., Inc. 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 (a biotechnology company) from the merger of Biogen, Inc. and IDEC Pharmaceuticals Corporation in November 2003.

PETER S. KIM Age 53

November 2009 Executive Vice President and President, Merck Research Laboratories, Merck & Co., Inc. responsible for the Company's research and development efforts worldwide

January 2008 Executive Vice President and President, Merck Research Laboratories, Merck & Co., Inc. responsible for the Company's research and development efforts worldwide

January 2003 President, Merck Research Laboratories, Merck & Co., Inc. responsible for the Company's research and development efforts worldwide

BRUCE N. KUHLIK Age 55

November 2009 Executive Vice President and General Counsel, Merck & Co., Inc. responsible for legal, communications, and public policy functions and The Merck Company Foundation (a not-for-profit charitable organization affiliated with the Company)

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

Table of Contents

August 2007 Senior Vice President and General Counsel, Merck & Co., Inc. 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, Merck & Co., Inc. primary responsibility for the Company's Vioxx litigation defense

MICHAEL ROSENBLATT, M.D. Age 64

December 2009 Executive Vice President and Chief Medical Officer, Merck & Co., Inc. the Company's primary voice to the global medical community on critical issues such as patient safety and oversight for the Company's Global Center for Scientific Affairs

Prior to December 2009, Dr. Rosenblatt was the Dean of Tufts University School of Medicine since 2003.

J. CHRIS SCALET Age 53

November 2009 Executive Vice President, Global Services, and Chief Information Officer, Merck & Co., Inc. responsible for Global Shared Services across the human resources, finance, site services and information services function; and the enterprise business process redesign initiative

January 2008 Executive Vice President, Global Services, and Chief Information Officer, Merck & Co., Inc. 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 Chief Information Officer, Merck & Co., Inc. responsible for Global Shared Services across the human resources, finance, site services and information services function; and the enterprise business process redesign initiative

ADAM H. SCHECHTER Age 47

May 2010 Executive Vice President and President, Global Human Health, Merck & Co., Inc. responsible for the Company's pharmaceutical and vaccine worldwide business

November 2009 President, Global Human Health, U.S. Market-Integration Leader, Merck & Co., Inc. commercial responsibility in the United States for the Company's portfolio of prescription medicines. Leader for the integration efforts for the Merck/Schering-Plough merger across all divisions and functions.

August 2007 President, Global Pharmaceuticals, Global Human Health, Merck & Co., Inc. 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, Merck & Co., Inc. commercial responsibility in the United States for the Company's portfolio of prescription medicines

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 |
|-------------|----------------|----------------|----------------|----------------|----------------|
| 2011 | \$ 1.52 | \$ 0.38 | \$ 0.38 | \$ 0.38 | \$ 0.38 |
| 2010 | \$ 1.52 | \$ 0.38 | \$ 0.38 | \$ 0.38 | \$ 0.38 |

Common Stock Market Prices

| 2011 | 4th Q | 3rd Q | 2nd Q | 1st Q |
|-------------|-----------------|-----------------|-----------------|-----------------|
| High | \$ 37.90 | \$ 36.56 | \$ 37.65 | \$ 37.62 |
| Low | \$ 30.54 | \$ 29.47 | \$ 33.00 | \$ 31.06 |
| 2010 | | | | |
| High | \$ 37.68 | \$ 37.58 | \$ 37.97 | \$ 41.56 |
| Low | \$ 33.94 | \$ 33.65 | \$ 30.70 | \$ 35.76 |

As of January 31, 2012, there were approximately 165,500 shareholders of record.

Table of Contents**Equity Compensation Plan Information**

The following table summarizes information about the options, warrants and rights and other equity compensation under the Company's equity compensation plans as of the close of business on December 31, 2011. The table does not include information about tax qualified plans such as the MSD Employee Savings and Security Plan and the Schering-Plough Employees' Savings Plan.

| Plan Category | Number of securities to be issued upon exercise of outstanding options, warrants and rights (a) | Weighted-average exercise price of outstanding options, warrants and rights (b) | Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c) |
|---|--|--|--|
| Equity compensation plans approved by security holders ⁽¹⁾ | 230,760,164 ⁽²⁾ | \$ 39.51 | 163,758,580 |
| Equity compensation plans not approved by security holders ⁽³⁾ | | | |
| Total | 230,760,164 | \$ 39.51 | 163,758,580 |

⁽¹⁾ Includes options to purchase shares of Company Common Stock and other rights under the following shareholder-approved plans: the Merck Sharp & Dohme 2001, 2004, 2007 and 2010 Incentive Stock Plans, the Merck & Co., Inc. 2001, 2006 and 2010 Non-Employee Directors Stock Option Plans, and the Merck & Co., Inc. Schering-Plough 1997, 2002 and 2006 Stock Incentive Plans.

⁽²⁾ Excludes approximately 14,295,025 shares of restricted stock units and 2,128,907 performance share units (assuming maximum payouts) under the Merck Sharp & Dohme 2004, 2007 and 2010 Incentive Stock Plans and 6,850,148 shares of restricted stock units and 292,905 performance share units (excluding accrued dividends) under the Merck & Co., Inc. Schering-Plough 2006 Stock Incentive Plan. Also excludes 427,474 shares of phantom stock deferred under the MSD Deferral Program.

⁽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 Rosetta Inpharmatics, Inc. 1997 and 2000 Employee Stock Option Plans. A total of 18,554 shares of Merck Common Stock may be purchased under the Assumed Plans, at a weighted average exercise price of \$52.51. No further grants may be made under any Assumed Plans.

Table of Contents**Performance Graph**

The following graph assumes a \$100 investment on December 31, 2006, and reinvestment of all dividends, in each of the Company's Common Shares, the S&P 500 Index, and a composite peer group of the major U.S.-based pharmaceutical companies, which are: Abbott Laboratories, Bristol-Myers Squibb Company, Johnson & Johnson, Eli Lilly and Company, and Pfizer Inc.

Comparison of Five-Year Cumulative Total Return*

Merck & Co., Inc., Composite Peer Group and S&P 500 Index

| | End of Period Value | 2011/2006 CAGR** |
|--------------|------------------------|---------------------|
| MERCK | \$ 166 | 11% |
| PEER GRP.*** | 119 | 3 |
| S&P 500 | 99 | 0 |

| | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 |
|-----------|--------|--------|-------|--------|--------|--------|
| MERCK | 100.00 | 113.75 | 73.83 | 147.09 | 151.26 | 165.69 |
| PEER GRP. | 100.00 | 101.95 | 90.90 | 98.06 | 97.63 | 118.68 |
| S&P 500 | 100.00 | 105.49 | 66.47 | 84.06 | 96.74 | 98.79 |

*The Performance Graph reflects Schering-Plough's stock performance from December 31, 2006 through the close of the Merger and Merck's stock performance from November 3, 2009 through December 31, 2011. Assumes the cash component of the merger consideration was reinvested in Merck stock at the closing price on November 3, 2009.

**Compound Annual Growth Rate

***On October 15, 2009, Wyeth and Pfizer Inc. completed their previously announced merger (the Pfizer/Wyeth Merger) where Wyeth became a wholly-owned subsidiary of Pfizer Inc. As discussed, on November 3, 2009, Merck and Schering-Plough completed the Merger (together with the Pfizer/Wyeth Merger, the Transactions) in which Merck (subsequently renamed Merck Sharp & Dohme Corp. (MSD)) became a wholly-owned subsidiary of Schering-Plough (subsequently renamed Merck & Co., Inc.). As a result of the Transactions, Wyeth and MSD no longer exist as publicly traded entities and ceased all trading of their common stock as of the close of business on their respective merger dates. Wyeth and MSD have been permanently removed from the peer group index.

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)

| | 2011 ⁽¹⁾ | 2010 ⁽²⁾ | 2009 ⁽³⁾ | 2008 ⁽⁴⁾ | 2007 ⁽⁵⁾ |
|---|---------------------|---------------------|-----------------------|---------------------|---------------------|
| Results for Year: | | | | | |
| Sales | \$48,047 | \$45,987 | \$27,428 | \$23,850 | \$24,198 |
| Materials and production | 16,871 | 18,396 | 9,019 | 5,583 | 6,141 |
| Marketing and administrative | 13,733 | 13,125 | 8,543 | 7,377 | 7,557 |
| Research and development | 8,467 | 11,111 | 5,845 | 4,805 | 4,883 |
| Restructuring costs | 1,306 | 985 | 1,634 | 1,033 | 327 |
| Equity income from affiliates | (610) | (587) | (2,235) | (2,561) | (2,977) |
| Other (income) expense, net | 946 | 1,304 | (10,668) | (2,318) | 4,775 |
| Income before taxes | 7,334 | 1,653 | 15,290 | 9,931 | 3,492 |
| Taxes on income | 942 | 671 | 2,268 | 1,999 | 95 |
| Net income | 6,392 | 982 | 13,022 | 7,932 | 3,397 |
| Less: Net income attributable to noncontrolling interests | 120 | 121 | 123 | 124 | 122 |
| Net income attributable to Merck & Co., Inc. | 6,272 | 861 | 12,899 | 7,808 | 3,275 |
| Basic earnings per common share attributable to Merck & Co., Inc. common shareholders | \$2.04 | \$0.28 | \$5.67 | \$3.65 | \$1.51 |
| Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders | \$2.02 | \$0.28 | \$5.65 | \$3.63 | \$1.49 |
| Cash dividends declared | 4,818 | 4,730 | 3,598 | 3,250 | 3,311 |
| Cash dividends paid per common share | \$1.52 | \$1.52 | \$1.52 ⁽⁶⁾ | \$1.52 | \$1.52 |
| Capital expenditures | 1,723 | 1,678 | 1,461 | 1,298 | 1,011 |
| Depreciation | 2,351 | 2,638 | 1,654 | 1,445 | 1,752 |
| Average common shares outstanding (millions) | 3,071 | 3,095 | 2,268 | 2,136 | 2,170 |
| Average common shares outstanding assuming dilution (millions) | 3,094 | 3,120 | 2,273 | 2,143 | 2,190 |
| Year-End Position: | | | | | |
| Working capital | \$16,936 | \$13,423 | \$12,791 | \$4,794 | \$2,787 |
| Property, plant and equipment, net | 16,297 | 17,082 | 18,279 | 12,000 | 12,346 |
| Total assets | 105,128 | 105,781 | 112,314 | 47,196 | 48,351 |
| Long-term debt | 15,525 | 15,482 | 16,095 | 3,943 | 3,916 |
| Total equity | 56,943 | 56,805 | 61,485 | 21,167 | 20,591 |
| Year-End Statistics: | | | | | |
| Number of stockholders of record | 166,100 | 171,000 | 175,600 | 165,700 | 173,000 |
| Number of employees | 86,000 | 94,000 | 100,000 | 55,200 | 59,800 |

⁽¹⁾ Amounts for 2011 include the amortization of purchase accounting adjustments, in-process research and development impairment charges reflected in research and development expenses, the impact of restructuring actions, an arbitration settlement charge, and the favorable impact of certain tax items, including a net favorable impact of approximately \$700 million relating to the settlement of a federal income tax audit.

⁽²⁾ Amounts for 2010 include the amortization of purchase accounting adjustments, in-process research and development impairment charges of \$2.4 billion reflected in research and development expenses, the impact of restructuring actions, a reserve related to Vioxx, the gain recognized on AstraZeneca LP's exercise of its option to acquire certain assets from the Company and the favorable impact of certain tax items. Amounts in 2010 include a reclassification of \$120 million of expenses from marketing and administrative to research and development.

⁽³⁾

Edgar Filing: Merck & Co. Inc. - Form 10-K

Amounts for 2009 include the impact of the merger with Schering-Plough Corporation on November 3, 2009, including the recognition of a gain representing the fair value step-up of Merck's previously held interest in the Merck/Schering-Plough partnership as a result of obtaining a controlling interest and the amortization of purchase accounting adjustments recorded in the post-Merger period. Also included in 2009, is a gain on the sale of Merck's interest in Merial Limited, the favorable impact of certain tax items and the impact of restructuring actions.

- (4) Amounts for 2008 include a gain on distribution from AstraZeneca LP, a gain related to the sale of the remaining worldwide rights to Aggrastat, the favorable impact of certain tax items, the impact of restructuring actions and an expense for a contribution to the Merck Company Foundation.*
- (5) 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, in-process research and development expense resulting from an acquisition, gains on sales of assets and product divestitures, as well as a net gain on the settlements of certain patent disputes.*
- (6) Amount reflects dividends paid to common shareholders of Merck. In addition, approximately \$144 million of dividends were paid subsequent to the merger with Schering-Plough, and \$431 million were paid prior to the merger, relating to common stock and preferred stock dividends declared by Schering-Plough in 2009.*

Table of Contents

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Description of Merck's Business

Merck & Co., Inc. (Merck or the Company) is a global health care company that delivers innovative health solutions through its prescription medicines, vaccines, biologic therapies, animal health, and consumer care products, which it markets directly and through its joint ventures. The Company's operations are principally managed on a products basis and are comprised of four operating segments, which are the Pharmaceutical, Animal Health, Consumer Care and Alliances segments, and one reportable segment, which is the Pharmaceutical segment. The Pharmaceutical segment includes human health pharmaceutical and vaccine products marketed either directly by the Company or through joint ventures. Human health pharmaceutical products consist of therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. The Company 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. Vaccine products consist of preventive pediatric, adolescent and adult vaccines, primarily administered at physician offices. The Company sells these human health vaccines primarily to physicians, wholesalers, physician distributors and government entities. The Company also has animal health operations that discover, develop, manufacture and market animal health products, including vaccines, which the Company sells to veterinarians, distributors and animal producers. Additionally, the Company has consumer care operations that develop, manufacture and market over-the-counter, foot care and sun care products, which are sold through wholesale and retail drug, food chain and mass merchandiser outlets.

On November 3, 2009, legacy Merck & Co., Inc. and Schering-Plough Corporation (Schering-Plough) merged (the Merger). The results of Schering-Plough's business have been included in Merck's financial statements only for periods subsequent to the completion of the Merger. Therefore, Merck's financial results for 2009 do not reflect a full year of Schering-Plough operations.

Overview

During 2011, the Company focused on accelerating revenue growth, reducing costs to drive efficiencies, allocating resources to drive future growth by making strategic investments in product launches, as well as in the emerging markets, and advancing and augmenting its research and development pipeline.

Worldwide sales totaled \$48.0 billion in 2011, an increase of 4% compared with \$46.0 billion in 2010. Foreign exchange favorably affected global sales performance by 2%. The revenue increase was driven largely by growth in *Januvia* and *Janumet*, treatments for type 2 diabetes, *Singulair*, a medicine for the chronic treatment of asthma and the relief of symptoms of allergic rhinitis, *Isentress*, an antiretroviral therapy for use in combination therapy for the treatment of HIV-1 infection, *Gardasil*, a vaccine to help prevent certain diseases caused by four types of human papillomavirus (HPV), *Simponi*, a treatment for inflammatory diseases, *RotaTeq*, a vaccine to help protect against rotavirus gastroenteritis in infants and children, *Zetia*, a cholesterol absorption inhibitor, *Pneumovax*, a vaccine to help prevent pneumococcal disease, and *Bridion*, for the reversal of certain muscle relaxants used during surgery. In addition, revenue in 2011 benefited from higher sales of the Company's animal health products and from the launch of *Victralis*, a treatment for chronic hepatitis C. These increases were partially offset by lower sales of *Cozaar* and *Hyzaar*, treatments for hypertension, which lost patent protection in the United States in April 2010 and in a number of major European markets in March 2010, as well as by lower sales of Caelyx, Subutex and Suboxone as the Company no longer has marketing rights to these products. Revenue was also negatively affected by lower sales of *Vytorin*, a cholesterol modifying medicine, *Temodar*, a treatment for certain types of brain tumors, *ProQuad*, a pediatric combination vaccine to help protect against measles, mumps, rubella and varicella, and *Varivax*, a vaccine to help prevent chickenpox (varicella). In addition, as discussed below, the ongoing implementation of certain provisions of U.S. health care reform legislation during 2011 resulted in further increases in Medicaid rebates and other impacts that reduced revenues. Additionally, many countries in the European Union (the EU) have undertaken austerity measures aimed at reducing costs in health care and have implemented pricing actions that negatively impacted sales in 2011.

In April 2011, Merck and Johnson & Johnson (J&J) reached an agreement to amend the agreement governing the distribution rights to *Remicade* and *Simponi*. This agreement concluded the arbitration proceeding

Table of Contents

J&J initiated in May 2009. Under the terms of the amended distribution agreement, Merck relinquished marketing rights for *Remicade* and *Simponi* to J&J in territories including Canada, Central and South America, the Middle East, Africa and Asia Pacific effective July 1, 2011. Merck retained exclusive marketing rights throughout Europe, Russia and Turkey (the Retained Territories). The Retained Territories represented approximately 70% of Merck's 2010 revenue of \$2.8 billion from *Remicade* and *Simponi*. In addition, beginning July 1, 2011, all profits derived from Merck's exclusive distribution of the two products in the Retained Territories are being equally divided between Merck and J&J. J&J also received a one-time payment from Merck of \$500 million in April 2011.

During 2011, the Company continued the advancement of drug candidates through its pipeline. *Victralis*, the Company's innovative oral medicine for the treatment of chronic hepatitis C, was approved by the U.S. Food and Drug Administration (the FDA) and the European Commission (the EC). The FDA also approved *Juvisync*, a new treatment for type 2 diabetes that combines the active ingredient in the glucose-lowering medication *Januvia* with the cholesterol-lowering medication *Zocor*. In addition, the EC approved *Zoely*, a monophasic combined oral contraceptive tablet for use by women to prevent pregnancy. Cubicin, an antibacterial agent with activity against methicillin-resistant *Staphylococcus aureus* (MRSA), for which the Company has licensed development and distribution rights in Japan, was approved for use in that country.

In February 2012, the FDA approved *Janumet XR*, a new treatment for type 2 diabetes that combines sitagliptin, which is the active component of *Januvia*, with extended-release metformin in a once-daily formulation; *Cosopt PF*, Merck's preservative-free formulation of *Cosopt* ophthalmic solution, indicated for the reduction of elevated intraocular pressure in appropriate patients with open-angle glaucoma or ocular hypertension; and *Zioptan*, a preservative-free prostaglandin analogue ophthalmic solution.

The Company also received additional indications for several of its existing products. During 2011, the FDA approved an expanded age indication for *Zostavax*, a vaccine to help prevent shingles (herpes zoster), to include adults ages 50 to 59. In addition, the FDA approved *Sylatron* for the adjuvant treatment of melanoma in patients with microscopic or gross nodal involvement. Also, *Simponi* received an indication in the EU for use in combination with methotrexate in adults with severe, active and progressive rheumatoid arthritis not previously treated with methotrexate, having been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function. In January 2012, the FDA approved the use of *Isentress*, in combination with other antiretroviral medicines, for the treatment of HIV-1 infection in pediatric patients two years of age and older and weighing at least 10 kg.

The Company currently has two candidates under review with the FDA: MK-8669, ridaforolimus, for the treatment of metastatic soft-tissue or bone sarcomas in patients who had a favorable response to chemotherapy and MK-0653C, *Zetia* (ezetimibe) combined with atorvastatin for the treatment of primary or mixed hyperlipidemia. MK-8669 is also under review in the EU.

The Company currently has 19 candidates in Phase III development and anticipates filing a New Drug Application (NDA) with the FDA with respect to certain of these candidates in 2012 including MK-4305, suvorexant, an investigational treatment for insomnia; MK-8616, *Bridion*, a medication for the reversal of certain muscle relaxants used during surgery; and V503, a nine-valent HPV vaccine. The Company also anticipates filings in 2013 for, among others, MK-0822, odanacatib, an investigational treatment for osteoporosis, and MK-0524A, *Tredaptive*, which is under development for the treatment of atherosclerosis.

Merck continues to pursue opportunities that have the potential to drive both near- and long-term growth. During 2011, the Company completed a variety of transactions including the acquisition of Inspire Pharmaceuticals, Inc., a specialty pharmaceutical company focused on developing and commercializing ophthalmic products. Additionally, the Company entered into transactions designed to strengthen its presence in emerging markets in the longer term.

Merck continues to realize cost savings across all areas of the Company. These savings result from various actions, including the Merger Restructuring Program discussed below, previously announced ongoing cost reduction activities, as well as from non-restructuring-related activities. As of the end of 2011, the Company has realized approximately \$2.9 billion in annual net cost savings from these activities since the Merger.

In July 2011, the Company announced the latest phase of its global restructuring program (the Merger Restructuring Program) that was initiated in conjunction with the integration of the legacy Merck and legacy

Table of Contents

Schering-Plough businesses. This Merger Restructuring Program is intended to optimize the cost structure of the combined company. As part of this latest phase, the Company expects to reduce its workforce measured at the time of the Merger by an additional 12% to 13% across the Company worldwide. A majority of the workforce reductions in this phase of the Merger Restructuring Program relate to manufacturing (including Animal Health), administrative and headquarters organizations. Previously announced workforce reductions of approximately 17% in earlier phases of the program primarily reflect the elimination of positions in sales, administrative and headquarters organizations, as well as from the sale or closure of certain manufacturing and research and development sites and the consolidation of office facilities. The Company will continue to hire employees in strategic growth areas of the business as necessary. The Company will continue to pursue productivity efficiencies and evaluate its manufacturing supply chain capabilities on an ongoing basis which may result in future restructuring actions. The Company recorded total pretax restructuring costs of \$1.8 billion in 2011, \$1.8 billion in 2010 and \$1.5 billion in 2009 related to this program. The restructuring actions under the Merger Restructuring Program are expected to be substantially completed by the end of 2013, with the exception of certain actions, principally manufacturing-related, which are expected to be substantially completed by 2015, with the total cumulative pretax costs estimated to be approximately \$5.8 billion to \$6.6 billion. The Company estimates that approximately two-thirds of the cumulative pretax costs relate to cash outlays, primarily related to 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. The Company expects the Merger Restructuring Program to yield annual savings by the end of 2013 of approximately \$3.5 billion to \$4.0 billion and annual savings upon completion of the program of approximately \$4.0 billion to \$4.6 billion.

During 2011, the Company continued to be affected by the U.S. health care reform legislation that was enacted in 2010 as additional provisions went into effect. Beginning in 2011, the law requires pharmaceutical manufacturers to pay a 50% discount to Medicare Part D beneficiaries when they are in the Medicare Part D coverage gap (i.e., the so-called "donut hole"). Approximately \$150 million was recorded as a reduction to revenue in 2011 related to the estimated impact of this provision of health care reform. Also, the Company recorded \$162 million of expenses for the annual health care reform fee, which the Company was required to pay beginning in 2011. The law also increased mandated Medicaid rebates, which reduced revenues by approximately \$179 million and \$170 million in 2011 and 2010, respectively.

Effective December 1, 2011, Richard T. Clark, chairman, retired from the Company and the Merck Board of Directors. Kenneth C. Frazier, Merck's president and chief executive officer, was elected by the Board to serve as chairman following Mr. Clark's retirement.

In November 2011, Merck's Board of Directors raised the Company's quarterly dividend to \$0.42 per share from \$0.38 per share.

Earnings per common share assuming dilution attributable to common shareholders (EPS) for 2011 were \$2.02, which reflect a net unfavorable impact resulting from acquisition-related costs, restructuring costs, as well as the charge related to the settlement of the arbitration proceeding with J&J discussed above, partially offset by the favorable impact of certain tax items and gains on the disposition of the Company's interest in the Johnson & Johnson[®]Merck Consumer Pharmaceuticals Company (JJMCP) joint venture and the sale of certain manufacturing facilities and related assets. Non-GAAP EPS in 2011 were \$3.77 excluding these items (see Non-GAAP Income and Non-GAAP EPS below).

Competition and the Health Care Environment

Competition

The markets in which the Company conducts its business and the pharmaceutical industry are highly competitive and highly regulated. The Company's competitors include other worldwide research-based pharmaceutical companies, smaller research companies with more limited therapeutic focus, and generic drug and consumer health care manufacturers. The Company's operations may be affected by technological advances of competitors, industry consolidation, patents granted to competitors, competitive combination products, new products of competitors, the generic availability of competitors' branded products, new information from clinical trials of marketed products or post-marketing surveillance and generic competition as the Company's products

Table of Contents

mature. In addition, patent positions are increasingly being challenged by competitors, and the outcome can be highly uncertain. An adverse result in a patent dispute can preclude commercialization of products or negatively affect sales of existing products and could result in the recognition of an impairment charge with respect to certain products. Competitive pressures have intensified as pressures in the industry have grown. The effect on operations of competitive factors and patent disputes cannot be predicted.

Pharmaceutical competition involves a rigorous 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 positioned to compete in the search for technological innovations. Additional resources required to meet market challenges 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 external alliances, such as joint ventures and licenses, and has been refining its sales and marketing efforts to further address changing industry conditions. However, the introduction of new products and processes by competitors may result in price reductions and product displacements, even for products protected by patents. For example, the number of compounds available to treat a particular disease typically increases over time and can result in slowed sales growth for the Company's products in that therapeutic category.

The highly competitive animal health business is affected by several factors including regulatory and legislative issues, scientific and technological advances, product innovation, the quality and price of the Company's products, effective promotional efforts and the frequent introduction of generic products by competitors.

The Company's consumer care operations face competition from other consumer health care businesses as well as retailers who carry their own private label brands. The Company's competitive position is affected by several factors, including regulatory and legislative issues, scientific and technological advances, the quality and price of the Company's products, promotional efforts and the growth of lower cost private label brands.

Health Care Environment

Global efforts toward health care cost containment continue to exert pressure on product pricing and market access. In the United States, federal and state governments for many years also have pursued methods to 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 and to provide discounts for outpatient medicines purchased by certain Public Health Service entities and disproportionate share hospitals (hospitals meeting certain criteria). 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. Merck is contracted to provide its pediatric vaccines to this program.

Against this backdrop, the United States enacted major health care reform legislation in 2010, which began to be implemented in 2011. Various insurance market reforms advanced in 2011 and will continue through full implementation in 2014. The new law is expected to expand access to health care to more than 32 million Americans by the end of the decade who did not previously have regular access to health care. With respect to the effect of the law on the pharmaceutical industry, the law increased the mandated Medicaid rebate from 15.1% to 23.1%, expanded the rebate to Medicaid managed care utilization, and increased the types of entities eligible for the federal 340B drug discount program. The law also requires pharmaceutical manufacturers to pay a 50% discount to Medicare Part D beneficiaries when they are in the Medicare Part D coverage gap (i.e., the so-called "donut hole"). Also, pharmaceutical manufacturers are now required to pay an annual health care reform fee. The total annual industry fee was \$2.5 billion in 2011 and will be \$2.8 billion in 2012. The fee is assessed on each company in proportion to its share of sales to certain government programs, such as Medicare and Medicaid.

The Company also faces increasing pricing pressure globally from managed care organizations, government agencies and programs that could negatively affect the Company's sales and profit margins. 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

Table of Contents

Improvement and Modernization Act of 2003 and the Patient Protection and Affordable Care Act. Changes to the health care system enacted as part of health care reform in the United States, as well as increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, could result in further pricing pressures.

In addition, in the effort to contain the U.S. federal deficit, the pharmaceutical industry could be considered a potential source of savings via legislative proposals that have been debated but not enacted in prior years. These types of revenue generating or cost saving proposals include direct price controls in the Medicare prescription drug program (Part D). In addition, Congress may again consider proposals to allow, under certain conditions, the importation of medicines from other countries. It remains very uncertain as to what proposals, if any, may be included as part of future federal budget deficit reduction proposals that would directly or indirectly affect the Company.

In 2011 and 2010, global efforts toward health care cost containment were intense in several European countries. Many countries have announced austerity measures, which include the implementation of pricing actions to reduce prices of generic and patented drugs. While the Company is taking steps to mitigate the impact in the EU, the austerity measures have negatively affected the Company's revenue performance in 2011 and 2010 and the Company anticipates the austerity measures will continue to negatively affect revenue performance in 2012.

Additionally, the global economic downturn and the sovereign debt issues in certain European countries, among other factors, have adversely impacted foreign receivables in certain European countries. While the Company continues to receive payment on these receivables, these conditions have resulted in an increase in the average length of time it takes to collect accounts receivable outstanding thereby adversely affecting cash flows.

The full impact of U.S. health care reform, as well as continuing budget pressures on governments around the world, cannot be predicted at this time.

In addressing cost containment pressures, the Company continues to attempt to demonstrate that its medicines provide value to patients and to those who pay for health care. In markets with historically low rates of government health care spending, the Company encourages those governments to increase their investments in order to improve their citizens' access to appropriate health care, including medicines.

Operating conditions have become more challenging under the global pressures of competition, industry regulation and cost containment efforts. Although no one can predict the effect of these and other factors on the Company's business, the Company continually takes measures to evaluate, adapt and improve the organization and its business practices to better meet customer needs and believes that it is well positioned to respond to the evolving health care environment and market forces.

Government Regulation

The pharmaceutical industry is subject to regulation by regional, country, state and local agencies around the world. Governmental regulation and legislation tend to focus on standards and processes for determining drug safety and effectiveness, as well as conditions for sale or reimbursement, especially related to the pricing of products.

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 and practices have increased the amount of time and resources necessary to develop new products and bring them to market in the United States.

The EU has adopted directives and other legislation concerning the classification, labeling, advertising, wholesale distribution, integrity of the supply chain, enhanced pharmacovigilance monitoring and approval for marketing of medicinal products for human use. These provide mandatory standards throughout the EU, which may be supplemented or implemented with additional regulations by the EU member states. 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.

The Company believes that it will continue to be able to conduct its operations, including launching new drugs into the market, in this regulatory environment.

Table of Contents

Access to Medicines

As a global health care company, Merck's primary role is to discover and develop innovative medicines and vaccines. The Company also recognizes that it has an important role to play in helping to improve access to its products around the world. The Company's efforts in this regard are wide-ranging. For example, the Company has been recognized for pricing many of its products through a differential pricing framework, taking into consideration such factors as a country's level of economic development and public health need. In addition, the Merck Patient Assistance Program provides medicines and adult vaccines for free to people who do not have prescription drug or health insurance coverage and who, without the Company's assistance, cannot afford their Merck medicine and vaccines.

Building on the Company's own efforts, Merck has undertaken collaborations with many stakeholders to improve access to medicines and enhance the quality of life for people around the world.

For example, in 2011, Merck announced that it would launch *Merck for Mothers*, a long-term effort with global health partners to create a world where no woman has to die from preventable complications of pregnancy and childbirth. The launch includes a 10-year, \$500 million initiative that applies Merck's scientific and business expertise to making proven solutions more widely available, developing new technologies and improving public awareness, policy efforts and private sector engagement for maternal mortality.

Merck has also in the past provided funds to The Merck Company Foundation, an independent organization, which has partnered with a variety of organizations dedicated to improving global health. One of these partnerships is The African Comprehensive HIV/AIDS Partnership in Botswana, a collaboration with the government of Botswana and the Bill & Melinda Gates Foundation, that was renewed in 2010 and supports Botswana's response to HIV/AIDS through a comprehensive and sustainable approach to HIV prevention, care, treatment, and support.

Privacy and Data Protection

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. There has been increased attention to privacy and data protection issues in both developed and emerging markets with the potential to affect directly the Company's business, including recently enacted laws and regulations in the United States, Europe, Asia and Latin America and increased enforcement activity in the United States and other developed markets.

Operating Results

Segment composition reflects certain managerial changes that have been implemented. Consumer Care product sales outside the United States and Canada, previously included in the Pharmaceutical segment, are now included in the Consumer Care segment. Segment disclosures for prior years have been recast on a comparable basis with 2011.

Sales

Worldwide sales totaled \$48.0 billion in 2011, an increase of 4% compared with \$46.0 billion in 2010. Foreign exchange favorably affected global sales performance by 2%. The revenue increase was driven largely by growth in *Januvia* and *Janumet*, *Singulair*, *Isentress*, *Gardasil*, *Simponi*, *RotaTeq*, *Zetia*, *Pneumovax* and *Bridion*. In addition, revenue in 2011 benefited from higher sales of the Company's animal health products and from the launch of *Victrelis*. These increases were partially offset by lower sales of *Cozaar* and *Hyzaar* which lost patent protection in the United States in April 2010 and in a number of major European markets in March 2010, as well as by lower sales of *Caelyx*, *Subutex* and *Suboxone* as the Company no longer has marketing rights to these products. Revenue was also negatively affected by lower sales of *Vytorin*, *Temodar*, *ProQuad* and *Varivax*. In addition, as discussed above, the ongoing implementation of certain provisions of U.S. health care reform legislation during 2011 resulted in further increases in Medicaid rebates and other impacts that reduced revenues.

Domestic sales were \$20.5 billion in 2011, an increase of 1% compared with \$20.2 billion in 2010. The domestic sales increase was driven by higher sales of *Singulair*, *Januvia*, *Gardasil*, *Janumet*, and *Isentress*, as well as by the launch of *Victrelis*. These increases were partially offset by lower sales of *Cozaar*, *Hyzaar*, *Vytorin*, *Varivax* and *ProQuad*.

Table of Contents

Foreign sales were \$27.6 billion in 2011, an increase of 7% compared with \$25.8 billion in 2010 driven by growth in Japan and in the emerging markets. Foreign exchange favorably affected foreign sales performance by 4% in 2011. Foreign sales growth reflects the strong performance of *Januvia*, *Janumet*, *Singulair*, *Simponi*, *Isentress*, *Zetia* and *Nasonex*, as well as higher sales of animal health products, partially offset by lower sales of *Cozaar*, *Hyzaar* and *Temodar*. Foreign sales represented 57% of total sales in 2011 and 56% of total sales in 2010.

While many of the Company's brands experienced positive growth trends in the EU during 2011, the environment in the EU continues to be challenging. Many countries have announced austerity measures, which include the implementation of pricing actions to reduce prices of generic and patented drugs. While the Company is taking steps to mitigate the impact in the EU, the austerity measures have negatively affected the Company's revenue performance in 2011 and the Company anticipates mid-single digit pricing pressures in 2012 across Europe as well as from the biennial price reductions in Japan.

Worldwide sales totaled \$46.0 billion in 2010 compared with \$27.4 billion in 2009. Foreign exchange favorably affected global sales performance by 1%. The revenue increase over 2009 was driven largely by incremental sales resulting from the inclusion of a full year of results in 2010 for legacy Schering-Plough products such as *Remicade*, *Nasonex*, *Temodar*, *PegIntron* and *Clarinex*, as well as by the inclusion of a full year of results for Merck/Schering-Plough Partnership (MSP Partnership) products *Zetia* and *Vytorin*. Prior to the Merger, substantially all sales of *Zetia* and *Vytorin* were recognized by the MSP Partnership and the results of Merck's interest in the MSP Partnership were recorded in *Equity income from affiliates*. As a result of the Merger, the MSP Partnership became wholly owned by the Company and therefore revenues from these products are now reflected in *Sales*. Additionally, the Company recognized a full year of sales in 2010 from legacy Schering-Plough animal health and consumer care products. Sales for 2009 only include revenue from legacy Schering-Plough and MSP Partnership products for the post-Merger period through December 31, 2009. Also contributing to the sales increase was growth in *Januvia* and *Janumet*, *Isentress* and *Singulair*. These increases were partially offset by lower sales of *Cozaar*, *Hyzaar*, *Fosamax* and *Fosamax Plus D*, and lower revenue from the Company's relationship with AZLP. Other products that experienced declines include *Gardasil* and *Zocor*. In addition, the implementation of certain provisions of U.S. health care reform legislation during 2010 resulted in increased Medicaid rebates and other impacts that reduced revenues.

Table of Contents

Sales⁽¹⁾ of the Company's products were as follows:

| <i>Years Ended December 31</i> | 2011 | 2010 | 2009 |
|--|-------------|-------------|-------------|
| Pharmaceutical: | | | |
| <i>Cardiovascular</i> | | | |
| Zetia | \$ 2,428 | \$ 2,297 | \$ 403 |
| Vytorin | 1,882 | 2,014 | 441 |
| Integrilin | 230 | 266 | 46 |
| <i>Diabetes and Obesity</i> | | | |
| Januvia | 3,324 | 2,385 | 1,922 |
| Janumet | 1,363 | 954 | 658 |
| <i>Diversified Brands</i> | | | |
| Cozaar/Hyzaar | 1,663 | 2,104 | 3,561 |
| Zocor | 456 | 468 | 558 |
| Propecia | 447 | 447 | 440 |
| Claritin Rx | 314 | 296 | 71 |
| Remeron | 241 | 223 | 38 |
| Vasotec/Vaseretic | 231 | 255 | 311 |
| Proscar | 223 | 216 | 291 |
| <i>Infectious Disease</i> | | | |
| Isentress | 1,359 | 1,090 | 752 |
| PegIntron | 657 | 737 | 149 |
| Cancidas | 640 | 611 | 617 |
| Primaxin | 515 | 610 | 689 |
| Invanz | 406 | 362 | 293 |
| Avelox | 322 | 316 | 66 |
| Noxafil | 230 | 198 | 34 |
| Crixivan/Stocrin | 192 | 206 | 206 |
| Rebetol | 174 | 221 | 36 |
| Victrelis | 140 | | |
| <i>Neurosciences and Ophthalmology</i> | | | |
| Maxalt | 639 | 550 | 575 |
| Cosopt/Trusopt | 477 | 484 | 503 |
| <i>Oncology</i> | | | |
| Temodar | 935 | 1,065 | 188 |
| Emend | 419 | 378 | 317 |
| Intron A | 194 | 209 | 38 |
| <i>Respiratory and Immunology</i> | | | |
| Singular | 5,479 | 4,987 | 4,660 |
| Remicade | 2,667 | 2,714 | 431 |
| Nasonex | 1,286 | 1,219 | 165 |
| Clarinex | 621 | 623 | 101 |
| Arcoxia | 431 | 398 | 358 |
| Simponi | 264 | 97 | 4 |
| Asmanex | 206 | 208 | 37 |
| Proventil | 155 | 210 | 26 |
| Dulera | 96 | 8 | |
| <i>Vaccines⁽²⁾</i> | | | |
| Gardasil | 1,209 | 988 | 1,118 |
| ProQuad/M-M-R II/Varivax | 1,202 | 1,378 | 1,369 |
| RotaTeq | 651 | 519 | 522 |
| Pneumovax | 498 | 376 | 346 |
| Zostavax | 332 | 243 | 277 |
| <i>Women's Health and Endocrine</i> | | | |
| Fosamax | 855 | 926 | 1,100 |
| NuvaRing | 623 | 559 | 88 |
| Follistim AQ | 530 | 528 | 96 |
| Implanon | 294 | 236 | 37 |
| Cerazette | 268 | 209 | 35 |
| Other pharmaceutical ⁽³⁾ | 3,521 | 3,879 | 1,263 |
| Total Pharmaceutical segment sales | 41,289 | 39,267 | 25,236 |
| Other segment sales ⁽⁴⁾ | 6,327 | 6,059 | 2,114 |

Edgar Filing: Merck & Co. Inc. - Form 10-K

| | | | |
|----------------------|------------------|-----------|-----------|
| Total segment sales | 47,616 | 45,326 | 27,350 |
| Other ⁽⁵⁾ | 431 | 661 | 78 |
| | \$ 48,047 | \$ 45,987 | \$ 27,428 |

⁽¹⁾ Sales of legacy Schering-Plough products in 2009 are included only for the post-Merger period. In addition, prior to the Merger, substantially all sales of Zetia and Vytorin were recognized by the MSP Partnership and the results of Merck's interest in the MSP Partnership were recorded in Equity income from affiliates. As a result of the Merger, the MSP Partnership became wholly owned by the Company; accordingly, all sales of MSP Partnership products after the Merger are reflected in the table above. Sales of Zetia and Vytorin in 2009 reflect Merck's sales of these products in Latin America which was not part of the MSP Partnership, as well as sales of these products for the post-Merger period in 2009.

⁽²⁾ 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.

⁽³⁾ Other pharmaceutical primarily reflects sales of other human health pharmaceutical products, including products within the franchises not listed separately.

⁽⁴⁾ Reflects other non-reportable segments including Animal Health and Consumer Care, and revenue from the Company's relationship with AZLP primarily relating to sales of Nexium, as well as Prilosec. Revenue from AZLP was \$1.2 billion, \$1.3 billion and \$1.4 billion in 2011, 2010 and 2009, respectively.

⁽⁵⁾ Other revenues are primarily comprised of miscellaneous corporate revenues, third-party manufacturing sales, sales related to divested products or businesses and other supply sales not included in segment results.

Table of Contents

Pharmaceutical Segment Sales

Cardiovascular

Worldwide sales of *Zetia* (also marketed as *Ezetrol* outside the United States), a cholesterol absorption inhibitor, increased 6% in 2011 to \$2.4 billion reflecting higher sales in international markets, particularly in Japan, due in part to the positive impact of foreign exchange, partially offset by volume declines in the United States. Global sales of *Vytorin* (marketed outside the United States as *Inegy*), a combination product containing the active ingredients of both *Zetia* and *Zocor*, declined 7% in 2011 to \$1.9 billion reflecting volume declines in the United States, partially offset by increases in international markets. Sales of *Zetia* and *Vytorin* were \$403 million and \$441 million, respectively, for the post-Merger period in 2009. Prior to the Merger, substantially all sales of these products were recognized by the MSP Partnership and the results of Merck's interest in the MSP Partnership were recorded in *Equity income from affiliates*. As a result of the Merger, the MSP Partnership became wholly owned by the Company and therefore revenues from these products are now reflected in *Sales*. Total sales of *Zetia* and *Vytorin* in 2009, including the sales recognized through the MSP Partnership, were \$2.2 billion and \$2.1 billion, respectively.

In January 2012, the FDA approved an updated label for *Vytorin* that includes results from the SHARP (Study of Heart and Renal Protection) clinical trial. In SHARP, *Vytorin* 10/20 mg lowered LDL (low-density lipoprotein) cholesterol in patients with moderate to severe chronic kidney disease, and major vascular events were reduced in the treatment group compared to placebo. The trial therefore demonstrated that treatment with *Vytorin* 10/20 mg versus placebo reduced the risk for major vascular events in this chronic kidney disease population. Because SHARP studied the combination of simvastatin and ezetimibe compared with placebo, it was not designed to assess the independent contributions of each drug to the observed effect; for this reason, the FDA did not approve a new indication for *Vytorin* or for *Zetia* and the study's efficacy results have not been incorporated into the label for *Zetia*.

As previously disclosed, the Data and Safety Monitoring Board (DSMB) for IMPROVE-IT, a large cardiovascular outcomes study evaluating *Zetia/Vytorin* in patients with acute coronary syndrome, plans to conduct a second interim analysis for efficacy when approximately 75% of the pre-specified (5,250) primary clinical endpoints have occurred. In September 2011, Merck was advised that the IMPROVE-IT executive committee had decided to schedule the study's second interim analysis in the first quarter of 2012, rather than as previously anticipated in late 2011.

Other products contained in the Cardiovascular franchise include among others, *Integrilin* Injection, a treatment for patients with acute coronary syndrome, which is sold by the Company in the United States and Canada.

Diabetes and Obesity

Global sales of *Januvia*, Merck's dipeptidyl peptidase-4 (DPP-4) inhibitor for the treatment of type 2 diabetes, rose 39% in 2011 to \$3.3 billion reflecting volume growth in the United States, as well as in international markets, particularly in Japan and across Europe. Sales of *Januvia* grew 24% in 2010 to \$2.4 billion reflecting continued growth both in the United States and internationally. 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.

Worldwide sales of *Janumet*, Merck's oral antihyperglycemic agent that combines sitagliptin (*Januvia*) with metformin in a single tablet to target all three key defects of type 2 diabetes, were \$1.4 billion in 2011, \$954 million in 2010 and \$658 million in 2009 reflecting growth internationally due in part to ongoing launches in certain markets, as well as growth in the United States.

In October 2011, the FDA approved *Juvisync*, a new treatment for type 2 diabetes that combines the glucose-lowering medication sitagliptin, the active component of *Januvia*, with the cholesterol-lowering medication *Zocor*. *Juvisync* is the first treatment option for health care providers to help patients who need the blood sugar-lowering benefits of a DPP-4 inhibitor and the cholesterol-lowering benefits of simvastatin, with the convenience of a single tablet once daily.

Table of Contents

In February 2012, the FDA approved *Janumet XR*, a new treatment for type 2 diabetes that combines sitagliptin with extended-release metformin. *Janumet XR* provides a convenient once-daily treatment option for health care providers and patients who need help to control their blood sugar.

On February 17, 2012, the FDA sent a Warning Letter to the Company relating to *Januvia* and *Janumet* stating that the Company did not fulfill a post-marketing requirement for a 3-month pancreatic safety study in a diabetic rodent model treated with sitagliptin. Merck has been in communication with the FDA regarding this study and Merck's efforts to complete it in a timely and satisfactory manner. Under the terms of the Warning Letter, within 30 days from the date of the letter, the Company must submit to the FDA a final study protocol for a new 3-month rodent study that will satisfy the FDA's requirements and a proposed revised timetable for completion of the study. Within 6 months from the date of the letter, the FDA expects that the Company will have obtained agreement with the FDA on an adequate study protocol and will have initiated the study. The letter states that failure to correct the violation may result in regulatory actions by the FDA, including, but not limited to, civil money penalties. Merck remains fully committed to fulfilling the FDA's requirements.

Diversified Brands

Merck's diversified brands are human health pharmaceutical products that are approaching the expiration of their marketing exclusivity or are no longer protected by patents in developed markets, but continue to be a core part of the Company's offering in other markets around the world.

Global sales of *Cozaar* and its companion agent *Hyzaar* (a combination of *Cozaar* and hydrochlorothiazide) for the treatment of hypertension declined 21% in 2011 to \$1.7 billion and fell 41% in 2010 to \$2.1 billion. The patents that provided U.S. market exclusivity for *Cozaar* and *Hyzaar* expired in April 2010. In addition, *Cozaar* and *Hyzaar* lost patent protection in a number of major European markets in March 2010. Accordingly, the Company has experienced significant declines in *Cozaar* and *Hyzaar* sales and the Company expects the declines to continue.

Other products contained in the Diversified Brands franchise include among others, *Zocor*, a statin for modifying cholesterol; *Propecia*, a product for the treatment of male pattern hair loss; prescription *Claritin* for the treatment of seasonal outdoor allergies and year-round indoor allergies; *Remeron*, an antidepressant; *Vasotec* and *Vaseretic* for hypertension and/or heart failure; and *Proscar*, a urology product for the treatment of symptomatic benign prostate enlargement. *Remeron* lost market exclusivity in the United States in January 2010 and has also lost market exclusivity in most major European markets. The formulation/use patent that provides U.S. market exclusivity for *Propecia* expires in October 2013, however as previously disclosed, by agreement, one generic manufacturer has been given the right to enter the market in January 2013 and another has been given the right to enter in July 2013.

Infectious Disease

Worldwide sales of *Isentress*, an HIV integrase inhibitor for use in combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment-naïve and treatment-experienced adults, grew 25% in 2011 to \$1.4 billion reflecting volume growth in the United States and internationally, partially offset by unfavorable pricing in European markets. Sales of *Isentress* increased 45% in 2010 to \$1.1 billion primarily due to positive performance in the United States, as well as internationally, resulting from continued uptake since launch. *Isentress* works by inhibiting the insertion of HIV DNA into human DNA by the integrase enzyme. Inhibiting integrase from performing this essential function helps to limit the ability of the virus to replicate and infect new cells. In January 2012, the FDA approved the use of *Isentress* in combination with other antiretroviral medicines, for the treatment of HIV-1 infection in pediatric patients two years of age and older and weighing at least 10 kg.

Worldwide sales of *PegIntron*, a treatment for chronic hepatitis C, were \$657 million in 2011, a decline of 11% compared with \$737 million of sales in 2010 reflecting competitive pressures. In addition, the Company believes the sales decline was attributable in part to patient treatment being delayed by health care providers in anticipation of new therapeutic options becoming available. In September 2010, the Company initiated a voluntary recall of *PegIntron* single dose RediPen injection in the United States after consultation with the FDA, as well as other recalls globally, resulting in a reduction to revenue in 2010 of approximately \$20 million representing estimated sales returns. In addition, the Company recognized a charge of approximately \$40 million in *Materials*

Table of Contents

and production primarily for inventory discard costs. The recall was conducted as a precautionary measure due to a third-party manufacturing issue that could have affected a small number of RediPens. The recall was specific to *PegIntron* RediPen and did not affect *PegIntron* vial products. Sales of *PegIntron* were \$149 million for the post-Merger period in 2009.

In May 2011, the FDA approved *Victrelis*, the Company's innovative oral medicine for the treatment of chronic hepatitis C. *Victrelis* is approved for the treatment of chronic hepatitis C genotype 1 infection, in combination with peginterferon alfa and ribavirin, in adult patients (18 years of age and older) with compensated liver disease, including cirrhosis, who are previously untreated or who have failed previous interferon and ribavirin therapy. *Victrelis* is an antiviral agent designed to interfere with the ability of the hepatitis C virus to replicate by inhibiting a key viral enzyme. In July 2011, the EC approved *Victrelis*. The EC's decision grants a single marketing authorization that is valid in the 27 countries that are members of the EU, as well as unified labeling applicable to Iceland, Liechtenstein and Norway. In addition to the United States, *Victrelis* has been launched in 19 markets including France, Germany, Canada and Brazil. Sales of *Victrelis* were \$140 million for 2011.

Sales of *Primaxin*, an anti-bacterial product, declined 16% in 2011 to \$515 million and decreased 11% in 2010 to \$610 million. These results primarily reflect lower volumes and unfavorable pricing due to competitive pressures. Patents on *Primaxin* have expired worldwide and multiple generics have been launched in Europe. Accordingly, the Company is experiencing a decline in sales of *Primaxin* and the Company expects the decline to continue.

Other products contained in the Infectious Disease franchise include among others, *Cancidas*, an anti-fungal product; *Invanz* for the treatment of certain infections; *Avelox*, a fluoroquinolone antibiotic for the treatment of certain respiratory and skin infections; *Noxafil* for the prevention of certain invasive fungal infections; *Crixivan* and *Stocrin*, antiretroviral therapies for the treatment of HIV infection; and *Rebetol* for use in combination with *PegIntron* for treating chronic hepatitis C. The compound patent that provides U.S. market exclusivity for *Cancidas* expires in September 2013.

Neurosciences and Ophthalmology

Global sales of *Maxalt*, Merck's tablet for the acute treatment of migraine, increased 16% in 2011 to \$639 million reflecting a higher inventory level and favorable pricing in the United States. Sales of *Maxalt* declined 4% in 2010 to \$550 million reflecting the generic availability of a competing product. The patent that provides U.S. market exclusivity for *Maxalt* will expire in December 2012. U.S. sales of *Maxalt* were \$451 million in 2011. In addition, the patent that provides market exclusivity for *Maxalt* will expire in a number of major European markets in February 2013. The Company anticipates that sales in the United States and in these European markets will decline significantly after these patent expiries.

Worldwide sales of ophthalmic products *Cosopt* and *Trusopt* declined 1% in 2011 to \$477 million reflecting unfavorable pricing and volume declines in Europe that were mitigated in part by the positive impact of foreign exchange, partially offset by higher *Cosopt* sales in Japan. Sales of *Cosopt* and *Trusopt* decreased 4% in 2010 to \$484 million. The patent that provided U.S. market exclusivity for *Cosopt* and *Trusopt* has expired. *Trusopt* has also lost market exclusivity in a number of major European markets. The patent for *Cosopt* will expire in a number of major European markets in March 2013 and the Company expects sales in those markets to decline significantly thereafter.

In February 2012, the FDA approved *Cosopt PF*, Merck's preservative-free formulation of *Cosopt* ophthalmic solution, indicated for the reduction of elevated intraocular pressure in appropriate patients with open-angle glaucoma or ocular hypertension. The Company plans to launch *Cosopt PF* by the end of 2012.

Bridion, for the reversal of certain muscle relaxants used during surgery, is currently approved and has been launched in many countries outside of the United States. Sales of *Bridion* were \$201 million in 2011 and \$103 million in 2010. *Bridion* is in Phase III development in the United States.

In 2009, the FDA approved *Saphris* (asenapine), an antipsychotic for the treatment of schizophrenia in adults and for the acute treatment, as monotherapy or adjunctive therapy to lithium or valproate, of manic or mixed episodes associated with bipolar I disorder in adults. In 2010, asenapine, sold under the brand name *Sycrest*, received marketing approval in the EU for the treatment of moderate to severe manic episodes associated with bipolar I disorder in adults. In 2010, Merck and H. Lundbeck A/S (Lundbeck) announced a worldwide

Table of Contents

commercialization agreement for *Sycrest* sublingual tablets (5 mg, 10 mg). Under the terms of the agreement, Lundbeck paid a fee and makes product supply payments in exchange for exclusive commercial rights to *Sycrest* in all markets outside the United States, China and Japan. Merck's sales of *Saphris* were \$120 million in 2011.

Merck continues to focus on building the brand awareness of *Saphris* in the United States and the Company continues to monitor and assess *Saphris/Sycrest* and the related intangible asset. If increasing the brand awareness or Lundbeck's launch of the product in the EU is not successful, the Company may take a non-cash impairment charge with respect to *Saphris/Sycrest*, and such charge could be material.

The Neurosciences and Ophthalmology franchise also included the products Subutex/Suboxone for the treatment of opiate addiction. In March 2010, Merck sold the rights to Subutex/Suboxone in nearly all markets back to Reckitt Benckiser Group PLC (Reckitt). The rights to the products in most major markets reverted to Reckitt on July 1, 2010; the remainder reverted to Reckitt during 2011 with the exception of some small markets. Sales of Subutex/Suboxone were \$111 million in 2010.

In February 2012, the FDA approved *Zioptan* (tafluprost), a preservative-free prostaglandin analog ophthalmic solution for reducing elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension. Merck has exclusive commercial rights to tafluprost in Western Europe (excluding Germany), North America, South America, Africa, the Middle East, India and Australia. *Zioptan* is marketed as *Saflutan* in certain markets outside the United States.

Oncology

Sales of *Temodar* (marketed as *Temodal* outside the United States), a treatment for certain types of brain tumors, declined 12% in 2011 to \$935 million from \$1.1 billion in 2010, primarily reflecting generic competition in Europe. Sales of *Temodar* were \$188 million for the post-Merger period in 2009. *Temodar* lost patent exclusivity in the EU in 2009. As previously disclosed, by agreement, one generic manufacturer has been given the right to enter the U.S. market in August 2013. The U.S. patent and exclusivity periods otherwise will expire in February 2014.

Global sales of *Emend*, a treatment for chemotherapy-induced nausea and vomiting, increased 11% in 2011 to \$419 million primarily reflecting growth in international markets. Sales of *Emend* increased 19% in 2010 to \$378 million driven by increases in the United States and due to the launch in Japan.

Other products in the Oncology franchise include among others, *Intron A*, an adjuvant treatment for melanoma. Marketing rights for Caelyx for the treatment of ovarian cancer, metastatic breast cancer and Kaposi's sarcoma transitioned to J&J as of December 31, 2010. Sales of Caelyx were \$284 million in 2010.

In March 2011, the FDA approved *Sylatron*, a once-weekly subcutaneous injection indicated for the adjuvant treatment of melanoma with microscopic or gross nodal involvement within 84 days of definitive surgical resection including complete lymphadenectomy.

Respiratory and Immunology

Worldwide sales of *Singulair*, a once-a-day oral medicine for the chronic treatment of asthma and for the relief of symptoms of allergic rhinitis, grew 10% in 2011 reaching \$5.5 billion driven by favorable pricing in the United States, volume growth in Japan and in emerging markets, as well as the beneficial impact of foreign exchange. Global sales of *Singulair* rose 7% to \$5.0 billion in 2010 reflecting price increases and positive performance in Japan. The patent that provides U.S. market exclusivity for *Singulair* expires in August 2012. The Company expects that within the two years following patent expiration, it will lose substantially all U.S. sales of *Singulair*, with most of those declines coming in the first full year following patent expiration. U.S. sales of *Singulair* were \$3.5 billion in 2011. In addition, the patent that provides market exclusivity for *Singulair* will expire in a number of major European markets in February 2013 and the Company expects sales of *Singulair* in those markets will decline significantly thereafter. The patent that provides market exclusivity for *Singulair* in Japan will expire in 2016.

Sales of *Remicade*, a treatment for inflammatory diseases, were \$2.7 billion in 2011, a decline of 2% compared with 2010. Foreign exchange favorably affected sales performance by 5% in 2011. Prior to July 1, 2011, *Remicade* was marketed by the Company outside of the United States (except in Japan and certain other Asian markets). As a result of the agreement reached in April 2011 to amend the agreement governing the distribution rights to *Remicade* and *Simponi* (as discussed above), effective July 1, 2011, Merck relinquished marketing rights for these products in certain territories including Canada, Central and South America, the Middle East, Africa and

Table of Contents

Asia Pacific. Sales performance in 2011 reflects these changes. In the Retained Territories, *Remicade* sales grew 13% in 2011, which reflect a 6% favorable impact from foreign exchange. Sales of *Remicade* were \$431 million for the post-Merger period in 2009. *Simponi*, a once-monthly subcutaneous treatment for certain inflammatory diseases was approved by the EC in October 2009. In January 2011, *Simponi* was approved in the EU for use in combination with methotrexate in adults with severe, active and progressive rheumatoid arthritis not previously treated with methotrexate, having been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function. Sales of *Simponi* were \$264 million in 2011 and \$97 million in 2010. The revenue increase was driven by growth in the Retained Territories, due in part to ongoing launches.

Global sales of *Nasonex*, an inhaled nasal corticosteroid for the treatment of nasal allergy symptoms, were \$1.3 billion in 2011, an increase of 5% compared with sales of \$1.2 billion in 2010, driven largely by volume growth in Japan and Latin America and the positive effect of foreign exchange, partially offset by volume declines in the United States. Sales of *Nasonex* were \$165 million for the post-Merger period in 2009.

Global sales of *Clarinex* (marketed as *Aerius* in many countries outside the United States), a non-sedating antihistamine, were \$621 million in 2011 compared with sales of \$623 million in 2010. Sales of *Clarinex* were \$101 million for the post-Merger period in 2009.

Other products included in the Respiratory and Immunology franchise include among others, *Arcoxia* for the treatment of arthritis and pain; *Asmanex*, an inhaled corticosteroid for asthma; *Proventil* Inhalation Aerosol for the relief of bronchospasm; and *Dulera* Inhalation Aerosol, a combination medicine for the treatment of asthma. In January 2012, Merck received a Complete Response Letter from the FDA for its supplemental New Drug Application (sNDA) for *Dulera*, for the treatment of chronic obstructive pulmonary disease. The Company plans to have further discussions with the FDA with regard to the Complete Response Letter.

Vaccines

The following discussion of vaccines does not include 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 included.

Worldwide sales of *Gardasil* recorded by Merck grew 22% in 2011 to \$1.2 billion driven by increased vaccination of males 9 to 26 years of age in the United States, higher sales in conjunction with the launch in Japan and growth in emerging markets, partially offset by lower government orders in Canada. Sales of *Gardasil* declined 12% to \$988 million in 2010 driven largely by declines in the United States and Australia. Sales in 2009 include \$51 million as a result of government purchases for the CDC's Strategic National Stockpile. *Gardasil*, the world's top-selling HPV vaccine, is indicated for girls and women 9 through 26 years of age for the prevention of cervical, vulvar, vaginal and anal cancer caused by HPV types 16 and 18, certain precancerous or dysplastic lesions caused by HPV types 6, 11, 16 and 18, and genital warts caused by HPV types 6 and 11. *Gardasil* is also approved in the United States for use in boys and men 9 through 26 years of age for the prevention of anal cancer caused by HPV types 16 and 18, anal dysplasias and precancerous lesions caused by HPV types 6, 11, 16 and 18, and genital warts caused by HPV types 6 and 11. 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 21% to 27% which vary by country and are included in *Materials and production* costs.

In recent years, the Company has experienced difficulties in producing its varicella zoster virus (VZV)-containing vaccines. These difficulties have resulted in supply constraints for *ProQuad*, *Varivax* and *Zostavax*. The Company is manufacturing bulk varicella and is producing doses of *Varivax* and *Zostavax*.

A limited quantity of *ProQuad*, a pediatric combination vaccine to help protect against measles, mumps, rubella and varicella, one of the VZV-containing vaccines, became available in the United States for ordering in the second quarter of 2010. This supply has been exhausted and *ProQuad* is no longer available for ordering. Merck's sales of *ProQuad* were \$34 million in 2011 and \$134 million in 2010. *ProQuad* was not available for ordering in 2009 due to supply constraints.

Merck's sales of *Varivax*, a vaccine to help prevent chickenpox (varicella), were \$831 million in 2011, \$929 million in 2010 and \$1.0 billion in 2009. Sales for 2010 and 2009 reflect \$48 million and \$64 million,

Table of Contents

respectively, of revenue as a result of government purchases for the CDC's Strategic National Stockpile. Merck's sales of *M-M-R II*, a vaccine to help protect against measles, mumps and rubella, were \$337 million in 2011, \$315 million in 2010 and \$331 million in 2009. Sales of *Varivax* and *M-M-R II* were affected by the unavailability of *ProQuad* as noted above.

Merck's sales of *RotaTeq*, a vaccine to help protect against rotavirus gastroenteritis in infants and children, grew 25% in 2011 to \$651 million reflecting favorable public sector inventory fluctuations and growth in emerging markets. Sales of *RotaTeq* declined 1% in 2010 to \$519 million. Sales during 2010 benefited modestly from a temporary competitor supply issue.

Sales of *Pneumovax*, a vaccine to help prevent pneumococcal disease, were \$498 million for 2011, \$376 million for 2010 and \$346 million for 2009. The increase in 2011 as compared with 2010 was primarily due to positive performance in the United States, due in part to favorable pricing, and in Japan.

Merck's sales of *Zostavax*, a vaccine to help prevent shingles (herpes zoster), were \$332 million in 2011, \$243 million in 2010 and \$277 million in 2009. Sales in all of these years were affected by supply issues. The Company has filled all backorders and resumed a normal supply schedule in the United States for *Zostavax*. The Company is increasing its promotional efforts for *Zostavax* in the United States. No broad international launches or immunization programs are currently planned for 2012.

In March 2011, the FDA approved an expanded age indication for *Zostavax* for the prevention of shingles to include adults ages 50 to 59. *Zostavax* is now indicated for the prevention of herpes zoster in individuals 50 years of age and older.

Merck's adult formulation of *Vaqta*, a vaccine against hepatitis A, is currently unavailable.

Women's Health and Endocrine

Worldwide sales of *Fosamax* and *Fosamax Plus D* (marketed as *Fosavance* throughout the EU and as *Fosamac* in Japan) for the treatment and, in the case of *Fosamax*, prevention of osteoporosis, declined 8% in 2011 to \$855 million and decreased 16% in 2010 to \$926 million. These medicines have lost market exclusivity in the United States and have also lost market exclusivity in most major European markets. Accordingly, the Company is experiencing sales declines within the *Fosamax* product franchise and the Company expects the declines to continue.

Worldwide sales of *NuvaRing*, a contraceptive product, grew 12% to \$623 million in 2011 from \$559 million during 2010 driven by positive performance in the United States and internationally, including the beneficial impact of foreign exchange. Sales of *NuvaRing* were \$88 million for the post-Merger period in 2009.

Global sales of *Follistim AQ* (marketed in most countries outside the United States as *Puregon*), a biological fertility treatment, were \$530 million in 2011 compared with \$528 million in 2010 reflecting growth in emerging markets offset by declines in Europe due primarily to supply constraints. Sales of *Follistim AQ* were \$96 million for the post-Merger period in 2009. *Puregon* lost market exclusivity in the EU in August 2009.

Other products contained in the Women's Health and Endocrine franchise include among others, *Implanon*, a single-rod subdermal contraceptive implant; and *Cerazette*, a progestin only oral contraceptive.

The Company is currently experiencing difficulty manufacturing certain women's health products. The Company is working to resolve these issues.

In August 2011, *Zoely*, an oral contraceptive, was granted marketing authorization by the EC for use by women to prevent pregnancy. *Zoely* is a combined oral contraceptive tablet containing a unique monophasic combination of two hormones: norgestrel acetate, a highly selective progesterone-derived progestin, and 17-beta estradiol, an estrogen that is similar to the one naturally present in a woman's body. The marketing authorization of *Zoely* applies to all 27 EU member states plus Iceland, Liechtenstein and Norway. Teva Pharmaceutical Industries Ltd. holds exclusive marketing rights for *Zoely* in France, Italy, Belgium and Spain.

In November 2011, Merck received a Complete Response Letter from the FDA for NOMAC/E2 (MK-8175A), which is being marketed as *Zoely* in the EU. The Company is planning to conduct an additional clinical study requested by the FDA and update the application in the future.

Table of Contents

Other

Animal Health

Animal Health includes pharmaceutical and vaccine products for the prevention, treatment and control of disease in all major farm and companion animal species. Animal Health sales are affected by intense competition and the frequent introduction of generic products. Global sales of Animal Health products grew 11% in 2011 to \$3.3 billion from \$2.9 billion in 2010. Foreign exchange favorably affected global sales performance by 3% in 2011. The increase in sales was driven by positive performance among cattle, swine, poultry and companion animal products. Global sales of Animal Health products were \$494 million for the post-Merger period in 2009.

Consumer Care

Consumer Care products include over-the-counter, foot care and sun care products such as *Claritin* non-drowsy antihistamines; *Dr. Scholl's* foot care products; *Coppertone* sun care products; and *MiraLAX*, a treatment for occasional constipation. Global sales of Consumer Care products increased 1% in 2011 to \$1.8 billion reflecting strong performance of *Coppertone*, offset by declines in *Dr. Scholl's* and *Claritin*. Consumer Care product sales were \$149 million for the post-Merger period in 2009. Consumer Care product sales are affected by competition and consumer spending patterns.

Alliances

AstraZeneca has an option to buy Merck's interest in a subsidiary, and through it, Merck's interest in Nexium and Prilosec, exercisable in 2012, and the Company believes that it is likely that AstraZeneca will exercise that option (see Selected Joint Venture and Affiliate Information below). If AstraZeneca exercises its option, the Company will no longer record equity income from AZLP and supply sales to AZLP will decline substantially.

Costs, Expenses and Other

| (\$ in millions) | 2011 | Change | 2010 | Change | 2009 |
|---|-----------|--------|-----------|--------|-----------|
| Materials and production | \$ 16,871 | -8% | \$ 18,396 | * | \$ 9,019 |
| Marketing and administrative ⁽¹⁾ | 13,733 | 5% | 13,125 | 54% | 8,543 |
| Research and development ⁽¹⁾⁽²⁾ | 8,467 | -24% | 11,111 | 90% | 5,845 |
| Restructuring costs | 1,306 | 33% | 985 | -40% | 1,634 |
| Equity income from affiliates | (610) | 4% | (587) | -74% | (2,235) |
| Other (income) expense, net | 946 | -27% | 1,304 | * | (10,668) |
| | \$ 40,713 | -8% | \$ 44,334 | * | \$ 12,138 |

* 100% or greater

⁽¹⁾ Amounts for 2010 include a reclassification of \$120 million of expenses from marketing and administrative to research and development.

⁽²⁾ Includes \$587 million and \$2.4 billion of IPR&D impairment charges in 2011 and 2010, respectively.

Materials and Production

Materials and production costs were \$16.9 billion in 2011, \$18.4 billion in 2010, and \$9.0 billion in 2009. Materials and production costs in 2009 include expenses related to the sale of legacy Schering-Plough and MSP Partnership products only for the post-Merger period. Costs were unfavorably affected by \$4.9 billion, \$4.6 billion and \$0.8 billion in 2011, 2010 and 2009, respectively, of expenses for the amortization of intangible assets recorded in connection with mergers and acquisitions. Additionally, expenses in 2010 and 2009 include \$2.0 billion and \$1.5 billion, respectively, of amortization of purchase accounting adjustments to Schering-Plough's inventories recognized as a result of the Merger. Costs in 2011 include an intangible asset impairment charge of \$118 million. The Company may recognize additional non-cash impairment charges in the future related to product intangibles that were measured at fair value and capitalized in connection with mergers and acquisitions and such charges could be material. Also included in materials and production were costs associated with restructuring activities

Edgar Filing: Merck & Co. Inc. - Form 10-K

which amounted to \$348 million, \$429 million and \$115 million in 2011, 2010 and 2009, respectively, including accelerated depreciation and asset write-offs related to the planned sale or closure of manufacturing facilities. Separation costs associated with manufacturing-related headcount reductions have been incurred and are reflected in *Restructuring costs* as discussed below.

Table of Contents

Gross margin was 64.9% in 2011 compared with 60.0% in 2010 and 67.1% in 2009. The amortization of intangible assets and purchase accounting adjustments to inventories, as well as the restructuring and impairment charges noted above had an unfavorable impact on gross margin of 11.4 percentage points in 2011, 15.2 percentage points in 2010 and 8.8 percentage points in 2009. The gross margin improvement in 2011 as compared with 2010 reflects changes in product mix and manufacturing efficiencies, as well as a benefit from foreign exchange.

Marketing and Administrative

Marketing and administrative expenses were \$13.7 billion in 2011, \$13.1 billion in 2010 and \$8.5 billion in 2009. The increase in 2011 as compared with 2010 was due in part to the unfavorable effect of foreign exchange and strategic investments made in emerging markets. Additionally, marketing and administrative expenses in 2011 include \$162 million of expenses for the annual health care reform fee required as part of U.S. health care reform legislation. Expenses for 2011 and 2010 include restructuring costs of \$119 million and \$144 million, respectively, primarily related to accelerated depreciation for facilities to be closed or divested. Separation costs associated with sales force reductions have been incurred and are reflected in *Restructuring costs* as discussed below. Expenses also include \$278 million and \$379 million of acquisition-related costs in 2011 and 2010, respectively, consisting largely of integration costs related to the Merger and for 2011 also consist of severance costs associated with the acquisition of Inspire Pharmaceuticals, Inc., which are not part of the Company's formal restructuring programs. Marketing and administrative expenses in 2009, which include expenses related to Schering-Plough activities only for the post-Merger period, include acquisition-related costs of \$371 million largely comprised of transaction costs directly related to the Merger (including advisory and legal fees) and integration costs.

Research and Development

Research and development expenses were \$8.5 billion in 2011, \$11.1 billion in 2010 and \$5.8 billion in 2009. Expenses in 2009 include expenses related to Schering-Plough activities only for the post-Merger period. Research and development expenses are comprised of the costs directly incurred by Merck Research Labs (MRL), the Company's research and development division that focuses on human health-related activities, which were approximately \$4.5 billion and \$4.9 billion for 2011 and 2010, respectively. Also included in research and development expenses are costs incurred by other divisions in support of research and development activities, including depreciation, production and general and administrative, as well as certain costs from operating segments, including Pharmaceutical, Animal Health and Consumer Care, which were \$3.2 billion and \$3.4 billion in the aggregate for 2011 and 2010, respectively. Research and development expenses in 2011 were favorably affected by cost savings resulting from restructuring activities.

Research and development expenses also include in-process research and development (IPR&D) impairment charges and research and development related restructuring charges. During 2011, the Company recorded IPR&D impairment charges of \$587 million primarily for pipeline programs that were abandoned and determined to have no alternative use, as well as for expected delays in the launch timing or changes in the cash flow assumptions for certain compounds. In addition, the impairment charges related to pipeline programs that had previously been deprioritized and were either deemed to have no alternative use during the period or were out-licensed to a third party for consideration that was less than the related asset's carrying value. During 2010, the Company recorded \$2.4 billion of IPR&D impairment charges. Of this amount, \$1.7 billion related to the write-down of the intangible asset for vorapaxar resulting from developments in the clinical program for this compound (see Research and Development below). The remaining \$763 million of IPR&D impairment charges in 2010 were attributable to compounds that were abandoned and determined to have either no alternative use or were returned to the respective licensor, as well as from expected delays in the launch timing or changes in the cash flow assumptions for certain compounds. The Company may recognize additional non-cash impairment charges in the future for the cancellation or delay of other pipeline programs that were measured at fair value and capitalized in connection with mergers and acquisitions and such charges could be material. Research and development expenses in 2011, 2010 and 2009 reflect \$138 million, \$428 million and \$232 million, respectively, of accelerated depreciation and asset abandonment costs associated with restructuring activities.

Share-Based Compensation

Total pretax share-based compensation expense was \$369 million in 2011, \$509 million in 2010 and \$415 million in 2009. At December 31, 2011, there was \$391 million of total pretax unrecognized compensation

Table of Contents

expense related to nonvested stock option, restricted stock unit and performance share unit awards which will be recognized over a weighted average period of 1.8 years. For segment reporting, share-based compensation costs are unallocated expenses.

Restructuring Costs

Restructuring costs were \$1.3 billion, \$985 million and \$1.6 billion in 2011, 2010 and 2009, respectively. Nearly all of the costs recorded in 2011 relate to the Merger Restructuring Program. Of the restructuring costs recorded in 2010, \$915 million related to the Merger Restructuring Program, \$77 million related to the global restructuring program initiated in 2008 (the 2008 Restructuring Program) and the remaining activity related to the legacy Schering-Plough program, which included a gain on the sale of a manufacturing facility. Of the restructuring costs recorded in 2009, \$1.4 billion related to the Merger Restructuring Program, \$178 million related to the 2008 Restructuring Program and \$39 million related to the legacy Schering-Plough program. In 2011, 2010 and 2009, separation costs of \$1.1 billion, \$768 million and \$1.4 billion, respectively, were incurred associated with actual headcount reductions, as well as estimated expenses under existing severance programs for headcount reductions that were probable and could be reasonably estimated. Merck eliminated 7,590 positions in 2011 (of which 6,880 related to the Merger Restructuring Program, 450 related to the 2008 Restructuring Program and 260 related to the legacy Schering-Plough program), 12,465 positions in 2010 (of which 11,410 related to the Merger Restructuring Program, 890 related to the 2008 Restructuring Program and the remainder to the legacy Schering-Plough program) and 3,525 positions in 2009 (most of which related to the 2008 Restructuring Program). 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 associated with pension and other postretirement benefit plans, share-based compensation plan costs, as well as contract termination and shutdown costs. For segment reporting, restructuring costs are unallocated expenses. Additional costs associated with the Company's restructuring activities are included in *Materials and production*, *Marketing and administrative* and *Research and development* as discussed above.

Equity Income from Affiliates

Equity income from affiliates, which reflects the performance of the Company's joint ventures and other equity method affiliates, increased 4% in 2011 to \$610 million primarily due to higher partnership returns from AZLP. During 2011, the Company divested its interest in the JJMCP joint venture. In 2010, equity income from affiliates declined to \$587 million from \$2.2 billion in 2009 as equity income from affiliates no longer included equity income from the MSP Partnership, which became wholly owned by the Company as a result of the Merger or from Merial Limited (Merial) due the sale of Merck's interest in 2009. In addition, lower partnership returns from AZLP, as well as lower equity income from SPMSD as a result of restructuring charges recorded by the joint venture, also contributed to the decline in 2010. (See Selected Joint Venture and Affiliate Information below.)

Other (Income) Expense, Net

Other (income) expense, net was \$946 million of expense in 2011 reflecting a \$500 million charge related to the resolution of the arbitration proceeding involving the Company's rights to market *Remicade* and *Simponi* (see Note 6 to the consolidated financial statements), a \$136 million gain on the disposition of the Company's interest in the JJMCP joint venture (see Note 10 to the consolidated financial statements), and a \$127 million gain on the sale of certain manufacturing facilities and related assets (see Note 5 to the consolidated financial statements). Other (income) expense, net in 2010 was \$1.3 billion of expense reflecting a \$950 million charge for the *Vioxx* Liability Reserve (see Note 12 to the consolidated financial statements), charges related to the settlement of certain pending AWP litigation, and \$200 million of exchange losses due to two Venezuelan currency devaluations as discussed below, partially offset by \$443 million of income recognized upon AstraZeneca's asset option exercise (see Note 10 to the consolidated financial statements) and \$102 million of income recognized on the settlement of certain disputed royalties. Other (income) expense, net was \$10.7 billion of income in 2009 primarily reflecting a \$7.5 billion gain resulting from recognizing Merck's previously held equity interest in the MSP Partnership at fair value as a result of obtaining control of the MSP Partnership in the Merger, and a \$3.2 billion gain on the sale of Merck's interest in Merial (see Note 10 to the consolidated financial statements).

Table of Contents

As noted above, exchange losses for 2010 reflect losses relating to Venezuelan currency devaluations. Effective January 11, 2010, the Venezuelan government devalued its currency from at BsF 2.15 per U.S. dollar to a two-tiered official exchange rate at (1) the essentials rate at BsF 2.60 per U.S. dollar and (2) the non-essentials rate at BsF 4.30 per U.S. dollar. In January 2010, the Company was required to remeasure its local currency operations in Venezuela to U.S. dollars as the Venezuelan economy was determined to be hyperinflationary. Throughout 2010, the Company settled its transactions at the essentials rate and therefore remeasured monetary assets and liabilities utilizing the essentials rate. In December 2010, the Venezuelan government announced it would eliminate the essentials rate and, effective January 1, 2011, all transactions would be settled at the official rate of at BsF 4.30 per U.S. dollar. As a result of this announcement, the Company remeasured its December 31, 2010 monetary assets and liabilities at the new official rate.

Segment Profits

| <i>(\$ in millions)</i> | 2011 | 2010 | 2009 |
|--------------------------------------|-----------|-----------|-----------|
| Pharmaceutical segment profits | \$ 25,617 | \$ 23,864 | \$ 15,715 |
| Other non-reportable segment profits | 2,703 | 2,559 | 1,735 |
| Other | (20,986) | (24,770) | (2,160) |
| Income before income taxes | \$ 7,334 | \$ 1,653 | \$ 15,290 |

Segment profits are comprised of segment revenues less certain elements of materials and production costs and operating expenses, including components of equity income or loss from affiliates and depreciation and amortization expenses. For internal management reporting presented to the chief operating decision maker, Merck does not allocate production costs, other than standard costs, research and development expenses or general and administrative expenses, nor 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 arbitration settlement charge, the gain on the divestiture of the JJMCP joint venture and a gain on the sale of certain manufacturing facilities and related assets recorded in 2011, the charge for the Vioxx Liability Reserve and the income recognized on AstraZeneca's asset option exercise both recognized in 2010 and the gains related to the MSP Partnership and the disposition of Merial in 2009. In addition, the amortization of purchase accounting adjustments and other acquisition-related costs, intangible asset impairment charges, restructuring costs, taxes paid at the joint venture level and a portion of equity income are also excluded from the determination of segment profits. Additionally, segment profits do not reflect other expenses from corporate and manufacturing cost centers and other miscellaneous income or expense. These unallocated items are reflected in Other in the above table. Also included in Other are miscellaneous corporate profits, operating profits related to third-party manufacturing sales, divested products or businesses, as well as other supply sales.

Pharmaceutical segment profits rose 7% in 2011 driven largely by the increase in sales and the gross margin improvement discussed above. Pharmaceutical segment profits increased 52% in 2010 driven largely by the inclusion of legacy Schering-Plough results.

Taxes on Income

The effective income tax rates of 12.8% in 2011, 40.6% in 2010 and 14.8% in 2009 reflect the impacts of purchase accounting adjustments and restructuring costs, partially offset by the beneficial impact of foreign earnings. In addition, the effective tax rate for 2011 also reflects a net favorable impact of approximately \$700 million relating to the settlement of Merck's 2002-2005 federal income tax audit, the favorable impact of certain foreign and state tax rate changes that resulted in a net \$270 million reduction of deferred tax liabilities on intangibles established in purchase accounting, and the impact of the \$500 million charge related to the resolution of the arbitration proceeding with J&J. The 2010 effective tax rate reflects the impact of the Vioxx Liability Reserve for which no tax impact was recorded, a \$147 million charge associated with a change in tax law that requires taxation of the prescription drug subsidy of the Company's retiree health benefit plans which was enacted in the first quarter of 2010 as part of U.S. health care reform legislation, and the impact of AstraZeneca's asset option exercise. These unfavorable impacts were partially offset by a \$391 million tax benefit from changes in a foreign

Table of Contents

entity's tax rate, which resulted in a reduction in deferred tax liabilities on product intangibles recorded in conjunction with the Merger, the favorable impact of the enactment of the tax extenders legislation, including the R&D tax credit, and the favorable impact of foreign earnings and dividends from the Company's foreign subsidiaries. The 2009 effective tax rate reflects the favorable impacts of increased income in lower tax jurisdictions, which includes the favorable impact of the MSP Partnership gain, and tax settlements, including the previously announced settlement with the Canada Revenue Agency (CRA). These favorable impacts were partially offset by the unfavorable effect of the gain on the sale of Merck's interest in Merial which was taxable in the United States at a combined federal and state tax rate of approximately 38.0%.

Net Income and Earnings per Common Share

Net income attributable to Merck & Co., Inc. was \$6.3 billion in 2011, \$861 million in 2010 and \$12.9 billion in 2009. EPS was \$2.02 in 2011, \$0.28 in 2010 and \$5.65 in 2009. The increases in net income and EPS in 2011 as compared with 2010 were primarily due to lower IPR&D impairment charges and amortization of inventory step-up, lower legal reserves and the favorable impact of tax settlements, partially offset by the arbitration settlement charge recorded in 2011 and the income recognized in 2010 on AstraZeneca's asset option exercise. The declines in net income and EPS in 2010 as compared with 2009 were primarily due to the gains recognized in 2009 associated with the MSP Partnership as a result of the Merger and the disposition of Merial, as well as incremental costs in 2010 as a result of the Merger, including the recognition of a full year of amortization of intangible assets and inventory step-up. In addition, IPR&D impairment charges, the charge to establish the Vioxx Liability Reserve, lower equity income from affiliates and the impact of U.S. health care reform legislation also contributed to the declines in net income and EPS in 2010 as compared with 2009. The income recognized on AstraZeneca's asset option exercise in 2010 benefited net income and EPS. EPS in 2009 was also affected by the dilutive impact of shares issued in the Merger.

Non-GAAP Income and Non-GAAP EPS

Non-GAAP income and non-GAAP EPS are alternative views of the Company's performance used by management that Merck is providing because management believes this information enhances investors' understanding of the Company's results. Non-GAAP income and non-GAAP EPS exclude certain items because of the nature of these items and the impact that they have on the analysis of underlying business performance and trends. The excluded items consist of acquisition-related costs, restructuring costs and certain other items. These excluded items are significant components in understanding and assessing financial performance. Therefore, the information on non-GAAP income and non-GAAP EPS should be considered in addition to, but not in lieu of, net income and EPS prepared in accordance with generally accepted accounting principles in the United States (GAAP). Additionally, since non-GAAP income and non-GAAP EPS are not measures determined in accordance with GAAP, they have no standardized meaning prescribed by GAAP and, therefore, may not be comparable to the calculation of similar measures of other companies.

Non-GAAP income and non-GAAP EPS are important internal measures for the Company. Senior management receives a monthly analysis of operating results that includes non-GAAP income and non-GAAP EPS and the performance of the Company is measured on this basis along with other performance metrics. Senior management's annual compensation is derived in part using non-GAAP income and non-GAAP EPS.

Table of Contents

A reconciliation between GAAP financial measures and non-GAAP financial measures is as follows:

| <i>(\$ in millions except per share amounts)</i> | 2011 | 2010 | 2009 |
|---|-----------|-----------|-----------|
| Pretax income as reported under GAAP | \$ 7,334 | \$ 1,653 | \$ 15,290 |
| Increase (decrease) for excluded items: | | | |
| Acquisition-related costs | 5,939 | 9,403 | 2,830 |
| Restructuring costs | 1,911 | 1,986 | 1,981 |
| Other items: | | | |
| Arbitration settlement charge | 500 | | |
| Gain on disposition of interest in JJMCP joint venture | (136) | | |
| Gain on sale of manufacturing facilities and related assets | (127) | | |
| Vioxx Liability Reserve | | 950 | |
| Income recognized on AstraZeneca's asset option exercise | | (443) | |
| Gain related to the MSP Partnership | | | (7,530) |
| Gain on disposition of interest in Merial | | | (3,163) |
| Other | 5 | | |
| | 15,426 | 13,549 | 9,408 |
| Taxes on income as reported under GAAP | 942 | 671 | 2,268 |
| Estimated tax benefit (expense) on excluded items | 1,697 | 1,798 | (390) |
| Tax benefit from settlement of federal income tax audit | 700 | | |
| Tax benefit from foreign and state tax rate changes | 270 | 391 | |
| Tax charge related to U.S. health care reform legislation | | (147) | |
| | 3,609 | 2,713 | 1,878 |
| Non-GAAP net income | 11,817 | 10,836 | 7,530 |
| Less: Net income attributable to noncontrolling interests | 120 | 121 | 123 |
| Non-GAAP net income attributable to Merck & Co., Inc. | \$ 11,697 | \$ 10,715 | \$ 7,407 |
| EPS assuming dilution as reported under GAAP | \$ 2.02 | \$ 0.28 | \$ 5.65 |
| EPS difference ⁽¹⁾ | 1.75 | 3.14 | (2.40) |
| Non-GAAP EPS assuming dilution | \$ 3.77 | \$ 3.42 | \$ 3.25 |

⁽¹⁾ Represents the difference between calculated GAAP EPS and calculated non-GAAP EPS, which may be different than the amount calculated by dividing the impact of the excluded items by the weighted-average shares for the applicable year.

Acquisition-Related Costs

Non-GAAP income and non-GAAP EPS exclude the ongoing impact of certain amounts recorded in connection with mergers and acquisitions. These amounts include the amortization of intangible assets and inventory step-up, as well as intangible asset impairment charges. Also excluded are integration and transaction costs associated with the Merger, as well as other costs associated with mergers and acquisitions, such as severance costs which are not part of the Company's formal restructuring programs. These costs are excluded because management believes that these costs are not representative of ongoing normal business activities.

Restructuring Costs

Non-GAAP income and non-GAAP EPS exclude costs related to restructuring actions, including restructuring activities related to the Merger (see Note 4 to the consolidated financial statements). These amounts include employee separation costs and accelerated depreciation associated with facilities to be closed or divested. Accelerated depreciation costs represent the difference between the depreciation expense to be recognized over the revised useful life of the site, based upon the anticipated date the site will be closed or divested, and depreciation

Table of Contents

expense as determined utilizing the useful life prior to the restructuring actions. The Company has undertaken restructurings of different types during the covered periods and therefore these charges should not be considered non-recurring; however, management excludes these amounts from non-GAAP income and non-GAAP EPS because it believes it is helpful for understanding the performance of the continuing business.

Certain Other Items

Non-GAAP income and non-GAAP EPS exclude certain other items. These items represent substantive, unusual items that are evaluated on an individual basis. Such evaluation considers both the quantitative and the qualitative aspect of their unusual nature and generally represent items that, either as a result of their nature or magnitude, management would not anticipate that they would occur as part of the Company's normal business on a regular basis. Certain other items are comprised of the arbitration settlement charge, the gain on the disposition of the Company's interest in the JJMCP joint venture, the gain associated with the sale of certain manufacturing facilities and related assets, the charge to establish the *Vioxx* Liability Reserve, the income recognized upon AstraZeneca's asset option exercise, the gain resulting from recognizing Merck's previously held equity interest in the MSP Partnership at fair value as a result of obtaining a controlling interest in the Merger and the gain on the divestiture of Merck's interest in Merial. Also excluded from non-GAAP income and non-GAAP EPS are the tax benefits from the settlement of a federal income tax audit, the favorable impact of certain foreign and state tax rate changes that resulted in a net reduction of deferred tax liabilities on intangibles established in purchase accounting, and the tax charge related to U.S. health care reform legislation.

Research and Development

A chart reflecting the Company's current research pipeline as of February 21, 2012 is set forth in Item 1. **Business Research and Development** above.

Research and Development Update

The Company currently has two candidates under regulatory review in the United States and internationally.

MK-8669, ridaforolimus, is an investigational oral mTOR (mammalian target of rapamycin) inhibitor under development for the treatment of metastatic soft-tissue or bone sarcomas in patients who had a favorable response to chemotherapy that was accepted for standard review by the FDA in September 2011. In August 2011, the European Medicines Agency accepted the marketing authorization application for ridaforolimus. As part of an exclusive license agreement with ARIAD Pharmaceuticals, Inc. (ARIAD), Merck is responsible for the development and worldwide commercialization of ridaforolimus. ARIAD has an option to co-promote ridaforolimus for sarcoma in the United States subject to execution of a co-promotion agreement.

MK-0653C, *Zetia* (ezetimibe) combined with atorvastatin was accepted for standard review by the FDA for the treatment of primary or mixed hyperlipidemia. In response to notice of the Company's filing, Pfizer Inc. (Pfizer) filed a patent infringement lawsuit in U.S. District Court against the Company asserting certain Pfizer patent rights in respect of atorvastatin. This lawsuit has the potential to bar FDA approval of the Company's NDA for up to 30 months (until January 6, 2014) subject to being shortened or lengthened by a court decision, or shortened by an agreement between the parties.

In addition to the candidates under regulatory review, the Company has 19 drug candidates in Phase III development targeting a broad range of diseases. The Company plans to file five major products for approval between 2012 and 2013, including: suvorexant (insomnia), *Bridion* (reversal of neuromuscular blockade), V503 (cervical cancer vaccine), odanacatib (osteoporosis) and *Tredaptive* (atherosclerosis).

MK-4305, suvorexant, is an investigational dual orexin receptor antagonist, a potential new approach to the treatment of insomnia. Orexins are neuropeptides (chemical messengers) that are released by specialized neurons in the hypothalamus region of the brain and are believed to be an important regulator of the brain's sleep-wake process. In February 2012, Merck announced that based on the positive results of two pivotal Phase III efficacy trials for suvorexant, the Company anticipates filing an NDA for MK-4305 with the FDA in 2012.

Table of Contents

MK-8616, *Bridion*, is a medication for the reversal of certain muscle relaxants used during surgery. *Bridion* is currently approved and has been launched in many countries outside of the United States. Prior to the Merger, Schering-Plough received a Not-Approvable Letter from the FDA for *Bridion*. The Company has conducted additional clinical trials to address the FDA's comments and plans to file an NDA for *Bridion* with the FDA in 2012.

V503 is a nine-valent HPV vaccine in development to help protect against certain HPV-related diseases. V503 incorporates antigens against five additional cancer-causing HPV types as compared with *Gardasil*. The Phase III clinical program, which includes an event-driven clinical trial, is ongoing and Merck continues to anticipate filing a Biologics License Application (BLA) for V503 with the FDA in 2012.

MK-0822, odanacatib, is an oral, once-weekly investigational treatment for osteoporosis in post-menopausal women. Osteoporosis is a disease that reduces bone density and strength and results in an increased risk of bone fractures. Odanacatib is a cathepsin K inhibitor that selectively inhibits the cathepsin K enzyme. Cathepsin K is known to play a central role in the function of osteoclasts, which are cells that break down existing bone tissue, particularly the protein components of bone. Inhibition of cathepsin K is a novel approach to the treatment of osteoporosis. Odanacatib continues to be studied to determine its safety and potential effects on hip, vertebral and non-vertebral fractures in an event-driven Phase III clinical trial. The Company anticipates filing an NDA for MK-0822 with the FDA in 2013.

MK-0524A is a drug candidate that combines extended-release 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 Not-Approvable 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 Merck wait for the results of the HPS2-THRIVE (Treatment of HDL to Reduce the Incidence of Vascular Events) event-driven cardiovascular outcomes study, which is expected to be completed in 2012. The Company anticipates filing an NDA with the FDA for MK-0524A in 2013. MK-0524A has been approved in more than 60 countries outside the United States 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) and is marketed as *Tredaptive* (or as *Cordaptive* in certain countries). *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.

MK-8962, *Elonva*, corifollitropin alpha injection, which has been approved in the EU for controlled ovarian stimulation in combination with a GnRH antagonist for the development of multiple follicles in women participating in an assisted reproductive technology program, is currently in Phase III development in the United States. Based on feedback from the FDA, additional data from an ongoing Phase III trial will be required at the time of filing. Merck now anticipates filing an NDA for *Elonva* with the FDA in 2013.

MK-6621, vernakalant i.v., is an investigational candidate for the treatment of atrial fibrillation which is being marketed as *Brinavess* in the EU. Merck acquired exclusive rights to develop and commercialize vernakalant i.v., as well as exclusive worldwide rights to oral formulations of vernakalant. Prior to Merck's acquisition of the rights to vernakalant i.v. in Canada, Mexico and the United States, the program was placed on clinical hold by the FDA and the Phase III, ACT V trial was suspended in 2010. ACT V has now been terminated. In the United States, the program remains on hold. The Company plans to have further discussions with the FDA.

MK-8175A, NOMAC/E2, which is being marketed as *Zoely* in the EU, is an oral contraceptive for use by women to prevent pregnancy. NOMAC/E2 is a combined oral contraceptive tablet containing a unique monophasic combination of two hormones: norgestrel acetate, a highly selective, progesterone-derived progestin, and 17-beta estradiol, an estrogen that is similar to the one naturally present in a woman's body. In November 2011, Merck received a Complete Response Letter from the FDA for NOMAC/E2. The Company is planning to conduct an additional clinical study requested by the FDA and update the application in the future.

Table of Contents

MK-5348, vorapaxar, is a thrombin receptor antagonist being developed for the prevention of thrombosis, or clot formation, and the reduction of cardiovascular events. Vorapaxar has been evaluated in two major clinical outcomes studies in different patient groups: TRACER (Thrombin Receptor Antagonist for Clinical Event Reduction in Acute Coronary Syndrome), a clinical outcomes trial in patients with acute coronary syndrome, and TRA-2P (Thrombin Receptor Antagonist in Secondary Prevention of atherothrombotic ischemic events), a secondary prevention study in patients with a previous heart attack or ischemic stroke, or with documented peripheral vascular disease. In February 2012, Merck announced the top-line results of the TRA-2P study. TRA-2P showed that the addition of vorapaxar to standard of care significantly reduced the risk of the protocol-specified primary endpoint of the composite of cardiovascular death, heart attack (myocardial infarction), stroke or urgent coronary revascularization compared to standard of care. There was a significant increase in bleeding, including intracranial hemorrhage, among patients taking vorapaxar in addition to standard of care, although there was a lower risk of intracranial hemorrhage in patients without a history of stroke. The full results of TRA-2P will be presented at the American College of Cardiology Scientific Sessions in March 2012. In November 2011, researchers presented results from the TRACER outcomes study at the American Heart Association Scientific Sessions, and the results have been published. TRACER did not achieve its primary endpoint. In January 2011, Merck and the external study investigators announced that the combined DSMB for the two clinical trials had reviewed the available safety and efficacy data, and recommended that patients in the TRACER trial discontinue study drug and investigators close out the study. Merck will review the data from both TRA-2P and TRACER with the investigators and other outside experts to help better understand the profile of this investigational medicine in specific patient populations and to determine next steps, including potential regulatory filings.

MK-0524B is a drug candidate that combines the novel approach to raising HDL-C and lowering triglycerides from extended-release niacin combined with laropirant with the proven benefits of simvastatin in one combination product. Merck anticipates filing an NDA for MK-0524B with the FDA in 2014.

MK-7243 is an investigational allergy immunotherapy sublingual tablet (AIT) in Phase III development for grass pollen allergy for which the Company has North American rights. AIT is a dissolvable oral tablet that is designed to prevent allergy symptoms by inducing a protective immune response against allergies, thereby treating the underlying cause of the disease. Merck is investigating AIT for the treatment of grass pollen allergic rhinoconjunctivitis in both children and adults. The Company anticipates filing an NDA for MK-7243 with the FDA in 2013.

MK-3641, an AIT for ragweed allergy, is also in Phase III development for the North American market. The Company anticipates filing an NDA for MK-3641 with the FDA in 2013.

MK-3814, preladenant, is a selective adenosine 2a receptor antagonist in Phase III development for treatment of Parkinson's disease. The Company anticipates filing an NDA for preladenant with the FDA in 2014.

MK-3415A, an investigational candidate for the treatment of *Clostridium difficile* infection, is a combination of two monoclonal antibodies used to treat patients with a single infusion. The Company anticipates filing an NDA for MK-3415A with the FDA in 2014.

V212 is an inactivated varicella-zoster virus vaccine in development for the prevention of herpes zoster. The Company is enrolling two Phase III trials, one in autologous hematopoietic cell transplant patients and the other in patients with solid tumor malignancies undergoing chemotherapy and hematological malignancies. The Company anticipates filing a BLA first with the autologous hematopoietic cell transplant data in 2014 and filing for the second indication in cancer patients at a later date.

V419 is an investigational hexavalent pediatric combination vaccine, which contains components of current vaccines, designed to help protect against six potentially serious diseases: diphtheria, tetanus, whooping cough (*Bordetella pertussis*), polio (poliovirus types 1, 2, and 3), invasive disease caused by *Haemophilus influenzae* type b, and hepatitis B that is being developed in collaboration with Sanofi-Pasteur. The Company anticipates filing a BLA for V419 with the FDA in 2014.

MK-0431E combines *Januvia* and atorvastatin in a single tablet and is being developed for the treatment of diabetes and atherosclerosis. The Company anticipates filing an NDA for MK-0431E with the FDA in 2014.

Table of Contents

MK-7009, vaniprevir, is an investigational, oral twice daily protease inhibitor for the treatment of chronic hepatitis C virus. The drug is in Phase III trials in Japan. The Company anticipates filing a new drug application for MK-7009 in Japan in 2014.

MK-0859, anacetrapib, is an investigational inhibitor of the cholesteryl ester transfer protein (CETP) that is being investigated in lipid management to raise HDL-C and reduce LDL-C. Based on the results from the Phase III DEFINE (Determining the Efficacy and Tolerability of CETP INhibition with AnacEtrapib) safety study of 1,623 patients with coronary heart disease or coronary heart disease risk equivalents, the Company initiated a large, event-driven cardiovascular clinical outcomes trial REVEAL (Randomized EValuation of the Effects of Anacetrapib Through Lipid-modification) involving patients with preexisting vascular disease. The Company continues to anticipate filing an NDA for anacetrapib with the FDA beyond 2015.

In 2011, Merck discontinued the clinical development program for telcagepant, the Company's investigational calcitonin gene-related peptide receptor antagonist for the treatment of acute migraine. The decision was based on an assessment of data across the clinical program. The Company also discontinued the clinical development program for MK-0431C, a combination of sitagliptin and pioglitazone, for the treatment of diabetes based on a review of the regulatory and commercial prospects for the combination drug candidate.

In 2012, Merck discontinued the clinical development program in the EU for MK-0887A, *Zenhale*, a fixed dose combination of two previously approved drugs for the treatment of asthma: mometasone furoate and formoterol fumarate dehydrate, which is marketed in the United States as *Dulera* Inhalation Aerosol.

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. The Company'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 approved medicines and vaccines through new indications and new formulations. Another important component of the Company'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, small proteins, antibodies) and RNAi. Further, Merck has moved to diversify its portfolio through its Merck BioVentures division, which has the potential to harness the market opportunity presented by biological medicine patent expiries by delivering high quality follow-on biologic products to enhance access for patients worldwide. The Company supplements its internal research with a 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's clinical pipeline includes candidates in multiple disease areas, including atherosclerosis, cancer, cardiovascular diseases, diabetes, infectious diseases, inflammatory/autoimmune diseases, insomnia, neurodegenerative diseases, ophthalmics, osteoporosis, respiratory diseases and women's health.

In-Process Research and Development

In connection with the Merger, the Company recorded the fair value of human and animal health research projects that were underway at Schering-Plough and the MSP Partnership. The fair value of projects allocated to the Pharmaceutical and Animal Health operating segments was \$5.3 billion and \$1.3 billion, respectively.

Some of the more significant projects include *Victrelis*, *Bridion* and vorapaxar, as well as an ezetimibe/atorvastatin combination product. *Victrelis*, a medicine for the treatment of hepatitis C, was approved by the FDA and in the EU in 2011. As noted above, the Company filed an NDA with the FDA in 2011 for the ezetimibe/atorvastatin combination product and the Company anticipates filing an NDA with the FDA in 2012 for *Bridion*.

During 2011 and 2010, approximately \$666 million and \$378 million, respectively, of IPR&D projects received marketing approval in a major market and the Company began amortizing these assets based on their estimated useful lives.

The Company has also recognized intangible assets for the fair value of research projects underway in connection with the SmartCells, Inc. acquisition during 2010 (see Note 5 to the consolidated financial statements) and the Inmed, Inc. acquisition in 2009.

Table of Contents

All of the IPR&D projects that remain in development are subject to the inherent risks and uncertainties in drug development and it is possible that the Company will not be able to successfully develop and complete the IPR&D programs and profitably commercialize the underlying product candidates. The time periods to receive approvals from the FDA and other regulatory agencies are subject to uncertainty. Significant delays in the approval process, or the Company's failure to obtain approval at all, would delay or prevent the Company from realizing revenues from these products. Additionally, if certain of the IPR&D programs fail or are abandoned during development, then the Company will not realize the future cash flows it has estimated and recorded as IPR&D as of the merger or acquisition date, and the Company may also not recover the research and development expenditures made since the Merger to further develop such program. If such circumstances were to occur, the Company's future operating results could be adversely affected and the Company may recognize impairment charges and such charges could be material.

During 2011, the Company recorded \$587 million of IPR&D impairment charges within *Research and development* expenses primarily for pipeline programs that were abandoned and determined to have no alternative use, as well as for expected delays in the launch timing or changes in the cash flow assumptions for certain compounds. In addition, the impairment charges related to pipeline programs that had previously been deprioritized and were either deemed to have no alternative use during the period or were out-licensed to a third party for consideration that was less than the related asset's carrying value.

During 2010, the Company recorded \$2.4 billion of IPR&D impairment charges. The Company determined that the developments in the clinical research program for vorapaxar discussed above constituted a triggering event that required the Company to evaluate the vorapaxar intangible asset for impairment. Utilizing market participant assumptions, and considering several different scenarios, the Company concluded that its best estimate of the current fair value of the intangible asset related to vorapaxar was \$350 million, which resulted in the recognition of an impairment charge of \$1.7 billion during 2010. In February 2012, Merck announced the top-line results of the TRA-2P study. As a result, Merck evaluated the vorapaxar intangible asset for impairment and concluded no further impairment was necessary as of December 31, 2011. As noted above, Merck will continue to review the data from both TRA-2P and TRACER with the investigators and other outside experts to help better understand the profile of this investigational medicine in specific patient populations and to determine next steps, including potential regulatory filings. During this process, the Company may be required to take further impairment charges related to vorapaxar. The remaining \$763 million of IPR&D impairment charges recorded in 2010 were attributable to compounds that were abandoned and determined to have either no alternative use or were returned to the respective licensor, as well as from expected delays in the launch timing or changes in the cash flow assumptions for certain compounds.

Additional research and development will be required before any of the remaining programs reach technological feasibility. The costs to complete the research projects will depend on whether the projects are brought to their final stages of development and are ultimately submitted to the FDA or other regulatory agencies for approval. As of December 31, 2011, the estimated costs to complete projects acquired in connection with the Merger in Phase III development for human health and the analogous stage of development for animal health were approximately \$1.3 billion.

Acquisitions, Research Collaborations and License Agreements

Merck continues to remain focused on pursuing opportunities that have the potential to drive both near- and long-term growth. During 2011, the Company completed transactions across a broad range of therapeutic categories, including early-stage technology transactions. Merck is actively monitoring the landscape for growth opportunities that meet the Company's strategic criteria.

In May 2011, Merck completed the acquisition of Inspire Pharmaceuticals, Inc. (Inspire), a specialty pharmaceutical company focused on developing and commercializing ophthalmic products. Under the terms of the merger agreement, Merck acquired all outstanding shares of common stock of Inspire at a price of \$5.00 per share in cash for a total of approximately \$420 million. The transaction was accounted for as an acquisition of a business; accordingly, the assets acquired and liabilities assumed were recorded at their respective fair values as of the acquisition date. The determination of fair value requires management to make significant estimates and assumptions. In connection with the acquisition, substantially all of the purchase price was allocated to Inspire's

Table of Contents

product and product right intangible assets and related deferred tax liabilities, a deferred tax asset relating to Inspire's net operating loss carryforwards, and goodwill. This transaction closed on May 16, 2011, and accordingly, the results of operations of the acquired business have been included in the Company's results of operations since the acquisition date. Pro forma financial information has not been included because Inspire's historical financial results are not significant when compared with the Company's financial results.

Selected Joint Venture and Affiliate Information

To expand its research base and realize synergies from combining capabilities, opportunities and assets, in previous years Merck has formed a number of joint ventures.

AstraZeneca LP

In 1982, Merck entered into an agreement with Astra AB (Astra) to develop and market Astra products under a royalty-bearing license. In 1993, Merck'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 Merck 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, 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 KBI products and such revenue was \$1.2 billion, \$1.3 billion and \$1.4 billion in 2011, 2010 and 2009, 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 Agreement, a preferential return representing Merck's share of undistributed AZLP GAAP earnings, and a variable return related to the Company's 1% limited partner interest. These returns aggregated \$574 million, \$546 million and \$674 million in 2011, 2010 and 2009, respectively.

In conjunction with the 1998 restructuring discussed above, Astra purchased an option (the Asset Option) for a payment of \$443 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). In April 2010, AstraZeneca exercised the Asset Option. Merck received \$647 million from AstraZeneca representing the net present value as of March 31, 2008 of projected future pretax revenue to be received by Merck from the Non-PPI Products, which was recorded as a reduction to the Company's investment in AZLP. The Company recognized the \$443 million of deferred income in 2010 as a component of *Other (income) expense, net*. In addition, in 1998, Merck granted Astra an option (the Shares Option) to buy Merck's common stock interest in KBI and, through it, Merck's interest in Nexium and Prilosec, exercisable in 2012. The exercise price for the Shares Option will be primarily based on the net present value of projected future pretax revenue to be received by Merck from Nexium and Prilosec as determined at the time of exercise, subject to certain true-up mechanisms. The Company believes that it is likely that AstraZeneca will exercise the Shares Option. If AstraZeneca exercises its option, the Company will no longer record equity income from AZLP and supply sales to AZLP will decline substantially.

Table of Contents*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.

Sales of joint venture products were as follows:

| (\$ in millions) | 2011 | 2010 | 2009 |
|----------------------|----------|----------|----------|
| <i>Gardasil</i> | \$ 253 | \$ 350 | \$ 549 |
| Influenza vaccines | 183 | 220 | 249 |
| Other viral vaccines | 105 | 93 | 112 |
| <i>RotaTeq</i> | 44 | 42 | 42 |
| Hepatitis vaccines | 39 | 25 | 44 |
| Other vaccines | 486 | 487 | 593 |
| | \$ 1,110 | \$ 1,217 | \$ 1,589 |

Johnson & Johnson°Merck Consumer Pharmaceuticals Company

In September 2011, Merck sold its 50% interest in the JJMCP joint venture to J&J. The venture between Merck and J&J was formed in 1989 to develop, manufacture, market and distribute certain over-the-counter (OTC) consumer products in the United States and Canada. Merck received a one-time payment of \$175 million and recognized a pretax gain of \$136 million in 2011 reflected in *Other (income) expense, net*. Merck's rights to the *Pepcid* brand outside the United States and Canada were not affected by this transaction. Following the transaction, J&J owns the venture's assets which include the exclusive rights to market OTC *Pepcid*, Mylanta, Mylicon and other local OTC brands where they are currently sold in the United States and Canada. The partnership assets also included a manufacturing facility. Termination of the JJMCP joint venture provides Merck with greater flexibility by allowing the Company to capitalize on its pipeline of potential prescription-to-OTC switches, as well as to actively pursue OTC licensing activities in the United States and Canada. Sales of products marketed by the joint venture were \$62 million for the period from January 1, 2011 until the September 29, 2011 divestiture date, \$129 million for 2010, and \$203 million for 2009.

Merck/Schering-Plough Partnership

In 2000, Merck and Schering-Plough (collectively, the Partners) entered into an agreement to create an equally owned partnership to develop and market in the United States new prescription medicines for cholesterol management. 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 provided for the sharing of operating income generated by the MSP Partnership based upon percentages that varied by product, sales level and country. Operating income included expenses that the Partners contractually agreed to share. Expenses incurred in support of the MSP Partnership but not shared between the Partners were not included in *Equity income from affiliates*; however, these costs were reflected in the overall results of the Partners.

The results from Merck's interest in the MSP Partnership prior to the Merger are reflected in *Equity income from affiliates* and were \$1.2 billion in 2009. As a result of the Merger, the MSP Partnership became wholly owned by the Company. Activity resulting from the sale of MSP Partnership products after the Merger has been consolidated with Merck's results. For a discussion of the performance of these products in 2011 and 2010, see Sales above.

Table of Contents

Sales of joint venture products were as follows⁽¹⁾:

| (\$ in millions) | Pre-Merger | 2009 Post-Merger | Total |
|------------------|------------|---------------------|----------|
| Vytorin | \$ 1,689 | \$ 371 | \$ 2,060 |
| Zetia | 1,698 | 370 | 2,068 |
| | \$ 3,387 | \$ 741 | \$ 4,128 |

⁽¹⁾ Amounts exclude sales of these products by the Partners outside of the MSP Partnership.
Merial Limited

In 2009, Merck sold its 50% interest in the Merial Limited (Merial) joint venture to sanofi-aventis. Merck and sanofi-aventis (then Rhône-Poulenc S.A.) formed Merial in 1997 by combining their animal health businesses into a fully integrated animal health company, which was a stand-alone joint venture, equally owned by each party. Merck received \$4.0 billion in cash and recorded a \$3.2 billion pretax gain in 2009 reflected in *Other income (expense), net*. Sales of products marketed by the joint venture were \$1.8 billion from January 1, 2009 until the September 17, 2009 divestiture date.

In March 2011, Merck and sanofi-aventis mutually terminated their agreement to form a new animal health joint venture. The termination of the agreement was without penalty to either party.

Capital Expenditures

Capital expenditures were \$1.7 billion in 2011, \$1.7 billion in 2010 and \$1.5 billion in 2009. Expenditures in the United States were \$1.2 billion in 2011, \$990 million in 2010 and \$982 million in 2009.

Depreciation expense was \$2.4 billion in 2011, \$2.6 billion in 2010 and \$1.7 billion in 2009 of which \$1.4 billion, \$1.7 billion and \$1.0 billion, respectively, applied to locations in the United States. Total depreciation expense in 2011, 2010 and 2009 included accelerated depreciation of \$589 million, \$849 million and \$348 million, respectively, associated with restructuring activities (see Note 4 to the consolidated financial statements).

Analysis of Liquidity and Capital Resources

Merck's strong financial profile enables it 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

| (\$ in millions) | 2011 | 2010 | 2009 |
|--|-----------|-----------|-----------|
| Working capital | \$ 16,936 | \$ 13,423 | \$ 12,791 |
| Total debt to total liabilities and equity | 16.7% | 16.9% | 15.6% |
| Cash provided by operations to total debt | 0.7:1 | 0.6:1 | 0.2:1 |

Cash provided by operating activities was \$12.4 billion in 2011, \$10.8 billion in 2010 and \$3.4 billion in 2009. The increase in cash provided by operating activities in 2011 as compared with 2010 reflects increased results of operations, partially offset by a \$500 million payment made to J&J as a result of the arbitration settlement, as well as net payments of approximately \$465 million to the Internal Revenue Service (IRS) as a result of the conclusion of its examination of certain of Merck's federal income tax returns as discussed below. The increase in cash provided by operating activities in 2010 as compared with 2009 primarily reflects the inclusion of a full year of legacy Schering-Plough operations, as well as \$4.1 billion of payments in 2009 into the Vioxx settlement funds and a \$660 million payment in 2009 made in connection with the previously disclosed settlement with the Canada Revenue Agency (CRA). Cash provided by operating activities continues to be the Company's primary source of funds to finance operating needs, capital expenditures, treasury stock purchases and dividends paid to shareholders. The global economic downturn and the sovereign debt issues, among other factors, have adversely impacted foreign receivables in certain European

countries (see Note 7 to the consolidated financial statements). While the Company

Table of Contents

continues to receive payment on these receivables, these conditions have resulted in an increase in the average length of time it takes to collect accounts receivable outstanding thereby adversely affecting cash provided by operating activities.

Cash used in investing activities was \$2.9 billion in 2011 compared with \$3.5 billion in 2010 primarily reflecting higher proceeds from the sales of securities and other investments and proceeds from the disposition of certain businesses, partially offset by higher purchases of securities and other investments. In addition, in 2010, proceeds from AstraZeneca's asset option exercise and a decrease in restricted assets contributed to cash flows from investing activities. Cash used in investing activities was \$3.5 billion in 2010 compared with cash provided by investing activities of \$3.2 billion in 2009. The change reflects lower proceeds from the sales of securities and other investments and higher purchases of securities and other investments in 2010, as well as a decrease in restricted assets, and proceeds from the disposition of Merck's interest in Merial in 2009, partially offset by the use of cash in 2009 to fund the Merger and the proceeds received in 2010 related to AstraZeneca's asset option exercise.

Cash used in financing activities was \$6.9 billion in 2011 compared with \$5.4 billion in 2010. The higher use of cash in financing activities was primarily driven by lower proceeds from the issuance of debt, higher purchases of treasury stock and higher payments on debt, partially offset by an increase in short-term borrowings. Cash used in financing activities was \$5.4 billion in 2010 compared with \$1.6 billion in 2009 reflecting lower proceeds from the issuance of debt, purchases of treasury stock in 2010, increased dividends paid to stockholders and higher payments on debt, partially offset by an increase in short-term borrowings. Dividends paid to stockholders were \$4.7 billion in 2011, \$4.7 billion in 2010 and \$3.2 billion in 2009.

In an effort to implement Merck's strategy to expand product offerings and capabilities in the emerging markets, the Company has and, anticipates in the future, will allocate capital and resources across those regions.

At December 31, 2011, the total of worldwide cash and investments was \$18.4 billion, including \$15.0 billion of cash, cash equivalents and short-term investments, and \$3.5 billion of long-term investments. A substantial majority of these cash and investments is held by foreign subsidiaries and would be subject to significant tax payments if such cash and investments were repatriated. However, cash provided by operating activities in the United States continues to be the Company's primary source of funds to finance domestic operating needs, capital expenditures, treasury stock purchases and dividends paid to shareholders.

In April 2011, the IRS concluded its examination of Merck's 2002-2005 federal income tax returns and as a result the Company was required to make net payments of approximately \$465 million. The Company's unrecognized tax benefits for the years under examination exceeded the adjustments related to this examination period and therefore the Company recorded a net \$700 million tax provision benefit in 2011. This net benefit reflects the decrease of unrecognized tax benefits for the years under examination partially offset by increases to the unrecognized tax benefits for years subsequent to the examination period as a result of this settlement. The Company disagrees with the IRS treatment of one issue raised during this examination and is appealing the matter through the IRS administrative process.

As previously disclosed, in October 2006, the CRA issued Merck 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. In accordance with the settlement, Merck paid an additional tax of approximately \$300 million and interest of approximately \$360 million with no additional amounts or penalties due on this assessment. The settlement was accounted for in the first quarter of 2009. Merck had previously established reserves for these matters. A portion of the taxes paid is expected to be creditable for U.S. tax purposes.

In addition, as previously disclosed, the CRA has proposed adjustments for 1999 and 2000 relating to other intercompany pricing matters and, in July 2011, the CRA issued assessments for other miscellaneous audit issues for tax years 2001-2004. These adjustments would increase Canadian tax due by approximately \$330 million plus approximately \$380 million of interest through December 31, 2011. The Company disagrees with the positions taken by the CRA and believes they are without merit. The Company continues to contest the assessments through the CRA appeals process. The CRA is expected to prepare similar adjustments for later years. Management believes that resolution of these matters will not have a material effect on the Company's financial position or liquidity.

In 2010, the IRS finalized its examination of Schering-Plough's 2003-2006 tax years. In this audit cycle, the Company reached an agreement with the IRS on an adjustment to income related to intercompany pricing

Table of Contents

matters. This income adjustment mostly reduced NOLs and other tax credit carryforwards. Additionally, the Company is seeking resolution of one issue raised during this examination through the IRS administrative appeals process. The Company's reserves for uncertain tax positions were adequate to cover all adjustments related to this examination period. The IRS began its examination of the 2007-2009 tax years for the Company in 2010.

The Company's contractual obligations as of December 31, 2011 are as follows:

Payments Due by Period

| (\$ in millions) | Total | 2012 | 2013 | 2014 | 2015 | 2016 | Thereafter |
|---|-----------|----------|----------|-------|----------|-------|------------|
| Purchase obligations ⁽¹⁾ | \$ 2,473 | \$ 1,221 | \$ 922 | | \$ 282 | | \$ 48 |
| Loans payable and current portion of long-term debt | 1,990 | 1,990 | | | | | |
| Long-term debt | 14,960 | | | 3,867 | | 2,936 | 8,157 |
| Interest related to debt obligations | 9,164 | 770 | 1,399 | | 981 | | 6,014 |
| Vioxx Liability Reserve and related interest | 958 | 958 | | | | | |
| Unrecognized tax benefits ⁽²⁾ | 308 | 308 | | | | | |
| Operating leases | 772 | 215 | 276 | | 166 | | 115 |
| | \$ 30,625 | \$ 5,462 | \$ 6,464 | | \$ 4,365 | | \$ 14,334 |

⁽¹⁾ During 2011, Merck entered into a transaction which will require the Company to make future bulk supply purchases of \$150 million over a maximum four-year period commencing upon the occurrence of certain predetermined events. This amount is not reflected in the table because the predetermined events have not yet occurred and therefore the timing of the resulting payments in any given year cannot yet be determined.

⁽²⁾ As of December 31, 2011, the Company's Consolidated Balance Sheet reflects liabilities for unrecognized tax benefits, interest and penalties of \$5.6 billion, including \$308 million reflected as a current liability. 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 2012 cannot be made.

Purchase obligations are enforceable and legally binding obligations for purchases of goods and services including 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 reflects \$469 million of long-dated notes that are subject to repayment at the option of the holders. Required funding obligations for 2012 relating to the Company's pension and other postretirement benefit plans are not expected to be material. However, the Company currently anticipates contributing approximately \$700 million and \$100 million, respectively, to its pension plans and other postretirement benefit plans during 2012.

In May 2011, the Company entered into a new \$2.0 billion, 364-day credit facility and a new \$2.0 billion four-year credit facility maturing in May 2015. The Company terminated its existing \$2.0 billion, 364-day credit facility which expired in May 2011 and its \$2.0 billion revolving credit facility that was scheduled to mature in August 2012. Both outstanding facilities provide backup liquidity for the Company's commercial paper borrowing facility and are to be used for general corporate purposes. The Company has not drawn funding from either facility.

In December 2010, Merck closed an underwritten public offering of \$2.0 billion senior unsecured notes consisting of \$850 million aggregate principal amount of 2.25% notes due 2016 and \$1.15 billion aggregate principal amount of 3.875% notes due 2021. Interest on the notes is payable semi-annually. The notes of each series are redeemable in whole or in part at any time, at the Company's option at varying redemption prices. Proceeds from the notes were used for general corporate purposes, including the reduction of short-term debt.

In December 2009, the Company filed a securities registration statement with the Securities and Exchange Commission (SEC) under the automatic shelf registration process available to well-known seasoned issuers which is effective for three years.

In connection with the Merger, effective as of November 3, 2009, the Company executed a full and unconditional guarantee of the then existing debt of its subsidiary Merck Sharp & Dohme Corp. (MSD) and MSD executed a full and unconditional guarantee of the then existing debt of the Company (excluding commercial paper), including for payments of principal and interest. These guarantees do not extend to debt issued subsequent to the Merger.

Table of Contents

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. 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 12 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 November 2011, the Board of Directors declared a quarterly dividend of \$0.42 per share on the Company's common stock for the first quarter of 2012.

In April 2011, Merck announced that its Board of Directors approved additional purchases of up to \$5.0 billion of Merck's common stock for its treasury. The Company purchased \$1.9 billion of its common stock (58 million shares) for its treasury during 2011. The Company has approximately \$4.5 billion remaining under this program and the previous November 2009 treasury stock purchase authorization. The treasury stock purchases have no time limit and will be made over time on the open market, in block transactions or in privately negotiated transactions. The Company purchased \$1.6 billion of its common stock during 2010. No purchases of treasury stock were made in 2009.

Financial Instruments Market Risk Disclosures

The Company manages the impact of foreign exchange rate movements and interest rate movements on its earnings, cash flows and fair values of assets and liabilities through operational means and through the use of various financial instruments, including derivative instruments.

A significant portion of the Company's revenues and earnings in foreign affiliates is exposed to changes in foreign exchange rates. The objectives and accounting related to the Company's foreign currency risk management program, as well as its interest rate risk management activities are discussed below.

Foreign Currency Risk Management

A significant portion of the Company's revenues are denominated in foreign currencies. The Company has established revenue hedging, balance sheet risk management, and net investment hedging 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 rates 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 hedge a portion of its forecasted foreign currency denominated third-party and intercompany distributor entity 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 third-party and intercompany distributor entity sales hedged as it gets closer to the expected date of the forecasted foreign currency denominated sales, 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 currency risk in the same manner. The Company 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 equivalent 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 U.S. dollar equivalent value of the anticipated foreign currency cash flows.

Table of Contents

In connection with the Company's revenue hedging program, a purchased collar option strategy may be utilized. With a purchased collar option strategy, the Company writes a local currency call option and purchases a local currency put option. As compared to a purchased put option strategy alone, a purchased collar strategy reduces the upfront costs associated with purchasing puts through the collection of premium by writing call options. If the U.S. dollar weakens relative to the currency of the hedged anticipated sales, the purchased put option value of the collar strategy reduces to zero and the Company benefits from the increase in the U.S. dollar equivalent value of its anticipated foreign currency cash flows, however this benefit would be capped at the strike level of the written call. If the U.S. dollar strengthens relative to the currency of the hedged anticipated sales, the written call option value of the collar strategy reduces to zero and the changes in the purchased put cash flows of the collar strategy would offset the decline in the expected future U.S. dollar equivalent cash flows of the hedged foreign currency sales.

The Company may also utilize forward contracts in its revenue hedging program. If the U.S. dollar strengthens relative to the currency of the hedged anticipated sales, the increase in the fair value of the forward contracts offsets the decrease in the expected future U.S. dollar cash flows of the hedged foreign currency sales. Conversely, if the U.S. dollar weakens, the decrease in the fair value of the forward contracts offsets 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 Merck's hedges would have declined by an estimated \$330 million and \$256 million, respectively, from a uniform 10% weakening of the U.S. dollar at December 31, 2011 and 2010. 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 would 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 mitigate the exposure of foreign currency denominated net monetary assets of foreign subsidiaries where the U.S. dollar is the functional currency from the effects of volatility in foreign exchange. In these instances, 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 from the monetary 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.

During 2009, the Company used, and may in the future use, 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. These derivative contracts are designated as fair value hedges.

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 strengthened by 10% against all currency exposures of the Company at December 31, 2011, *Income before taxes* would have declined by approximately \$165 million in 2011. Because the Company was in a net long position relative to its major foreign currencies after consideration of forward contracts, a uniform strengthening of the U.S. dollar will yield the largest overall potential net loss in earnings due to exchange. At December 31, 2010, the Company was in a net short position relative to its major foreign currencies after consideration of forward contracts, therefore a uniform 10% weakening of the U.S. dollar would have reduced *Income before taxes* by \$127 million. 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%

Table of Contents

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.

Effective January 11, 2010, the Venezuelan government devalued its currency from at BsF 2.15 per U.S. dollar to a two-tiered official exchange rate at (1) the essentials rate at BsF 2.60 per U.S. dollar and (2) the non-essentials rate at BsF 4.30 per U.S. dollar. In January 2010, the Company was required to remeasure its local currency operations in Venezuela to U.S. dollars as the Venezuelan economy was determined to be hyperinflationary. Throughout 2010, the Company settled its transactions at the essentials rate and therefore remeasured monetary assets and liabilities utilizing the essentials rate. In December 2010, the Venezuelan government announced it would eliminate the essentials rate and, effective January 1, 2011, all transactions would be settled at the official rate of at BsF 4.30 per U.S. dollar. As a result of this announcement, the Company remeasured its December 31, 2010 monetary assets and liabilities at the new official rate.

The Company also uses forward exchange contracts to hedge its net investment in foreign operations against movements in exchange rates. The forward contracts are designated as hedges of the net investment in a foreign operation. The Company hedges a portion of the net investment in certain of its foreign operations and measures ineffectiveness based upon changes in spot foreign exchange rates. The effective portion of the unrealized gains or losses on these contracts is recorded in foreign currency translation adjustment within other comprehensive income (*OCI*), and remains in *Accumulated Other Comprehensive Income* (*AOCI*) until either the sale or complete or substantially complete liquidation of the subsidiary. The cash flows from these contracts are reported as investing activities in the Consolidated Statement of Cash Flows.

Foreign exchange risk is also managed through the use of foreign currency debt. The Company's senior unsecured euro-denominated notes have been designated as, and are effective as, economic hedges of the net investment in a foreign operation. Accordingly, foreign currency transaction gains or losses due to spot rate fluctuations on the euro-denominated debt instruments are included in foreign currency translation adjustment within *OCI*.

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.

In February 2011, the Company entered into nine pay-floating, receive-fixed interest rate swap contracts with notional amounts of \$3.5 billion in the aggregate designated as fair value hedges for fixed-rate notes in which the notional amounts matched the amount of the hedged fixed-rate notes.

Two interest rate swap contracts designated as fair value hedges of fixed-rate notes matured in 2011 with notional amounts of \$125 million each that effectively converted the Company's \$250 million, 5.125% fixed-rate notes due 2011 to floating rate instruments. The interest rate swap contracts were designated hedges of the fair value changes in the notes attributable to changes in the benchmark London Interbank Offered Rate (*LIBOR*) swap rate. The fair value changes in the notes attributable to changes in the benchmark interest rate were recorded in interest expense and offset by the fair value changes in the swap contracts. Also during 2011, the Company terminated pay-floating, receive-fixed interest rate swap contracts designated as fair value hedges of fixed-rate notes in which the notional amounts match the amount of the hedged fixed-rate notes. These swaps effectively converted \$5.1 billion of its fixed-rate notes, with maturity dates varying from March 2015 to June 2019, to floating rate instruments. The interest rate swap contracts were designated hedges of the fair value changes in the notes attributable to changes in the benchmark *LIBOR* swap rate. As a result of the swap terminations, the Company received \$288 million in cash, which included \$43 million in accrued interest. The unamortized adjustment to the carrying value of the debt associated with the interest rate swap contracts of \$245 million is being amortized as a reduction of interest expense over the respective 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 affected by changes in interest rates. The market value of the Company's

Table of Contents

medium- to long-term fixed-rate investments is modestly affected 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 Merck'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, 2011 and 2010 would have positively affected the net aggregate market value of these instruments by \$1.2 billion and \$1.0 billion, respectively. A one percentage point decrease at December 31, 2011 and 2010 would have negatively affected the net aggregate market value by \$1.4 billion and \$1.2 billion, respectively. The fair value of Merck's debt was determined using pricing models reflecting one percentage point shifts in the appropriate yield curves. The fair values of Merck's investments were determined using a combination of pricing and duration models.

Critical Accounting Policies

The Company's consolidated financial statements are prepared in conformity with GAAP and, accordingly, include certain amounts that are based on management's best estimates and judgments. Estimates are used when accounting for amounts recorded in connection with mergers and acquisitions, including initial fair value determinations of assets and liabilities, primarily IPR&D and other intangible assets, as well as subsequent fair value measurement. Additionally, estimates are used in determining such items as provisions for sales discounts and returns, depreciable and amortizable lives, recoverability of inventories, including those 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, restructuring costs, impairments of long-lived assets (including intangible assets and goodwill) 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.

Mergers and Acquisitions

In a business combination, the acquisition method of accounting requires that the assets acquired and liabilities assumed be recorded as of the date of the merger or acquisition at their respective fair values with limited exceptions. Assets acquired and liabilities assumed in a business combination that arise from contingencies are recognized at fair value if fair value can reasonably be estimated. If the acquisition date fair value of an asset acquired or liability assumed that arises from a contingency cannot be determined, the asset or liability is recognized if probable and reasonably estimable; if these criteria are not met, no asset or liability is recognized. Fair value is defined 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. Accordingly, the Company may be required to value assets at fair value measures that do not reflect the Company's intended use of those assets. Any excess of the purchase price (consideration transferred) over the estimated fair values of net assets acquired is recorded as goodwill. Transaction costs and costs to restructure the acquired company are expensed as incurred. The operating results of the acquired business are reflected in the Company's consolidated financial statements after the date of the merger or acquisition. If the Company determines the assets acquired do not meet the definition of a business under the acquisition method of accounting, the transaction will be accounted for as an acquisition of assets rather than a business combination and, therefore, no goodwill will be recorded. The fair values of intangible assets, including acquired IPR&D, are determined utilizing information available near the merger or acquisition date based on expectations and assumptions that are deemed reasonable by management. Given the considerable judgment involved in determining fair values, the Company typically obtains assistance from third-party valuation specialists for significant items. Amounts allocated to acquired IPR&D are capitalized and accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the projects. Upon successful completion of each project, Merck will make a separate determination as to the then useful life of the asset and begin amortization. The judgments made in determining estimated fair values assigned to assets acquired and liabilities assumed in a business combination, as well as asset lives, can materially affect the Company's results of operations.

The fair values of identifiable intangible assets related to currently marketed products and product rights are primarily determined by using an income approach through which fair value is estimated based on each asset's discounted projected net cash flows. The Company's estimates of market participant net cash flows consider

Table of Contents

historical and projected pricing, margins and expense levels; the performance of competing products where applicable; relevant industry and therapeutic area growth drivers and factors; current and expected trends in technology and product life cycles; the time and investment that will be required to develop products and technologies; the ability to obtain marketing and regulatory approvals; the ability to manufacture and commercialize the products; the extent and timing of potential new product introductions by the Company's competitors; and the life of each asset's underlying patent, if any. The net cash flows are then probability-adjusted where appropriate to consider the uncertainties associated with the underlying assumptions, as well as the risk profile of the net cash flows utilized in the valuation. The probability-adjusted future net cash flows of each product are then discounted to present value utilizing an appropriate discount rate.

The fair values of identifiable intangible assets related to IPR&D are determined using an income approach, through which fair value is estimated based on each asset's probability-adjusted future net cash flows, which reflect the different stages of development of each product and the associated probability of successful completion. The net cash flows are then discounted to present value using an appropriate discount rate.

Revenue Recognition

Revenues from sales of products are recognized at the time of delivery 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. In addition, revenues are recorded net of time value of money discounts for customers for which collection of accounts receivable is expected to be in excess of one year.

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 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, health maintenance organizations, pharmacy benefit managers 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 2011, 2010 or 2009.

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

| (\$ in millions) | 2011 | 2010 |
|----------------------------|----------|----------|
| Balance January 1 | \$ 1,307 | \$ 1,373 |
| Current provision | 5,392 | 4,702 |
| Adjustments to prior years | 81 | (9) |
| Payments | (4,956) | (4,759) |
| Balance December 31 | \$ 1,824 | \$ 1,307 |

Table of Contents

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 \$87 million and \$1.7 billion, respectively, at December 31, 2011 and \$117 million and \$1.2 billion, respectively, at December 31, 2010.

The Company maintains a returns policy that allows its U.S. pharmaceutical customers to return product within a specified period prior to and subsequent to the expiration date (generally, three to 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 for U.S. pharmaceutical sales was approximately 1.0% of net sales in 2011, 2010 and 2009.

Through its distribution programs with U.S. wholesalers, the Company encourages wholesalers to align purchases with underlying demand and maintain inventories below specified levels. The terms of the programs 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 programs includes items such as sales trends, inventory on-hand, on-order quantity and product returns.

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 estimated 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 affected 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, 2011 were \$127 million and at December 31, 2010 were \$197 million.

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 12 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. Some of the significant factors considered in the review of these legal defense reserves are 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 its litigation; the number of cases being brought against the Company;

Table of Contents

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 associated litigation. The amount of legal defense reserves as of December 31, 2011 and 2010 of approximately \$240 million and \$190 million, respectively, represents the Company's best estimate of the minimum amount of defense costs to be incurred in connection with its outstanding litigation; however, events such as additional trials and other events that could arise in the course of its litigation could affect the ultimate amount of legal 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 reserves at any time in the future if, based upon the factors set forth, it believes it would be appropriate to do so.

The Company and its subsidiaries are parties 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. In the past, Merck performed a worldwide survey 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. As definitive information became available during the course of investigations and/or remedial efforts at each site, estimates were refined and accruals were established or adjusted accordingly. These estimates and related accruals continue to be refined annually.

The Company believes that there are no compliance issues associated with applicable environmental laws and regulations that would have a material adverse effect on the Company. Expenditures for remediation and environmental liabilities were \$25 million in 2011, and are estimated at \$93 million in the aggregate for the years 2012 through 2016. In management's opinion, the liabilities for all environmental matters that are probable and reasonably estimable have been accrued and totaled \$171 million and \$185 million at December 31, 2011 and 2010, 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 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 \$133 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 expenses all share-based payment awards to employees, including grants of stock options, 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 periodic benefit cost for pension and other postretirement benefit plans totaled \$665 million in 2011, \$696 million in 2010 and \$511 million in 2009. The higher costs in 2011 and 2010 as compared with 2009 are primarily due to incremental costs associated with the Merger. 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

Table of Contents

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, 2011, the discount rates for the Company's U.S. pension and other postretirement benefit plans ranged from 4.00% to 5.00% compared with a range of 4.00% to 5.60% at December 31, 2010.

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 2012, the Company's expected rate of return will range from 5.75% to 8.75% compared to a range of 5.25% to 8.75% in 2011 for its U.S. pension and other postretirement benefit plans.

The Company has established investment guidelines for its U.S. pension and other postretirement plans to create an asset allocation that is expected to deliver a rate of return sufficient to meet the long-term obligation of each plan, given an acceptable level of risk. 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 obligations. 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. For non-U.S. pension plans, the targeted investment portfolio varies based on the duration of pension liabilities and local government rules and regulations. Although a significant percentage of plan assets are invested in U.S. equities, concentration risk is mitigated through the use of strategies that are diversified within management guidelines.

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 \$84 million favorable (unfavorable) impact on its net periodic 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 \$36 million favorable (unfavorable) impact on its net periodic benefit cost. Required funding obligations for 2012 relating to the Company's pension and other postretirement benefit plans are not expected to be material. 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 *AOCI*. 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 *AOCI* in excess of certain thresholds are amortized into net periodic benefit cost over the average remaining service life of employees. Amortization of net losses for the Company's U.S. plans at December 31, 2011 is expected to increase net periodic benefit cost by approximately \$8 million annually from 2012 through 2016.

Restructuring Costs

Restructuring costs have been recorded in connection with restructuring programs designed to reduce the 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. When accruing these costs, the Company will recognize the amount within a range of costs that is the best estimate within the range. When no amount within the range is a better estimate than any other amount, the Company recognizes the minimum amount within the range. 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.

Table of Contents

Severance and other related costs are reflected within *Restructuring costs*. Asset-related charges are reflected within *Materials and production costs*, *Marketing and administrative expenses* and *Research and development expenses* depending upon the nature of the asset.

Impairments of Long-Lived Assets

The Company assesses changes in economic, regulatory and legal 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 may not be recoverable. 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.

Goodwill represents the excess of the consideration transferred over the fair value of net assets of businesses purchased and is assigned to reporting units. The Company tests its goodwill for impairment on at least an annual basis, or more frequently if impairment indicators exist, by first assessing qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount. Some of the factors considered in the assessment include general macro economic conditions, conditions specific to the industry and market, cost factors which could have a significant effect on earnings or cash flows, the overall financial performance of the reporting unit, and whether there have been sustained declines in the Company's share price. Additionally, the Company evaluates the extent to which the fair value exceeded the carrying value of the reporting unit at the last date a valuation was performed. If the Company concludes it is more likely than not that the fair value of a reporting unit is less than its carrying amount, a quantitative fair value test is performed.

Other acquired intangibles (excluding IPR&D) are recorded at fair value, assigned an estimated useful life, and are amortized primarily on a straight-line basis over their estimated useful lives. When events or circumstances warrant a review, the Company will assess recoverability from future operations using pretax undiscounted cash flows derived from the lowest appropriate asset groupings. Impairments are recognized in operating results to the extent that the carrying value of the intangible asset exceeds its fair value, which is determined based on the net present value of estimated future cash flows.

IPR&D represents the fair value assigned to incomplete research projects that the Company acquires through business combinations which, at the time of acquisition, have not reached technological feasibility. The amounts are capitalized and accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the project. The Company tests IPR&D for impairment at least annually, or more frequently if impairment indicators exist, through a one-step test that compares the fair value of the IPR&D intangible asset with its carrying value. For impairment testing purposes, the Company may combine separately recorded IPR&D intangible assets into one unit of account based on the relevant facts and circumstances. Generally, the Company will combine IPR&D intangible assets for testing purposes if they operate as a single asset and are essentially inseparable. If the fair value is less than the carrying amount, an impairment loss is recognized within the Company's operating results.

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, for equity securities, the Company's ability and intent to hold the investments. For debt securities, an other-than-temporary impairment has occurred if the Company does not expect to recover the entire amortized cost basis of the debt security. If the Company does not intend to sell the impaired debt security, and it is not more likely than not it will be required to sell the debt security before the recovery of its amortized cost basis, the amount of the other-than-temporary impairment recognized in earnings is limited to the portion attributed to credit loss. The remaining portion of the other-than-temporary impairment related to other factors is recognized in *OCI*.

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. 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 17 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, 2011, foreign earnings of \$44.3 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 and it would not be practicable to determine the amount of the related unrecognized deferred income tax liability.

Recently Issued Accounting Standards

In June 2011, the FASB issued amended guidance on the presentation of comprehensive income in financial statements. This amendment provides companies the option to present the components of net income and other comprehensive income either as one continuous statement of comprehensive income or as two separate but consecutive statements. It eliminates the option to present components of other comprehensive income as part of the statement of changes in stockholders' equity. The provisions of this new guidance are effective for interim and annual periods beginning in 2012. The adoption of this new guidance will not impact the Company's financial position, results of operations or cash flows.

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 "anticipates," "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.

Table of Contents

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 this Form 10-K and Forms 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, 2011 and 2010, and the related consolidated statements of income, of equity and of cash flows for each of the three years in the period ended December 31, 2011, the notes to consolidated financial statements, and the report dated February 27, 2012 of PricewaterhouseCoopers LLP, independent registered public accounting firm, are as follows:

Consolidated Statement of Income**Consolidated Statement of Income**

Merck & Co., Inc. and Subsidiaries

Years Ended December 31

(\$ in millions except per share amounts)

| | 2011 | 2010 | 2009 |
|---|------------------|-------------|-------------|
| Sales | \$ 48,047 | \$ 45,987 | \$ 27,428 |
| Costs, Expenses and Other | | | |
| Materials and production | 16,871 | 18,396 | 9,019 |
| Marketing and administrative | 13,733 | 13,125 | 8,543 |
| Research and development | 8,467 | 11,111 | 5,845 |
| Restructuring costs | 1,306 | 985 | 1,634 |
| Equity income from affiliates | (610) | (587) | (2,235) |
| Other (income) expense, net | 946 | 1,304 | (10,668) |
| | 40,713 | 44,334 | 12,138 |
| Income Before Taxes | 7,334 | 1,653 | 15,290 |
| Taxes on Income | 942 | 671 | 2,268 |
| Net Income | 6,392 | 982 | 13,022 |
| Less: Net Income Attributable to Noncontrolling Interests | 120 | 121 | 123 |
| Net Income Attributable to Merck & Co., Inc. | \$ 6,272 | \$ 861 | \$ 12,899 |
| Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders | \$ 2.04 | \$ 0.28 | \$ 5.67 |
| Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders | \$ 2.02 | \$ 0.28 | \$ 5.65 |

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

Table of Contents

Consolidated Balance Sheet

Consolidated Balance Sheet

Merck & Co., Inc. and Subsidiaries

December 31

(\$ in millions except per share amounts)

| | 2011 | 2010 |
|---|------------|------------|
| Assets | | |
| Current Assets | | |
| Cash and cash equivalents | \$ 13,531 | \$ 10,900 |
| Short-term investments | 1,441 | 1,301 |
| Accounts receivable (net of allowance for doubtful accounts of \$131 in 2011 and \$104 in 2010) | 8,261 | 7,344 |
| Inventories (excludes inventories of \$1,379 in 2011 and \$1,194 in 2010 classified in Other assets see Note 8) | 6,254 | 5,868 |
| Deferred income taxes and other current assets | 3,694 | 3,651 |
| Total current assets | 33,181 | 29,064 |
| Investments | 3,458 | 2,175 |
| Property, Plant and Equipment (at cost) | | |
| Land | 623 | 658 |
| Buildings | 12,733 | 11,945 |
| Machinery, equipment and office furnishings | 16,919 | 15,894 |
| Construction in progress | 2,198 | 2,066 |
| | 32,473 | 30,563 |
| Less: accumulated depreciation | 16,176 | 13,481 |
| | 16,297 | 17,082 |
| Goodwill | 12,155 | 12,378 |
| Other Intangibles, Net | 34,302 | 39,456 |
| Other Assets | 5,735 | 5,626 |
| | \$ 105,128 | \$ 105,781 |
| Liabilities and Equity | | |
| Current Liabilities | | |
| Loans payable and current portion of long-term debt | \$ 1,990 | \$ 2,400 |
| Trade accounts payable | 2,462 | 2,308 |
| Accrued and other current liabilities | 9,731 | 8,514 |
| Income taxes payable | 781 | 1,243 |
| Dividends payable | 1,281 | 1,176 |
| Total current liabilities | 16,245 | 15,641 |
| Long-Term Debt | 15,525 | 15,482 |
| Deferred Income Taxes and Noncurrent Liabilities | 16,415 | 17,853 |
| Merck & Co., Inc. Stockholders' Equity | | |
| Common stock, \$0.50 par value | | |
| Authorized 6,500,000,000 shares | | |
| Issued 3,576,948,356 shares in 2011 and 2010 | 1,788 | 1,788 |
| Other paid-in capital | 40,663 | 40,701 |
| Retained earnings | 38,990 | 37,536 |
| Accumulated other comprehensive loss | (3,132) | (3,216) |
| | 78,309 | 76,809 |
| Less treasury stock, at cost: | | |
| 536,109,713 shares in 2011; | | |

Edgar Filing: Merck & Co. Inc. - Form 10-K

| | | |
|--|-------------------|-------------------|
| 494,841,533 shares in 2010 | 23,792 | 22,433 |
| Total Merck & Co., Inc. stockholders' equity | 54,517 | 54,376 |
| Noncontrolling Interests | 2,426 | 2,429 |
| Total equity | 56,943 | 56,805 |
| | \$ 105,128 | \$ 105,781 |

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

Table of Contents**Consolidated Statement of Equity****Consolidated Statement of Equity**

Merck & Co., Inc. and Subsidiaries

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

| | Common Stock | Other Paid-In Capital | Retained Earnings | Accumulated Other Comprehensive Loss | Treasury Stock | Non- controlling Interests | Total |
|---|-------------------------|--------------------------------------|------------------------------|---|---------------------------|---|------------------|
| Balance January 1, 2009 | \$ 30 | \$ 8,319 | \$ 43,699 | \$ (2,554) | \$ (30,736) | \$ 2,409 | \$ 21,167 |
| Net income attributable to Merck & Co., Inc. | | | 12,899 | | | | 12,899 |
| Total other comprehensive loss, net of tax | | | | (213) | | | (213) |
| Comprehensive income, net of tax | | | | | | | 12,686 |
| Schering-Plough merger | 1,752 | 30,861 | | | (1,964) | 14 | 30,663 |
| Cancellations of treasury stock | (5) | | (11,595) | | 11,600 | | |
| Preferred stock conversions | | 5 | | | | | 5 |
| Cash dividends declared on common stock (\$1.52 per share) | | | (3,598) | | | | (3,598) |
| Net income attributable to noncontrolling interests | | | | | | 123 | 123 |
| Distributions attributable to noncontrolling interests | | | | | | (119) | (119) |
| Share-based compensation plans and other | 4 | 498 | | | 56 | | 558 |
| Balance December 31, 2009 | 1,781 | 39,683 | 41,405 | (2,767) | (21,044) | 2,427 | 61,485 |
| Net income attributable to Merck & Co., Inc. | | | 861 | | | | 861 |
| Total other comprehensive loss, net of tax | | | | (449) | | | (449) |
| Comprehensive income, net of tax | | | | | | | 412 |
| Cash dividends declared on common stock (\$1.52 per share) | | | (4,730) | | | | (4,730) |
| Mandatory conversion of 6% convertible preferred stock | 2 | 132 | | | | | 134 |
| Treasury stock shares purchased | | | | | (1,593) | | (1,593) |
| Net income attributable to noncontrolling interests | | | | | | 121 | 121 |
| Distributions attributable to noncontrolling interests | | | | | | (119) | (119) |
| Share-based compensation plans and other | 5 | 886 | | | 204 | | 1,095 |
| Balance December 31, 2010 | 1,788 | 40,701 | 37,536 | (3,216) | (22,433) | 2,429 | 56,805 |
| Net income attributable to Merck & Co., Inc. | | | 6,272 | | | | 6,272 |
| Total other comprehensive income, net of tax | | | | 84 | | | 84 |
| Comprehensive income, net of tax | | | | | | | 6,356 |
| Cash dividends declared on common stock (\$1.56 per share) | | | (4,818) | | | | (4,818) |
| Treasury stock shares purchased | | | | | (1,921) | | (1,921) |
| Net income attributable to noncontrolling interests | | | | | | 120 | 120 |
| Distributions attributable to noncontrolling interests | | | | | | (120) | (120) |
| Share-based compensation plans and other | | (38) | | | 562 | (3) | 521 |
| Balance December 31, 2011 | \$ 1,788 | \$ 40,663 | \$ 38,990 | \$ (3,132) | \$ (23,792) | \$ 2,426 | \$ 56,943 |

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

Table of Contents

Consolidated Statement of Cash Flows

Consolidated Statement of Cash Flows

Merck & Co., Inc. and Subsidiaries

*Years Ended December 31**(\$ in millions)*

| | 2011 | 2010 | 2009 |
|---|----------|---------|-----------|
| Cash Flows from Operating Activities | | | |
| Net income | \$ 6,392 | \$ 982 | \$ 13,022 |
| Adjustments to reconcile net income to net cash provided by operating activities: | | | |
| Depreciation and amortization | 7,427 | 7,381 | 2,576 |
| Intangible asset impairment charges | 705 | 2,441 | |
| Gain on disposition of interest in equity method investment | (136) | | (3,163) |
| Gain on AstraZeneca LP asset option exercise | | (443) | |
| Gain related to Merck/Schering-Plough partnership | | | (7,530) |
| Equity income from affiliates | (610) | (587) | (2,235) |
| Dividends and distributions from equity affiliates | 216 | 324 | 1,724 |
| Deferred income taxes | (1,537) | (1,092) | 1,821 |
| Share-based compensation | 369 | 509 | 415 |
| Other | 323 | 377 | (535) |
| Net changes in assets and liabilities: | | | |
| Accounts receivable | (1,168) | (1,089) | 165 |
| Inventories | (678) | 1,990 | 1,211 |
| Trade accounts payable | 182 | 124 | (45) |
| Accrued and other current liabilities | 1,444 | 35 | (4,003) |
| Income taxes payable | (277) | 128 | (365) |
| Noncurrent liabilities | (7) | (98) | 231 |
| Other | (262) | (160) | 103 |
| Net Cash Provided by Operating Activities | 12,383 | 10,822 | 3,392 |
| Cash Flows from Investing Activities | | | |
| Capital expenditures | (1,723) | (1,678) | (1,461) |
| Purchases of securities and other investments | (7,325) | (7,197) | (3,071) |
| Proceeds from sales of securities and other investments | 6,149 | 4,561 | 10,942 |
| Proceeds from sale of interest in equity method investment | 175 | | 4,000 |
| Acquisitions of businesses, net of cash acquired | (373) | (256) | (130) |
| Dispositions of businesses, net of cash divested | 323 | | |
| Schering-Plough merger, net of cash acquired | | | (12,843) |
| Proceeds from AstraZeneca LP asset option exercise | | 647 | |
| Decrease in restricted assets | | 276 | 5,548 |
| Other | (116) | 150 | 171 |
| Net Cash (Used in) Provided by Investing Activities | (2,890) | (3,497) | 3,156 |
| Cash Flows from Financing Activities | | | |
| Net change in short-term borrowings | 1,076 | 90 | (2,422) |
| Payments on debt | (1,547) | (1,341) | (25) |
| Proceeds from issuance of debt | | 1,999 | 4,228 |
| Purchases of treasury stock | (1,921) | (1,593) | |
| Dividends paid to stockholders | (4,691) | (4,734) | (3,215) |
| Other dividends paid | (120) | (119) | (264) |
| Proceeds from exercise of stock options | 321 | 363 | 186 |

Edgar Filing: Merck & Co. Inc. - Form 10-K

| | | | |
|--|-----------|-----------|----------|
| Other | (22) | (106) | (126) |
| Net Cash Used in Financing Activities | (6,904) | (5,441) | (1,638) |
| Effect of Exchange Rate Changes on Cash and Cash Equivalents | 42 | (295) | 33 |
| Net Increase in Cash and Cash Equivalents | 2,631 | 1,589 | 4,943 |
| Cash and Cash Equivalents at Beginning of Year | 10,900 | 9,311 | 4,368 |
| Cash and Cash Equivalents at End of Year | \$ 13,531 | \$ 10,900 | \$ 9,311 |
| Supplemental Cash Flow Information (See Note 3) | | | |

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

Table of Contents

Notes to Consolidated Financial Statements

Notes to Consolidated Financial Statements

Merck & Co., Inc. and Subsidiaries

(\$ in millions except per share amounts)

1. Nature of Operations

Merck & Co., Inc. (Merck or the Company) is a global health care company that delivers innovative health solutions through its prescription medicines, vaccines, biologic therapies, animal health, and consumer care products, which it markets directly and through its joint ventures. The Company's operations are principally managed on a products basis and are comprised of four operating segments, which are the Pharmaceutical, Animal Health, Consumer Care and Alliances segments, and one reportable segment, which is the Pharmaceutical segment. The Pharmaceutical segment includes human health pharmaceutical and vaccine products marketed either directly by the Company or through joint ventures. Human health pharmaceutical products consist of therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. The Company 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. Vaccine products consist of preventive pediatric, adolescent and adult vaccines, primarily administered at physician offices. The Company sells these human health vaccines primarily to physicians, wholesalers, physician distributors and government entities. The Company also has animal health operations that discover, develop, manufacture and market animal health products, including vaccines, which the Company sells to veterinarians, distributors and animal producers. Additionally, the Company has consumer care operations that develop, manufacture and market over-the-counter, foot care and sun care products, which are sold through wholesale and retail drug, food chain and mass merchandiser outlets.

On November 3, 2009, legacy Merck & Co., Inc. and Schering-Plough Corporation (Schering-Plough) merged (the Merger). The results of Schering-Plough's business have been included in Merck's financial statements only for periods subsequent to the completion of the Merger. Therefore, Merck's financial results for 2009 do not reflect a full year of Schering-Plough operations.

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 shareholders' interests are shown as *Noncontrolling interests* in equity. 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.

Mergers and Acquisitions In a business combination, the acquisition method of accounting requires that the assets acquired and liabilities assumed be recorded as of the date of the merger or acquisition at their respective fair values with limited exceptions. Assets acquired and liabilities assumed in a business combination that arise from contingencies are recognized at fair value if fair value can reasonably be estimated. If the acquisition date fair value of an asset acquired or liability assumed that arises from a contingency cannot be determined, the asset or liability is recognized if probable and reasonably estimable; if these criteria are not met, no asset or liability is recognized. Fair value is defined 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. Accordingly, the Company may be required to value assets at fair value measures that do not reflect the Company's intended use of those assets. Any excess of the purchase price (consideration transferred) over the estimated fair values of net assets acquired is recorded as goodwill. Transaction costs and costs to restructure the acquired company are expensed as incurred. The operating results of the acquired business are reflected in the Company's consolidated financial statements after the date of the merger or acquisition. If the Company determines the assets acquired do not meet the definition of a business under the acquisition method of accounting, the transaction will be accounted for as an acquisition of assets rather than a business combination and, therefore, no goodwill will be recorded.

Table of Contents

Foreign Currency Translation The net assets of international subsidiaries where the local currencies have been determined to be the functional currencies are translated into U.S. dollars using current exchange rates. The U.S. dollar effects that arise from translating the net assets of these subsidiaries at changing rates are recorded in the foreign currency translation account, which is included in *Accumulated other comprehensive income (loss)* (*AOCI*) and reflected as a separate component of equity. For those subsidiaries that operate in highly inflationary economies and for those subsidiaries where the U.S. dollar has been determined to be the functional currency, non-monetary foreign currency assets and liabilities are translated using historical rates, while monetary assets and liabilities are translated at current rates, with the U.S. dollar effects of rate changes included in *Other (income) expense, net*. As a result of the Merger, the functional currency of the operations at each of the Company's international subsidiaries has been reevaluated and has resulted in a change in functional currency at certain 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 a substantial majority of domestic pharmaceutical and vaccine inventories is determined using the last-in, first-out (*LIFO*) method for both financial reporting 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. Fair values of the Company's investments are 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. Changes in fair value that are considered temporary are reported net of tax in *Other Comprehensive Income* (*OCI*). For declines in the fair value of equity securities that are considered other-than-temporary, impairment losses are charged to *Other (income) expense, net*. 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, for equity securities, the Company's ability and intent to hold the investments. For debt securities, an other-than-temporary impairment has occurred if the Company does not expect to recover the entire amortized cost basis of the debt security. If the Company does not intend to sell the impaired debt security, and it is not more likely than not it will be required to sell the debt security before the recovery of its amortized cost basis, the amount of the other-than-temporary impairment recognized in earnings, recorded in *Other (income) expense, net*, is limited to the portion attributed to credit loss. The remaining portion of the other-than-temporary impairment related to other factors is recognized in *OCI*. Realized gains and losses for both debt and equity securities are included in *Other (income) expense, net*.

Revenue Recognition Revenues from sales of products are recognized at the time of delivery 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. In addition, revenues are recorded net of time value of money discounts for customers for which collection of accounts receivable is expected to be in excess of one year. 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 the provisions for chargebacks and rebates included in *Accounts receivable* and *Accrued and other current liabilities* were \$87 million and \$1.7 billion, respectively, at December 31, 2011 and \$117 million and \$1.2 billion, respectively, at December 31, 2010.

The Company recognizes revenue from the sales of vaccines to the Federal government for placement into vaccine stockpiles 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*.

Table of Contents

Depreciation Depreciation is provided over the estimated useful lives of the assets, principally using the straight-line method. For tax purposes, accelerated tax 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. Capitalized software costs are included in *Property, plant and equipment* and amortized beginning when the software project is substantially complete and the asset is ready for its intended use. Capitalized software costs associated with the Company's multi-year implementation of an enterprise-wide resource planning system are being amortized over 6 to 10 years. At December 31, 2011 and 2010, there was approximately \$360 million and \$457 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.

Goodwill Goodwill represents the excess of the consideration transferred over the fair value of net assets of businesses purchased. Goodwill is assigned to reporting units and evaluated for impairment on at least an annual basis, or more frequently if impairment indicators exist, by first assessing qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount. If the Company concludes it is more likely than not that the fair value of a reporting unit is less than its carrying amount, a quantitative fair value test is performed. Based upon the Company's most recent annual impairment test completed as of October 1, 2011, it is more likely than not that the fair value of each reporting unit was in excess of its carrying value.

Acquired Intangibles Acquired intangibles include products and product rights, tradenames and patents, which are recorded at fair value, assigned an estimated useful life, and are amortized primarily on a straight-line basis over their estimated useful lives ranging from 3 to 40 years (see Note 9). When events or circumstances warrant a review, the Company will assess recoverability of acquired intangibles from future operations using pretax undiscounted cash flows derived from the lowest appropriate asset groupings. Impairments are recognized in operating results to the extent that the carrying value of the intangible asset exceeds its fair value, which is determined based on the net present value of estimated future cash flows.

In-Process Research and Development In-process research and development (IPR&D) represents the fair value assigned to incomplete research projects that the Company acquires through business combinations which, at the time of acquisition, have not reached technological feasibility. The amounts are capitalized and are accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the projects. Upon successful completion of each project, Merck will make a determination as to the then useful life of the intangible asset, generally determined by the period in which substantially all of the cash flows are expected to be generated, and begin amortization. The Company tests IPR&D for impairment at least annually, or more frequently if impairment indicators exist, through a one-step test that compares the fair value of IPR&D intangible asset with its carrying value. If the fair value is less than the carrying amount, an impairment loss is recognized within the Company's operating results.

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. Nonrefundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made. Research and development expenses include restructuring costs in all periods and IPR&D impairment charges of \$587 million and \$2.4 billion in 2011 and 2010, respectively.

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

Table of Contents

Restructuring Costs The Company records liabilities for costs associated with exit or disposal activities in the period in which the liability is incurred. In accordance with existing benefit arrangements, employee termination costs are accrued when the restructuring actions are probable and estimable. When accruing these costs, the Company will recognize the amount within a range of costs that is the best estimate within the range. When no amount within the range is a better estimate than any other amount, the Company recognizes the minimum amount within the range. Costs for one-time termination benefits in which the employee is required to render service until termination in order to receive the benefits are recognized ratably over the future service period.

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.

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. The Company recognizes interest and penalties associated with uncertain tax positions as a component of *Taxes on income* in the Consolidated Statement of Income.

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 when accounting for amounts recorded in connection with mergers and acquisitions, including initial fair value determinations of assets and liabilities, primarily IPR&D and other intangible assets, as well as subsequent fair value measurement. Additionally, estimates are used in determining such items as provisions for sales discounts and returns, depreciable and amortizable lives, recoverability of inventories, including those 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, restructuring costs, impairments of long-lived assets (including intangible assets and goodwill) and investments, and 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 to the current year presentation.

Recently Adopted Accounting Standards During 2011, the following new accounting standards issued by the FASB were adopted by the Company.

On January 1, 2011, the Company prospectively adopted new guidance for revenue recognition with multiple deliverables for revenue arrangements entered into or materially modified on or after the adoption date. This guidance eliminates the residual method under the current guidance and replaces it with the relative selling price method when allocating revenue in a multiple deliverable arrangement. The selling price for each deliverable shall be determined using vendor specific objective evidence of selling price, if it exists, otherwise third-party evidence of selling price shall be used. If neither exists for a deliverable, the vendor shall use its best estimate of the selling price for that deliverable. The effect of adoption on the Company's financial position and results of operations was not material.

On October 1, 2011, in conjunction with its annual goodwill impairment testing, the Company early adopted amended guidance that simplifies how an entity tests goodwill for impairment. The amended guidance allows companies to first assess qualitative factors to determine if it is more likely than not that the fair value of a reporting unit is less than its carrying value and whether to perform step one of the two-step goodwill impairment test.

Table of Contents

Recently Issued Accounting Standards In June 2011, the FASB issued amended guidance on the presentation of comprehensive income in financial statements. This amendment provides companies the option to present the components of net income and other comprehensive income either as one continuous statement of comprehensive income or as two separate but consecutive statements. It eliminates the option to present components of other comprehensive income as part of the statement of changes in stockholders' equity. The provisions of this new guidance are effective for interim and annual periods beginning in 2012. The adoption of this new guidance will not impact the Company's financial position, results of operations or cash flows.

3. Merger

On November 3, 2009, Merck and Schering-Plough completed the Merger. In the Merger, Schering-Plough acquired all of the shares of Merck, which became a wholly-owned subsidiary of Schering-Plough and was renamed Merck Sharp & Dohme Corp (MSD). Schering-Plough continued as the surviving public company and was renamed Merck & Co., Inc. However, for accounting purposes only, the Merger was treated as an acquisition with Merck considered the accounting acquirer. Under the terms of the Merger agreement, each issued and outstanding share of Schering-Plough common stock was converted into the right to receive a combination of \$10.50 in cash and 0.5767 of a share of the common stock of the Company. Each issued and outstanding share of Merck common stock was automatically converted into a share of the common stock of the newly combined company. Based on the closing price of Merck stock on November 3, 2009, the consideration received by Schering-Plough shareholders was valued at \$28.19 per share, or \$49.6 billion in the aggregate. The cash portion of the consideration was funded with a combination of existing cash, including from the sale of Merck's interest in Merial Limited, the sale or redemption of investments and the issuance of debt. Upon completion of the Merger, each issued and outstanding share of Schering-Plough 6% Mandatory Convertible Preferred Stock (Schering-Plough 6% preferred stock) not converted in accordance with the terms of the preferred stock remained outstanding as one share of Merck 6% Mandatory Convertible Preferred Stock (6% preferred stock) having the rights set forth in the Merck certificate of incorporation which rights were substantially similar to the rights of the Schering-Plough 6% preferred stock. In August 2010, the outstanding 6% preferred stock automatically converted by its terms into the right to receive cash and shares of Merck common stock (see Note 13).

The Merger expanded the Company's pipeline of product candidates, broadened the Company's commercial portfolio, expanded its global presence and increased its manufacturing capabilities. Additionally, the Company expects to realize substantial cost savings and synergies, including opportunities for consolidation in both sales and marketing and research and development.

Table of Contents

Calculation of Consideration Transferred (in millions except per share/unit amounts)

| | | |
|--|-------------------|--------------------|
| Schering-Plough common stock shares outstanding at November 3, 2009 (net of treasury shares) | 1,641 | |
| Units of merger consideration arising from conversion of 6% preferred stock | 75 ⁽¹⁾ | |
| Shares and units eligible | 1,716 | |
| Cash per share/unit | \$ 10.50 | |
| Cash consideration for outstanding shares/units | | \$ 18,016 |
| 6% preferred stock make-whole dividend payments | | 98 ⁽²⁾ |
| Value of Schering-Plough deferred stock units settled in cash | | 156 ⁽³⁾ |
| Total cash consideration | | \$ 18,270 |
| Shares and units eligible | 1,716 | |
| Common stock exchange ratio per share/unit | 0.5767 | |
| Equivalent Merck shares | 989 | |
| Shares issued to settle certain performance-based awards | 1 | |
| Merck shares issued | 990 | |
| Merck common stock share price on November 3, 2009 | \$ 30.67 | |
| Common stock equity consideration | | \$ 30,370 |
| Fair value of 6% preferred stock not converted | | 215 |
| Fair value of other share-based compensation awards | | 525 ⁽⁴⁾ |
| Employee benefit related amounts payable as a result of the Merger | | 192 |
| Total consideration transferred | | \$ 49,572 |

⁽¹⁾ Upon completion of the Merger and for a period of 15 days thereafter, holders of 6% preferred stock were entitled to convert each share of 6% preferred stock into a number of units of merger consideration equal to the make-whole conversion rate of 8.2021 determined in accordance with the terms of the preferred stock. This amount represents the units of merger consideration relating to the 6% preferred stock converted by those holders in the 15-day period following the Merger.

⁽²⁾ Represents the present value of all remaining dividend payments (from the conversion date through the mandatory conversion date on August 13, 2010) paid to holders of 6% preferred stock that elected to convert in connection with the Merger using the discount rate as stipulated by the terms of the preferred stock.

⁽³⁾ Represents the cash consideration paid to holders of Schering-Plough deferred stock units issued in 2007 and prior which were converted into the right to receive cash as specified in the Merger agreement attributable to precombination service.

⁽⁴⁾ Represents the fair value of Schering-Plough stock option, performance share unit and deferred stock unit replacement awards attributable to precombination service issued to holders of these awards in the Merger. The fair value of outstanding Schering-Plough stock option and performance share unit awards issued in 2007 and prior, which immediately vested at the effective time of the Merger, was attributed to precombination service and included in the consideration transferred. Stock option, performance share unit and deferred stock unit awards for 2008 and 2009 did not immediately vest upon completion of the Merger. For these awards, the fair value of the awards attributed to precombination service was included as part of the consideration transferred and the fair value attributed to postcombination service is being recognized as compensation cost over the requisite service period in the postcombination financial statements of Merck.

Table of Contents*Supplemental Pro Forma Data*

Schering-Plough's results of operations have been included in Merck's financial statements for periods subsequent to the completion of the Merger. Schering-Plough contributed revenues of \$3.4 billion and estimated losses of \$2.2 billion to Merck for the period from the consummation of the Merger through December 31, 2009. The following unaudited supplemental pro forma data presents consolidated information as if the Merger had been completed on January 1, 2008:

| <i>Year Ended December 31</i> | 2009 (Unaudited) |
|---|---------------------|
| Sales | \$ 45,964 |
| Net income attributable to Merck & Co., Inc. | 5,935 |
| Basic earnings per common share attributable to Merck & Co., Inc. common shareholders | \$ 1.91 |
| Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders | \$ 1.90 |

The unaudited supplemental pro forma data reflect the application of the following adjustments:

The consolidation of the Merck/Schering-Plough partnership (the MSP Partnership) which became wholly owned by the Company;

Additional depreciation and amortization expense that would have been recognized assuming fair value adjustments to inventory, property, plant and equipment and intangible assets;

Additional interest expense and financing costs that would have been incurred on borrowing arrangements and loss of interest income on cash and short-term investments used to fund the Merger;

Transaction costs associated with the Merger; and

Conversion of a portion of outstanding 6% preferred stock.

The unaudited supplemental pro forma financial information does not reflect the potential realization of cost savings relating to the integration of the two companies. The pro forma data should not be considered indicative of the results that would have occurred if the Merger and related borrowings had been consummated on January 1, 2008, nor are they indicative of future results.

4. Restructuring*Merger Restructuring Program*

In February 2010, the Company commenced actions under a global restructuring program (the Merger Restructuring Program) in conjunction with the integration of the legacy Merck and legacy Schering-Plough businesses. This Merger Restructuring Program is intended to optimize the cost structure of the combined company. Additional actions under the program continued during 2010. In July 2011, the Company announced the latest phase of the Merger Restructuring Program during which the Company expects to reduce its workforce measured at the time of the Merger by an additional 12% to 13% across the Company worldwide. A majority of the workforce reductions in this phase of the Merger Restructuring Program relate to manufacturing (including Animal Health), administrative and headquarters organizations. Previously announced workforce reductions of approximately 17% in earlier phases of the program primarily reflect the elimination of positions in sales, administrative and headquarters organizations, as well as from the sale or closure of certain manufacturing and research and development sites and the consolidation of office facilities. The Company will continue to hire employees in strategic growth areas of the business as necessary. The Company will continue to pursue productivity efficiencies and evaluate its manufacturing supply chain capabilities on an ongoing basis which may result in future restructuring actions.

Edgar Filing: Merck & Co. Inc. - Form 10-K

The Company recorded total pretax restructuring costs of \$1.8 billion in 2011, \$1.8 billion in 2010 and \$1.5 billion in 2009 related to this program. Since inception of the Merger Restructuring Program through December 31, 2011, Merck has recorded total pretax accumulated costs of approximately \$5.1 billion and eliminated approximately 18,430 positions comprised of employee separations, as well as the elimination of

Table of Contents

contractors and more than 2,500 positions that were vacant at the time of the Merger. The restructuring actions under the Merger Restructuring Program are expected to be substantially completed by the end of 2013, with the exception of certain actions, principally manufacturing-related, which are expected to be substantially completed by 2015, with the total cumulative pretax costs estimated to be approximately \$5.8 billion to \$6.6 billion. The Company estimates that approximately two-thirds of the cumulative pretax costs relate to cash outlays, primarily related to 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.

2008 Global Restructuring Program

In October 2008, Merck 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 the Company worldwide. Pretax restructuring costs of \$45 million, \$176 million and \$475 million were recorded in 2011, 2010 and 2009, respectively, related to the 2008 Restructuring Program. Since inception of the 2008 Restructuring Program through December 31, 2011, Merck has recorded total pretax accumulated costs of \$1.6 billion and eliminated approximately 6,250 positions comprised of employee separations and the elimination of contractors and vacant positions. The 2008 Restructuring Program was substantially completed by the end of 2011, with the exception of certain manufacturing-related actions, which are expected to be completed by 2015, with the total cumulative pretax costs estimated to be up to \$2.0 billion. The Company estimates that two-thirds of the cumulative pretax costs relate to 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.

For segment reporting, restructuring charges are unallocated expenses.

Table of Contents

The following table summarizes the charges related to Merger Restructuring Program and 2008 Restructuring Program activities by type of cost:

| | Separation Costs | Accelerated Depreciation | Other | Total |
|-------------------------------------|---------------------|-----------------------------|--------|----------|
| Year Ended December 31, 2011 | | | | |
| Merger Restructuring Program | | | | |
| Materials and production | \$ | \$ 282 | \$ 17 | \$ 299 |
| Marketing and administrative | | 108 | 11 | 119 |
| Research and development | | 151 | (17) | 134 |
| Restructuring costs | 1,117 | | 177 | 1,294 |
| | 1,117 | 541 | 188 | 1,846 |
| 2008 Restructuring Program | | | | |
| Materials and production | | 24 | 5 | 29 |
| Research and development | | 4 | | 4 |
| Restructuring costs | (6) | | 18 | 12 |
| | (6) | 28 | 23 | 45 |
| | \$ 1,111 | \$ 569 | \$ 211 | \$ 1,891 |
| Year Ended December 31, 2010 | | | | |
| Merger Restructuring Program | | | | |
| Materials and production | \$ | \$ 241 | \$ 74 | \$ 315 |
| Marketing and administrative | | 145 | 2 | 147 |
| Research and development | | 364 | 54 | 418 |
| Restructuring costs | 708 | | 207 | 915 |
| | 708 | 750 | 337 | 1,795 |
| 2008 Restructuring Program | | | | |
| Materials and production | | 67 | 25 | 92 |
| Marketing and administrative | | | (3) | (3) |
| Research and development | | 10 | | 10 |
| Restructuring costs | 60 | | 17 | 77 |
| | 60 | 77 | 39 | 176 |
| | \$ 768 | \$ 827 | \$ 376 | \$ 1,971 |
| Year Ended December 31, 2009 | | | | |
| Merger Restructuring Program | | | | |
| Materials and production | \$ | \$ 43 | \$ | \$ 43 |
| Restructuring costs | 1,338 | | 79 | 1,417 |
| | 1,338 | 43 | 79 | 1,460 |
| 2008 Restructuring Program | | | | |
| Materials and production | | 70 | (5) | 65 |
| Research and development | | 228 | 4 | 232 |
| Restructuring costs | 14 | | 164 | 178 |
| | 14 | 298 | 163 | 475 |
| | \$ 1,352 | \$ 341 | \$ 242 | \$ 1,935 |

Table of Contents

Separation costs are associated with actual headcount reductions, as well as those headcount reductions which were probable and could be reasonably estimated. In 2011, approximately 6,880 positions were eliminated under the Merger Restructuring Program and approximately 450 positions were eliminated under the 2008 Restructuring Program. During 2010, approximately 11,410 positions were eliminated under the Merger Restructuring Program and approximately 890 positions were eliminated under the 2008 Restructuring Program. During 2009, approximately 3,160 positions were eliminated under the 2008 Restructuring Program and approximately 140 positions were eliminated under the Merger Restructuring Program. These position eliminations were comprised of actual headcount reductions and the elimination of contractors and vacant positions. During 2009, certain employees anticipated to be separated as part of planned restructuring actions for the 2008 Restructuring Program were instead transferred to the buyer in conjunction with the sale of a facility. Accordingly, the accrual of separation costs associated with these employees was reversed resulting in a reduction to expenses.

Accelerated depreciation costs primarily relate to manufacturing, research and administrative facilities and equipment to be sold or closed as part of the programs. Accelerated depreciation costs represent the difference between the depreciation expense to be recognized over the revised useful life of the site, based upon the anticipated date the site will be closed or divested, and depreciation expense as determined utilizing the useful life prior to the restructuring actions. 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.

Other activity in 2011, 2010 and 2009 includes \$72 million, \$152 million and \$15 million, respectively, of asset abandonment, shut-down and other related costs and, in 2010, approximately \$65 million of contract termination costs. Additionally, other activity includes \$53 million, \$88 million and \$109 million in 2011, 2010 and 2009, respectively, for other employee-related costs such as curtailment, settlement and termination charges associated with pension and other postretirement benefit plans (see Note 15) and share-based compensation costs. Other activity also reflects net pretax gains (losses) resulting from sales of facilities and related assets in 2011, 2010 and 2009 of \$10 million, \$49 million and \$(52) million, respectively.

Adjustments to the recorded amounts were not material in any period.

Table of Contents

The following table summarizes the charges and spending relating to Merger Restructuring Program and 2008 Restructuring Program activities:

| | Separation Costs | Accelerated Depreciation | Other | Total |
|---|---------------------|-----------------------------|--------------|-----------------|
| Merger Restructuring Program | | | | |
| Restructuring reserves January 1, 2010 | \$ 1,303 | \$ | \$ | \$ 1,303 |
| Expenses | 708 | 750 | 337 | 1,795 |
| (Payments) receipts, net | (1,152) | | (143) | (1,295) |
| Non-cash activity | | (750) | (130) | (880) |
| Restructuring reserves December 31, 2010 | 859 | | 64 | 923 |
| Expenses | 1,117 | 541 | 188 | 1,846 |
| (Payments) receipts, net | (832) | | (245) | (1,077) |
| Non-cash activity | | (541) | 44 | (497) |
| Restructuring reserves December 31, 2011⁽¹⁾ | \$ 1,144 | \$ | \$ 51 | \$ 1,195 |
| 2008 Restructuring Program | | | | |
| Restructuring reserves January 1, 2010 | \$ 249 | \$ | \$ | \$ 249 |
| Expenses | 60 | 77 | 39 | 176 |
| (Payments) receipts, net | (113) | | (15) | (128) |
| Non-cash activity | | (77) | (24) | (101) |
| Restructuring reserves December 31, 2010 | 196 | | | 196 |
| Expenses | (6) | 28 | 23 | 45 |
| (Payments) receipts, net | (64) | | (21) | (85) |
| Non-cash activity | | (28) | (2) | (30) |
| Restructuring reserves December 31, 2011⁽¹⁾ | \$ 126 | \$ | \$ | \$ 126 |

⁽¹⁾ The cash outlays associated with the Merger Restructuring Program are expected to be substantially completed by the end of 2013 with the exception of certain actions, principally manufacturing-related, which are expected to be substantially completed by 2015. The cash outlays associated with the remaining restructuring reserves for the 2008 Restructuring Program are primarily manufacturing-related and are expected to be completed by the end of 2015.

Legacy Schering-Plough Program

Prior to the Merger, Schering-Plough commenced a Productivity Transformation Program which was designed to reduce and avoid costs and increase productivity. During 2011, 2010 and 2009, the Company recorded \$20 million, \$22 million and \$7 million, respectively, of accelerated depreciation costs included in *Materials and production* costs. In addition, *Restructuring costs* reflect a \$7 million net gain in 2010 primarily related to the sale of a manufacturing facility and \$39 million of separation costs in 2009. The remaining reserve related to this plan, which is substantially complete, was \$18 million and \$47 million at December 31, 2011 and 2010, respectively.

5. Acquisitions, Divestitures, Research Collaborations and License Agreements

In May 2011, Merck completed the acquisition of Inspire Pharmaceuticals, Inc. (Inspire), a specialty pharmaceutical company focused on developing and commercializing ophthalmic products. Under the terms of the merger agreement, Merck acquired all outstanding shares of common stock of Inspire at a price of \$5.00 per share in cash for a total of approximately \$420 million. The transaction was accounted for as an acquisition of a business; accordingly, the assets acquired and liabilities assumed were recorded at their respective fair values as of the acquisition date. The determination of fair value requires management to make significant estimates and assumptions. In connection with the acquisition, substantially all of the purchase price was allocated to Inspire's product and product right intangible assets and related deferred tax liabilities, a deferred tax asset relating to Inspire's net operating loss carryforwards, and goodwill. This transaction closed on May 16, 2011, and accordingly,

Table of Contents

the results of operations of the acquired business have been included in the Company's results of operations since the acquisition date. Pro forma financial information has not been included because Inspire's historical financial results are not significant when compared with the Company's financial results.

In March 2011, the Company sold the Merck BioManufacturing Network, a provider of contract manufacturing and development services for the biopharmaceutical industry and wholly owned by Merck, to Fujifilm Corporation (Fujifilm). Under the terms of the agreement, Fujifilm purchased all of the equity interests in two Merck subsidiaries which together owned all of the assets of the Merck BioManufacturing Network comprising facilities located in Research Triangle Park, North Carolina and Billingham, United Kingdom. As part of the agreement with Fujifilm, Merck has committed to certain continued development and manufacturing activities with these two companies. The transaction resulted in a gain of \$127 million in 2011 reflected in *Other (income) expense, net*. The Company acquired the facility located in Billingham, United Kingdom when it completed the acquisition of Avecia Biologics Limited in February 2010.

In December 2010, the Company acquired all of the outstanding stock of SmartCells, Inc. (SmartCells), a private company developing a glucose responsive insulin formulation for the treatment of diabetes mellitus. The total purchase consideration, which the Company determined had a fair value at the acquisition date of \$138 million, included an upfront cash payment, contingent consideration consisting of future clinical development and regulatory milestones, as well as contingent consideration on future sales of products resulting from the acquisition. The transaction was accounted for as an acquisition of a business; accordingly, the assets acquired and liabilities assumed were recorded at their respective fair values as of the acquisition date. The determination of fair value requires management to make significant estimates and assumptions. In connection with the acquisition, substantially all of the preliminary purchase price was allocated to IPR&D. The remaining net assets acquired were not significant. The fair value of the contingent consideration was determined by utilizing a probability weighted estimated cash flow stream adjusted for the expected timing of each payment. Subsequent to the acquisition date, on a quarterly basis, the contingent consideration liability is remeasured at current fair value with changes recorded in earnings, which have been *de minimis*. This transaction closed on December 6, 2010, and accordingly, the results of operations of the acquired business have been included in the Company's results of operations since the acquisition date. Pro forma financial information has not been included because SmartCells' historical financial results are not significant when compared with the Company's financial results.

In May 2010, Merck announced that it had restructured its co-development and co-commercialization agreement with ARIAD Pharmaceuticals, Inc. (ARIAD) for ridaforolimus (MK-8669), an investigational orally available mTOR inhibitor currently being evaluated for the treatment of multiple cancer types, to an exclusive license agreement. Under the restructured agreement, Merck acquired full control of the development and worldwide commercialization of ridaforolimus. ARIAD received a \$50 million upfront fee, which the Company recorded as research and development expense in 2010, and is eligible to receive milestone payments associated with regulatory filings and approvals of ridaforolimus in multiple cancer indications and achievement of significant sales thresholds. In lieu of the profit split on U.S. sales provided for in the previous agreement, ARIAD will now receive royalties on global net sales of ridaforolimus, and all sales will be recorded by Merck. Merck assumed responsibility for all activities and acquired decision rights on matters relating to the development, manufacturing and commercialization of ridaforolimus. The Investigational New Drug Application has been transferred to Merck and Merck is leading all interactions with regulatory agencies. During 2011, ridaforolimus was accepted for review by the Food and Drug Administration (the FDA) and the European Medicines Agency. The agreement with ARIAD is terminable by Merck upon nine months notice, or immediately upon a good faith determination of a serious safety issue. The agreement is terminable by either party as a result of insolvency by the other party or an uncured material breach by the other party or by ARIAD for a failure by Merck to perform certain product development responsibilities.

6. Collaborative Arrangements

The Company continues its strategy of establishing external alliances to complement its substantial internal research capabilities, including research collaborations, licensing preclinical and clinical compounds and technology platforms to drive both near- and long-term growth. The Company supplements its internal research with a licensing and external alliance strategy focused on the entire spectrum of collaborations from early research to late-stage compounds, as well as new technologies across a broad range of therapeutic areas. These arrangements

Table of Contents

often include upfront payments and royalty or profit share payments, contingent upon the occurrence of certain future events linked to the success of the asset in development, as well as expense reimbursements or payments to the third party.

Cozaar/Hyzaar

In 1989, Merck and E.I. duPont de Nemours and Company (DuPont) agreed to form a long-term research and marketing collaboration to develop a class of therapeutic agents for high blood pressure and heart disease, discovered by DuPont, called angiotensin II receptor antagonists, which include *Cozaar* and *Hyzaar*. In return, Merck provided DuPont marketing rights in the United States and Canada to its prescription medicines, *Sinemet* and *Sinemet CR* (the Company has since regained global marketing rights to *Sinemet* and *Sinemet CR*). Pursuant to a 1994 agreement with DuPont, the Company has an exclusive licensing agreement to market *Cozaar* and *Hyzaar* in return for royalties and profit share payments to DuPont. The patents that provided market exclusivity in the United States for *Cozaar* and *Hyzaar* expired in April 2010. In addition, *Cozaar* and *Hyzaar* lost patent protection in a number of major European markets in March 2010.

Remicade/Simponi

In 1998, a subsidiary of Schering-Plough entered into a licensing agreement with Centocor Ortho Biotech Inc. (Centocor), a Johnson & Johnson (J&J) company, to market *Remicade*, which is prescribed for the treatment of inflammatory diseases. In 2005, Schering-Plough's subsidiary exercised an option under its contract with Centocor for license rights to develop and commercialize *Simponi* (golimumab), a fully human monoclonal antibody. The Company had exclusive marketing rights to both products outside the United States, Japan and certain other Asian markets. In December 2007, Schering-Plough and Centocor revised their distribution agreement regarding the development, commercialization and distribution of both *Remicade* and *Simponi*, extending the Company's rights to exclusively market *Remicade* to match the duration of the Company's exclusive marketing rights for *Simponi*. In addition, Schering-Plough and Centocor agreed to share certain development costs relating to *Simponi*'s auto-injector delivery system. On October 6, 2009, the European Commission approved *Simponi* as a treatment for rheumatoid arthritis and other immune system disorders in two presentations – a novel auto-injector and a prefilled syringe. As a result, the Company's marketing rights for both products extend for 15 years from the first commercial sale of *Simponi* in the European Union (the EU) following the receipt of pricing and reimbursement approval within the EU.

In April 2011, Merck and J&J reached an agreement to amend the agreement governing the distribution rights to *Remicade* and *Simponi*. Under the terms of the amended distribution agreement, Merck relinquished marketing rights for *Remicade* and *Simponi* to J&J in territories including Canada, Central and South America, the Middle East, Africa and Asia Pacific effective July 1, 2011. Merck retained exclusive marketing rights throughout Europe, Russia and Turkey (the Retained Territories). In addition, beginning July 1, 2011, all profits derived from Merck's exclusive distribution of the two products in the Retained Territories are being equally divided between Merck and J&J. Under the prior terms of the distribution agreement, the contribution income (profit) split, which was at 58% to Merck and 42% to J&J, would have declined for Merck and increased for J&J each year until 2014, when it would have been equally divided. J&J also received a one-time payment from Merck of \$500 million in April 2011, which the Company recorded as a charge to *Other (income) expense, net* in 2011.

7. Financial Instruments

Derivative Instruments and Hedging Activities

The Company manages the impact of foreign exchange rate movements and interest rate movements on its earnings, cash flows and fair values of assets and liabilities through operational means and through the use of various financial instruments, including derivative instruments.

A significant portion of the Company's revenues and earnings in foreign affiliates is exposed to changes in foreign exchange rates. The objectives and accounting related to the Company's foreign currency risk management program, as well as its interest rate risk management activities are discussed below.

Table of Contents

Foreign Currency Risk Management

A significant portion of the Company's revenues are denominated in foreign currencies. The Company has established revenue hedging, balance sheet risk management, and net investment hedging 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 rates 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 hedge a portion of its forecasted foreign currency denominated third-party and intercompany distributor entity 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 third-party and intercompany distributor entity sales hedged as it gets closer to the expected date of the forecasted foreign currency denominated sales, 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 currency risk in the same manner. The Company 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 equivalent 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 U.S. dollar equivalent value of the anticipated foreign currency cash flows.

In connection with the Company's revenue hedging program, a purchased collar option strategy may be utilized. With a purchased collar option strategy, the Company writes a local currency call option and purchases a local currency put option. As compared to a purchased put option strategy alone, a purchased collar strategy reduces the upfront costs associated with purchasing puts through the collection of premium by writing call options. If the U.S. dollar weakens relative to the currency of the hedged anticipated sales, the purchased put option value of the collar strategy reduces to zero and the Company benefits from the increase in the U.S. dollar equivalent value of its anticipated foreign currency cash flows, however this benefit would be capped at the strike level of the written call. If the U.S. dollar strengthens relative to the currency of the hedged anticipated sales, the written call option value of the collar strategy reduces to zero and the changes in the purchased put cash flows of the collar strategy would offset the decline in the expected future U.S. dollar equivalent cash flows of the hedged foreign currency sales.

The Company may also utilize forward contracts in its revenue hedging program. If the U.S. dollar strengthens relative to the currency of the hedged anticipated sales, the increase in the fair value of the forward contracts offsets the decrease in the expected future U.S. dollar cash flows of the hedged foreign currency sales. Conversely, if the U.S. dollar weakens, the decrease in the fair value of the forward contracts offsets the increase in the value of the anticipated foreign currency cash flows.

The fair values of these derivative contracts are recorded as either assets (gain positions) or liabilities (loss positions) in the Consolidated Balance Sheet. Changes in the fair value of derivative contracts are recorded each period in either current earnings or *OCI*, depending on whether the derivative is designated as part of a hedge transaction and, if so, the type of hedge transaction. For derivatives that are designated as cash flow hedges, the effective portion of the unrealized gains or losses on these contracts is recorded in *AOCI* and reclassified into *Sales* when the hedged anticipated revenue is recognized. The hedge relationship is highly effective and hedge ineffectiveness has been *de minimis*. For those derivatives which are not designated as cash flow hedges, unrealized gains or losses are recorded to *Sales* each period. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows. The Company does not enter into derivatives for trading or speculative purposes.

The primary objective of the balance sheet risk management program is to mitigate the exposure of foreign currency denominated net monetary assets of foreign subsidiaries where the U.S. dollar is the functional

Table of Contents

currency from the effects of volatility in foreign exchange. In these instances, 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 from the monetary 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.

Monetary assets and liabilities denominated in a currency other than the functional currency of a given subsidiary 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.

During 2009, the Company used, and may in the future use, 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. These derivative contracts are designated as fair value hedges. Accordingly, changes in the fair value of the hedged securities due to fluctuations in spot rates are recorded in *Other (income) expense, net*, and are offset by the fair value changes in the forward contracts attributable to spot rate fluctuations. 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, as well as hedge ineffectiveness, were not significant for 2009. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

The Company also uses forward exchange contracts to hedge its net investment in foreign operations against movements in exchange rates. The forward contracts are designated as hedges of the net investment in a foreign operation. The Company hedges a portion of the net investment in certain of its foreign operations and measures ineffectiveness based upon changes in spot foreign exchange rates. The effective portion of the unrealized gains or losses on these contracts is recorded in foreign currency translation adjustment within *OCI*, and remains in *AOCI* until either the sale or complete or substantially complete liquidation of the subsidiary. The cash flows from these contracts are reported as investing activities in the Consolidated Statement of Cash Flows.

Foreign exchange risk is also managed through the use of foreign currency debt. The Company's senior unsecured euro-denominated notes have been designated as, and are effective as, economic hedges of the net investment in a foreign operation. Accordingly, foreign currency transaction gains or losses due to spot rate fluctuations on the euro-denominated debt instruments are included in foreign currency translation adjustment within *OCI*. Included in the cumulative translation adjustment are pretax gains of \$6 million in 2011, \$277 million in 2010 and \$78 million for the post-Merger period in 2009 from euro-denominated notes which have been designated as, and are effective as, economic hedges of the net investment in a foreign operation.

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.

In February 2011, the Company entered into nine pay-floating, receive-fixed interest rate swap contracts with notional amounts of \$3.5 billion in the aggregate designated as fair value hedges for fixed-rate notes in which the notional amounts matched the amount of the hedged fixed-rate notes.

Two interest rate swap contracts designated as fair value hedges of fixed-rate notes matured in 2011 with notional amounts of \$125 million each that effectively converted the Company's \$250 million, 5.125% fixed-rate notes due 2011 to floating rate instruments. The interest rate swap contracts were designated hedges of the fair

Table of Contents

value changes in the notes attributable to changes in the benchmark London Interbank Offered Rate (LIBOR) swap rate. The fair value changes in the notes attributable to changes in the benchmark interest rate were recorded in interest expense and offset by the fair value changes in the swap contracts. Also during 2011, the Company terminated pay-floating, receive-fixed interest rate swap contracts designated as fair value hedges of fixed-rate notes in which the notional amounts match the amount of the hedged fixed-rate notes. These swaps effectively converted \$5.1 billion of its fixed-rate notes, with maturity dates varying from March 2015 to June 2019, to floating rate instruments. The interest rate swap contracts were designated hedges of the fair value changes in the notes attributable to changes in the benchmark LIBOR swap rate. As a result of the swap terminations, the Company received \$288 million in cash, which included \$43 million in accrued interest. The unamortized adjustment to the carrying value of the debt associated with the interest rate swap contracts of \$245 million is being amortized as a reduction of interest expense over the respective term of the notes. The cash flows from these contracts are reported as operating activities in the Consolidated Statement of Cash Flows.

Presented in the table below is the fair value of derivatives segregated between those derivatives that are designated as hedging instruments and those that are not designated as hedging instruments as of December 31:

| (\$ in millions) | Balance Sheet Caption | 2011 | | | 2010 | | |
|---|--|------------------------|-------------------------|-------------------------|------------------------|-------------------------|-------------------------|
| | | Fair Value of Asset | Derivative Liability | U.S. Dollar Notional | Fair Value of Asset | Derivative Liability | U.S. Dollar Notional |
| Derivatives Designated as Hedging Instruments | | | | | | | |
| Foreign exchange contracts (current) | Deferred income taxes and other current assets | \$ 196 | \$ | \$ 3,727 | \$ 167 | \$ | \$ 2,344 |
| Foreign exchange contracts (non-current) | Other assets | 420 | | 4,956 | 310 | | 3,720 |
| Foreign exchange contracts (current) | Accrued and other current liabilities | | 53 | 1,718 | | 18 | 1,505 |
| Foreign exchange contracts (non-current) | Deferred income taxes and noncurrent liabilities | | 1 | 104 | | 6 | 503 |
| Interest rate swaps (non-current) | Other assets | | | | 56 | | 1,000 |
| Interest rate swaps (non-current) | Deferred income taxes and noncurrent liabilities | | | | | 7 | 850 |
| | | \$ 616 | \$ 54 | \$ 10,505 | \$ 533 | \$ 31 | \$ 9,922 |
| Derivatives Not Designated as Hedging Instruments | | | | | | | |
| Foreign exchange contracts (current) | Deferred income taxes and other current assets | \$ 139 | \$ | \$ 5,306 | \$ 95 | \$ | \$ 6,295 |
| Foreign exchange contracts (current) | Accrued and other current liabilities | | 54 | 5,013 | | 30 | 4,229 |
| | | \$ 139 | \$ 54 | \$ 10,319 | \$ 95 | \$ 30 | \$ 10,524 |
| | | \$ 755 | \$ 108 | \$ 20,824 | \$ 628 | \$ 61 | \$ 20,446 |

Table of Contents

The table below provides information on the location and pretax gain or loss amounts for derivatives that are: (i) designated in a fair value hedging relationship, (ii) designated in a cash flow hedging relationship, (iii) designated in a foreign currency net investment hedging relationship and (iv) not designated in a hedging relationship:

| <i>Years Ended December 31</i> | 2011 | 2010 |
|---|-----------------|----------------|
| <i>Derivatives designated in fair value hedging relationships</i> | | |
| Interest rate swap contracts | | |
| Amount of gain recognized in <i>Other (income) expense, net</i> on derivatives | \$ (196) | \$ (23) |
| Amount of loss recognized in <i>Other (income) expense, net</i> on hedged item | 196 | 23 |
| <i>Derivatives designated in foreign currency cash flow hedging relationships</i> | | |
| Foreign exchange contracts | | |
| Amount of loss reclassified from <i>AOCI to Sales</i> | 85 | 7 |
| Amount of loss (gain) recognized in <i>OCI</i> on derivatives | 143 | (103) |
| <i>Derivatives designated in foreign currency net investment hedging relationships</i> | | |
| Foreign exchange contracts | | |
| Amount of gain recognized in <i>Other (income) expense, net</i> on derivatives ⁽¹⁾ | (10) | (1) |
| Amount of loss recognized in <i>OCI</i> on derivatives | 122 | 24 |
| <i>Derivatives not designated in a hedging relationship</i> | | |
| Foreign exchange contracts | | |
| Amount of gain recognized in <i>Other (income) expense, net</i> on derivatives ⁽²⁾ | (113) | (33) |
| Amount of gain recognized in <i>Sales</i> | | (81) |

⁽¹⁾ There was no ineffectiveness on the hedge. Represents the amount excluded from hedge effectiveness testing.

⁽²⁾ These derivative contracts mitigate changes in the value of remeasured foreign currency denominated monetary assets and liabilities attributable to changes in foreign currency exchange rates.

At December 31, 2011, the Company estimates \$18 million of pretax net unrealized losses on derivatives maturing within the next 12 months that hedge foreign currency denominated sales over that same period will be reclassified from *AOCI to Sales*. The amount ultimately reclassified to *Sales* may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity.

Investments in Debt and Equity Securities

Information on available-for-sale investments at December 31 is as follows:

| | 2011 | | | | 2010 | | | |
|---------------------------------------|-------------------|-----------------------|-------------------------|----------------|-------------------|-----------------------|-------------------------|----------------|
| | Fair Value | Amortized Cost | Gross Unrealized | | Fair Value | Amortized Cost | Gross Unrealized | |
| | | | Gains | Losses | | | Gains | Losses |
| Corporate notes and bonds | \$ 2,032 | \$ 2,024 | \$ 16 | \$ (8) | \$ 1,133 | \$ 1,124 | \$ 12 | \$ (3) |
| Commercial paper | 1,029 | 1,029 | | | 1,046 | 1,046 | | |
| U.S. government and agency securities | 1,021 | 1,018 | 3 | | 500 | 501 | 1 | (2) |
| Municipal securities | | | | | 361 | 359 | 4 | (2) |
| Asset-backed securities | 292 | 292 | 1 | (1) | 171 | 170 | 1 | |
| Mortgage-backed securities | 223 | 223 | 1 | (1) | 112 | 108 | 5 | (1) |
| Foreign government bonds | 72 | 72 | | | 10 | 10 | | |
| Other debt securities | 3 | 1 | 2 | | 3 | 1 | 2 | |
| Equity securities | 397 | 383 | 14 | | 321 | 295 | 34 | (8) |
| | \$ 5,069 | \$ 5,042 | \$ 37 | \$ (10) | \$ 3,657 | \$ 3,614 | \$ 59 | \$ (16) |

Available-for-sale debt securities included in *Short-term investments* totaled \$1.4 billion at December 31, 2011. Of the remaining debt securities, \$2.9 billion mature within five years. At December 31, 2011, there were no debt securities pledged as collateral.

Table of Contents

Fair Value Measurements

Fair value is defined 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. The Company uses a fair value hierarchy which maximizes the use of observable inputs and minimizes the use of unobservable inputs when measuring fair value. There are three levels of inputs used to measure fair value with Level 1 having the highest priority and Level 3 having the lowest:

Level 1 Quoted prices (unadjusted) in active markets for identical assets or liabilities.

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.

Level 3 Unobservable inputs that are supported by little or no market activity. The Company's Level 3 assets are those whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques with significant unobservable inputs, as well as instruments for which the determination of fair value requires significant judgment or estimation.

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 at December 31 are summarized below:

| | Fair Value Measurements Using | | | | Fair Value Measurements Using | | | |
|---|-------------------------------|-------------|--------------|----------|-------------------------------|-------------|--------------|----------|
| | Quoted Prices | | | | Quoted Prices | | | |
| | In | Significant | | | In | Significant | | |
| | Active | | | | Active | | | |
| | Markets | Other | Significant | | Markets | Other | Significant | |
| | for | Observable | Unobservable | | for | Observable | Unobservable | |
| | Identical Assets | Inputs | Inputs | | Identical Assets | Inputs | Inputs | |
| (Level | (Level 2) | (Level 3) | Total | (Level | (Level 2) | (Level 3) | Total | |
| 1) | | | | 1) | | | | |
| | 2011 | | | | 2010 | | | |
| Assets | | | | | | | | |
| Investments | | | | | | | | |
| Corporate notes and bonds | \$ | \$ 2,032 | \$ | \$ 2,032 | \$ | \$ 1,133 | \$ | \$ 1,133 |
| Commercial paper | | 1,029 | | 1,029 | | 1,046 | | 1,046 |
| U.S. government and agency securities | | 1,021 | | 1,021 | | 500 | | 500 |
| Municipal securities | | | | | | 361 | | 361 |
| Asset-backed securities ⁽¹⁾ | | 292 | | 292 | | 171 | | 171 |
| Mortgage-backed securities ⁽¹⁾ | | 223 | | 223 | | 99 | 13 | 112 |
| Foreign government bonds | | 72 | | 72 | | 10 | | 10 |
| Equity securities | 205 | 22 | | 227 | 117 | 23 | | 140 |
| Other debt securities | | 3 | | 3 | | 3 | | 3 |
| | 205 | 4,694 | | 4,899 | 117 | 3,346 | 13 | 3,476 |
| Other assets | | | | | | | | |
| Securities held for employee compensation | 170 | | | 170 | 181 | | | 181 |
| Derivative assets ⁽²⁾ | | | | | | | | |
| Purchased currency options | | 613 | | 613 | | 477 | | 477 |
| Forward exchange contracts | | 142 | | 142 | | 95 | | 95 |
| Interest rate swaps | | | | | | 56 | | 56 |
| | | 755 | | 755 | | 628 | | 628 |
| Total assets | \$ 375 | \$ 5,449 | \$ | \$ 5,824 | \$ 298 | \$ 3,974 | \$ 13 | \$ 4,285 |
| Liabilities | | | | | | | | |
| Derivative liabilities ⁽²⁾ | | | | | | | | |
| Forward exchange contracts | \$ | \$ 107 | \$ | \$ 107 | \$ | \$ 54 | \$ | \$ 54 |
| Written currency options | | 1 | | 1 | | | | |
| Interest rate swaps | | | | | | 7 | | 7 |
| Total liabilities | \$ | \$ 108 | \$ | \$ 108 | \$ | \$ 61 | \$ | \$ 61 |

⁽¹⁾ Primarily 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. Mortgage-backed securities represent AAA-rated securities issued or unconditionally guaranteed as to payment of principal and interest by U.S. government agencies.

⁽²⁾ The fair value determination of derivatives includes the impact of the credit risk of counterparties to the derivatives and the Company's own credit risk, the effects of which were not significant.

There were no significant transfers between Level 1 and Level 2 during 2011. As of December 31, 2011, Cash and cash equivalents of \$13.5 billion included \$12.7 billion of cash equivalents (which are considered Level 2 in the fair value hierarchy).

Level 3 Valuation Techniques

Edgar Filing: Merck & Co. Inc. - Form 10-K

The Company's Level 3 investment securities included certain mortgage-backed securities valued primarily using pricing models that 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.

Table of Contents

The table below provides a summary of the changes in fair value of all financial assets measured at fair value on a recurring basis using significant unobservable inputs (Level 3):

| <i>Years Ended December 31</i> | 2011 | 2010 |
|--|--------------|--------------|
| Beginning balance January 1 | \$ 13 | \$ 72 |
| Sales | (13) | (67) |
| Total realized and unrealized gains (losses) | | |
| Included in: | | |
| Earnings ⁽¹⁾ | | 18 |
| Comprehensive income | | (10) |
| Ending balance December 31 | \$ | \$ 13 |
| Losses recorded in earnings for Level 3 assets still held at December 31 | \$ | \$ |

⁽¹⁾ Amounts are recorded in Other (income) expense, net.
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 loans payable and long-term debt (including current portion) at December 31, 2011 was \$19.5 billion compared with a carrying value of \$17.5 billion and at December 31, 2010 was \$18.7 billion compared with a carrying value of \$17.9 billion. Fair value was estimated using quoted dealer prices.

Concentrations of Credit Risk

On an ongoing basis, the Company monitors concentrations of credit risk associated with corporate and government 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. Approximately three-quarters of the Company's cash and cash equivalents are invested in three highly rated money market funds.

The majority of the Company's accounts receivable arise from product sales in the United States and Europe and are primarily due from drug wholesalers and retailers, hospitals, government agencies, managed health care providers and pharmacy benefit managers. The Company monitors the financial performance and creditworthiness of its customers so that it can properly assess and respond to changes in their credit profile. The Company also continues to monitor economic conditions, including the volatility associated with international sovereign economies, and associated impacts on the financial markets and its business, taking into consideration the global economic downturn and the sovereign debt issues in certain European countries. The Company continues to monitor the credit and economic conditions within Greece, Spain, Italy and Portugal, among other members of the EU. These deteriorating economic conditions, as well as inherent variability of timing of cash receipts, have resulted in, and may continue to result in, an increase in the average length of time that it takes to collect accounts receivable outstanding. As such, time value of money discounts have been recorded for those customers for which collection of accounts receivable is expected to be in excess of one year. The Company does not expect to have write-offs or adjustments to accounts receivable which would have a material adverse effect on its financial position, liquidity or results of operations.

As of December 31, 2011, the Company's accounts receivable in Greece, Italy, Spain and Portugal totaled approximately \$1.6 billion. Of this amount, hospital and public sector receivables were approximately \$1.1 billion in the aggregate, of which approximately 8%, 36%, 47% and 9% related to Greece, Italy, Spain and Portugal, respectively. As of December 31, 2011, the Company's total accounts receivable outstanding for more than one year were approximately \$400 million, of which approximately 90% related to accounts receivable in Greece, Italy, Spain and Portugal, mostly comprised of hospital and public sector receivables.

Table of Contents

As previously disclosed, the Company received zero coupon bonds from the Greek government in settlement of 2007-2009 receivables related to certain government sponsored institutions. During 2011, the Company sold a portion of these bonds. The Company had recorded impairment charges to reduce the remaining bonds to fair value. During 2012, the Company sold the remaining bonds. During 2011 and 2012, the Company has continued to receive payments on 2011 and 2010 Greek hospital and public sector receivables.

During 2011, the Company factored approximately \$45 million of hospital and public sector accounts receivable on a non-recourse basis in Spain and Italy. In December 2011, the Company executed a factoring of approximately \$110 million of hospital and public sector accounts receivable in Italy; the factoring is subject to certain closing conditions.

The Company's five largest customers, Cardinal Health, Inc., McKesson Corporation, AmerisourceBergen Corporation, Alliance Healthcare, and Zuellig Pharma Ltd., represented, in aggregate, approximately one-fourth of accounts receivable at December 31, 2011. 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.

Derivative financial instruments are executed under International Swaps and Derivatives Association master agreements. The master agreements with several of the Company's financial institution counterparties also include credit support annexes. These annexes contain provisions that require collateral to be exchanged depending on the value of the derivative assets and liabilities, the Company's credit rating, and the credit rating of the counterparty. As of December 31, 2011 and 2010, the Company had received cash collateral of \$327 million and \$157 million, respectively, from various counterparties and the obligation to return such collateral is recorded in *Accrued and other current liabilities*. The Company had not advanced any cash collateral to counterparties as of December 31, 2011 or 2010.

8. Inventories

Inventories at December 31 consisted of:

| | 2011 | 2010 |
|-----------------------------------|----------|----------|
| Finished goods | \$ 1,983 | \$ 1,484 |
| Raw materials and work in process | 5,396 | 5,449 |
| Supplies | 297 | 315 |
| Total (approximates current cost) | 7,676 | 7,248 |
| Reduction to LIFO costs | (43) | (186) |
| | \$ 7,633 | \$ 7,062 |
| Recognized as: | | |
| Inventories | \$ 6,254 | \$ 5,868 |
| Other assets | 1,379 | 1,194 |

Inventories valued under the LIFO method comprised approximately 27% and 26% of inventories at December 31, 2011 and 2010, respectively. Amounts recognized as *Other assets* are comprised almost entirely of raw materials and work in process inventories. At December 31, 2011 and 2010, these amounts included \$1.3 billion and \$1.0 billion, respectively, of inventories not expected to be sold within one year, largely vaccines. In addition, these amounts included \$127 million and \$197 million at December 31, 2011 and 2010, respectively, of inventories produced in preparation for product launches.

Table of Contents**9. Goodwill and Other Intangibles**

The following table summarizes goodwill activity by segment:

| | Pharmaceutical | All Other | Total |
|---|------------------|-----------------|------------------|
| Goodwill balance January 1, 2010 | \$ 10,005 | \$ 2,033 | \$ 12,038 |
| Additions | 166 | | 166 |
| Other ⁽¹⁾ | 174 | | 174 |
| Goodwill balance December 31, 2010 | 10,345 | 2,033 | 12,378 |
| Additions | 144 | | 144 |
| Other ⁽¹⁾ | (382) | 15 | (367) |
| Goodwill balance December 31, 2011 | \$ 10,107 | \$ 2,048 | \$ 12,155 |

⁽¹⁾ Other includes cumulative translation adjustments on goodwill balances, the reclassification of goodwill from the Pharmaceutical segment to the Consumer Care segment as a result of a segment change that occurred in 2011 (see Note 20), and certain other adjustments.

Other intangibles at December 31 consisted of:

| | 2011 | | | 2010 | | |
|--|-----------------------|--------------------------|-----------|-----------------------|--------------------------|-----------|
| | Gross Carrying Amount | Accumulated Amortization | Net | Gross Carrying Amount | Accumulated Amortization | Net |
| Products and product rights ⁽¹⁾ | \$ 41,937 | \$ 11,872 | \$ 30,065 | \$ 40,797 | \$ 6,953 | \$ 33,844 |
| In-process research and development ⁽²⁾ | 2,671 | | 2,671 | 3,885 | | 3,885 |
| Tradenames | 1,523 | 170 | 1,353 | 1,565 | 123 | 1,442 |
| Other | 895 | 682 | 213 | 858 | 573 | 285 |
| Total identifiable intangible assets | \$ 47,026 | \$ 12,724 | \$ 34,302 | \$ 47,105 | \$ 7,649 | \$ 39,456 |

⁽¹⁾ During 2011, the Company recorded an impairment charge of \$118 million related to a marketed product.

⁽²⁾ Amounts capitalized as in-process research and development are accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or abandonment of the projects. Upon successful completion of each project, the Company will make a separate determination as to the then useful life of the assets and begin amortization. During 2011 and 2010, approximately \$666 million and \$378 million, respectively, of IPR&D was reclassified to products and product rights upon receipt of marketing approval in a major market.

In connection with the Merger, the Company recorded the fair value of human and animal health research projects that were underway at Schering-Plough and the MSP Partnership. Some of the more significant projects include *Victralis*, *Bridion* and vorapaxar, as well as an ezetimibe/atorvastatin combination product. *Victralis* was approved by the FDA and in the EU in 2011. The Company filed an NDA with the FDA in 2011 for the ezetimibe/atorvastatin combination product. Vorapaxar is in Phase III clinical development. *Bridion*, which is approved in many countries outside of the United States, remains in Phase III clinical development in the United States.

During 2011, the Company recorded \$587 million of IPR&D impairment charges within *Research and development* expenses primarily for pipeline programs that were abandoned and determined to have no alternative use, as well as for expected delays in the launch timing or changes in the cash flow assumptions for certain compounds. In addition, the impairment charges related to pipeline programs that had previously been deprioritized and were either deemed to have no alternative use during the period or were out-licensed to a third party for consideration that was less than the related assets carrying value.

During 2010, the Company recorded \$2.4 billion of IPR&D impairment charges within *Research and development* expenses. Of this amount, \$1.7 billion related to the write-down of the vorapaxar intangible asset. The Company determined that developments in the clinical research

Edgar Filing: Merck & Co. Inc. - Form 10-K

program for vorapaxar, including the termination of a clinical trial, constituted a triggering event that required the Company to evaluate the vorapaxar intangible asset

Table of Contents

for impairment. The Company continues to monitor the remaining \$350 million asset value for vorapaxar for further impairment. The remaining \$763 million of IPR&D impairment charges recorded in 2010 were attributable to compounds that were abandoned and determined to have either no alternative use or were returned to the respective licensor, as well as from expected delays in the launch timing or changes in the cash flow assumptions for certain compounds.

All of the IPR&D projects that remain in development are subject to the inherent risks and uncertainties in drug development and it is possible that the Company will not be able to successfully develop and complete the IPR&D programs and profitably commercialize the underlying product candidates.

Aggregate amortization expense primarily recorded within *Materials and production* costs was \$5.1 billion in 2011, \$4.7 billion in 2010 and \$922 million in 2009. The estimated aggregate amortization expense for each of the next five years is as follows: 2012, \$5.0 billion; 2013, \$4.8 billion; 2014, \$4.3 billion; 2015, \$4.2 billion; 2016, \$3.7 billion.

10. 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> | 2011 | 2010 | 2009 |
|--------------------------------------|---------------|--------|----------|
| AstraZeneca LP | \$ 574 | \$ 546 | \$ 674 |
| Merck/Schering-Plough ⁽¹⁾ | | | 1,195 |
| Other ⁽²⁾ | 36 | 41 | 366 |
| | \$610 | \$ 587 | \$ 2,235 |

⁽¹⁾ Upon completion of the Merger in 2009, the MSP Partnership became wholly owned by the Company (see below).

⁽²⁾ Primarily reflects results from Sanofi Pasteur MSD, Johnson & Johnson[®]Merck Consumer Pharmaceuticals Company (which was disposed of on September 29, 2011), as well as Merial Limited (which was disposed of on September 17, 2009).

AstraZeneca LP

In 1982, Merck entered into an agreement with Astra AB (Astra) to develop and market Astra products under a royalty-bearing license. In 1993, Merck'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 Merck 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, 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 KBI products and such revenue was \$1.2 billion, \$1.3 billion and \$1.4 billion in 2011, 2010 and 2009, 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, a preferential return representing Merck's share of undistributed AZLP GAAP earnings, and a variable return related to the Company's 1% limited partner interest.

Table of Contents

In conjunction with the 1998 restructuring discussed above, Astra purchased an option (the *Asset Option*) for a payment of \$443 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*). In April 2010, AstraZeneca exercised the Asset Option. Merck received \$647 million from AstraZeneca representing the net present value as of March 31, 2008 of projected future pretax revenue to be received by Merck from the Non-PPI Products, which was recorded as a reduction to the Company's investment in AZLP. The Company recognized the \$443 million of deferred income in 2010 as a component of *Other (income) expense, net*. In addition, in 1998, Merck granted Astra an option (the *Shares Option*) to buy Merck's common stock interest in KBI and, through it, Merck's interest in Nexium and Prilosec, exercisable in 2012. The exercise price for the Shares Option will be primarily based on the net present value of projected future pretax revenue to be received by Merck from Nexium and Prilosec as determined at the time of exercise, subject to certain true-up mechanisms. The Company believes that it is likely that AstraZeneca will exercise the Shares Option.

Summarized financial information for AZLP is as follows:

| <i>Years Ended December 31</i> | 2011 | 2010 | 2009 |
|------------------------------------|-----------------|----------|----------|
| Sales | \$ 4,659 | \$ 4,991 | \$ 5,744 |
| Materials and production costs | 2,023 | 2,568 | 3,137 |
| Other expense, net | 1,392 | 886 | 1,194 |
| Income before taxes ⁽¹⁾ | 1,244 | 1,537 | 1,413 |

| <i>December 31</i> | 2011 | 2010 |
|---------------------|-----------------|----------|
| Current assets | \$ 4,251 | \$ 3,486 |
| Noncurrent assets | 250 | 289 |
| Current liabilities | 3,915 | 3,613 |

⁽¹⁾ Merck's partnership returns from AZLP are generally contractually determined as noted above and are not based on a percentage of income from AZLP, other than with respect to Merck's 1% limited partnership interest.

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 \$1.1 billion for 2011, \$1.2 billion for 2010 and \$1.6 billion for 2009.

Johnson & Johnson^oMerck Consumer Pharmaceuticals Company

In September 2011, Merck sold its 50% interest in the Johnson & Johnson^oMerck Consumer Pharmaceuticals Company (*JJMCP*) joint venture to J&J. The venture between Merck and J&J was formed in 1989 to develop, manufacture, market and distribute certain over-the-counter (*OTC*) consumer products in the United States and Canada. Merck received a one-time payment of \$175 million and recognized a pretax gain of \$136 million in 2011 reflected in *Other (income) expense, net*. Merck's rights to the *Pepcid* brand outside the United States and Canada were not affected by this transaction. Following the transaction, J&J owns the venture's assets which include the exclusive rights to market OTC *Pepcid*, *Mylanta*, *Mylicon* and other local OTC brands where they are currently sold in the United States and Canada. The partnership assets also included a manufacturing facility. Sales of products marketed by the joint venture were \$62 million for the period from January 1, 2011 until the September 29, 2011 divestiture date, \$129 million for 2010 and \$203 million for 2009.

Merck/Schering-Plough Partnership

In 2000, Merck and Schering-Plough (collectively, the *Partners*) entered into an agreement to create an equally owned partnership to develop and market in the United States new prescription medicines for cholesterol management. 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

Table of Contents

United States). The cholesterol agreements provided for the sharing of operating income generated by the MSP Partnership based upon percentages that varied by product, sales level and country. Operating income included expenses that the Partners contractually agreed to share. Expenses incurred in support of the MSP Partnership but not shared between the Partners were not included in *Equity income from affiliates*; however, these costs were reflected in the overall results of the Partners.

As a result of the Merger, the MSP Partnership became wholly owned by the Company. Merck's share of the results of the MSP Partnership through the date of the Merger is reflected in *Equity income from affiliates*. Activity resulting from the sale of MSP Partnership products after the Merger has been consolidated with Merck's results.

See Note 12 for information with respect to litigation involving the MSP Partnership and the Partners related to the sale and promotion of *Zetia* and *Vytorin*.

Summarized financial information for the MSP Partnership is as follows:

| | Period from January 1, through November 3, 2009 |
|---|---|
| Sales | \$ 3,387 |
| <i>Vytorin</i> | 1,689 |
| <i>Zetia</i> | 1,698 |
| Materials and production costs | 144 |
| Other expense, net | 849 |
| Income before taxes | \$ 2,394 |
| Merck's share of income before taxes ⁽¹⁾ | \$ 1,198 |

⁽¹⁾ 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 Merck and the MSP Partnership, including milestone payments.
Merial Limited

In 2009, Merck sold its 50% interest in the Merial Limited (Merial) joint venture to sanofi-aventis. Merck and sanofi-aventis (then Rhône-Poulenc S.A.) formed Merial in 1997 by combining their animal health businesses into a fully integrated animal health company, which was a stand-alone joint venture, equally owned by each party. Merck received \$4.0 billion in cash and recorded a \$3.2 billion pretax gain in 2009 reflected in *Other income (expense), net*. Sales of products marketed by the joint venture were \$1.8 billion from January 1, 2009 until the September 17, 2009 divestiture date.

In March 2011, Merck and sanofi-aventis mutually terminated their agreement to form a new animal health joint venture. The termination of the agreement was without penalty to either party.

Investments in affiliates accounted for using the equity method, including the above joint ventures, totaled \$886 million at December 31, 2011 and \$494 million at December 31, 2010. These amounts are reported in *Other assets*. Amounts due from the above joint ventures included in *Deferred income taxes and other current assets* were \$276 million at December 31, 2011 and \$348 million at December 31, 2010.

Table of Contents

Summarized information for those affiliates (excluding the MSP Partnership and AZLP disclosed separately above) is as follows:

| <i>Years Ended December 31</i> | 2011⁽¹⁾ | 2010 | 2009 ⁽²⁾ |
|--------------------------------|---------------------------|----------|---------------------|
| Sales | \$ 1,331 | \$ 1,486 | \$ 3,767 |
| Materials and production costs | 584 | 598 | 1,225 |
| Other expense, net | 642 | 776 | 1,564 |
| Income before taxes | 105 | 112 | 978 |

| <i>December 31</i> | 2011 | 2010 |
|------------------------|---------------|--------|
| Current assets | \$ 614 | \$ 699 |
| Noncurrent assets | 75 | 254 |
| Current liabilities | 478 | 442 |
| Noncurrent liabilities | 140 | 133 |

⁽¹⁾ Includes information for JJMCP until its divestiture on September 29, 2011.

⁽²⁾ Includes information for Merial until its divestiture on September 17, 2009.

11. Loans Payable, Long-Term Debt and Other Commitments

Loans payable at December 31, 2011 included \$1.1 billion of commercial paper, \$403 million of short-term foreign borrowings and \$469 million of long-dated notes that are subject to repayment at the option of the holders. Loans payable at December 31, 2010 included \$1.5 billion of notes that were due in 2011, \$250 million of commercial paper, \$142 million of short-term foreign borrowings and \$496 million of long-dated notes that are subject to repayment at the option of the holders.

Long-term debt at December 31 consisted of:

| | 2011 | 2010 |
|--|------------------|-----------|
| 5.375% euro-denominated notes due 2014 | \$ 2,062 | \$ 2,105 |
| 6.50% notes due 2033 | 1,314 | 1,318 |
| 5.30% notes due 2013 | 1,308 | 1,337 |
| 5.00% notes due 2019 | 1,300 | 1,243 |
| 6.55% notes due 2037 | 1,148 | 1,151 |
| 3.875% notes due 2021 | 1,147 | 1,147 |
| 6.00% notes due 2017 | 1,134 | 1,109 |
| 4.00% notes due 2015 | 1,068 | 1,042 |
| 4.75% notes due 2015 | 1,064 | 1,053 |
| 2.25% notes due 2016 | 882 | 841 |
| 5.85% notes due 2039 | 749 | 749 |
| 4.375% notes due 2013 | 508 | 515 |
| 6.4% debentures due 2028 | 499 | 499 |
| 5.75% notes due 2036 | 498 | 498 |
| 5.95% debentures due 2028 | 498 | 498 |
| 6.3% debentures due 2026 | 248 | 248 |
| Other | 98 | 129 |
| | \$ 15,525 | \$ 15,482 |

Other (as presented in the table above) included \$28 million of borrowings at variable rates averaging 0.2% for 2011 and 0.4% for 2010. Other also included foreign borrowings of \$62 million and \$98 million at December 31, 2011 and 2010, respectively, at varying rates up to 8.5% for 2011 and 8.5% for 2010.

Table of Contents

With the exception of the 4.375% notes due 2013 and the 6.3% debentures due 2026, the notes listed in the table above are redeemable in whole or in part, at Merck's option at any time, at varying redemption prices.

In connection with the Merger, effective as of November 3, 2009, the Company executed a full and unconditional guarantee of the then existing debt of its subsidiary MSD and MSD executed a full and unconditional guarantee of the then existing debt of the Company (excluding commercial paper), including for payments of principal and interest. These guarantees do not extend to debt issued subsequent to the Merger.

Certain of the Company's borrowings require that Merck comply with financial covenants including a requirement that the Total Debt to Capitalization Ratio (as defined in the applicable agreements) not exceed 60%. At December 31, 2011, the Company was in compliance with these covenants.

The aggregate maturities of long-term debt for each of the next five years are as follows: 2012, \$24 million; 2013, \$1.8 billion; 2014, \$2.1 billion; 2015, \$2.1 billion; 2016, \$893 million.

In May 2011, the Company entered into a new \$2.0 billion, 364-day credit facility and a new \$2.0 billion four-year credit facility maturing in May 2015. The Company terminated its existing \$2.0 billion, 364-day credit facility which expired in May 2011 and its \$2.0 billion revolving credit facility that was scheduled to mature in August 2012. Both outstanding facilities provide backup liquidity for the Company's commercial paper borrowing facility and are to be used for general corporate purposes. The Company has not drawn funding from either facility.

Rental expense under operating leases, net of sublease income, was \$411 million in 2011, \$431 million in 2010 and \$237 million in 2009. The minimum aggregate rental commitments under noncancellable leases are as follows: 2012, \$215 million; 2013, \$157 million; 2014, \$119 million; 2015, \$98 million; 2016, \$68 million and thereafter, \$115 million. The Company has no significant capital leases.

12. 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. Except for the *Vioxx* Litigation and the *ENHANCE* Litigation (each as defined below) for which separate assessments are provided in this Note, in the opinion of the Company, it is unlikely that the resolution of these matters will be material to the Company's financial position, results of operations or cash flows.

Given the preliminary nature of the litigation discussed below, including the *Vioxx* Litigation and the *ENHANCE* Litigation, and the complexities involved in these matters, the Company is unable to reasonably estimate a possible loss or range of possible loss for such matters until the Company knows, among other factors, (i) what claims, if any, will survive dispositive motion practice, (ii) the extent of the claims, including the size of any potential class, particularly when damages are not specified or are indeterminate, (iii) how the discovery process will affect the litigation, (iv) the settlement posture of the other parties to the litigation and (v) any other factors that may have a material effect on the litigation.

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

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

Table of Contents

Vioxx Litigation

Product Liability Lawsuits

As previously disclosed, Merck is a defendant in approximately 100 federal and state lawsuits alleging personal injury or economic loss as a result of the purchase or use of *Vioxx*. Most of the remaining cases are coordinated in a multidistrict litigation in the U.S. District Court for the Eastern District of Louisiana (the *Vioxx* MDL) before Judge Eldon E. Fallon. (All of the actions discussed in this paragraph and in *Other Lawsuits* below are collectively referred to as the *Vioxx* Product Liability Lawsuits.)

There were no U.S. *Vioxx* Product Liability Lawsuits tried in 2011 and there is one currently scheduled for trial in 2012. Merck has previously disclosed the outcomes of several *Vioxx* Product Liability Lawsuits that were tried prior to 2011. All post-trial appeals are now resolved: on December 16, 2011, the Texas Supreme Court denied plaintiff's petition for review in *Ernst v. Merck*. Merck has previously disclosed the details associated with the *Ernst* case.

Other Lawsuits

There are pending in various U.S. courts putative class actions purportedly brought on behalf of individual purchasers or users of *Vioxx* seeking reimbursement for alleged economic loss. In the *Vioxx* MDL proceeding, approximately 30 such class actions remain. In June 2010, Merck moved to strike the class claims or for judgment on the pleadings regarding the master complaint, which includes the above-referenced cases, and briefing on that motion was completed in September 2010. The *Vioxx* MDL court heard oral argument on Merck's motion in October 2010 and took it under advisement.

In 2008, a Missouri state court certified a class of Missouri plaintiffs seeking reimbursement for out-of-pocket costs relating to *Vioxx*. Trial is scheduled to begin on May 21, 2012. In addition, in Indiana, plaintiffs filed a motion to certify a class of Indiana *Vioxx* purchasers in a case pending before the Circuit Court of Marion County, Indiana. In April 2010, a Kentucky state court denied Merck's motion for summary judgment and certified a class of Kentucky plaintiffs seeking reimbursement for out-of-pocket costs relating to *Vioxx*. The trial court subsequently entered an amended class certification order on January 27, 2011. Merck appealed that order to the Kentucky Court of Appeals and on February 10, 2012, the Kentucky Court of Appeals reversed the trial court's amended class certification order and denied certification of a class of Kentucky plaintiffs.

Merck has also been named as a defendant in several lawsuits brought by, or on behalf of, government entities. Eleven of these suits are being brought by state Attorneys General and one has been brought on behalf of a county. All of these actions are in the *Vioxx* MDL proceeding. These actions allege that Merck misrepresented the safety of *Vioxx*. All but one of these suits seek recovery for expenditures on *Vioxx* by government-funded health care programs, such as Medicaid, along with other relief, such as penalties and attorneys' fees. An action brought by the Attorney General of Kentucky seeks only penalties for alleged Consumer Fraud Act violations. Judge Fallon remanded the Kentucky case to state court on January 3, 2012. Merck is appealing that decision. The lawsuit brought by the county is a putative class action filed by Santa Clara County, California on behalf of all similarly situated California counties. Merck moved for judgment on the pleadings in the case brought by Santa Clara County in September 2011, and the court heard oral argument on the motion on January 18, 2012. In addition, Merck moved to dismiss the case brought by the Attorney General of Oklahoma in December 2010.

In March 2010, Judge Fallon partially granted and partially denied Merck's motion for summary judgment in the Louisiana Attorney General case. A trial on the remaining claims before Judge Fallon was completed in April 2010 and Judge Fallon found in favor of Merck in June 2010 dismissing the Louisiana Attorney General's remaining claims with prejudice. The Louisiana Attorney General filed a notice of appeal, and the Fifth Circuit dismissed the appeal without prejudice pursuant to its scheduling rules in October 2011 after the Louisiana Attorney General requested a stay of the appeal.

Shareholder Lawsuits

As previously disclosed, in addition to the *Vioxx* Product Liability Lawsuits, various putative class actions and individual lawsuits under federal securities laws and state laws have been filed against Merck and various current and former officers and directors (the *Vioxx* Securities Lawsuits). The *Vioxx* Securities Lawsuits are coordinated in a multidistrict litigation in the U.S. District Court for the District of New Jersey before Judge

Table of Contents

Stanley R. Chesler, and have been consolidated for all purposes. On August 8, 2011, Judge Chesler granted in part and denied in part Merck's motion to dismiss the Fifth Amended Class Action Complaint in the consolidated securities action. Among other things, the claims based on statements made on or after the voluntary withdrawal of *Vioxx* on September 30, 2004 have been dismissed. On October 7, 2011, defendants answered the Fifth Amended Class Action Complaint. Discovery is currently proceeding in accordance with the court's scheduling order. Under the scheduling order, plaintiff's class certification motion must be filed by April 10, 2012, and fact discovery must be completed by March 13, 2013.

As previously disclosed, several individual securities lawsuits filed by foreign institutional investors also are consolidated with the *Vioxx* Securities Lawsuits. In October 2011, plaintiff's filed amended complaints in each of the pending individual securities lawsuits. Also in October 2011, a new individual securities lawsuit was filed in the District of New Jersey by several foreign institutional investors; that case is also consolidated with the *Vioxx* Securities Lawsuits. On January 20, 2012, defendants filed motions to dismiss in one of the individual lawsuits (the ABP Lawsuit). By stipulation and order, defendants are not required to respond to the complaints in the remaining individual securities lawsuits until the resolution of any motions to dismiss in the ABP Lawsuit.

In addition, as previously disclosed, various putative class actions had been filed in federal court under the Employee Retirement Income Security Act (ERISA) against Merck and certain current and former officers and directors (the *Vioxx* ERISA Lawsuits). Those cases were consolidated before Judge Chesler. On August 16, 2011, the parties reached an agreement in principle in which Merck would pay \$49.5 million to settle the *Vioxx* ERISA Lawsuits. On November 29, 2011, Judge Chesler granted final approval of the settlement and dismissed the *Vioxx* ERISA Lawsuits with prejudice.

International Lawsuits

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

Following trial of a representative action in 2009, a first instance judge of the Federal Court in Australia entered orders in 2010 that dismissed all claims against Merck. With regard to Merck's Australian subsidiary, Merck Sharp & Dohme (Australia) Pty Ltd (MSD Australia), the court dismissed certain claims but awarded the applicant, whom the court found suffered a myocardial infarction (MI) after ingesting *Vioxx* for approximately 33 months, AU \$330,465 based on statutory claims that *Vioxx* was not fit for purpose or of merchantable quality, even though the court rejected the applicant's claim that Merck and MSD Australia knew or ought to have known prior to the voluntary withdrawal of *Vioxx* in September 2004 that *Vioxx* materially increased the risk of MI. The court also determined which of its findings of fact and law were common to the claims of other group members whose individual claims would proceed with reference to those findings. MSD Australia appealed the adverse findings and the Full Federal Court (the Full Court) heard the appeal and a cross-appeal in August 2011. In October 2011, the Full Court allowed MSD Australia's appeal and set aside the judgment in favor of the applicant and dismissed his action. The Full Court held that *Vioxx* was not proven to be the cause of the applicant's MI and that MSD Australia is not liable to the applicant for damages in negligence or under the former Trade Practices Act. The Full Court also affirmed the first instance decision in favor of MSD Australia on the applicant's statutory defect claim, holding that MSD Australia's state of the art defense was proven based on the development of scientific knowledge over time. The effect of this decision upon the claims of the remaining group members remains to be determined. The applicant is seeking leave to appeal the Full Court's judgment to the High Court of Australia.

On January 19, 2012, Merck announced that it had entered into an agreement (the Canada Settlement Agreement) to resolve all claims (including certain class actions and putative class actions) related to *Vioxx* in Canada. The agreement is pending approval by courts in Canada's provinces.

If the Canada Settlement Agreement is approved and specified conditions (including among others a right of Merck to terminate if there are opt-outs) are met, which conditions are set forth in certain Merck termination rights and accordingly may be waived by Merck, Merck would make payments aggregating from a minimum of C\$21,806,250 (approximately \$21.5 million U.S. dollars at December 31, 2011) up to a maximum of C\$36,881,250 (approximately \$36.3 million U.S. dollars at December 31, 2011) (the Canada Settlement Amount). The exact Canada Settlement Amount will depend on the number of individuals who submit

Table of Contents

documented claims and are determined to meet certain threshold Gates relating to the alleged injury event and alleged usage of *Vioxx*. In addition to payments to eligible claimants who experienced a diagnosed MI, sudden cardiac death or diagnosed ischemic stroke, the settlement also includes fixed payments of C\$3,500,000 to provinces and territories, C\$6,000,000 towards class counsel fees and C\$1,000,000 for administrative expenses involved in the implementation of the Canada Settlement Agreement; should approved legal fees or administrative expenses exceed the specified amounts, any excess would be paid from the amount to be funded for eligible claimants and derivative claimants. The Company recorded a reserve in the fourth quarter of 2011 for this settlement.

The Canada Settlement Agreement provides that Merck denies all allegations, denies that any damages are payable and does not concede or admit any liability. Merck will not make any payment, other than to pay notice dissemination costs and certain other administrative costs, unless and until approvals by courts in all Canada's provinces have been secured and all termination rights have expired without Merck having terminated the Canada Settlement Agreement in its entirety. Merck also has certain rights to terminate the Canada Settlement Agreement in part, in relation to provinces or territories other than Ontario or Quebec.

Insurance

The Company has Directors and Officers insurance coverage applicable to the *Vioxx* Securities Lawsuits with remaining stated upper limits of approximately \$175 million. As a result of the previously disclosed insurance 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, Merck received subpoenas from the Department of Justice (DOJ) requesting information related to Merck's research, marketing and selling activities with respect to *Vioxx* in a federal health care investigation under criminal statutes. As previously disclosed, in March 2009, Merck received a letter from the U.S. Attorney's Office for the District of Massachusetts identifying it as a target of the grand jury investigation regarding *Vioxx*. In 2010, the Company established a \$950 million reserve (the *Vioxx* Liability Reserve) in connection with the anticipated resolution of the DOJ's investigation.

On November 22, 2011, the Company announced that it had reached a resolution with federal and state authorities regarding this matter, pending court approval. Under civil settlement agreements signed with the United States and individually with 44 states and the District of Columbia, Merck will pay approximately two-thirds of the *Vioxx* Liability Reserve to resolve civil allegations related to *Vioxx*. As a result, the United States and the participating states have released Merck from civil liability related to the government's allegations regarding the sale and promotion of *Vioxx*. The Company also has agreed to plead guilty to one count of misdemeanor misbranding of *Vioxx* under the Federal Food, Drug, and Cosmetic Act by promoting the drug for the treatment of rheumatoid arthritis prior to the FDA's approval of that indication in April 2002. The Company will pay a fine of approximately one-third of the *Vioxx* Liability Reserve to the federal government as part of the plea agreement.

On December 16, 2011, the U.S. District Court for the District of Massachusetts conducted a hearing with regard to the resolution. During that hearing, the parties advised the court as to the nature of the resolution and the core documents comprising the resolution. The court scheduled a subsequent hearing for March 2012, during which the court may issue a ruling concerning whether it accepts Merck's plea and the resolution.

Reserves

The Company believes that it has meritorious defenses to the *Vioxx* Product Liability Lawsuits, *Vioxx* Securities Lawsuits and *Vioxx* Foreign Lawsuits (collectively, 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 remaining *Vioxx* Lawsuits. As noted above, the Company has established the *Vioxx* Liability Reserve and a reserve

Table of Contents

with respect to the Canada Settlement Agreement. The Company has established no other liability reserves with respect to the *Vioxx* Litigation. Unfavorable outcomes in the *Vioxx* Litigation could have a material adverse effect on the Company's financial position, liquidity and results of operations.

Other Product Liability Litigation

Fosamax

As previously disclosed, Merck is a defendant in product liability lawsuits in the United States involving *Fosamax* (the *Fosamax* Litigation). As of December 31, 2011, approximately 2,345 cases, which include approximately 2,800 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 approximately 1,180 of these actions, plaintiffs allege, among other things, that they have suffered osteonecrosis of the jaw (ONJ), generally subsequent to invasive dental procedures, such as tooth extraction or dental implants and/or delayed healing, in association with the use of *Fosamax*. In addition, plaintiffs in approximately 1,165 of these actions generally allege that they sustained femur fractures and/or other bone injuries in association with the use of *Fosamax*.

Cases Alleging ONJ and/or Other Jaw Related Injuries

In August 2006, the Judicial Panel on Multidistrict Litigation (the JPML) ordered that certain *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 U.S. District Court for the Southern District of New York. As a result of the JPML order, approximately 945 of the cases are before Judge Keenan. Judge Keenan issued a Case Management Order (and various amendments thereto) which set forth a schedule governing the proceedings 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. In the first *Fosamax* MDL trial, *Boles v. Merck*, the *Fosamax* MDL court declared a mistrial because the eight person jury could not reach a unanimous verdict. The *Boles* case was retried in June 2010 and resulted in a verdict in favor of the plaintiff in the amount of \$8 million. Merck filed post-trial motions seeking judgment as a matter of law or, in the alternative, a new trial. In October 2010, the court denied Merck's post-trial motions but *sua sponte* ordered a remittitur reducing the verdict to \$1.5 million. Plaintiff rejected the remittitur ordered by the court and requested a new trial on damages, which is scheduled to take place on September 10, 2012. Merck intends to appeal the verdict in *Boles* after the new trial on damages has concluded.

In the next *Fosamax* MDL trial, *Maley v. Merck*, the jury in May 2010 returned a unanimous verdict in Merck's favor. In February 2010, Judge Keenan selected a new bellwether case, *Judith Graves v. Merck*, to replace the *Flemings v. Merck* bellwether case, which the *Fosamax* MDL court dismissed when it granted summary judgment in favor of Merck. In November 2010, the Second Circuit affirmed the court's granting of summary judgment in favor of Merck in the *Flemings* case. In *Graves*, the jury returned a unanimous verdict in favor of Merck in November 2010. The jury in *Secrest v. Merck* returned a unanimous verdict in favor of Merck in October 2011.

The next trial scheduled in the *Fosamax* MDL was *Raber v. Merck*, which was subsequently dismissed. In addition, in February 2011, Judge Keenan ordered that there will be two further bellwether trials conducted in the *Fosamax* MDL: *Spano v. Merck* is scheduled to be tried on May 7, 2012; *Jellema v. Merck* was scheduled to be tried on May 7, 2012, but was dismissed by the plaintiff. A replacement case will be selected in the first quarter of 2012 and that case will be tried beginning on November 13, 2012.

Outside the *Fosamax* MDL, a trial in Florida, *Anderson v. Merck*, was scheduled to begin in June 2010 but the Florida state court postponed the trial date and a new date has been set for January 14, 2013. The trial ready date in *Carballo v. Merck* has been continued from August 22, 2011 until April 30, 2012. The *Ward v. Merck* case is scheduled to be tried on June 11, 2012.

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. In October 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

Table of Contents

existing dental and jaw-related injuries, including ONJ, but not solely seeking medical monitoring, be designated as a mass tort for centralized management purposes before Judge Carol E. Higbee in Atlantic County Superior Court. As of December 31, 2011, approximately 225 ONJ cases were pending against Merck in Atlantic County, New Jersey. In July 2009, Judge Higbee entered a Case Management Order (and various amendments thereto) setting forth a schedule that contemplates completing fact and expert discovery in an initial group of cases to be reviewed for trial. In February 2011, the jury in *Rosenberg v. Merck*, the first trial in the New Jersey coordinated proceeding, returned a verdict in Merck's favor. A trial in the *Sessner v. Merck* case commenced on February 27, 2012. The *Flores v. Merck* case was scheduled to be tried jointly with *Sessner v. Merck*, but on February 27, 2012, Judge Higbee severed the *Flores* case from the *Sessner* trial. The *Flores* trial will be rescheduled.

In California, the parties are reviewing the claims of three plaintiffs in the *Carrie Smith, et al. v. Merck* case and the claims in *Pedrojetti v. Merck*. The cases of one or more of these plaintiffs are expected to be tried in mid-2012.

Discovery is ongoing in the *Fosamax* MDL litigation, the New Jersey coordinated proceeding, and the remaining jurisdictions where *Fosamax* cases are pending. The Company intends to defend against these lawsuits.

Cases Alleging Femur Fractures and/or Other Bone Injuries

As of December 31, 2011, approximately 825 cases alleging femur fractures and/or other bone injuries have been filed in New Jersey state court and are pending before Judge Higbee in Atlantic County Superior Court. The parties have selected an initial group of 30 cases to be reviewed through fact discovery. Plaintiffs subsequently dismissed or advised that they will dismiss seven of the cases that were selected and discovery in the remaining cases is continuing. No trial dates for any of the New Jersey state femur fracture cases have been set.

In March 2011, Merck submitted a Motion to Transfer to the JPML seeking to have all federal cases alleging femur fractures and other bone injuries consolidated into one multidistrict litigation for coordinated pre-trial proceedings. The Motion to Transfer was granted in May 2011, and all federal cases involving allegations of femur fracture or other bone injuries have been or will be transferred to the District of New Jersey where the *Fosamax* MDL is sited. Judge Garrett Brown was initially assigned to preside over this second *Fosamax* MDL proceeding, but Judge Joel Pisano was assigned to preside over the litigation in November 2011 due to Judge Brown's retirement. A Case Management Order has been entered that requires the parties to review 40 cases (later reduced to 33 cases) with a fact discovery deadline of July 31, 2012, an expert discovery deadline of November 28, 2012, and a projected trial date for the first case to be tried sometime after March 1, 2013.

A petition was filed seeking to coordinate all femur fracture cases filed in California state court before a single judge in Orange County, California. The petition was granted and Judge Ronald L. Bauer has been appointed to preside over the coordinated proceedings, but he is expected to be replaced by Judge Steven Perk in 2012. No scheduling order has yet been entered.

Additionally, there are four femur fracture cases pending in other state courts and one femur fracture case pending in federal court outside of the MDL. One case each is pending in the state courts of Massachusetts, Florida, Alabama, and Georgia, and one is pending in federal court in Texas. There is also one osteonecrosis of the hip case pending in federal court in Idaho.

Discovery is ongoing in the federal and state courts where femur fracture cases are pending and the Company intends to defend against these lawsuits.

NuvaRing

As previously disclosed, beginning in May 2007, a number of complaints were filed in various jurisdictions asserting claims against the Company's subsidiaries Organon USA, Inc., Organon Pharmaceuticals USA, Inc., Organon International (collectively, "Organon"), and Schering-Plough arising from Organon's marketing and sale of *NuvaRing*, a combined hormonal contraceptive vaginal ring. The plaintiffs contend that Organon and Schering-Plough, among other things, failed to adequately design and manufacture *NuvaRing* and failed to adequately warn of the alleged increased risk of venous thromboembolism ("VTE") posed by *NuvaRing*, and/or downplayed the risk of VTE. The plaintiffs seek damages for injuries allegedly sustained from their product use, including some alleged deaths, heart attacks and strokes. The majority of the cases are currently pending in a federal multidistrict litigation (the "*NuvaRing* MDL") venued in Missouri and in a coordinated proceeding in New Jersey state court.

Table of Contents

As of December 31, 2011, there were approximately 950 *NuvaRing* cases. Of these cases, approximately 820 are or will be pending in the *NuvaRing* MDL in the U.S. District Court for the Eastern District of Missouri before Judge Rodney Sippel, and approximately 125 are pending in coordinated discovery proceedings in the Bergen County Superior Court of New Jersey before Judge Brian R. Martinotti. Four additional cases are pending in various other state courts.

Pursuant to orders of Judge Sippel in the *NuvaRing* MDL, the parties originally selected a pool of more than twenty cases to prepare for trial and that pool has since been narrowed to eight cases from which the first trials in the *NuvaRing* MDL will be selected. Pursuant to Judge Martinotti's order in the New Jersey proceeding, the parties selected ten trial pool cases to be prepared for trial. The parties have completed fact discovery in the originally selected trial pool cases in each jurisdiction and the Company anticipates expert discovery to be completed in those first trial pool cases by the summer of 2012. Certain of the cases in the original trial pool have been voluntarily dismissed and in two cases judgment was entered in Merck's favor. As a result, certain replacement trial pool cases remain in fact discovery. Moreover, on January 31, 2012, the parties in the New Jersey coordinated proceeding selected an additional 10 trial pool cases for completion of fact discovery.

The Company anticipates that status conferences will be held in each coordinated proceeding following the completion of expert discovery in the summer of 2012 to determine a methodology for selecting the first cases to be tried. At that time, the parties will also discuss the time frame for filing motions relating to admissibility of expert testimony and causation. The Company intends to defend against these lawsuits.

Propecia/Proscar

As previously disclosed, Merck is a defendant in product liability lawsuits in the United States involving *Propecia* and/or *Proscar*. As of December 31, 2011, approximately 70 lawsuits involving a total of approximately 170 plaintiffs (in a few instances spouses are joined in the suits) who allege that they have experienced persistent sexual side effects following cessation of treatment with *Propecia* and/or *Proscar* have been filed against Merck. The lawsuits, which are in their early stages, are pending in federal courts in New Jersey, Washington, Washington D.C., Florida, Illinois, Colorado, Missouri and Ohio, and in state court in New Jersey. Certain of the federal plaintiffs have petitioned the JPML to have the federal lawsuits consolidated for pretrial purposes, and certain of the New Jersey state court plaintiffs have petitioned for consolidation of the New Jersey state court cases. Resolution of these motions remains pending. The Company intends to defend against these lawsuits.

Governmental Proceedings

Effective August 2, 2010, Merck and the U.S. Department of Health & Human Services Office of Inspector General (HHS-OIG) executed a Unified Corporate Integrity Agreement (Unified CIA) which replaced the individual CIAs that had been signed by Merck and Schering-Plough prior to the Merger. The Unified CIA incorporated certain of the requirements of the individual CIAs of Merck and Schering-Plough and was similar, although not identical, to those legacy CIAs. Merck assumed the compliance obligations of the Unified CIA through February 5, 2013. Effective November 22, 2011, Merck and HHS-OIG executed a New Corporate Integrity Agreement (the New CIA), which replaced the Unified CIA and has a term of five years.

As previously disclosed, Merck has received a Civil Investigative Demand (CID) issued by the DOJ addressed to Inspire Pharmaceuticals, Inc., a company acquired by Merck in May 2011. The CID advises that it relates to a False Claims Act investigation concerning allegations that Inspire caused the submission of false claims to federal health benefits programs for the drug AzaSite by marketing it for the treatment of indications not approved by the FDA. The Company is cooperating with the government in its investigation.

As previously disclosed, the Company has received a subpoena from the DOJ requesting information relating to the Company's marketing and selling activities with respect to *Integrilin* and *Avelox*, from January 2003 to June 2010, in a civil federal health care investigation. The Company has also previously disclosed that it has received a subpoena requesting information related to the Company's marketing and selling activities with respect to *Temodar*, *PegIntron* and *Intron A*, from January 1, 2004 to the present, in a federal health care investigation under criminal statutes. The Company is cooperating with the DOJ's investigations.

Table of Contents

As previously disclosed, the Company has received letters from the DOJ and the SEC that seek information about activities in a number of countries and reference the Foreign Corrupt Practices Act. The Company is cooperating with the agencies in their requests and believes that this inquiry is part of a broader review of pharmaceutical industry practices in foreign countries. In that regard, the Company has received and may continue to receive additional requests for information from either or both of the DOJ and the SEC.

Vytorin/Zetia Litigation

As previously disclosed, in April 2008, a Merck shareholder filed a putative class action lawsuit in federal court which has been consolidated in the District of New Jersey with another federal securities lawsuit under the caption *In re Merck & Co., Inc. Vytorin Securities Litigation*. An amended consolidated complaint was filed in October 2008 and named as defendants Merck; Merck/Schering-Plough Pharmaceuticals, LLC; and certain of the Company's current and former officers and directors. The complaint alleges that Merck delayed releasing unfavorable results of the ENHANCE clinical trial regarding the efficacy of *Vytorin* and that Merck made false and misleading statements about expected earnings, knowing that once the results of the ENHANCE study were released, sales of *Vytorin* would decline and Merck's earnings would suffer. In December 2008, Merck and the other defendants moved to dismiss this lawsuit on the grounds that the plaintiffs failed to state a claim for which relief can be granted. In September 2009, the court denied defendants' motion to dismiss. In June 2011, lead plaintiffs filed a motion for leave to further amend the consolidated complaint, which was granted on February 7, 2012. The parties are currently briefing lead plaintiffs' motion for class certification.

There is a similar consolidated, putative class action securities lawsuit pending in the District of New Jersey, filed by a Schering-Plough shareholder against Schering-Plough and its former Chairman, President and Chief Executive Officer, Fred Hassan, under the caption *In re Schering-Plough Corporation/ENHANCE Securities Litigation*. The amended consolidated complaint was filed in September 2008 and names as defendants Schering-Plough; Merck/Schering-Plough Pharmaceuticals; certain of the Company's current and former officers and directors; and underwriters who participated in an August 2007 public offering of Schering-Plough's common and preferred stock. In December 2008, Schering-Plough and the other defendants filed motions to dismiss this lawsuit on the grounds that the plaintiffs failed to state a claim for which relief can be granted. In September 2009, the court denied defendants' motion to dismiss. The parties are currently briefing lead plaintiffs' motion for class certification.

As previously disclosed, in April 2008, a member of a Merck ERISA plan filed a putative class action lawsuit against Merck and certain of the Company's current and former officers and directors alleging they breached their fiduciary duties under ERISA. Since that time, there have been other similar ERISA lawsuits filed against Merck 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*. A consolidated amended complaint was filed in February 2009, and names as defendants Merck and various current and former members of the Company's Board of Directors. The plaintiffs allege that the ERISA plans investment in Merck stock was imprudent because Merck's earnings were 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. In April 2009, Merck and the other defendants moved to dismiss this lawsuit on the grounds that the plaintiffs failed to state a claim for which relief can be granted. In September 2009, the court denied defendants' motion to dismiss.

There is a similar consolidated, putative class action ERISA lawsuit currently pending in the District of New Jersey, filed by a member of a Schering-Plough ERISA plan against Schering-Plough and certain of its current and former officers and directors, alleging they breached their fiduciary duties under ERISA, and under the caption *In re Schering-Plough Corp. ENHANCE ERISA Litigation*. The consolidated amended complaint was filed in October 2009 and names as defendants Schering-Plough, various then-current and former members of Schering-Plough's Board of Directors and then-current and former members of committees of Schering-Plough's Board of Directors. In November 2009, the Company and the other defendants filed a motion to dismiss this lawsuit on the grounds that the plaintiffs failed to state a claim for which relief can be granted. That motion was denied in June 2010. On November 4, 2011, the parties reached an agreement in principle to settle the matter. On November 7, 2011, the parties informed the court that they would submit a motion for preliminary approval of the settlement on a

Table of Contents

class-wide basis. On November 14, 2011, the court ordered the case dismissed without costs and without prejudice to the right, upon good cause shown within 60 days, to seek to reopen the action if the settlement is not consummated. On January 9, 2012, the court extended that 60-day period by an additional 60 days.

In November 2009, a stockholder of the Company filed a shareholder derivative lawsuit, *In re Local No. 38 International Brotherhood of Electrical Workers Pension Fund v. Clark* (*Local No. 38*), in the District of New Jersey, on behalf of the nominal defendant, the Company, and all shareholders of the Company, against the Company; certain of the Company's officers, directors and alleged insiders; and certain of the predecessor companies' former officers, directors and alleged insiders for alleged breaches of fiduciary duties, waste, unjust enrichment and gross mismanagement. A similar shareholder derivative lawsuit, *Cain v. Hassan*, was filed by a Schering-Plough stockholder in the District of New Jersey. This lawsuit is against the Company, Schering-Plough's then-current Board of Directors, and certain of the Company's then-current and former officers, directors and alleged insiders. The plaintiffs in both *Local No. 38* and *Cain v. Hassan* alleged that the defendants withheld the ENHANCE study results and made false and misleading statements, thereby deceiving and causing harm to the Company and Schering-Plough, respectively, and to the investing public, unjustly enriching insiders and wasting corporate assets. The plaintiff in *Local No. 38* voluntarily dismissed that suit without prejudice in July 2011. Also in July 2011, the intervenor-plaintiff in the *Cain v. Hassan* action filed a second amended complaint. The defendants moved to dismiss the second amended complaint in October 2011. In December 2011, the parties in *Cain v. Hassan* executed a stipulation of settlement that would terminate the litigation, and plaintiff moved for approval of the settlement. The proposed settlement does not include payment of any monetary consideration, other than immaterial legal fees to plaintiffs' counsel. A hearing will be held on February 28, 2012 on the motion for approval of the settlement.

In November 2010, a Company shareholder filed a derivative lawsuit in state court in New Jersey. This case, captioned *Rose v. Hassan*, asserts claims that are substantially identical to the claims alleged in *Cain v. Hassan*. In April 2011, the defendants in *Rose v. Hassan* moved to stay the case or to dismiss it without prejudice in favor of the federal derivative action. In August 2011, the New Jersey state court dismissed *Rose v. Hassan* without prejudice. In September 2011, the plaintiff in *Rose v. Hassan* filed a notice of appeal. On January 17, 2012, plaintiff moved for an additional 60 days to file an appeal brief in the event that the *Cain v. Hassan* settlement is not approved.

Discovery in the federal lawsuits referred to in this section (collectively, the ENHANCE Litigation) has been coordinated and is substantially complete. The Company believes that it has meritorious defenses to the ENHANCE Litigation and intends to vigorously defend against these lawsuits. 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 ENHANCE Litigation. Unfavorable outcomes resulting from the ENHANCE Litigation could have a material adverse effect on the Company's financial position, liquidity and results of operations.

Insurance

The Company has Directors and Officers insurance coverage applicable to the *Vytorin* shareholder lawsuits brought by legacy Schering-Plough shareholders with stated upper limits of approximately \$250 million. The Company has Fiduciary and other insurance for the *Vytorin* ERISA lawsuits with stated upper limits of approximately \$265 million. 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 limits.

Commercial Litigation

AWP Litigation

As previously disclosed, the Company and/or certain of its subsidiaries remain defendants in cases brought by various states alleging manipulation by pharmaceutical manufacturers of Average Wholesale Prices (AWP), which are sometimes used by public and private payors in calculating provider reimbursement levels. The outcome of these lawsuits could include substantial damages, the imposition of substantial fines and penalties and injunctive or administrative remedies.

Table of Contents

During 2011, the Company settled certain AWP cases brought by the states of Utah, South Carolina, Alaska, Idaho, Kentucky, Pennsylvania, Mississippi, Wisconsin, Iowa, and Massachusetts and by certain New York counties. The Company and/or certain of its subsidiaries continue to be defendants in cases brought by 10 states.

K-DUR Antitrust Litigation

As previously disclosed, in June 1997 and January 1998, Schering-Plough settled patent litigation with Upsher-Smith, Inc. (Upsher-Smith) and ESI Lederle, Inc. (Lederle), respectively, relating to generic versions of K-DUR, Schering-Plough's long-acting potassium chloride product supplement used by cardiac patients, for which Lederle and Upsher-Smith had filed Abbreviated New Drug Applications (ANDAs). Following the commencement of an administrative proceeding by the United States Federal Trade Commission (the FTC) in 2001 alleging anti-competitive effects from those settlements (which has been resolved in Schering-Plough's favor), putative class and non-class action suits were filed on behalf of direct and indirect purchasers of K-DUR against Schering-Plough, Upsher-Smith and Lederle and were consolidated in a multi-district litigation in the U.S. District Court for the District of New Jersey. These suits claimed violations of federal and state antitrust laws, as well as other state statutory and common law causes of action, and sought unspecified damages. In April 2008, the indirect purchasers voluntarily dismissed their case. In February 2009, a Special Master recommended that the District Court dismiss the remaining lawsuits on summary judgment and, in March 2010, the District Court adopted the recommendation, granted summary judgment to the defendants, and dismissed the matter in its entirety. Plaintiffs have appealed this decision to the Third Circuit Court of Appeals. Defendants are simultaneously appealing a December 2008 decision by the District Court to certify certain direct purchaser plaintiffs' claims as a class action.

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. To protect its patent rights, the Company may file patent infringement lawsuits against such generic companies. Certain products of the Company (or marketed via agreements with other companies) currently involved in such patent infringement litigation in the United States include: AzaSite, *Cancidas*, *Nasonex*, Nexium, *Noxafil*, *Vytorin* and *Zetia*. Similar lawsuits defending the Company's patent rights may exist in other countries. 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 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 and, with respect to legacy Schering-Plough products, potentially significant intangible asset impairment charges.

AzaSite In May 2011, a patent infringement suit was filed in the United States against Sandoz Inc. (Sandoz) in respect of Sandoz's application to the FDA seeking pre-patent expiry approval to market a generic version of AzaSite. The lawsuit automatically stays FDA approval of Sandoz's ANDA until October 2013 or until an adverse court decision, if any, whichever may occur earlier.

Cancidas In November 2009, a patent infringement lawsuit was filed in the United States against Teva Parenteral Medicines, Inc. (TPM) in respect of TPM's application to the FDA seeking pre-patent expiry approval to sell a generic version of *Cancidas*. That lawsuit has been dismissed with no rights granted to TPM. Also, in March 2010, a patent infringement lawsuit was filed in the United States against Sandoz in respect of Sandoz's application to the FDA seeking pre-patent expiry approval to sell a generic version of *Cancidas*. In June 2011, Sandoz amended its challenge to Merck's *Cancidas* patents stating that it did not seek FDA approval any earlier than the expiry of a patent which occurs on July 26, 2015, but Sandoz did maintain its challenge to a *Cancidas* patent which expires on September 28, 2017. Therefore, the lawsuit will continue, however, the FDA cannot approve Sandoz's application any earlier than July 26, 2015.

Integrilin In February 2009, a patent infringement lawsuit was filed (jointly with Millennium Pharmaceuticals, Inc.) in the United States against TPM in respect of TPM's application to the FDA seeking approval to sell a generic version of *Integrilin* prior to the expiry of the last to expire listed patent. In October 2011, the parties entered a settlement agreement allowing TPM to sell a generic version of *Integrilin* beginning June 2, 2015.

Table of Contents

Nasonex In December 2009, a patent infringement suit was filed in the United States against Apotex Corp. (Apotex) in respect of Apotex s application to the FDA seeking pre-patent expiry approval to market a generic version of *Nasonex*. The lawsuit automatically stays FDA approval of Apotex s ANDA until May 2012 or until an adverse court decision, if any, whichever may occur earlier. A trial is expected to take place during 2012.

Nexium In November 2005, a patent infringement lawsuit was filed (jointly with AstraZeneca) in the United States against Ranbaxy Laboratories Ltd. (Ranbaxy) in respect of Ranbaxy s application to the FDA seeking pre-patent expiry approval to sell a generic version of Nexium. As previously disclosed, AstraZeneca, Merck and Ranbaxy entered into a settlement agreement which provided that Ranbaxy will be entitled to bring its generic esomeprazole product to market in the United States on May 27, 2014. The Company and AstraZeneca each received a CID from the FTC in July 2008 regarding the settlement agreement with Ranbaxy. The Company is cooperating with the FTC in responding to this CID. In March 2006, a patent infringement lawsuit was filed (jointly with AstraZeneca) against IVAX Pharmaceuticals, Inc. (IVAX) (later acquired by Teva Pharmaceuticals, Inc. (Teva)), in respect of IVAX s application to the FDA seeking pre-patent expiry approval to sell a generic version of Nexium. In January 2010, AstraZeneca, Merck and Teva/IVAX entered into a settlement agreement which provides that Teva/IVAX will be entitled to bring its generic esomeprazole product to market in the United States on May 27, 2014. Patent infringement lawsuits have also been filed in the United States against Dr. Reddy s Laboratories (Dr. Reddy s), Sandoz and Lupin Ltd. (Lupin) in respect to their respective applications to the FDA seeking pre-patent expiry approval to sell generic versions of Nexium. In January 2011, AstraZeneca, Merck and Dr. Reddy s entered into a settlement agreement which provides that Dr. Reddy s will be entitled to bring its generic esomeprazole product to market in the United States on May 27, 2014. In June 2011, AstraZeneca, Merck and Sandoz entered into a settlement agreement which provides that Sandoz will be entitled to bring its generic esomeprazole product to market in the United States on May 27, 2014. In January 2012, AstraZeneca, Merck and Lupin entered into a settlement agreement which provides that Lupin will be entitled to bring its generic esomeprazole product to market in the United States on May 27, 2014. In February 2011, a patent infringement lawsuit was filed (jointly with AstraZeneca) in the United States against Hamni USA, Inc. (Hamni) in respect of Hamni s application to the FDA seeking pre-patent expiry approval to sell a generic version of Nexium. In August 2011, a patent infringement lawsuit was filed (jointly with AstraZeneca) in the United States against Hetero Drugs, Ltd., Unit III (Hetero) in respect of Hetero s application to the FDA seeking pre-patent expiry approval to sell a generic version of Nexium. In January 2012, a patent infringement lawsuit was filed (jointly with AstraZeneca) in the United States against Torrent Pharmaceuticals Ltd. (Torrent) in respect of Torrent s application to the FDA seeking pre-patent expiry approval to sell a generic version of Nexium. A patent infringement lawsuit was also filed (jointly with AstraZeneca) in February 2010 in the United States against Sun Pharma Global Fze (Sun Pharma) in respect of its application to the FDA seeking pre-patent expiry approval to sell a generic version of Nexium IV. In October 2011, AstraZeneca, Merck and Sun Pharma entered into a settlement agreement which provides that Sun Pharma will be entitled to bring its generic esomeprazole IV product to market in the United States on January 1, 2014.

Noxafil In May 2011, a patent infringement suit was filed in the United States against Sandoz in respect of Sandoz s application to the FDA seeking pre-patent expiry approval to market a generic version of *Noxafil*. The lawsuit automatically stays FDA approval of Sandoz s ANDA until September 2013 or until an adverse court decision, if any, whichever may occur earlier.

NuvaRing In February 2011, a patent infringement suit was brought against Merck in the International Trade Commission (the ITC) by Femina Pharma Incorporated (Femina) in respect of the product *NuvaRing*. The complaint alleged that *NuvaRing* infringes a patent owned by Femina. Femina s ITC complaint sought an exclusion order against the importation of *NuvaRing* into the United States. A hearing began in the ITC proceeding on January 17, 2012 and on January 18, 2012 Femina withdrew its complaint and terminated the action. In addition, in November 2011, Femina brought a patent infringement lawsuit against Merck in the Eastern District of Virginia asserting that *NuvaRing* infringes the same patent. That case was stayed pending the outcome of the ITC proceeding and the Company believes that Femina intends to pursue the litigation in the Eastern District of Virginia.

Propecia In December 2010, a patent infringement lawsuit was filed in the United States against Hetero Drugs Limited (Hetero) in respect of Hetero s application to the FDA seeking pre-patent expiry approval to sell a generic version of *Propecia*. In March 2011, the Company settled this lawsuit with Hetero by agreeing to allow Hetero to sell a generic 1 mg finasteride product beginning on July 1, 2013.

Table of Contents

Temodar In July 2007, a patent infringement action was filed (jointly with Cancer Research Technologies, Limited (CRT)) in the United States against Barr Laboratories (Barr) (later acquired by Teva) in respect of Barr's application to the FDA seeking pre-patent expiry approval to sell a generic version of *Temodar*. In January 2010, the court issued a decision finding the CRT patent unenforceable on grounds of prosecution laches and inequitable conduct. In November 2010, the appeals court issued a decision reversing the trial court's finding. In December 2010, Barr filed a petition seeking a rehearing *en banc* of the appeal, which petition was denied. In June 2011, Barr filed a petition for review by the U.S. Supreme Court, which was denied. By virtue of an agreement that Barr not launch a product during the appeal process, the Company has agreed that Barr can launch a product in August 2013.

In September 2010, a patent infringement lawsuit was filed (jointly with CRT) in the United States against Sun Pharmaceutical Industries Inc. (Sun) in respect of Sun's application to the FDA seeking pre-patent expiry approval to sell a generic version of *Temodar*. The lawsuit automatically stayed FDA approval of Sun's ANDA until February 2013 or until an adverse court decision, if any, whichever may occur earlier. In November 2010, a patent infringement lawsuit was filed (jointly with CRT) in the United States against Accord HealthCare Inc. (Accord) in respect of its application to the FDA seeking pre-patent expiry approval to sell a generic version of *Temodar*. The lawsuit automatically stayed FDA approval of Accord's application until April 13, 2013 or until an adverse court decision, if any, whichever may occur earlier. The Company and CRT entered into agreements with Sun and Accord to stay the respective lawsuits pending the outcome of the U.S. Supreme Court appeal process in the Barr lawsuit. In light of the U.S. Supreme Court's denial of Barr's petition, Sun and Accord have agreed to withdraw their challenges to the *Temodar* patent and the respective lawsuits have been withdrawn.

Vytorin In December 2009, a patent infringement lawsuit was filed in the United States against Mylan Pharmaceuticals, Inc. (Mylan) in respect of Mylan's application to the FDA seeking pre-patent expiry approval to sell a generic version of *Vytorin*. The lawsuit automatically stays FDA approval of Mylan's application until May 2012 or until an adverse court decision, if any, whichever may occur earlier. A trial against Mylan jointly in respect of *Zetia* and *Vytorin* was conducted in December 2011. A decision is expected in 2012. In February 2010, a patent infringement lawsuit was filed in the United States against Teva in respect of Teva's application to the FDA seeking pre-patent expiry approval to sell a generic version of *Vytorin*. In July 2011, the patent infringement lawsuit was dismissed and Teva agreed not to sell generic versions of *Zetia* or *Vytorin* until the Company's exclusivity rights expire on April 25, 2017, except in certain circumstances. In August 2010, a patent infringement lawsuit was filed in the United States against Impax Laboratories Inc. (Impax) in respect of Impax's application to the FDA seeking pre-patent expiry approval to sell a generic version of *Vytorin*. An agreement was reached with Impax to stay the lawsuit pending the outcome of the lawsuit with Mylan. In October 2011, a patent infringement lawsuit was filed in the United States against Actavis Inc. (Actavis) in respect of Actavis' application to the FDA seeking pre-patent expiry approval to sell a generic version of *Vytorin*. The lawsuit automatically stays FDA approval of Actavis' application until May 2012 or until an adverse court decision, if any, whichever may occur earlier.

Zetia In March 2007, a patent infringement lawsuit was filed in the United States against Glenmark Pharmaceuticals Inc., USA and its parent corporation (collectively, Glenmark) in respect of Glenmark's application to the FDA seeking pre-patent expiry approval to sell a generic version of *Zetia*. In May 2010, Glenmark agreed to a settlement by virtue of which Glenmark will be permitted to launch its generic product in the United States on December 12, 2016, subject to receiving final FDA approval. In June 2010, a patent infringement lawsuit was filed in the United States against Mylan in respect of Mylan's application to the FDA seeking pre-patent expiry approval to sell a generic version of *Zetia*. The lawsuit automatically stays FDA approval of Mylan's application until December 2012 or until an adverse court decision, if any, whichever may occur earlier. A trial against Mylan jointly in respect of *Zetia* and *Vytorin* was conducted in December 2011. A decision is expected in 2012. In September 2010, a patent infringement lawsuit was filed in the United States against Teva in respect of Teva's application to the FDA seeking pre-patent expiry approval to sell a generic version of *Zetia*. In July 2011, the patent infringement lawsuit was dismissed without any rights granted to Teva.

Other Litigation

There are various other pending legal proceedings involving the Company, principally product liability and intellectual property lawsuits. While it is not feasible to predict the outcome of such proceedings, in the opinion

Table of Contents

of the Company, either the likelihood of loss is remote or any reasonably possible loss associated with the resolution of such proceedings is not expected to be material to the Company's financial position, results of operations or cash flows either individually or in the aggregate.

Legal Defense Reserves

Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable. Some of the significant factors considered in the review of these legal defense reserves are 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 its litigation; 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 associated litigation. The amount of legal defense reserves as of December 31, 2011 and 2010 of approximately \$240 million and \$190 million, respectively, represents the Company's best estimate of the minimum amount of defense costs to be incurred in connection with its outstanding litigation; however, events such as additional trials and other events that could arise in the course of its litigation could affect the ultimate amount of legal 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 reserves at any time in the future if, based upon the factors set forth, it believes it would be appropriate to do so.

Environmental Matters

The Company and its subsidiaries are parties 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 final 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 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 U.S. 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, surface water and soil contamination found at the site of a former Merck subsidiary in Merced, California. Certain of the other defendants in this suit have settled with plaintiffs regarding some or all aspects of plaintiffs' claims. This lawsuit is proceeding in a phased manner. A jury trial commenced in February 2011 during which a jury was asked to make certain factual findings regarding whether contamination moved off-site to any areas where plaintiffs could have been exposed to such contamination and, if so, when, where and in what amounts. Defendants in this Phase 1 trial included Merck and three of the other original 12 defendants. In March 2011, the Phase 1 jury returned a mixed verdict, finding in favor of Merck and the other defendants as to some, but not all, of plaintiffs' claims. Specifically, the jury found that contamination from the site did not enter or affect plaintiffs' municipal water supply wells or any private domestic wells. The jury found, however, that plaintiffs could have been exposed to contamination via air emissions prior to 1994, as well as via surface water in the form of storm drainage channeled into an adjacent irrigation canal, including during a flood in April 2006. In response to post-trial motions by Merck and other defendants, on September 7, 2011, the court

Table of Contents

entered an order setting aside a part of the Phase I jury's findings that had been in favor of plaintiffs. Specifically, the court held that plaintiffs could not have been exposed to any contamination in surface or flood water during the April 2006 flood or, in fact, at any time later than 1991. Merck's motion for reconsideration of the remainder of the jury's Phase I verdict that was adverse to Merck was denied. Following the retirement of the judge handling this case, on September 21, 2011, the case was assigned to Judge David O. Carter of the U.S. District Court for the Central District of California. Judge Carter has selected 10 plaintiffs whose claims will be reviewed and, depending on the outcome of Merck's anticipated summary judgment motions, possibly tried in early 2013.

As previously disclosed, the DOJ and the U.S. Environmental Protection Agency (the "EPA") notified the Company that they were pursuing civil penalties against Merck in excess of \$2 million for alleged violations of air, water and waste regulations resulting from the EPA's multi-media inspections of Merck's West Point and Riverside, Pennsylvania facilities in 2006 and Merck's subsequent information submissions to the EPA. A Stipulation settling this matter was filed in the U.S. District Court for the Middle District of Pennsylvania on September 28, 2011, pursuant to which the Company denied all alleged violations and agreed to a civil penalty in the amount of \$1.5 million. Following the court's approval of the Stipulation on November 17, 2011, Merck paid the civil penalty to the United States and all claims against Merck were dismissed with prejudice.

In management's opinion, the liabilities for all environmental matters that are probable and reasonably estimable have been accrued and totaled \$171 million and \$185 million at December 31, 2011 and 2010, 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 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 \$133 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.

13. Equity

The Merck certificate of incorporation authorizes 6,500,000,000 shares of common stock and 20,000,000 shares of preferred stock. Of the authorized shares of preferred stock, there was a series of 11,500,000 shares which was designated as 6% mandatory convertible preferred stock.

6% Mandatory Convertible Preferred Stock

In connection with the Merger, holders of Schering-Plough 6% preferred stock received 6% preferred stock (which rights were substantially similar to the rights of the Schering-Plough 6% preferred stock) in accordance with the Merck Restated Certificate of Incorporation. As a result of the Merger, the 6% preferred stock became subject to the "make-whole" acquisition provisions of the preferred stock effective as of November 3, 2009. During the make-whole acquisition conversion period that ended on November 19, 2009, the 6% preferred stock was convertible at a make-whole conversion rate of 8.2021. For each share of preferred stock that was converted during this period, the holder received \$86.12 in cash and 4.7302 Merck common shares. Holders also received a dividend make-whole payment of between \$10.79 and \$10.82 per share depending on the date of the conversion. A total of 9,110,423 shares of 6% preferred stock were converted into 43,093,881 shares of Merck common stock and cash payments of approximately \$785 million were made to those holders who converted. In addition, make-whole dividend payments of \$98 million were made to those holders who converted representing the present value of all remaining future dividend payments from the conversion date through the mandatory conversion date on August 13, 2010 using the discount rate as stipulated by the terms of the preferred stock.

On August 13, 2010, the remaining outstanding 6% mandatory convertible preferred stock automatically converted by its terms into the right to receive cash and shares of Merck common stock. For each share of 6% mandatory convertible preferred stock, holders received \$85.06 in cash and 4.6719 shares of Merck common stock. As a result of the conversion, approximately \$72 million was paid to the holders and approximately 4 million Merck common shares were issued.

Table of Contents*Capital Stock*

A summary of common stock and treasury stock transactions (shares in millions) is as follows:

| | 2011 | | 2010 | | 2009 | |
|--|-----------------|-------------------|-----------------|-------------------|-----------------|-------------------|
| | Common Stock | Treasury Stock | Common Stock | Treasury Stock | Common Stock | Treasury Stock |
| Balance January 1 | 3,577 | 495 | 3,563 | 454 | 2,984 | 876 |
| Mandatory conversion of 6% convertible preferred stock | | | 4 | | | |
| Issuances of shares in connection with the Merger | | | | | 1,054 | 64 |
| Issuances ⁽¹⁾ | | (17) | 10 | (6) | 9 | (2) |
| Purchases of treasury stock | | 58 | | 47 | | |
| Cancellations of treasury stock ⁽²⁾ | | | | | (484) | (484) |
| Balance December 31 | 3,577 | 536 | 3,577 | 495 | 3,563 | 454 |

⁽¹⁾ Issuances primarily reflect activity under share-based compensation plans.

⁽²⁾ Pursuant to the Merger agreement, certain of Merck's treasury shares were cancelled.

Noncontrolling Interests

In connection with the 1998 restructuring of AMI, Merck 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 *Noncontrolling interests*. If AstraZeneca exercises the Shares Option (see Note 10) this preferred stock obligation will be retired.

14. Share-Based Compensation Plans

The Company has share-based compensation plans under which employees, non-employee directors and employees of certain of the Company's equity method investees may be granted options to purchase shares of Company common stock at the fair market value at the time of grant. In addition to stock options, the Company grants performance share units (PSUs) and restricted stock units (RSUs) to certain management level employees. These plans were approved by the Company's shareholders.

As a result of the Merger, the Schering-Plough 2006 Stock Incentive Plan (Schering-Plough 2006 SIP) was amended and restated. Share-based compensation instruments remain available for future grant under the Schering-Plough 2006 SIP to Merck employees who were employees of Schering-Plough prior to the Merger. As such, there are outstanding share-based compensation instruments, as well as share-based compensation instruments available for future grant, under legacy Merck and legacy Schering-Plough incentive plans.

Also, as a result of the Merger, certain share-based compensation instruments previously granted under the Schering-Plough 2006 SIP and other legacy Schering-Plough incentive plans were exchanged for Merck replacement awards. Other awards related to precombination services became payable in cash. The fair value of replacement awards attributable to precombination service was \$525 million and is included in the calculation of consideration transferred (see Note 3). A significant portion of the legacy Schering-Plough awards vested in the opening balance sheet at the time of the Merger. Those Schering-Plough share-based compensation instruments that did not immediately vest upon completion of the Merger were exchanged for Merck replacement awards that generally vest on the same basis as the original grants made under the Schering-Plough legacy incentive plans and immediately vested if the employee was terminated by the Company within two years of the Merger under certain circumstances. The fair value of Merck replacement awards attributed to postcombination services is being recognized as compensation cost subsequent to the Merger over the requisite service period of the awards.

At December 31, 2011, 164 million shares collectively were authorized for future grants under the Company's share-based compensation plans. Prior to the Merger, employee share-based compensation awards were settled primarily with treasury shares. Subsequent to the Merger, these awards are either being settled with newly issued shares or treasury shares.

Table of Contents

Employee stock options are granted to purchase shares of Company stock at the fair market value at the time of grant. These awards generally vest one-third each year over a three-year period, with a contractual term of 7-10 years. RSUs are stock awards that are granted to employees and entitle the holder to shares of common stock as the awards vest. The fair value of the stock option and RSU awards is determined and fixed on the grant date based on the Company's stock price. PSUs are stock awards where the ultimate number of shares issued will be contingent on the Company's performance against a pre-set objective or set of objectives. The fair value of each PSU is determined on the date of grant based on the Company's stock price. For RSUs and certain PSUs granted before December 31, 2009 employees participate in dividends on the same basis as common shares and such dividends are nonforfeitable by the holder. For RSUs and PSUs issued on or after January 1, 2010, dividends declared during the vesting period are payable to the employees only upon vesting. The fair value of stock option, RSU and PSU replacement awards was determined and fixed at the time of the Merger. Over the PSU performance period, the number of shares of stock that are expected to be issued will be adjusted based on the probability of achievement of a performance target and final compensation expense will be recognized based on the ultimate number of shares issued. RSU and PSU distributions will be in shares of Company stock after the end of the vesting or performance period, generally three years, subject to the terms applicable to such awards.

Total pretax share-based compensation cost recorded in 2011, 2010 and 2009 was \$369 million, \$509 million and \$415 million, respectively, with related income tax benefits of \$118 million, \$173 million and \$132 million, respectively.

The Company uses the Black-Scholes option pricing model for determining the fair value of option grants. In applying this model, the Company uses both historical data and current market data to estimate the fair value of its options. The Black-Scholes model requires several assumptions including expected dividend yield, risk-free interest rate, volatility, and term of the options. The expected dividend yield is based on historical patterns of dividend payments. The risk-free rate is based on the rate at grant date of zero-coupon U.S. Treasury Notes with a term equal to the expected term of the option. Expected volatility is estimated using a blend of historical and implied volatility. The historical component is based on historical monthly price changes. The implied volatility is obtained from market data on the Company's traded options. The expected life represents the amount of time that options granted are expected to be outstanding, based on historical and forecasted exercise behavior.

The weighted average exercise price of options granted in 2011, 2010 and 2009 was \$36.47, \$34.30 and \$24.31 per option, respectively. The weighted average fair value of options granted in 2011, 2010 and 2009 was \$5.39, \$7.99 and \$4.02 per option, respectively, and were determined using the following assumptions:

| <i>Years Ended December 31</i> | 2011 | 2010 | 2009 |
|--------------------------------|--------------|-------------|-------------|
| Expected dividend yield | 4.3% | 4.1% | 6.3% |
| Risk-free interest rate | 2.5% | 2.8% | 2.2% |
| Expected volatility | 23.4% | 33.7% | 33.8% |
| Expected life (years) | 7.0 | 6.8 | 6.1 |

Summarized information relative to stock option plan activity (options in thousands) is as follows:

| | Number of Options | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term | Aggregate Intrinsic Value |
|--------------------------------------|----------------------|--|---|---------------------------------|
| Outstanding January 1, 2011 | 272,241 | \$ 42.26 | | |
| Granted | 8,209 | 36.47 | | |
| Exercised | (12,435) | 25.80 | | |
| Forfeited | (37,255) | 63.54 | | |
| Outstanding December 31, 2011 | 230,760 | \$ 39.51 | 4.11 | \$ 910 |
| Exercisable December 31, 2011 | 203,573 | \$ 40.67 | 3.67 | \$ 706 |

Table of Contents

Additional information pertaining to stock option plans is provided in the table below:

| <i>Years Ended December 31</i> | 2011 | 2010 | 2009 |
|---|---------------|--------|--------|
| Total intrinsic value of stock options exercised | \$ 125 | \$ 177 | \$ 119 |
| Fair value of stock options vested ⁽¹⁾ | 189 | 290 | 311 |
| Cash received from the exercise of stock options | 321 | 363 | 186 |

⁽¹⁾ The fair value of stock options vested in 2009 excludes the fair value of options that vested as a result of the Merger attributable to precombination service.

A summary of nonvested RSU and PSU activity (shares in thousands) is as follows:

| | RSUs | | PSUs | |
|------------------------------------|---------------------|---|---------------------|---|
| | Number of Shares | Weighted Average Grant Date Fair Value | Number of Shares | Weighted Average Grant Date Fair Value |
| Nonvested January 1, 2011 | 20,438 | \$ 32.88 | 1,529 | \$ 33.58 |
| Granted | 8,181 | 36.36 | 1,011 | 31.35 |
| Vested | (5,951) | 34.31 | (908) | 34.64 |
| Forfeited | (1,523) | 34.11 | (119) | 31.97 |
| Nonvested December 31, 2011 | 21,145 | \$ 33.73 | 1,513 | \$ 31.58 |

At December 31, 2011, there was \$391 million of total pretax unrecognized compensation expense related to nonvested stock options, RSU and PSU awards which will be recognized over a weighted average period of 1.8 years. For segment reporting, share-based compensation costs are unallocated expenses.

15. Pension and Other Postretirement Benefit Plans

The Company has defined benefit pension plans covering eligible employees in the United States and in certain of its international subsidiaries. Pension benefits in the United States are based on a formula that considers final average pay and years of credited service. In addition, the Company provides medical, dental and life insurance benefits, principally to its eligible U.S. retirees and similar benefits to their dependents, through its other postretirement benefit plans. In December 2011, changes to the Company's benefit plans were approved, as discussed below. The Company uses December 31 as the year-end measurement date for all of its pension plans and other postretirement benefit plans.

Net Periodic Benefit Cost

The net periodic benefit cost for pension and other postretirement benefit plans consisted of the following components:

| <i>Years Ended December 31</i> | Pension Benefits | | | Other Postretirement Benefits | | |
|--------------------------------|------------------|--------|--------|-------------------------------|--------|--------|
| | 2011 | 2010 | 2009 | 2011 | 2010 | 2009 |
| Service cost | \$ 619 | \$ 584 | \$ 397 | \$ 110 | \$ 108 | \$ 75 |
| Interest cost | 718 | 688 | 450 | 141 | 148 | 108 |
| Expected return on plan assets | (972) | (891) | (662) | (142) | (132) | (98) |
| Net amortization | 201 | 148 | 136 | (17) | 8 | 19 |
| Termination benefits | 59 | 54 | 89 | 29 | 42 | 10 |
| Curtailments | (86) | (50) | (6) | 1 | (10) | (10) |
| Settlements | 4 | (1) | 3 | | | |
| Net periodic benefit cost | \$ 543 | \$ 532 | \$ 407 | \$ 122 | \$ 164 | \$ 104 |

Table of Contents

The higher costs in 2011 and 2010 as compared with 2009 are primarily due to incremental costs associated with the Merger. The net periodic benefit cost attributable to U.S. pension plans included in the above table was \$406 million in 2011, \$289 million in 2010 and \$289 million in 2009.

In connection with restructuring actions (see Note 4), termination charges were recorded in 2011, 2010 and 2009 on pension and other postretirement benefit plans related to expanded eligibility for certain employees exiting Merck. Also, in connection with these restructuring activities, curtailments were recorded in 2011, 2010 and 2009 on pension and other postretirement benefit plans.

In addition, settlements were recorded in 2011, 2010 and 2009 on certain domestic and international pension plans.

Obligations and Funded Status

Summarized information about the changes in plan assets and benefit obligation, the funded status and the amounts recorded at December 31 is as follows:

| | Pension Benefits | | Other Postretirement Benefits | |
|--|------------------|------------|-------------------------------|------------|
| | 2011 | 2010 | 2011 | 2010 |
| Fair value of plan assets January 1 | \$ 12,705 | \$ 10,835 | \$ 1,685 | \$ 1,523 |
| Actual return on plan assets | 6 | 1,458 | (20) | 237 |
| Company contributions | 556 | 1,062 | 58 | 32 |
| Mergers, acquisitions and divestitures | (202) | 162 | | |
| Effects of exchange rate changes | 56 | (74) | | |
| Benefits paid | (581) | (573) | (95) | (107) |
| Settlements | (78) | (196) | | |
| Other | 19 | 31 | | |
| Fair value of plan assets December 31 | \$ 12,481 | \$ 12,705 | \$ 1,628 | \$ 1,685 |
| Benefit obligation January 1 | 13,978 | 13,183 | 2,745 | 2,614 |
| Service cost | 619 | 584 | 110 | 108 |
| Interest cost | 718 | 688 | 141 | 148 |
| Mergers, acquisitions and divestitures | (180) | 174 | | |
| Actuarial losses (gains) | 688 | 280 | (266) | 41 |
| Benefits paid | (581) | (573) | (95) | (107) |
| Effects of exchange rate changes | 53 | (138) | (3) | 2 |
| Plan amendments | (763) | 1 | (150) | (113) |
| Curtailments | (150) | (136) | 16 | 3 |
| Termination benefits | 59 | 54 | 29 | 42 |
| Settlements | (78) | (196) | | |
| Other | 53 | 57 | 2 | 7 |
| Benefit obligation December 31 | \$ 14,416 | \$ 13,978 | \$ 2,529 | \$ 2,745 |
| Funded status December 31 | \$ (1,935) | \$ (1,273) | \$ (901) | \$ (1,060) |
| Recognized as: | | | | |
| Other assets | \$ 669 | \$ 812 | \$ 391 | \$ 346 |
| Accrued and other current liabilities | (81) | (67) | (10) | (10) |
| Deferred income taxes and noncurrent liabilities | (2,523) | (2,018) | (1,282) | (1,396) |

Table of Contents

The fair value of U.S. pension plan assets included in the preceding table was \$6.8 billion and \$7.2 billion at December 31, 2011 and 2010, respectively, and the projected benefit obligation of U.S. pension plans was \$8.7 billion and \$8.4 billion, respectively. Approximately 40% of the Company's pension projected benefit obligation both at December 31, 2011 and 2010 relates to international defined benefit plans, of which each individual plan is not significant relative to the total projected benefit obligation.

At December 31, 2011 and 2010, the accumulated benefit obligation was \$12.9 billion and \$11.8 billion, respectively, for all pension plans, of which \$7.8 billion and \$6.9 billion, respectively, related to U.S. pension plans.

For pension plans with projected benefit obligations in excess of plan assets at December 31, 2011 and 2010, the fair value of plan assets was \$9.3 billion and \$4.3 billion, respectively, and the benefit obligations were \$11.9 billion and \$6.4 billion, respectively. For those plans with accumulated benefit obligations in excess of plan assets at December 31, 2011 and 2010, the fair value of plan assets was \$3.6 billion and \$2.6 billion, respectively, and the accumulated benefit obligations were \$5.4 billion and \$3.8 billion, respectively.

Plan Assets

Entities are required to use a fair value hierarchy which maximizes the use of observable inputs and minimizes the use of unobservable inputs when measuring fair value. There are three levels of inputs used to measure fair value with Level 1 having the highest priority and Level 3 having the lowest:

Level 1 Quoted prices (unadjusted) in active markets for identical assets or liabilities.

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.

Level 3 Unobservable inputs that are supported by little or no market activity. The Level 3 assets are those whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques with significant unobservable inputs, as well as instruments for which the determination of fair value requires significant judgment or estimation. At December 31, 2011 and 2010, \$637 million and \$648 million, respectively, or approximately 5.0% of the Company's pension investments at each year end, were categorized as Level 3 assets.

If the inputs used to measure the financial assets 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

The fair values of the Company's pension plan assets at December 31 by asset category are as follows:

| | Fair Value Measurements Using | | | | Fair Value Measurements Using | | | |
|--------------------------------------|--|---|--|-----------|---|---|--|-----------|
| | Quoted Prices In Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) | Total | Quoted Prices In Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) | Total |
| | 2011 | | | | 2010 | | | |
| Assets | | | | | | | | |
| Cash and cash equivalents | \$ 93 | \$ 217 | \$ | \$ 310 | \$ 54 | \$ 213 | \$ | \$ 267 |
| <i>Investment funds</i> | | | | | | | | |
| U.S. large cap equities | 65 | 2,244 | | 2,309 | 36 | 2,208 | | 2,244 |
| U.S. small/mid cap equities | 9 | 710 | | 719 | 9 | 1,266 | | 1,275 |
| Non-U.S. developed markets equities | 390 | 1,735 | | 2,125 | 390 | 1,703 | | 2,093 |
| Non-U.S. emerging markets equities | 82 | 575 | | 657 | 101 | 644 | | 745 |
| Government and agency obligations | 119 | 632 | | 751 | 158 | 526 | | 684 |
| Corporate obligations | 112 | 193 | | 305 | 111 | 179 | | 290 |
| Fixed income obligations | | 144 | | 144 | 1 | 73 | | 74 |
| Real estate ⁽¹⁾ | | 9 | 144 | 153 | | 8 | 165 | 173 |
| <i>Equity securities</i> | | | | | | | | |
| U.S. large cap | 330 | | | 330 | 458 | | | 458 |
| U.S. small/mid cap | 1,085 | | | 1,085 | 737 | | | 737 |
| Non-U.S. developed markets | 623 | | | 623 | 915 | | | 915 |
| <i>Fixed income securities</i> | | | | | | | | |
| Government and agency obligations | | 1,248 | | 1,248 | | 1,186 | | 1,186 |
| Corporate obligations | | 703 | | 703 | | 644 | | 644 |
| Mortgage and asset-backed securities | | 275 | | 275 | | 279 | | 279 |
| <i>Other investments</i> | | | | | | | | |
| Insurance contracts ⁽²⁾ | | 138 | 428 | 566 | | 159 | 420 | 579 |
| Derivatives | | 141 | | 141 | 1 | 48 | | 49 |
| Other | 3 | 42 | 65 | 110 | 5 | 31 | 63 | 99 |
| | \$ 2,911 | \$ 9,006 | \$ 637 | \$ 12,554 | \$ 2,976 | \$ 9,167 | \$ 648 | \$ 12,791 |
| Liabilities | | | | | | | | |
| Derivatives | \$ | \$ 55 | \$ | \$ 55 | \$ | \$ 83 | \$ | \$ 83 |

⁽¹⁾ The plans' Level 3 investments in real estate are generally valued by market appraisals.

⁽²⁾ The plans' Level 3 investments in insurance contracts are generally valued using a crediting rate that approximates market returns and invest in underlying securities whose market values are unobservable and determined using pricing models, discounted cash flow methodologies, or similar techniques.

Table of Contents

The table below provides a summary of the changes in fair value, including transfers in and/or out, of all financial assets measured at fair value using significant unobservable inputs (Level 3) for the Company's pension plan assets:

| | 2011 | | | | 2010 | | | |
|---|------------------------|----------------|-------|--------|------------------------|----------------|-------|--------|
| | Insurance Contracts | Real Estate | Other | Total | Insurance Contracts | Real Estate | Other | Total |
| Beginning balance January 1 | \$ 420 | \$ 165 | \$ 63 | \$ 648 | \$ 310 | \$ 185 | \$ 73 | \$ 568 |
| Actual return on plan assets | | | | | | | | |
| Relating to assets still held at | | | | | | | | |
| December 31 | 16 | (7) | (2) | 7 | (2) | 4 | 2 | 4 |
| Relating to assets sold during the year | 1 | | 4 | 5 | | 1 | 2 | 3 |
| Purchases | 19 | 13 | (3) | 29 | 26 | 31 | 13 | 70 |
| Sales | (28) | (27) | 3 | (52) | (14) | (56) | (27) | (97) |
| Transfers to Level 3 | | | | | 100 | | | 100 |
| Ending balance December 31 | \$ 428 | \$ 144 | \$ 65 | \$ 637 | \$ 420 | \$ 165 | \$ 63 | \$ 648 |

The fair values of the Company's other postretirement benefit plan assets at December 31 by asset category are as follows:

| | Fair Value Measurements Using | | | | Fair Value Measurements Using | | | |
|--------------------------------------|---|---|--|----------|---|---|--|----------|
| | Quoted Prices In Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) | Total | Quoted Prices In Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) | Total |
| | 2011 | | | | 2010 | | | |
| Assets | | | | | | | | |
| Cash and cash equivalents | \$ 28 | \$ 40 | \$ | \$ 68 | \$ 2 | \$ 62 | \$ | \$ 64 |
| <i>Investment funds</i> | | | | | | | | |
| U.S. large cap equities | | 444 | | 444 | | 472 | | 472 |
| U.S. small/mid cap equities | | 286 | | 286 | | 343 | | 343 |
| Non-U.S. developed markets equities | 60 | 101 | | 161 | 73 | 99 | | 172 |
| Non-U.S. emerging markets equities | 30 | 65 | | 95 | 38 | 88 | | 126 |
| Fixed income obligations | | 34 | | 34 | | 53 | | 53 |
| <i>Equity securities</i> | | | | | | | | |
| U.S. large cap | 4 | | | 4 | 1 | | | 1 |
| U.S. small/mid cap | 101 | | | 101 | 85 | | | 85 |
| Non-U.S. developed markets | 94 | | | 94 | 120 | | | 120 |
| <i>Fixed income securities</i> | | | | | | | | |
| Government and agency obligations | | 76 | | 76 | | 62 | | 62 |
| Corporate obligations | | 208 | | 208 | | 145 | | 145 |
| Mortgage and asset-backed securities | | 46 | | 46 | | 35 | | 35 |
| Other fixed income obligations | | 12 | | 12 | | 9 | | 9 |
| | \$ 317 | \$ 1,312 | \$ | \$ 1,629 | \$ 319 | \$ 1,368 | \$ | \$ 1,687 |

Total pension and other postretirement benefit plan assets excluded from the fair value hierarchy include interest receivable, as well as payables and receivables related to purchases and sales of investments, respectively.

The Company has established investment guidelines for its U.S. pension and other postretirement plans to create an asset allocation that is expected to deliver a rate of return sufficient to meet the long-term obligation of each plan, given an acceptable level of risk. 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 obligations. The expected annual standard

Table of Contents

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. For non-U.S. pension plans, the targeted investment portfolio varies based on the duration of pension liabilities and local government rules and regulations. Although a significant percentage of plan assets are invested in U.S. equities, concentration risk is mitigated through the use of strategies that are diversified within management guidelines.

Expected Contributions

Contributions to the pension plans and other postretirement benefit plans during 2012 are expected to be approximately \$700 million and \$100 million, respectively.

Expected Benefit Payments

Expected benefit payments are as follows:

| | Pension Benefits | Other Postretirement Benefits |
|-------------|---------------------|-------------------------------------|
| 2012 | \$ 603 | \$ 125 |
| 2013 | 575 | 127 |
| 2014 | 593 | 133 |
| 2015 | 647 | 140 |
| 2016 | 678 | 146 |
| 2017 - 2021 | 4,123 | 810 |

Expected benefit payments are based on the same assumptions used to measure the benefit obligations and include estimated future employee service.

Amounts Recognized in Other Comprehensive Income

Net loss amounts 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. Net loss amounts in excess of certain thresholds are amortized into net pension and other postretirement benefit cost over the average remaining service life of employees. The following amounts were reflected as components of *OCI*:

| | Pension Plans | | | Other Postretirement Benefit Plans | | |
|---|---------------|--------|--------|---------------------------------------|--------|-------|
| Years Ended December 31 | 2011 | 2010 | 2009 | 2011 | 2010 | 2009 |
| Net (loss) gain arising during the period | \$ (1,628) | \$ 361 | \$ 303 | \$ 106 | \$ 66 | \$ 71 |
| Prior service credit (cost) arising during the period | 783 | 1 | (1) | 133 | 99 | (24) |
| | \$ (845) | \$ 362 | \$ 302 | \$ 239 | \$ 165 | \$ 47 |
| Net loss amortization included in benefit cost | \$ 196 | \$ 140 | \$ 127 | \$ 38 | \$ 55 | \$ 68 |
| Prior service cost (credit) amortization included in benefit cost | 5 | 8 | 9 | (55) | (47) | (49) |
| | \$ 201 | \$ 148 | \$ 136 | \$ (17) | \$ 8 | \$ 19 |

The estimated net loss (gain) and prior service cost (credit) amounts that will be amortized from *AOCI* into net pension and postretirement benefit cost during 2012 are \$237 million and \$(66) million, respectively, for pension plans and are \$37 million and \$(67) million, respectively, for other postretirement benefit plans.

Table of Contents*Actuarial Assumptions*

The Company reassesses its benefit plan assumptions on a regular basis. The weighted average assumptions used in determining pension plan and U.S. pension and other postretirement benefit plan information are as follows:

| <i>December 31</i> | 2011 | Pension Plans | | 2011 | U.S. Pension and Other Postretirement Benefit Plans | |
|--|--------------|---------------|-------|--------------|---|-------|
| | | 2010 | 2009 | | 2010 | 2009 |
| Net periodic benefit cost | | | | | | |
| Discount rate | 5.20% | 5.50% | 5.80% | 5.40% | 5.90% | 6.15% |
| Expected rate of return on plan assets | 7.50% | 7.60% | 7.90% | 8.70% | 8.70% | 8.75% |
| Salary growth rate | 4.20% | 4.15% | 4.30% | 4.50% | 4.50% | 4.50% |
| Benefit obligation | | | | | | |
| Discount rate | 4.70% | 5.20% | 5.50% | 4.80% | 5.40% | 5.90% |
| Salary growth rate | 4.00% | 4.20% | 4.15% | 4.50% | 4.50% | 4.50% |

The 2009 net cost rates in the preceding table include costs associated with the Schering-Plough benefit plans from the date of the Merger through December 31, 2009.

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 and is determined on a country basis. In developing the expected rate of return within each country, long-term historical returns data are considered as well as actual returns on the plan assets and other capital markets experience. Using this reference information, the long-term return expectations for each asset category and a weighted average expected return for each country's target portfolio is developed, according to the allocation among those investment categories. The expected portfolio performance reflects the contribution of active management as appropriate. For 2012, the Company's expected rate of return will range from 5.75% to 8.75% compared to a range of 5.25% to 8.75% in 2011 for its U.S. pension and other postretirement benefit plans.

The health care cost trend rate assumptions for other postretirement benefit plans are as follows:

| <i>December 31</i> | 2011 | 2010 |
|--|-------------|------|
| Health care cost trend rate assumed for next year | 7.9% | 8.3% |
| Rate to which the cost trend rate is assumed to decline | 5.0% | 5.0% |
| Year that the trend rate reaches the ultimate trend rate | 2018 | 2018 |

A one percentage point change in the health care cost trend rate would have had the following effects:

| | One Percentage Point | |
|--|----------------------|-----------------|
| | Increase | Decrease |
| Effect on total service and interest cost components | \$ 50 | \$ (39) |
| Effect on benefit obligation | \$ 381 | \$ (311) |

Benefit Plan Changes

In December 2011, the Compensation and Benefits Committee of the Company's Board of Directors approved management's proposal to change Merck's primary U.S. defined benefit pension plans' benefit formulas to cash balance formulas beginning for service on or after January 1, 2013. Active participants in these plans as of December 31, 2012 will accrue pension benefits prospectively using the new cash balance formulas based on age, service, pay and interest. However, during a transition period from January 1, 2013 through December 31, 2019, participants will earn the greater of the benefit as calculated under the employee's legacy final average pay formula or their new cash balance formula. For all years of service after December 31, 2019, participants will earn future benefits under only the cash balance formula. The changes to these plans reduced pension benefit obligations at

Table of Contents

December 31, 2011 by approximately \$752 million with a corresponding offset to *AOCI*, largely attributable to the change from using final average pay to career average pay, which will be amortized as reduction to net periodic benefit cost over the employees' future service period (approximately 11 years).

Also in December 2011, the Company approved changes to its U.S. retiree healthcare plans, including changes for certain employees to the contribution subsidy level and eligibility criteria for subsidized retiree medical coverage and the elimination of certain retiree dental coverage, that will reduce Merck's future costs related to these plans. These changes reduced the Company's benefit obligations related to the U.S. retiree healthcare plans at December 31, 2011 by approximately \$150 million with a corresponding offset to *AOCI*, which will be amortized as reduction to net periodic benefit cost over the employees' future service period (approximately 11 years).

Savings Plans

The Company also maintains defined contribution savings plans in the United States, including plans assumed in connection with the Merger. The Company matches a percentage of each employee's contributions consistent with the provisions of the plan for which the employee is eligible. Total employer contributions to these plans in 2011, 2010 and 2009 were \$166 million, \$155 million and \$111 million, respectively.

16. Other (Income) Expense, Net

| <i>Years Ended December 31</i> | 2011 | 2010 | 2009 |
|--------------------------------|-----------------|-----------------|--------------------|
| Interest income | \$ (199) | \$ (83) | \$ (210) |
| Interest expense | 749 | 715 | 460 |
| Exchange losses (gains) | 143 | 214 | (12) |
| Other, net | 253 | 458 | (10,906) |
| | \$ 946 | \$ 1,304 | \$ (10,668) |

The increase in interest income in 2011 as compared with 2010 primarily reflects higher average investment balances. The decline in interest income and increase in interest expense in 2010 as compared with 2009 is largely attributable to the Merger. Exchange losses in 2010 reflect \$200 million of losses due to two Venezuelan currency devaluations as discussed below. Other, net (as presented in the table above) in 2011 reflects a \$500 million charge related to the resolution of the arbitration proceeding involving the Company's rights to market *Remicade* and *Simponi* (see Note 6), a \$136 million gain on the disposition of the Company's interest in the JJMCP joint venture (see Note 10), and a \$127 million gain on the sale of certain manufacturing facilities and related assets (see Note 5). Other, net in 2010 reflects a \$950 million charge for the *Vioxx* Liability Reserve (see Note 12), and charges related to the settlement of certain pending AWP litigation, partially offset by \$443 million of income recognized upon AstraZeneca's asset option exercise (see Note 10) and \$102 million of income recognized on the settlement of certain disputed royalties. Other, net in 2009 primarily reflects a \$7.5 billion gain resulting from recognizing Merck's previously held equity interest in the MSP Partnership at fair value as a result of obtaining control of the MSP Partnership in the Merger and a \$3.2 billion gain on the sale of Merck's interest in Merial (see Note 10).

As noted above, exchange losses for 2010 reflect losses relating to Venezuelan currency devaluations. Effective January 11, 2010, the Venezuelan government devalued its currency from at BsF 2.15 per U.S. dollar to a two-tiered official exchange rate at (1) the essentials rate at BsF 2.60 per U.S. dollar and (2) the non-essentials rate at BsF 4.30 per U.S. dollar. In January 2010, the Company was required to remeasure its local currency operations in Venezuela to U.S. dollars as the Venezuelan economy was determined to be hyperinflationary. Throughout 2010, the Company settled its transactions at the essentials rate and therefore remeasured monetary assets and liabilities utilizing the essentials rate. In December 2010, the Venezuelan government announced it would eliminate the essentials rate and, effective January 1, 2011, all transactions would be settled at the official rate of at BsF 4.30 per U.S. dollar. As a result of this announcement, the Company remeasured its December 31, 2010 monetary assets and liabilities at the new official rate.

Table of Contents

Interest paid was \$600 million in 2011, \$763 million in 2010 and \$351 million in 2009, which excludes commitment fees. Interest paid for 2011 is net of \$288 million received by the Company from the termination of certain interest rate swap contracts during the year (see Note 7).

17. Taxes on Income

A reconciliation between the effective tax rate and the U.S. statutory rate is as follows:

| | 2011 | | 2010 | | 2009 | |
|--|----------|----------|---------|----------|----------|----------|
| | Amount | Tax Rate | Amount | Tax Rate | Amount | Tax Rate |
| U.S. statutory rate applied to income before taxes | \$ 2,567 | 35.0% | \$ 579 | 35.0% | \$ 5,352 | 35.0% |
| Differential arising from: | | | | | | |
| Foreign earnings | (2,220) | (30.3) | (1,878) | (113.6) | (1,216) | (8.0) |
| Federal and state tax settlements | (721) | (9.8) | (17) | (1.0) | (108) | (0.7) |
| Tax rate changes | (295) | (4.0) | (391) | (23.7) | (198) | (1.3) |
| Unremitted foreign earnings | (86) | (1.2) | (217) | (13.1) | 27 | 0.2 |
| IPR&D impairment charges | (5) | (0.1) | 484 | 29.3 | | |
| Amortization of purchase accounting adjustments | 875 | 11.9 | 1,394 | 84.3 | 760 | 5.0 |
| Arbitration settlement charge | 177 | 2.4 | | | | |
| Restructuring | 163 | 2.2 | 134 | 8.1 | 264 | 1.7 |
| State taxes | 72 | 1.0 | (42) | (2.6) | 185 | 1.2 |
| Gain on equity investments | 21 | 0.3 | 15 | 0.9 | (2,540) | (16.6) |
| Vioxx Liability Reserve | | | 332 | 20.1 | | |
| U.S. health care reform legislation | 50 | 0.7 | 147 | 8.9 | | |
| Other ⁽¹⁾ | 344 | 4.7 | 131 | 8.0 | (258) | (1.7) |
| | \$ 942 | 12.8% | \$ 671 | 40.6% | \$ 2,268 | 14.8% |

⁽¹⁾ Other includes the tax effect of contingency reserves, research credits, export incentives and miscellaneous items.

The 2011 and 2010 tax rate reconciliation percentages reflect the impact of the significant decline in the Company's income before taxes resulting primarily from a full year of acquisition-related costs, including IPR&D impairment charges, and restructuring charges, as well as the arbitration settlement charge in 2011 and the charge for the Vioxx Liability Reserve in 2010.

Income before taxes consisted of:

| Years Ended December 31 | 2011 | 2010 | 2009 |
|-------------------------|----------|----------|-----------|
| Domestic | \$ 2,626 | \$ 1,154 | \$ 5,318 |
| Foreign | 4,708 | 499 | 9,972 |
| | \$ 7,334 | \$ 1,653 | \$ 15,290 |

Table of Contents

Taxes on income consisted of:

| <i>Years Ended December 31</i> | 2011 | 2010 | 2009 |
|--------------------------------|----------------|----------------|-----------------|
| <i>Current provision</i> | | | |
| Federal | \$ 859 | \$ 399 | \$ (55) |
| Foreign | 1,568 | 1,446 | 495 |
| State | 52 | (82) | 7 |
| | 2,479 | 1,763 | 447 |
| <i>Deferred provision</i> | | | |
| Federal | (584) | 764 | 2,095 |
| Foreign | (683) | (1,777) | (437) |
| State | (270) | (79) | 163 |
| | (1,537) | (1,092) | 1,821 |
| | \$ 942 | \$ 671 | \$ 2,268 |

Deferred income taxes at December 31 consisted of:

| | 2011 | | 2010 | |
|---|---------------|--------------------|---------------|--------------------|
| | Assets | Liabilities | Assets | Liabilities |
| Intangibles | \$ | \$ 5,329 | \$ | \$ 6,669 |
| Inventory related | 66 | 325 | 97 | 436 |
| Accelerated depreciation | 140 | 1,244 | 137 | 1,407 |
| Unremitted foreign earnings | | 2,413 | | 2,535 |
| Equity investments | | 280 | | 121 |
| Pensions and other postretirement benefits | 1,179 | 149 | 1,041 | 127 |
| Compensation related | 768 | | 732 | |
| Unrecognized tax benefits | 788 | | 846 | |
| Net operating losses and other tax credit carryforwards | 538 | | 582 | |
| Other | 2,294 | 108 | 2,094 | 121 |
| Subtotal | 5,773 | 9,848 | 5,529 | 11,416 |
| Valuation allowance | (246) | | (196) | |
| Total deferred taxes | \$ 5,527 | \$ 9,848 | \$ 5,333 | \$ 11,416 |
| Net deferred income taxes | | \$ 4,321 | | \$ 6,083 |
| Recognized as: | | | | |
| Deferred income taxes and other current assets | \$ 827 | | \$ 879 | |
| Other assets | 497 | | 472 | |
| Income taxes payable | | \$ 19 | | \$ 23 |
| Deferred income taxes and noncurrent liabilities | | 5,626 | | 7,411 |

The Company has net operating loss (NOL) carryforwards in several jurisdictions. As of December 31, 2011, approximately \$239 million of deferred taxes on NOL carryforwards relate to foreign jurisdictions, none of which are individually significant. Approximately \$194 million of valuation allowances have been established on these foreign NOL carryforwards. In addition, the Company has approximately \$299 million of deferred tax assets relating to various U.S. tax credit carryforwards and NOL carryforwards. Of these amounts, \$247 million is expected to be fully utilized prior to expiry.

Table of Contents

Income taxes paid in 2011, 2010 and 2009 were \$2.7 billion, \$1.6 billion and \$958 million, respectively. Stock option exercises did not have a significant impact on taxes paid in 2011, 2010 or 2009.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

| | 2011 | 2010 | 2009 |
|--|----------|----------|----------|
| Balance January 1 | \$ 4,919 | \$ 4,743 | \$ 3,665 |
| Additions related to current year positions | 695 | 479 | 333 |
| Additions related to prior year positions | 145 | 124 | 49 |
| Additions related to the Merger | | | 1,578 |
| Reductions for tax positions of prior years ⁽¹⁾ | (1,223) | (157) | (547) |
| Settlements | (259) | (256) | (332) |
| Lapse of statute of limitations | | (14) | (3) |
| Balance December 31 | \$ 4,277 | \$ 4,919 | \$ 4,743 |

⁽¹⁾ Amount for 2011 reflects the conclusion of the IRS examination of Merck's 2002-2005 federal income tax returns and the resolution of the interest rate swap dispute with the IRS, both as discussed below.

If the Company were to recognize the unrecognized tax benefits of \$4.3 billion at December 31, 2011, the income tax provision would reflect a favorable net impact of \$3.6 billion.

The Company is under examination by numerous tax authorities in various jurisdictions globally. The Company believes that it is reasonably possible that the total amount of unrecognized tax benefits as of December 31, 2011 could decrease by up to \$600 million in the next 12 months as a result of various audit closures, settlements or the expiration of the statute of limitations. The ultimate finalization of the Company's examinations with relevant taxing authorities can include formal administrative and legal proceedings, which could have a significant impact on the timing of the reversal of unrecognized tax benefits. The Company believes that its reserves for uncertain tax positions are adequate to cover existing risks or exposures.

Interest and penalties associated with uncertain tax positions amounted to a (benefit) expense of \$(95) million in 2011, \$144 million in 2010 and \$(163) million in 2009. Liabilities for accrued interest and penalties were \$1.3 billion and \$1.6 billion as of December 31, 2011 and 2010, respectively.

In April 2011, the IRS concluded its examination of Merck's 2002-2005 federal income tax returns and as a result the Company was required to make net payments of approximately \$465 million. The Company's unrecognized tax benefits for the years under examination exceeded the adjustments related to this examination period and therefore the Company recorded a net \$700 million tax provision benefit in 2011. This net benefit reflects the decrease of unrecognized tax benefits for the years under examination partially offset by increases to the unrecognized tax benefits for years subsequent to the examination period as a result of this settlement. The Company disagrees with the IRS treatment of one issue raised during this examination and is appealing the matter through the IRS administrative process.

As previously disclosed, in October 2006, the Canada Revenue Agency (CRA) issued Merck 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. In accordance with the settlement, Merck paid an additional tax of approximately \$300 million and interest of approximately \$360 million with no additional amounts or penalties due on this assessment. The settlement was accounted for in the first quarter of 2009. Merck had previously established reserves for these matters. A portion of the taxes paid is expected to be creditable for U.S. tax purposes.

In addition, as previously disclosed, the CRA has proposed adjustments for 1999 and 2000 relating to other intercompany pricing matters and, in July 2011, the CRA issued assessments for other miscellaneous audit issues for tax years 2001-2004. These adjustments would increase Canadian tax due by approximately \$330 million plus approximately \$380 million of interest through December 31, 2011. The Company disagrees with the positions taken by the CRA and believes they are without merit. The Company continues to contest the assessments through the CRA appeals process. The CRA is expected to prepare similar adjustments for later years. Management believes that resolution of these matters will not have a material effect on the Company's financial position or liquidity.

Table of Contents

In October 2001, Internal Revenue Service (IRS) auditors asserted that two interest rate swaps that Schering-Plough entered into with an unrelated party should be re-characterized as loans from affiliated companies, resulting in additional tax liability for the 1991 and 1992 tax years. In September 2004, Schering-Plough made payments to the IRS in the amount of \$194 million for income taxes and \$279 million for interest. The Company's tax reserves were adequate to cover these payments. Schering-Plough filed refund claims for the taxes and interest with the IRS in December 2004. Following the IRS's denial of Schering-Plough's claims for a refund, Schering-Plough filed suit in May 2005 in the U.S. District Court for the District of New Jersey for refund of the full amount of taxes and interest. A decision in favor of the government was announced in August 2009 and affirmed by the U.S. Court of Appeals for the Third Circuit in June 2011.

In 2010, the IRS finalized its examination of Schering-Plough's 2003-2006 tax years. In this audit cycle, the Company reached an agreement with the IRS on an adjustment to income related to intercompany pricing matters. This income adjustment mostly reduced NOLs and other tax credit carryforwards. Additionally, the Company is seeking resolution of one issue raised during this examination through the IRS administrative appeals process. The Company's reserves for uncertain tax positions were adequate to cover all adjustments related to this examination period. The IRS began its examination of the 2007-2009 tax years in 2010.

In addition, various state and foreign tax examinations are in progress. For most of its other significant tax jurisdictions (both U.S. state and foreign), the Company's income tax returns are open for examination for the period 2001 through 2011.

At December 31, 2011, foreign earnings of \$44.3 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 and it would not be practicable to determine the amount of the related unrecognized deferred income tax liability. In addition, the Company has subsidiaries operating in Puerto Rico and Singapore under tax incentive grants that begin to expire in 2013.

18. Earnings per Share

The Company calculates earnings per share pursuant to the two-class method, which is an earnings allocation formula that determines earnings per share for common stock and participating securities according to dividends declared and participation rights in undistributed earnings. Under this method, all earnings (distributed and undistributed) are allocated to common shares and participating securities based on their respective rights to receive dividends. RSUs and certain PSUs granted before December 31, 2009 to certain management level employees (see Note 14) participate in dividends on the same basis as common shares and such dividends are nonforfeitable by the holder. As a result, these RSUs and PSUs meet the definition of a participating security. For RSUs and PSUs issued on or after January 1, 2010, dividends declared during the vesting period are payable to the employees only upon vesting and therefore such RSUs and PSUs do not meet the definition of a participating security.

Table of Contents

The calculations of earnings per share under the two-class method are as follows:

| <i>Years Ended December 31</i> | 2011 | 2010 | 2009 |
|---|-----------------|---------|-----------|
| <i>Basic Earnings per Common Share</i> | | | |
| Net income attributable to Merck & Co., Inc. | \$ 6,272 | \$ 861 | \$ 12,899 |
| Less: Income allocated to participating securities | 15 | 2 | 46 |
| Net income allocated to common shareholders | \$ 6,257 | \$ 859 | \$ 12,853 |
| Average common shares outstanding | 3,071 | 3,095 | 2,268 |
| | \$ 2.04 | \$ 0.28 | \$ 5.67 |
| <i>Earnings per Common Share Assuming Dilution</i> | | | |
| Net income attributable to Merck & Co., Inc. | \$ 6,272 | \$ 861 | \$ 12,899 |
| Less: Income allocated to participating securities | 15 | 2 | 46 |
| Net income allocated to common shareholders | \$ 6,257 | \$ 859 | \$ 12,853 |
| Average common shares outstanding | 3,071 | 3,095 | 2,268 |
| Common shares issuable ⁽¹⁾ | 23 | 25 | 5 |
| Average common shares outstanding assuming dilution | 3,094 | 3,120 | 2,273 |
| | \$ 2.02 | \$ 0.28 | \$ 5.65 |

⁽¹⁾Issuable primarily under share-based compensation plans.

In 2011, 2010 and 2009, 169 million, 174 million and 228 million, respectively, of common shares issuable under share-based compensation plans were excluded from the computation of earnings per common share assuming dilution because the effect would have been antidilutive.

Table of Contents**19. Other Comprehensive Income (Loss)**

The components of *Other comprehensive income (loss)* are as follows:

| | Pretax | Tax | After Tax |
|---|----------|----------|-----------|
| Year Ended December 31, 2011 | | | |
| Net unrealized loss on derivatives | \$ (143) | \$ 56 | \$ (87) |
| Net loss realization | 83 | (33) | 50 |
| Derivatives | (60) | 23 | (37) |
| Net unrealized loss on investments | (10) | 5 | (5) |
| Net gain realization | (7) | 2 | (5) |
| Investments | (17) | 7 | (10) |
| Benefit plan net (loss) gain and prior service cost (credit), net of amortization | (422) | 119 | (303) |
| Cumulative translation adjustment | 435 | (1) | 434 |
| | \$ (64) | \$ 148 | \$ 84 |
| Year Ended December 31, 2010 | | | |
| Net unrealized gain on derivatives | \$ 120 | \$ (41) | \$ 79 |
| Net loss realization | 7 | (3) | 4 |
| Derivatives | 127 | (44) | 83 |
| Net unrealized gain on investments | 41 | (11) | 30 |
| Net gain realization | (48) | 16 | (32) |
| Investments | (7) | 5 | (2) |
| Benefit plan net (loss) gain and prior service cost (credit), net of amortization | 683 | (257) | 426 |
| Cumulative translation adjustment | (835) | (121) | (956) |
| | \$ (32) | \$ (417) | \$ (449) |
| Year Ended December 31, 2009 | | | |
| Net unrealized loss on derivatives | \$ (316) | \$ 125 | \$ (191) |
| Net loss realization | 61 | (24) | 37 |
| Derivatives | (255) | 101 | (154) |
| Net unrealized gain on investments | 208 | (31) | 177 |
| Net gain realization | (230) | 23 | (207) |
| Investments | (22) | (8) | (30) |
| Benefit plan net (loss) gain and prior service cost (credit), net of amortization | 504 | (219) | 285 |
| Cumulative translation adjustment | (314) | | (314) |
| | \$ (87) | \$ (126) | \$ (213) |

Also included in cumulative translation adjustment are pretax gains (losses) of approximately \$392 million and \$(1.2) billion for 2011 and 2010, respectively, relating to translation impacts of intangible assets recorded in conjunction with the Merger.

Table of Contents

The components of *Accumulated other comprehensive loss* are as follows:

| <i>December 31</i> | 2011 | 2010 |
|--|-------------------|-------------------|
| Net unrealized gain on derivatives | \$ 4 | \$ 41 |
| Net unrealized gain on investments | 21 | 31 |
| Pension plan net loss | (2,793) | (1,837) |
| Other postretirement benefit plan net loss | (402) | (486) |
| Pension plan prior service cost | 502 | (15) |
| Other postretirement benefit plan prior service credit | 347 | 295 |
| Cumulative translation adjustment | (811) | (1,245) |
| | \$ (3,132) | \$ (3,216) |

20. Segment Reporting

The Company's operations are principally managed on a products basis and are comprised of four operating segments—Pharmaceutical, Animal Health, Consumer Care and Alliances (which includes revenue and equity income from the Company's relationship with AZLP). The Animal Health, Consumer Care and Alliances segments are not material for separate reporting and are included in all other in the table below. The Pharmaceutical segment includes human health pharmaceutical and vaccine products marketed either directly by the Company or through joint ventures. Human health pharmaceutical products consist of therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. The Company 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. Vaccine products consist of preventive pediatric, adolescent and adult vaccines, primarily administered at physician offices. The Company sells these human health vaccines primarily to physicians, wholesalers, physician distributors and government entities. A large component of pediatric and adolescent vaccines is sold to the U.S. Centers for Disease Control and Prevention Vaccines for Children program, which is funded by the U.S. government. Additionally, the Company sells vaccines to the Federal government for placement into vaccine stockpiles. The Company also has animal health operations that discover, develop, manufacture and market animal health products, including vaccines, which the Company sells to veterinarians, distributors and animal producers. Additionally, the Company has consumer care operations that develop, manufacture and market over-the-counter, foot care and sun care products, which are sold through wholesale and retail drug, food chain and mass merchandiser outlets. Segment composition reflects certain managerial changes that have been implemented. Consumer Care product sales outside the United States and Canada, previously included in the Pharmaceutical segment, are now included in the Consumer Care segment. Segment disclosures for prior years have been recast on a comparable basis with 2011.

Table of Contents

The accounting policies for the segments described above are the same as those described in Note 2. Revenues and profits for these segments are as follows:

| | Pharmaceutical | All Other | Total |
|--------------------------------------|------------------|-----------------|------------------|
| <i>Year Ended December 31, 2011</i> | | | |
| Segment sales | \$ 41,289 | \$ 6,327 | \$ 47,616 |
| Segment profits | 25,617 | 2,703 | 28,320 |
| Included in segment profits: | | | |
| Equity income from affiliates | 59 | 318 | 377 |
| Depreciation and amortization | (51) | (20) | (71) |
| <i>Year Ended December 31, 2010</i> | | | |
| Segment sales | \$ 39,267 | \$ 6,059 | \$ 45,326 |
| Segment profits | 23,864 | 2,559 | 26,423 |
| Included in segment profits: | | | |
| Equity income from affiliates | 90 | 323 | 413 |
| Depreciation and amortization | (101) | (17) | (118) |
| <i>Year Ended December 31, 2009</i> | | | |
| Segment sales | \$ 25,236 | \$ 2,114 | \$ 27,350 |
| Segment profits | 15,715 | 1,735 | 17,450 |
| Included in segment profits: | | | |
| Equity income from affiliates | 1,330 | 752 | 2,082 |
| Depreciation and amortization | (100) | (4) | (104) |

Segment profits are comprised of segment sales less certain elements of materials and production costs and operating expenses, including components of equity income or loss from affiliates and depreciation and amortization expenses. For internal management reporting presented to the chief operating decision maker, Merck does not allocate production costs, other than standard costs, research and development expenses or general and administrative expenses, nor 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.

Table of ContentsSales⁽¹⁾ of the Company's products were as follows:

| <i>Years Ended December 31</i> | 2011 | 2010 | 2009 |
|--|-------------|-------------|-------------|
| Pharmaceutical: | | | |
| <i>Cardiovascular</i> | | | |
| Zetia | \$ 2,428 | \$ 2,297 | \$ 403 |
| Vytorin | 1,882 | 2,014 | 441 |
| Integrilin | 230 | 266 | 46 |
| <i>Diabetes and Obesity</i> | | | |
| Januvia | 3,324 | 2,385 | 1,922 |
| Janumet | 1,363 | 954 | 658 |
| <i>Diversified Brands</i> | | | |
| Cozaar/Hyzaar | 1,663 | 2,104 | 3,561 |
| Zocor | 456 | 468 | 558 |
| Propecia | 447 | 447 | 440 |
| Claritin Rx | 314 | 296 | 71 |
| Remeron | 241 | 223 | 38 |
| Vasotec/Vaseretic | 231 | 255 | 311 |
| Proscar | 223 | 216 | 291 |
| <i>Infectious Disease</i> | | | |
| Isentress | 1,359 | 1,090 | 752 |
| PegIntron | 657 | 737 | 149 |
| Cancidas | 640 | 611 | 617 |
| Primaxin | 515 | 610 | 689 |
| Invanz | 406 | 362 | 293 |
| Avelox | 322 | 316 | 66 |
| Noxafil | 230 | 198 | 34 |
| Crixivan/Stocrin | 192 | 206 | 206 |
| Rebetol | 174 | 221 | 36 |
| Vitreolis | 140 | | |
| <i>Neurosciences and Ophthalmology</i> | | | |
| Maxalt | 639 | 550 | 575 |
| Cosopt/Trusopt | 477 | 484 | 503 |
| <i>Oncology</i> | | | |
| Temodar | 935 | 1,065 | 188 |
| Emend | 419 | 378 | 317 |
| Intron A | 194 | 209 | 38 |
| <i>Respiratory and Immunology</i> | | | |
| Singulair | 5,479 | 4,987 | 4,660 |
| Remicade | 2,667 | 2,714 | 431 |
| Nasonex | 1,286 | 1,219 | 165 |
| Clarinx | 621 | 623 | 101 |
| Arcoxia | 431 | 398 | 358 |
| Simponi | 264 | 97 | 4 |
| Asmanex | 206 | 208 | 37 |
| Proventil | 155 | 210 | 26 |
| Dulera | 96 | 8 | |
| <i>Vaccines⁽²⁾</i> | | | |
| Gardasil | 1,209 | 988 | 1,118 |
| ProQuad/M-M-R II/Varivax | 1,202 | 1,378 | 1,369 |
| RotaTeq | 651 | 519 | 522 |
| Pneumovax | 498 | 376 | 346 |
| Zostavax | 332 | 243 | 277 |
| <i>Women's Health and Endocrine</i> | | | |
| Fosamax | 855 | 926 | 1,100 |
| NuvaRing | 623 | 559 | 88 |
| Follistim AQ | 530 | 528 | 96 |
| Implanon | 294 | 236 | 37 |
| Cerazette | 268 | 209 | 35 |
| Other pharmaceutical ⁽³⁾ | 3,521 | 3,879 | 1,263 |
| Total Pharmaceutical segment sales | 41,289 | 39,267 | 25,236 |
| Other segment sales ⁽⁴⁾ | 6,327 | 6,059 | 2,114 |

Edgar Filing: Merck & Co. Inc. - Form 10-K

| | | | |
|----------------------|------------------|------------------|------------------|
| Total segment sales | 47,616 | 45,326 | 27,350 |
| Other ⁽⁵⁾ | 431 | 661 | 78 |
| | \$ 48,047 | \$ 45,987 | \$ 27,428 |

⁽¹⁾ Sales of legacy Schering-Plough products in 2009 are included only for the post-Merger period. In addition, prior to the Merger, substantially all sales of Zetia and Vytorin were recognized by the MSP Partnership and the results of Merck's interest in the MSP Partnership were recorded in Equity income from affiliates. As a result of the Merger, the MSP Partnership became wholly owned by the Company; accordingly, all sales of MSP Partnership products after the Merger are reflected in the table above. Sales of Zetia and Vytorin in 2009 reflect Merck's sales of these products in Latin America which was not part of the MSP Partnership, as well as sales of these products for the post-Merger period in 2009.

⁽²⁾ 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.

⁽³⁾ Other pharmaceutical primarily reflects sales of other human health pharmaceutical products, including products within the franchises not listed separately.

⁽⁴⁾ Reflects other non-reportable segments, including Animal Health and Consumer Care, and revenue from the Company's relationship with AZLP primarily relating to sales of Nexium, as well as Prilosec. Revenue from AZLP was \$1.2 billion, \$1.3 billion and \$1.4 billion in 2011, 2010 and 2009, respectively.

⁽⁵⁾ Other revenues are primarily comprised of miscellaneous corporate revenues, third-party manufacturing sales, sales related to divested products or businesses and other supply sales not included in segment results.

Table of Contents

Consolidated revenues by geographic area where derived are as follows:

| <i>Years Ended December 31</i> | 2011 | 2010 | 2009 |
|--------------------------------|------------------|-----------|-----------|
| United States | \$ 20,495 | \$ 20,226 | \$ 14,401 |
| Europe, Middle East and Africa | 13,782 | 13,497 | 7,326 |
| Japan | 4,835 | 3,768 | 2,452 |
| Other | 8,935 | 8,496 | 3,249 |
| | \$ 48,047 | \$ 45,987 | \$ 27,428 |

A reconciliation of total segment profits to consolidated *Income before taxes* is as follows:

| <i>Years Ended December 31</i> | 2011 | 2010 | 2009 |
|---|------------------|-----------|-----------|
| Segment profits | \$ 28,320 | \$ 26,423 | \$ 17,450 |
| Other profits (losses) | 90 | 90 | (137) |
| Adjustments | 940 | 401 | 399 |
| Unallocated: | | | |
| Interest income | 199 | 83 | 210 |
| Interest expense | (749) | (715) | (460) |
| Equity income from affiliates | 234 | 175 | 153 |
| Depreciation and amortization | (2,436) | (2,671) | (1,696) |
| Research and development | (8,467) | (11,111) | (5,845) |
| Amortization of purchase accounting adjustments | (5,000) | (6,566) | (2,286) |
| Restructuring costs | (1,306) | (985) | (1,634) |
| Arbitration settlement charge | (500) | | |
| Vioxx Liability Reserve | | (950) | |
| Gain on AstraZeneca asset option exercise | | 443 | |
| Gain related to MSP Partnership | | | 7,530 |
| Gain on Merial divestiture | | | 3,163 |
| Other expenses, net | (3,991) | (2,964) | (1,557) |
| | \$ 7,334 | \$ 1,653 | \$ 15,290 |

Other profits (losses) are primarily comprised of miscellaneous corporate profits (losses), as well as operating profits (losses) related to third-party manufacturing sales, divested products or businesses and other supply sales. Adjustments represent the elimination of the effect of double counting certain items of income and expense. Equity income from affiliates includes taxes paid at the joint venture level and a portion of equity income that is not reported in segment profits. Other expenses, net, include expenses from corporate and manufacturing cost centers and other miscellaneous income (expense), net.

Property, plant and equipment, net by geographic area where located is as follows:

| <i>Years Ended December 31</i> | 2011 | 2010 | 2009 |
|--------------------------------|------------------|-----------|-----------|
| United States | \$ 10,646 | \$ 11,078 | \$ 11,770 |
| Europe, Middle East and Africa | 3,780 | 4,014 | 2,884 |
| Japan | 279 | 315 | 284 |
| Other | 1,592 | 1,675 | 3,341 |
| | \$ 16,297 | \$ 17,082 | \$ 18,279 |

The Company does not disaggregate assets on a products and services basis for internal management reporting and, therefore, such information is not presented.

Table of Contents

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Merck & Co., Inc:

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of income, equity and cash flows present fairly, in all material respects, the financial position of Merck & Co., Inc. and its subsidiaries at December 31, 2011 and December 31, 2010, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2011 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, Merck maintained, in all material respects, effective internal control over financial reporting as of December 31, 2011, based on criteria established in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Merck's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report under Item 9A. Our responsibility is to express opinions on these financial statements and on Merck's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

PricewaterhouseCoopers LLP

Florham Park, New Jersey

February 27, 2012

Table of Contents**(b) Supplementary Data**

Selected quarterly financial data for 2011 and 2010 are contained in the Condensed Interim Financial Data table below.

Condensed Interim Financial Data (Unaudited)

| <i>(\$ in millions except per share amounts)</i> | 4th Q | 3rd Q ⁽¹⁾ | 2nd Q ⁽²⁾ | 1st Q ⁽³⁾ |
|---|------------------|----------------------|----------------------|----------------------|
| 2011⁽⁴⁾ | | | | |
| Sales | \$ 12,294 | \$ 12,022 | \$ 12,151 | \$ 11,580 |
| Materials and production | 4,176 | 4,352 | 4,284 | 4,059 |
| Marketing and administrative | 3,704 | 3,340 | 3,525 | 3,164 |
| Research and development | 2,419 | 1,954 | 1,936 | 2,158 |
| Restructuring costs | 533 | 119 | 668 | (14) |
| Equity income from affiliates | (257) | (161) | (55) | (138) |
| Other (income) expense, net | 139 | 66 | 121 | 622 |
| Income before taxes | 1,580 | 2,352 | 1,672 | 1,729 |
| Net income attributable to Merck & Co., Inc. | 1,512 | 1,692 | 2,024 | 1,043 |
| Basic earnings per common share attributable to Merck & Co., Inc. common shareholders | \$ 0.50 | \$ 0.55 | \$ 0.65 | \$ 0.34 |
| Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders | \$ 0.49 | \$ 0.55 | \$ 0.65 | \$ 0.34 |
| 2010⁽⁴⁾ | | | | |
| Sales | \$ 12,094 | \$ 11,125 | \$ 11,346 | \$ 11,422 |
| Materials and production | 4,440 | 4,191 | 4,549 | 5,216 |
| Marketing and administrative | 3,537 | 3,192 | 3,175 | 3,222 |
| Research and development | 4,559 | 2,322 | 2,179 | 2,051 |
| Restructuring costs | 121 | 50 | 526 | 288 |
| Equity income from affiliates | (171) | (236) | (43) | (138) |
| Other (income) expense, net | 309 | 1,108 | (281) | 167 |
| (Loss) income before taxes | (701) | 498 | 1,241 | 616 |
| Net (loss) income attributable to Merck & Co., Inc. | (531) | 342 | 752 | 299 |
| Basic (loss) earnings per common share attributable to Merck & Co., Inc. common shareholders | \$ (0.17) | \$ 0.11 | \$ 0.24 | \$ 0.10 |
| (Loss) earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders | \$ (0.17) | \$ 0.11 | \$ 0.24 | \$ 0.09 |

⁽¹⁾ Amounts for 2010 include the impact of the Vioxx Liability Reserve (see Note 12).

⁽²⁾ Amounts for 2011 include a net benefit relating to the settlement of a federal income tax audit (see Note 17). Amounts for 2010 reflect the income recognized on AstraZeneca's asset option exercise (see Note 10).

⁽³⁾ Amounts for 2011 include a charge relating to the resolution of the arbitration proceeding with J&J (see Note 6).

⁽⁴⁾ Amounts for 2011 and 2010 reflect the impacts of the Merger, including the amortization of purchase accounting adjustments and in-process research and development impairment charges (see Note 9). Amounts for 2011 and 2010 also include the impact of restructuring actions (see Note 4).

Table of Contents

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

Not applicable.

Item 9A. Controls and Procedures.

Management of the Company, with the participation of its Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the Company's disclosure controls and procedures. Based on their evaluation, as of the end of the period covered by this Form 10-K, the Company's Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Act")) are effective.

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) of the Act. Management conducted an evaluation of the effectiveness of internal control over financial reporting based on the framework in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based on this evaluation, management concluded that internal control over financial reporting was effective as of December 31, 2011. PricewaterhouseCoopers LLP, an independent registered public accounting firm, has performed its own assessment of the effectiveness of the Company's internal control over financial reporting and its attestation report is included in this Form 10-K filing.

As previously disclosed, the Company is in the process of a multi-year implementation of an enterprise-wide resource planning ("ERP") system. The Company completed the legacy Merck U.S. ERP deployment in the second quarter of 2010 and various deployments of the ERP in Canada and most major European markets during 2011. In 2012, it is expected that the ERP will be deployed in additional markets and also certain U.S. operations. In addition, in response to business integration activities, the Company has and will continue to further align and streamline the design and operation of the financial control environment to be responsive to the changing business model.

Management's Report

Management's Responsibility for Financial Statements

Responsibility for the integrity and objectivity of the Company's financial statements rests with management. The financial statements report on management's stewardship of Company assets. These statements are prepared in conformity with generally accepted accounting principles and, accordingly, include amounts that are based on management's best estimates and judgments. Nonfinancial information included in the Annual Report on Form 10-K has also been prepared by management and is consistent with the financial statements.

To assure that financial information is reliable and assets are safeguarded, management maintains an effective system of internal controls and procedures, important elements of which include: careful selection, training and development of operating and financial managers; an organization that provides appropriate division of responsibility; and communications aimed at assuring that Company policies and procedures are understood throughout the organization. A staff of internal auditors regularly monitors the adequacy and application of internal controls on a worldwide basis.

To ensure that personnel continue to understand the system of internal controls and procedures, and policies concerning good and prudent business practices, the Company periodically conducts the Management's Stewardship Program for key management and financial personnel. This program reinforces the importance and understanding of internal controls by reviewing key corporate policies, procedures and systems. In addition, the Company has compliance programs, including an ethical business practices program to reinforce the Company's long-standing commitment to high ethical standards in the conduct of its business.

The financial statements and other financial information included in the Annual Report on Form 10-K fairly present, in all material respects, the Company's financial condition, results of operations and cash flows. Our formal certification to the Securities and Exchange Commission is included in this Form 10-K filing.

Table of Contents

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Securities Exchange Act of 1934. The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States of America. Management conducted an evaluation of the effectiveness of internal control over financial reporting based on the framework in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that internal control over financial reporting was effective as of December 31, 2011.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The effectiveness of the Company's internal control over financial reporting as of December 31, 2011, has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

Kenneth C. Frazier
Chairman, President

and Chief Executive Officer

Item 9B. Other Information.

None.

Peter N. Kellogg
Executive Vice President

and Chief Financial Officer

Table of Contents

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The required information on directors and nominees is incorporated by reference from the discussion under Item 1. Election of Directors of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 22, 2012. Information on executive officers is set forth in Part I of this document on pages 34 through 37.

The required information on compliance with Section 16(a) of the Securities Exchange Act of 1934 is incorporated by reference from the discussion under the heading "Section 16(a) Beneficial Ownership Reporting Compliance" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 22, 2012.

The Company has adopted a Code of Conduct *Our Values and Standards* applicable to all employees, including the principal executive officer, principal financial officer, and principal accounting officer. The Code of Conduct is available on the Company's website at www.merck.com/about/code_of_conduct.pdf. The Company intends to post on this website any amendments to, or waivers from, its Code of Conduct. A printed copy will be sent, without charge, to any shareholder who requests it by writing to the Chief Ethics Officer of Merck & Co., Inc., One Merck Drive, Whitehouse Station, NJ 08889-0100.

The required information on the identification of the audit committee and the audit committee financial expert is incorporated by reference from the discussion under the heading "Board Committees" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 22, 2012.

Item 11. Executive Compensation.

The information required on executive compensation is incorporated by reference from the discussion under the headings "Compensation Discussion and Analysis", "Summary Compensation Table", "All Other Compensation" table, "Grants of Plan-Based Awards" table, "Outstanding Equity Awards" table, "Option Exercises and Stock Vested" table, "Retirement Plan Benefits and related Pension Benefits" table, "Nonqualified Deferred Compensation and related tables", "Potential Payments Upon Termination or Change in Control", including the discussion under the subheadings "Separation", "Individual Agreements" and "Change in Control", as well as all footnote information to the various tables, of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 22, 2012.

The required information on director compensation is incorporated by reference from the discussion under the heading "Director Compensation and related Director Compensation" table and "Schedule of Director Fees" table of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 22, 2012.

The required information under the headings "Compensation Committee Interlocks and Insider Participation" and "Compensation and Benefits Committee Report" is incorporated by reference from the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 22, 2012.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Information with respect to securities authorized for issuance under equity compensation plans is set forth in Part II of this document on page 39. Information with respect to security ownership of certain beneficial owners and management is incorporated by reference from the discussion under the heading "Security Ownership of Certain Beneficial Owners and Management" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 22, 2012.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The required information on transactions with related persons is incorporated by reference from the discussion under the heading "Related Person Transactions" of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 22, 2012.

Table of Contents

The required information on director independence is incorporated by reference from the discussion under the heading Independence of Directors of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 22, 2012.

Item 14. Principal Accountant Fees and Services.

The information required for this item is incorporated by reference from the discussion under Audit Committee beginning with the caption Pre-Approval Policy for Services of Independent Registered Public Accounting Firm through All Other Fees of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 22, 2012.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) The following documents are filed as part of this Form 10-K

1. Financial Statements

Consolidated statement of income for the years ended December 31, 2011, 2010 and 2009

Consolidated balance sheet as of December 31, 2011 and 2010

Consolidated statement of equity for the years ended December 31, 2011, 2010 and 2009

Consolidated statement of cash flows for the years ended December 31, 2011, 2010 and 2009

Notes to consolidated financial statements

Report of PricewaterhouseCoopers LLP, independent registered public accounting firm

2. Financial Statement Schedules

Schedules are omitted because they are either not required or not applicable.

Financial statements of affiliates carried on the equity basis have been omitted because, considered individually or in the aggregate, such affiliates do not constitute a significant subsidiary.

Table of Contents

3. Exhibits

Exhibit

| Number | Description |
|---------------|--|
| 2.1 | Master Restructuring Agreement dated as of June 19, 1998 between Astra AB, Merck & Co., Inc., Astra Merck Inc., Astra USA, Inc., KB USA, L.P., Astra Merck Enterprises, Inc., KBI Sub Inc., Merck Holdings, Inc. and Astra Pharmaceuticals, L.P. (Portions of this Exhibit are subject to a request for confidential treatment filed with the Commission) Incorporated by reference to MSD's Form 10-Q Quarterly Report for the period ended June 30, 1998 |
| 2.2 | Agreement and Plan of Merger by and among Merck & Co., Inc., Schering-Plough Corporation, Blue, Inc. and Purple, Inc. dated as of March 8, 2009 Incorporated by reference to Schering-Plough's Current Report on Form 8-K filed March 11, 2009 |
| 2.3 | Share Purchase Agreement, dated July 29, 2009, by and among Merck & Co., Inc., Merck SH Inc., Merck Sharp & Dohme (Holdings) Limited and sanofi-aventis Incorporated by reference to MSD's Current Report on Form 8-K dated July 31, 2009 |
| 3.1 | Restated Certificate of Incorporation of Merck & Co., Inc. (November 3, 2009) Incorporated by reference to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 |
| 3.2 | By-Laws of Merck & Co., Inc. (effective November 3, 2009) Incorporated by reference to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 |
| 4.1 | Indenture, dated as of April 1, 1991, between Merck & Co., Inc. and Morgan Guaranty Trust Company of New York, as Trustee Incorporated by reference to Exhibit 4 to MSD's Registration Statement on Form S-3 (No. 33-39349) |
| 4.2 | First Supplemental Indenture between Merck & Co., Inc. and First Trust of New York, National Association, as Trustee Incorporated by reference to Exhibit 4(b) to MSD's Registration Statement on Form S-3 (No. 333-36383) |
| 4.3 | Second Supplemental Indenture, dated November 3, 2009, among Merck Sharp & Dohme Corp., Merck & Co., Inc. and U.S. Bank Trust National Association, as Trustee Incorporated by reference to Exhibit 4.3 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 |
| 4.4 | Indenture, dated November 26, 2003, between Schering-Plough and The Bank of New York as Trustee Incorporated by reference to Exhibit 4.1 to Schering-Plough's Current Report on Form 8-K filed November 28, 2003 |
| 4.5 | First Supplemental Indenture (including Form of Note), dated November 26, 2003 Incorporated by reference to Exhibit 4.2 to Schering-Plough's Current Report on Form 8-K filed November 28, 2003 |
| 4.6 | Second Supplemental Indenture (including Form of Note), dated November 26, 2003 Incorporated by reference to Exhibit 4.3 to Schering-Plough's Current Report on Form 8-K filed November 28, 2003 |
| 4.7 | Third Supplemental Indenture (including Form of Note), dated September 17, 2007 Incorporated by reference to Exhibit 4.1 to Schering-Plough's Current Report on Form 8-K filed September 17, 2007 |
| 4.8 | Fourth Supplemental Indenture (including Form of Note), dated October 1, 2007 Incorporated by reference to Exhibit 4.1 to Schering-Plough's Current Report on Form 8-K filed October 2, 2007 |
| 4.9 | Fifth Supplemental Indenture, dated November 3, 2009, among Merck Sharp & Dohme Corp., Merck & Co., Inc. and The Bank of New York Mellon, as Trustee Incorporated by reference to Exhibit 4.4 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 |
| 4.10 | Indenture, dated as of January 6, 2010, between Merck & Co., Inc. and U.S. Bank Trust National Association, as Trustee Incorporated by reference to Exhibit 4.1 to Merck & Co., Inc.'s Current Report on Form 8-K filed December 10, 2010 |
| *10.1 | Executive Incentive Plan (as amended effective February 27, 1996) Incorporated by reference to MSD's Form 10-K Annual Report for the fiscal year ended December 31, 1995 |
| *10.2 | Merck Sharp & Dohme Corp. Deferral Program, including Base Salary Deferral Plan (effective as amended and restated as of November 3, 2009) Incorporated by reference to Exhibit 10.15 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 |

Table of Contents

Exhibit

| Number | Description |
|---------------|---|
| *10.3 | Merck Sharp & Dohme Corp. 2001 Incentive Stock Plan (amended and restated as of November 3, 2009) Incorporated by reference to Exhibit 10.9 to Merck & Co., Inc. s Current Report on Form 8-K filed November 4, 2009 |
| *10.4 | Merck Sharp & Dohme Corp. 2004 Incentive Stock Plan (amended and restated as of November 3, 2009) Incorporated by reference to Exhibit 10.8 to Merck & Co., Inc. s Current Report on Form 8-K filed November 4, 2009 |
| *10.5 | Merck Sharp & Dohme Corp. 2007 Incentive Stock Plan (effective as amended and restated as of November 3, 2009) Incorporated by reference to Exhibit 10.7 to Merck & Co., Inc. s Current Report on Form 8-K filed November 4, 2009 |
| *10.6 | Amendment One to the Merck Sharp & Dohme Corp. 2007 Incentive Stock Plan (effective February 15, 2010) Incorporated by reference to Exhibit 10.2 to Merck & Co., Inc. s Current Report on Form 8-K filed February 18, 2010 |
| *10.7 | 1997 Stock Incentive Plan Incorporated by reference to Exhibit 10 to Schering-Plough s 10-Q for the period ended September 30, 1997 |
| *10.8 | Amendment to 1997 Stock Incentive Plan (effective February 22, 1999) Incorporated by reference to Exhibit 10(a) to Schering-Plough s 10-Q for the period ended March 31, 1999 |
| *10.9 | Amendment to the 1997 Stock Incentive Plan (effective February 25, 2003) Incorporated by reference to Exhibit 10(c) to Schering-Plough s 10-K for the year ended December 31, 2002 |
| *10.10 | 2002 Stock Incentive Plan (as amended to February 25, 2003) Incorporated by reference to Exhibit 10(d) to Schering-Plough s 10-K for the year ended December 31, 2002 |
| *10.11 | Merck & Co., Inc. Schering-Plough 2006 Stock Incentive Plan (as amended and restated, effective November 3, 2009) Incorporated by reference to Exhibit 10.13 to Merck & Co., Inc. s Current Report on Form 8-K filed November 4, 2009 |
| *10.12 | Merck & Co., Inc. 2010 Incentive Stock Plan (effective as of May 1, 2010) Incorporated by reference to Merck & Co., Inc. s Schedule 14A filed April 12, 2010 |
| *10.13 | Stock option terms for a non-qualified stock option under the Merck Sharp & Dohme Corp. 2007 Incentive Stock Plan and the Schering-Plough 2006 Stock Incentive Plan Incorporated by reference to Exhibit 10.3 to Merck & Co., Inc. s Current Report on Form 8-K filed February 15, 2010 |
| *10.14 | Restricted stock unit terms for annual grant under the Merck Sharp & Dohme Corp. 2007 Incentive Stock Plan and the Schering-Plough 2006 Stock Incentive Plan Incorporated by reference to Exhibit 10.4 to Merck & Co., Inc. s Current Report on Form 8-K filed February 15, 2010 |
| *10.15 | Restricted stock unit terms for Leader Shares grant under the Merck & Co., Inc. 2007 Incentive Stock Plan Incorporated by reference to MSD s Form 10-Q Quarterly Report for the period ended March 31, 2009 |
| *10.16 | Restricted stock unit terms for 2011 grants for Richard T. Clark under the Merck & Co., Inc. 2010 Incentive Stock Plan Incorporated by reference to Merck & Co. s Form 10-Q Quarterly Report for the period ended March 31, 2011 |
| *10.17 | Stock option terms for 2011 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan Incorporated by reference to Merck & Co., Inc. s Form 10-Q Quarterly Report for the period ended March 31, 2011 |
| *10.18 | Restricted stock unit terms for 2011 quarterly and annual grants under the Merck & Co., Inc. 2010 Incentive Stock Plan Incorporated by reference to Merck & Co., Inc. s Form 10-Q Quarterly Report for the period ended March 31, 2011 |
| *10.19 | Performance share unit terms for 2011 grants under the Merck & Co., Inc. 2010 Incentive Stock Plan Incorporated by reference to Merck & Co., Inc. s Form 10-Q Quarterly Report for the period ended March 31, 2011 |
| *10.20 | Stock option terms for 2012 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan |
| *10.21 | Restricted stock unit terms for 2012 quarterly and annual grants under the Merck & Co., Inc. 2010 Incentive Stock Plan |

Table of Contents

Exhibit

| Number | Description |
|---------------|--|
| *10.22 | Merck & Co., Inc. Change in Control Separation Benefits Plan Incorporated by reference to Merck & Co., Inc. s Current Report on Form 8-K dated November 23, 2009 |
| *10.23 | Amendment One to Merck & Co., Inc. Change in Control Separation Benefits Plan (effective February 15, 2010) Incorporated by reference to Exhibit 10.1 to Merck & Co., Inc. s Current Report on Form 8-K filed February 18, 2010 |
| *10.24 | MSD Separation Benefits Plan for Nonunion Employees (amended and restated effective as of October 1, 2010) Incorporated by reference to Merck & Co., Inc. s Form 10-K Annual Report for the fiscal year ended December 31, 2010 |
| *10.25 | MSD Special Separation Program for Separated Employees (amended and restated effective as of October 1, 2010) Incorporated by reference to Merck & Co., Inc. s Form 10-K Annual Report for the fiscal year ended December 31, 2010 |
| *10.26 | MSD Special Separation Program for Bridged Employees (amended and restated effective as of October 1, 2010) Incorporated by reference to Merck & Co., Inc. s Form 10-K Annual Report for the fiscal year ended December 31, 2010 |
| *10.27 | MSD Special Separation Program for Separated Retirement Eligible Employees (amended and restated effective as of October 1, 2010) Incorporated by reference to Merck & Co., Inc. s Form 10-K Annual Report for the fiscal year ended December 31, 2010 |
| *10.28 | Merck & Co., Inc. U.S. Separation Benefits Plan (effective as of January 1, 2012) |
| *10.29 | Important Information on the Separation Program Applicable to Legacy Merck Rebadged Employees (effective as of January 1, 2012) |
| *10.30 | Important Information on the Separation Program Applicable to Legacy Merck Separated Retirement Eligible Employees (effective as of January 1, 2012) |
| *10.31 | Important Information on the Separation Program Applicable to Legacy Merck Separated Employees (effective as of January 1, 2012) |
| *10.32 | Important Information on the Separation Program Applicable to Legacy Merck Bridge-Eligible Employees (effective as of January 1, 2012) |
| *10.33 | Important Information on the Separation Program Applicable to Legacy Schering Rebadged Employees (effective as of January 1, 2012) |
| *10.34 | Important Information on the Separation Program Applicable to Legacy Schering Separated Retirement Eligible Employees (effective as of January 1, 2012) |
| *10.35 | Important Information on the Separation Program Applicable to Legacy Schering Separated Employees (effective as of January 1, 2012) |
| *10.36 | Schering-Plough Corporation Severance Benefit Plan (as amended and restated effective November 3, 2009) Incorporated by reference to Merck & Co., Inc. s Form 10-K Annual Report for the fiscal year ended December 31, 2009 |
| *10.37 | Merck & Co., Inc. 2001 Non-Employee Directors Stock Option Plan (amended and restated as of November 3, 2009) Incorporated by reference to Exhibit 10.11 to Merck & Co., Inc. s Current Report on Form 8-K filed November 4, 2009 |
| *10.38 | Merck & Co., Inc. 2006 Non-Employee Directors Stock Option Plan (amended and restated as of November 3, 2009) Incorporated by reference to Exhibit 10.5 to Merck & Co., Inc. s Current Report on Form 8-K filed November 4, 2009 |
| *10.39 | Merck & Co., Inc. 2010 Non-Employee Directors Stock Option Plan (amended and restated as of December 1, 2010) Incorporated by reference to Merck & Co., Inc. s Form 10-K Annual Report for the fiscal year ended December 31, 2010 |
| *10.40 | Retirement Plan for the Directors of Merck & Co., Inc. (amended and restated June 21, 1996) Incorporated by reference to MSD s Form 10-Q Quarterly Report for the period ended June 30, 1996 |
| *10.41 | Merck & Co., Inc. Plan for Deferred Payment of Directors Compensation (effective as amended and restated as of December 1, 2010) Incorporated by reference to Merck & Co., Inc. s Form 10-K Annual Report for the fiscal year ended December 31, 2010 |
| *10.42 | Offer Letter between Merck & Co., Inc. and Peter S. Kim, dated December 15, 2000 Incorporated by reference to MSD s Form 10-K Annual Report for the fiscal year ended December 31, 2003 |

Table of Contents

Exhibit

| Number | Description |
|---------------|--|
| *10.43 | Offer Letter between Merck & Co., Inc. and Peter N. Kellogg, dated June 18, 2007 Incorporated by reference to MSD's Current Report on Form 8-K dated June 28, 2007 |
| *10.44 | Form of employment agreement effective upon a change of control between Schering-Plough and certain executives for new agreements beginning in January 1, 2008 Incorporated by reference to Exhibit 10(e)(xv) to Schering-Plough's 10-K for the year ended December 31, 2008 |
| 10.45 | Share Purchase Agreement between Akzo Nobel N.V., Schering-Plough International C.V., and Schering-Plough Corporation Incorporated by reference to Exhibit 10.1 to Schering-Plough's 8-K filed October 2, 2007 |
| 10.46 | Amended and Restated License and Option Agreement dated as of July 1, 1998 between Astra AB and Astra Merck Inc. Incorporated by reference to MSD's Form 10-Q Quarterly Report for the period ended June 30, 1998 |
| 10.47 | KBI Shares Option Agreement dated as of July 1, 1998 by and among Astra AB, Merck & Co., Inc. and Merck Holdings, Inc. Incorporated by reference to MSD's Form 10-Q Quarterly Report for the period ended June 30, 1998 |
| 10.48 | KBI-E Asset Option Agreement dated as of July 1, 1998 by and among Astra AB, Merck & Co., Inc., Astra Merck Inc. and Astra Merck Enterprises Inc. Incorporated by reference to MSD's Form 10-Q Quarterly Report for the period ended June 30, 1998 |
| 10.49 | KBI Supply Agreement dated as of July 1, 1998 between Astra Merck Inc. and Astra Pharmaceuticals, L.P. (Portions of this Exhibit are subject to a request for confidential treatment filed with the Commission). Incorporated by reference to MSD's Form 10-Q Quarterly Report for the period ended June 30, 1998 |
| 10.50 | Second Amended and Restated Manufacturing Agreement dated as of July 1, 1998 among Merck & Co., Inc., Astra AB, Astra Merck Inc. and Astra USA, Inc. Incorporated by reference to MSD's Form 10-Q Quarterly Report for the period ended June 30, 1998 |
| 10.51 | Limited Partnership Agreement dated as of July 1, 1998 between KB USA, L.P. and KBI Sub Inc. Incorporated by reference to MSD's Form 10-Q Quarterly Report for the period ended June 30, 1998 |
| 10.52 | Distribution Agreement dated as of July 1, 1998 between Astra Merck Enterprises Inc. and Astra Pharmaceuticals, L.P. Incorporated by reference to MSD's Form 10-Q Quarterly Report for the period ended June 30, 1998 |
| 10.53 | Agreement to Incorporate Defined Terms dated as of June 19, 1998 between Astra AB, Merck & Co., Inc., Astra Merck Inc., Astra USA, Inc., KB USA, L.P., Astra Merck Enterprises Inc., KBI Sub Inc., Merck Holdings, Inc. and Astra Pharmaceuticals, L.P. Incorporated by reference to MSD's Form 10-Q Quarterly Report for the period ended June 30, 1998 |
| 10.54 | Form of Voting Agreement made and entered into as of October 30, 2006 by and between Merck & Co., Inc. and Sirna Therapeutics, Inc. Incorporated by reference to MSD's Current Report on Form 8-K dated October 30, 2006 |
| 10.55 | Commitment Letter by and among Merck & Co., Inc., J.P. Morgan Securities Inc. and JPMorgan Chase Bank, N.A. dated as of March 8, 2009 Incorporated by reference to MSD's Current Report on Form 8-K dated March 8, 2009 |
| 10.56 | Incremental Credit Agreement dated as of May 6, 2009, among Merck & Co., Inc., the Guarantors and Lenders party thereto, and JPMorgan Chase Bank, N.A., as Administrative Agent Incorporated by reference to MSD's Current Report on Form 8-K dated May 6, 2009 |
| 10.57 | Asset Sale Facility Agreement dated as of May 6, 2009, among Merck & Co., Inc., the Guarantors and Lenders party thereto, and JPMorgan Chase Bank, N.A., as Administrative Agent Incorporated by reference to MSD's Current Report on Form 8-K dated May 6, 2009 |
| 10.58 | Bridge Loan Agreement dated as of May 6, 2009, among Merck & Co., Inc., the Guarantors and Lenders party thereto, and JPMorgan Chase Bank, N.A., as Administrative Agent Incorporated by reference to MSD's Current Report on Form 8-K dated May 6, 2009 |
| 10.59 | Amendment No. 1 to Amended and Restated Five-Year Credit Agreement dated as of April 20, 2009 among Merck & Co., Inc., the Lenders party thereto and Citicorp USA, Inc., as Administrative Agent Incorporated by reference to Exhibit 10.1 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 |

Table of Contents

Exhibit

| Number | Description |
|---------------|---|
| 10.60 | Guarantee and Joinder Agreement dated as of November 3, 2009 by Merck & Co., Inc., the Guarantor, for the benefit of the Guaranteed Parties Incorporated by reference to Exhibit 10.3 to Merck & Co., Inc. s Current Report on Form 8-K filed November 4, 2009 |
| 10.61 | Guarantor Joinder Agreement dated as of November 3, 2009, by Merck & Co., Inc., the Guarantor and JPMorgan Chase Bank, N.A., as Administrative Agent Incorporated by reference to Exhibit 10.4 to Merck & Co., Inc. s Current Report on Form 8-K filed November 4, 2009 |
| 10.62 | Call Option Agreement, dated July 29, 2009, by and among Merck & Co., Inc., Schering-Plough Corporation and sanofi-aventis Incorporated by reference to MSD s Current Report on Form 8-K dated July 31, 2009 |
| 10.63 | Termination Agreement, dated as of September 17, 2009, by and among Merck & Co., Inc., Merck SH Inc., Merck Sharp & Dohme (Holdings) Limited, sanofi-aventis, sanofi 4 and Merial Limited Incorporated by reference to MSD s Current Report on Form 8-K dated September 21, 2009 |
| 10.64 | Letter Agreement dated April 14, 2003 relating to Consent Decree Incorporated by reference to Exhibit 99.3 to Schering-Plough s 10-Q for the period ended March 31, 2003 |
| 10.65 | Distribution agreement between Schering-Plough and Centocor, Inc., dated April 3, 1998 Incorporated by reference to Exhibit 10(u) to Schering-Plough s Amended 10-K for the year ended December 31, 2003, filed May 3, 2004 |
| 10.66 | Amendment Agreement to the Distribution Agreement between Centocor, Inc., CAN Development, LLC, and Schering-Plough (Ireland) Company Incorporated by reference to Exhibit 10.1 to Schering-Plough s Current Report on Form 8-K filed December 21, 2007 |
| 12 | Computation of Ratios of Earnings to Fixed Charges |
| 21 | Subsidiaries of Merck & Co., Inc. |
| 23.1 | Consent of Independent Registered Public Accounting Firm Contained on page 159 of this Report |
| 24.1 | Power of Attorney |
| 24.2 | Certified Resolution of Board of Directors |
| 31.1 | Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer |
| 31.2 | Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer |
| 32.1 | Section 1350 Certification of Chief Executive Officer |
| 32.2 | Section 1350 Certification of Chief Financial Officer |
| 101 | The following materials from Merck & Co., Inc. s Annual Report on Form 10-K for the fiscal year ended December 31, 2011, formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Statement of Income, (ii) the Consolidated Balance Sheet, (iii) the Consolidated Statement of Cash Flow, and (iv) Notes to Consolidated Financial Statements. |

* Management contract or compensatory plan or arrangement.

Certain portions of the exhibit have been omitted pursuant to a request for confidential treatment. The non-public information has been filed separately with the Securities and Exchange Commission pursuant to rule 24b-2 under the Securities Exchange Act of 1934, as amended.

Table of Contents**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: February 28, 2012

MERCK & CO., INC.

By: KENNETH C. FRAZIER
(Chairman, President and Chief Executive Officer)

By: /S/ CELIA A. COLBERT
Celia A. Colbert
(Attorney-in-Fact)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

| Signatures | Title | Date |
|--------------------------|--|-------------------|
| KENNETH C. FRAZIER | Chairman, President and Chief Executive Officer; Principal Executive Officer; Director | February 28, 2012 |
| PETER N. KELLOGG | Executive Vice President and Chief Financial Officer; Principal Financial Officer | February 28, 2012 |
| JOHN CANAN | Senior Vice President and Global Controller; Principal Accounting Officer | February 28, 2012 |
| LESLIE A. BRUN | Director | February 28, 2012 |
| THOMAS R. CECH | Director | February 28, 2012 |
| THOMAS H. GLOCER | Director | February 28, 2012 |
| STEVEN F. GOLDSTONE | Director | February 28, 2012 |
| WILLIAM B. HARRISON, JR. | Director | February 28, 2012 |
| HARRY R. JACOBSON | Director | February 28, 2012 |
| WILLIAM N. KELLEY | Director | February 28, 2012 |
| C. ROBERT KIDDER | Director | February 28, 2012 |
| ROCHELLE B. LAZARUS | Director | February 28, 2012 |
| CARLOS E. REPRESAS | Director | February 28, 2012 |
| PATRICIA F. RUSSO | Director | February 28, 2012 |
| ANNE M. TATLOCK | Director | February 28, 2012 |
| CRAIG B. THOMPSON | Director | February 28, 2012 |
| WENDELL P. WEEKS | Director | February 28, 2012 |
| PETER C. WENDELL | Director | February 28, 2012 |

Celia A. Colbert, by signing her name hereto, does hereby sign this document pursuant to powers of attorney of attorney duly executed by the persons named, filed with the Securities and Exchange Commission as an exhibit to this document, on behalf of such persons, all in the capacities and on the date stated, such persons including a majority of the directors of the Company.

By: /S/ CELIA A. COLBERT
Celia A. Colbert
(Attorney-in-Fact)

Table of Contents

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (Nos. 333-164482, 333-163858 and 333-163546) and on Form S-8 (Nos. 333-173025, 333-173024, 333-162882, 333-162883, 333-162884, 333-162885, 333-162886, 033-57111, 333-112421, 333-134281, 333-121089, 333-30331, 333-87077, 333-153542, 333-162007, 333-91440 and 333-105567) of Merck & Co., Inc. of our report dated February 27, 2012 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

PricewaterhouseCoopers LLP

Florham Park, New Jersey

February 27, 2012

Table of Contents**EXHIBIT INDEX****Exhibit**

| Number | Description |
|---------------|--|
| 2.1 | Master Restructuring Agreement dated as of June 19, 1998 between Astra AB, Merck & Co., Inc., Astra Merck Inc., Astra USA, Inc., KB USA, L.P., Astra Merck Enterprises, Inc., KBI Sub Inc., Merck Holdings, Inc. and Astra Pharmaceuticals, L.P. (Portions of this Exhibit are subject to a request for confidential treatment filed with the Commission) Incorporated by reference to MSD's Form 10-Q Quarterly Report for the period ended June 30, 1998 |
| 2.2 | Agreement and Plan of Merger by and among Merck & Co., Inc., Schering-Plough Corporation, Blue, Inc. and Purple, Inc. dated as of March 8, 2009 Incorporated by reference to Schering-Plough's Current Report on Form 8-K filed March 11, 2009 |
| 2.3 | Share Purchase Agreement, dated July 29, 2009, by and among Merck & Co., Inc., Merck SH Inc., Merck Sharp & Dohme (Holdings) Limited and sanofi-aventis Incorporated by reference to MSD's Current Report on Form 8-K dated July 31, 2009 |
| 3.1 | Restated Certificate of Incorporation of Merck & Co., Inc. (November 3, 2009) Incorporated by reference to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 |
| 3.2 | By-Laws of Merck & Co., Inc. (effective November 3, 2009) Incorporated by reference to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 |
| 4.1 | Indenture, dated as of April 1, 1991, between Merck & Co., Inc. and Morgan Guaranty Trust Company of New York, as Trustee Incorporated by reference to Exhibit 4 to MSD's Registration Statement on Form S-3 (No. 33-39349) |
| 4.2 | First Supplemental Indenture between Merck & Co., Inc. and First Trust of New York, National Association, as Trustee Incorporated by reference to Exhibit 4(b) to MSD's Registration Statement on Form S-3 (No. 333-36383) |
| 4.3 | Second Supplemental Indenture, dated November 3, 2009, among Merck Sharp & Dohme Corp., Merck & Co., Inc. and U.S. Bank Trust National Association, as Trustee Incorporated by reference to Exhibit 4.3 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 |
| 4.4 | Indenture, dated November 26, 2003, between Schering-Plough and The Bank of New York as Trustee Incorporated by reference to Exhibit 4.1 to Schering-Plough's Current Report on Form 8-K filed November 28, 2003 |
| 4.5 | First Supplemental Indenture (including Form of Note), dated November 26, 2003 Incorporated by reference to Exhibit 4.2 to Schering-Plough's Current Report on Form 8-K filed November 28, 2003 |
| 4.6 | Second Supplemental Indenture (including Form of Note), dated November 26, 2003 Incorporated by reference to Exhibit 4.3 to Schering-Plough's Current Report on Form 8-K filed November 28, 2003 |
| 4.7 | Third Supplemental Indenture (including Form of Note), dated September 17, 2007 Incorporated by reference to Exhibit 4.1 to Schering-Plough's Current Report on Form 8-K filed September 17, 2007 |
| 4.8 | Fourth Supplemental Indenture (including Form of Note), dated October 1, 2007 Incorporated by reference to Exhibit 4.1 to Schering-Plough's Current Report on Form 8-K filed October 2, 2007 |
| 4.9 | Fifth Supplemental Indenture, dated November 3, 2009, among Merck Sharp & Dohme Corp., Merck & Co., Inc. and The Bank of New York Mellon, as Trustee Incorporated by reference to Exhibit 4.4 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 |
| 4.10 | Indenture, dated as of January 6, 2010, between Merck & Co., Inc. and U.S. Bank Trust National Association, as Trustee Incorporated by reference to Exhibit 4.1 to Merck & Co., Inc.'s Current Report on Form 8-K filed December 10, 2010 |
| *10.1 | Executive Incentive Plan (as amended effective February 27, 1996) Incorporated by reference to MSD's Form 10-K Annual Report for the fiscal year ended December 31, 1995 |
| *10.2 | Merck Sharp & Dohme Corp. Deferral Program, including Base Salary Deferral Plan (effective as amended and restated as of November 3, 2009) Incorporated by reference to Exhibit 10.15 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 |
| *10.3 | Merck Sharp & Dohme Corp. 2001 Incentive Stock Plan (amended and restated as of November 3, 2009) Incorporated by reference to Exhibit 10.9 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 |

Table of Contents

Exhibit

| Number | Description |
|---------------|---|
| *10.4 | Merck Sharp & Dohme Corp. 2004 Incentive Stock Plan (amended and restated as of November 3, 2009) Incorporated by reference to Exhibit 10.8 to Merck & Co., Inc. s Current Report on Form 8-K filed November 4, 2009 |
| *10.5 | Merck Sharp & Dohme Corp. 2007 Incentive Stock Plan (effective as amended and restated as of November 3, 2009) Incorporated by reference to Exhibit 10.7 to Merck & Co., Inc. s Current Report on Form 8-K filed November 4, 2009 |
| *10.6 | Amendment One to the Merck Sharp & Dohme Corp. 2007 Incentive Stock Plan (effective February 15, 2010) Incorporated by reference to Exhibit 10.2 to Merck & Co., Inc. s Current Report on Form 8-K filed February 18, 2010 |
| *10.7 | 1997 Stock Incentive Plan Incorporated by reference to Exhibit 10 to Schering-Plough s 10-Q for the period ended September 30, 1997 |
| *10.8 | Amendment to 1997 Stock Incentive Plan (effective February 22, 1999) Incorporated by reference to Exhibit 10(a) to Schering-Plough s 10-Q for the period ended March 31, 1999 |
| *10.9 | Amendment to the 1997 Stock Incentive Plan (effective February 25, 2003) Incorporated by reference to Exhibit 10(c) to Schering-Plough s 10-K for the year ended December 31, 2002 |
| *10.10 | 2002 Stock Incentive Plan (as amended to February 25, 2003) Incorporated by reference to Exhibit 10(d) to Schering-Plough s 10-K for the year ended December 31, 2002 |
| *10.11 | Merck & Co., Inc. Schering-Plough 2006 Stock Incentive Plan (as amended and restated, effective November 3, 2009) Incorporated by reference to Exhibit 10.13 to Merck & Co., Inc. s Current Report on Form 8-K filed November 4, 2009 |
| *10.12 | Merck & Co., Inc. 2010 Incentive Stock Plan (effective as of May 1, 2010) Incorporated by reference to Merck & Co., Inc. s Schedule 14A filed April 12, 2010 |
| *10.13 | Stock option terms for a non-qualified stock option under the Merck Sharp & Dohme Corp. 2007 Incentive Stock Plan and the Schering-Plough 2006 Stock Incentive Plan Incorporated by reference to Exhibit 10.3 to Merck & Co., Inc. s Current Report on Form 8-K filed February 15, 2010 |
| *10.14 | Restricted stock unit terms for annual grant under the Merck Sharp & Dohme Corp. 2007 Incentive Stock Plan and the Schering-Plough 2006 Stock Incentive Plan Incorporated by reference to Exhibit 10.4 to Merck & Co., Inc. s Current Report on Form 8-K filed February 15, 2010 |
| *10.15 | Restricted stock unit terms for Leader Shares grant under the Merck & Co., Inc. 2007 Incentive Stock Plan Incorporated by reference to MSD s Form 10-Q Quarterly Report for the period ended March 31, 2009 |
| *10.16 | Restricted stock unit terms for 2011 grants for Richard T. Clark under the Merck & Co., Inc. 2010 Incentive Stock Plan Incorporated by reference to Merck & Co. s Form 10-Q Quarterly Report for the period ended March 31, 2011 |
| *10.17 | Stock option terms for 2011 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan Incorporated by reference to Merck & Co., Inc. s Form 10-Q Quarterly Report for the period ended March 31, 2011 |
| *10.18 | Restricted stock unit terms for 2011 quarterly and annual grants under the Merck & Co., Inc. 2010 Incentive Stock Plan Incorporated by reference to Merck & Co., Inc. s Form 10-Q Quarterly Report for the period ended March 31, 2011 |
| *10.19 | Performance share unit terms for 2011 grants under the Merck & Co., Inc. 2010 Incentive Stock Plan Incorporated by reference to Merck & Co., Inc. s Form 10-Q Quarterly Report for the period ended March 31, 2011 |
| *10.20 | Stock option terms for 2012 quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan |
| *10.21 | Restricted stock unit terms for 2012 quarterly and annual grants under the Merck & Co., Inc. 2010 Incentive Stock Plan |
| *10.22 | Merck & Co., Inc. Change in Control Separation Benefits Plan Incorporated by reference to Merck & Co., Inc. s Current Report on Form 8-K dated November 23, 2009 |
| *10.23 | Amendment One to Merck & Co., Inc. Change in Control Separation Benefits Plan (effective February 15, 2010) Incorporated by reference to Exhibit 10.1 to Merck & Co., Inc. s Current Report on Form 8-K filed February 18, 2010 |

Table of Contents

Exhibit

| Number | Description |
|---------------|--|
| *10.24 | MSD Separation Benefits Plan for Nonunion Employees (amended and restated effective as of October 1, 2010) Incorporated by reference to Merck & Co., Inc. s Form 10-K Annual Report for the fiscal year ended December 31, 2010 |
| *10.25 | MSD Special Separation Program for Separated Employees (amended and restated effective as of October 1, 2010) Incorporated by reference to Merck & Co., Inc. s Form 10-K Annual Report for the fiscal year ended December 31, 2010 |
| *10.26 | MSD Special Separation Program for Bridged Employees (amended and restated effective as of October 1, 2010) Incorporated by reference to Merck & Co., Inc. s Form 10-K Annual Report for the fiscal year ended December 31, 2010 |
| *10.27 | MSD Special Separation Program for Separated Retirement Eligible Employees (amended and restated effective as of October 1, 2010) Incorporated by reference to Merck & Co., Inc. s Form 10-K Annual Report for the fiscal year ended December 31, 2010 |
| *10.28 | Merck & Co., Inc. U.S. Separation Benefits Plan (effective as of January 1, 2012) |
| *10.29 | Important Information on the Separation Program Applicable to Legacy Merck Rebadged Employees (effective as of January 1, 2012) |
| *10.30 | Important Information on the Separation Program Applicable to Legacy Merck Separated Retirement Eligible Employees (effective as of January 1, 2012) |
| *10.31 | Important Information on the Separation Program Applicable to Legacy Merck Separated Employees (effective as of January 1, 2012) |
| *10.32 | Important Information on the Separation Program Applicable to Legacy Merck Bridge-Eligible Employees (effective as of January 1, 2012) |
| *10.33 | Important Information on the Separation Program Applicable to Legacy Schering Rebadged Employees (effective as of January 1, 2012) |
| *10.34 | Important Information on the Separation Program Applicable to Legacy Schering Separated Retirement Eligible Employees (effective as of January 1, 2012) |
| *10.35 | Important Information on the Separation Program Applicable to Legacy Schering Separated Employees (effective as of January 1, 2012) |
| *10.36 | Schering-Plough Corporation Severance Benefit Plan (as amended and restated effective November 3, 2009) Incorporated by reference to Merck & Co., Inc. s Form 10-K Annual Report for the fiscal year ended December 31, 2009 |
| *10.37 | Merck & Co., Inc. 2001 Non-Employee Directors Stock Option Plan (amended and restated as of November 3, 2009) Incorporated by reference to Exhibit 10.11 to Merck & Co., Inc. s Current Report on Form 8-K filed November 4, 2009 |
| *10.38 | Merck & Co., Inc. 2006 Non-Employee Directors Stock Option Plan (amended and restated as of November 3, 2009) Incorporated by reference to Exhibit 10.5 to Merck & Co., Inc. s Current Report on Form 8-K filed November 4, 2009 |
| *10.39 | Merck & Co., Inc. 2010 Non-Employee Directors Stock Option Plan (amended and restated as of December 1, 2010) Incorporated by reference to Merck & Co., Inc. s Form 10-K Annual Report for the fiscal year ended December 31, 2010 |
| *10.40 | Retirement Plan for the Directors of Merck & Co., Inc. (amended and restated June 21, 1996) Incorporated by reference to MSD s Form 10-Q Quarterly Report for the period ended June 30, 1996 |
| *10.41 | Merck & Co., Inc. Plan for Deferred Payment of Directors Compensation (effective as amended and restated as of December 1, 2010) Incorporated by reference to Merck & Co., Inc. s Form 10-K Annual Report for the fiscal year ended December 31, 2010 |
| *10.42 | Offer Letter between Merck & Co., Inc. and Peter S. Kim, dated December 15, 2000 Incorporated by reference to MSD s Form 10-K Annual Report for the fiscal year ended December 31, 2003 |
| *10.43 | Offer Letter between Merck & Co., Inc. and Peter N. Kellogg, dated June 18, 2007 Incorporated by reference to MSD s Current Report on Form 8-K dated June 28, 2007 |
| *10.44 | Form of employment agreement effective upon a change of control between Schering-Plough and certain executives for new agreements beginning in January 1, 2008 Incorporated by reference to Exhibit 10(e)(xv) to Schering-Plough s 10-K for the year ended December 31, 2008 |

Table of Contents

Exhibit

| Number | Description |
|---------------|--|
| 10.45 | Share Purchase Agreement between Akzo Nobel N.V., Schering-Plough International C.V., and Schering-Plough Corporation Incorporated by reference to Exhibit 10.1 to Schering-Plough's 8-K filed October 2, 2007 |
| 10.46 | Amended and Restated License and Option Agreement dated as of July 1, 1998 between Astra AB and Astra Merck Inc. Incorporated by reference to MSD's Form 10-Q Quarterly Report for the period ended June 30, 1998 |
| 10.47 | KBI Shares Option Agreement dated as of July 1, 1998 by and among Astra AB, Merck & Co., Inc. and Merck Holdings, Inc. Incorporated by reference to MSD's Form 10-Q Quarterly Report for the period ended June 30, 1998 |
| 10.48 | KBI-E Asset Option Agreement dated as of July 1, 1998 by and among Astra AB, Merck & Co., Inc., Astra Merck Inc. and Astra Merck Enterprises Inc. Incorporated by reference to MSD's Form 10-Q Quarterly Report for the period ended June 30, 1998 |
| 10.49 | KBI Supply Agreement dated as of July 1, 1998 between Astra Merck Inc. and Astra Pharmaceuticals, L.P. (Portions of this Exhibit are subject to a request for confidential treatment filed with the Commission). Incorporated by reference to MSD's Form 10-Q Quarterly Report for the period ended June 30, 1998 |
| 10.50 | Second Amended and Restated Manufacturing Agreement dated as of July 1, 1998 among Merck & Co., Inc., Astra AB, Astra Merck Inc. and Astra USA, Inc. Incorporated by reference to MSD's Form 10-Q Quarterly Report for the period ended June 30, 1998 |
| 10.51 | Limited Partnership Agreement dated as of July 1, 1998 between KB USA, L.P. and KBI Sub Inc. Incorporated by reference to MSD's Form 10-Q Quarterly Report for the period ended June 30, 1998 |
| 10.52 | Distribution Agreement dated as of July 1, 1998 between Astra Merck Enterprises Inc. and Astra Pharmaceuticals, L.P. Incorporated by reference to MSD's Form 10-Q Quarterly Report for the period ended June 30, 1998 |
| 10.53 | Agreement to Incorporate Defined Terms dated as of June 19, 1998 between Astra AB, Merck & Co., Inc., Astra Merck Inc., Astra USA, Inc., KB USA, L.P., Astra Merck Enterprises Inc., KBI Sub Inc., Merck Holdings, Inc. and Astra Pharmaceuticals, L.P. Incorporated by reference to MSD's Form 10-Q Quarterly Report for the period ended June 30, 1998 |
| 10.54 | Form of Voting Agreement made and entered into as of October 30, 2006 by and between Merck & Co., Inc. and Sirna Therapeutics, Inc. Incorporated by reference to MSD's Current Report on Form 8-K dated October 30, 2006 |
| 10.55 | Commitment Letter by and among Merck & Co., Inc., J.P. Morgan Securities Inc. and JPMorgan Chase Bank, N.A. dated as of March 8, 2009 Incorporated by reference to MSD's Current Report on Form 8-K dated March 8, 2009 |
| 10.56 | Incremental Credit Agreement dated as of May 6, 2009, among Merck & Co., Inc., the Guarantors and Lenders party thereto, and JPMorgan Chase Bank, N.A., as Administrative Agent Incorporated by reference to MSD's Current Report on Form 8-K dated May 6, 2009 |
| 10.57 | Asset Sale Facility Agreement dated as of May 6, 2009, among Merck & Co., Inc., the Guarantors and Lenders party thereto, and JPMorgan Chase Bank, N.A., as Administrative Agent Incorporated by reference to MSD's Current Report on Form 8-K dated May 6, 2009 |
| 10.58 | Bridge Loan Agreement dated as of May 6, 2009, among Merck & Co., Inc., the Guarantors and Lenders party thereto, and JPMorgan Chase Bank, N.A., as Administrative Agent Incorporated by reference to MSD's Current Report on Form 8-K dated May 6, 2009 |
| 10.59 | Amendment No. 1 to Amended and Restated Five-Year Credit Agreement dated as of April 20, 2009 among Merck & Co., Inc., the Lenders party thereto and Citicorp USA, Inc., as Administrative Agent Incorporated by reference to Exhibit 10.1 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 |
| 10.60 | Guarantee and Joinder Agreement dated as of November 3, 2009 by Merck & Co., Inc., the Guarantor, for the benefit of the Guaranteed Parties Incorporated by reference to Exhibit 10.3 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 |
| 10.61 | Guarantor Joinder Agreement dated as of November 3, 2009, by Merck & Co., Inc., the Guarantor and JPMorgan Chase Bank, N.A., as Administrative Agent Incorporated by reference to Exhibit 10.4 to Merck & Co., Inc.'s Current Report on Form 8-K filed November 4, 2009 |

Table of Contents

Exhibit

| Number | Description |
|---------------|---|
| 10.62 | Call Option Agreement, dated July 29, 2009, by and among Merck & Co., Inc., Schering-Plough Corporation and sanofi-aventis Incorporated by reference to MSD's Current Report on Form 8-K dated July 31, 2009 |
| 10.63 | Termination Agreement, dated as of September 17, 2009, by and among Merck & Co., Inc., Merck SH Inc., Merck Sharp & Dohme (Holdings) Limited, sanofi-aventis, sanofi 4 and Merial Limited Incorporated by reference to MSD's Current Report on Form 8-K dated September 21, 2009 |
| 10.64 | Letter Agreement dated April 14, 2003 relating to Consent Decree Incorporated by reference to Exhibit 99.3 to Schering-Plough's 10-Q for the period ended March 31, 2003 |
| 10.65 | Distribution agreement between Schering-Plough and Centocor, Inc., dated April 3, 1998 Incorporated by reference to Exhibit 10(u) to Schering-Plough's Amended 10-K for the year ended December 31, 2003, filed May 3, 2004 |
| 10.66 | Amendment Agreement to the Distribution Agreement between Centocor, Inc., CAN Development, LLC, and Schering-Plough (Ireland) Company Incorporated by reference to Exhibit 10.1 to Schering-Plough's Current Report on Form 8-K filed December 21, 2007 |
| 12 | Computation of Ratios of Earnings to Fixed Charges |
| 21 | Subsidiaries of Merck & Co., Inc. |
| 23.1 | Consent of Independent Registered Public Accounting Firm Contained on page 159 of this Report |
| 24.1 | Power of Attorney |
| 24.2 | Certified Resolution of Board of Directors |
| 31.1 | Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer |
| 31.2 | Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer |
| 32.1 | Section 1350 Certification of Chief Executive Officer |
| 32.2 | Section 1350 Certification of Chief Financial Officer |
| 101 | The following materials from Merck & Co., Inc.'s Annual Report on Form 10-K for the fiscal year ended December 31, 2011, formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Statement of Income, (ii) the Consolidated Balance Sheet, (iii) the Consolidated Statement of Cash Flow, and (iv) Notes to Consolidated Financial Statements. |

**Management contract or compensatory plan or arrangement.*

Certain portions of the exhibit have been omitted pursuant to a request for confidential treatment. The non-public information has been filed separately with the Securities and Exchange Commission pursuant to rule 24b-2 under the Securities Exchange Act of 1934, as amended.