

Merck & Co. Inc.  
Form 10-K  
February 28, 2013  
Table of Contents

As filed with the Securities and Exchange Commission on February 28, 2013

**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, 2012

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.**

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

One Merck Drive

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:**

<i>Title of Each Class</i>	<i>Name of Each Exchange on which Registered</i>
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, 2013: 3,022,367,538.	

Aggregate market value of Common Stock (\$0.50 par value) held by non-affiliates on June 30, 2012 based on closing price on June 30, 2012: \$126,837,000,000.

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*  
Proxy Statement for the Annual Meeting of

*Part of Form 10-K*  
Part III

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

Shareholders to be held May 28, 2013, to be filed with the  
Securities and Exchange Commission within 120 days after the  
close of the fiscal year covered by this report

**Table of Contents****Table of Contents**

	<b>Page</b>
<b><u>Part I</u></b>	
Item 1. <u>Business</u>	1
Item 1A. <u>Risk Factors</u>	21
<u>Cautionary Factors that May Affect Future Results</u>	31
Item 1B. <u>Unresolved Staff Comments</u>	32
Item 2. <u>Properties</u>	33
Item 3. <u>Legal Proceedings</u>	33
Item 4. <u>Mine Safety Disclosures</u>	33
<u>Executive Officers of the Registrant</u>	33
<b><u>Part II</u></b>	
Item 5. <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	37
Item 6. <u>Selected Financial Data</u>	40
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	41
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	80
Item 8. <u>Financial Statements and Supplementary Data</u>	81
(a) <u>Financial Statements</u>	81
<u>Notes to Consolidated Financial Statements</u>	85
<u>Report of Independent Registered Public Accounting Firm</u>	136
(b) <u>Supplementary Data</u>	137
Item 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	138
Item 9A. <u>Controls and Procedures</u>	138
<u>Management's Report</u>	138
Item 9B. <u>Other Information</u>	139
<b><u>Part III</u></b>	
Item 10. <u>Directors, Executive Officers and Corporate Governance</u>	140
Item 11. <u>Executive Compensation</u>	140
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	140
Item 13. <u>Certain Relationships and Related Transactions, and Director Independence</u>	140
Item 14. <u>Principal Accountant Fees and Services</u>	141
<b><u>Part IV</u></b>	
Item 15. <u>Exhibits and Financial Statement Schedules</u>	141
<u>Signatures</u>	147
<u>Consent of Independent Registered Public Accounting Firm</u>	148

**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, as well as club stores and specialty channels.

For financial information and other information about the Company's segments, 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**

Merck continued to execute on its strategic priorities during 2012 despite facing several business challenges, including the August U.S. patent expiration for *Singulair* (montelukast), a medicine indicated for the chronic treatment of asthma and the relief of symptoms of allergic rhinitis. Worldwide sales were \$47.3 billion in 2012, a decline of 2% compared with 2011, including a 3% unfavorable effect from foreign exchange. Excluding the impact of foreign exchange, sales increased 1% reflecting growth of key products and within key geographic regions which offset the impact of the U.S. *Singulair* patent expiration. The Company also reduced operating expenses by efficiently managing costs through targeted reductions. In addition, the Company generated new clinical data and advanced certain key research and development pipeline programs.

The Company's four-part growth strategy is focused on; one, executing on its core business, which includes its largest markets, its core brands, new launch brands, and research and development efforts targeted at therapeutic areas with the greatest future patient demand and scientific opportunity; two, expanding geographically into high-growth markets; three, extending into complementary businesses of consumer care and animal health; and four, effectively managing costs while continuing to invest for future growth.

Beginning with the Company's sales performance in its largest markets during 2012, despite the adverse effects of the U.S. *Singulair* patent expiry which caused a significant and rapid decline in U.S. *Singulair* sales, sales in the United States were relatively flat compared to the prior year reflecting strong growth of key brands including *Januvia* (sitagliptin) and *Janumet* (sitagliptin/metformin HCl), treatments for type 2 diabetes, *Zostavax* (Zoster Vaccine Live), a vaccine to help prevent shingles (herpes zoster), *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 ), *Victrelis* (boceprevir), a treatment for chronic hepatitis C, and *Isentress* (raltegravir), an antiretroviral therapy for use in combination therapy for the treatment of HIV-1 infection. Turning to Europe and Canada, the Company continues to experience positive volume growth trends for many of its key

---

**Table of Contents**

brands, including *Victrelis*, *Januvia*, *Janumet*, and *Simponi* (golimumab), a treatment for inflammatory diseases; however, this growth only partially offset increased generic erosion and the price declines stemming from the economic issues and related fiscal austerity measures in this region.

With respect to research and development efforts, the Company continued the advancement of drug candidates through its pipeline in 2012. The Company currently has three candidates under review with the U.S. Food and Drug Administration (the FDA): MK-4305, suvorexant, an investigational treatment for insomnia; MK-8616, sugammadex sodium injection, a medication for the reversal of certain muscle relaxants used during surgery; and MK-0653C, an investigational combination of ezetimibe and atorvastatin for the treatment of primary or mixed hyperlipidemia. MK-8109, vintafolide, an investigational cancer candidate, is under review in the European Union (the EU). In addition, the Company currently has 16 candidates in Phase III development and anticipates filing a New Drug Application (NDA) or a Biologics License Application (BLA), as applicable, with the FDA with respect to several of these candidates in 2013.

In December 2012, the Company announced the HPS2-THRIVE (Heart Protection Study 2-Treatment of HDL to Reduce the Incidence of Vascular Events) study of *Tredaptive* (extended-release niacin/laropipant) did not meet its primary endpoint. As a result, the Company does not plan to seek regulatory approval for the medicine in the United States. In January 2013, Merck began taking steps to suspend the availability of *Tredaptive* outside the United States. Also, on February 1, 2013, the Company announced that it had recently received and was reviewing safety and efficacy data from a Phase III study involving MK-0822, odanacatib, the Company's investigational treatment for osteoporosis in post-menopausal women. As a result of its review of this data, the Company concluded that review of additional data from the previously planned, ongoing extension study was warranted and that filing an application for approval with the FDA should be delayed. As previously announced, the Company is conducting a blinded extension of the trial in approximately 8,200 women, which will provide additional safety and efficacy data. Merck now anticipates that it will file applications for approval of odanacatib in 2014 with additional data from the extension trial. The Company continues to believe that odanacatib will have the potential to address unmet medical needs in patients with osteoporosis.

Merck continues to pursue opportunities for establishing external alliances to complement its substantial internal research capabilities, including research collaborations, as well as licensing preclinical and clinical compounds and technology platforms that have the potential to drive both near- and long-term growth. During 2012, the Company completed a variety of transactions spanning different therapeutic areas and clinical stages including licensing agreements with Endocyte, Inc. (Endocyte) for vintafolide (MK-8109), an investigational cancer candidate, and with AiCuris for a portfolio of investigational medicines targeting human cytomegalovirus, including letermovir (MK-8228).

Consistent with the second element of the Company's strategy to expand geographically in high-growth markets such as Japan and key emerging markets, the Company continued to invest in these markets in 2012. Emerging market sales grew 4% in 2012, including a 4% unfavorable impact of foreign exchange, despite the loss of sales from *Remicade* (infliximab) and *Simponi*, treatments for inflammatory diseases, in markets relinquished to Johnson & Johnson (J&J) as part of the arbitration settlement agreement in 2011 as discussed below. China continues to be an important growth driver with sales exceeding \$1.0 billion in 2012, representing growth of 25% over the prior year, including a 3% favorable effect from foreign exchange. Growth in Japan was 6% during 2012, tempered by generic competition and the biennial price cuts early in the year. Merck has entered into several transactions designed to strengthen its presence in the emerging markets in the longer term. The Company's joint venture with Simcere Pharmaceutical Group in China began preliminary operations in late-2012.

The third component of Merck's strategy relates to the complementary businesses of Consumer Care and Animal Health. Merck's Animal Health business continues as a solid contributor with 4% revenue growth in 2012, including a 5% unfavorable effect from foreign exchange, reflecting growth in the cattle, poultry, companion animal and swine product lines. Sales of Consumer Care products grew 6% in 2012, including a 1% unfavorable effect from foreign exchange, led by the *Dr. Scholl's* franchise and higher sales of *Coppertone*, *MiraLAX* and *Claritin*.

As noted, the last element of the Company's strategy is to tightly manage costs while also investing for growth. Consistent with these efforts, Merck remains committed to driving continuous productivity improvements across the enterprise and continues to realize cost savings across all areas of the Company. These savings result

---

**Table of Contents**

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 2012, the Company had achieved its projected \$3.5 billion in annual net cost savings from these activities since the merger with Schering-Plough Corporation ( Schering-Plough ) (the Merger ).

The global restructuring program that was initiated in conjunction with the integration of the legacy Merck and legacy Schering-Plough businesses (the Merger Restructuring Program ) is intended to optimize the cost structure of the combined company. The workforce reductions associated with this plan relate to 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 recorded total pretax restructuring costs of \$951 million in 2012, \$1.8 billion in 2011 and \$1.8 billion in 2010 related to this program. Costs associated with the Company's restructuring actions are included in *Materials and production* costs, *Marketing and administrative* expenses, *Research and development* expenses and *Restructuring costs*. 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. Subsequent to the Merger, the Company has rationalized a number of manufacturing sites worldwide. The remaining actions under this program will result in additional manufacturing facility rationalizations, which are expected to be substantially completed by 2016. The Company now expects the estimated total cumulative pretax costs for this program to be approximately \$7.2 billion to \$7.5 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.

In November 2012, Merck's Board of Directors raised the Company's quarterly dividend to \$0.43 per share from \$0.42 per share.

In February 2013, Merck reached an agreement in principle with plaintiffs to resolve two federal securities class-action lawsuits pending in the U.S. District Court for the District of New Jersey against Merck, Schering-Plough and certain of their current and former officers and directors (the ENHANCE Litigation ). Under the proposed agreement, Merck will pay \$215 million to resolve the securities class action against all of the Merck defendants and \$473 million to resolve the securities class action against all of the Schering-Plough defendants. In connection with the settlement, Merck recorded a pretax and after-tax charge of \$493 million in 2012 which reflects \$195 million of anticipated insurance recoveries.

Earnings per common share assuming dilution attributable to common shareholders ( EPS ) for 2012 were \$2.00, which reflect a net unfavorable impact resulting from acquisition-related costs and restructuring costs, as well as the charge related to the ENHANCE Litigation noted above. Non-GAAP EPS in 2012 were \$3.82 excluding these items (see Non-GAAP Income and Non-GAAP EPS below).

**Table of Contents****Product Sales**

Sales of the Company's products were as follows:

(\$ in millions)	2012	2011	2010
Primary Care and Women's Health			
<i>Cardiovascular</i>			
Zetia	\$ 2,567	\$ 2,428	\$ 2,297
Vytorin	1,747	1,882	2,014
<i>Diabetes and Obesity</i>			
Januvia	4,086	3,324	2,385
Janumet	1,659	1,363	954
<i>Respiratory</i>			
Singulair	3,853	5,479	4,987
Nasonex	1,268	1,286	1,219
Clarinet	393	621	623
Dulera	207	96	8
Asmanex	185	206	208
<i>Women's Health and Endocrine</i>			
Fosamax	676	855	926
NuvaRing	623	623	559
Follistim AQ	468	530	528
Implanon	348	294	236
Cerazette	271	268	209
<i>Other</i>			
Maxalt	638	639	550
Arcoxia	453	431	398
Avelox	201	322	316
Hospital and Specialty			
<i>Immunology</i>			
Remicade	2,076	2,667	2,714
Simponi	331	264	97
<i>Infectious Disease</i>			
Isentress	1,515	1,359	1,090
PegIntron	653	657	737
Cancidas	619	640	611
Victrelis	502	140	
Invanz	445	406	362
Primaxin	384	515	610
Noxafil	258	230	198
<i>Oncology</i>			
Temodar	917	935	1,065
Emend	489	419	378
<i>Other</i>			
Cosopt/Trusopt	444	477	484
Bridion	261	201	103
Integrilin	211	230	266
Diversified Brands			
Cozaar/Hyzaar	1,284	1,663	2,104
Propecia	424	447	447
Zocor	383	456	468
Claritin Rx	244	314	296
Remeron	232	241	223
Proscar	217	223	216
Vasotec/Vaseretic	192	231	255
<i>Vaccines <sup>(1)</sup></i>			
Gardasil	1,631	1,209	988
ProQuad/M-M-R II/Varivax	1,273	1,202	1,378
Zostavax	651	332	243
RotaTeq	601	651	519
Pneumovax	580	498	376
Other pharmaceutical <sup>(2)</sup>	4,141	4,035	4,622



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

Total Pharmaceutical segment sales	<b>40,601</b>	41,289	39,267
Other segment sales <sup>(3)</sup>	<b>6,412</b>	6,428	6,159
Total segment sales	<b>47,013</b>	47,717	45,426
Other <sup>(4)</sup>	<b>254</b>	330	561
	<b>\$ 47,267</b>	\$ 48,047	\$ 45,987

<sup>(1)</sup> 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.

<sup>(2)</sup> Other pharmaceutical primarily reflects sales of other human health pharmaceutical products, including products within the franchises not listed separately.

<sup>(3)</sup> Reflects the non-reportable segments of Animal Health, Consumer Care and Alliances. The Alliances segment includes revenue from the Company relationship with AZLP.

<sup>(4)</sup> 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:

#### Primary Care and Women's Health

Cardiovascular: *Zetia* (marketed as *Ezetrol* outside the United States); and *Vytorin* (ezetimibe/simvastatin) (marketed as *Inegy* outside the United States), cholesterol modifying medicines.

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

Respiratory: *Singulair*; *Nasonex* (mometasone furoate monohydrate), an inhaled nasal corticosteroid for the treatment of nasal allergy symptoms; *Clarinet* (desloratadine), a non-sedating antihistamine; *Dulera* Inhalation Aerosol (mometasone furoate/formoterol fumarate dihydrate), a combination medicine for the treatment of asthma; and *Asmanex Twisthaler* (mometasone furoate inhalation powder), an inhaled corticosteroid for first-line maintenance treatment of asthma in patients 4 years of age 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* (follitropin beta injection), a biological fertility treatment; *Implanon* (etonogestrel implant), a single-rod subdermal contraceptive implant; and *Cerazette* (desogestrel), a progestin only oral contraceptive.

Other: *Maxalt* (rizatriptan benzoate), a product for acute treatment of migraine; *Arcoxia* (etoricoxib) for the treatment of arthritis and pain; and *Avelox* (moxifloxacin), which the Company only markets in the United States, a broad-spectrum fluoroquinolone antibiotic for the treatment of certain respiratory and skin infections.

#### Hospital and Specialty

Immunology: *Remicade* and *Simponi* for the treatment of inflammatory diseases.

Infectious Disease: *ISENTRESS*; *PegIntron* (peginterferon alpha-2b), a treatment for chronic hepatitis C; *Cancidas* (caspofungin acetate), an anti-fungal product; *Victrelis*; *Invanz* (ertapenem sodium) for the treatment of certain infections; *Primaxin* (imipenem and cilastatin sodium), an anti-bacterial product; and *Noxafil* (posaconazole) for the prevention of invasive fungal infections.

Oncology: *Temodar* (temozolomide) (marketed as *Temodal* outside the United States), a treatment for certain types of brain tumors; and *Emend* (aprepitant) for the prevention of chemotherapy-induced and post-operative nausea and vomiting.

Other: *Cosopt* (dorzolamide hydrochloride-timolol maleate ophthalmic solution) and *Trusopt* (dorzolamide hydrochloride ophthalmic solution), ophthalmic products; *Bridion* (sugammadex sodium injection), a medication for the reversal of certain muscle relaxants used during surgery; and *Integrilin* (eptifibatide), a treatment for patients with acute coronary syndrome.

#### Diversified Brands

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

#### Vaccines

*Gardasil*; *ProQuad* (Measles, Mumps, Rubella and Varicella Virus Vaccine Live), a pediatric combination vaccine to help protect against measles, mumps, rubella and varicella; *M-M-R II* (Measles, Mumps and Rubella Virus Vaccine Live), a vaccine to help prevent measles, mumps and rubella; *Varivax* (Varicella Virus Vaccine Live), a vaccine to help prevent chickenpox (varicella); *Zostavax*; *RotaTeq* (Rotavirus Vaccine, Live Oral, Pentavalent), a vaccine to help protect against rotavirus gastroenteritis in infants and children; and *Pneumovax* (pneumococcal

vaccine polyvalent), a vaccine to help prevent pneumococcal disease.

---

## **Table of Contents**

### *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; *Zuprevo* for bovine respiratory disease; *Zilmax* and *Revalor* to 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 *Activyl/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* for relief of 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.

## **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

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

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.

## **Table of Contents**

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 to buy Merck's common stock interest in KBI and, through it, Merck's interest in Nexium and Prilosec as well as AZLP, exercisable in 2012. In June 2012, Merck and AstraZeneca amended the 1998 option agreement. The updated agreement eliminated AstraZeneca's option to acquire Merck's interest in KBI in 2012 and provides AstraZeneca a new option to acquire Merck's interest in KBI in June 2014. As a result of the amended agreement, Merck continues to record supply sales and equity income from the partnership. In 2014, AstraZeneca has the option to purchase Merck's interest in KBI based in part on the value of Merck's interest in Nexium and Prilosec. AstraZeneca's option is exercisable between March 1, 2014 and April 30, 2014. If AstraZeneca chooses to exercise this option, the closing date is expected to be June 30, 2014. Under the amended agreement, AstraZeneca will make a payment to Merck upon closing of \$327 million, reflecting an estimate of the fair value of Merck's interest in Nexium and Prilosec. This portion of the exercise price is subject to a true-up in 2018 based on actual sales from closing in 2014 to June 2018. The exercise price will also include an additional amount equal to a multiple of ten times Merck's average 1% annual profit allocation in the partnership for the three years prior to exercise. The Company believes that it is likely that AstraZeneca will exercise its option in 2014. If AstraZeneca exercises its option, the Company will no longer record equity income from AZLP and supply sales to AZLP will decline substantially.

### *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.

### **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,

---

## **Table of Contents**

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 ( 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*. 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. 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.

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 hospitals serving a disproportionate share of low income or uninsured patients.

---

**Table of Contents**

Against this backdrop, the United States enacted major health care reform legislation in 2010, which began to be implemented in 2010. Various insurance market reforms have advanced and will continue through full implementation in 2014. The law is expected to expand access to health care to about 32 million Americans by the end of the decade who did not previously have insurance coverage. With respect to the effect of the law on the pharmaceutical industry, the mandated Medicaid rebate increased 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% point of service discount to Medicare Part D beneficiaries when they are in the Medicare Part D coverage gap (i.e., the so-called "donut hole"). Approximately \$210 million and \$150 million was recorded by Merck as a reduction to revenue in 2012 and 2011, respectively, related to the donut hole provision. Also, pharmaceutical manufacturers are now required to pay an annual health care reform fee. The total annual industry fee was \$2.8 billion in 2012 and will be \$2.8 billion in 2013. 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 recorded \$190 million and \$162 million of costs within *Marketing and administrative* expenses in 2012 and 2011, respectively, for the annual health care reform fee.

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 of 2010. 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. These types of revenue generating or cost saving proposals include additional 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.

Efforts toward health care cost containment remain 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 and mandatory switches to generic drugs. While the Company is taking steps to mitigate the impact in the EU, the austerity measures continued to negatively affect the Company's revenue performance in 2012 and the Company anticipates the austerity measures will continue to negatively affect revenue performance in 2013.

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

Governments in many emerging markets are also focused on constraining health care costs and have enacted price controls and related measures that aim to put pressure on the price of pharmaceuticals and constrain market access. The Company anticipates that pricing pressures and market access challenges will continue in 2013 to varying degrees in the emerging markets.

The Company's focus on and share of revenue from emerging markets has increased. Countries in these markets may be subject to conditions that can affect the Company's efforts to continue to grow in emerging markets, including potential political instability, significant currency fluctuation and controls, financial crises, limited or changing availability of funding for health care, and other developments that may adversely impact the business environment for the Company. Further, the Company may engage third-party agents to assist in operating in emerging market countries, which may affect its ability to realize continued growth and may also increase the Company's risk exposure.



## **Table of Contents**

The full impact of 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 engages in public policy advocacy with policymakers and continues to attempt to demonstrate that its medicines provide value to patients and to those who pay for health care. The Company seeks to work with government policymakers to encourage a long-term approach to sustainable health care financing that ensures access to innovative medicines and does not disproportionately target pharmaceuticals as a source of budget savings. 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.

Certain markets outside of the United States have implemented health technology assessments and other cost management strategies which require additional data, reviews and administrative processes, all of which increase the complexity and costs of obtaining product reimbursement and exert downward pressure on reimbursement available and obtained.

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, 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 and include a set of principles that the Company strives to embed into its operations and business strategies to guide the Company's worldwide approach to expanding access to health care. 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 in the United States 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.

## **Table of Contents**

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 to reduce maternal mortality.

Merck has also in the past provided funds to the Merck 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 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, as well as club stores and specialty channels.

## **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 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. 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:

<b>Product</b>	<b>Year of Expiration (in the U.S.)<sup>(1)</sup></b>
<i>Propecia</i> <sup>(2)</sup>	2013 (formulation/use)
<i>Asmanex</i>	2014 (use)/2018 (formulation)
<i>Avelox</i> <sup>(3)</sup>	2014
<i>Dulera</i>	2014 (use)/2017(formulation)/2020 (combination)
<i>Integrilin</i>	2014 (compound)/2015 (use/formulation)
<i>Nasonex</i> <sup>(4)</sup>	2014 (use/formulation)/2018(formulation)
<i>Temodar</i> <sup>(5)</sup>	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> <sup>(6)</sup> / <i>Vytorin</i>	2017
<i>NuvaRing</i>	2018 (delivery system)
<i>Noxafil</i>	2019
<i>RotaTeq</i>	2019
<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>Zioptan</i>	2022 (with pending Patent Term Restoration)
<i>Isentress</i>	2023
<i>Victrelis</i>	2024 (with pending Patent Term Restoration)
<i>Gardasil</i>	2028

<sup>(1)</sup> Compound patent unless otherwise noted. Certain of the products listed may be the subject of patent litigation. See Item 8. *Financial Statements and Supplementary Data, Note 11. Contingencies and Environmental Liabilities* below.

<sup>(2)</sup> By agreement, a generic manufacturer entered the U.S. market in January 2013, and another has been given the right to enter in July 2013 with a generic version of Propecia.

<sup>(3)</sup> By agreement, a generic manufacturer may launch a generic version of Avelox in the United States in February 2014.

<sup>(4)</sup> By agreement, a generic manufacturer has been granted rights under Merck's Nasonex use patent in the United States. In addition, a recent court decision found that a proposed generic product by a generic manufacturer would not infringe on Merck's Nasonex formulation patent. Thus, if the generic manufacturer's application is approved by the FDA, it can enter the market in the United States with a generic version of Nasonex. That decision is under appeal.

<sup>(5)</sup> By agreement, a generic manufacturer may launch a generic version of Temodar in the United States in August 2013.

<sup>(6)</sup> By agreement, a generic manufacturer may launch a generic version of Zetia in the United States in December 2016.

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

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

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.

The patent that provides U.S. market exclusivity for *Avelox* expires in March 2014; however, by agreement, a generic manufacturer may launch a generic version of *Avelox* in the United States in February 2014. Also, the patent that provides market exclusivity in the United States for *Temodar* will expire in February 2014; however, by agreement, a generic manufacturer may launch a generic version of *Temodar* in the United States in August 2013. The Company anticipates that sales in the United States will decline significantly after these patent expiries.

**Table of Contents**

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 an 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 in the United States by the FDA. Additional patent term may be provided for these pipeline candidates based on Patent Term Restoration and Pediatric Exclusivity.

**Currently Anticipated**

<b>Under Review</b>	<b>Year of Expiration (in the U.S.)<sup>(1)(2)(3)(4)</sup></b>
MK-0653C (ezetimibe/atorvastatin)	2017
MK-8616 (sugammadex sodium injection)	2021
MK-4305 (suvorexant)	2029

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

**Currently Anticipated**

<b>Phase III Drug Candidate</b>	<b>Year of Expiration (in the U.S.)<sup>(1)(2)(3)(4)</sup></b>
V212 (inactivated varicella zoster virus ( VZV ) vaccine)	2016 (method of use)
MK-8175A (NOMAC/E2)	2017 (use)
MK-8962 (corifollitropin alfa injection)	2018 (formulation)
V419 (pediatric hexavalent combination vaccine)	2020 (method of making/vectors)
MK-3814 (preladenant)	2021
MK-3641 (ragweed)	2023
MK-7243 (grass pollen)	2023
MK-0822 (odanacatib)	2024
MK-5348 (vorapaxar)	2024
MK-8109 (vintafolide)	2024
MK-0859 (anacetrapib)	2027
MK-3222 (psoriasis)	2028 (composition)
MK-3415A (actoxumab/bezlotoxumab)	2028
V503 (HPV vaccine (9 valent))	2028
MK-3102 (diabetes mellitus)	2030

<sup>(1)</sup> Compound patent unless otherwise noted.

<sup>(2)</sup> 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.

<sup>(3)</sup> 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.

<sup>(4)</sup> 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.

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

For further information with respect to the Company's patents, see Item 1A. Risk Factors and Item 8. Financial Statements and Supplementary Data, Note 11. 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 2012 on patent and know-how licenses and other rights amounted to \$352 million. Merck also incurred royalty expenses amounting to \$1.3 billion in 2012 under patent and know-how licenses it holds.

---

## **Table of Contents**

### **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 13,600 people are employed in the Company's research activities. Research and development expenses were \$8.2 billion in 2012, \$8.5 billion in 2011, and \$11.1 billion in 2010 (which included restructuring costs in all years, as well as \$200 million, \$587 million and \$2.4 billion of in-process research and development impairment charges in 2012, 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 biosimilars, which have 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, 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 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 effects that could limit the compound's usefulness. In some situations, the clinical program incorporates adaptive design methodology to use accumulating data to decide how to modify aspects of the ongoing clinical study as it continues, without undermining the validity and integrity of the trial. One type of adaptive clinical trial is an adaptive Phase IIa/IIb trial design, a two-stage trial design consisting of a Phase IIa proof-of-concept stage and a Phase IIb dose-optimization finding stage. 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

## Table of Contents

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 or BLA is submitted, received and accepted for review by the agency. Within 60 days after receipt, 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. Pursuant to the Prescription Drug User Fee Act V, the FDA review period target for NDAs or original BLAs is either six months, for priority review, or ten months, for a standard review, from the time the application is deemed sufficiently complete. Once the review timelines are determined, 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.

The primary method the Company uses to obtain marketing authorization of pharmaceutical products in the EU is through the centralized procedure. This procedure is compulsory for certain pharmaceutical products, in particular those using biotechnological processes, and is also available for certain new chemical compounds and products. A company seeking to market an innovative pharmaceutical product through the centralized procedure must file a complete set of safety data and efficacy data as part of a Marketing Authorization Application (MAA) with the European Medicines Agency (EMA). After the EMA evaluates the MAA, it provides a recommendation to the EC and the EC then approves or denies the MAA. It is also possible for new chemical products to obtain marketing authorization in the EU through a mutual recognition procedure, in which an application is made to a single member state, and if the member state approves the pharmaceutical product under a national procedure, then the applicant may submit that approval to the mutual recognition procedure of some or all other member states.

### *Research and Development Update*

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

MK-4305, suvorexant, an investigational insomnia medicine in a new class of medicines called orexin receptor antagonists for use in patients with difficulty falling or staying asleep, is under review by the FDA. Suvorexant will be evaluated by the Controlled Substance Staff of the FDA during NDA review. If approved by the FDA, suvorexant will become available after a schedule assessment and determination has been completed by the U.S. Drug Enforcement Administration, which routinely occurs after FDA approval. The Company has also submitted a new drug application for suvorexant to the health authorities in Japan and is continuing with plans to seek approval for suvorexant in other countries around the world.

MK-8616, sugammadex sodium injection, is an investigational agent for the reversal of neuromuscular blockade induced by rocuronium or vecuronium (neuromuscular blocking agents) under review by the FDA. Neuromuscular blockade is used in anesthesiology to induce muscle relaxation during surgery. If approved, MK-8616 would be the first in a new class of medicines in the United States known as selective relaxant binding agents to be used in the surgical setting. In 2008, the FDA did not approve the original NDA for sugammadex sodium injection, requesting additional data related to hypersensitivity (allergic) reactions and coagulation (bleeding) events. Merck submitted these requested data within the NDA resubmission, which the FDA deemed complete for review. The Company expects the FDA's review to be completed in the first half of 2013. Sugammadex sodium injection is approved and has been launched in many countries outside of the United States where it is marketed as *Bridion*.



---

**Table of Contents**

MK-8109, vintafolide, is an investigational cancer candidate under review by the EMA. As part of an exclusive license agreement with Endocyte, Merck is responsible for the development and worldwide commercialization of vintafolide in oncology. The EMA accepted the MAA filings for vintafolide and Endocyte's investigational companion diagnostic imaging agent, etarfolatide, for the targeted treatment of patients with folate-receptor positive platinum-resistant ovarian cancer in combination with pegylated liposomal doxorubicin. Both vintafolide and etarfolatide have been granted orphan drug status by the EC. Vintafolide is in Phase III development in the United States.

MK-0653C is an investigational combination of ezetimibe and atorvastatin for the treatment of primary or mixed hyperlipidemia under review by the FDA. An updated NDA for MK-0653C was deemed complete for review by the FDA after Merck submitted additional data in response to the FDA's Complete Response Letter issued in 2012. Merck expects the FDA's review to be completed in the first half of 2013. Merck is continuing to move forward with planned filings for the ezetimibe and atorvastatin combination tablet in additional countries around the world.

In addition to the candidates under regulatory review, the Company has 16 drug candidates in Phase III development targeting a broad range of diseases. The Company anticipates filing an NDA or a BLA, as applicable, with the FDA with respect to several of these candidates in 2013.

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*. As previously disclosed, the 14,000-patient Phase III event-driven clinical study of V503 is ongoing. Merck anticipates filing a BLA for V503 with the FDA in 2013.

MK-8962, corifollitropin alpha injection, which is being marketed as *Elonva* in the EU, is an investigational fertility treatment for controlled ovarian stimulation in women participating in *in vitro* fertilization or intracytoplasmic sperm injection currently in Phase III development in the United States. Merck continues to anticipate filing an NDA for MK-8962 with the FDA in 2013.

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 March 2012, results from the TRA-2P study of vorapaxar were presented at the American College of Cardiology Annual Scientific Session and published concurrently in the online edition of the *New England Journal of Medicine*. In the study, the addition of vorapaxar to standard of care (e.g. aspirin or thienopyridine or both) resulted in a significantly greater reduction in the risk of the composite of cardiovascular death, heart attack, stroke or urgent coronary revascularization. There was also a significant increase in bleeding, including intracranial hemorrhage, among patients taking vorapaxar in addition to standard of care, although the risk of intracranial hemorrhage was lower in patients without a history of stroke. 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 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. Following a review of the clinical trial data and discussions with external experts, Merck plans to file applications for vorapaxar in the United States and EU in 2013 seeking an indication for the prevention of cardiovascular events in patients with a history of heart attack and no history of transient ischemic attack or stroke.

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 has submitted a BLA for MK-7243 with the FDA.

---

**Table of Contents**

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

MK-8175A, NOMAC/E2, which is being marketed as *Zoely* in the EU, is an investigational 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: nomegestrol 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 conducting an additional clinical study requested by the FDA and plans to update the application in the future.

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. In July 2012, Merck announced an update on the Phase III trial assessing fracture risk reduction with odanacatib. The independent Data Monitoring Committee (the DMC) for the study completed its first planned interim analysis for efficacy and recommended that the study be closed early due to robust efficacy and a favorable benefit-risk profile. The DMC noted that safety issues remain in certain selected areas and made recommendations with respect to following up on them. On February 1, 2013, Merck announced that it had recently received and was reviewing safety and efficacy data from the Phase III trial. As a result of its review of this data, the Company concluded that review of additional data from the previously planned, ongoing extension study was warranted and that filing an application for approval with the FDA should be delayed. As previously announced, the Company is conducting a blinded extension of the trial in approximately 8,200 women, which will provide additional safety and efficacy data. Merck now anticipates that it will file applications for approval of odanacatib in 2014 with additional data from the extension trial. The Company continues to believe that odanacatib will have the potential to address unmet medical needs in patients with osteoporosis.

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 MK-3814 with the FDA in 2014.

V212 is an inactivated VZV 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-7009, vaniprevir, is an investigational, oral twice-daily protease inhibitor for the treatment of chronic hepatitis C virus for development in Japan only. The Company anticipates filing a new drug application for MK-7009 in Japan in 2014.

MK-3102 is an investigational once-weekly DPP-4 inhibitor in development for the treatment of type 2 diabetes. The Company anticipates filing an NDA for MK-3102 with the FDA beyond 2014.

MK-3222 is an anti-interleukin-23 monoclonal antibody candidate being investigated for the treatment of psoriasis. The Company anticipates filing a BLA for MK-3222 with the FDA beyond 2014.

MK-3415A, actoxumab/bezlotoxumab, 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 now anticipates filing a BLA for MK-3415A with the FDA in 2015.

---

**Table of Contents**

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 that is predicted to be completed in 2017. The Company continues to anticipate filing an NDA for anacetrapib with the FDA beyond 2015.

MK-8931 is Merck's novel investigational oral  $\beta$ -amyloid precursor protein site-cleaving enzyme (BACE) inhibitor for the treatment of Alzheimer's disease. In December 2012, Merck announced the initiation of a Phase II/III clinical trial (EPOCH) designed to evaluate the safety and efficacy of MK-8931 versus placebo in patients with mild-to-moderate Alzheimer's disease.

MK-8669, ridaforolimus, is an investigational oral mTOR (mammalian target of rapamycin) inhibitor under development for cancer indications. In June 2012, Merck announced that the FDA issued a Complete Response Letter regarding the NDA for ridaforolimus as a treatment for metastatic soft tissue or bone sarcoma. The Complete Response Letter states that the FDA cannot approve the application in its present form, and that additional clinical trial(s) would need to be conducted to further assess safety and efficacy. In November 2012, Merck formally notified the EMA of its decision to withdraw the MAA for ridaforolimus that was accepted by the EMA in 2011. The Company no longer plans to pursue the sarcoma indication in the United States or the EU, but will continue to support patients enrolled in ongoing clinical trials. Merck remains committed to pursuing ridaforolimus in other cancer indications. As part of an exclusive license agreement with ARIAD Pharmaceuticals, Inc. ( ARIAD ), Merck is responsible for the development and worldwide commercialization of ridaforolimus in oncology.

In December 2012, Merck announced the HPS2-THRIVE study of MK-0524A, *Tredaptive*, did not meet its primary endpoint. In the study, adding the combination of extended-release niacin and laropiprant to statin therapy did not significantly further reduce the risk of the combination of coronary deaths, non-fatal heart attacks, strokes or revascularizations compared to statin therapy. In addition, there was a statistically significant increase in the incidence of some types of non-fatal serious adverse events in the group that received extended-release niacin/laropiprant compared to statin therapy. Merck does not plan to seek regulatory approval for the medicine in the United States. In January 2013, based on the understanding of the preliminary data from the HPS2-THRIVE study and in consultation with regulatory authorities, Merck began taking steps to suspend the availability of *Tredaptive*, which is approved for use in certain countries outside of the United States. The clinical development program for MK-0524B, a combination product of extended-release niacin with laropiprant and simvastatin, had previously been discontinued.

In 2012, Merck announced that it will return the global marketing and development rights for both the intravenous and oral formulations for vernakalant, a treatment for atrial fibrillation, to Cardiome Pharma Corp. for business reasons. Merck also decided in 2012 to discontinue the clinical development program for MK-0431E, a combination product of sitagliptin and atorvastatin for the treatment of type 2 diabetes, for business reasons.

**Table of Contents**

The chart below reflects the Company's research pipeline as of February 22, 2013. 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.

<b>Phase II</b>	<b>Phase III (Phase III entry date)</b>	<b>Under Review</b>
<b>Allergy</b>	<b>Allergy</b>	<b>Atherosclerosis</b>
MK-8237, Immunotherapy(1)	MK-7243, Grass pollen (March 2008)(1)(3) MK-3641, Ragweed (September 2009)(1)	MK-0653C (ezetimibe/atorvastatin) (U.S.)
<b>Alzheimer's Disease</b>		<b>Insomnia</b>
MK-8931(2)	<b>Atherosclerosis</b> MK-0859 (anacetrapib) (May 2008)	MK-4305 (suvorexant) (U.S.)
<b>Asthma</b>		<b>Neuromuscular Blockade Reversal</b>
MK-1029	<b>Clostridium difficile Infection</b> MK-3415A (actoxumab/bezlotoxumab) (November 2011)	MK-8616 (sugammadex sodium injection) (U.S.)
<b>Bacterial Infection</b>		<b>Platinum-Resistant Ovarian Cancer</b>
MK-7655	<b>Contraception</b> MK-8175A (NOMAC/E2) (U.S.) (June 2006)(4)	MK-8109 (vintafolide) (EU)
<b>Cancer</b>		<b>Footnotes:</b> (1) North American rights only. (2) Phase II/III adaptive design. (3) The Company has submitted a BLA for MK-7243 and now awaits acceptance for review by the FDA. (4) In November 2011, Merck received a Complete Response Letter from the FDA for NOMAC/E2 (MK-8175A). The Company is conducting an additional clinical study requested by the FDA and plans to update the application in the future. (5) For development in Japan only.
MK-0646 (dalotuzumab)	<b>Diabetes Mellitus</b> MK-3102 (September 2012)	
MK-1775		
MK-2206	<b>Fertility</b> MK-8962 (corifollitropin alfa injection) (U.S.) (July 2006)	
MK-7965 (dinaciclib)(2)		
MK-8669 (ridaforolimus)		
<b>CMV Prophylaxis in Transplant Patients</b>		
MK-8228 (letermovir)	<b>Hepatitis C</b> MK-7009 (vaniprevir) (June 2011)(5)	

**Contraception, Medicated IUS**

MK-8342

**Herpes Zoster**

V212 (inactivated VZV vaccine) (December 2010)

**Contraception, Next Generation Ring**

MK-8175A

**HPV-Related Cancers**

MK-8342B

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

**Hepatitis C**

MK-5172

**Osteoporosis**

MK-8742

MK-0822 (odanacatib) (September 2007)

**HIV**

MK-1439

**Parkinson's Disease**

MK-3814 (preladenant) (July 2010)

**Insomnia**

MK-6096

**Pediatric Hexavalent Combination Vaccine**

V419 (April 2011)

**Melanoma**

MK-3475

**Platinum-Resistant Ovarian Cancer**

MK-8109 (vintafolide) (U.S.) (April 2011)

**Migraine**

MK-1602

**Psoriasis**

MK-3222 (December 2012)

**Overactive Bladder**

MK-4618

**Thrombosis**

MK-5348 (vorapaxar) (September 2007)

**Pneumoconjugate Vaccine**

V114

**Rheumatoid Arthritis**

MK-8457

**Employees**

As of December 31, 2012, the Company had approximately 83,000 employees worldwide, with approximately 32,500 employed in the United States, including Puerto Rico. Approximately 31% of worldwide employees of the Company are represented by various collective bargaining groups.

In 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 designed to optimize the cost structure of the combined company. These initial actions, which are expected to result in workforce reductions of approximately 17%, 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. In July 2011, the Company initiated further actions under the Merger Restructuring Program through 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 associated with these additional actions relate to manufacturing (including

---

## **Table of Contents**

Animal Health), administrative and headquarters organizations. Since inception of the Merger Restructuring Program through December 31, 2012, Merck has eliminated approximately 22,400 positions comprised of employee separations, as well as the elimination of contractors and vacant positions.

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, 2012, Merck has eliminated approximately 6,400 positions comprised of employee separations and the elimination of contractors and vacant positions.

## **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 \$14 million in 2012, \$25 million in 2011 and \$16 million in 2010, and are estimated at \$84 million in the aggregate for the years 2013 through 2017. 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 \$145 million at December 31, 2012. 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 \$112 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 2012, 57% of sales in 2011 and 56% of sales in 2010.

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.

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

## **Available Information**

The Company's Internet website address is [www.merck.com](http://www.merck.com). The Company will make available, free of charge at the 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

---

## **Table of Contents**

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' four standing committees are available on the Company's website at [www.merck.com/about/leadership](http://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.

***Singulair* and *Maxalt* lost market exclusivity in the United States in 2012, and the Company is experiencing a significant decline in sales of those products. In addition, *Singulair* and *Maxalt* will each lose market exclusivity in the EU in 2013 and the Company expects a significant decline in sales of those products in these markets.**

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 provided U.S. market exclusivity for *Singulair*, which in 2012 was the Company's second largest selling product globally, and which had U.S. sales of \$2.2 billion, expired in August 2012. Accordingly, the Company experienced a significant and rapid decline in U.S. *Singulair* sales, which declined 97% in the fourth quarter of 2012 to \$25 million as compared to the fourth quarter of 2011. The patent that provided market exclusivity for *Singulair* expired in a number of major European markets in February 2013 and the Company expects a significant and rapid decline in sales of *Singulair* in those markets. The patent that provided U.S. market exclusivity for *Maxalt* expired in December 2012. Also, the patent that provides market exclusivity for *Maxalt* will expire in a number of major European markets in August 2013. The Company anticipates that sales in the United States, which were approximately \$491 million in 2012, and in these European markets will decline significantly as a result of these patent expiries. Also, two additional Company products, *Temodar* and *Propecia*, will lose market exclusivity in the United States in 2013 and the Company anticipates that sales will decline significantly.

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 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



---

## **Table of Contents**

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 11. 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. As discussed above, in 2012, a court decision found that a proposed generic product by a generic manufacturer would not infringe on the Company's *Nasonex* formulation patent. If the generic manufacturer's application is approved by the FDA, it can enter the market in the United States with a generic version of *Nasonex* which would adversely affect sales of *Nasonex*. 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 or in other circumstances, 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 *Januvia*, *Remicade*, *Zetia*, *Vytorin*, *Janumet*, *Isentress*, *Nasonex* and *Gardasil*. 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 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.

---

## **Table of Contents**

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; payers may refuse to cover or reimburse the new product; 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 *Singulair* and *Maxalt* in 2012 and *Temodar* and *Propecia* in 2013, lose market exclusivity 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 the market or fail to succeed 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;

failure in certain markets to obtain reimbursement commensurate with the level of innovation and clinical benefit presented by the product;

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 mergers and acquisitions.

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

many cases, the FDA requirements have increased the amount of time and money necessary to develop new

## **Table of Contents**

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 a 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.**

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 and the EU, political pressure to reduce spending on prescription drugs has led to legislation and other measures 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 the Company's patents may not 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, more convenient to use 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 products that were measured at fair value and capitalized in connection with mergers and acquisitions, 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.

### **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 of 2010. 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, including the EU, 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 in the United States 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 2012, Merck incurred additional costs as a result of the law, including increased Medicaid rebates and other impacts

---

**Table of Contents**

that reduced revenues. In 2010, the minimum rebate to states participating in the Medicaid program 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 pharmaceutical manufacturers to pay a 50% point of service discount to Medicare Part D beneficiaries when they are in the Medicare Part D coverage gap (i.e., the so-called "donut hole"). Approximately \$210 million and \$150 million was recorded by Merck as a reduction to revenue in 2012 and 2011, respectively, related to the donut hole provision. Also, the Company is required to pay an annual health care reform fee, which is 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 2012 was \$2.8 billion and will be \$2.8 billion in 2013. The Company recorded \$190 million and \$162 million of costs within *Marketing and administrative* expenses in 2012 and 2011, respectively, for the annual health care reform fee.

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.

Global efforts toward health care cost containment continue to exert pressure on product pricing and market access worldwide. In many international markets, government-mandated pricing actions have reduced prices of generic and patented drugs. In addition, other austerity measures negatively affected the Company's revenue performance in 2012. The Company anticipates these pricing actions and other austerity measures will continue to negatively affect revenue performance in 2013.

The Company continues to monitor the credit and economic conditions within Greece, Spain, Italy and Portugal, among other members of the EU. These 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 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, 2012, the Company's accounts receivable in Greece, Italy, Spain and Portugal totaled approximately \$1.1 billion. Of this amount, hospital and public sector receivables were approximately \$800 million in the aggregate, of which approximately 18%, 37%, 36% and 9% related to Greece, Italy, Spain and Portugal, respectively. As of December 31, 2012, the Company's total accounts receivable outstanding for more than one year were approximately \$200 million, of which approximately 70% 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 and lawsuits from certain states that did not participate in a previously-disclosed settlement, 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



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

inclusion in a nationwide MDL (the Shareholder MDL ), and have been consolidated for all purposes. 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* International Lawsuits .)

## Table of Contents

The *Vioxx* litigation is discussed more fully in Item 8. Financial Statements and Supplementary Data, Note 11. Contingencies and Environmental Liabilities below. The Company believes that it has meritorious defenses to the *Vioxx* Product Liability Lawsuits, *Vioxx* Securities Lawsuits and *Vioxx* International 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 material reserves for any potential liability relating to the remaining *Vioxx* Lawsuits although it has established reserves related to the settlement of the Canadian *Vioxx* litigation and with respect to certain other *Vioxx* Product Liability Lawsuits, including a previously-disclosed settlement relating to a lawsuit brought by a class of Missouri plaintiffs, all of which are discussed in Item 8. Financial Statements and Supplementary Data, Note 11. 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 the IMPROVE-IT trial could have a material adverse effect on such sales.**

The Company sells *Vytorin* and *Zetia*. As previously disclosed, in January 2008, the Company 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 presenting with acute coronary syndrome. No incremental benefit of ezetimibe/simvastatin on cardiovascular morbidity and mortality over and above that demonstrated for simvastatin has been established. In 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.

The IMPROVE-IT trial is scheduled for completion in 2014. In the IMPROVE-IT trial, blinded interim efficacy analyses were conducted by the DSMB for the trial when approximately 50% and 75% of the endpoints were accrued, respectively. In each case, the DSMB recommended continuing the trial without change in design. At the time of the second interim efficacy analysis, the DSMB stated it planned to review the data again in approximately nine months; that review has been scheduled for March 2013, at which point nine months of additional data will have been adjudicated. If, based on the results of that review, 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.

---

**Table of Contents**

**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 the Company cannot offset the devaluations, the Company's financial performance within such countries could be adversely affected.

For instance, in February 2013, the Venezuelan government devalued its currency. As a result of that devaluation, the Company will recognize losses due to exchange.

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 2012, 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 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 affected 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.

---

## **Table of Contents**

### **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. The size and complexity of the Company's computer systems makes them potentially vulnerable to service interruption, malicious intrusion and random attacks. In addition, data privacy or security breaches by employees or others may pose a risk that data, including intellectual property or personal information, may be exposed to unauthorized individuals or to the public. There can be no assurance that the Company's efforts to protect its data and systems will prevent service interruption or the loss of critical or sensitive information which could result in financial, legal, business or reputational harm to the Company.

### **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 affected 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, 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

---

## **Table of Contents**

multiple jurisdictions, such as the United States and 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.

### **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



**Table of Contents**

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, such as *Singulair* and *Maxalt*, 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 *Fosamax*.

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

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

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.

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

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



**Table of Contents**

**Item 2. Properties.**

The Company's corporate headquarters is currently located in Whitehouse Station, New Jersey, although the Company has announced that it intends to move its headquarters to Summit, New Jersey in 2015. 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. Merck's Animal Health global headquarters functions are located in Summit, New Jersey. Principal U.S. research facilities are located in Rahway, Kenilworth and Summit, New Jersey, West Point, Pennsylvania, Palo Alto, California, Boston, Massachusetts, and Elkhorn, Nebraska (Animal Health). Principal research facilities outside the U.S. are located in the Netherlands, Switzerland and China. 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 \$2.0 billion in 2012, \$1.7 billion in 2011 and \$1.7 billion in 2010. In the United States, these amounted to \$1.3 billion for 2012, \$1.2 billion for 2011 and \$990 million in 2010. Abroad, such expenditures amounted to \$662 million for 2012, \$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 11. 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, 2013)**

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 58

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

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

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

---

**Table of Contents**

ADELE D. AMBROSE Age 56

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

JOHN CANAN Age 56

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

WILLIE A. DEESE Age 57

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

RICHARD R. DELUCA, JR. Age 50

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.

CUONG VIET DO Age 46

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.

CLARK GOLESTANI Age 46

December 2012 Executive Vice President and Chief Information Officer, Merck & Co., Inc. responsible for Merck's global information technology (IT)

August 2008 Vice President, Merck Research Laboratories Information Technology, Merck & Co., Inc. responsible for global IT for Merck's Research & Development division, including Basic Research, PreClinical, Clinical and Regulatory

November 2006 Vice President, Corporate Information Technology, Merck & Co., Inc. responsible for global IT supporting Finance, Human Resources, Procurement, Legal, Public Affairs, Site Services, Real Estate, and Shared Business Services operations



---

**Table of Contents**

MIRIAM M. GRADDICK-WEIR Age 58

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

BRIDGETTE P. HELLER Age 51

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 Global Baby Business Unit from 2007 to 2010.

MICHAEL J. HOLSTON Age 50

June 2012 Executive Vice President and Chief Ethics and Compliance Officer, Merck & Co., Inc. responsible for the Company's compliance function, including Global Safety & Environment, Systems Assurance, Ethics and Privacy

Prior to June 2012, Mr. Holston was Executive Vice President, General Counsel and Board Secretary for Hewlett-Packard Company (a technology company) since 2007, where he oversaw the legal, compliance, government affairs, privacy and ethics operations.

PETER N. KELLOGG Age 56

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

PETER S. KIM Age 54

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

BRUCE N. KUHLIK Age 56

November 2009 Executive Vice President and General Counsel, Merck & Co., Inc. responsible for legal, communications, and public policy functions

January 2008 Executive Vice President and General Counsel, Merck & Co., Inc. responsible for legal, communications, and public policy functions

MICHAEL ROSENBLATT, M.D. Age 65

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.



**Table of Contents**

ADAM H. SCHECHTER Age 48

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

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

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

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

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

**Cash Dividends Paid per Common Share**

	Year	4th Q	3rd Q	2nd Q	1st Q
<b>2012</b>	<b>\$ 1.68</b>	<b>\$ 0.42</b>	<b>\$ 0.42</b>	<b>\$ 0.42</b>	<b>\$ 0.42</b>
2011	\$ 1.52	\$ 0.38	\$ 0.38	\$ 0.38	\$ 0.38

**Common Stock Market Prices**

	4th Q	3rd Q	2nd Q	1st Q
<b>2012</b>				
<b>High</b>	<b>\$ 48.00</b>	<b>\$ 45.70</b>	<b>\$ 41.75</b>	<b>\$ 39.43</b>
<b>Low</b>	<b>\$ 40.02</b>	<b>\$ 41.06</b>	<b>\$ 37.02</b>	<b>\$ 36.91</b>
<b>2011</b>				
High	\$ 37.90	\$ 36.56	\$ 37.65	\$ 37.62
Low	\$ 30.54	\$ 29.47	\$ 33.00	\$ 31.06

As of January 31, 2013, there were approximately 156,850 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, 2012. 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.

<b>Plan Category</b>	<b>Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)</b>	<b>Weighted-average exercise price of outstanding options, warrants and rights (b)</b>	<b>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)</b>
Equity compensation plans approved by security holders <sup>(1)</sup>	165,756,073 <sup>(2)</sup>	\$ 39.47	179,527,854
Equity compensation plans not approved by security holders			
<b>Total</b>	<b>165,756,073</b>	<b>\$ 39.47</b>	<b>179,527,854</b>

<sup>(1)</sup> 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.

<sup>(2)</sup> Excludes approximately 18,216,551 shares of restricted stock units and 2,255,251 performance share units (assuming maximum payouts) under the Merck Sharp & Dohme 2004, 2007 and 2010 Incentive Stock Plans and 4,526,616 shares of restricted stock units and 247,410 performance share units (excluding accrued dividends) under the Merck & Co., Inc. Schering-Plough 2006 Stock Incentive Plan. Also excludes 318,476 shares of phantom stock deferred under the MSD Employee Deferral Program and 473,582 shares of phantom stock deferred under the MSD Directors Deferral Program.



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

The following graph assumes a \$100 investment on December 31, 2007, 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

	<b>End of Period Value</b>	<b>2012/2007 CAGR**</b>
MERCK	\$ 165	11%
PEER GRP.***	134	6
S&P 500	109	2

	2007	2008	2009	2010	2011	2012
MERCK	100.00	64.90	129.31	132.97	145.66	164.78
PEER GRP.	100.00	89.16	96.19	95.77	116.41	133.75
S&P 500	100.00	63.01	79.69	91.71	93.62	108.60

\*The Performance Graph reflects Schering-Plough's stock performance from December 31, 2007 through the close of the Merger and Merck's stock performance from November 3, 2009 through December 31, 2012. 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)

	2012 <sup>(1)</sup>	2011 <sup>(2)</sup>	2010 <sup>(3)</sup>	2009 <sup>(4)</sup>	2008 <sup>(5)</sup>
<b>Results for Year:</b>					
Sales	\$ 47,267	\$ 48,047	\$ 45,987	\$ 27,428	\$ 23,850
Materials and production	16,446	16,871	18,396	9,019	5,583
Marketing and administrative	12,776	13,733	13,125	8,543	7,377
Research and development	8,168	8,467	11,111	5,845	4,805
Restructuring costs	664	1,306	985	1,634	1,033
Equity income from affiliates	(642)	(610)	(587)	(2,235)	(2,561)
Other (income) expense, net	1,116	946	1,304	(10,668)	(2,318)
Income before taxes	8,739	7,334	1,653	15,290	9,931
Taxes on income	2,440	942	671	2,268	1,999
Net income	6,299	6,392	982	13,022	7,932
Less: Net income attributable to noncontrolling interests	131	120	121	123	124
Net income attributable to Merck & Co., Inc.	6,168	6,272	861	12,899	7,808
Basic earnings per common share attributable to Merck & Co., Inc. common shareholders	\$2.03	\$2.04	\$0.28	\$5.67	\$3.65
Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	\$2.00	\$2.02	\$0.28	\$5.65	\$3.63
Cash dividends declared	5,173	4,818	4,730	3,598	3,250
Cash dividends paid per common share	\$1.68	\$1.52	\$1.52	\$1.52 <sup>(6)</sup>	\$1.52
Capital expenditures	1,954	1,723	1,678	1,461	1,298
Depreciation	1,999	2,351	2,638	1,654	1,445
Average common shares outstanding (millions)	3,041	3,071	3,095	2,268	2,136
Average common shares outstanding assuming dilution (millions)	3,076	3,094	3,120	2,273	2,143
<b>Year-End Position:</b>					
Working capital	\$ 16,509	\$ 16,936	\$ 13,423	\$ 12,791	\$ 4,794
Property, plant and equipment, net	16,030	16,297	17,082	18,279	12,000
Total assets	106,132	105,128	105,781	112,314	47,196
Long-term debt	16,254	15,525	15,482	16,095	3,943
Total equity	55,463	56,943	56,805	61,485	21,167
<b>Year-End Statistics:</b>					
Number of stockholders of record	157,400	166,100	171,000	175,600	165,700
Number of employees	83,000	86,000	94,000	100,000	55,200

<sup>(1)</sup> Amounts for 2012 include the amortization of purchase accounting adjustments, a net charge recorded in connection with a litigation settlement, in-process research and development impairment charges reflected in research and development expenses, the impact of restructuring actions and the favorable impact of certain tax items.

<sup>(2)</sup> 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.

<sup>(3)</sup> 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 litigation, a 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.

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

- <sup>(4)</sup> 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.
- <sup>(5)</sup> 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 Foundation.
- <sup>(6)</sup> 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, as well as club stores and specialty channels.

**Overview**

Merck continued to execute on its strategic priorities during 2012 despite facing several business challenges, including the August U.S. patent expiration for *Singulair*, a medicine indicated for the chronic treatment of asthma and the relief of symptoms of allergic rhinitis. Worldwide sales were \$47.3 billion in 2012, a decline of 2% compared with 2011, including a 3% unfavorable effect from foreign exchange. Excluding the impact of foreign exchange, sales increased 1% reflecting growth of key products and within key geographic regions which offset the impact of the U.S. *Singulair* patent expiration. The Company also reduced operating expenses by efficiently managing costs through targeted reductions. In addition, the Company generated new clinical data and advanced certain key research and development pipeline programs.

The Company's four-part growth strategy is focused on; one, executing on its core business, which includes its largest markets, its core brands, new launch brands, and research and development efforts targeted at therapeutic areas with the greatest future patient demand and scientific opportunity; two, expanding geographically into high-growth markets; three, extending into complementary businesses of consumer care and animal health; and four, effectively managing costs while continuing to invest for future growth.

Beginning with the Company's sales performance in its largest markets during 2012, despite the adverse effects of the U.S. *Singulair* patent expiry which caused a significant and rapid decline in U.S. *Singulair* sales, sales in the United States were relatively flat compared to the prior year reflecting strong growth of key brands including *Januvia* and *Janumet*, treatments for type 2 diabetes, *Zostavax*, a vaccine to help prevent shingles (herpes zoster), *Gardasil*, a vaccine to help prevent certain diseases caused by four types of human papillomavirus ( HPV ), *Vitreolis*, a treatment for chronic hepatitis C, and *Isentress*, an antiretroviral therapy for use in combination therapy for the treatment of HIV-1 infection. Turning to Europe and Canada, the Company continues to experience positive volume growth trends for many of its key brands, including *Vitreolis*, *Januvia*, *Janumet*, and *Simponi*, a treatment for inflammatory diseases; however, this growth only partially offset increased generic erosion and the price declines stemming from the economic issues and related fiscal austerity measures in this region.

With respect to research and development efforts, the Company continued the advancement of drug candidates through its pipeline in 2012. The Company currently has three candidates under review with the U.S. Food and Drug Administration (the FDA ): MK-4305, suvorexant, an investigational treatment for insomnia; MK-8616, sugammadex sodium injection, a medication for the reversal of certain muscle relaxants used during surgery; and MK-0653C, an investigational combination of ezetimibe and atorvastatin for the treatment of primary or mixed hyperlipidemia. MK-8109, vintafolide, an investigational cancer candidate, is under review in the European Union

## Table of Contents

(the EU). In addition, the Company currently has 16 candidates in Phase III development and anticipates filing a New Drug Application (NDA) or a Biologics License Application (BLA), as applicable, with the FDA with respect to several of these candidates in 2013.

In December 2012, the Company announced the HPS2-THRIVE (Heart Protection Study 2-Treatment of HDL to Reduce the Incidence of Vascular Events) study of *Tredaptive* (extended-release niacin/laropiprant) did not meet its primary endpoint. As a result, the Company does not plan to seek regulatory approval for the medicine in the United States. In January 2013, Merck began taking steps to suspend the availability of *Tredaptive* outside the United States. Also, on February 1, 2013, the Company announced that it had recently received and was reviewing safety and efficacy data from a Phase III study involving MK-0822, odanacatib, the Company's investigational treatment for osteoporosis in post-menopausal women. As a result of its review of this data, the Company concluded that review of additional data from the previously planned, ongoing extension study was warranted and that filing an application for approval with the FDA should be delayed. As previously announced, the Company is conducting a blinded extension of the trial in approximately 8,200 women, which will provide additional safety and efficacy data. Merck now anticipates that it will file applications for approval of odanacatib in 2014 with additional data from the extension trial. The Company continues to believe that odanacatib will have the potential to address unmet medical needs in patients with osteoporosis.

Merck continues to pursue opportunities for establishing external alliances to complement its substantial internal research capabilities, including research collaborations, as well as licensing preclinical and clinical compounds and technology platforms that have the potential to drive both near- and long-term growth. During 2012, the Company completed a variety of transactions spanning different therapeutic areas and clinical stages including licensing agreements with Endocyte, Inc. (Endocyte) for vintafolide (MK-8109), an investigational cancer candidate, and with AiCuris for a portfolio of investigational medicines targeting human cytomegalovirus, including letermovir (MK-8228).

Consistent with the second element of the Company's strategy to expand geographically in high-growth markets such as Japan and key emerging markets, the Company continued to invest in these markets in 2012. Emerging market sales grew 4% in 2012, including a 4% unfavorable impact of foreign exchange, despite the loss of sales from *Remicade* and *Simponi*, treatments for inflammatory diseases, in markets relinquished to Johnson & Johnson (J&J) as part of the arbitration settlement agreement in 2011 as discussed below. China continues to be an important growth driver with sales exceeding \$1.0 billion in 2012, representing growth of 25% over the prior year, including a 3% favorable effect from foreign exchange. Growth in Japan was 6% during 2012, tempered by generic competition and the biennial price cuts early in the year. Merck has entered into several transactions designed to strengthen its presence in the emerging markets in the longer term. The Company's joint venture with Sincere Pharmaceutical Group in China began preliminary operations in late-2012.

The third component of Merck's strategy relates to the complementary businesses of Consumer Care and Animal Health. Merck's Animal Health business continues as a solid contributor with 4% revenue growth in 2012, including a 5% unfavorable effect from foreign exchange, reflecting growth in the cattle, poultry, companion animal and swine product lines. Sales of Consumer Care products grew 6% in 2012, including a 1% unfavorable effect from foreign exchange, led by the *Dr. Scholl's* franchise and higher sales of *Coppertone*, *MiraLAX* and *Claritin*.

As noted, the last element of the Company's strategy is to tightly manage costs while also investing for growth. Consistent with these efforts, Merck remains committed to driving continuous productivity improvements across the enterprise and 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 2012, the Company had achieved its projected \$3.5 billion in annual net cost savings from these activities since the merger with Schering-Plough Corporation (Schering-Plough) (the Merger).

The global restructuring program that was initiated in conjunction with the integration of the legacy Merck and legacy Schering-Plough businesses (the Merger Restructuring Program) is intended to optimize the cost structure of the combined company. The workforce reductions associated with this plan relate to 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 recorded total pretax restructuring costs of \$951 million in 2012, \$1.8 billion in 2011 and \$1.8 billion in

---

**Table of Contents**

2010 related to this program. Costs associated with the Company's restructuring actions are included in *Materials and production costs*, *Marketing and administrative expenses*, *Research and development expenses* and *Restructuring costs*. 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. Subsequent to the Merger, the Company has rationalized a number of manufacturing sites worldwide. The remaining actions under this program will result in additional manufacturing facility rationalizations, which are expected to be substantially completed by 2016. The Company now expects the estimated total cumulative pretax costs for this program to be approximately \$7.2 billion to \$7.5 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.

In November 2012, Merck's Board of Directors raised the Company's quarterly dividend to \$0.43 per share from \$0.42 per share.

In February 2013, Merck reached an agreement in principle with plaintiffs to resolve two federal securities class-action lawsuits pending in the U.S. District Court for the District of New Jersey against Merck, Schering-Plough and certain of their current and former officers and directors (the ENHANCE Litigation). Under the proposed agreement, Merck will pay \$215 million to resolve the securities class action against all of the Merck defendants and \$473 million to resolve the securities class action against all of the Schering-Plough defendants. In connection with the settlement, Merck recorded a pretax and after-tax charge of \$493 million in 2012 which reflects \$195 million of anticipated insurance recoveries.

Earnings per common share assuming dilution attributable to common shareholders (EPS) for 2012 were \$2.00, which reflect a net unfavorable impact resulting from acquisition-related costs and restructuring costs, as well as the charge related to the ENHANCE Litigation noted above. Non-GAAP EPS in 2012 were \$3.82 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 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 hospitals serving a disproportionate share of low income or uninsured patients.

Against this backdrop, the United States enacted major health care reform legislation in 2010, which began to be implemented in 2010. Various insurance market reforms have advanced and will continue through full implementation in 2014. The law is expected to expand access to health care to about 32 million Americans by the end of the decade who did not previously have insurance coverage. With respect to the effect of the law on the pharmaceutical industry, the mandated Medicaid rebate increased 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% point of service discount to Medicare Part D beneficiaries when they are in the Medicare Part D coverage gap (i.e., the so-called "donut hole"). Approximately \$210 million and \$150 million was recorded by Merck as a reduction to revenue in 2012 and 2011, respectively, related to the donut hole provision. Also, pharmaceutical manufacturers are now required to pay an annual health care reform fee. The total annual industry fee was \$2.8 billion in 2012 and will be \$2.8 billion in 2013. 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 recorded \$190 million and \$162 million of costs within *Marketing and administrative* expenses in 2012 and 2011, respectively, for the annual health care reform fee.

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 of 2010. 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. These types of revenue generating or cost saving proposals include additional 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.

Efforts toward health care cost containment remain 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 and mandatory switches to generic drugs. While the Company is taking steps to mitigate the impact in the EU, the austerity measures continued to negatively affect the Company's revenue performance in 2012 and the Company anticipates the austerity measures will continue to negatively affect revenue performance in 2013.

## **Table of Contents**

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

Governments in many emerging markets are also focused on constraining health care costs and have enacted price controls and related measures that aim to put pressure on the price of pharmaceuticals and constrain market access. The Company anticipates that pricing pressures and market access challenges will continue in 2013 to varying degrees in the emerging markets.

The Company's focus on and share of revenue from emerging markets has increased. Countries in these markets may be subject to conditions that can affect the Company's efforts to continue to grow in emerging markets, including potential political instability, significant currency fluctuation and controls, financial crises, limited or changing availability of funding for health care, and other developments that may adversely impact the business environment for the Company. Further, the Company may engage third-party agents to assist in operating in emerging market countries, which may affect its ability to realize continued growth and may also increase the Company's risk exposure.

The full impact of 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 engages in public policy advocacy with policymakers and continues to attempt to demonstrate that its medicines provide value to patients and to those who pay for health care. The Company seeks to work with government policymakers to encourage a long-term approach to sustainable health care financing that ensures access to innovative medicines and does not disproportionately target pharmaceuticals as a source of budget savings. 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.

Certain markets outside of the United States have implemented health technology assessments and other cost management strategies which require additional data, reviews and administrative processes, all of which increase the complexity and costs of obtaining product reimbursement and exert downward pressure on reimbursement available and obtained.

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.



## **Table of Contents**

The Company believes that it will continue to be able to conduct its operations, including launching new drugs, 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 and include a set of principles that the Company strives to embed into its operations and business strategies to guide the Company's worldwide approach to expanding access to health care. 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 in the United States 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 to reduce maternal mortality.

Merck has also in the past provided funds to the Merck 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 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**

### *Sales*

Worldwide sales totaled \$47.3 billion in 2012, a decline of 2% compared with \$48.0 billion in 2011. Foreign exchange unfavorably affected global sales performance by 3%. The sales decrease was driven primarily by *Singulair*, which lost market exclusivity in the United States in August 2012 resulting in a significant and rapid decline in U.S. *Singulair* sales. The sales decline was also driven by lower sales of *Remicade*, a treatment for inflammatory diseases, largely as a result of the arbitration settlement agreement with J&J in 2011 as discussed below. In addition, lower sales of *Cozaar* and *Hyzaar*, treatments for hypertension, *Clarinox*, a non-sedating antihistamine, *Fosamax*, for the treatment of osteoporosis, *Vytorin*, a cholesterol modifying medicine, *Primaxin*, an anti-bacterial product, and *Avelox*, a broad-spectrum fluoroquinolone antibiotic for the treatment of certain respiratory and skin infections, as well as lower revenue from the Company's relationship with AstraZeneca LP (AZLP) also contributed to the sales decline in 2012. These declines were largely offset by higher sales of *Januvia*, *Gardasil*, *Victrelis*, *Zostavax*, *Janumet*, *Isentress*, *Zetia*, a cholesterol modifying medicine, *Dulera*, a combination medicine for the treatment of asthma, as well as by higher sales of the Company's animal health and consumer care products.

Sales in the United States were \$20.4 billion in 2012, a decline of 1% compared with \$20.5 billion in 2011. The sales decrease was driven by lower sales of *Singulair*, *Vytorin*, *Avelox*, *Cozaar* and *Hyzaar*, as well as lower revenue from the Company's relationship with AZLP. These declines were largely offset by higher sales of

**Table of Contents**

*Januvia*, *Zostavax*, *Gardasil*, *Victrelis*, *Janumet*, *Isentress*, *Pneumovax*, a vaccine to help prevent pneumococcal disease, *Zetia* and *Dulera*, as well as higher sales of animal health and consumer care products.

International sales were \$26.9 billion in 2012, a decline of 2% compared with \$27.6 billion in 2011. Foreign exchange unfavorably affected international sales performance by 4% in 2012. Declines in Europe and Canada were partially offset by growth in Japan and certain of the emerging markets, particularly in China. Lower sales of *Remicade* led the decline, along with lower sales of *Cozaar*, *Hyzaar*, *Singulair*, *Fosamax* and *Clarinex*, partially offset by growth in *Januvia*, *Victrelis*, *Gardasil* and *Janumet*. International sales represented 57% of total sales in both 2012 and 2011.

Global efforts toward health care cost containment continue to exert pressure on product pricing and market access worldwide. In many international markets, government-mandated pricing actions have reduced prices of generic and patented drugs. In addition, other austerity measures negatively affected the Company's revenue performance in 2012. The Company anticipates these pricing actions and other austerity measures will continue to negatively affect revenue performance in 2013.

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*, a vaccine to help protect against rotavirus gastroenteritis in infants and children, *Zetia*, *Pneumovax* 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 *Victrelis*. These increases were partially offset by lower sales of *Cozaar*, *Hyzaar*, *Vytorin*, *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). Revenue was also negatively affected by lower sales of *Caelyx*, *Subutex* and *Suboxone* as the Company no longer has marketing rights to these products. In addition, 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 as compared with 2010.

**Table of Contents**

Sales of the Company's products were as follows:

(\$ in millions)	2012	2011	2010
Primary Care and Women's Health			
<i>Cardiovascular</i>			
Zetia	\$ 2,567	\$ 2,428	\$ 2,297
Vytorin	1,747	1,882	2,014
<i>Diabetes and Obesity</i>			
Januvia	4,086	3,324	2,385
Janumet	1,659	1,363	954
<i>Respiratory</i>			
Singulair	3,853	5,479	4,987
Nasonex	1,268	1,286	1,219
Clarinet	393	621	623
Dulera	207	96	8
Asmanex	185	206	208
<i>Women's Health and Endocrine</i>			
Fosamax	676	855	926
NuvaRing	623	623	559
Follistim AQ	468	530	528
Implanon	348	294	236
Cerazette	271	268	209
<i>Other</i>			
Maxalt	638	639	550
Arcoxia	453	431	398
Avelox	201	322	316
Hospital and Specialty			
<i>Immunology</i>			
Remicade	2,076	2,667	2,714
Simponi	331	264	97
<i>Infectious Disease</i>			
Isentress	1,515	1,359	1,090
PegIntron	653	657	737
Cancidas	619	640	611
Victrelis	502	140	
Invanz	445	406	362
Primaxin	384	515	610
Noxafil	258	230	198
<i>Oncology</i>			
Temodar	917	935	1,065
Emend	489	419	378
<i>Other</i>			
Cosopt/Trusopt	444	477	484
Bridion	261	201	103
Integrilin	211	230	266
Diversified Brands			
Cozaar/Hyzaar	1,284	1,663	2,104
Propecia	424	447	447
Zocor	383	456	468
Claritin Rx	244	314	296
Remeron	232	241	223
Proscar	217	223	216
Vasotec/Vaseretic	192	231	255
<i>Vaccines<sup>(1)</sup></i>			
Gardasil	1,631	1,209	988
ProQuad/M-M-R II/Varivax	1,273	1,202	1,378
Zostavax	651	332	243
RotaTeq	601	651	519
Pneumovax	580	498	376
Other pharmaceutical <sup>(2)</sup>	4,141	4,035	4,622
Total Pharmaceutical segment sales	40,601	41,289	39,267
Other segment sales <sup>(3)</sup>	6,412	6,428	6,159

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

Total segment sales	<b>47,013</b>	47,717	45,426
Other <sup>(4)</sup>	<b>254</b>	330	561
	<b>\$ 47,267</b>	\$ 48,047	\$ 45,987

<sup>(1)</sup> 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.

<sup>(2)</sup> Other pharmaceutical primarily reflects sales of other human health pharmaceutical products, including products within the franchises not listed separately.

<sup>(3)</sup> Represents the non-reportable segments of Animal Health, Consumer Care and Alliances. The Alliances segment includes revenue from the Company's relationship with AZLP.

<sup>(4)</sup> 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***Primary Care and Women's Health*

## Cardiovascular

Worldwide sales of *Zetia* (also marketed as *Ezetrol* outside the United States), a cholesterol absorption inhibitor, increased 6% in 2012 to \$2.6 billion, including a 2% unfavorable effect from foreign exchange. The sales increase reflects positive performance in the United States due to pricing, as well as volume growth in Japan, partially offset by volume declines in the United States. Sales of *Zetia* increased 6% in 2011 to \$2.4 billion, including a 3% favorable effect from foreign exchange. The increase reflects higher sales in international markets, particularly in Japan, 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 2012 to \$1.7 billion, including a 3% unfavorable effect from foreign exchange. The sales decline reflects volume declines in the United States, partially offset by pricing in the United States and volume growth in certain international markets. Worldwide sales of *Vytorin* declined 7% in 2011 to \$1.9 billion reflecting volume declines in the United States, partially offset by increases in international markets.

In March 2012, the Data Safety Monitoring Board (the DSMB) of the IMPROVE-IT trial, a large cardiovascular outcomes study evaluating ezetimibe/simvastatin against simvastatin alone in patients presenting with acute coronary syndrome, completed the second pre-specified interim efficacy analysis of the study. The DSMB conducted the planned interim efficacy analysis after the trial had reached approximately 75% of the targeted 5,250 clinical endpoints called for in the study design. The DSMB recommended that the study continue without change in design and stated it planned to review the data again in approximately nine months. That review has been scheduled for March 2013, at which point nine months of additional data will have been adjudicated. Merck remains blinded to IMPROVE-IT safety and efficacy data. IMPROVE-IT is an 18,000 patient event-driven trial and, based on the current rate at which events are being reported, the Company now anticipates the targeted 5,250 clinical endpoints for study completion will be reached in 2014.

In December 2012, Merck announced the HPS2-THRIVE study of *Tredaptive* did not meet its primary endpoint (see Research and Development below). Subsequently, based on the understanding of the preliminary data from the HPS2-THRIVE study and in consultation with regulatory authorities, Merck began taking steps to suspend the availability of *Tredaptive*, which is approved for use in certain countries outside of the United States. The Company recognized approximately \$40 million of costs in 2012 associated with suspending the availability of *Tredaptive*. Sales of *Tredaptive* were \$17 million in 2012.

## Diabetes and Obesity

Global sales of *Januvia*, Merck's dipeptidyl peptidase-4 (DPP-4) inhibitor for the treatment of type 2 diabetes, rose 23% in 2012 to \$4.1 billion and grew 39% in 2011 to \$3.3 billion reflecting volume growth in the United States, as well as in international markets, particularly in Japan. Foreign exchange unfavorably affected sales performance by 2% in 2012 and favorably affected sales performance by 3% in 2011.

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 \$1.7 billion in 2012, an increase of 22% compared with 2011, reflecting volume growth in the United States, the emerging markets and Europe. Global sales of *Janumet* were \$1.4 billion in 2011 compared with \$954 million in 2010 reflecting growth internationally due in part to ongoing launches in certain markets, as well as growth in the United States. Foreign exchange unfavorably affected sales performance by 4% in 2012 and favorably affected sales performance by 2% in 2011.

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.

As previously disclosed, 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. The Company completed the study and

**Table of Contents**

submitted the study report to the FDA in December 2012. The FDA has recently reviewed the submission and concluded that the post-marketing requirement has been fulfilled.

**Respiratory**

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, declined 30% to \$3.9 billion in 2012 driven primarily by lower sales in the United States. Revenue declines in Europe, Canada and Latin America also contributed to the *Singulair* sales decline. The patent that provided U.S. market exclusivity for *Singulair* expired on August 3, 2012 and the Company experienced a significant and rapid decline in U.S. *Singulair* sales thereafter. U.S. sales of *Singulair* declined 97% in the fourth quarter to \$25 million. U.S. sales of *Singulair* decreased 39% to \$2.2 billion for the full year of 2012 driven by lower sales after the U.S. patent expiry in August. In addition, the patent that provided market exclusivity for *Singulair* expired in a number of major European markets in February 2013 and the Company expects a significant and rapid reduction in sales of *Singulair* in those markets. The patent that provides market exclusivity for *Singulair* in Japan will expire in 2016. In 2012, sales of *Singulair* were \$602 million in Europe and \$668 million in Japan. Global sales of *Singulair* grew 10% in 2011 to \$5.5 billion, including a 2% favorable impact of foreign exchange, driven primarily by favorable pricing in the United States, as well as volume growth in Japan and in the emerging markets.

Global sales of *Nasonex*, an inhaled nasal corticosteroid for the treatment of nasal allergy symptoms, declined 1% in 2012 to \$1.3 billion, including a 1% unfavorable impact from foreign exchange. Sales performance reflects price declines in Europe and lower volumes in the United States, largely offset by higher prices in the United States. In 2009, Apotex Inc. and Apotex Corp. (collectively, Apotex) filed an Abbreviated New Drug Application with the FDA seeking approval to sell its generic version of *Nasonex*. In June 2012, the U.S. District Court for the District of New Jersey ruled against the Company in a patent infringement suit against Apotex holding that Apotex's generic version of *Nasonex* does not infringe on the Company's formulation patent (see Note 11 to the consolidated financial statements). The Company has appealed the U.S. District Court decision. If generic versions become available, significant losses of *Nasonex* sales could occur and the Company may take a non-cash impairment charge with respect to the value of the *Nasonex* intangible asset, which had a carrying value of approximately \$1.9 billion at December 31, 2012. If the *Nasonex* intangible asset is determined to be impaired, the impairment charge could be material. As a result of the unfavorable U.S. District Court decision, the Company evaluated the *Nasonex* intangible asset for impairment and concluded that it was not impaired. U.S. sales of *Nasonex* were \$597 million in 2012. Worldwide sales of *Nasonex* increased 5% in 2011 to \$1.3 billion, including a 1% favorable effect from foreign exchange. The sales increase was driven largely by volume growth in Japan and Latin America, partially offset by volume declines in the United States.

Global sales of *Clarinex* (marketed as *Aerius* in many countries outside the United States), a non-sedating antihistamine, declined 37% in 2012 to \$393 million driven by lower volumes in Europe and the United States as a result of generic competition. As previously disclosed, by virtue of litigation settlements, certain generic manufacturers were given the right to enter the U.S. market in 2012 and several generic versions have been launched. The Company anticipates that sales of *Clarinex* will continue to decline. Worldwide sales of *Clarinex* were \$621 million in 2011 compared with \$623 million in 2010.

Global sales of *Dulera* Inhalation Aerosol, a combination medicine for the treatment of asthma, were \$207 million in 2012 compared with \$96 million in 2011 reflecting volume growth in the United States. *Dulera* Inhalation Aerosol was approved by the FDA in June 2010. In January 2012, Merck received a Complete Response Letter from the FDA on the Company's supplemental New Drug Application for *Dulera*, for the treatment of chronic obstructive pulmonary disease. The Company is planning to conduct an additional clinical study and update the application in the future.

**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 21% in 2012 to \$676 million and decreased 8% in 2011 to \$855 million. These medicines have lost market exclusivity in the United States and in most major European markets. During 2012, declines in Japan and the emerging markets also contributed to the sales decrease. The Company expects the declines within the *Fosamax* product franchise to continue.

**Table of Contents**

Worldwide sales of *NuvaRing*, a vaginal contraceptive product, were \$623 million in 2012, comparable with sales in 2011. Foreign exchange unfavorably affected sales performance by 3% in 2012. Excluding the unfavorable impact of foreign exchange, sales performance in 2012 reflects volume growth in the emerging markets and positive performance in Europe. Global sales of *NuvaRing* grew 12% to \$623 million in 2011, including a 3% beneficial effect from foreign exchange, driven by positive performance in the United States and internationally.

Global sales of *Follistim AQ* (marketed in most countries outside the United States as *Puregon*), a biological fertility treatment, declined 12% in 2012 to \$468 million, including a 3% unfavorable effect from foreign exchange, driven largely by declines in Europe resulting from supply issues and pricing. Sales of *Follistim AQ* 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. *Puregon* lost market exclusivity in the EU in August 2009.

The Company is currently experiencing difficulty manufacturing certain women's health products. The Company is working to resolve these issues, which were not material to the Company's results of operations.

**Other**

Global sales of *Maxalt*, a product for the acute treatment of migraine, were \$638 million in 2012, comparable with sales in 2011. Sales performance in 2012 reflects higher sales in the United States driven by favorable pricing, offset by volume declines in Europe and Canada due to generic erosion. Sales of *Maxalt* increased 16% in 2011 to \$639 million reflecting a higher inventory level and favorable pricing in the United States. The patent that provided U.S. market exclusivity for *Maxalt* expired in December 2012 and the Company is experiencing a decline in U.S. *Maxalt* sales and expects the decline to continue. In addition, the patent that provides market exclusivity for *Maxalt* will expire in a number of major European markets in August 2013 and the Company anticipates that sales in those European markets will decline significantly after these patent expiries. In 2012, sales of *Maxalt* were \$491 million in the United States and \$92 million in Europe.

Sales of *Avelox*, a broad-spectrum fluoroquinolone antibiotic for the treatment of certain respiratory and skin infections marketed by the Company in the United States, declined 37% in 2012 to \$201 million due primarily to a competitor's product becoming available in generic form. Sales of *Avelox* grew 2% in 2011 to \$322 million. The patent that provides U.S. market exclusivity for *Avelox* expires in March 2014; however, by agreement, a generic manufacturer may launch a generic version of *Avelox* in February 2014.

Other products included in Primary Care and Women's Health include among others, *Asmanex Twisthaler*, an inhaled corticosteroid for asthma; *Implanon*, a single-rod subdermal contraceptive implant; *Cerazette*, a progestin only oral contraceptive; and *Arcoxia*, for the treatment of arthritis and pain.

**Hospital and Specialty****Immunology**

Sales of *Remicade*, a treatment for inflammatory diseases, were \$2.1 billion in 2012, a decline of 22% compared with 2011, and were \$2.7 billion in 2011, a decline of 2% compared with 2010. Foreign exchange unfavorably affected global sales performance by 6% in 2012 and 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*, 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 Asia Pacific. Merck retained exclusive marketing rights throughout Europe, Russia and Turkey (the Retained Territories). In the Retained Territories, *Remicade* sales declined 2% in 2012, which reflects an 8% unfavorable effect from foreign exchange and volume growth in Europe. Sales of *Remicade* in the Retained Territories grew 13% in 2011, which reflects a 6% favorable impact from foreign exchange. *Simponi*, a once-monthly subcutaneous treatment for certain inflammatory diseases was approved by the European Commission (the EC) in October 2009. Sales of *Simponi* were \$331 million in 2012, \$264 million in 2011 and \$97 million in 2010. The revenue increases were driven by growth in the Retained Territories due in part to ongoing launches. In July 2012, a submission was made to the European Medicines Agency (the EMA) requesting approval of *Simponi* for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy.

**Table of Contents**

## 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, grew 11% in 2012 to \$1.5 billion driven primarily by volume growth in the United States, Latin America and the Asia Pacific region. Global sales of *Isentress* rose 25% in 2011 to \$1.4 billion reflecting volume growth in the United States and internationally, partially offset by unfavorable pricing in European markets. Foreign exchange unfavorably affected global sales performance by 4% in 2012 and favorably affected sales performance by 3% in 2011.

Worldwide sales of *PegIntron*, a treatment for chronic hepatitis C, declined 1% in 2012 to \$653 million, including an unfavorable effect from foreign exchange of 4%. Excluding the unfavorable impact of foreign exchange, sales performance reflects volume growth and favorable pricing in the United States and volume growth in certain of the emerging markets. Sales of *PegIntron* declined 11% in 2011 to \$657 million, including a 4% favorable effect from foreign exchange, reflecting competitive pressures.

Global sales of *Cancidas*, an anti-fungal product, declined 3% in 2012 to \$619 million, including a 5% unfavorable effect from foreign exchange. Excluding the unfavorable impact of foreign exchange, sales performance in 2012 reflects growth in the emerging markets. Sales of *Cancidas* grew 5% in 2011 to \$640 million, including a 4% favorable effect from foreign exchange, reflecting higher sales in Europe and Canada, partially offset by declines in the United States.

Global sales of *Victrelis*, the Company's innovative oral medicine for the treatment of chronic hepatitis C, were \$502 million in 2012 compared with \$140 million in 2011, driven by post-launch growth in the United States and internationally, particularly in Europe. *Victrelis* was approved by the FDA in May 2011 and by the EC in July 2011. *Victrelis* is approved in 70 countries and has launched in 45 of those markets.

Sales of *Primaxin*, an anti-bacterial product, declined 25% in 2012 to \$384 million and decreased 16% in 2011 to \$515 million. Patents on *Primaxin* have expired worldwide and multiple generics have been launched.

## Oncology

Sales of *Temodar* (marketed as *Temodal* outside the United States), a treatment for certain types of brain tumors, declined 2% in 2012 to \$917 million, including a 2% unfavorable effect from foreign exchange. Sales declines in Europe from generic competition were offset by price increases in the United States. Sales of *Temodar* decreased 12% in 2011 to \$935 million, including a 3% favorable effect from foreign exchange, primarily reflecting generic competition in Europe. *Temodar* lost patent exclusivity in the EU in 2009. As previously disclosed, by agreement, a generic manufacturer may launch a generic version of *Temodar* in the United States in August 2013. Accordingly, the Company anticipates U.S. sales of *Temodar*, which were \$423 million in 2012, will decline significantly in 2013. The U.S. patent and exclusivity periods will otherwise expire in February 2014.

Global sales of *Emend*, for the prevention of chemotherapy-induced and post-operative nausea and vomiting, increased 17% in 2012 to \$489 million, including a 2% unfavorable effect from foreign exchange. The sales increase reflects volume growth in the United States and Japan. Sales of *Emend* increased 11% in 2011 to \$419 million primarily reflecting growth in international markets.

## Other

Worldwide sales of ophthalmic products *Cosopt* and *Trusopt* declined 7% in 2012 to \$444 million, including a 4% unfavorable effect from foreign exchange. The sales decline primarily reflects lower sales in Europe due to generic erosion and price reductions, mitigated in part by higher *Cosopt* sales in Japan. Sales of *Cosopt* and *Trusopt* declined 1% in 2011 to \$477 million, including a 5% favorable impact of foreign exchange, reflecting unfavorable pricing and volume declines in Europe, partially offset by higher *Cosopt* sales in Japan. 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.

*Bridion* (sugammadex sodium injection), for the reversal of certain muscle relaxants used during surgery, is approved and has been launched in many countries outside of the United States. Sales of *Bridion* were \$261 million in 2012, \$201 million in 2011 and \$103 million in 2010. Sugammadex sodium injection is currently under review by the FDA.



## Table of Contents

In 2009, the FDA approved *Saphris* (asenapine), an antipsychotic indicated for the treatment of schizophrenia and bipolar I disorder in adults. In 2010, asenapine, sold under the brand name *Sycrest*, received marketing approval in the EU for the treatment of bipolar I disorder in adults. In 2010, Merck and H. Lundbeck A/S (Lundbeck) announced a worldwide 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 \$166 million in 2012 and \$120 million in 2011. Merck continues to focus on building and maintaining the brand awareness of *Saphris* in the United States. If these efforts in the United States or Lundbeck's on-going launch of the product in the EU are not successful, the Company may take a non-cash impairment charge with respect to the value of the *Saphris/Sycrest* intangible asset, which had a carrying value of approximately \$550 million at December 31, 2012. If the *Saphris/Sycrest* intangible asset is determined to be impaired, the impairment charge could be material.

Other products contained in Hospital and Specialty include among others, *Invanz*, for the treatment of certain infections; *Noxafil*, for the prevention of certain invasive fungal infections; and *Integrilin*, a treatment for patients with acute coronary syndrome, which is sold by the Company in the United States and Canada.

### *Diversified Brands*

Merck's diversified brands include 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), treatments for hypertension, declined 23% in 2012 to \$1.3 billion and decreased 21% in 2011 to \$1.7 billion. The patents that provided market exclusivity for *Cozaar* and *Hyzaar* in the United States and in a number of major international markets have expired. Accordingly, the Company is experiencing significant declines in *Cozaar* and *Hyzaar* sales and the Company expects the declines to continue.

Other products contained in Diversified Brands include among others, *Propecia*, a product for the treatment of male pattern hair loss; *Zocor*, a statin for modifying cholesterol; prescription *Claritin*, a treatment for seasonal outdoor allergies and year-round indoor allergies; *Remeron*, an antidepressant; *Proscar*, a urology product for the treatment of symptomatic benign prostate enlargement; and *Vasotec* and *Vaseretic*, hypertension and/or heart failure products. 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 entered the U.S. market in January 2013 and another has been given the right to enter in July 2013. Accordingly, the Company anticipates U.S. sales of *Propecia*, which were \$124 million in 2012, will decline significantly in 2013.

### *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 35% in 2012 to \$1.6 billion driven primarily by growth in the United States, reflecting continued uptake in males and approximately \$45 million of government purchases for the U.S. Centers for Disease Control and Prevention (the CDC) Pediatric Vaccine Stockpile, as well as growth in the emerging markets, particularly in Latin America and the Asia Pacific region, and in Japan. Sales of *Gardasil* rose 22% in 2011 to \$1.2 billion driven by greater uptake in males 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. *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

## **Table of Contents**

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 has resolved the supply constraints in the United States and anticipates limited launches in international markets for *Zostavax* in 2013 as noted below.

*ProQuad*, a pediatric combination vaccine to help protect against measles, mumps, rubella and varicella, one of the VZV-containing vaccines, became available again in the United States for ordering in October 2012. Merck's sales of *ProQuad* were \$61 million in 2012, \$34 million in 2011 and \$134 million in 2010. Sales in all of these years were affected by supply constraints.

Merck's sales of *Varivax*, a vaccine to help prevent chickenpox (varicella), were \$846 million in 2012, \$831 million in 2011 and \$929 million in 2010. Sales for 2010 reflect \$48 million of government purchases for the CDC's Pediatric Vaccine Stockpile. Merck's sales of *M-M-R II*, a vaccine to help protect against measles, mumps and rubella, were \$365 million in 2012, \$337 million in 2011 and \$315 million in 2010. Sales growth in 2012 was driven primarily by higher volumes in the United States. Sales of *Varivax* and *M-M-R II* were affected by *ProQuad* supply constraints discussed above.

Merck's sales of *Zostavax*, a vaccine to help prevent shingles (herpes zoster) in adults 50 years of age and older, were \$651 million in 2012, \$332 million in 2011 and \$243 million in 2010. Sales performance in 2012 reflects supply availability and increased promotional efforts in the United States. Sales in 2011 and 2010 were affected by supply issues. The Company anticipates limited launches outside of the United States later in 2013.

Merck's sales of *RotaTeq*, a vaccine to help protect against rotavirus gastroenteritis in infants and children, declined 8% in 2012 to \$601 million reflecting favorable public sector inventory fluctuations in 2011, partially offset by volume growth in the emerging markets and Japan in 2012. Merck's sales of *RotaTeq* grew 25% in 2011 to \$651 million reflecting favorable public sector inventory fluctuations and growth in emerging markets.

Merck's sales of *Pneumovax*, a vaccine to help prevent pneumococcal disease, grew 17% in 2012 to \$580 million due primarily to growth in the United States as a result of price increases and higher volumes, partially offset by declines in Japan. Sales of *Pneumovax* increased 33% in 2011 to \$498 million due to positive performance in the United States, due in part to favorable pricing, and growth in Japan.

Merck's adult formulation of *Vaqta*, a vaccine against hepatitis A which was experiencing supply issues, became available in the third quarter of 2012.

## **Other Segments**

### *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 4% in 2012 to \$3.4 billion and increased 11% in 2011 to \$3.3 billion. Foreign exchange unfavorably affected global sales performance by 5% in 2012 and favorably affected global sales performance by 4% in 2011. The increase in sales in both periods was driven by positive performance among cattle, poultry, companion animal and swine products.

### *Consumer Care*

Consumer Care products include over-the-counter, foot care and sun care products such as *Claritin* non-drowsy antihistamines; *MiraLAX*, for the relief of occasional constipation; *Dr. Scholl's* foot care products; and *Coppertone* sun care products. Global sales of Consumer Care products grew 6% in 2012, including a 1% unfavorable effect from foreign exchange, to \$2.0 billion reflecting higher sales of *Dr. Scholl's*, *Coppertone*, *MiraLAX* and *Claritin*, partially offset by lower sales of *Marvelon*, an oral contraceptive, which is an over-the-

## Table of Contents

counter product in China. Sales 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 are affected by competition and consumer spending patterns. In January 2013, the FDA approved *Oxytrol for Women*, the first and only over-the-counter treatment for overactive bladder in women, which the Company anticipates will be available to customers in fall 2013.

### Alliances

The alliances segment includes results from the Company's relationship with AZLP. Revenue from AZLP, primarily relating to sales of Nexium and Prilosec, was \$915 million in 2012, \$1.2 billion in 2011 and \$1.3 billion in 2010. AstraZeneca has an option to buy Merck's interest in a subsidiary, and through it, Merck's interest in Nexium and Prilosec, exercisable in 2014, 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)	2012	Change	2011	Change	2010
Materials and production	\$ 16,446	-3%	\$ 16,871	-8%	\$ 18,396
Marketing and administrative	12,776	-7%	13,733	5%	13,125
Research and development <sup>(1)</sup>	8,168	-4%	8,467	-24%	11,111
Restructuring costs	664	-49%	1,306	33%	985
Equity income from affiliates	(642)	5%	(610)	4%	(587)
Other (income) expense, net	1,116	18%	946	-27%	1,304
	\$ 38,528	-5%	\$ 40,713	-8%	\$ 44,334

<sup>(1)</sup> Includes \$200 million, \$587 million and \$2.4 billion of IPR&D impairment charges in 2012, 2011 and 2010, respectively.

#### Materials and Production

Materials and production costs were \$16.4 billion in 2012, \$16.9 billion in 2011 and \$18.4 billion in 2010. Costs include expenses for the amortization of intangible assets recorded in connection with mergers and acquisitions which totaled \$4.9 billion in each of 2012 and 2011 and \$4.6 billion in 2010. Additionally, expenses in 2011 and 2010 include \$89 million and \$2.0 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 which amounted to \$188 million, \$348 million and \$429 million in 2012, 2011 and 2010, 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.

Gross margin was 65.2% in 2012 compared with 64.9% in 2011 and 60.0% in 2010. The amortization of intangible assets and purchase accounting adjustments to inventories, as well as the restructuring and impairment charges noted above reduced gross margin by 10.7 percentage points in 2012, 11.4 percentage points in 2011 and 15.2 percentage points in 2010. Excluding these impacts, the gross margin decline in 2012 as compared with 2011 reflects the significant decline in *Singulair* sales as a result of the loss of U.S. market exclusivity, partially offset by improvements resulting from other changes in product mix. The Company anticipates that gross margin will continue to be negatively affected by the *Singulair* U.S. patent expiry which occurred in August 2012 and by the *Singulair* patent expiries in major European markets which occurred in February 2013. In addition, anticipated generic competition in the United States for *Maxalt* and *Propecia* will also negatively impact gross margin in 2013. 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.

## Table of Contents

### *Marketing and Administrative*

Marketing and administrative expenses declined 7% in 2012 to \$12.8 billion due to the favorable effect of foreign exchange, a decline in promotion costs and lower selling costs resulting from restructuring activities. Marketing and administrative expenses grew 5% to \$13.7 billion in 2011 due in part to the unfavorable effect of foreign exchange and strategic investments made in emerging markets. Marketing and administrative expenses in 2012 and 2011 include \$190 million and \$162 million, respectively, of expenses for the annual health care reform fee required as part of U.S. health care reform legislation. Expenses for 2012, 2011 and 2010 include restructuring costs of \$90 million, \$119 million and \$144 million, respectively, related primarily 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 \$272 million, \$278 million and \$379 million of acquisition-related costs in 2012, 2011 and 2010, respectively, consisting of incremental, third-party integration costs related to the Merger, including costs related to legal entity and system integration. Acquisition-related costs 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.

### *Research and Development*

Research and development expenses were \$8.2 billion in 2012, \$8.5 billion in 2011 and \$11.1 billion in 2010. Research and development expenses are comprised of the costs directly incurred by Merck Research Laboratories (MRL), the Company's research and development division that focuses on human health-related activities, which were approximately \$4.5 billion in each of 2012 and 2011 and were \$4.9 billion in 2010. 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 the Pharmaceutical, Animal Health and Consumer Care segments, which in the aggregate were \$3.4 billion, \$3.2 billion and \$3.4 billion for 2012, 2011 and 2010, respectively. Research and development expenses in 2012 and 2011 were favorably affected by cost savings resulting from restructuring activities. Included in research and development expenses in 2012 were upfront payments of approximately \$260 million related to agreements with Endocyte and AiCuris. (See *Research and Development* below.)

Research and development expenses also include in-process research and development (IPR&D) impairment charges and research and development-related restructuring charges. During 2012, the Company recorded \$200 million of IPR&D impairment charges primarily for pipeline programs that had previously been deprioritized and were subsequently deemed to have no alternative use during the period. 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. 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. 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 2012, 2011 and 2010 reflect \$57 million, \$138 million and \$428 million, respectively, of accelerated depreciation and asset abandonment costs associated with restructuring activities. In 2012, the Company recorded an adjustment to accelerated depreciation costs included in research and development expenses revising previously recorded amounts for certain facilities.

### *Share-Based Compensation*

Total pretax share-based compensation expense was \$335 million in 2012, \$369 million in 2011 and \$509 million in 2010. At December 31, 2012, there was \$370 million of total pretax unrecognized compensation expense related to nonvested stock option, restricted stock unit and performance share unit awards which will be

---

## Table of Contents

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 \$664 million, \$1.3 billion and \$985 million in 2012, 2011 and 2010, respectively. Nearly all of the costs recorded in 2012 and 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. In 2012, 2011 and 2010, separation costs of \$489 million, \$1.1 billion and \$768 million, 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 approximately 4,255 positions in 2012 (of which 3,975 related to the Merger Restructuring Program, 155 related to the 2008 Restructuring Program and 125 related to the legacy Schering-Plough program), approximately 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) and approximately 12,465 positions in 2010 (of which 11,410 related to the Merger Restructuring Program, 890 related to the 2008 Restructuring Program and 165 to the legacy Schering-Plough 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 5% in 2012 to \$642 million and grew 4% in 2011 to \$610 million due primarily to higher partnership returns from AZLP. During 2011, the Company divested its interest in the Johnson & Johnson<sup>o</sup>Merck Consumer Pharmaceuticals Company ( JJMCP ) joint venture. (See Selected Joint Venture and Affiliate Information below.)

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

Other (income) expense, net was \$1.1 billion of expense in 2012 compared with \$946 million of expense in 2011 driven primarily by a \$493 million net charge in 2012 relating to the settlement of the ENHANCE Litigation (see Note 11 to the consolidated financial statements) and gains recognized in 2011 of \$136 million on the disposition of the Company's interest in the JJMCP joint venture (see Note 9 to the consolidated financial statements) and \$127 million on the sale of certain manufacturing facilities and related assets (see Note 4 to the consolidated financial statements), partially offset by a \$500 million charge in 2011 related to the resolution of the arbitration proceeding involving the Company's rights to market *Remicade* and *Simponi* (see Note 5 to the consolidated financial statements) and higher interest income in 2012. Other (income) expense, net in 2010 was \$1.3 billion of expense reflecting a \$950 million charge to settle certain litigation related to *Vioxx* (the *Vioxx* Liability Reserve), 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 9 to the consolidated financial statements) and \$102 million of income recognized on the settlement of certain disputed royalties.

In February 2013, the Venezuelan government devalued its currency (Bolívar Fuertes) from 4.30 VEF per U.S. dollar to 6.30 VEF per U.S. dollar. The Company anticipates that it will recognize losses due to exchange of approximately \$150 million in the first quarter of 2013 resulting from the remeasurement of the local monetary assets and liabilities at the new rate. Since January 2010, Venezuela has been designated hyperinflationary and, as a result, local foreign operations are remeasured in U.S. dollars with the impact recorded in results of operations. As noted above, exchange losses for 2010 reflect losses relating to Venezuelan currency devaluations. Effective January 11, 2010, the Venezuelan government devalued its currency to a two-tiered official exchange rate with an essentials rate and a non-essentials rate. In December 2010, the Venezuelan government announced it would

**Table of Contents**

eliminate the essentials rate effective January 1, 2011. 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>	<b>2012</b>	2011	2010
Pharmaceutical segment profits	<b>\$ 25,852</b>	\$ 25,617	\$ 23,864
Other non-reportable segment profits	<b>3,163</b>	2,995	2,849
Other	<b>(20,276)</b>	(21,278)	(25,060)
Income before income taxes	<b>\$ 8,739</b>	\$ 7,334	\$ 1,653

Segment profits are comprised of segment sales less standard costs, certain operating expenses directly incurred by the segment, 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 materials and production costs, other than standard costs, the majority of 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 is the charge related to the settlement of the ENHANCE Litigation recorded in 2012, the arbitration settlement charge, the gain on the divestiture of the Company's interest in the JJMCP joint venture and a gain on the sale of certain manufacturing facilities and related assets recorded in 2011, and the charge for the *Vioxx* Liability Reserve and the income recognized on AstraZeneca's asset option exercise both recognized in 2010. 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 (losses), as well as operating profits (losses) related to third-party manufacturing sales, divested products or businesses, and other supply sales.

Pharmaceutical segment profits increased 1% in 2012 driven primarily by lower operating expenses mostly offset by the effects of the loss of U.S. market exclusivity for *Singulair*. Pharmaceutical segment profits rose 7% in 2011 driven largely by the increase in sales and the gross margin improvement discussed above.

*Taxes on Income*

The effective income tax rates of 27.9% in 2012, 12.8% in 2011 and 40.6% in 2010 reflect the impacts of acquisition-related costs and restructuring costs, partially offset by the beneficial impact of foreign earnings. The effective tax rate for 2012 also reflects the favorable impacts of a tax settlement with the Canada Revenue Agency (the *CRA*), the realization of foreign tax credits and the impact of a favorable ruling on a state tax matter. In addition, the 2012 effective tax rate reflects the unfavorable impact of the net charge recorded in connection with the settlement of the ENHANCE Litigation for which no tax benefit was recorded and does not reflect any impacts for the R&D tax credit, which expired on December 31, 2011. As a result of legislation passed in 2013 that extended the R&D tax credit, both the 2012 and 2013 R&D tax credits will be recognized in 2013; however, the entire 2012 R&D tax credit will be recognized in the first quarter of 2013. The effective tax rate for 2011 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 unfavorable 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 entity's tax rate, which resulted in a reduction in deferred tax liabilities on product intangibles recorded in conjunction with the Merger, and the favorable impact of foreign earnings and dividends from the Company's foreign subsidiaries.

---

**Table of Contents**

*Net Income and Earnings per Common Share*

Net income attributable to Merck & Co., Inc. was \$6.2 billion in 2012, \$6.3 billion in 2011 and \$861 million in 2010. EPS was \$2.00 in 2012, \$2.02 in 2011 and \$0.28 in 2010. The decreases in net income and EPS in 2012 as compared with 2011 were due primarily to the net charge recorded in connection with the settlement of the ENHANCE Litigation, the effects of the loss of U.S. market exclusivity for *Singulair* in 2012 and the favorable impact of tax items in 2011, partially offset by lower marketing and administrative expenses, lower restructuring costs and lower intangible asset impairment charges in 2012 and the arbitration settlement charge recorded in 2011. 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.

*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>	<b>2012</b>	2011	2010
Pretax income as reported under GAAP	<b>\$ 8,739</b>	\$ 7,334	\$ 1,653
Increase (decrease) for excluded items:			
Acquisition-related costs	<b>5,344</b>	5,939	9,403
Restructuring costs	<b>999</b>	1,911	1,986
Other items:			
Net charge related to settlement of ENHANCE Litigation	<b>493</b>		
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)
Other		5	
	<b>15,575</b>	15,426	13,549
Taxes on income as reported under GAAP	<b>2,440</b>	942	671
Estimated tax benefit (expense) on excluded items	<b>1,261</b>	1,697	1,798
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)
	<b>3,701</b>	3,609	2,713
Non-GAAP net income	<b>11,874</b>	11,817	10,836
Less: Net income attributable to noncontrolling interests	<b>131</b>	120	121
Non-GAAP net income attributable to Merck & Co., Inc.	<b>\$ 11,743</b>	\$ 11,697	\$ 10,715
EPS assuming dilution as reported under GAAP	<b>\$ 2.00</b>	\$ 2.02	\$ 0.28
EPS difference <sup>(1)</sup>	<b>1.82</b>	1.75	3.14
Non-GAAP EPS assuming dilution	<b>\$ 3.82</b>	\$ 3.77	\$ 3.42

<sup>(1)</sup> 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 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 incremental, third-party integration costs associated with the Merger, such as costs related to legal entity and system integration, 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 3 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 expense as determined utilizing the useful life prior to the restructuring actions. The Company has undertaken



---

## **Table of Contents**

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 net charge recorded in connection with the settlement of the ENHANCE Litigation, 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 and the income recognized upon AstraZeneca's asset option exercise. 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 22, 2013 is set forth in Item 1. Business Research and Development above.

### *Research and Development Update*

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

MK-4305, suvorexant, an investigational insomnia medicine in a new class of medicines called orexin receptor antagonists for use in patients with difficulty falling or staying asleep, is under review by the FDA. Suvorexant will be evaluated by the Controlled Substance Staff of the FDA during NDA review. If approved by the FDA, suvorexant will become available after a schedule assessment and determination has been completed by the U.S. Drug Enforcement Administration, which routinely occurs after FDA approval. The Company has also submitted a new drug application for suvorexant to the health authorities in Japan and is continuing with plans to seek approval for suvorexant in other countries around the world.

MK-8616, sugammadex sodium injection, is an investigational agent for the reversal of neuromuscular blockade induced by rocuronium or vecuronium (neuromuscular blocking agents) under review by the FDA. Neuromuscular blockade is used in anesthesiology to induce muscle relaxation during surgery. If approved, MK-8616 would be the first in a new class of medicines in the United States known as selective relaxant binding agents to be used in the surgical setting. In 2008, the FDA did not approve the original NDA for sugammadex sodium injection, requesting additional data related to hypersensitivity (allergic) reactions and coagulation (bleeding) events. Merck submitted these requested data within the NDA resubmission, which the FDA deemed complete for review. The Company expects the FDA's review to be completed in the first half of 2013. Sugammadex sodium injection is approved and has been launched in many countries outside of the United States where it is marketed as *Bridion*.

MK-8109, vintafolide, is an investigational cancer candidate under review by the EMA. As part of an exclusive license agreement with Endocyte, Merck is responsible for the development and worldwide commercialization of vintafolide in oncology. The EMA accepted the marketing authorization application filings for vintafolide and Endocyte's investigational companion diagnostic imaging agent, etarfolatide, for the targeted treatment of patients with folate-receptor positive platinum-resistant ovarian cancer in combination with pegylated liposomal doxorubicin. Both vintafolide and etarfolatide have been granted orphan drug status by the EC. Vintafolide is in Phase III development in the United States.

MK-0653C is an investigational combination of ezetimibe and atorvastatin for the treatment of primary or mixed hyperlipidemia under review by the FDA. An updated NDA for MK-0653C was deemed complete for

---

## Table of Contents

review by the FDA after Merck submitted additional data in response to the FDA's Complete Response Letter issued in 2012. Merck expects the FDA's review to be completed in the first half of 2013. Merck is continuing to move forward with planned filings for the ezetimibe and atorvastatin combination tablet in additional countries around the world.

In addition to the candidates under regulatory review, the Company has 16 drug candidates in Phase III development targeting a broad range of diseases. The Company anticipates filing an NDA or a BLA, as applicable, with the FDA with respect to several of these candidates in 2013.

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*. As previously disclosed, the 14,000-patient Phase III event-driven clinical study of V503 is ongoing. Merck anticipates filing a BLA for V503 with the FDA in 2013.

MK-8962, corifollitropin alpha injection, which is being marketed as *Elonva* in the EU, is an investigational fertility treatment for controlled ovarian stimulation in women participating in *in vitro* fertilization or intracytoplasmic sperm injection currently in Phase III development in the United States. Merck continues to anticipate filing an NDA for MK-8962 with the FDA in 2013.

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 March 2012, results from the TRA-2P study of vorapaxar were presented at the American College of Cardiology Annual Scientific Session and published concurrently in the online edition of the *New England Journal of Medicine*. In the study, the addition of vorapaxar to standard of care (e.g. aspirin or thienopyridine or both) resulted in a significantly greater reduction in the risk of the composite of cardiovascular death, heart attack, stroke or urgent coronary revascularization. There was also a significant increase in bleeding, including intracranial hemorrhage, among patients taking vorapaxar in addition to standard of care, although the risk of intracranial hemorrhage was lower in patients without a history of stroke. 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. Following a review of the clinical trial data and discussions with external experts, Merck plans to file applications for vorapaxar in the United States and EU in 2013 seeking an indication for the prevention of cardiovascular events in patients with a history of heart attack and no history of transient ischemic attack or stroke.

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 has submitted a BLA for MK-7243 with the FDA.

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

MK-8175A, NOMAC/E2, which is being marketed as *Zoely* in the EU, is an investigational 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: nomegestrol 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 conducting an additional clinical study requested by the FDA and plans to update the application in the future.

**Table of Contents**

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. In July 2012, Merck announced an update on the Phase III trial assessing fracture risk reduction with odanacatib. The independent Data Monitoring Committee (the DMC) for the study completed its first planned interim analysis for efficacy and recommended that the study be closed early due to robust efficacy and a favorable benefit-risk profile. The DMC noted that safety issues remain in certain selected areas and made recommendations with respect to following up on them. On February 1, 2013, Merck announced that it had recently received and was reviewing safety and efficacy data from the Phase III trial. As a result of its review of this data, the Company concluded that review of additional data from the previously planned, ongoing extension study was warranted and that filing an application for approval with the FDA should be delayed. As previously announced, the Company is conducting a blinded extension of the trial in approximately 8,200 women, which will provide additional safety and efficacy data. Merck now anticipates that it will file applications for approval of odanacatib in 2014 with additional data from the extension trial. The Company continues to believe that odanacatib will have the potential to address unmet medical needs in patients with osteoporosis.

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 MK-3814 with the FDA in 2014.

V212 is an inactivated VZV 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-7009, vaniprevir, is an investigational, oral twice-daily protease inhibitor for the treatment of chronic hepatitis C virus for development in Japan only. The Company anticipates filing a new drug application for MK-7009 in Japan in 2014.

MK-3102 is an investigational once-weekly DPP-4 inhibitor in development for the treatment of type 2 diabetes. The Company anticipates filing an NDA for MK-3102 with the FDA beyond 2014.

MK-3222 is an anti-interleukin-23 monoclonal antibody candidate being investigated for the treatment of psoriasis. The Company anticipates filing a BLA for MK-3222 with the FDA beyond 2014.

MK-3415A, actoxumab/bezlotoxumab, 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 now anticipates filing a BLA for MK-3415A with the FDA in 2015.

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 that is predicted to be completed in 2017. The Company continues to anticipate filing an NDA for anacetrapib with the FDA beyond 2015.

MK-8931 is Merck's novel investigational oral  $\beta$ -amyloid precursor protein site-cleaving enzyme (BACE) inhibitor for the treatment of Alzheimer's disease. In December 2012, Merck announced the initiation of a Phase II/III clinical trial (EPOCH) designed to evaluate the safety and efficacy of MK-8931 versus placebo in patients with mild-to-moderate Alzheimer's disease.

## Table of Contents

MK-8669, ridaforolimus, is an investigational oral mTOR (mammalian target of rapamycin) inhibitor under development for cancer indications. In June 2012, Merck announced that the FDA issued a Complete Response Letter regarding the NDA for ridaforolimus as a treatment for metastatic soft tissue or bone sarcoma. The Complete Response Letter states that the FDA cannot approve the application in its present form, and that additional clinical trial(s) would need to be conducted to further assess safety and efficacy. In November 2012, Merck formally notified the EMA of its decision to withdraw the marketing authorization application for ridaforolimus that was accepted by the EMA in 2011. The Company no longer plans to pursue the sarcoma indication in the United States or the EU, but will continue to support patients enrolled in ongoing clinical trials. Merck remains committed to pursuing ridaforolimus in other cancer indications. As part of an exclusive license agreement with ARIAD Pharmaceuticals, Inc. ( ARIAD ), Merck is responsible for the development and worldwide commercialization of ridaforolimus in oncology.

In December 2012, Merck announced the HPS2-THRIVE study of MK-0524A, *Tredaptive*, did not meet its primary endpoint. In the study, adding the combination of extended-release niacin and laropiprant to statin therapy did not significantly further reduce the risk of the combination of coronary deaths, non-fatal heart attacks, strokes or revascularizations compared to statin therapy. In addition, there was a statistically significant increase in the incidence of some types of non-fatal serious adverse events in the group that received extended-release niacin/laropiprant compared to statin therapy. Merck does not plan to seek regulatory approval for the medicine in the United States. In January 2013, based on the understanding of the preliminary data from the HPS2-THRIVE study and in consultation with regulatory authorities, Merck began taking steps to suspend the availability of *Tredaptive*, which is approved for use in certain countries outside of the United States. The clinical development program for MK-0524B, a combination product of extended-release niacin with laropiprant and simvastatin, had previously been discontinued.

In 2012, Merck announced that it will return the global marketing and development rights for both the intravenous and oral formulations for vernakalant, a treatment for atrial fibrillation, to Cardiome Pharma Corp. for business reasons. Merck also decided in 2012 to discontinue the clinical development program for MK-0431E, a combination product of sitagliptin and atorvastatin for the treatment of type 2 diabetes, for business reasons.

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 biosimilars, which have 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, osteoporosis, respiratory diseases and women's health.

### *In-Process Research and Development*

In connection with mergers and acquisitions, the Company has recorded the fair value of incomplete research projects which, at the time of acquisition, had not yet reached technological feasibility. At December 31, 2012, the balance of IPR&D was \$2.4 billion.

Some of the more significant projects in late-stage development include sugammadex sodium injection and an ezetimibe/atorvastatin combination product, both of which are currently under review by the FDA as noted above, as well as vorapaxar, which remains in Phase III clinical development.

---

## **Table of Contents**

During 2012, 2011 and 2010, approximately \$78 million, \$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.

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 acquisition date, and the Company may also not recover the research and development expenditures made since the acquisition 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 2012, the Company recorded \$200 million of IPR&D impairment charges within *Research and development* expenses primarily for pipeline programs that had previously been deprioritized and were subsequently deemed to have no alternative use during the period. During 2011, the Company recorded \$587 million of IPR&D impairment charges 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 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. 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, 2012, the estimated costs to complete projects acquired in connection with mergers and acquisitions in Phase III development for human health and the analogous stage of development for animal health were approximately \$1.2 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 2012, 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 October 2012, Merck and AiCuris entered into an exclusive licensing agreement which provides Merck with worldwide rights to develop and commercialize candidates in AiCuris' novel portfolio of investigational medicines targeting human cytomegalovirus ( HCMV ), including letermovir (MK-8228), an oral, late-stage antiviral candidate being investigated for the treatment and prevention of HCMV infection in transplant recipients. AiCuris received an upfront payment of \$110 million (approximately \$140 million), which the Company recorded as research and development expense, and is eligible for milestone payments of up to \$332.5 million based on successful achievement of development, regulatory and commercialization goals for HCMV candidates, including letermovir, an additional back-up candidate as well as other Phase I candidates designed to act via an

**Table of Contents**

alternate mechanism. In addition, AiCuris will be entitled to receive royalty payments reflecting the advanced stage of the clinical program on any potential products that result from the agreement. Merck will be responsible for all development activities and costs. The agreement may be terminated by either party in the event of a material uncured breach or insolvency. The agreement may be terminated by Merck at any time in the event that any of the compounds licensed from AiCuris develop an adverse safety profile or any material adverse issue arises related to the development, efficacy or dosing regimen of any of the compounds, and/or in the event that certain patents are invalid and/or unenforceable in certain jurisdictions. Merck (i) may terminate the agreement with respect to certain compounds after successful completion of the first proof of concept clinical trial or (ii) must terminate the agreement with respect to certain compounds if Merck fails to minimally invest in such compounds. In addition, Merck may terminate the agreement as a whole at any time upon six months prior written notice at any time after completion of the first Phase III clinical trial for a compound. AiCuris may terminate the agreement in the event that Merck challenges any AiCuris patent covering the compounds licensed from AiCuris. Upon termination of the agreement, depending upon the circumstances, the parties have varying rights and obligations with respect to the continued development and commercialization of compounds and, in the case of termination for cause by Merck, certain royalty obligations.

In April 2012, the Company entered into an agreement with Endocyte to develop and commercialize Endocyte's novel investigational therapeutic candidate vintafolide (MK-8109). Vintafolide is currently being evaluated in a Phase III clinical trial for folate-receptor positive platinum-resistant ovarian cancer (PROCEED) and a Phase II trial for non-small cell lung cancer. Under the agreement, Merck gained worldwide rights to develop and commercialize vintafolide. Endocyte received a \$120 million upfront payment, which the Company recorded as research and development expense, and is eligible for milestone payments of up to \$880 million based on the successful achievement of development, regulatory and commercialization goals for vintafolide for a total of six cancer indications. In addition, if vintafolide receives regulatory approval, Merck and Endocyte will share equally profit and losses in the United States. Endocyte will receive a royalty on sales of the product in the rest of the world. Endocyte has retained the right to co-promote vintafolide with Merck in the United States and Merck has the exclusive right to promote vintafolide in the rest of world. Endocyte will be responsible for the majority of funding and completion of the PROCEED trial. Merck will be responsible for all other development activities and development costs and have all decision rights for vintafolide. Merck has the right to terminate the agreement on 90 days notice. Merck and Endocyte both have the right to terminate the agreement due to the material breach or insolvency of the other party. Endocyte has the right to terminate the agreement in the event that Merck challenges an Endocyte patent right relating to vintafolide. Upon termination of the agreement, depending upon the circumstances, the parties have varying rights and obligations with respect to the continued development and commercialization of vintafolide and, in the case of termination for cause by Merck, certain royalty obligations and U.S. profit and loss sharing. Endocyte is responsible for the development, manufacture and commercialization worldwide of etarfolatide, a non-invasive companion diagnostic imaging agent that is used to identify folate receptor positive tumor cells. As discussed above, in 2012, the EMA accepted the marketing authorization application filings for vintafolide and etarfolatide for platinum resistant ovarian cancer.

**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

**Table of Contents**

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 \$915 million, \$1.2 billion and \$1.3 billion in 2012, 2011 and 2010, 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 \$621 million, \$574 million and \$546 million in 2012, 2011 and 2010, 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 to buy Merck's common stock interest in KBI and, through it, Merck's interest in Nexium and Prilosec as well as AZLP, exercisable in 2012. In June 2012, Merck and AstraZeneca amended the 1998 option agreement. The updated agreement eliminated AstraZeneca's option to acquire Merck's interest in KBI in 2012 and provides AstraZeneca a new option to acquire Merck's interest in KBI in June 2014. As a result of the amended agreement, Merck continues to record supply sales and equity income from the partnership. In 2014, AstraZeneca has the option to purchase Merck's interest in KBI based in part on the value of Merck's interest in Nexium and Prilosec. AstraZeneca's option is exercisable between March 1, 2014 and April 30, 2014. If AstraZeneca chooses to exercise this option, the closing date is expected to be June 30, 2014. Under the amended agreement, AstraZeneca will make a payment to Merck upon closing of \$327 million, reflecting an estimate of the fair value of Merck's interest in Nexium and Prilosec. This portion of the exercise price is subject to a true-up in 2018 based on actual sales from closing in 2014 to June 2018. The exercise price will also include an additional amount equal to a multiple of ten times Merck's average 1% annual profit allocation in the partnership for the three years prior to exercise. The Company believes that it is likely that AstraZeneca will exercise its option in 2014. If AstraZeneca exercises its option, the Company will no longer record equity income from AZLP and supply sales to AZLP will decline substantially.

*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:

<i>(\$ in millions)</i>	2012	2011	2010
<i>Gardasil</i>	\$ 264	\$ 253	\$ 350
Influenza vaccines	161	183	220
Other viral vaccines	107	105	93
<i>RotaTeq</i>	47	44	42
Hepatitis vaccines	31	39	25
Other vaccines	474	486	487
	<b>\$ 1,084</b>	<b>\$ 1,110</b>	<b>\$ 1,217</b>

**Table of Contents***Johnson & Johnson<sup>o</sup>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 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*. 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 and \$129 million for 2010.

**Capital Expenditures**

Capital expenditures were \$2.0 billion in 2012, \$1.7 billion in 2011 and \$1.7 billion in 2010. Expenditures in the United States were \$1.3 billion in 2012, \$1.2 billion in 2011 and \$990 million in 2010.

Depreciation expense was \$2.0 billion in 2012, \$2.4 billion in 2011 and \$2.6 billion in 2010 of which \$1.3 billion, \$1.4 billion and \$1.7 billion, respectively, applied to locations in the United States. Total depreciation expense in 2012, 2011 and 2010 included accelerated depreciation of \$235 million, \$589 million and \$849 million, respectively, associated with restructuring activities (see Note 3 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**

<i>(\$ in millions)</i>	2012	2011	2010
Working capital	<b>\$ 16,509</b>	\$ 16,936	\$ 13,423
Total debt to total liabilities and equity	<b>19.4%</b>	16.7%	16.9%
Cash provided by operations to total debt	<b>0.5:1</b>	0.7:1	0.6:1

Cash provided by operating activities was \$10.0 billion in 2012, \$12.4 billion in 2011 and \$10.8 billion in 2010. Cash provided by operating activities in 2012 reflects higher contributions of \$1.3 billion to its defined benefit plans as compared with 2011. Cash provided by operating activities in 2012 also reflects the payment of \$960 million (including interest) related to the resolution of certain litigation related to *Vioxx*. 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 (the IRS) as a result of the conclusion of its examination of certain of Merck's federal income tax returns as discussed below. 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 affected foreign receivables in certain European countries (see Note 6 to the consolidated financial statements). The Company continues to receive payment on these receivables, including significant collections during 2012 in connection with the Spanish government's debt stabilization/stimulus plan. Additionally, the Company continues to expand in the emerging markets where payment terms tend to be longer. The conditions in the EU and the emerging markets 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.



---

**Table of Contents**

Cash used in investing activities was \$6.8 billion in 2012 compared with \$2.9 billion in 2011 primarily reflecting higher purchases of securities and other investments, partially offset by higher proceeds from the sales of securities and other investments. 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 financing activities in 2012 was \$3.3 billion compared with \$6.9 billion in 2011. The lower use of cash in financing activities was primarily driven by proceeds from the issuance of debt, lower payments on debt and higher proceeds from the exercise of stock options, partially offset by increased purchases of treasury stock, a decrease in short-term borrowings and higher dividends paid to stockholders. 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.

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, 2012, the total of worldwide cash and investments was \$23.4 billion, including \$16.1 billion of cash, cash equivalents and short-term investments, and \$7.3 billion of long-term investments. Generally 80%-90% of these cash and investments are held by foreign subsidiaries and would be subject to significant tax payments if such cash and investments were repatriated in the form of dividends. The Company records U.S. deferred tax liabilities for certain unremitted earnings, but when amounts earned overseas are expected to be indefinitely reinvested outside of the United States, no accrual for U.S. taxes is provided. The amount of cash and investments held by U.S. and foreign subsidiaries fluctuates due to a variety of factors including the timing and receipt of payments in the normal course of business. 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.

As previously disclosed, the Canada Revenue Agency (the CRA) had proposed adjustments for 1999 and 2000 relating to intercompany pricing matters and, in July 2011, the CRA issued assessments for other miscellaneous audit issues for tax years 2001-2004. In 2012, Merck and the CRA reached a settlement for these years that calls for Merck to pay additional Canadian tax of approximately \$65 million. The Company's unrecognized tax benefits related to these matters exceeded the settlement amount and therefore the Company recorded a net \$112 million tax provision benefit in 2012. A portion of the taxes paid is expected to be creditable for U.S. tax purposes. The Company had previously established reserves for these matters. The resolution of these matters did not have a material effect on the Company's results of operations, financial position or liquidity.

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 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.

**Table of Contents**

The Company's contractual obligations as of December 31, 2012 are as follows:

**Payments Due by Period**

(\$ in millions)	Total	2013	2014	2015	2016	2017	Thereafter
Purchase obligations <sup>(1)</sup>	\$ 1,241	\$ 551	\$ 505		\$ 176		\$ 9
Loans payable and current portion of long-term debt	4,288	4,288					
Long-term debt	15,803			4,129		1,936	9,738
Interest related to debt obligations	8,758	800		1,277		1,022	5,659
ENHANCE Litigation settlement <sup>(2)</sup>	688	688					
Unrecognized tax benefits <sup>(3)</sup>	739	739					
Operating leases	835	203		318		169	145
	\$ 32,352	\$ 7,269		\$ 6,229		\$ 3,303	\$ 15,551

<sup>(1)</sup> 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.

<sup>(2)</sup> As discussed in Note 11 to the consolidated financial statements, the Company settled the ENHANCE Litigation. Assuming the settlement is approved by the court, the Company anticipates it will pay \$688 million in 2013 in connection with the settlement; however, the Company expects that \$195 million of this amount will be recovered through insurance.

<sup>(3)</sup> As of December 31, 2012, the Company's Consolidated Balance Sheet reflects liabilities for unrecognized tax benefits, interest and penalties of \$5.6 billion, including \$739 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 2013 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. Also excluded from research and development obligations are potential future funding commitments of up to approximately \$130 million for investments in research venture capital funds. Loans payable and current portion of long-term debt reflects \$328 million of long-dated notes that are subject to repayment at the option of the holders. Required funding obligations for 2013 relating to the Company's pension and other postretirement benefit plans are not expected to be material. However, the Company currently anticipates contributing approximately \$340 million and \$40 million, respectively, to its pension plans and other postretirement benefit plans during 2013.

In May 2012, the Company terminated its existing credit facilities and entered into a new \$4.0 billion, five-year credit facility maturing in May 2017. The facility provides backup liquidity for the Company's commercial paper borrowing facility and is to be used for general corporate purposes. The Company has not drawn funding from this facility.

In September 2012, the Company closed an underwritten public offering of \$2.5 billion senior unsecured notes consisting of \$1.0 billion aggregate principal amount of 1.1% notes due 2018, \$1.0 billion aggregate principal amount of 2.4% notes due 2022 and \$500 million aggregate principal amount of 3.6% notes due 2042. 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 contributions to the Company's pension plans and the repayment of outstanding commercial paper and certain debt maturities.

In December 2012, 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.

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 that date.

---

## **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 11 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 2012, the Board of Directors declared a quarterly dividend of \$0.43 per share on the Company's common stock payable in January 2013.

In April 2011, Merck's Board of Directors approved additional purchases of up to \$5.0 billion of Merck's common stock for its treasury. The Company purchased \$2.6 billion of its common stock (62 million shares) for its treasury during 2012. The Company has approximately \$1.9 billion remaining under this program. 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 \$1.9 billion and \$1.6 billion of its common stock during 2011 and 2010, respectively.

### **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*

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. 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

**Table of Contents**

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 \$453 million and \$330 million, respectively, from a uniform 10% weakening of the U.S. dollar at December 31, 2012 and 2011. 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.

A sensitivity analysis to changes in the value of the U.S. dollar on foreign currency denominated derivatives, investments and monetary assets and liabilities indicated that if the U.S. dollar uniformly weakened by 10% against all currency exposures of the Company at December 31, 2012, *Income before taxes* would have declined by approximately \$20 million in 2012. Because the Company was in a net short position relative to its major foreign currencies after consideration of forward contracts, a uniform weakening of the U.S. dollar will yield the largest overall potential net loss in earnings due to exchange. At December 31, 2011, the Company was in a net long position relative to its major foreign currencies after consideration of forward contracts, therefore a uniform 10% strengthening of the U.S. dollar would have reduced *Income before taxes* by approximately \$165 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% 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.

In February 2013, the Venezuelan government devalued its currency (Bolívar Fuertes) from 4.30 VEF per U.S. dollar to 6.30 VEF per U.S. dollar. The Company anticipates that it will recognize losses due to exchange of approximately \$150 million in the first quarter of 2013 resulting from the remeasurement of the local monetary assets and liabilities at the new rate. Since January 2010, Venezuela has been designated hyperinflationary and, as a

## **Table of Contents**

result, local foreign operations are remeasured in U.S. dollars with the impact recorded in results of operations. In addition, effective January 11, 2010, the Venezuelan government devalued its currency to a two-tiered official exchange rate with an essentials rate and a non-essentials rate. In December 2010, the Venezuelan government announced it would eliminate the essentials rate effective January 1, 2011. 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.

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 certain of its fixed-rate notes 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. As a result of the swap terminations, the Company received \$288 million in cash, which included \$43 million in accrued interest. The corresponding \$245 million basis adjustment of the debt associated with the terminated interest rate swap contracts was deferred and 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 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 and debt from a change in interest rates indicated that a one percentage point increase in interest rates at December 31, 2012 and 2011 would have positively affected the net aggregate market value of these instruments by \$1.2 billion each year. A one percentage point decrease at December 31, 2012 and 2011 would have negatively affected the net aggregate market value by \$1.4 billion each year. 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

---

**Table of Contents**

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 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.

**Table of Contents***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 2012, 2011 or 2010.

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

<i>(\$ in millions)</i>	<b>2012</b>	2011
Balance January 1	<b>\$ 1,824</b>	\$ 1,307
Current provision	<b>5,694</b>	5,392
Adjustments to prior years	<b>89</b>	81
Payments	<b>(5,734)</b>	(4,956)
Balance December 31	<b>\$ 1,873</b>	\$ 1,824

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 \$120 million and \$1.8 billion, respectively, at December 31, 2012 and were \$87 million and \$1.7 billion, respectively, at December 31, 2011.

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 12 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 U.S. net pharmaceutical sales in 2012, 2011 and 2010.

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

---

## **Table of Contents**

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, 2012 and 2011 were \$196 million and \$127 million, respectively.

### *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 11 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; 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, 2012 and 2011 of approximately \$260 million and \$240 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



---

## **Table of Contents**

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 \$14 million in 2012, and are estimated at \$84 million in the aggregate for the years 2013 through 2017. In management's opinion, the liabilities for all environmental matters that are probable and reasonably estimable have been accrued and totaled \$145 million and \$171 million at December 31, 2012 and 2011, 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 \$112 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 \$509 million in 2012, \$665 million in 2011 and \$696 million in 2010. The decline in net periodic benefit cost for pension and other postretirement benefit plans in 2012 as compared with 2011 and 2010 is largely attributable to the benefit plan design changes approved in December 2011 (see Note 14 to the consolidated financial statements). Pension and other postretirement benefit plan information for financial reporting purposes is calculated using actuarial assumptions including a discount rate for plan benefit obligations and an expected rate of return on plan assets.

The Company reassesses its benefit plan assumptions on a regular basis. For both the pension and other postretirement benefit plans, the discount rate is evaluated on measurement dates and modified to reflect the prevailing market rate of a portfolio of high-quality fixed-income debt instruments that would provide the future cash flows needed to pay the benefits included in the benefit obligation as they come due. At December 31, 2012, the discount rates for the Company's U.S. pension and other postretirement benefit plans ranged from 3.00% to 4.20% compared with a range of 4.00% to 5.00% at December 31, 2011.

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 2013, the Company's expected rate of return will range from 6.00% to 8.75% compared to a range of 5.75% to 8.75% in 2012 for its U.S. pension and other postretirement benefit plans.

## Table of Contents

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 \$67 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 \$34 million favorable (unfavorable) impact on its net periodic benefit cost. Required funding obligations for 2013 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, 2012 is expected to increase net periodic benefit cost by approximately \$7 million annually from 2013 through 2017.

### *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. 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.

## **Table of Contents**

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*.

### *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

---

## **Table of Contents**

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 16 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, 2012, foreign earnings of \$53.4 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 July 2012, the FASB issued amended guidance that simplifies how an entity tests indefinite-lived intangibles for impairment. The amended guidance will allow companies to first assess qualitative factors to determine whether it is more-likely-than-not that an indefinite-lived intangible asset is impaired as a basis for determining whether it is necessary to perform the quantitative impairment test. The updated guidance is effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012, with early adoption permitted. The effect of adoption on the Company's financial position and results of operations is not expected to be material.

### **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 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. 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, 2012 and 2011, and the related consolidated statements of income, of comprehensive income, of equity and of cash flows for each of the three years in the period ended December 31, 2012, the notes to consolidated financial statements, and the report dated February 26, 2013 of PricewaterhouseCoopers LLP, independent registered public accounting firm, are as follows:

**Consolidated Statement of Income**

Merck & Co., Inc. and Subsidiaries

*Years Ended December 31*

*(\$ in millions except per share amounts)*

	2012	2011	2010
Sales	\$ 47,267	\$ 48,047	\$ 45,987
Costs, Expenses and Other			
Materials and production	16,446	16,871	18,396
Marketing and administrative	12,776	13,733	13,125
Research and development	8,168	8,467	11,111
Restructuring costs	664	1,306	985
Equity income from affiliates	(642)	(610)	(587)
Other (income) expense, net	1,116	946	1,304
	38,528	40,713	44,334
Income Before Taxes	8,739	7,334	1,653
Taxes on Income	2,440	942	671
Net Income	6,299	6,392	982
Less: Net Income Attributable to Noncontrolling Interests	131	120	121
Net Income Attributable to Merck & Co., Inc.	\$ 6,168	\$ 6,272	\$ 861
Basic Earnings per Common Share Attributable to Merck & Co., Inc.			
Common Shareholders	\$ 2.03	\$ 2.04	\$ 0.28
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders	\$ 2.00	\$ 2.02	\$ 0.28

**Consolidated Statement of Comprehensive Income**

Merck & Co., Inc. and Subsidiaries

*Years Ended December 31*

*(\$ in millions)*

	2012	2011	2010
Net Income Attributable to Merck & Co., Inc.	\$ 6,168	\$ 6,272	\$ 861
Other Comprehensive (Loss) Income Net of Taxes:			
Net unrealized (loss) gain on derivatives, net of reclassifications	(101)	(37)	83
Net unrealized gain (loss) on investments, net of reclassifications	52	(10)	(2)
Benefit plan net (loss) gain and prior service (credit) cost, net of amortization	(1,321)	(303)	426

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

Cumulative translation adjustment	(180)	434	(956)
	(1,550)	84	(449)
Comprehensive Income Attributable to Merck & Co., Inc.	<b>\$ 4,618</b>	\$ 6,356	\$ 412

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

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

Merck &amp; Co., Inc. and Subsidiaries

December 31

(\$ in millions except per share amounts)

	2012	2011
<b>Assets</b>		
Current Assets		
Cash and cash equivalents	\$ 13,451	\$ 13,531
Short-term investments	2,690	1,441
Accounts receivable (net of allowance for doubtful accounts of \$163 in 2012 and \$131 in 2011)	7,672	8,261
Inventories (excludes inventories of \$1,606 in 2012 and \$1,379 in 2011 classified in Other assets see Note 7)	6,535	6,254
Deferred income taxes and other current assets	4,509	3,694
Total current assets	34,857	33,181
Investments	7,305	3,458
Property, Plant and Equipment (at cost)		
Land	591	623
Buildings	13,196	12,733
Machinery, equipment and office furnishings	17,188	16,919
Construction in progress	2,440	2,198
	33,415	32,473
Less: accumulated depreciation	17,385	16,176
	16,030	16,297
Goodwill	12,134	12,155
Other Intangibles, Net	29,083	34,302
Other Assets	6,723	5,735
	\$ 106,132	\$ 105,128
<b>Liabilities and Equity</b>		
Current Liabilities		
Loans payable and current portion of long-term debt	4,315	1,990
Trade accounts payable	1,753	2,023
Accrued and other current liabilities	9,737	10,170
Income taxes payable	1,200	781
Dividends payable	1,343	1,281
Total current liabilities	18,348	16,245
Long-Term Debt	16,254	15,525
Deferred Income Taxes and Noncurrent Liabilities	16,067	16,415
Merck & Co., Inc. Stockholders' Equity		
Common stock, \$0.50 par value		
Authorized 6,500,000,000 shares		
Issued 3,577,103,522 shares in 2012 and 2011	1,788	1,788
Other paid-in capital	40,646	40,663
Retained earnings	39,985	38,990
Accumulated other comprehensive loss	(4,682)	(3,132)
	77,737	78,309
Less treasury stock, at cost:		
550,468,221 shares in 2012;		
536,109,713 shares in 2011	24,717	23,792
Total Merck & Co., Inc. stockholders' equity	53,020	54,517
Noncontrolling Interests	2,443	2,426

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

Total equity	55,463	56,943
	<b>\$ 106,132</b>	<b>\$ 105,128</b>

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



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

Merck &amp; Co., Inc. and Subsidiaries

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

	<b>Common Stock</b>	<b>Other Paid-In Capital</b>	<b>Retained Earnings</b>	<b>Accumulated Other Comprehensive Loss</b>	<b>Treasury Stock</b>	<b>Non- controlling Interests</b>	<b>Total</b>
Balance January 1, 2010	\$ 1,781	\$ 39,683	\$ 41,405	\$ (2,767)	\$ (21,044)	\$ 2,427	\$ 61,485
Net income attributable to Merck & Co., Inc.			861				861
Other comprehensive loss, net of tax				(449)			(449)
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
Other comprehensive income, net of tax				84			84
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
<b>Net income attributable to Merck &amp; Co., Inc.</b>			<b>6,168</b>				<b>6,168</b>
<b>Other comprehensive loss, net of tax</b>				<b>(1,550)</b>			<b>(1,550)</b>
<b>Cash dividends declared on common stock (\$1.69 per share)</b>			<b>(5,173)</b>				<b>(5,173)</b>
<b>Treasury stock shares purchased</b>					<b>(2,591)</b>		<b>(2,591)</b>
<b>Net income attributable to noncontrolling interests</b>						<b>131</b>	<b>131</b>
<b>Distributions attributable to noncontrolling interests</b>						<b>(120)</b>	<b>(120)</b>
<b>Share-based compensation plans and other</b>		<b>(17)</b>			<b>1,666</b>	<b>6</b>	<b>1,655</b>
Balance December 31, 2012	\$ 1,788	\$ 40,646	\$ 39,985	\$ (4,682)	\$ (24,717)	\$ 2,443	\$ 55,463

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

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

Merck &amp; Co., Inc. and Subsidiaries

Years Ended December 31

(\$ in millions)

	2012	2011	2010
<b>Cash Flows from Operating Activities</b>			
Net income	\$ 6,299	\$ 6,392	\$ 982
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	6,978	7,427	7,381
Intangible asset impairment charges	200	705	2,441
Gain on disposition of interest in equity method investment		(136)	
Gain on AstraZeneca LP asset option exercise			(443)
Equity income from affiliates	(642)	(610)	(587)
Dividends and distributions from equity affiliates	291	216	324
Deferred income taxes	669	(1,537)	(1,092)
Share-based compensation	335	369	509
Other	28	323	377
Net changes in assets and liabilities:			
Accounts receivable	349	(1,168)	(1,089)
Inventories	(482)	(678)	1,990
Trade accounts payable	(302)	182	124
Accrued and other current liabilities	(717)	1,444	35
Income taxes payable	(34)	(277)	128
Noncurrent liabilities	(1,747)	(7)	(98)
Other	(1,203)	(262)	(160)
Net Cash Provided by Operating Activities	10,022	12,383	10,822
<b>Cash Flows from Investing Activities</b>			
Capital expenditures	(1,954)	(1,723)	(1,678)
Purchases of securities and other investments	(12,841)	(7,325)	(7,197)
Proceeds from sales of securities and other investments	7,783	6,149	4,561
Proceeds from sale of interest in equity method investment		175	
Acquisitions of businesses, net of cash acquired		(373)	(256)
Dispositions of businesses, net of cash divested		323	
Proceeds from AstraZeneca LP asset option exercise			647
Decrease in restricted assets	34		276
Other	173	(116)	150
Net Cash Used in Investing Activities	(6,805)	(2,890)	(3,497)
<b>Cash Flows from Financing Activities</b>			
Net change in short-term borrowings	624	1,076	90
Payments on debt	(22)	(1,547)	(1,341)
Proceeds from issuance of debt	2,562		1,999
Purchases of treasury stock	(2,591)	(1,921)	(1,593)
Dividends paid to stockholders	(5,116)	(4,691)	(4,734)
Other dividends paid	(120)	(120)	(119)
Proceeds from exercise of stock options	1,310	321	363
Other	86	(22)	(106)
Net Cash Used in Financing Activities	(3,267)	(6,904)	(5,441)
Effect of Exchange Rate Changes on Cash and Cash Equivalents	(30)	42	(295)
Net (Decrease) Increase in Cash and Cash Equivalents	(80)	2,631	1,589
Cash and Cash Equivalents at Beginning of Year	13,531	10,900	9,311

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

Cash and Cash Equivalents at End of Year	<b>\$ 13,451</b>	\$ 13,531	\$ 10,900
--	------------------	-----------	-----------

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

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

Merck &amp; Co., Inc. and Subsidiaries

(\$ in millions except per share amounts)

**1. Nature of Operations**

Merck & 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, as well as club stores and specialty channels.

**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.

*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

**Table of Contents**

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*.

*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 likelihood 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 if 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 \$120 million and \$1.8 billion, respectively, at December 31, 2012 and \$87 million and \$1.7 billion, respectively, at December 31, 2011.

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*.

*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*.

---

## **Table of Contents**

**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, 2012 and 2011, there was approximately \$385 million and \$390 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, 2012, the Company concluded goodwill was not impaired.

**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 8). 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 the IPR&D intangible asset with its carrying value. If the fair value is less than the carrying amount, an impairment loss is recognized in 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 \$200 million, \$587 million and \$2.4 billion in 2012, 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.

**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.

**Table of Contents**

*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 measurements. 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 2012, the Company retrospectively adopted amended guidance from the Financial Accounting Standards Board (the FASB) on the presentation of comprehensive income in financial statements. As a result of adopting this guidance, the Company has presented a separate Statement of Comprehensive Income. The adoption of this new guidance did not impact the Company's financial position, results of operations or cash flows.

*Recently Issued Accounting Standards* In July 2012, the FASB issued amended guidance that simplifies how an entity tests indefinite-lived intangibles for impairment. The amended guidance will allow companies to first assess qualitative factors to determine whether it is more-likely-than-not that an indefinite-lived intangible asset is impaired as a basis for determining whether it is necessary to perform the quantitative impairment test. The updated guidance is effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012, with early adoption permitted. The effect of adoption on the Company's financial position and results of operations is not expected to be material.

**3. Restructuring***Merger Restructuring Program*

In 2010, subsequent to the Merck and Schering-Plough Corporation ( Schering-Plough ) merger (the Merger), 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 designed to optimize the cost structure of the combined company. These initial actions, which are expected to result in workforce reductions of approximately 17%, 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. In July 2011, the Company initiated further actions under the Merger Restructuring Program through 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 associated with these additional actions relate to manufacturing (including Animal Health),

---

**Table of Contents**

administrative and headquarters organizations. The Company will continue to hire employees in strategic growth areas of the business as necessary.

The Company recorded total pretax restructuring costs of \$951 million in 2012, \$1.8 billion in 2011 and \$1.8 billion in 2010 related to this program. Since inception of the Merger Restructuring Program through December 31, 2012, Merck has recorded total pretax accumulated costs of approximately \$6.1 billion and eliminated approximately 22,400 positions comprised of employee separations, as well as the elimination of contractors and vacant positions. 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. Subsequent to the Merger, the Company has rationalized a number of manufacturing sites worldwide. The remaining actions under this program will result in additional manufacturing facility rationalizations, which are expected to be substantially completed by 2016. The Company now expects the estimated total cumulative pretax costs for this program to be approximately \$7.2 billion to \$7.5 billion. The increase from original estimates primarily reflects accelerated depreciation related to additional facility closures identified during the Company's ongoing assessment of worldwide capacity requirements for its manufacturing, research and administrative facilities subsequent to the Merger, including the recently announced move of the Company's worldwide headquarters to Summit, New Jersey. 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 \$48 million, \$45 million and \$176 million were recorded in 2012, 2011 and 2010, respectively, related to the 2008 Restructuring Program. Since inception of the 2008 Restructuring Program through December 31, 2012, Merck has recorded total pretax accumulated costs of \$1.7 billion and eliminated approximately 6,400 positions comprised of employee separations and the elimination of contractors and vacant positions. The 2008 Restructuring Program was substantially completed in 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
<i>Year Ended December 31, 2012</i>				
<i>Merger Restructuring Program</i>				
Materials and production	\$	\$ 92	\$ 70	\$ 162
Marketing and administrative		75	6	81
Research and development		53	4	57
Restructuring costs	497		154	651
	497	220	234	951
<i>2008 Restructuring Program</i>				
Materials and production		7	19	26
Marketing and administrative		8	1	9
Restructuring costs	(8)		21	13
	(8)	15	41	48
	\$ 489	\$ 235	\$ 275	\$ 999
<i>Year Ended December 31, 2011</i>				
<i>Merger Restructuring Program</i>				
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
<i>2008 Restructuring Program</i>				
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
<i>Year Ended December 31, 2010</i>				
<i>Merger Restructuring Program</i>				
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
<i>2008 Restructuring Program</i>				
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

**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 2012, 2011 and 2010 approximately 3,975, 6,880 and 11,410 positions, respectively, were eliminated under the Merger Restructuring Program and approximately 155, 450 and 890 positions, respectively, were eliminated under the 2008 Restructuring Program. These position eliminations were comprised of actual headcount reductions and the elimination of contractors and vacant positions.

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. Anticipated site closure dates, particularly related to manufacturing locations, have been and may continue to be adjusted to reflect changes resulting from regulatory or other factors.

Other activity in 2012, 2011 and 2010 includes \$155 million, \$72 million and \$152 million, respectively, of asset abandonment, shut-down and other related costs and, in 2010, also includes approximately \$65 million of contract termination costs. Additionally, other activity includes \$35 million, \$53 million and \$88 million in 2012, 2011 and 2010, respectively, for other employee-related costs such as curtailment, settlement and termination charges associated with pension and other postretirement benefit plans (see Note 14) and share-based compensation costs. Other activity also reflects net pretax gains resulting from sales of facilities and related assets in 2012, 2011 and 2010 of \$28 million, \$10 million and \$49 million, respectively.

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

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

	Separation Costs	Accelerated Depreciation	Other	Total
<b>Merger Restructuring Program</b>				
Restructuring reserves January 1, 2011	\$ 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	1,144		51	1,195
<b>Expenses</b>	<b>497</b>	<b>220</b>	<b>234</b>	<b>951</b>
<b>(Payments) receipts, net</b>	<b>(942)</b>		<b>(170)</b>	<b>(1,112)</b>
<b>Non-cash activity</b>		<b>(220)</b>	<b>(96)</b>	<b>(316)</b>
<b>Restructuring reserves December 31, 2012<sup>(1)</sup></b>	<b>\$ 699</b>	<b>\$</b>	<b>\$ 19</b>	<b>\$ 718</b>
<b>2008 Restructuring Program</b>				
Restructuring reserves January 1, 2011	\$ 196	\$	\$	\$ 196
Expenses	(6)	28	23	45
(Payments) receipts, net	(64)		(21)	(85)
Non-cash activity		(28)	(2)	(30)
Restructuring reserves December 31, 2011	126			126
<b>Expenses</b>	<b>(8)</b>	<b>15</b>	<b>41</b>	<b>48</b>
<b>(Payments) receipts, net</b>	<b>(41)</b>		<b>(21)</b>	<b>(62)</b>
<b>Non-cash activity</b>		<b>(15)</b>	<b>(20)</b>	<b>(35)</b>
<b>Restructuring reserves December 31, 2012<sup>(1)</sup></b>	<b>\$ 77</b>	<b>\$</b>	<b>\$</b>	<b>\$ 77</b>

<sup>(1)</sup> 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 2016. 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.

**Table of Contents***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 and 2010, the Company recorded \$20 million and \$22 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. This program was substantially complete at the end of 2011.

**4. Acquisitions, Divestitures, Research Collaborations and License Agreements**

In October 2012, Merck and AiCuris entered into an exclusive licensing agreement which provides Merck with worldwide rights to develop and commercialize candidates in AiCuris' novel portfolio of investigational medicines targeting human cytomegalovirus ( HCMV ), including letermovir (MK-8228), an oral, late-stage antiviral candidate being investigated for the treatment and prevention of HCMV infection in transplant recipients. AiCuris received an upfront payment of \$110 million (approximately \$140 million), which the Company recorded as research and development expense, and is eligible for milestone payments of up to \$332.5 million based on successful achievement of development, regulatory and commercialization goals for HCMV candidates, including letermovir, an additional back-up candidate as well as other Phase I candidates designed to act via an alternate mechanism. In addition, AiCuris will be entitled to receive royalty payments reflecting the advanced stage of the clinical program on any potential products that result from the agreement. Merck will be responsible for all development activities and costs. The agreement may be terminated by either party in the event of a material uncured breach or insolvency. The agreement may be terminated by Merck at any time in the event that any of the compounds licensed from AiCuris develop an adverse safety profile or any material adverse issue arises related to the development, efficacy or dosing regimen of any of the compounds, and/or in the event that certain patents are invalid and/or unenforceable in certain jurisdictions. Merck (i) may terminate the agreement with respect to certain compounds after successful completion of the first proof of concept clinical trial or (ii) must terminate the agreement with respect to certain compounds if Merck fails to minimally invest in such compounds. In addition, Merck may terminate the agreement as a whole at any time upon six months prior written notice at any time after completion of the first Phase III clinical trial for a compound. AiCuris may terminate the agreement in the event that Merck challenges any AiCuris patent covering the compounds licensed from AiCuris. Upon termination of the agreement, depending upon the circumstances, the parties have varying rights and obligations with respect to the continued development and commercialization of compounds and, in the case of termination for cause by Merck, certain royalty obligations.

In April 2012, the Company entered into an agreement with Endocyte, Inc. ( Endocyte ) to develop and commercialize Endocyte's novel investigational therapeutic candidate vintafolide (MK-8109). Vintafolide is currently being evaluated in a Phase III clinical trial for folate-receptor positive platinum-resistant ovarian cancer (PROCEED) and a Phase II trial for non-small cell lung cancer. Under the agreement, Merck gained worldwide rights to develop and commercialize vintafolide. Endocyte received a \$120 million upfront payment, which the Company recorded as research and development expense, and is eligible for milestone payments of up to \$880 million based on the successful achievement of development, regulatory and commercialization goals for vintafolide for a total of six cancer indications. In addition, if vintafolide receives regulatory approval, Merck and Endocyte will share equally profits and losses in the United States. Endocyte will receive a royalty on sales of the product in the rest of the world. Endocyte has retained the right to co-promote vintafolide with Merck in the United States and Merck has the exclusive right to promote vintafolide in the rest of world. Endocyte will be responsible for the majority of funding and completion of the PROCEED trial. Merck will be responsible for all other development activities and development costs and have all decision rights for vintafolide. Merck has the right to terminate the agreement on 90 days notice. Merck and Endocyte both have the right to terminate the agreement due to the material breach or insolvency of the other party. Endocyte has the right to terminate the agreement in the event that Merck challenges an Endocyte patent right relating to vintafolide. Upon termination of the agreement, depending upon the circumstances, the parties have varying rights and obligations with respect to the continued development and commercialization of vintafolide and, in the case of termination for cause by Merck, certain royalty obligations and U.S. profit and loss sharing.

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

**Table of Contents**

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, 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 purchase certain development and manufacturing services at fair value from Fujifilm over a three-year period following the closing of the transaction. The transaction resulted in a gain of \$127 million in 2011 reflected in *Other (income) expense, net*.

**5. Collaborative Arrangements**

The Company continues its strategy of establishing external alliances to complement its substantial internal research capabilities, including research collaborations, as well as 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 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 had an exclusive licensing agreement to market *Cozaar* and *Hyzaar* in return for royalties and profit share payments to DuPont. This agreement terminated on December 31, 2012 in accordance with its terms. As a result of the termination of the agreement, Merck no longer shares profits from, or marketing costs related to, the sale of *Cozaar* and *Hyzaar* with DuPont. However, under a separate agreement, the trademarks for *Cozaar* and *Hyzaar* were permanently transferred to Merck in exchange for Merck paying a trademark royalty to DuPont based on sales of *Cozaar* and *Hyzaar* for a period of 10 years.

*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*, 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

**Table of Contents**

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. 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.

**6. 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.

*Foreign Currency Risk Management*

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. 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

**Table of Contents**

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, but serve as economic hedges of forecasted sales, unrealized gains or losses are recorded in *Sales* each period. The cash flows from both designated and non-designated 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 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.

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 losses of \$31 million in 2012 and pretax gains of \$6 million in 2011 and \$277 million in 2010 from the euro-denominated notes.

**Table of Contents***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.

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 certain of its fixed-rate notes 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. As a result of the swap terminations, the Company received \$288 million in cash, which included \$43 million in accrued interest. The corresponding \$245 million basis adjustment of the debt associated with the terminated interest rate swap contracts was deferred and 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 on a gross basis segregated between those derivatives that are designated as hedging instruments and those that are not designated as hedging instruments as of December 31:

	Balance Sheet Caption	2012			2011		
		Fair Value of Asset	Derivative Liability	U.S. Dollar Notional	Fair Value of Asset	Derivative Liability	U.S. Dollar Notional
<i>Derivatives Designated as Hedging Instruments</i>							
Foreign exchange contracts (current)	Deferred income taxes and other current assets	\$ 281	\$	\$ 6,646	\$ 196	\$	\$ 3,727
Foreign exchange contracts (non-current)	Other assets	387		5,989	420		4,956
Foreign exchange contracts (current)	Accrued and other current liabilities		13	938		53	1,718
Foreign exchange contracts (non-current)	Deferred income taxes and noncurrent liabilities					1	104
		\$ 668	\$ 13	\$ 13,573	\$ 616	\$ 54	\$ 10,505
<i>Derivatives Not Designated as Hedging Instruments</i>							
Foreign exchange contracts (current)	Deferred income taxes and other current assets	\$ 55	\$	\$ 4,548	\$ 139	\$	\$ 5,306
Foreign exchange contracts (non-current)	Other assets	8		232			
Foreign exchange contracts (current)	Accrued and other current liabilities		216	8,203		54	5,013
		\$ 63	\$ 216	\$ 12,983	\$ 139	\$ 54	\$ 10,319
		\$ 731	\$ 229	\$ 26,556	\$ 755	\$ 108	\$ 20,824

**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>	<b>2012</b>	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>	<b>50</b>	85	7
Amount of loss (gain) recognized in <i>OCI</i> on derivatives	<b>204</b>	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 <sup>(1)</sup>	<b>(20)</b>	(10)	(1)
Amount of (gain) loss recognized in <i>OCI</i> on derivatives	<b>(208)</b>	122	24
<i>Derivatives not designated in a hedging relationship</i>			
Foreign exchange contracts			
Amount of loss (gain) recognized in <i>Other (income) expense, net</i> on derivatives <sup>(2)</sup>	<b>382</b>	(113)	(33)
Amount of loss (gain) recognized in <i>Sales</i>	<b>30</b>		(81)

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

<sup>(2)</sup> 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, 2012, the Company estimates \$138 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.



**Table of Contents****Investments in Debt and Equity Securities**

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

	2012				2011			
	Fair		Gross Unrealized		Fair		Gross Unrealized	
	Value	Amortized Cost	Gains	Losses	Value	Amortized Cost	Gains	Losses
Corporate notes and bonds	\$ 5,063	\$ 5,013	\$ 52	\$ (2)	\$ 2,032	\$ 2,024	\$ 16	\$ (8)
Commercial paper	2,150	2,150			1,029	1,029		
U.S. government and agency securities	1,206	1,204	2		1,021	1,018	3	
Asset-backed securities	837	835	3	(1)	292	292	1	(1)
Mortgage-backed securities	435	436	2	(3)	223	223	1	(1)
Foreign government bonds	108	107	1		72	72		
Other debt securities					3	1	2	
Equity securities	403	370	33		397	383	14	
	\$ 10,202	\$ 10,115	\$ 93	\$ (6)	\$ 5,069	\$ 5,042	\$ 37	\$ (10)

Available-for-sale debt securities included in *Short-term investments* totaled \$2.7 billion at December 31, 2012. Of the remaining debt securities, \$6.4 billion mature within five years. At December 31, 2012 and 2011, there were no debt securities pledged as collateral.

**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. 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 In Active Markets for Identical Assets (Level 1)		Significant Other Observable Inputs (Level 2)		Quoted Prices In Active Markets for Identical Assets (Level 1)		Significant Other Observable Inputs (Level 2)	
			Significant Unobservable Inputs (Level 3)	Total			Significant Unobservable Inputs (Level 3)	Total
	2012				2011			
<b>Assets</b>								
<i>Investments</i>								
Corporate notes and bonds	\$	\$ 5,063	\$	\$ 5,063	\$	\$ 2,032	\$	\$ 2,032
Commercial paper		2,150		2,150		1,029		1,029
U.S. government and agency securities		1,206		1,206		1,021		1,021
Asset-backed securities <sup>(1)</sup>		837		837		292		292
Mortgage-backed securities <sup>(1)</sup>		435		435		223		223
Foreign government bonds		108		108		72		72
Equity securities	196			196	205			227
Other debt securities						3		3
	196	9,799		9,995	205	4,694		4,899
<i>Other assets</i>								
Securities held for employee compensation	169	38		207	170			170
<i>Derivative assets<sup>(2)</sup></i>								
Purchased currency options		546		546		613		613
Forward exchange contracts		185		185		142		142
		731		731		755		755
Total assets	\$ 365	\$ 10,568	\$	\$ 10,933	\$ 375	\$ 5,449	\$	\$ 5,824
<b>Liabilities</b>								
<i>Derivative liabilities<sup>(2)</sup></i>								
Forward exchange contracts	\$	\$ 216	\$	\$ 216	\$	\$ 107	\$	\$ 107
Written currency options		13		13		1		1
Total liabilities	\$	\$ 229	\$	\$ 229	\$	\$ 108	\$	\$ 108

<sup>(1)</sup> 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.

<sup>(2)</sup> 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 transfers between Level 1 and Level 2 during 2012. As of December 31, 2012, Cash and cash equivalents of \$13.5 billion included \$12.5 billion of cash equivalents (which would be considered Level 2 in the fair value hierarchy).

*Other Fair Value Measurements*

Some of the Company's financial instruments, such as cash and cash equivalents, receivables and payables, are reflected in the balance sheet at carrying value, which approximates fair value due to their short-term nature.

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

The estimated fair value of loans payable and long-term debt (including current portion) at December 31, 2012 was \$22.8 billion compared with a carrying value of \$20.6 billion and at December 31, 2011 was \$19.5 billion compared with a carrying value of \$17.5 billion. Fair value was estimated using recent observable market prices and would be considered Level 2 in the fair value hierarchy.

### **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

---

**Table of Contents**

instruments that meet high credit quality standards, as specified in the Company's investment policy guidelines. Approximately 50% of the Company's cash and cash equivalents are invested in five 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, Italy, Spain and Portugal, among other members of the EU. These 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. At December 31, 2012, the Company classified approximately \$475 million of accounts receivable not expected to be collected within one year to *Other assets*. 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, 2012, the Company's accounts receivable in Greece, Italy, Spain and Portugal totaled approximately \$1.1 billion. Of this amount, hospital and public sector receivables were approximately \$800 million in the aggregate, of which approximately 18%, 37%, 36% and 9% related to Greece, Italy, Spain and Portugal, respectively. As of December 31, 2012, the Company's total accounts receivable outstanding for more than one year were approximately \$200 million, of which approximately 70% related to accounts receivable in Greece, Italy, Spain and Portugal, mostly comprised of hospital and public sector receivables.

During 2012, the Company collected approximately \$60 million of accounts receivable from the government of Portugal, which pertained to accounts receivable outstanding from 2011 and prior. Also during 2012, the Company collected approximately \$500 million of accounts receivable in connection with the Spanish government's debt stabilization/stimulus plan. In addition, the Company completed non-recourse factorings of approximately \$230 million in 2012 of hospital and public sector accounts receivable in Italy.

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. The Company had recorded impairment charges to reduce the bonds to fair value. During 2011, the Company sold a portion of these bonds and the remainder was sold during 2012. During 2011 and 2012, the Company has continued to receive payments on 2011 and 2010 Greek hospital and public sector receivables.

Additionally, the Company continues to expand in the emerging markets. Payment terms in these markets tend to be longer, resulting in an increase in accounts receivable balances in certain of these markets.

The Company's customers with the largest accounts receivable balances are: Cardinal Health, Inc., McKesson Corporation, AmerisourceBergen Corporation, Alliance Healthcare, Zuellig Pharma Ltd. (Asia Pacific) and Grupo Casa Saba (Mexico), which represented, in aggregate, approximately one-fourth of total accounts receivable at December 31, 2012. 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, 2012 and 2011, the Company had received cash collateral of \$305 million and \$327 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, 2012 or 2011.

**Table of Contents****7. Inventories**

Inventories at December 31 consisted of:

	2012	2011
Finished goods	\$ 1,924	\$ 1,983
Raw materials and work in process	5,921	5,396
Supplies	244	297
Total (approximates current cost)	8,089	7,676
Increase (reduction) to LIFO costs	52	(43)
	\$ 8,141	\$ 7,633
Recognized as:		
Inventories	\$ 6,535	\$ 6,254
Other assets	1,606	1,379

Inventories valued under the LIFO method comprised approximately 26% and 27% of inventories at December 31, 2012 and 2011, respectively. Amounts recognized as *Other assets* are comprised almost entirely of raw materials and work in process inventories. At December 31, 2012 and 2011, these amounts included \$1.4 billion and \$1.3 billion, respectively, of inventories not expected to be sold within one year. In addition, these amounts included \$196 million and \$127 million at December 31, 2012 and 2011, respectively, of inventories produced in preparation for product launches.

**8. Goodwill and Other Intangibles**

The following table summarizes goodwill activity by segment:

	Pharmaceutical	All Other	Total
Goodwill balance January 1, 2011	\$ 10,345	\$ 2,033	\$ 12,378
Additions	144		144
Other <sup>(1)</sup>	(382)	15	(367)
Goodwill balance December 31, 2011	10,107	2,048	12,155
Other <sup>(1)</sup>	(21)		(21)
<b>Goodwill balance December 31, 2012</b>	<b>\$ 10,086</b>	<b>\$ 2,048</b>	<b>\$ 12,134</b>

<sup>(1)</sup> Other includes cumulative translation adjustments on goodwill balances and certain other adjustments. In addition, the amounts in 2011 reflect the reclassification of goodwill from the Pharmaceutical segment to the Consumer Care segment as a result of a segment change.

Other intangibles at December 31 consisted of:

	2012			2011		
	Gross Carrying Amount	Accumulated Amortization	Net	Gross Carrying Amount	Accumulated Amortization	Net
Products and product rights	\$ 41,932	\$ 16,678	\$ 25,254	\$ 41,937	\$ 11,872	\$ 30,065
In-process research and development	2,393		2,393	2,671		2,671
Tradenames	1,521	236	1,285	1,523	170	1,353
Other	896	745	151	895	682	213
	\$ 46,742	\$ 17,659	\$ 29,083	\$ 47,026	\$ 12,724	\$ 34,302



**Table of Contents**

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. Some of the Company's more significant acquired intangibles related to marketed products at December 31, 2012 include *Zetia*, \$5.9 billion; *Vytorin*, \$3.2 billion; *Nasonex*, \$1.9 billion, *Claritin*, \$1.6 billion and *NuvaRing*, \$1.0 billion. During 2011, the Company recorded an impairment charge of \$118 million related to a marketed product.

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. Amounts capitalized as IPR&D 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 2012 and 2011, \$78 million and \$666 million, respectively, of IPR&D was reclassified to products and product rights upon receipt of marketing approval in a major market. Some of the more significant projects in late-stage development include sugammadex sodium injection and an ezetimibe/atorvastatin combination product, both of which are currently under review by the FDA, and vorapaxar, which remains in Phase III clinical development.

During 2012, the Company recorded \$200 million of IPR&D impairment charges within *Research and development* expenses primarily for pipeline programs that had previously been deprioritized and were subsequently deemed to have no alternative use during the period. During 2011, the Company recorded \$587 million of IPR&D impairment charges 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 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 program for vorapaxar, including the termination of a clinical trial, constituted a triggering event that required the Company to evaluate the vorapaxar intangible asset 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 \$5.0 billion in 2012, \$5.1 billion in 2011 and \$4.7 billion in 2010. The estimated aggregate amortization expense for each of the next five years is as follows: 2013, \$4.7 billion; 2014, \$4.4 billion; 2015, \$4.1 billion; 2016, \$3.5 billion; 2017, \$3.2 billion.

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

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

<i>Years Ended December 31</i>	<b>2012</b>	2011	2010
AstraZeneca LP	<b>\$ 621</b>	\$ 574	\$ 546
Other <sup>(1)</sup>	<b>21</b>	36	41
	<b>\$642</b>	\$ 610	\$ 587

<sup>(1)</sup> Primarily reflects results from Sanofi Pasteur MSD and Johnson & Johnson<sup>®</sup>Merck Consumer Pharmaceuticals Company (which was disposed of on September 29, 2011).

---

**Table of Contents**
*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 \$915 million, \$1.2 billion and \$1.3 billion in 2012, 2011 and 2010, 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.

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 to buy Merck's common stock interest in KBI and, through it, Merck's interest in Nexium and Prilosec as well as AZLP, exercisable in 2012. In June 2012, Merck and AstraZeneca amended the 1998 option agreement. The updated agreement eliminated AstraZeneca's option to acquire Merck's interest in KBI in 2012 and provides AstraZeneca a new option to acquire Merck's interest in KBI in June 2014. As a result of the amended agreement, Merck continues to record supply sales and equity income from the partnership. In 2014, AstraZeneca has the option to purchase Merck's interest in KBI based in part on the value of Merck's interest in Nexium and Prilosec. AstraZeneca's option is exercisable between March 1, 2014 and April 30, 2014. If AstraZeneca chooses to exercise this option, the closing date is expected to be June 30, 2014. Under the amended agreement, AstraZeneca will make a payment to Merck upon closing of \$327 million, reflecting an estimate of the fair value of Merck's interest in Nexium and Prilosec. This portion of the exercise price is subject to a true-up in 2018 based on actual sales from closing in 2014 to June 2018. The exercise price will also include an additional amount equal to a multiple of ten times Merck's average 1% annual profit allocation in the partnership for the three years prior to exercise. The Company believes that it is likely that AstraZeneca will exercise its option in 2014.



**Table of Contents**

Summarized financial information for AZLP is as follows:

<i>Years Ended December 31</i>	<b>2012</b>	2011	2010
Sales	<b>\$ 4,694</b>	\$ 4,659	\$ 4,991
Materials and production costs	<b>2,177</b>	2,023	2,568
Other expense, net	<b>1,312</b>	1,392	886
Income before taxes <sup>(1)</sup>	<b>1,205</b>	1,244	1,537

<i>December 31</i>	<b>2012</b>	2011
Current assets	<b>\$ 3,662</b>	\$ 4,251
Noncurrent assets	<b>206</b>	250
Current liabilities	<b>3,145</b>	3,915

<sup>(1)</sup> 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 2012, \$1.1 billion for 2011 and \$1.2 billion for 2010.

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

In September 2011, Merck sold its 50% interest in the Johnson & Johnson<sup>o</sup>Merck 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 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*. 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 and \$129 million for 2010.

Investments in affiliates accounted for using the equity method, including the above joint ventures, totaled \$1.3 billion at December 31, 2012 and \$886 million at December 31, 2011. These amounts are reported in *Other assets*. Amounts due from the above joint ventures included in *Deferred income taxes and other current assets* were \$302 million at December 31, 2012 and \$276 million at December 31, 2011.

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

<i>Years Ended December 31</i>	<b>2012</b>	2011 <sup>(1)</sup>	2010
Sales	<b>\$ 1,295</b>	\$ 1,331	\$ 1,486
Materials and production costs	<b>573</b>	584	598
Other expense, net	<b>705</b>	642	776
Income before taxes	<b>17</b>	105	112

<i>December 31</i>	<b>2012</b>	2011
Current assets	<b>\$ 971</b>	\$ 614
Noncurrent assets	<b>112</b>	75
Current liabilities	<b>480</b>	478
Noncurrent liabilities	<b>97</b>	140

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

*(1) Includes information for the JIMCP joint venture until its divestiture on September 29, 2011.*

**Table of Contents****10. Loans Payable, Long-Term Debt and Other Commitments**

Loans payable at December 31, 2012 included \$1.8 billion of notes due in 2013, \$1.7 billion of commercial paper, \$454 million of short-term foreign borrowings and \$328 million of long-dated notes that are subject to repayment at the option of the holder. 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. The weighted-average interest rate of the commercial paper borrowings was 0.15% and 0.11% at December 31, 2012 and 2011, respectively.

Long-term debt at December 31 consisted of:

	2012	2011
5.375% euro-denominated notes due 2014	\$ 2,058	\$ 2,062
6.50% notes due 2033	1,310	1,314
5.00% notes due 2019	1,294	1,300
3.875% notes due 2021	1,147	1,147
6.55% notes due 2037	1,146	1,148
6.00% notes due 2017	1,112	1,134
4.00% notes due 2015	1,049	1,068
4.75% notes due 2015	1,044	1,064
2.40% notes due 2022	1,000	
1.10% notes due 2018	998	
2.25% notes due 2016	874	882
5.85% notes due 2039	749	749
6.40% debentures due 2028	499	499
5.75% notes due 2036	498	498
5.95% debentures due 2028	498	498
3.60% notes due 2042	492	
6.30% debentures due 2026	248	248
5.30% notes due 2013		1,308
4.375% notes due 2013		508
Other	238	98
	<b>\$ 16,254</b>	<b>\$ 15,525</b>

Other (as presented in the table above) included \$165 million and \$28 million at December 31, 2012 and 2011, respectively, of borrowings at variable rates averaging 0.1% for 2012 and 0.2% for 2011. Other also included foreign borrowings of \$70 million and \$62 million at December 31, 2012 and 2011, respectively, at varying rates up to 8.5%.

With the exception of 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 September 2012, the Company closed an underwritten public offering of \$2.5 billion senior unsecured notes consisting of \$1.0 billion aggregate principal amount of 1.1% notes due 2018, \$1.0 billion aggregate principal amount of 2.4% notes due 2022 and \$500 million aggregate principal amount of 3.6% notes due 2042. 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 contributions to the Company's pension plans and the repayment of outstanding commercial paper and certain debt maturities.

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

---

## **Table of Contents**

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, 2012, 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: 2013, \$1.8 billion; 2014, \$2.1 billion; 2015, \$2.1 billion; 2016, \$884 million; 2017, \$1.1 billion.

In May 2012, the Company terminated its existing credit facilities and entered into a new \$4.0 billion, five-year credit facility maturing in May 2017. The facility provides backup liquidity for the Company's commercial paper borrowing facility and is to be used for general corporate purposes. The Company has not drawn funding from this facility.

Rental expense under operating leases, net of sublease income, was \$396 million in 2012, \$411 million in 2011 and \$431 million in 2010. The minimum aggregate rental commitments under noncancellable leases are as follows: 2013, \$203 million; 2014, \$172 million; 2015, \$146 million; 2016, \$97 million; 2017, \$72 million and thereafter, \$145 million. The Company has no significant capital leases.

### **11. Contingencies and Environmental Liabilities**

The Company is involved in various claims and legal proceedings of a nature considered normal to its business, including product liability, intellectual property, and commercial litigation, as well as additional matters such as antitrust actions and environmental matters. Except for the *Vioxx* Litigation (as defined below) for which a separate assessment is 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 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. 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.

#### ***Vioxx* Litigation**

##### *Product Liability Lawsuits*

As previously disclosed, Merck is a defendant in approximately 90 federal and state lawsuits (the *Vioxx* Product Liability 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.

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



**Table of Contents**

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*. On October 15, 2012, the parties executed a settlement agreement to resolve the litigation. The Company established a reserve of \$39 million in the third quarter of 2012 in connection with that settlement agreement, which is the minimum amount that the Company is required to pay under the agreement. The court preliminarily approved the agreement and the class notice and claims program is underway.

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. That case has been dormant for several years. 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 in January 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. The plaintiff petitioned the Kentucky Supreme Court to review the Court of Appeals' order and, on November 16, 2012, the Kentucky Supreme Court granted review. Briefing before the Kentucky Supreme Court is underway.

Merck has also been named as a defendant in lawsuits brought by state Attorneys General in five states. All of these actions except for the Kentucky action are in the *Vioxx* MDL proceeding. These actions allege that Merck misrepresented the safety of *Vioxx*. These suits seek recovery for expenditures on *Vioxx* by government-funded health care programs, such as Medicaid, and/or penalties for alleged Consumer Fraud Act violations. The Kentucky action is currently scheduled to proceed to trial in Kentucky state court in October 2013. On January 10, 2013, Merck finalized a settlement in the action filed by the Pennsylvania Attorney General under which Merck agreed to pay Pennsylvania \$8.25 million in exchange for the dismissal of its lawsuit.

*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 Stanley R. Chesler, and have been consolidated for all purposes. In August 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. In October 2011, defendants answered the Fifth Amended Class Action Complaint. On April 10, 2012, plaintiffs filed a motion for class certification and, on January 30, 2013, Judge Chesler granted that motion. Discovery is currently proceeding in accordance with the court's scheduling order.

As previously disclosed, several individual securities lawsuits filed by foreign institutional investors also are consolidated with the *Vioxx* Securities Lawsuits. In October 2011, plaintiffs filed amended complaints in each of the pending individual securities lawsuits. Also in October 2011, a new individual securities lawsuit (the KBC 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). Briefing on the motions to dismiss was completed on March 26, 2012. On August 1, 2012, Judge Chesler granted in part and denied in part the motions to dismiss the ABP Lawsuit. Among other things, certain alleged misstatements and omissions were dismissed as inactionable and all state law claims were dismissed in full. On September 15, 2012, defendants answered the complaints in all individual actions other than the KBC Lawsuit; on the same day, defendants moved to dismiss the complaint in the KBC Lawsuit on statute of limitations grounds. On December 20, 2012, Judge Chesler denied the motion to dismiss the KBC Lawsuit and, on January 4, 2013, defendants answered the complaint in the KBC Lawsuit. Discovery is currently proceeding in the individual securities lawsuits together with discovery in the class action.

---

## **Table of Contents**

### *Insurance*

The Company has Directors and Officers insurance coverage applicable to the *Vioxx* Securities Lawsuits with remaining stated upper limits of approximately \$170 million, which is currently being used to partially fund the Company's legal fees. 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.

### *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* International Lawsuits). As previously disclosed, the Company has entered into an agreement to resolve all claims related to *Vioxx* in Canada pursuant to which the Company will pay a minimum of approximately \$21 million but not more than an aggregate maximum of approximately \$36 million. The agreement is pending approval by courts in Canada's provinces.

### *Reserves*

The Company believes that it has meritorious defenses to the remaining *Vioxx* Product Liability Lawsuits, *Vioxx* Securities Lawsuits and *Vioxx* International 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. The Company has established a reserve with respect to the Canadian settlement and with respect to certain other *Vioxx* Product Liability Lawsuits, including the Missouri matter discussed above. The Company also has an immaterial remaining reserve relating to the previously disclosed *Vioxx* investigation for the non-participating states with which litigation is continuing. 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, 2012, approximately 4,560 cases, which include approximately 5,140 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 1,230 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 3,330 of these actions generally allege that they sustained femur fractures and/or other bone injuries (Femur Fractures) 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* ONJ MDL) for coordinated pre-trial proceedings. The *Fosamax* ONJ 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 960 of the cases are before Judge Keenan. In the first *Fosamax* ONJ MDL trial, *Boles v. Merck*, the *Fosamax* ONJ 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

---

**Table of Contents**

the verdict to \$1.5 million. Plaintiff rejected the remittitur ordered by the court and requested a new trial on damages. Plaintiff and Merck subsequently entered into a confidential stipulation as to the amount of plaintiff's damages that enabled Merck to appeal the underlying judgment, and Merck filed its appeal in the *Boles* case on October 18, 2012. Prior to 2013, three other cases were tried to verdict in the *Fosamax* ONJ MDL. Defense verdicts in favor of Merck were returned in each of those three cases. Plaintiffs have filed an appeal in two of the cases *Graves v. Merck* and *Secrest v. Merck*. On January 30, 2013, the U.S. Court of Appeals for the Second Circuit affirmed the judgment in Merck's favor in *Secrest*.

In February 2011, Judge Keenan ordered that there will be two further bellwether trials conducted in the *Fosamax* ONJ MDL. *Spano v. Merck* and *Jellema v. Merck* were selected by the court to be tried in 2012, but each case was dismissed by the plaintiffs. On March 28, 2012, the court selected *Scheinberg v. Merck* as the next case to be tried. Trial in the *Scheinberg* case began on January 14, 2013 and, on February 5, 2013, the jury returned a mixed verdict finding in favor of Merck on plaintiff's design defect claim and finding in favor of plaintiff on her failure to warn claim awarding her \$285 thousand in compensatory damages.

Outside the *Fosamax* ONJ MDL, in Florida, *Carballo v. Merck* was set for trial on October 15, 2012, but plaintiff dismissed the case and refiled it in the *Fosamax* ONJ MDL. *Anderson v. Merck* had been set for trial on January 14, 2013, but plaintiff dismissed the case prior to trial.

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 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, 2012, approximately 260 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. In April 2012, the jury in *Sessner v. Merck*, the second case tried in New Jersey, also returned a verdict in Merck's favor. Plaintiffs have filed an appeal in both cases.

In California, the parties are reviewing the claims of two 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 may be tried in 2013.

Discovery is ongoing in the *Fosamax* ONJ MDL litigation, the New Jersey coordinated proceeding, and the remaining jurisdictions where *Fosamax* ONJ cases are pending. The Company intends to defend against these lawsuits.

*Cases Alleging Femur Fractures*

In March 2011, Merck submitted a Motion to Transfer to the JPML seeking to have all federal cases alleging Femur Fractures 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 have been or will be transferred to a multidistrict litigation in the District of New Jersey (the *Fosamax* Femur Fracture MDL). As a result of the JPML order, approximately 820 cases were pending in the *Fosamax* Femur Fracture MDL as of December 31, 2012. A Case Management Order has been entered that requires the parties to review 40 cases (later reduced to 33 cases). Judge Joel Pisano has selected four cases from that group to be tried as the initial bellwether cases in the *Fosamax* Femur Fracture MDL and has set an April 8, 2013 trial date for the first bellwether case, which will be *Glynn v. Merck*. The *Zessin v. Merck* case is set to be tried in September 2013; the *Young v. Merck* case is set to be tried in January 2014; and the *Johnson v. Merck* case is set to be tried in May 2014.

As of December 31, 2012, approximately 2,075 cases alleging Femur Fractures 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. Judge Higbee has set March 11, 2013 as the date for the first trial of the New Jersey state Femur Fracture cases, which will be *Su v. Merck*.



---

## Table of Contents

As of December 31, 2012, approximately 420 cases alleging Femur Fractures have been filed in California state court. 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 Steven Perk is now presiding over the coordinated proceedings. No scheduling order has yet been entered.

Additionally, there are eight Femur Fracture cases pending in other state courts. A trial date has been set for August 12, 2013 for the *Barnes v. Merck* case pending in Alabama state court.

Discovery is ongoing in the *Fosamax* Femur Fracture MDL and in 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 the Company 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.

As of December 31, 2012, there were approximately 1,315 *NuvaRing* cases. Of these cases, approximately 1,105 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 200 are pending in coordinated discovery proceedings in the Bergen County Superior Court of New Jersey before Judge Brian R. Martinotti. Five 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 20 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. The first *NuvaRing* MDL trial is expected to take place in the summer of 2013. Pursuant to Judge Martinotti's order in the New Jersey proceeding, the parties selected nine trial pool cases to be prepared for trial and the first trial is expected to commence in May 2013. The parties have completed fact discovery in the originally selected trial pool cases in each jurisdiction and expert discovery has been completed in those first trial pool cases. Certain replacement trial pool cases remain in fact discovery.

The Company has filed motions related to the admissibility of expert testimony and motions for summary judgment. The Company expects substantive hearings on the motions for summary judgment to take place in the New Jersey cases in early 2013, followed by substantive hearings on the admissibility of expert testimony after the resolution of the summary judgment motions. The Company expects substantive hearings on the motions for summary judgment in the *NuvaRing* MDL cases to take place in spring 2013, followed by hearings on the admissibility of expert testimony. The Company has certain insurance coverage available to it, which is currently being used to partially fund the Company's legal fees. 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, 2012, approximately 385 lawsuits involving a total of approximately 550 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, have been filed in various federal courts and in state court in New Jersey. The federal lawsuits have been consolidated for pretrial purposes in a federal MDL before Judge John Gleeson of the Eastern District of New York. The matters pending in state court in New Jersey have been consolidated before Judge Jessica Mayer in Middlesex County. The Company intends to defend against these lawsuits.

---

## **Table of Contents**

### ***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. On March 1, 2012, defendants filed a motion for summary judgment. On September 25, 2012, the court granted lead plaintiffs' amended motion for class certification and denied defendants' motion for summary judgment. On February 13, 2013, Merck announced that it had reached an agreement in principle with plaintiffs to settle this matter for \$215 million. The settlement is subject to court approval. The proposed settlement has been reflected in the Company's 2012 financial results as discussed below.

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, LLC; 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' motions to dismiss. On March 1, 2012, the Schering-Plough defendants filed a motion for partial summary judgment and the underwriter defendants filed a motion for summary judgment. On September 25, 2012, the court granted lead plaintiffs' amended motion for class certification and denied defendants' motions for summary judgment. On February 13, 2013, Merck announced that it had reached an agreement in principle with plaintiffs to settle this matter for \$473 million. The settlement is subject to court approval. If approved, this settlement will exhaust the remaining Directors and Officers insurance coverage applicable to the *Vytorin* lawsuits brought by the legacy Schering-Plough shareholders. The proposed settlement has been reflected in the Company's 2012 financial results and, together with the settlement described in the preceding paragraph, resulted in an aggregate charge of \$493 million after taking into account anticipated insurance recoveries of \$195 million.

### **Governmental Proceedings**

As previously disclosed, Merck has received a Civil Investigative Demand (CID) issued by the Department of Justice (the DOJ) addressed to Inspire, 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 DOJ in its investigation.

As previously disclosed, the Company received a subpoena from the U.S. Attorney's Office for the Eastern District of California in 2010 requesting information in a civil federal health care investigation relating to the Company's marketing and selling activities with respect to Integrilin and *Avelox* from January 2003 to June 2010. In December 2012, the U.S. District Court for the Eastern District of California unsealed a complaint that a former employee of the Company had filed against it in 2009 under the federal False Claims Act and the False Claims Acts of various states. The complaint alleges that the Company caused false claims to be made to federal and state health care programs by promoting Integrilin for unapproved indications and providing unlawful payments and benefits to physicians and others to increase the utilization of Integrilin and *Avelox*. The federal government and the states under whose statutes the suit was filed each had the right, after investigating these allegations, to intervene in this suit and assume responsibility for its direction, but each of them has notified the court that they decline to intervene. The Company intends to defend against the suit.

---

## **Table of Contents**

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 has been informed by the U.S. Attorney's Office for the District of Massachusetts that this subpoena will not be enforced and that no further action on the Company's part is required.

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.

As previously disclosed, on June 21, 2012, the U.S. District Court for the Eastern District of Pennsylvania unsealed a complaint that has been filed against the Company under the federal False Claims Act by two former employees alleging, among other things, that the Company defrauded the U.S. government by falsifying data in connection with a clinical study conducted on the mumps component of the Company's *M-M-R II* vaccine. The complaint alleges the fraud took place between 1999 and 2001. The U.S. government had the right to participate in and take over the prosecution of this lawsuit, but has notified the court that it declined to exercise that right. The two former employees are pursuing the lawsuit without the involvement of the U.S. government. In addition, a putative class action lawsuit has been filed against the Company in the Eastern District of Pennsylvania on behalf of direct purchasers of the *M-M-R II* vaccine which is predicated on the allegations in the False Claims Act complaint and charges that the Company misrepresented the efficacy of the *M-M-R II* vaccine in violation of federal antitrust laws and various state consumer protection laws. The Company intends to defend against these lawsuits.

## **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.

Since the start of 2012, the Company has settled certain AWP cases brought by the states of Alabama, Alaska, Kansas, Kentucky, Louisiana, Oklahoma, and Mississippi. The Company and/or certain of its subsidiaries continue to be defendants in cases brought by six states.

The Company has also been reinstated as a defendant in a putative class action in New Jersey Superior Court which alleges on behalf of third-party payers and individuals that manufacturers inflated drug prices by manipulation of AWP and other means. This case was originally dismissed against the Company without prejudice in 2007. The Company intends to defend against this lawsuit.

### *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 U.S. 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 March 2010, the District Court granted summary judgment to the defendants on the remaining lawsuits and dismissed the matter in its entirety. However, in July 2012, the 3rd Circuit

---

**Table of Contents**

Court of Appeals reversed the District Court’s judgment and remanded the case for further proceedings. At the same time, the 3rd Circuit upheld a December 2008 decision by the District Court to certify certain direct purchaser plaintiffs’ claims as a class action.

In August 2012, the Company filed a petition for certiorari with the U.S. Supreme Court seeking review of the Third Circuit’s reversal of summary judgment. The Supreme Court has taken no action on that petition, but in December 2012 it granted certiorari in an unrelated case in which the 11th Circuit Court of Appeals reached a decision that appears in conflict with the 3rd Circuit’s holding in the Company’s case. The Company expects that the issue it sought to raise with the Supreme Court will be resolved by the Supreme Court’s pending decision in this 11th Circuit case.

*Nexium Antitrust Litigation*

As previously disclosed, in September 2012, the Company and certain of its subsidiaries were among the defendants named in a putative class action lawsuit brought on behalf of direct purchasers of Nexium in federal court in New Jersey. The lawsuit alleges violations of federal antitrust law arising from settlements reached by and among the defendants to resolve certain patent litigation relating to the entry of generic esomeprazole on the U.S. market. Specifically, the plaintiffs contend that these settlements had the effect of impermissibly delaying the entry of generic esomeprazole in the United States and extending the monopoly power of Nexium, leading to higher average market prices. On January 8, 2013, the Company and its subsidiaries were dismissed without prejudice from the lawsuit.

*Coupon Litigation*

As previously disclosed, since March 2012, a number of private health plans have filed separate putative class action lawsuits against the Company alleging that Merck’s coupon programs injured health insurers by reducing beneficiary co-payment amounts, thereby allegedly causing beneficiaries to purchase higher-priced drugs than they otherwise would have purchased and increasing the insurers’ reimbursement costs. The actions, which are pending in the U.S. District Court for the District of New Jersey, seek damages and injunctive relief barring the Company from issuing coupons that would reduce beneficiary co-pays on behalf of putative nationwide classes of health insurers. Similar actions relating to manufacturer coupon programs have been filed against several other pharmaceutical manufacturers in a variety of federal courts. The Company intends to defend against these lawsuits.

**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, *Emend* for Injection, Integrilin, *Nasonex*, Nexium, *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 products acquired through mergers and acquisitions, potentially significant intangible asset impairment charges.

**AzaSite** In May 2011, a patent infringement lawsuit 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.

**Emend for Injection** In May 2012, 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 market a generic version of *Emend* for Injection. The lawsuit automatically stays FDA approval of Sandoz’s ANDA until July 2015 or until an adverse court decision, if any, whichever may occur earlier. In June 2012, a patent infringement lawsuit was filed in the United States against Accord Healthcare, Inc. US, Accord Healthcare, Inc. and Intas

**Table of Contents**

**Pharmaceuticals Ltd** (collectively, **Intas**) in respect of Intas' application to the FDA seeking pre-patent expiry approval to market a generic version of *Emend* for Injection. The lawsuit automatically stays FDA approval of Intas' ANDA until July 2015 or until an adverse court decision, if any, whichever may occur earlier.

**Integrilin** In February 2009, a patent infringement lawsuit was filed (jointly with Millennium Pharmaceuticals, Inc.) in the United States against Teva Parenteral Medicines, Inc. (**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. In November 2012, a patent infringement lawsuit was filed against APP Pharmaceuticals, Inc. and Fresenius Kabi USA Inc. (collectively **APP**) in respect of APP'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. The lawsuit automatically stays FDA approval of APP's ANDA until April 2015 or until an adverse court decision, if any, whichever may occur earlier.

**Nasonex** In December 2009, a patent infringement lawsuit 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*. A trial in this matter was held in April 2012. A decision was issued on June 15, 2012, holding that the Merck patent covering mometasone furoate monohydrate was valid, but that it was not infringed by Apotex's proposed product. The finding of non-infringement is under appeal.

**Nexium** Patent infringement lawsuits were brought (jointly with AstraZeneca) in the United States against the following generic companies: Ranbaxy Laboratories Ltd., IVAX Pharmaceuticals, Inc. (later acquired by Teva Pharmaceuticals, Inc. (**Teva**)), Dr. Reddy's Laboratories, Sandoz, Lupin Ltd., Hetero Drugs Limited Unit III and Torrent Pharmaceuticals Ltd. in response to each generic company's application seeking pre-patent expiry approval to sell a generic version of Nexium. Settlements have been reached in each of these lawsuits, the terms of which provide that the respective generic company may bring a generic version of esomeprazole product to market on May 27, 2014. In addition, 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, which lawsuit was settled with an 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. Finally, additional patent infringement lawsuits have been filed (jointly with AstraZeneca) in the United States against Hamni USA, Inc. (**Hamni**) and Mylan Laboratories Limited (**Mylan Labs**) related to their applications to the FDA seeking pre-patent expiry approval to sell generic versions of Nexium. The Hamni and Mylan Labs applications to the FDA remain stayed until May 2013 and August 2014, respectively, or until earlier adverse court decisions, if any, whichever may occur earlier.

**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*. A trial against Mylan jointly in respect of *Zetia* and *Vytorin* was conducted in December 2011. In April 2012, the court issued a decision finding the patent valid and enforceable. Accordingly, Mylan's ANDA will not be approvable until April 25, 2017. On February 7, 2013, the Court of Appeals for the Federal Circuit affirmed the lower court decision. 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*. An agreement was reached with Actavis to stay the lawsuit pending the outcome of the lawsuit with Mylan.

**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,

---

## **Table of Contents**

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*. A trial against Mylan jointly in respect of *Zetia* and *Vytorin* was conducted in December 2011. In April 2012, the court issued a decision finding the patent valid and enforceable. Accordingly, Mylan's ANDA will not be approvable until April 25, 2017. On February 7, 2013, the Court of Appeals for the Federal Circuit affirmed the lower court decision. 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. In September 2012, 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 *Zetia*. The lawsuit automatically stays FDA approval of Sandoz's ANDA until February 2015 or until an adverse court decision, if any, whichever may occur earlier.

## **Environmental Litigation**

As previously disclosed, approximately 2,200 plaintiffs 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 I trial included Merck and three of the other original 12 defendants. In March 2011, the Phase I 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 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 selected 10 plaintiffs whose claims would be reviewed and, depending on the outcome of Merck's summary judgment motions, possibly tried in early 2013. Plaintiffs subsequently withdrew the claim of one of those 10 plaintiffs, leaving nine whose claims may proceed to trial. The court has dismissed the claims of 1,083 of the plaintiffs in this action whose claims were precluded by aspects of the Phase I jury findings and the court's subsequent orders. Subject to the court's anticipated rulings on defendants' potentially dispositive summary judgment and other pre-trial motions, trial of the nine selected trial plaintiffs' claims is anticipated to begin near the end of March 2013.

## **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 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.

---

**Table of Contents****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, 2012 and December 31, 2011 of approximately \$260 million and \$240 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.

In management's opinion, the liabilities for all environmental matters that are probable and reasonably estimable have been accrued and totaled \$145 million and \$171 million at December 31, 2012 and 2011, 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 \$112 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.

**12. 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.

**Table of Contents***Capital Stock*

A summary of common stock and treasury stock transactions (shares in millions) is as follows:

	2012		2011		2010	
	Common Stock	Treasury Stock	Common Stock	Treasury Stock	Common Stock	Treasury Stock
Balance January 1	3,577	536	3,577	495	3,563	454
Purchases of treasury stock		62		58		47
Issuances <sup>(1)</sup>		(48)		(17)	10	(6)
Mandatory conversion of 6% convertible preferred stock <sup>(2)</sup>					4	
Balance December 31	3,577	550	3,577	536	3,577	495

<sup>(1)</sup> Issuances primarily reflect activity under share-based compensation plans.

<sup>(2)</sup> In 2010, the remaining outstanding 6% mandatory convertible preferred stock not converted in connection with the Merger automatically converted by its terms into the right to receive cash and 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.

*Noncontrolling Interests*

In connection with the 1998 restructuring of AMI, Merck assumed \$2.4 billion par value preferred stock with a dividend rate of 5% per annum, which is carried by KBI and included in *Noncontrolling interests*. If AstraZeneca exercises its option to acquire Merck's interest in AZLP (see Note 9) this preferred stock obligation will be retired.

**13. Share-Based Compensation Plans**

The Company has share-based compensation plans under which the Company grants restricted stock units ( RSUs ) and performance share units ( PSUs ) to certain management level employees. In addition, 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. These plans were approved by the Company's shareholders.

At December 31, 2012, 180 million shares collectively were authorized for future grants under the Company's share-based compensation plans. These awards are settled primarily with treasury shares.

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. 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 2012, 2011 and 2010 was \$335 million, \$369 million and \$509 million, respectively, with related income tax benefits of \$105 million, \$118 million and \$173 million, respectively.



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

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-

**Table of Contents**

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 2012, 2011 and 2010 was \$39.51, \$36.47 and \$34.30 per option, respectively. The weighted average fair value of options granted in 2012, 2011 and 2010 was \$5.47, \$5.39 and \$7.99 per option, respectively, and were determined using the following assumptions:

<i>Years Ended December 31</i>	<b>2012</b>	2011	2010
Expected dividend yield	<b>4.4%</b>	4.3%	4.1%
Risk-free interest rate	<b>1.3%</b>	2.5%	2.8%
Expected volatility	<b>25.2%</b>	23.4%	33.7%
Expected life (years)	<b>7.0</b>	7.0	6.8

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, 2012	230,760	\$ 39.51		
<b>Granted</b>	<b>7,641</b>	<b>39.51</b>		
<b>Exercised</b>	<b>(44,177)</b>	<b>29.64</b>		
<b>Forfeited</b>	<b>(28,283)</b>	<b>55.20</b>		
<b>Outstanding December 31, 2012</b>	<b>165,941</b>	<b>\$ 39.46</b>	<b>3.90</b>	<b>\$ 762</b>
<b>Exercisable December 31, 2012</b>	<b>149,407</b>	<b>\$ 39.64</b>	<b>3.45</b>	<b>\$ 700</b>

Additional information pertaining to stock option plans is provided in the table below:

<i>Years Ended December 31</i>	<b>2012</b>	2011	2010
Total intrinsic value of stock options exercised	<b>\$ 528</b>	\$ 125	\$ 177
Fair value of stock options vested	<b>80</b>	189	290
Cash received from the exercise of stock options	<b>1,310</b>	321	363

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, 2012	21,145	\$ 33.73	1,513	\$ 31.58
<b>Granted</b>	<b>6,899</b>	<b>39.45</b>	<b>996</b>	<b>35.35</b>
<b>Vested</b>	<b>(4,340)</b>	<b>28.43</b>	<b>(756)</b>	<b>31.52</b>
<b>Forfeited</b>	<b>(961)</b>	<b>36.02</b>	<b>(105)</b>	<b>33.38</b>
<b>Nonvested December 31, 2012</b>	<b>22,743</b>	<b>\$ 36.38</b>	<b>1,648</b>	<b>\$ 33.78</b>



**Table of Contents**

At December 31, 2012, there was \$370 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.

**14. 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. 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 are accruing 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.

In addition, the Company provides medical benefits, principally to its eligible U.S. retirees and their dependents, through its other postretirement benefit plans. 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.

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		
	2012	2011	2010	2012	2011	2010
Service cost	\$ 555	\$ 619	\$ 584	\$ 82	\$ 110	\$ 108
Interest cost	661	718	688	121	141	148
Expected return on plan assets	(970)	(972)	(891)	(136)	(142)	(132)
Net amortization	185	201	148	(35)	(17)	8
Termination benefits	27	59	54	18	29	42
Curtailements	(10)	(86)	(50)	(7)	1	(10)
Settlements	18	4	(1)			
Net periodic benefit cost	\$ 466	\$ 543	\$ 532	\$ 43	\$ 122	\$ 164

The decline in net periodic benefit cost for pension and other postretirement benefit plans in 2012 as compared with 2011 and 2010 is largely attributable to the benefit plan design changes discussed above. The changes to Merck's primary U.S. defined benefit pension plans and U.S. retiree healthcare plans reduced benefit obligations at December 31, 2011 by \$752 million and \$150 million, respectively, with a corresponding offset to *AOCI*, which is being amortized as reduction to net periodic benefit cost over the employees' future service period (approximately 11 years).

The net periodic benefit cost attributable to U.S. pension plans included in the above table was \$268 million in 2012, \$406 million in 2011 and \$289 million in 2010.

In connection with restructuring actions (see Note 3), termination charges were recorded in 2012, 2011 and 2010 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 2012, 2011 and 2010 on pension and other postretirement benefit plans.

In addition, settlements were recorded in 2012, 2011 and 2010 on certain domestic and international pension plans.

**Table of Contents***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	
	2012	2011	2012	2011
Fair value of plan assets January 1	\$ 12,481	\$ 12,705	\$ 1,628	\$ 1,685
Actual return on plan assets	1,739	6	200	(20)
Company contributions	1,853	556	48	58
Mergers, acquisitions and divestitures		(202)		
Effects of exchange rate changes	3	56		
Benefits paid	(673)	(581)	(115)	(95)
Settlements	(75)	(78)		
Other	21	19	(1)	
Fair value of plan assets December 31	\$ 15,349	\$ 12,481	\$ 1,760	\$ 1,628
Benefit obligation January 1	14,416	13,978	2,529	2,745
Service cost	555	619	82	110
Interest cost	661	718	121	141
Mergers, acquisitions and divestitures		(180)		
Actuarial losses (gains)	2,660	688	88	(266)
Benefits paid	(673)	(581)	(115)	(95)
Effects of exchange rate changes	67	53		(3)
Plan amendments	2	(763)	(86)	(150)
Curtailments	(17)	(150)	1	16
Termination benefits	27	59	18	29
Settlements	(75)	(78)		
Other	23	53	12	2
Benefit obligation December 31	\$ 17,646	\$ 14,416	\$ 2,650	\$ 2,529
Funded status December 31	\$ (2,297)	\$ (1,935)	\$ (890)	\$ (901)
Recognized as:				
Other assets	\$ 355	\$ 669	\$ 506	\$ 391
Accrued and other current liabilities	(50)	(81)	(9)	(10)
Deferred income taxes and noncurrent liabilities	(2,602)	(2,523)	(1,387)	(1,282)

---

## **Table of Contents**

The fair value of U.S. pension plan assets included in the preceding table was \$8.7 billion and \$6.8 billion at December 31, 2012 and 2011, respectively, and the projected benefit obligation of U.S. pension plans was \$10.0 billion and \$8.7 billion, respectively. Approximately 44% and 40% of the Company's pension projected benefit obligation at December 31, 2012 and 2011, respectively, relates to international defined benefit plans, of which each individual plan is not significant relative to the total projected benefit obligation.

At December 31, 2012 and 2011, the accumulated benefit obligation was \$15.9 billion and \$12.9 billion, respectively, for all pension plans, of which \$9.0 billion and \$7.8 billion, respectively, related to U.S. pension plans.

For pension plans with projected benefit obligations in excess of plan assets at December 31, 2012 and 2011, the fair value of plan assets was \$12.8 billion and \$9.3 billion, respectively, and the benefit obligations were \$15.5 billion and \$11.9 billion, respectively. For those plans with accumulated benefit obligations in excess of plan assets at December 31, 2012 and 2011, the fair value of plan assets was \$6.1 billion and \$3.6 billion, respectively, and the accumulated benefit obligations were \$7.7 billion and \$5.4 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, 2012 and 2011, \$692 million and \$637 million, respectively, or approximately 5% 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
	2012				2011			
<b>Assets</b>								
Cash and cash equivalents	\$ 142	\$ 587	\$	\$ 729	\$ 93	\$ 217	\$	\$ 310
<i>Investment funds</i>								
U.S. large cap equities	63	2,899		2,962	65	2,226		2,291
U.S. small/mid cap equities	10	954		964	9	710		719
Non-U.S. developed markets equities	610	2,133		2,743	390	1,735		2,125
Non-U.S. emerging markets equities	121	771		892	82	575		657
Government and agency obligations	279	720		999	119	632		751
Corporate obligations	166	94		260	112	193		305
Fixed income obligations	14	206		220		144		144
Real estate <sup>(1)</sup>	4	14	141	159		9	144	153
<i>Equity securities</i>								
U.S. large cap	351			351	330			330
U.S. small/mid cap	1,258			1,258	1,085			1,085
Non-U.S. developed markets	668			668	623			623
<i>Fixed income securities</i>								
Government and agency obligations	2	1,052		1,054		1,248		1,248
Corporate obligations		1,008		1,008		703		703
Mortgage and asset-backed securities		269		269		275		275
<i>Other investments</i>								
Insurance contracts <sup>(2)</sup>		117	496	613		138	428	566
Derivatives		162		162		141		141
Other		53	55	108	3	42	65	110
<b>Liabilities</b>								
Derivatives	\$	\$ 70	\$	\$ 70	\$	\$ 55	\$	\$ 55
	\$ 3,688	\$ 10,969	\$ 692	\$ 15,349	\$ 2,911	\$ 8,933	\$ 637	\$ 12,481

<sup>(1)</sup> The plans' Level 3 investments in real estate funds are generally valued by market appraisals of the underlying investments in the funds.

<sup>(2)</sup> 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:

	2012				2011			
	Insurance Contracts	Real Estate	Other	Total	Insurance Contracts	Real Estate	Other	Total
Balance January 1	\$ 428	\$ 144	\$ 65	\$ 637	\$ 420	\$ 165	\$ 63	\$ 648
Actual return on plan assets:								
Relating to assets still held at December 31								
31	35	20	(2)	53	16	(7)	(2)	7
Relating to assets sold during the year	1	(12)	5	(6)	1		4	5
Purchases	21		4	25	19	13	(3)	29
Sales	(11)	(1)	(14)	(26)	(28)	(27)	3	(52)
Transfers to Level 3	22	(10)	(3)	9				
Balance December 31	\$ 496	\$ 141	\$ 55	\$ 692	\$ 428	\$ 144	\$ 65	\$ 637

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
	2012				2011			
<b>Assets</b>								
Cash and cash equivalents	\$ 27	\$ 48	\$	\$ 75	\$ 28	\$ 40	\$	\$ 68
<i>Investment funds</i>								
U.S. large cap equities		275		275		443		443
U.S. small/mid cap equities		150		150		286		286
Non-U.S. developed markets equities	37	76		113	60	101		161
Non-U.S. emerging markets equities	37	75		112	30	65		95
Fixed income obligations	3	23		26		34		34
<i>Equity securities</i>								
U.S. large cap	6			6	4			4
U.S. small/mid cap	101			101	101			101
Non-U.S. developed markets	32			32	94			94
<i>Fixed income securities</i>								
Government and agency obligations		298		298		76		76
Corporate obligations		310		310		208		208
Mortgage and asset-backed securities		238		238		46		46
Other fixed income obligations		24		24		12		12
	\$ 243	\$ 1,517	\$	\$ 1,760	\$ 317	\$ 1,311	\$	\$ 1,628

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 2013 are expected to be approximately \$340 million and \$40 million, respectively.

*Expected Benefit Payments*

Expected benefit payments are as follows:

	Pension Benefits	Other Postretirement Benefits
2013	\$ 643	\$ 123
2014	636	128
2015	693	133
2016	713	138
2017	742	143
2018 - 2022	4,566	802

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*:

Years Ended December 31	Pension Plans			Other Postretirement Benefit Plans		
	2012	2011	2010	2012	2011	2010
Net (loss) gain arising during the period	\$ (1,907)	\$ (1,628)	\$ 361	\$ (24)	\$ 106	\$ 66
Prior service (cost) credit arising during the period	(13)	783	1	78	133	99
Net loss amortization included in benefit cost	\$ 256	\$ 196	\$ 140	\$ 31	\$ 38	\$ 55
Prior service (credit) cost amortization included in benefit cost	(71)	5	8	(66)	(55)	(47)
	\$ 185	\$ 201	\$ 148	\$ (35)	\$ (17)	\$ 8

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 2013 are \$410 million and \$(72) million, respectively, for pension plans and are \$25 million and \$(73) 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>	<b>2012</b>	Pension Plans		U.S. Pension and Other Postretirement Benefit Plans		
		2011	2010	<b>2012</b>	2011	2010
<b>Net periodic benefit cost</b>						
Discount rate	<b>4.70%</b>	5.20%	5.50%	<b>4.80%</b>	5.40%	5.90%
Expected rate of return on plan assets	<b>7.50%</b>	7.50%	7.60%	<b>8.70%</b>	8.70%	8.70%
Salary growth rate	<b>4.00%</b>	4.20%	4.15%	<b>4.50%</b>	4.50%	4.50%
<b>Benefit obligation</b>						
Discount rate	<b>3.90%</b>	4.70%	5.20%	<b>4.10%</b>	4.80%	5.40%
Salary growth rate	<b>4.20%</b>	4.00%	4.20%	<b>4.50%</b>	4.50%	4.50%

For both the pension and other postretirement benefit plans, the discount rate is evaluated on measurement dates and modified to reflect the prevailing market rate of a portfolio of high-quality fixed-income debt instruments that would provide the future cash flows needed to pay the benefits included in the benefit obligation as they come due. 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 2013, the Company's expected rate of return will range from 6.00% to 8.75% compared to a range of 5.75% to 8.75% in 2012 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>	<b>2012</b>	2011
Health care cost trend rate assumed for next year	<b>7.5%</b>	7.9%
Rate to which the cost trend rate is assumed to decline	<b>5.0%</b>	5.0%
Year that the trend rate reaches the ultimate trend rate	<b>2018</b>	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	<b>\$ 38</b>	<b>\$ (30)</b>
Effect on benefit obligation	<b>\$ 396</b>	<b>\$ (324)</b>

*Savings Plans*

The Company also maintains defined contribution savings plans in the United States. 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 2012, 2011 and 2010 were \$146 million, \$166 million and \$155 million, respectively.

**Table of Contents****15. Other (Income) Expense, Net**

<i>Years Ended December 31</i>	<b>2012</b>	2011	2010
Interest income	<b>\$ (232)</b>	\$ (145)	\$ (83)
Interest expense	<b>714</b>	695	715
Exchange losses	<b>185</b>	143	214
Other, net	<b>449</b>	253	458
	<b>\$ 1,116</b>	\$ 946	\$ 1,304

The increase in interest income in 2012 as compared with 2011 reflects the accretion of time value of money discounts related to certain accounts receivables, including accelerated accretion related to significant collections of accounts receivable in Spain (see Note 6). The increase in interest income in 2011 as compared with 2010 primarily reflects higher average investment balances. 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 2012 reflects a \$493 million net charge related to the settlement of the ENHANCE Litigation (see Note 11). Other, net 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 5), a \$136 million gain on the disposition of the Company's interest in the JJMCP joint venture (see Note 9), and a \$127 million gain on the sale of certain manufacturing facilities and related assets (see Note 4). Other, net in 2010 reflects a \$950 million charge to settle certain *Vioxx* litigation, 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 9) and \$102 million of income recognized on the settlement of certain disputed royalties.

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. In addition, as noted above, exchange losses for 2010 reflect losses relating to Venezuelan currency devaluations. Effective January 11, 2010, the Venezuelan government devalued its currency to a two-tiered official exchange rate with an essentials rate and a non-essentials rate. In December 2010, the Venezuelan government announced it would eliminate the essentials rate effective January 1, 2011. As a result of this announcement, the Company remeasured its December 31, 2010 monetary assets and liabilities at the new official rate.

Interest paid was \$898 million in 2012, \$600 million in 2011 and \$763 million in 2010, 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 6).

**Table of Contents****16. Taxes on Income**

A reconciliation between the effective tax rate and the U.S. statutory rate is as follows:

	2012		2011		2010	
	Amount	Tax Rate	Amount	Tax Rate	Amount	Tax Rate
U.S. statutory rate applied to income before taxes	\$ 3,059	35.0%	\$ 2,567	35.0%	\$ 579	35.0%
Differential arising from:						
Foreign earnings	(1,955)	(22.4)	(2,220)	(30.3)	(1,878)	(113.6)
Tax settlements	(113)	(1.3)	(721)	(9.8)	(17)	(1.0)
Unremitted foreign earnings	(11)	(0.1)	(86)	(1.2)	(217)	(13.1)
Amortization of purchase accounting adjustments	905	10.3	875	11.9	1,394	84.3
Vioxx and ENHANCE litigation settlements	98	1.2			332	20.1
Restructuring	62	0.7	163	2.2	134	8.1
U.S. health care reform legislation	60	0.7	50	0.7	147	8.9
Tax rate changes	57	0.6	(295)	(4.0)	(391)	(23.7)
IPR&D impairment charges	40	0.5	(5)	(0.1)	484	29.3
Arbitration settlement charge			177	2.4		
State taxes	31	0.3	72	1.0	(42)	(2.6)
Other <sup>(1)</sup>	207	2.4	365	5.0	146	8.9
	\$ 2,440	27.9%	\$ 942	12.8%	\$ 671	40.6%

<sup>(1)</sup> Other includes the tax effect of contingency reserves, research credits and miscellaneous items.

The foreign earnings tax rate differentials in the tax rate reconciliation above primarily reflect the impacts of operations in jurisdictions with different tax rates than the United States, particularly Singapore, Ireland, Switzerland and Puerto Rico (which operates under a tax incentive grant), where the earnings have been indefinitely reinvested, thereby yielding a favorable impact on the effective tax rate as compared with the 35% U.S. statutory rate. The foreign earnings tax rate differentials do not include the impact of IPR&D impairment charges, amortization of purchase accounting adjustments, restructuring costs and the arbitration settlement charge. These items are presented separately as they each represent a significant, separately disclosed pretax cost or charge, and a substantial portion of each of these items relates to jurisdictions with lower tax rates than the United States. Therefore, the impact of recording these expense items in lower tax rate jurisdictions is an unfavorable impact on the effective tax rate as compared to the 35% U.S. statutory rate.

Income before taxes consisted of:

Years Ended December 31	2012	2011	2010
Domestic	\$ 4,500	\$ 2,626	\$ 1,154
Foreign	4,239	4,708	499
	\$ 8,739	\$ 7,334	\$ 1,653

**Table of Contents**

Taxes on income consisted of:

<i>Years Ended December 31</i>	2012	2011	2010
<i>Current provision</i>			
Federal	\$ 1,346	\$ 859	\$ 399
Foreign	651	1,568	1,446
State	(226)	52	(82)
	1,771	2,479	1,763
<i>Deferred provision</i>			
Federal	749	(584)	764
Foreign	(323)	(683)	(1,777)
State	243	(270)	(79)
	669	(1,537)	(1,092)
	\$ 2,440	\$ 942	\$ 671

Deferred income taxes at December 31 consisted of:

	2012		2011	
	Assets	Liabilities	Assets	Liabilities
Intangibles	\$	\$ 4,584	\$	\$ 5,329
Inventory related	79	488	66	325
Accelerated depreciation	129	1,348	140	1,244
Unremitted foreign earnings		2,435		2,413
Equity investments		451		280
Pensions and other postretirement benefits	1,098	109	1,179	149
Compensation related	748		768	
Unrecognized tax benefits	706		788	
Net operating losses and other tax credit carryforwards	425		538	
Other	1,798	91	2,294	108
Subtotal	4,983	9,506	5,773	9,848
Valuation allowance	(107)		(246)	
Total deferred taxes	\$ 4,876	\$ 9,506	\$ 5,527	\$ 9,848
Net deferred income taxes		\$ 4,630		\$ 4,321
Recognized as:				
Deferred income taxes and other current assets	\$ 624		\$ 827	
Other assets	527		497	
Income taxes payable		\$ 41		\$ 19
Deferred income taxes and noncurrent liabilities		5,740		5,626

The Company has net operating loss ( NOL ) carryforwards in several jurisdictions. As of December 31, 2012, approximately \$194 million of deferred taxes on NOL carryforwards relate to foreign jurisdictions, none of which are individually significant. Approximately \$107 million of valuation allowances have been established on these foreign NOL carryforwards. In addition, the Company has approximately \$231 million of deferred tax assets relating to various U.S. tax credit carryforwards and NOL carryforwards, all of which are expected to be fully utilized prior to expiry.

**Table of Contents**

Income taxes paid in 2012, 2011 and 2010 were \$2.5 billion, \$2.7 billion and \$1.6 billion, respectively. Tax benefits relating to stock option exercises reflected in paid-in capital were \$94 million in 2012. These amounts were not material in 2011 or 2010.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

	2012	2011	2010
Balance January 1	\$ 4,277	\$ 4,919	\$ 4,743
Additions related to current year positions	496	695	479
Additions related to prior year positions	58	145	124
Reductions for tax positions of prior years <sup>(1)</sup>	(320)	(1,223)	(157)
Settlements	(67)	(259)	(256)
Lapse of statute of limitations	(19)		(14)
Balance December 31	\$ 4,425	\$ 4,277	\$ 4,919

<sup>(1)</sup> Amount for 2012 reflects the settlement with the CRA as discussed below. 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 \$4.4 billion at December 31, 2012, the income tax provision would reflect a favorable net impact of \$3.8 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, 2012 could decrease by up to \$900 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 \$(88) million in 2012, \$(95) million in 2011 and \$144 million in 2010. Liabilities for accrued interest and penalties were \$1.2 billion and \$1.3 billion as of December 31, 2012 and 2011, respectively.

As previously disclosed, the Canada Revenue Agency (the CRA) had proposed adjustments for 1999 and 2000 relating to intercompany pricing matters and, in July 2011, the CRA issued assessments for other miscellaneous audit issues for tax years 2001-2004. In 2012, Merck and the CRA reached a settlement for these years that calls for Merck to pay additional Canadian tax of approximately \$65 million. The Company's unrecognized tax benefits related to these matters exceeded the settlement amount and therefore the Company recorded a net \$112 million tax provision benefit in 2012. A portion of the taxes paid is expected to be creditable for U.S. tax purposes. The Company had previously established reserves for these matters. The resolution of these matters did not have a material effect on the Company's results of operations, financial position or liquidity.

In April 2011, the Internal Revenue Service (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 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.

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.



**Table of Contents**

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 2012.

At December 31, 2012, foreign earnings of \$53.4 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.

**17. 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 13) 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.

The calculations of earnings per share under the two-class method are as follows:

<i>Years Ended December 31</i>	<b>2012</b>	2011	2010
<i>Basic Earnings per Common Share</i>			
Net income attributable to Merck & Co., Inc.	<b>\$ 6,168</b>	\$ 6,272	\$ 861
Less: Income allocated to participating securities	<b>3</b>	15	2
Net income allocated to common shareholders	<b>\$ 6,165</b>	\$ 6,257	\$ 859
Average common shares outstanding	<b>3,041</b>	3,071	3,095
	<b>\$ 2.03</b>	\$ 2.04	\$ 0.28
<i>Earnings per Common Share Assuming Dilution</i>			
Net income attributable to Merck & Co., Inc.	<b>\$ 6,168</b>	\$ 6,272	\$ 861
Less: Income allocated to participating securities	<b>3</b>	15	2
Net income allocated to common shareholders	<b>\$ 6,165</b>	\$ 6,257	\$ 859
Average common shares outstanding	<b>3,041</b>	3,071	3,095
Common shares issuable <sup>(1)</sup>	<b>35</b>	23	25
Average common shares outstanding assuming dilution	<b>3,076</b>	3,094	3,120
	<b>\$ 2.00</b>	\$ 2.02	\$ 0.28

<sup>(1)</sup> Issuable primarily under share-based compensation plans.

In 2012, 2011 and 2010, 104 million, 169 million and 174 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****18. Other Comprehensive (Loss) Income**

The components of *Other comprehensive (loss) income* are as follows:

	Pretax	Tax	After Tax
<b>Year Ended December 31, 2012</b>			
Net unrealized loss on derivatives	\$ (198)	\$ 77	\$ (121)
Net loss realization	33	(13)	20
Derivatives	(165)	64	(101)
Net unrealized gain on investments	74	(10)	64
Net gain realization	(13)	1	(12)
Investments	61	(9)	52
Benefit plan net (loss) gain and prior service (credit) cost, net of amortization	(1,716)	395	(1,321)
Cumulative translation adjustment	(99)	(81)	(180)
	\$ (1,919)	\$ 369	\$ (1,550)
<b>Year Ended December 31, 2011</b>			
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 (credit) cost, net of amortization	(422)	119	(303)
Cumulative translation adjustment	435	(1)	434
	\$ (64)	\$ 148	\$ 84
<b>Year Ended December 31, 2010</b>			
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 gain (loss) and prior service cost (credit), net of amortization	683	(257)	426
Cumulative translation adjustment	(835)	(121)	(956)
	\$ (32)	\$ (417)	\$ (449)

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>	<b>2012</b>	2011
Net unrealized (loss) gain on derivatives	\$ (97)	\$ 4
Net unrealized gain on investments	73	21
Pension plan net loss	<b>(4,056)</b>	(2,793)
Other postretirement benefit plan net loss	<b>(414)</b>	(402)
Pension plan prior service credit	<b>449</b>	502
Other postretirement benefit plan prior service credit	<b>354</b>	347
Cumulative translation adjustment	<b>(991)</b>	(811)
	<b>\$ (4,682)</b>	\$ (3,132)

**19. 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, as well as club stores and specialty channels.

The accounting policies for the segments described above are the same as those described in Note 2.

**Table of Contents**

Sales of the Company's products were as follows:

	2012	2011	2010
Primary Care and Women's Health			
<i>Cardiovascular</i>			
Zetia	\$ 2,567	\$ 2,428	\$ 2,297
Vytorin	1,747	1,882	2,014
<i>Diabetes and Obesity</i>			
Januvia	4,086	3,324	2,385
Janumet	1,659	1,363	954
<i>Respiratory</i>			
Singulair	3,853	5,479	4,987
Nasonex	1,268	1,286	1,219
Clarinet	393	621	623
Dulera	207	96	8
Asmanex	185	206	208
<i>Women's Health and Endocrine</i>			
Fosamax	676	855	926
NuvaRing	623	623	559
Follistim AQ	468	530	528
Implanon	348	294	236
Cerazette	271	268	209
<i>Other</i>			
Maxalt	638	639	550
Arcoxia	453	431	398
Avelox	201	322	316
Hospital and Specialty			
<i>Immunology</i>			
Remicade	2,076	2,667	2,714
Simponi	331	264	97
<i>Infectious Disease</i>			
Isentress	1,515	1,359	1,090
PegIntron	653	657	737
Cancidas	619	640	611
Victrilis	502	140	
Invanz	445	406	362
Primaxin	384	515	610
Noxafil	258	230	198
<i>Oncology</i>			
Temodar	917	935	1,065
Emend	489	419	378
<i>Other</i>			
Cosopt/Trusopt	444	477	484
Bridion	261	201	103
Integrilin	211	230	266
Diversified Brands			
Cozaar/Hyzaar	1,284	1,663	2,104
Propecia	424	447	447
Zocor	383	456	468
Claritin Rx	244	314	296
Remeron	232	241	223
Proscar	217	223	216
Vasotec/Vaseretic	192	231	255
<i>Vaccines<sup>(1)</sup></i>			
Gardasil	1,631	1,209	988
ProQuad/M-M-R II/Varivax	1,273	1,202	1,378
Zostavax	651	332	243
RotaTeq	601	651	519
Pneumovax	580	498	376
Other pharmaceutical <sup>(2)</sup>	4,141	4,035	4,622
Total Pharmaceutical segment sales	40,601	41,289	39,267
Other segment sales <sup>(3)</sup>	6,412	6,428	6,159

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

Total segment sales	47,013	47,717	45,426
Other <sup>(4)</sup>	254	330	561
	<b>\$ 47,267</b>	<b>\$ 48,047</b>	<b>\$ 45,987</b>

*(1) 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.*

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

*(3) Represents the non-reportable segments of Animal Health, Consumer Care and Alliances. The Alliances segment includes revenue from the Company's relationship with AZLP.*

*(4) 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>	<b>2012</b>	2011	2010
United States	<b>\$ 20,392</b>	\$ 20,495	\$ 20,226
Europe, Middle East and Africa	<b>12,990</b>	13,782	13,497
Japan	<b>5,102</b>	4,835	3,768
Other	<b>8,783</b>	8,935	8,496
	<b>\$ 47,267</b>	\$ 48,047	\$ 45,987

A reconciliation of total segment profits to consolidated *Income before taxes* is as follows:

<i>Years Ended December 31</i>	<b>2012</b>	2011	2010
Segment profits:			
Pharmaceutical segment	<b>\$ 25,852</b>	\$ 25,617	\$ 23,864
Other segments	<b>3,163</b>	2,995	2,849
Total segment profits	<b>29,015</b>	28,612	26,713
Other profits (losses)	<b>26</b>	(11)	(8)
Unallocated:			
Interest income	<b>232</b>	145	83
Interest expense	<b>(714)</b>	(695)	(715)
Equity income from affiliates	<b>102</b>	41	(18)
Depreciation and amortization	<b>(2,059)</b>	(2,412)	(2,671)
Research and development	<b>(7,240)</b>	(7,527)	(10,710)
Amortization of purchase accounting adjustments	<b>(4,872)</b>	(5,000)	(6,566)
Restructuring costs	<b>(664)</b>	(1,306)	(985)
Net charge related to settlement of ENHANCE Litigation	<b>(493)</b>		
Arbitration settlement charge		(500)	
Vioxx Liability Reserve			(950)
Gain on AstraZeneca asset option exercise			443
Other unallocated, net	<b>(4,594)</b>	(4,013)	(2,963)
	<b>\$ 8,739</b>	\$ 7,334	\$ 1,653

Segment profits are comprised of segment sales less standard costs and certain operating expenses directly incurred by the segments. For internal management reporting presented to the chief operating decision maker, Merck does not allocate materials and production costs, other than standard costs, the majority of 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. In addition, costs related to restructuring activities, as well as the amortization of purchase accounting adjustments are not allocated to segments.

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.

Other unallocated, net includes expenses from corporate and manufacturing cost centers, product intangible asset impairment charges, gain or losses on sales of businesses and other miscellaneous income or expense items.

**Table of Contents**

Equity income from affiliates and depreciation and amortization included in segment profits is as follows:

	Pharmaceutical	All Other	Total
<i>Year Ended December 31, 2012</i>			
<b>Included in segment profits:</b>			
<b>Equity income from affiliates</b>	<b>\$ 36</b>	<b>\$ 504</b>	<b>\$ 540</b>
<b>Depreciation and amortization</b>	<b>(25)</b>	<b>(20)</b>	<b>(45)</b>
<i>Year Ended December 31, 2011</i>			
<b>Included in segment profits:</b>			
Equity income from affiliates	59	510	569
Depreciation and amortization	(51)	(20)	(71)
<i>Year Ended December 31, 2010</i>			
<b>Included in segment profits:</b>			
Equity income from affiliates	90	515	605
Depreciation and amortization	(101)	(17)	(118)

Property, plant and equipment, net by geographic area where located is as follows:

<i>Years Ended December 31</i>	2012	2011	2010
United States	<b>\$ 10,490</b>	\$ 10,646	\$ 11,078
Europe, Middle East and Africa	<b>3,688</b>	3,780	4,014
Japan	<b>243</b>	279	315
Other	<b>1,609</b>	1,592	1,675
	<b>\$ 16,030</b>	\$ 16,297	\$ 17,082

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, comprehensive income, equity and cash flows present fairly, in all material respects, the financial position of Merck & Co., Inc. and its subsidiaries at December 31, 2012 and December 31, 2011, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2012 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, 2012, 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 26, 2013

**Table of Contents****(b) Supplementary Data**

Selected quarterly financial data for 2012 and 2011 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 <sup>(1)</sup>	3rd Q	2nd Q <sup>(2)</sup>	1st Q <sup>(3)</sup>
<b>2012<sup>(4)</sup></b>				
<b>Sales</b>	<b>\$ 11,738</b>	<b>\$ 11,488</b>	<b>\$ 12,311</b>	<b>\$ 11,731</b>
<b>Materials and production</b>	<b>4,160</b>	<b>4,137</b>	<b>4,112</b>	<b>4,037</b>
<b>Marketing and administrative</b>	<b>3,390</b>	<b>3,063</b>	<b>3,249</b>	<b>3,074</b>
<b>Research and development</b>	<b>2,224</b>	<b>1,918</b>	<b>2,165</b>	<b>1,862</b>
<b>Restructuring costs</b>	<b>191</b>	<b>110</b>	<b>144</b>	<b>219</b>
<b>Equity income from affiliates</b>	<b>(231)</b>	<b>(158)</b>	<b>(142)</b>	<b>(110)</b>
<b>Other (income) expense, net</b>	<b>669</b>	<b>200</b>	<b>103</b>	<b>142</b>
<b>Income before taxes</b>	<b>1,335</b>	<b>2,218</b>	<b>2,680</b>	<b>2,507</b>
<b>Net income attributable to Merck &amp; Co., Inc.</b>	<b>908</b>	<b>1,729</b>	<b>1,793</b>	<b>1,738</b>
<b>Basic earnings per common share attributable to Merck &amp; Co., Inc. common shareholders</b>	<b>\$ 0.30</b>	<b>\$ 0.57</b>	<b>\$ 0.59</b>	<b>\$ 0.57</b>
<b>Earnings per common share assuming dilution attributable to Merck &amp; Co., Inc. common shareholders</b>	<b>\$ 0.30</b>	<b>\$ 0.56</b>	<b>\$ 0.58</b>	<b>\$ 0.56</b>
<b>2011<sup>(4)</sup></b>				
<b>Sales</b>	<b>\$ 12,294</b>	<b>\$ 12,022</b>	<b>\$ 12,151</b>	<b>\$ 11,580</b>
<b>Materials and production</b>	<b>4,176</b>	<b>4,352</b>	<b>4,284</b>	<b>4,059</b>
<b>Marketing and administrative</b>	<b>3,704</b>	<b>3,340</b>	<b>3,525</b>	<b>3,164</b>
<b>Research and development</b>	<b>2,419</b>	<b>1,954</b>	<b>1,936</b>	<b>2,158</b>
<b>Restructuring costs</b>	<b>533</b>	<b>119</b>	<b>668</b>	<b>(14)</b>
<b>Equity income from affiliates</b>	<b>(257)</b>	<b>(161)</b>	<b>(55)</b>	<b>(138)</b>
<b>Other (income) expense, net</b>	<b>139</b>	<b>66</b>	<b>121</b>	<b>622</b>
<b>Income before taxes</b>	<b>1,580</b>	<b>2,352</b>	<b>1,672</b>	<b>1,729</b>
<b>Net income attributable to Merck &amp; Co., Inc.</b>	<b>1,512</b>	<b>1,692</b>	<b>2,024</b>	<b>1,043</b>
<b>Basic earnings per common share attributable to Merck &amp; Co., Inc. common shareholders</b>	<b>\$ 0.50</b>	<b>\$ 0.55</b>	<b>\$ 0.65</b>	<b>\$ 0.34</b>
<b>Earnings per common share assuming dilution attributable to Merck &amp; Co., Inc. common shareholders</b>	<b>\$ 0.49</b>	<b>\$ 0.55</b>	<b>\$ 0.65</b>	<b>\$ 0.34</b>

<sup>(1)</sup> Amounts for 2012 include a net charge related to a litigation settlement (see Note 11).

<sup>(2)</sup> Amounts for 2011 include a net benefit relating to the settlement of a federal income tax audit (see Note 16).

<sup>(3)</sup> Amounts for 2011 include a charge relating to the resolution of the arbitration proceeding with J&J (see Note 5).

<sup>(4)</sup> Amounts for 2012 and 2011 reflect acquisition-related costs (see Note 8) and the impact of restructuring actions (see Note 3).



---

**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. Based on this evaluation, management concluded that internal control over financial reporting was effective as of December 31, 2012. 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.

**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, annually all employees of the Company are required to complete Code of Conduct training, which includes financial stewardship. This training 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, 2012.

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, 2012, 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 Proposal 1. Election of Directors of the Company's Proxy Statement for the Annual Meeting of Shareholders to be held May 28, 2013. Information on executive officers is set forth in Part I of this document on pages 33 through 36.

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 28, 2013.

The Company has 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](http://www.merck.com/about/code_of_conduct.pdf). Every Merck employee is responsible for adhering to business practices that are in accordance with the law and with ethical principles that reflect the highest standards of corporate and individual behavior. A printed copy will be sent, without charge, to any shareholder who requests it by writing to the Chief Ethics and Compliance 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 28, 2013.

**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, "Pension Benefits" table, "Nonqualified Deferred Compensation and related table", "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 28, 2013.

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 28, 2013.

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 28, 2013.

**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 38. 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 28, 2013.

**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 28, 2013.



**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 28, 2013.

**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 28, 2013.

**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, 2012, 2011 and 2010

Consolidated statement of comprehensive income for the years ended December 31, 2012, 2011 and 2010

Consolidated balance sheet as of December 31, 2012 and 2011

Consolidated statement of equity for the years ended December 31, 2012, 2011 and 2010

Consolidated statement of cash flows for the years ended December 31, 2012, 2011 and 2010

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**

<b>Number</b>	<b>Description</b>
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 January 1, 2013) Incorporated by reference to Merck & Co., Inc.'s Current Report on Form 8-K filed December 21, 2011
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, dated as of October 1, 1997, 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
4.11	Third Supplemental Indenture, dated May 1, 2012, among Merck Sharp & Dohme Corp., Schering Corporation, Merck & Co., Inc. and U.S. Bank Trust National Association, as Trustee Incorporated by reference to Merck & Co., Inc.'s Form 10-Q Quarterly Report for the quarter year ended March 31, 2012
*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

**Table of Contents****Exhibit**

<b>Number</b>	<b>Description</b>
*10.2	Merck & Co., Inc. Deferral Program Including the Base Salary Deferral Plan (Amended and Restated effective January 1, 2013)
*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	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
*10.8	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
*10.9	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
*10.10	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
*10.11	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
*10.12	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
*10.13	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
*10.14	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
*10.15	Form of Performance share unit terms for 2011 and 2012 grants under the Merck & Co., Inc. 2010 Incentive Stock Plan
*10.16	Stock option terms for 2012 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-K Annual Report for the fiscal year ended December 31, 2011
*10.17	Restricted stock unit terms for 2012 quarterly and annual grants under the Merck & Co., Inc. 2010 Incentive Stock Plan Incorporated by reference to Merck & Co., Inc. s Form 10-K Annual Report for the fiscal year ended December 31, 2011
*10.18	Performance share unit terms for 2012 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, 2012
*10.19	Form of Stock option agreement for 2013 and later quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan
*10.20	Form of Restricted stock unit agreement for 2013 and later quarterly and annual grants under the Merck & Co., Inc. 2010 Incentive Stock Plan

**Table of Contents****Exhibit**

<b>Number</b>	<b>Description</b>
*10.21	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
*10.22	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
*10.23	Merck & Co., Inc. Change in Control Separation Benefits Plan (Effective as Amended and Restated, as of January 1, 2013) Incorporated by reference to Merck & Co., Inc. s Current Report on Form 8-K dated November 29, 2012
*10.24	Merck & Co., Inc. U.S. Separation Benefits Plan (effective as of January 1, 2012) Incorporated by reference to Merck & Co., Inc. s Form 10-K Annual Report for the fiscal year ended December 31, 2011
*10.25	Merck & Co., Inc. U.S. Separation Benefits Plan (effective as of January 1, 2013)
*10.26	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
*10.27	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
*10.28	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
*10.29	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
*10.30	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
*10.31	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
*10.32	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
*10.33	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
10.34	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
10.35	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
10.36	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
10.37	Amended and Restated KBI Shares Option Agreement dated as of June 26, 2012 by and among AstraZeneca AB, Merck Sharp & Dohme Corp. and Merck Holdings LLC Incorporated by reference to Merck & Co., Inc. s Form 10-Q Quarterly Report for the period ended September 30, 2012
10.38	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
10.39	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



**Table of Contents****Exhibit**

<b>Number</b>	<b>Description</b>
10.40	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
10.41	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
10.42	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
10.43	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
10.44	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
10.45	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
10.46	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
10.47	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
10.48	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
10.49	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
10.50	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
10.51	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
10.52	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
10.53	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
10.54	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
10.55	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
10.56	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

**Table of Contents**

**Exhibit**

<b>Number</b>	<b>Description</b>
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 148 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, 2012, formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Statement of Income, (ii) the Consolidated Statement of Comprehensive Income, (iii) the Consolidated Balance Sheet, (iv) the Consolidated Statement of Cash Flows, and (v) 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, 2013

MERCK & CO., INC.

By: KENNETH C. FRAZIER  
(Chairman, President and Chief Executive Officer)

By: /S/ GERALYN S. RITTER  
Geraldyn S. Ritter  
(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, 2013
PETER N. KELLOGG	Executive Vice President and Chief Financial Officer; Principal Financial Officer	February 28, 2013
JOHN CANAN	Senior Vice President Finance-Global Controller; Principal Accounting Officer	February 28, 2013
LESLIE A. BRUN	Director	February 28, 2013
THOMAS R. CECH	Director	February 28, 2013
THOMAS H. GLOCER	Director	February 28, 2013
WILLIAM B. HARRISON, JR.	Director	February 28, 2013
C. ROBERT KIDDER	Director	February 28, 2013
ROCHELLE B. LAZARUS	Director	February 28, 2013
CARLOS E. REPRESAS	Director	February 28, 2013
PATRICIA F. RUSSO	Director	February 28, 2013
CRAIG B. THOMPSON	Director	February 28, 2013
WENDELL P. WEEKS	Director	February 28, 2013
PETER C. WENDELL	Director	February 28, 2013

Geraldyn S. Ritter, by signing her name hereto, does hereby sign this document pursuant to powers 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/ GERALYN S. RITTER  
Geraldyn S. Ritter  
(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. 333-185248, 333-185245, 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 26, 2013 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 26, 2013

**Table of Contents****EXHIBIT INDEX****Exhibit**

<b>Number</b>	<b>Description</b>
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 January 1, 2013) Incorporated by reference to Merck & Co., Inc.'s Current Report on Form 8-K filed December 21, 2011
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, dated as of October 1, 1997, 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
4.11	Third Supplemental Indenture, dated May 1, 2012, among Merck Sharp & Dohme Corp., Schering Corporation, Merck & Co., Inc. and U.S. Bank Trust National Association, as Trustee Incorporated by reference to Merck & Co., Inc.'s Form 10-Q Quarterly Report for the quarter year ended March 31, 2012
*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

**Table of Contents****Exhibit**

<b>Number</b>	<b>Description</b>
*10.2	Merck & Co., Inc. Deferral Program Including the Base Salary Deferral Plan (Amended and Restated effective January 1, 2013)
*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	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
*10.8	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
*10.9	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
*10.10	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
*10.11	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
*10.12	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
*10.13	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
*10.14	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
*10.15	Form of Performance share unit terms for 2011 and 2012 grants under the Merck & Co., Inc. 2010 Incentive Stock Plan
*10.16	Stock option terms for 2012 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-K Annual Report for the fiscal year ended December 31, 2011
*10.17	Restricted stock unit terms for 2012 quarterly and annual grants under the Merck & Co., Inc. 2010 Incentive Stock Plan Incorporated by reference to Merck & Co., Inc. s Form 10-K Annual Report for the fiscal year ended December 31, 2011
*10.18	Performance share unit terms for 2012 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, 2012
*10.19	Form of Stock option agreement for 2013 and later quarterly and annual non-qualified option grants under the Merck & Co., Inc. 2010 Incentive Stock Plan
*10.20	Form of Restricted stock unit agreement for 2013 and later quarterly and annual grants under the Merck & Co., Inc. 2010 Incentive Stock Plan

**Table of Contents****Exhibit**

<b>Number</b>	<b>Description</b>
*10.21	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
*10.22	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
*10.23	Merck & Co., Inc. Change in Control Separation Benefits Plan (Effective as Amended and Restated, as of January 1, 2013) Incorporated by reference to Merck & Co., Inc. s Current Report on Form 8-K dated November 29, 2012
*10.24	Merck & Co., Inc. U.S. Separation Benefits Plan (effective as of January 1, 2012) Incorporated by reference to Merck & Co., Inc. s Form 10-K Annual Report for the fiscal year ended December 31, 2011
*10.25	Merck & Co., Inc. U.S. Separation Benefits Plan (effective as of January 1, 2013)
*10.26	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
*10.27	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
*10.28	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
*10.29	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
*10.30	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
*10.31	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
*10.32	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
*10.33	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
10.34	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
10.35	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
10.36	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
10.37	Amended and Restated KBI Shares Option Agreement dated as of June 26, 2012 by and among AstraZeneca AB, Merck Sharp & Dohme Corp. and Merck Holdings LLC Incorporated by reference to Merck & Co., Inc. s Form 10-Q Quarterly Report for the period ended September 30, 2012
10.38	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

**Table of Contents****Exhibit**

<b>Number</b>	<b>Description</b>
10.39	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
10.40	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
10.41	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
10.42	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
10.43	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
10.44	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
10.45	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
10.46	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
10.47	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
10.48	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
10.49	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
10.50	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
10.51	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
10.52	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
10.53	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
10.54	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
10.55	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



**Table of Contents**

**Exhibit**

<b>Number</b>	<b>Description</b>
10.56	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 148 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, 2012, formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Statement of Income, (ii) the Consolidated Statement of Comprehensive Income, (iii) the Consolidated Balance Sheet, (iv) the Consolidated Statement of Cash Flows, and (v) 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.*