

Merck & Co. Inc.
Form 10-K
March 01, 2010

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As filed with the Securities and Exchange Commission on March 1, 2010

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

FORM 10-K

(MARK ONE)

- b** **Annual Report Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**
For the Fiscal Year Ended December 31, 2009
- or
- o** **Transition Report Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**
For the transition period from _____ to _____

Commission File No. 1-6571

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

Incorporated in New Jersey

*I.R.S. Employer
Identification No. 22-1918501*

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
Mandatory Convertible Preferred Stock	New York Stock Exchange

Number of shares of Common Stock (\$0.50 par value) outstanding as of January 29, 2010: 3,115,317,260.

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Aggregate market value of Common Stock (\$0.50 par value) held by non-affiliates on June 30, 2009 based on closing price on June 30, 2009: \$41,003,000,000.

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:

<i>Document</i>	<i>Part of Form 10-K</i>
Proxy Statement for the Annual Meeting of Shareholders to be held May 25, 2010, to be filed with the Securities and Exchange Commission within 120 days after the close of the fiscal year covered by this report	Part III

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Table of Contents**PART I****Item 1. Business.**

On November 3, 2009, Merck & Co., Inc. (Old Merck) and Schering-Plough Corporation (Schering-Plough) completed their previously-announced merger (the Merger). In the Merger, Schering-Plough acquired all of the shares of Old Merck, which became a wholly-owned subsidiary of Schering-Plough and was renamed Merck Sharp & Dohme Corp. Schering-Plough continued as the surviving public company and was renamed Merck & Co., Inc. (New Merck or the Company). However, for accounting purposes only, the Merger was treated as an acquisition with Old Merck considered the accounting acquirer. Accordingly, the accompanying financial statements reflect Old Merck's stand-alone operations as they existed prior to the completion of the Merger. The results of Schering-Plough's business have been included in New Merck's financial statements only for periods subsequent to the completion of the Merger. Therefore, New Merck's financial results for 2009 do not reflect a full year of legacy Schering-Plough operations. References in this report and in the accompanying financial statements to Merck for periods prior to the Merger refer to Old Merck and for periods after the completion of the Merger to New Merck.

The Company is a global health care company that delivers innovative health solutions through its medicines, vaccines, biologic therapies, and consumer and animal 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 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, 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 preventative 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's professional representatives communicate the effectiveness, safety and value of its pharmaceutical and vaccine products to health care professionals in private practice, group practices and managed care organizations. The Company also has animal health operations that discover, develop, manufacture and market animal health products, including vaccines. The Company's professional representatives communicate the safety and value of the Company's animal health products to veterinarians, distributors and animal producers. Additionally, the Company has consumer health care operations that develop, manufacture and market Over-the-Counter (OTC), foot care and sun care products, which are sold through wholesale and retail drug, food chain and mass merchandiser outlets in the United States and Canada.

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

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Overview

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As discussed above, the Merger was completed on November 3, 2009. In the Merger, Old Merck shareholders received one share of common stock of New Merck for each share of Old Merck stock that they owned, and Schering-Plough shareholders received 0.5767 of a share of common stock of New Merck and \$10.50 in cash for each share of Schering-Plough stock that they owned. The consideration in the Merger was valued at \$49.6 billion in the aggregate. Schering-Plough was Old Merck's long-term partner in the Merck/Schering-Plough cholesterol partnership (the MSP Partnership). The cash portion of the consideration was funded with a

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combination of existing cash, including proceeds from the sale of Old Merck's interest in Merial Limited, the sale or redemption of investments and the issuance of debt.

The combined company has a research and development pipeline with greater depth and breadth and many promising drug candidates, a significantly broader portfolio of medicines and an expanded presence in key international markets, particularly in high-growth emerging markets. The Company anticipates that the efficiencies gained from the Merger will allow it to invest in promising pipeline candidates, as well as strategic external research and development opportunities.

The combination increased the Company's pipeline of early, mid- and late stage product candidates, including a significant increase in the number of potential medicines the Company has in Phase III development to 19 candidates. Additionally, a number of candidates are currently under review in the United States and internationally.

The Merger also is expected to accelerate the expansion into therapeutic areas that Old Merck has focused on in recent years with the addition of Schering-Plough's established presence and expertise in oncology, neuroscience and novel biologics. Further, the Merger is expected to broaden the Company's commercial portfolio with leading franchises in key therapeutic areas, including cardiovascular, respiratory, oncology, neuroscience, infectious diseases, immunology and women's health. Additionally, the combined company is expected to realize potential benefits from its animal health business and portfolio of consumer health brands, including *Claritin*, *Coppertone* and *Dr. Scholl's*. Many of the legacy Schering-Plough's products are expected to have long periods of marketing exclusivity and, by leveraging the combined company's expanded product offerings, the Company expects to benefit from additional revenue growth opportunities. For example, the combined company is expected to have expanded opportunities for life-cycle management through the introduction of potential new combinations and formulations of existing products of the two legacy companies. Also, the Company will have an expanded global presence and a more geographically diverse revenue base. Schering-Plough's significant international presence will accelerate Old Merck's own international growth efforts.

During 2009, revenue increased 15% driven largely by the incremental sales resulting from the inclusion of the post-Merger results of legacy Schering-Plough products, such as *Remicade* (infliximab), a treatment for inflammatory diseases, *Temodar* (temozolomide), a treatment for certain types of brain tumors, *Nasonex* (mometasone furoate monohydrate) nasal spray, an inhaled nasal corticosteroid for the treatment of nasal allergy symptoms, and *PegIntron* (peginterferon alpha-2b) for treating chronic hepatitis C, as well as the recognition of revenue from sales of *Zetia* (ezetimibe) and *Vytorin* (ezetimibe/simvastatin), cholesterol modifying medicines. Prior to the Merger, sales of *Zetia* and *Vytorin* were recognized by the MSP Partnership and the results of Old Merck's interest in the MSP Partnership were recorded in *Equity income from affiliates*. As a result of the Merger, the MSP Partnership is now wholly-owned by the Company and therefore revenues from these products for the post-Merger period are reflected in *Sales*. Additionally, the Company recognized sales in the post-Merger period from legacy Schering-Plough animal health and consumer health care products. Also contributing to the sales increase was growth in *Januvia* (sitagliptin phosphate) and *Janumet* (sitagliptin phosphate and metformin hydrochloride) for the treatment of type 2 diabetes, *Isentress* (raltegravir), an antiretroviral therapy for the treatment of HIV infection, *Singulair* (montelukast sodium), a medicine indicated for the chronic treatment of asthma and the relief of symptoms of allergic rhinitis, *Varivax* (Varicella Virus Vaccine Live), a vaccine to help prevent chickenpox (varicella), and *Pneumovax* (pneumococcal vaccine polyvalent), a vaccine to help prevent pneumococcal disease. These increases were partially offset by lower sales of *Fosamax* (alendronate sodium) for the treatment and prevention of osteoporosis. *Fosamax* and *Fosamax Plus D* (alendronate sodium/cholecalciferol) lost market exclusivity for substantially all formulations in the United States in February 2008 and April 2008, respectively. Revenue was also negatively affected by lower sales of *Gardasil* [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant], a vaccine to help prevent cervical, vulvar and vaginal cancers, precancerous or dysplastic lesions, and genital warts caused by human papillomavirus (HPV) types 6, 11, 16 and 18, *Cosopt* (dorzolamide hydrochloride and timolol maleate ophthalmic

solution)/*Trusopt* (dorzolamide hydrochloride ophthalmic solution), ophthalmic products which lost U.S. market exclusivity in October 2008, and lower revenue from the Company's relationship with AstraZeneca LP (AZLP). Other products experiencing declines include *RotaTeq* (Rotavirus Vaccine, Live, Oral, Pentavalent), a vaccine to help protect against rotavirus gastroenteritis in infants and

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children, *Zocor* (simvastatin), the Company's statin for modifying cholesterol, and *Primaxin* (imipenem and cilastatin sodium) for the treatment of bacterial infections.

As a result of the Merger, the Company expects to achieve substantial cost savings across all areas, including from consolidation in both sales and marketing and research and development, the application of the Company's lean manufacturing and sourcing strategies to the expanded operations, and the full integration of the MSP Partnership.

In February 2010, the Company announced the first phase of a new global restructuring program (the Merger Restructuring Program) in conjunction with the integration of the legacy Merck and legacy Schering-Plough businesses. This Merger Restructuring Program is intended to optimize the cost structure of the combined Company. As part of the first phase of the Merger Restructuring Program, by the end of 2012, the Company expects to reduce its total workforce by approximately 15% across all areas of the Company worldwide. The Company also plans to eliminate 2,500 vacant positions as part of the first phase of the program. These workforce reductions will primarily come from the elimination of duplicative positions in sales, administrative and headquarters organizations, as well as from the consolidation of certain manufacturing facilities and research and development operations. The Company will continue to hire new employees in strategic growth areas of the business during this period. Certain actions, such as the ongoing reevaluation of manufacturing and research and development facilities worldwide, have not yet been completed, but will be included later in 2010 in other phases of the Merger Restructuring Program. In connection with the first phase of the Merger Restructuring Program, separation costs under the Company's existing severance programs worldwide were recorded in the fourth quarter of 2009 to the extent such costs were probable and reasonably estimable. The Company recorded pretax restructuring costs of \$1.5 billion, primarily employee separation costs, related to the Merger Restructuring Program in the fourth quarter of 2009. This first phase of the Merger Restructuring Program is expected to be completed by the end of 2012 with the total pretax costs estimated to be \$2.6 billion to \$3.3 billion. The Company estimates that approximately 85% of the cumulative pretax costs relate to cash outlays, primarily related to employee separation expense. Approximately 15% of the cumulative pretax costs are non-cash, relating primarily to the accelerated depreciation of facilities to be closed or divested.

The Company expects this first phase of the Merger Restructuring Program to yield annual savings in 2012 of approximately \$2.6 billion to \$3.0 billion. These anticipated savings relate only to the first phase of the Merger Restructuring Program and therefore are only a portion of the estimated \$3.5 billion of incremental annual savings originally disclosed when the Merger was announced. The Company expects that additional savings will be generated by subsequent phases of the Merger Restructuring Program that will be announced later this year, as well as by non-restructuring related activities, such as procurement savings initiatives. These cost savings, which are expected to come from all areas of the Company's pharmaceutical business, are in addition to the previously announced ongoing cost reduction initiatives at both legacy companies.

As a result of the Merger, the Company obtained a controlling interest in the MSP Partnership and it is now owned 100% by the Company. Accordingly, the Company was required to remeasure Merck's previously held equity interest in the MSP Partnership at its merger-date fair value and recognize the resulting gain in earnings. As a result, the Company recorded a gain of \$7.5 billion recognized in *Other (income) expense, net* in 2009. Also during 2009, Old Merck sold its 50% interest in Merial Limited (Merial) to sanofi-aventis for \$4 billion in cash. The sale resulted in the recognition of a \$3.2 billion gain reflected in *Other (income) expense, net* in 2009. See Note 10 to the consolidated financial statements in Item 8. Financial Statements and Supplementary Data below for further information.

Earnings per common share (EPS) assuming dilution for 2009 were \$5.65, which reflect a net impact of \$2.40 resulting from gains related to the MSP Partnership and the sale of Merial, partially offset by increased expenses from the amortization of purchase accounting adjustments, restructuring and merger-related costs. EPS in 2009 were also affected by the dilutive impact of shares issued in the Merger.

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<i>(\$ in millions)</i>	2009	2008	2007
Pharmaceutical:			
<i>Bone, Respiratory, Immunology and Dermatology</i>			
Singulair	\$ 4,659.7	\$ 4,336.9	\$ 4,266.3
Fosamax	1,099.8	1,552.7	3,049.0
Propecia	440.3	429.1	405.4
Remicade	430.7		
Arcoxia	357.5	377.3	329.1
Nasonex	164.9		
Clarinex	100.6		
Asmanex	37.0		
<i>Cardiovascular</i>			
Vytorin	440.8	84.2	84.3
Zetia	402.9	6.4	6.5
Integrilin	45.9		
<i>Diabetes and Obesity</i>			
Januvia	1,922.1	1,397.1	667.5
Janumet	658.4	351.1	86.4
<i>Infectious Disease</i>			
Isentress	751.8	361.1	41.3
Primaxin	688.9	760.4	763.5
Cancidas	616.7	596.4	536.9
Invanz	292.9	265.0	190.2
Crixivan/Stocrin	206.1	275.1	310.2
PegIntron	148.7		
Avelox	66.2		
Rebetol	36.1		
<i>Mature Brands</i>			
Cozaar/Hyzaar	3,560.7	3,557.7	3,350.1
Zocor	558.4	660.1	876.5
Vasotec/Vaseretic	310.8	356.7	494.6
Proscar	290.9	323.5	411.0
Claritin Rx	71.1		
Proventil	26.2		
<i>Neurosciences and Ophthalmology</i>			
Maxalt	574.5	529.2	467.3
Cosopt/Trusopt	503.5	781.2	786.8
Remeron	38.5		
Subutex/Suboxone	36.3		
<i>Oncology</i>			
Emend	313.1	259.7	201.7
Temodar	188.1		

Caelyx	46.5		
Intron A	38.4		
Vaccines ⁽²⁾			
ProQuad/M-M-R II/Varivax	1,368.5	1,268.5	1,347.1
Gardasil	1,118.4	1,402.8	1,480.6
RotaTeq	521.9	664.5	524.7
Pneumovax	345.6	249.3	233.2
Zostavax	277.4	312.4	236.0
<i>Women's Health and Endocrine</i>			
Follistim/Puregon	96.5		
NuvaRing	88.3		
Other Pharmaceutical ⁽³⁾	1,294.9	922.9	1,136.6
	25,236.5	22,081.3	22,282.8
Other segment revenues ⁽⁴⁾	2,114.0	1,694.1	1,848.1
Total segment revenues	27,350.5	23,775.4	24,130.9
Other ⁽⁵⁾	77.8	74.9	66.8
	\$ 27,428.3	\$ 23,850.3	\$ 24,197.7

⁽¹⁾ Sales of legacy Schering-Plough products only reflect results for the post-Merger period through December 31, 2009. Sales of MSP Partnership products Zetia and Vytorin represent sales for the post-Merger period through December 31, 2009. Prior to the Merger, sales of Zetia and Vytorin were primarily recognized by the MSP Partnership and the results of Old Merck's interest in the MSP Partnership were recorded in Equity income from affiliates. Sales of Zetia and Vytorin in 2008 and 2007 reflect Old Merck's sales of these products in Latin America which was not part of the MSP Partnership.

⁽²⁾ These amounts do not reflect sales of vaccines sold in most major European markets through the Company's joint venture, Sanofi Pasteur MSD, the results of which are reflected in Equity income from affiliates. These amounts do, however, reflect supply sales to Sanofi Pasteur MSD.

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

⁽⁴⁾ Reflects other non-reportable segments, including animal health and consumer health care, and revenue from the Company's relationship with AZLP primarily relating to sales of Nexium, as well as Prilosec. Revenue from AZLP was \$1.4 billion, \$1.6 billion and \$1.7 billion in 2009, 2008 and 2007, respectively.

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

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Pharmaceutical

The Company's pharmaceutical products include therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. Among these are:

Bone, Respiratory, Immunology and Dermatology: *Singulair*; *Remicade*; *Fosamax*; *Nasonex*; *Propecia* (finasteride), a product for the treatment of male pattern hair loss; *Clarinet* (desloratadine), a non-sedating antihistamine for the treatment of allergic rhinitis; *Arcoxia* (etoricoxib) for the treatment of arthritis and pain; and *Asmanex Twisthaler* (mometasone furoate inhalation powder), an oral dry-powder corticosteroid inhaler for first-line maintenance treatment of asthma.

Cardiovascular Disease: *Zetia* (marketed as *Ezetrol* outside the United States); *Vytorin* (marketed as *Inegy* outside the United States) and *Integrilin* (eptifibatide) Injection, a platelet receptor GP IIb/IIIa inhibitor for the treatment of patients with acute coronary syndrome and those undergoing percutaneous coronary intervention in the United States, as well as for the prevention of early myocardial infarction in patients with acute coronary syndrome in most countries.

Diabetes and Obesity: *Januvia* and *Janumet*.

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

Mature Brands: *Cozaar* (losartan potassium); *Hyzaar* (losartan potassium and hydrochlorothiazide); *Vasotec* (enalapril maleate) and *Vaseretic* (enalapril maleate-hydrochlorothiazide), the Company's most significant hypertension and/or heart failure products; *Zocor*; *Proscar* (finasteride), a urology product for the treatment of symptomatic benign prostate enlargement; *Claritin Rx*; and *Proventil HFA* (albuterol) inhalation aerosol for the relief of bronchospasm in patients 12 years or older.

Neurosciences and Ophthalmology: *Maxalt* (rizatriptan benzoate), an acute migraine product; *Cosopt* and *Trusopt*, Merck's largest-selling ophthalmological products; *Remeron* (mirtazapine), an antidepressant; *Subutex*, a sublingual tablet formulation of buprenorphine; and *Suboxone*, a sublingual tablet combination of buprenorphine and naloxone, marketed by the Company in certain countries outside the United States for the treatment of opiate addiction.

Oncology: *Temodar/Temodal*; *Emend* (aprepitant) for the prevention of chemotherapy-induced and post-operative nausea and vomiting; *Caelyx* (pegylated liposomal doxorubicin hydrochloride), a long-circulating formulation of the cancer drug doxorubicin marketed by the Company outside the United States for the treatment of certain ovarian cancers, Kaposi's sarcoma and metastatic breast cancer; and *Intron A* for Injection, marketed for chronic hepatitis B and C and numerous anticancer indications worldwide, including as adjuvant therapy for malignant melanoma.

Vaccines: *M-M-R II* (Measles, Mumps and Rubella Virus Vaccine Live), a vaccine against measles, mumps and rubella; *ProQuad* (Measles, Mumps, Rubella and Varicella Virus Vaccine Live), a pediatric combination vaccine against measles, mumps, rubella and varicella; *Varivax*; *Gardasil*; *RotaTaq*; *Pneumovax*; and *Zostavax* (Zoster Vaccine Live).

Women's Health: *Follistim/Puregon* (follitropin beta injection), a fertility treatment; and *NuvaRing* (etonogestrel/ethinyl estradiol), a vaginal contraceptive ring.

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 treatment of fertility

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disorders in cattle; *Regumate/Matrix* fertility management for swine and horses; *Resflor* combination broad-spectrum antibiotic and non-steroidal anti-inflammatory drug for bovine respiratory disease; *Zilmax* and *Revalor* to improve production efficiencies in beef cattle; *M+Pac* swine pneumonia vaccine; and *Porcilis* vaccine line for infectious diseases in swine.

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

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

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

Consumer Health Care

The Consumer Health Care segment develops, manufactures and markets OTC, foot care and sun care products. Principal products in this segment include:

OTC Products: *Claritin* non-drowsy antihistamines; *MiraLAX* treatment for occasional constipation; *Coricidin HBP* decongestant-free cold/flu medicine for people with high blood pressure; *Afrin* nasal decongestant spray; and *Correctol* laxative tablets.

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, dry oils and lip-protection products and sunless tanning products; and *Solarcaine* sunburn relief products.

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 July 2009, the U.S. Food and Drug Administration (FDA) approved an expanded indication for *Isentress*. The broadened indication now includes use in the treatment of adult patients starting HIV-1 therapy for the first time (treatment-naïve), as well as in treatment-experienced adult patients.

In August 2009, the FDA approved *Saphris* (asenapine) sublingual tablets for acute treatment of schizophrenia in adults and acute treatment of manic or mixed episodes associated with bipolar I disorder with or without psychotic features in adults. *Saphris* can be used as a first-line treatment and is the first psychotropic drug to receive initial approval for both of these indications simultaneously.

In October 2009, the FDA approved *Gardasil* for use in boys and men 9 through 26 years of age for the prevention of genital warts caused by HPV types 6 and 11, making *Gardasil* the only HPV vaccine approved for use in males. *Gardasil* is also the only HPV vaccine that protects against HPV types 6 and 11 which cause approximately 90 percent of all genital warts cases. In addition, on October 21, 2009, Old Merck announced that the U.S. Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) supports the permissive use of *Gardasil* for boys and young men ages 9 to 26, which means that *Gardasil* may be given to males ages 9 to 26 to

reduce the likelihood of acquiring genital warts at the discretion of the patient's health care provider. The ACIP also voted to recommend that funding be provided for the use of *Gardasil* in males through the Vaccines for Children program.

In October 2009, the European Commission (EC) approved *Simponi* (golimumab), a once-monthly, subcutaneous treatment for certain inflammatory diseases.

In December 2009, the FDA approved *Zegerid OTC* (omeprazole 20 mg/sodium bicarbonate 1100 mg capsules) for OTC treatment of frequent heartburn.

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In January 2010, Merck received EC approval of *Elonva* (corifollitropin alpha injection), a new fertility treatment. *Elonva* is indicated for controlled ovarian stimulation in combination with a GnRH antagonist for the development of multiple follicles in women participating in an assisted reproductive technology program.

Joint Ventures

Merck/Schering-Plough Partnership

In 2000, Old Merck and Schering-Plough (collectively, the legacy companies) entered into an agreement to create an equally-owned partnership to develop and market in the United States new prescription medicines for cholesterol management. In December 2001, the cholesterol-management partnership was expanded to include all the countries of the world, excluding Japan. In October 2002, *Zetia*, the first in a new class of cholesterol-lowering agents, was launched in the United States. In July 2004, *Vytorin*, a combination product containing the active ingredients of both *Zetia* and *Zocor*, was approved in the United States.

As previously disclosed, in January 2008, the legacy companies announced the results of the Effect of Combination Ezetimibe and High-Dose Simvastatin vs. Simvastatin Alone on the Atherosclerotic Process in Patients with Heterozygous Familial Hypercholesterolemia (ENHANCE) clinical trial, an imaging trial in 720 patients with heterozygous familial hypercholesterolemia, a rare genetic condition that causes very high levels of LDL bad cholesterol and greatly increases the risk for premature coronary artery disease. As previously reported, despite the fact that ezetimibe/simvastatin 10/80 mg (*Vytorin*) significantly lowered LDL bad cholesterol more than simvastatin 80 mg alone, there was no significant difference between treatment with ezetimibe/simvastatin and simvastatin alone on the pre-specified primary endpoint, a change in the thickness of carotid artery walls over two years as measured by ultrasound. The Improved Reduction in High-Risk Subjects Presenting with Acute Coronary Syndrome (IMPROVE-IT) trial is underway and is designed to provide cardiovascular outcomes data for ezetimibe/simvastatin in patients with acute coronary syndrome. No incremental benefit of ezetimibe/simvastatin on cardiovascular morbidity and mortality over and above that demonstrated for simvastatin has been established. In January 2009, the FDA announced that it had completed its review of the final clinical study report of ENHANCE. The FDA stated that the results from ENHANCE did not change its position that elevated LDL cholesterol is a risk factor for cardiovascular disease and that lowering LDL cholesterol reduces the risk for cardiovascular disease. For a discussion concerning litigation arising out of the ENHANCE study, see Item 1A. Risk Factors and Item 3. Legal Proceedings below.

On July 21, 2008, efficacy and safety results from the Simvastatin and Ezetimibe in Aortic Stenosis (SEAS) study were announced. SEAS was designed to evaluate whether intensive lipid lowering with *Vytorin* 10/40 mg would reduce the need for aortic valve replacement and the risk of cardiovascular morbidity and mortality versus placebo in patients with asymptomatic mild to moderate aortic stenosis who had no indication for statin therapy. *Vytorin* failed to meet its primary endpoint for the reduction of major cardiovascular events. In the study, patients in the group who took *Vytorin* 10/40 mg had a higher incidence of cancer than the group who took placebo. There was also a nonsignificant increase in deaths from cancer in patients in the group who took *Vytorin* versus those who took placebo. Cancer and cancer deaths were distributed across all major organ systems. The Company believes the cancer finding in SEAS is likely to be an anomaly that, taken in light of all the available data, does not support an association with *Vytorin*. In August 2008, the FDA announced that it was investigating the results from the SEAS trial. In December 2009, the FDA announced that it had completed its review of the data from the SEAS trial as well as a review of interim data from the Study of Heart and Renal Protection (SHARP) and IMPROVE-IT trials. Based on currently available information, the FDA indicated it believed it is unlikely that *Vytorin* or *Zetia* increase the risk of cancer-related death. The SHARP trial is expected to be completed in 2010. The IMPROVE-IT trial is scheduled for completion in 2013. In the IMPROVE-IT trial, a blinded interim efficacy analysis will be conducted by the Data Safety Monitoring Board for the trial when approximately 50% of the endpoints have been accrued. That interim analysis is expected to be conducted in 2010.

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

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

In 1998, Old Merck and Astra restructured the joint venture whereby Old 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 (the AstraZeneca merger), became the exclusive distributor of the products for which KBI retained rights.

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

Management's Discussion and Analysis of Financial Condition and Results of Operations below, after certain adjustments, Old Merck recorded an aggregate pretax gain of \$2.2 billion in 2008.

In conjunction with the 1998 restructuring, Astra purchased an option (the Asset Option) for a payment of \$443.0 million, which was recorded as deferred income, to buy Old Merck's interest in the KBI products, excluding the gastrointestinal medicines *Nexium* (esomeprazole) and *Prilosec* (the Non-PPI Products). AstraZeneca can exercise the Asset Option in the first half of 2010 at an exercise price of \$647 million which represents the net present value as of March 31, 2008 of projected future pretax revenue to be received by the Company from the Non-PPI Products (the Appraised Value). On February 26, 2010, AstraZeneca notified the Company that it was exercising the Asset Option. Old Merck also had the right to require Astra to purchase such interest in 2008 at the Appraised Value. In February 2008, Old Merck advised AstraZeneca that it would not exercise the Asset Option, thus the \$443.0 million remains deferred but will be recognized when the Asset Option is consummated. In addition, in 1998, Old Merck granted Astra an option (the Shares Option) to buy Old Merck's common stock interest in KBI and, therefore, Old Merck's interest in *Nexium* and *Prilosec*, exercisable two years after Astra's exercise of the Asset Option. Astra can also exercise the Shares Option in 2017 or if combined annual sales of the two products fall below a minimum amount provided, in each case, only so long as AstraZeneca's Asset Option has been exercised in 2010. The exercise price for the Shares Option is based on the net present value of estimated future net sales of *Nexium* and *Prilosec* as determined at the time of exercise, subject to certain true-up mechanisms.

Sanofi Pasteur MSD

In 1994, Old 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. Old Merck and Sanofi Pasteur contributed, among other things, their European vaccine businesses for equal shares in the joint venture, known as Pasteur Mérieux MSD, S.N.C. (now Sanofi Pasteur MSD, S.N.C.). The joint venture maintains a presence, directly or through affiliates or branches, in

Belgium, Italy, Germany, Spain, France, Austria, Ireland, Sweden, Portugal, the Netherlands, Switzerland and the United Kingdom and through distributors in the rest of its territory.

Table of Contents*Johnson & Johnson^oMerck Consumer Pharmaceuticals Company*

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

Merial Limited

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

On September 17, 2009, Old Merck sold its 50% interest in Merial to sanofi-aventis for \$4 billion in cash. The sale resulted in the recognition of a \$3.2 billion gain reflected in *Other income (expense), net* in 2009. Also, in connection with the sale of Merial, Old Merck, sanofi-aventis and Schering-Plough signed a call option agreement. Under the terms of the call option agreement, following the closing of the Merger, sanofi-aventis has an option to require the Company to combine its Intervet/Schering-Plough Animal Health business with Merial to form an animal health joint venture that would be owned equally by the Company and sanofi-aventis. As part of the call option agreement, the value of Merial has been fixed at \$8 billion. The minimum total value received by the Company and its affiliates for contributing Intervet/Schering-Plough to the combined entity would be \$9.25 billion (subject to customary transaction adjustments), consisting of a floor valuation of Intervet/Schering-Plough which is fixed at a minimum of \$8.5 billion (subject to potential upward revision based on a valuation exercise by the two parties) and an additional payment by sanofi-aventis of \$750 million. Based on the valuation exercise of Intervet/Schering-Plough and the customary transaction adjustments, if Merial and Intervet/Schering-Plough are combined, a payment may be required to be paid by either party to make the joint venture equally owned by the Company and sanofi-aventis. This payment would true-up the value of the contributions so that they are equal. Any formation of a new animal health joint venture with sanofi-aventis is subject to customary closing conditions including antitrust review in the United States and Europe. Prior to the closing of the Merger, the agreements provided Old Merck with certain rights to terminate the call option for a fee of \$400 million. The recognition of the termination fee was deferred until the fourth quarter of 2009 when the conditions that could have triggered its payment lapsed.

Licenses

In 1998, a subsidiary of Schering-Plough entered into a licensing agreement with Centocor, Inc., now a Johnson & Johnson 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 has exclusive marketing rights to both products outside the United States, Japan and certain Asian markets. In December 2007, Schering-Plough and Centocor revised their distribution agreement regarding the development, commercialization and distribution of both *Remicade* and *Simponi*, extending the Company's rights to exclusively market *Remicade* to match the duration of the Company's exclusive marketing rights for *Simponi*. In addition, Schering-Plough and Centocor agreed to share certain development costs relating to *Simponi*'s auto-injector delivery system. On October 6, 2009, the EC approved *Simponi* as a treatment for rheumatoid arthritis and other immune system disorders in two presentations—a novel auto-injector and a prefilled syringe. As a result, the Company's marketing rights for both products extend for 15 years from the first commercial sale of *Simponi* within the EU following the receipt of pricing and reimbursement approval within the EU. After operating expenses and subject to certain adjustments, the Company is entitled to receive an approximate 60% share of profits on the Company's distribution in the Company's marketing territory. Beginning in 2010, the share of profits will change over time to a 50% share of profits by 2014 for both products and the share of profits will

remain fixed thereafter for the remainder of the term. The Company may independently develop and market *Simponi* for a Crohn's disease indication in its territories, with an option for Centocor to participate. Centocor has instituted an arbitration proceeding to terminate this agreement and the Company's rights to distribute these products. See Item 1A. Risk Factors and Item 3. Legal Proceedings below.

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Competition

The markets in which the Company conducts its business and the pharmaceutical industry are highly competitive and highly regulated. 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, 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 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.

Global efforts toward healthcare cost containment continue to exert pressure on product pricing and access. In addressing cost containment pressure, the Company makes a continuing effort to demonstrate that its medicines provide value to patients and to those who pay for health care. In addition, pricing flexibility across the Company's product portfolio has encouraged growing use of its medicines and mitigated the effects of increasing cost pressures on individual medicines.

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

The Company anticipates that the worldwide trend toward cost containment will continue, resulting in ongoing pressures on healthcare budgets. In the United States, major healthcare reform has been introduced and passed in both houses of Congress. A final revised bill which unifies both versions may be considered and adopted into law. The impact of such actions, as well as budget pressures on governments in the United States and other nations, cannot be predicted at this time. As the Company continues to successfully launch new products, contribute to health care debates and monitor reforms, its new products, policies and strategies should enable it to maintain a strong position in the changing economic environment.

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

Access to Medicines

The Company is also committed to improving access to medicines and enhancing the quality of life for people around the world. To cite just one example, The African Comprehensive HIV/AIDS Partnerships in

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Botswana, a partnership between the government of Botswana, the Bill & Melinda Gates Foundation and The Merck Company Foundation/Merck & Co., Inc., is supporting Botswana's response to HIV/AIDS through a comprehensive and sustainable approach to HIV prevention, care, treatment, and support.

To further catalyze access to HIV medicines in developing countries, the Company makes no profit on the sale of its current HIV/AIDS medicines in the world's poorest countries and those hardest hit by the pandemic, and offers its HIV/AIDS medicines at significantly reduced prices to medium-income countries. In February 2007, Old Merck announced that it had again reduced the price of *Stocrin* in the least developed countries of the world and those hardest hit by the pandemic. Through these and other actions, the Company is working independently and with partners in both the public and private sectors to address the most critical barriers to access to medicines in the developing world. Addressing these barriers requires investments in education, training and health infrastructure and to improve capacity achieved through increased international assistance and sustainable financing.

In addition, Old Merck has committed to providing *RotaTeq* to the Global Alliance for Vaccines and Immunization-eligible countries at prices at which it does not profit. Also, in 2009, Old Merck and The Wellcome Trust established the MSD Wellcome Trust Hilleman Laboratories, a joint venture in India to develop vaccines for millions of people in some of the poorest areas of the world.

Government Regulation

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

In the United States, the government expanded access for senior citizens to prescription drug coverage by enacting the Medicare Prescription Drug Improvement and Modernization Act of 2003, which was signed into law in December 2003. Prescription drug coverage began on January 1, 2006. This legislation supports the Company's goal of improving access to medicines by expanding insurance coverage, while preserving market-based incentives for pharmaceutical innovation. At the same time, the legislation has helped control the cost of prescription drug costs through competitive pressures and by encouraging the appropriate use of medicines. As mentioned above, in the United States major healthcare reform has been introduced and passed in both houses of Congress. A final revised bill which unifies both versions may be considered and adopted into law. The U.S. Congress has also considered, and may consider again, proposals to increase the government's role in pharmaceutical pricing in the Medicare program. These proposals may include removing the current legal prohibition against the Secretary of the Health and Human Services intervening in price negotiations between Medicare drug benefit program plans and pharmaceutical companies. They may also include mandating the payment of rebates for some or all of the pharmaceutical utilization in Medicare drug benefit plans. In addition, Congress may again consider proposals to allow, under certain conditions, the importation of medicines from other countries.

For many years, the pharmaceutical industry has been under federal and state oversight with the approval process for new drugs, drug safety, advertising and promotion, drug purchasing and reimbursement programs, and formularies. The Company believes that it will continue to be able to conduct its operations, including the introduction of new drugs to the market, in this regulatory environment.

The Company continues to work with private and public payors to slow increases in healthcare spending. Also, U.S. federal and state governments have pursued methods to directly reduce the cost of drugs and vaccines for

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

Initiatives in some states seek rebates beyond the minimum required by Medicaid legislation, in some cases for patients beyond those who are eligible for Medicaid. Under the Federal Vaccines for Children entitlement program, the U.S. Centers for Disease Control and Prevention (CDC) funds and purchases recommended pediatric vaccines at a public sector price for the immunization of Medicaid-eligible, uninsured, Native American and certain underinsured children. Old Merck was awarded a CDC contract in 2009 for the supply of pediatric vaccines for the Vaccines for Children program.

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

In January 2008, the EC launched a sector inquiry in the pharmaceutical industry under the rules of EU competition law. As part of this inquiry, Old Merck's offices in Germany were inspected by the authorities beginning in January 2008. The preliminary report of the EC was issued on November 28, 2008, and following the public consultation period, the final report was issued in July 2009. The final report confirmed that there has been a decline in the number of novel medicines reaching the market and instances of delayed market entry of generic medicines and discussed industry practices that may have contributed to these phenomena. While the EC has issued further inquiries with respect to the subject of the investigation, the EC has not alleged that the Company or any of its subsidiaries have engaged in any unlawful practices.

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

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, and there has been an increasing attention to privacy and data protection issues with the potential to affect directly the Company's business, including recently enacted laws and regulations in the United States and internationally requiring notification to individuals and government authorities of security breaches involving certain categories of personal information.

Distribution

The Company sells its human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions. Human health vaccines are sold primarily to physicians, wholesalers, physician distributors and government entities. The Company's professional representatives communicate the effectiveness,

safety and value of the Company's pharmaceutical and vaccine products to health care professionals in private practice, group practices and managed care organizations. The Company's professional representatives communicate the safety and value of the Company's animal health products to veterinarians, distributors and animal producers. The Company's OTC, foot care and sun care products are sold through wholesale and retail drug, food chain and mass merchandiser outlets.

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

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

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

Product⁽¹⁾	Year of Expiration (in U.S.)
<i>Cozaar</i>	2010
<i>Hyzaar</i>	2010
<i>Crixivan</i>	2012 (compound)/2018 (formulation)
<i>Maxalt</i>	2012 (compound)/2014 (other)
<i>Singulair</i>	2012
<i>Cancidas</i>	2013 (compound)/2015 (composition)
<i>Propecia⁽²⁾</i>	2013 (formulation/use)
<i>Asmanex</i>	2014 (use)/2018 (formulation)
<i>Avelox</i>	2014
<i>Integrilin</i>	2014 (compound)/2015 (use/formulation)
<i>Nasonex</i>	2014 (use/formulation)/2018(formulation)
<i>Temodar⁽³⁾</i>	2014
<i>Emend</i>	2015
<i>Follistim/Puregon</i>	2015
<i>PegIntron</i>	2015 (conjugates)/2020 (Mature IFN-alpha)
<i>Zolinza</i>	2015
<i>Invanz</i>	2016 (compound)/2017 (composition)
<i>Zostavax</i>	2016
<i>Zetia/Vytorin</i>	2017
<i>NuvaRing</i>	2018 (delivery system)
<i>Noxafil</i>	2019
<i>RotaTeq</i>	2019
<i>Clarinex⁽⁴⁾</i>	2020 (formulation)
<i>Comvax</i>	2020 (method of making/vectors)
<i>Intron A</i>	2020
<i>Recombivax</i>	2020 (method of making/vectors)
<i>Saphris/Sycrest</i>	2020 (use/formulation) (subject to pending Patent Term Restoration application)
<i>Januvia/Janumet</i>	2022 (compound)/2026 (salt)
<i>Isentress</i>	2023
<i>Gardasil</i>	2026 (method of making/use/product by process)

⁽¹⁾ *Compound patent unless otherwise noted.*

⁽²⁾ *By agreement, Dr. Reddy's Laboratories may launch a generic on January 1, 2013.*

⁽³⁾ *In January 2010, a court held the patent for Temodar to be unenforceable. That decision is being appealed. See Item 3. Legal Proceedings Patent Litigation below.*

⁽⁴⁾ *By virtue of litigation settlement, generics have been given the right to enter the market as of 2012.*

While the expiration of a product patent normally results in a loss of market exclusivity for the covered pharmaceutical product, commercial benefits may continue to be derived from: (i) later-granted patents on processes and intermediates related to the most economical method of manufacture of the active ingredient of such product; (ii) patents relating to the use of such product; (iii) patents relating to novel compositions and formulations; and (iv) in the United States and certain other countries, market exclusivity that may be available under relevant law. The effect

of product patent expiration on pharmaceutical products also depends upon many other factors such as the nature of the market and the position of the product in it, the growth of the market, the complexities and economics of the process for manufacture of the active ingredient of the product and the requirements of new drug provisions of the Federal Food, Drug and Cosmetic Act or similar laws and regulations in other countries.

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The patents that provide U.S. market exclusivity for *Cozaar* and *Hyzaar* expire in April 2010. In addition, the patent for *Cozaar* will expire in a number of major European markets in March 2010. *Hyzaar* lost patent protection in major European markets in February 2010. The Company expects that sales of these products will decline rapidly after expiration of these patents, particularly in the United States since there are expected to be multiple sources of generic products at the time of patent expiry. In addition, the patent that provides U.S. market exclusivity for *Singulair* expires in August 2012. The Company expects that within the two years following patent expiration, it will lose substantially all U.S. sales of *Singulair*, with most of those declines coming in the first full year following patent expiration. Also, the patent for *Singulair* will expire in a number of major European markets in August 2012 and the Company expects sales of *Singulair* in those markets will decline significantly thereafter.

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

For further information with respect to the Company's patents, see Item 1A. Risk Factors and Item 3. Legal Proceedings Patent Litigation below.

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

Royalties received during 2009 on patent and know-how licenses and other rights amounted to \$218.9 million. Merck also paid royalties amounting to \$1.27 billion in 2009 under patent and know-how licenses it holds.

Research and Development

The Company's business is characterized by the introduction of new products or new uses for existing products through a strong research and development program. Approximately 17,200 people are employed in the Company's research activities. Research and development expenses (which included restructuring costs) were \$5.8 billion in 2009, \$4.8 billion in 2008 and \$4.9 billion in 2007. 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 new 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 and RNAi. Further, Merck moved to diversify its portfolio by creating a new division, Merck BioVentures, which has the potential to harness the market opportunity presented by biological medicine patent expiries by delivering high quality follow-on biologic products to enhance access for patients worldwide. The Company will continue to pursue appropriate external licensing opportunities.

The integration plans for research and development are focused on integrating the research operations of the legacy companies, including providing an effective transition for employees, realizing projected merger synergies in the form of cost savings and revenue growth opportunities, and maintaining momentum in the Company's late-stage pipeline. During 2009, Merck continued implementing a new model for its basic research global operating strategy at legacy Merck Research Laboratories sites. The new model will align franchise and function as well as align resources with disease area priorities and balance capacity across discovery phases and allow the Company to act upon those programs with the highest probability of success. Additionally, across all

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disease area priorities, the Company's strategy is designed to expand access to worldwide external science and incorporate external research as a key component of the Company's early discovery pipeline in order to translate basic research productivity into late-stage clinical success.

The Company's clinical pipeline includes candidates in multiple disease areas, including anemia, atherosclerosis, cancer, diabetes, heart disease, hypertension, infectious diseases, inflammatory/autoimmune diseases, migraine, neurodegenerative diseases, ophthalmics, osteoporosis, psychiatric diseases, respiratory disease and women's health. The Company supplements its internal research with an aggressive licensing and external alliance strategy focused on the entire spectrum of collaborations from early research to late-stage compounds, as well as new technologies.

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 New Drug Application (NDA) for a drug or the Biologics License Application (BLA) for a vaccine or biologic submitted to the FDA for the required approval.

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

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

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

Research and Development Update

In connection with the Merger, the Company is assessing its pipeline to identify the most promising, high-potential compounds for development. The Company has completed the prioritization of its clinical development

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programs. The Company is continuing to work on the prioritization of its value adding programs related to currently marketed products and to its preclinical/discovery programs. The Company anticipates that the full prioritization process will be completed by the first half of 2010. In connection with this process, the Company may recognize non-cash impairment charges for the cancellation of certain legacy Schering-Plough pipeline programs that were measured at fair value and capitalized in connection with the Merger. These non-cash impairment charges, which are anticipated to be excluded from the Company's non-GAAP earnings, could be material to the Company's future GAAP earnings.

The Company currently has a number of candidates under regulatory review in the United States and internationally. Additionally, the Company has 19 drug candidates in Phase III development.

MK-6621, vernakalant (IV), is an investigational candidate for the treatment of atrial fibrillation currently undergoing regulatory review in the EU. In April 2009, Old Merck and Cardiome Pharma Corp. (Cardiome) announced a collaboration and license agreement for the development and commercialization of vernakalant which provides Merck exclusive rights outside of the United States, Canada and Mexico to the intravenous formulation of vernakalant. Vernakalant (oral) is currently in Phase II development. Merck has exclusive global rights to the oral formulation of vernakalant for the maintenance of normal heart rhythm in patients with atrial fibrillation.

SCH 418131, MFF, is a combination of two previously approved drugs for the treatment of asthma: mometasone (*Asmanex*) and formoterol (*Foradil*). The Company is aiming to create a new option for patients by bringing these two key treatments together. In July 2009, Schering-Plough announced that it had filed an NDA with the FDA for MFF. MFF is also currently under regulatory review in the EU.

SCH 900121, NOMAC/E2, is an oral contraceptive that combines a selective progestin with estradiol, the estrogen that women produce naturally. The drug is currently under regulatory review in the EU. It is in Phase III development for the U.S. market.

SCH 900274, *Saphris*, asenapine, a central nervous system compound for bipolar I disorder and schizophrenia, is currently undergoing regulatory review in the EU. The FDA approved *Saphris* in August 2009.

SCH 900616, *Bridion*, sugammadex, is a medication designed to rapidly reverse the effects of certain muscle relaxants used as part of general anesthesia to ensure patients remain immobile during surgical procedures. It differs from other reversal agents that can only be administered once the muscle relaxant begins to wear off. *Bridion* has received regulatory approval in the EU, Australia, New Zealand and Japan, and is under regulatory review in other markets, including the United States. Prior to the Merger, Schering-Plough received a complete response letter from the FDA for *Bridion*. Following further communication from the FDA, the Company is assessing the agency's feedback in order to determine a new timetable for response.

SCH 503034, boceprevir, is a hepatitis C protease inhibitor currently under development. Boceprevir is fully enrolled in its Phase III program, which the Company expects to conclude in mid-2010. The Company expects to submit an NDA to the FDA for boceprevir by the end of 2010 for both treatment-experienced and treatment-naïve patients with hepatitis C.

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

SCH 697243, an allergy immunotherapy sublingual tablet (AIT) for grass pollen allergy, is being developed by the Company. In November 2009, SCH 697243 met the primary endpoint in a Phase III study of adult subjects in the United States with a history of grass pollen induced rhinoconjunctivitis with or without asthma. The investigational grass AIT treatment is designed to work by inducing a protective immune response against grass pollen allergy and providing sustained prevention of allergy symptoms, treating both the symptoms and the underlying cause of the disease.

SCH 039641, an AIT for ragweed allergy, is also in Phase III development for the U.S. market.

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SCH 530348, vorapaxar, is a thrombin receptor antagonist or antiplatelet protease activated receptor-1 inhibitor being studied for the prevention and treatment of thrombosis. In November 2009, Merck announced completion of patient enrollment of more than 26,000 patients in the TRA 2°P-TIMI 50 clinical trial, a Phase III, randomized, double-blind, placebo-controlled, multinational study. The trial will assess the ability of SCH 530348 to prevent major cardiovascular events when added to current antiplatelet regimens (aspirin or aspirin plus an ADP inhibitor) in patients who have previously experienced a heart attack or stroke or who have peripheral arterial disease. SCH 530348 is also being studied in the treatment of patients with acute coronary syndrome in the ongoing Phase III Thrombin Receptor Antagonist for Clinical Event Reduction in Acute Coronary Syndrome trial, led by the Duke Clinical Research Institute. The Company anticipates filing an NDA for vorapaxar with the FDA in 2011.

MK-2452, tafluprost, is a preservative free, synthetic analogue of the prostaglandin F₂ for the reduction of elevated intraocular pressure in appropriate patients with primary open-angle glaucoma and ocular hypertension. In April 2009, Old Merck and Santen announced a worldwide licensing agreement for tafluprost.

As previously disclosed, Old Merck submitted for filing an NDA with the FDA for MK-0653C, ezetimibe combined with atorvastatin, which is an investigational medication for the treatment of dyslipidemia, and the FDA refused to file the application. The FDA has identified additional manufacturing and stability data that are needed and the Company is assessing the FDA's response and anticipates filing in 2011.

MK-0431C, a candidate currently in Phase III clinical development, combines *Januvia* with pioglitazone, another type 2 diabetes therapy. The Company continues to anticipate filing an NDA for MK-0431C with the FDA in 2011.

MK-0822, odanacatib, is an oral, once-weekly investigational treatment for osteoporosis. Osteoporosis is a disease which 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 September 2009, data from a Phase IIB clinical study of odanacatib were presented at the 31st Annual Meeting of the American Society for Bone and Mineral Research which showed that when stopping treatment after two years the increases in lower back (lumbar spine) bone mineral density (BMD) were reversed over the next year, while BMD at the hip (femoral neck) remained above levels observed at the start of the study. Additionally, three years of treatment with odanacatib 50 mg demonstrated increases in BMD at key fracture sites and minimal impact on the formation of new bone as measured by biochemical markers of bone turnover. Odanacatib is currently in Phase III clinical trials and is being evaluated in a large-scale, global outcomes study to determine its effects on vertebral, hip and non-vertebral fractures. The Company continues to anticipate filing an NDA with the FDA in 2012.

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

MK-0524A is a drug candidate that combines extended-release (ER) niacin and a novel flushing inhibitor, laropiprant. MK-0524A has demonstrated the ability to lower LDL-cholesterol (LDL-C or bad cholesterol), raise HDL-cholesterol (HDL-C or good cholesterol) and lower triglycerides with significantly less flushing than traditional extended release niacin alone. High LDL-C, low HDL-C and elevated triglycerides are risk factors associated with heart attacks and strokes. In April 2008, Old Merck received a non-approvable action letter from the FDA in response to its NDA for MK-0524A. At a meeting to discuss the letter, the FDA stated that additional efficacy and safety data were required and suggested that Old Merck wait for the results of the Treatment of HDL to Reduce the Incidence of Vascular Events (HPS2-THRIVE) cardiovascular outcomes study, which is expected to be completed in 2012. The Company anticipates filing an NDA with the FDA for MK-0524A in 2012. MK-0524A has been approved in more than 45 countries outside the United States for the treatment of dyslipidemia, particularly in patients with combined mixed

dyslipidemia (characterized by elevated levels of LDL-C and triglycerides and low HDL-C) and in patients with primary hypercholesterolemia (heterozygous familial and non-familial) and is marketed as *Tredaptive* (or as *Cordaptive* in certain countries). *Tredaptive* should be used in patients in combination with statins, when the cholesterol lowering effects of statin monotherapy is inadequate. *Tredaptive* can be used as monotherapy only in patients in whom statins are considered inappropriate or not tolerated.

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

MK-0859, anacetrapib, is an inhibitor of the cholesteryl ester transfer protein that has shown promise in lipid management by raising HDL-C and reducing LDL-C without raising blood pressure. In November 2009, Merck announced that in a Phase IIb study in 589 patients with primary hypercholesterolemia or mixed hyperlipidemia treated with anacetrapib as monotherapy or co-administered with atorvastatin, there were persistent lipid effects in the higher dose arms in both the monotherapy and co-administration treatment groups eight weeks after stopping active therapy with anacetrapib. The effect of CETP inhibition on cardiovascular risk has yet to be established. A Phase III trial, titled DEFINE, is ongoing to further evaluate the safety and efficacy of anacetrapib in patients with coronary heart disease. The Company anticipates filing an NDA with the FDA beyond 2015.

As previously disclosed, in 2009, Old Merck announced it was delaying the filing of the U.S. application for telcagepant (MK-0974), the Company's investigational calcitonin gene-related peptide (CGRP)-receptor antagonist for the intermittent treatment of acute migraine. The decision was based on findings from a Phase IIa exploratory study in which a small number of patients taking telcagepant twice daily for three months for the prevention of migraine were found to have marked elevations in liver transaminases. The daily dosing regimen in the prevention study was different than the dosing regimen used in Phase III studies in which telcagepant was intermittently administered in one or two doses to treat individual migraine attacks as they occurred. Other studies with telcagepant for the acute, intermittent treatment of migraine continue. Following meetings with regulatory agencies at the end of 2009, Merck is planning to conduct an additional safety study as part of the overall Phase III program for telcagepant. The results of this study will inform planned filings for approval.

SCH 900395, acadesine, is a potential first-in class adenosine regulating agent for ischemia reperfusion-injury in patients undergoing heart bypass surgery. Patient enrollment in the RED CABG Phase III clinical trial was initiated in 2009.

SCH 417690, vicriviroc, for the treatment of HIV infection (treatment experienced) was evaluated in two Phase III studies in this patient population, and it was announced in January 2010 that the primary efficacy endpoint was not met. Merck will not submit an NDA to the FDA for vicriviroc in treatment-experienced HIV-infected patients at this time but will continue to evaluate vicriviroc as first-line therapy for treatment-naive patients.

As previously disclosed, in 2007, Cubist Pharmaceuticals, Inc. (Cubist) entered into a license agreement with Old Merck for the development and commercialization of Cubicin (daptomycin for injection, MK-3009) in Japan. Merck will develop and commercialize Cubicin through its wholly-owned subsidiary, Banyu Pharmaceutical Co., Ltd. Cubist commercializes Cubicin in the United States. MK-3009 is currently in Phase III development.

MK-4305 is an orexin receptor antagonist, a potential new approach to the treatment of chronic insomnia, currently in Phase III development.

SCH 900962, *Elonva*, corifollitropin alpha injection, which has been approved in the EC for controlled ovarian stimulation in combination with a GnRH antagonist for the development of multiple follicles in women participating in an assisted reproductive technology program, is currently in Phase III development in the United States.

Merck has terminated the internal clinical development program for esmirtazapine (SCH 900265) for hot flashes and insomnia for strategic reasons.

As previously disclosed, in 2009, Old Merck announced that preliminary results for the pivotal Phase III study of rolofylline (MK-7418), its investigational medicine for the treatment of acute heart failure, showed that rolofylline did not meet the primary or secondary efficacy endpoints. Old Merck terminated the clinical development program for rolofylline.

The chart below reflects the Company's current research pipeline as of February 12, 2010. Candidates shown in Phase III include specific products. 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

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commercialization in a given therapeutic area. Small molecules and biologics are given MK-number or SCH-number designations and vaccine candidates are given V-number designations. Candidates in Phase I, additional indications in the same therapeutic area and additional claims, line extensions or formulations for in-line products are not shown.

Phase II

Allergy

SCH 900237⁽²⁾

Anemia

MK-2578

Asthma

MK-0476C

Atrial Fibrillation

MK-6621 (vernakalant [oral])

Cancer

MK-0646 (dalotuzumab)

SCH 727965 (dinaciclib)

SCH 900776

Clostridium difficile Infection

MK-3415A

COPD

SCH 527123

Diabetes

MK-0941

MK-3577

Hepatitis C

MK-7009 (vaniprevir)

HIV

SCH 417690 (vicriviroc)

Hot Flashes

MK-6913

Hypertension

MK-0736

Insomnia

MK-6096

Osteoporosis

MK-5442

Parkinson s Disease

SCH 420814 (preladenant)

Pediatric Vaccine

V419

Progeria

SCH 066336, *Sarasar* (lonafarnib)

Schizophrenia

MK-8998

SCH 900435

Staph Infection

V710

Thrombosis

MK-4448 (betrixaban)

Phase III⁽⁶⁾

Allergy

SCH 697243, Grass pollen⁽²⁾

SCH 039641, Ragweed⁽²⁾

Anesthesia Reversal

SCH 900616 (sugammadex) (U.S.)⁽⁴⁾

Atherosclerosis

MK-0524A (extended-release niacin/ laropiprant) (U.S.)⁽³⁾

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

MK-0859 (anacetrapib)

Cervical Cancer

V503

Contraception

SCH 900121 (NOMAC/E2) (U.S.)

Diabetes

MK-0431C (*Januvia*/pioglitazone)

Fertility

SCH 900962 (corifollitropin alfa injection) (U.S.)⁽³⁾

Glaucoma

MK-2452 (tafluprost) (U.S.)⁽⁴⁾

Hepatitis C

SCH 503034 (boceprevir)

Insomnia

MK-4305

Ischemia-Reperfusion Injury

SCH 900395 (acadesine)

Migraine

MK-0974 (telcagepant)

Osteoporosis

MK-0822 (odanacatib)

Sarcoma

MK-8669 (ridaforolimus)

Staph Infection

MK-3009 (daptomycin for injection)⁽⁵⁾

Thrombosis

SCH 530348 (vorapaxar) (TRA)

Under Review

Asthma

SCH 418131 (mometasone/ formoterol combination) (U.S./EU)

Atrial Fibrillation

MK-6621 (vernakalant [IV]) (EU)⁽¹⁾

Contraception

SCH 900121 (NOMAC/E2) (EU)

Schizophrenia/Bipolar I Disorder

SCH 900274 (asenapine) (EU)

Footnotes:

- (1) Exclusive rights outside of the United States, Canada and Mexico to vernakalant (IV)
- (2) North American rights only
- (3) Approved in certain countries in Europe
- (4) Approved in certain countries in Europe and Japan
- (5) Japanese rights only
- (6) MK-0653C fixed dose combination of ezetimibe and atorvastatin is anticipated to be submitted to the U.S. FDA in 2011 and commercialized when regulatory and legal requirements have been satisfied

Employees

As of December 31, 2009, the Company had approximately 100,000 employees worldwide, with approximately 42,000 employed in the United States, including Puerto Rico. Approximately 28% of worldwide employees of the Company are represented by various collective bargaining groups.

In October 2008, Old 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 all areas of the Company worldwide by the end of 2011. About 40% of the total

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reductions will occur in the United States. As part of the 2008 Restructuring Program, Old Merck is streamlining management layers by reducing its total number of senior and mid-level executives globally.

Prior to the Merger, Schering-Plough commenced a Productivity Transformation Program, which was designed to reduce and avoid costs and increase productivity.

In February 2010, the Company announced the first phase of a new global restructuring program (the Merger Restructuring Program) in conjunction with the integration of the legacy Merck and legacy Schering-Plough businesses. This Merger Restructuring Program is intended to optimize the cost structure of the combined Company. As part of the first phase of the Merger Restructuring Program, by the end of 2012, the Company expects to reduce its total workforce by approximately 15% across all areas of the Company worldwide. The Company also plans to eliminate 2,500 vacant positions as part of the first phase of the program. These workforce reductions will primarily come from the elimination of duplicative positions in sales, administrative and headquarters organizations, as well as from the consolidation of certain manufacturing facilities and research and development operations.

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. In 2009, Merck incurred capital expenditures of approximately \$33.6 million for environmental protection facilities. The Company is also remediating environmental contamination resulting from past industrial activity at certain of its sites. Expenditures for remediation and environmental liabilities were \$16.6 million in 2009, \$34.5 million in 2008, \$19.5 million in 2007, and are estimated at \$55 million for the years 2010 through 2013. These amounts do not consider potential recoveries from other parties. The Company has taken an active role in identifying and providing for these costs and, in management's opinion, the liabilities for all environmental matters, which are probable and reasonably estimable, have been accrued and totaled \$161.8 million at December 31, 2009. 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 \$170.0 million in the aggregate. Management also does not believe that these expenditures should have a material adverse effect on the Company's financial position, results of operations, liquidity or capital resources for any year.

Geographic Area Information

The Company's operations outside the United States are conducted primarily through subsidiaries. Sales worldwide by subsidiaries outside the United States were 47% of sales in 2009, 44% of sales in 2008 and 39% of sales in 2007. The increase in proportion of sales outside the United States in 2009 is primarily due to the inclusion of results of Schering-Plough following the close of the Merger.

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

As a result of the Merger, 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. The Company will make available, free of charge at the Investor Information portion of its website, its Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and all amendments to those reports filed or furnished pursuant to

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Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after such reports are electronically filed with, or furnished to, the Securities and Exchange Commission (SEC).

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

Item 1A. Risk Factors.

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

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

The Company depends upon patents to provide it with exclusive marketing rights for its products for some period of time. As product patents for several of the Company's products have recently expired, or are about to expire, in the United States and in other countries, the Company faces strong competition from lower 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 patents that provide U.S. market exclusivity for *Cozaar* and *Hyzaar* expire in April 2010. In addition, the patent for *Cozaar* will expire in a number of major European markets in March 2010. *Hyzaar* lost patent protection in major European markets in February 2010. The Company expects significant declines in sales of these products after such times. In addition, the patent that provides U.S. market exclusivity for *Singulair* expires in August 2012. The Company expects that within the two years following patent expiration, it will lose substantially all U.S. sales of *Singulair*, with most of those declines coming in the first full year following patent expiration. Also, the patent for *Singulair* will expire in a number of major European markets in August 2012 and the Company expects sales of *Singulair* in those markets will decline significantly thereafter.

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.

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

The Company's ability to generate profits and operating cash flow depends largely upon the continued profitability of the Company's key products, such as *Singulair*, *Remicade*, *Vytorin*, *Zetia*, *Januvia*, *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 (as in the recent case of *Temodar*), increased costs associated with manufacturing, generic or OTC 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.

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.

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Like other major pharmaceutical companies, in order to remain competitive, the Company must continue to launch new products each year. Declines in sales of products, such as *Fosamax*, *Cozaar* and *Hyzaar*, 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. 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 *Research and Development* above. Each phase of testing is highly regulated, and during each phase there is a substantial risk that the Company will encounter serious obstacles or will not achieve its goals, and accordingly the Company may abandon a product in which it has invested substantial amounts of time and resources. Some of the risks encountered in the research and development process include the following: pre-clinical testing of a new compound may yield disappointing results; clinical trials of a new drug may not be successful; a new drug may not be effective or may have harmful side effects; a new drug may not be approved by the FDA for its intended use; it may not be possible to obtain a patent for a new drug; or sales of a new product may be disappointing.

The Company cannot state with certainty when or whether any of its products now under development will be approved or launched; whether it will be able to develop, license or otherwise acquire compounds, product candidates or products; or whether any products, once launched, will be commercially successful. The Company must maintain a continuous flow of successful new products and successful new indications or brand extensions for existing products sufficient both to cover its substantial research and development costs and to replace sales that are lost as profitable products, such as *Fosamax*, *Cozaar* and *Hyzaar*, lose patent protection or are displaced by competing products or therapies. Failure to do so in the short term or long term would have a material adverse effect on the Company's business, results of operations, cash flow, financial position and prospects.

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

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

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

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

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

- preclusion from commercialization by the proprietary rights of others.

In connection with the Merger, the Company is assessing its pipeline to identify the most promising, high-potential compounds for development. The Company has completed the prioritization of its clinical development programs.

The Company is continuing to work on the prioritization of its value adding programs related to currently marketed products and to its preclinical/discovery programs. The Company anticipates that the full prioritization process will be completed by the first half of 2010. In connection with this process, the Company may recognize non-cash impairment charges for the cancellation of certain legacy Schering-Plough pipeline programs that were measured at fair value and capitalized in connection with the Merger. These non-cash impairment charges, which are anticipated to be excluded from the Company's non-GAAP earnings, could be material to the Company's future GAAP earnings.

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

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

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

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

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

Even if the Company succeeds in obtaining patents covering its products, third parties or government authorities may challenge or seek to invalidate or circumvent its patents and patent applications. It is important for the Company's business to defend successfully the patent rights that provide market exclusivity for its products. The Company is often involved in patent disputes relating to challenges to its patents or infringement and similar claims against the Company. The Company aggressively defends its important patents both within and outside the United States, including by filing claims of infringement against other parties. See Item 3. Legal Proceedings Patent Litigation below. In particular, manufacturers of generic pharmaceutical products from time to time file Abbreviated New Drug Applications (ANDA) with the FDA seeking to market generic forms of the Company's products prior to the expiration of relevant patents owned by the Company. The Company normally responds by vigorously defending its patent, including by filing lawsuits alleging patent infringement. Patent litigation and other challenges to the Company's patents are costly and unpredictable and may deprive the Company of market exclusivity for a patented product or, in some cases, third party patents may prevent the Company from marketing and selling a product in a particular geographic area.

Additionally, certain foreign governments have indicated that compulsory licenses to patents may be granted in the case of national emergencies, which could diminish or eliminate sales and profits from those regions and negatively affect the Company's results of operations. Further, recent court decisions relating to other companies' U.S. patents,

potential U.S. legislation relating to patent reform, as well as regulatory initiatives may result in further erosion of intellectual property protection.

If one or more important products lose patent protection in profitable markets, sales of those products are likely to decline significantly as a result of generic versions of those products becoming available and, in the case of certain products, such a loss could result in an 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.

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The Company's hypertension products *Cozaar* and *Hyzaar* will each lose patent protection in the United States in April 2010. In addition, the patent for *Cozaar* will expire in a number of major European markets in March 2010. *Hyzaar* lost patent protection in major European markets in February 2010. The Company expects significant declines in the sales of these products after such times. In addition, the patent that provides U.S. market exclusivity for *Singulair* expires in August 2012. The Company expects that within the two years following patent expiration, it will lose substantially all U.S. sales of *Singulair*, with most of those declines coming in the first full year following patent expiration. Also, the patent for *Singulair* will expire in a number of major European markets in August 2012 and the Company expects sales of *Singulair* in those markets will decline significantly thereafter.

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

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

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

The Company faces intense competition from new products.

The Company's products face intense competition from competitors' products. This competition may increase as new products enter the market. In such an event, the competitors' products may be safer or more effective or more effectively marketed and sold than the Company's products. Alternatively, in the case of generic competition, they may be equally safe and effective products 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.

The Company faces pricing pressure with respect to its products.

The Company faces increasing pricing pressure globally from managed care organizations, institutions and 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 (the 2003 Act). The 2003 Act included a prescription drug benefit for individuals that first went into effect on January 1, 2006. The increased purchasing power of entities that negotiate on behalf of Medicare beneficiaries could result in further pricing pressures.

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

The Company believes that the healthcare industry will continue to be subject to increasing regulation as well as political and legal action, as future proposals to reform the healthcare system are considered by Congress and state legislatures. Recently, major health care reform has been introduced and passed in both houses of Congress. A final revised bill which unifies both versions may be considered and adopted into law. Congress may

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also choose not to take action on comprehensive reform and instead move to consider more incremental health care proposals that may or may not involve pharmaceutical-related issues.

Some of the proposals included in the House and Senate versions of health reform could adversely affect the Company's sales and profit margins. If enacted, these proposals could call for government intervention in pharmaceutical pricing, changes in government reimbursement, or increased rebates and discounts on sales related to state and federal government programs among other changes. Other proposals that might be enacted that would adversely affect our business include legalization of commercial drug importation into the United States, and involuntary approval of medicines for OTC use. In addition, individual states have enacted or proposed regulations that restrict certain sales and marketing activities and/or require tracking and disclosure of payments and other financial support to healthcare professionals. Similar regulations may be proposed at the federal level. Such regulations could adversely affect the Company's sales and profit margins.

Any of these new legislative initiatives, if enacted, may further increase government regulation of or other government involvement in healthcare, lower reimbursement rates and otherwise change the operating environment for healthcare companies. Government regulations applicable to the Company's current or future products, or the interpretation of existing regulations, might change and thereby prevent the Company from marketing some or all of its products and services for a period of time or indefinitely.

The Company cannot predict the likelihood of all future changes in the healthcare 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 Company is experiencing difficulties and delays in the manufacturing of certain of its products.

As previously disclosed, Old Merck has, in the past, experienced difficulties in manufacturing certain of its vaccines and other products. These issues are continuing, in particular, with respect to the manufacture of bulk varicella which is required for production of the Company's varicella zoster virus-containing vaccines, such as *Varivax*, *ProQuad* and *Zostavax*. Similarly, Schering-Plough has, in the past, experienced difficulties manufacturing certain of its animal health products. The Company is working on these issues, but there can be no assurance of when or if these issues will be finally resolved.

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

The Company faces significant litigation related to *Vioxx*.

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

In addition to the *Vioxx* Product Liability Lawsuits, various purported class actions and individual lawsuits have been brought against Old Merck and several current and former officers and directors of the Company alleging that Old Merck made false and misleading statements regarding *Vioxx* in violation of the federal and state securities laws (all of these suits are referred to as the *Vioxx* Securities Lawsuits). On April 12, 2007, Judge Chesler granted defendants motion to dismiss the complaint with prejudice. Plaintiffs appealed Judge Chesler s decision to the United States Court of Appeals for the Third Circuit. On September 9, 2008, the Third Circuit issued an opinion reversing Judge Chesler s order and remanding the case to the District Court. Old Merck filed a petition for a writ of certiorari with the United States Supreme Court, which was granted. Oral argument was held in the Supreme Court on November 30, 2009 and a decision is expected in the first half of 2010. While Old Merck s

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petition for certiorari was pending, plaintiffs filed their Consolidated and Fifth Amended Class Action Complaint in the District Court. On May 1, 2009, defendants moved to dismiss the Fifth Amended Class Action Complaint; that motion has been withdrawn without prejudice to refile it pending the outcome in the Supreme Court. In addition, various putative class actions have been brought against Old Merck and several current and former employees, officers, and directors of the Company alleging violations of ERISA. (All of these suits are referred to as the *Vioxx* ERISA Lawsuits and, together with the *Vioxx* Securities Lawsuits the *Vioxx* Shareholder Lawsuits. The *Vioxx* Shareholder Lawsuits are discussed more fully in Item 3. Legal Proceedings below.) Old Merck has also been named as a defendant in actions in various countries outside the United States. (All of these suits are referred to as the *Vioxx* Foreign Lawsuits.) Old Merck has also been sued by ten states, five counties and New York City with respect to the marketing of *Vioxx*.

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

The *Vioxx* product liability litigation is discussed more fully in Item 3. Legal Proceedings below. A trial in a representative action in Australia concluded on June 25, 2009, in the Federal Court of Australia. The named plaintiff, who alleges he suffered an MI, seeks to represent others in Australia who ingested *Vioxx* and suffered an MI, thrombotic stroke, unstable angina, transient ischemic attack or peripheral vascular disease. The trial judge has reserved decision in this matter.

The Company currently anticipates that two U.S. *Vioxx* Product Liability Lawsuits will be tried in 2010. The Company cannot predict the timing of any other trials related to the *Vioxx* Litigation. The Company believes that it has meritorious defenses to the *Vioxx* Product Liability Lawsuits, *Vioxx* Shareholder Lawsuits and *Vioxx* Foreign Lawsuits (collectively, the *Vioxx* Lawsuits) and will vigorously defend against them. The Company's insurance coverage with respect to the *Vioxx* Lawsuits will not be adequate to cover its defense costs and any losses.

During 2009, Merck spent approximately \$244 million in the aggregate in legal defense costs worldwide related to (i) the *Vioxx* Lawsuits, and (ii) the *Vioxx* Investigations (collectively, the *Vioxx* Litigation). In 2009, Merck recorded charges of \$75 million, including \$35 million in the fourth quarter, to add to the reserve solely for its future legal defense costs related to the *Vioxx* Litigation which was \$279 million at December 31, 2008 and \$110 million (the *Vioxx* Reserve) at December 31, 2009. The amount of the *Vioxx* Reserve is based on certain assumptions, described below under Item 3. Legal Proceedings, and is the best estimate of the minimum amount that the Company believes will be incurred in connection with the remaining aspects of the *Vioxx* Litigation, however, events such as additional trials in the *Vioxx* Litigation and other events that could arise in the course of the *Vioxx* Litigation could affect the ultimate amount of defense costs to be incurred by the Company.

The Company is not currently able to estimate any additional amounts that it may be required to pay in connection with the *Vioxx* Lawsuits or *Vioxx* Investigations. These proceedings are still expected to continue for years and the Company 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 *Vioxx* Lawsuits not included in the Settlement Program. Other than a reserve established in connection with the settlement of the shareholder derivative actions discussed below under Item 3.

Legal Proceedings, the Company has not established any reserves for any potential liability relating to the *Vioxx* Lawsuits not included in the Settlement Program or the *Vioxx* Investigations.

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

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

The Company sells *Vytorin* and *Zetia*. As previously disclosed, in January 2008, the legacy companies announced the results of the ENHANCE clinical trial, an imaging trial in 720 patients with heterozygous familial hypercholesterolemia, a rare genetic condition that causes very high levels of LDL bad cholesterol and greatly increases the risk for premature coronary artery disease. As previously reported, despite the fact that ezetimibe/simvastatin 10/80 mg (*Vytorin*) significantly lowered LDL bad cholesterol more than simvastatin 80 mg alone, there was no significant difference between treatment with ezetimibe/simvastatin and simvastatin alone on the pre-specified primary endpoint, a change in the thickness of carotid artery walls over two years as measured by ultrasound. The IMPROVE-IT trial is underway and is designed to provide cardiovascular outcomes data for ezetimibe/simvastatin in patients with acute coronary syndrome. No incremental benefit of ezetimibe/simvastatin on cardiovascular morbidity and mortality over and above that demonstrated for simvastatin has been established. In January 2009, the FDA announced that it had completed its review of the final clinical study report of ENHANCE. The FDA stated that the results from ENHANCE did not change its position that elevated LDL cholesterol is a risk factor for cardiovascular disease and that lowering LDL cholesterol reduces the risk for cardiovascular disease. For a discussion concerning litigation arising out of the ENHANCE study, see Item 3. Legal Proceedings below.

As previously disclosed, the legacy companies have received several letters addressed to both companies from the House Committee on Energy and Commerce, its Subcommittee on Oversight and Investigations (O&I), and the Ranking Minority Member of the Senate Finance Committee, collectively seeking a combination of witness interviews, documents and information on a variety of issues related to the ENHANCE clinical trial, the sale and promotion of *Vytorin*, as well as sales of stock by corporate officers. In addition, the legacy companies received three additional letters from O&I, seeking certain information and documents related to the SEAS clinical trial, which is described in more detail below. The legacy companies also each received subpoenas from the New York and New Jersey State Attorneys General Offices and a letter from the Connecticut Attorney General seeking similar information and documents. Finally, in September 2008, the legacy companies received a letter from the Civil Division of the DOJ informing it that the DOJ is investigating whether the companies' conduct relating to the promotion of *Vytorin* caused false claims to be submitted to federal health care programs. The Company is cooperating with these investigations. As previously disclosed, a number of shareholder lawsuits arising out of the ENHANCE study have been brought against Old Merck and Schering-Plough.

In July 2008, efficacy and safety results from the SEAS study were announced. SEAS was designed to evaluate whether intensive lipid lowering with *Vytorin* 10/40 mg would reduce the need for aortic valve replacement and the risk of cardiovascular morbidity and mortality versus placebo in patients with asymptomatic mild to moderate aortic stenosis who had no indication for statin therapy. *Vytorin* failed to meet its primary endpoint for the reduction of major cardiovascular events. In the study, patients in the group who took *Vytorin* 10/40 mg had a higher incidence of cancer than the group who took placebo. There was also a nonsignificant increase in deaths from cancer in patients in the group who took *Vytorin* versus those who took placebo. Cancer and cancer deaths were distributed across all major organ systems. The Company believes the cancer finding in SEAS is likely to be an anomaly that, taken in light of all the available data, does not support an association with *Vytorin*. In August 2008, the FDA announced that it was investigating the results from the SEAS trial. In December 2009, the FDA announced that it had completed its review of the data from the SEAS trial as well as a review of interim data from the SHARP and IMPROVE-IT trials. Based on currently available information, the FDA indicated it believed it is unlikely that *Vytorin* or *Zetia* increase the risk of cancer-related death. The SHARP trial is expected to be completed in 2010. The IMPROVE-IT trial is scheduled for completion in 2013. In the IMPROVE-IT trial, a blinded interim efficacy analysis will be conducted by the Data Safety Monitoring Board for the trial when approximately 50% of the endpoints have been accrued. That interim analysis is expected to be conducted in 2010. If, based on the results of the interim analysis, the trial were to be halted

because of concerns related to *Vytorin*, that could have a material adverse effect on sales of *Vytorin* and *Zetia*. Similarly, as noted above, the SHARP trial is expected to be completed in 2010. Negative results from the SHARP trial could also have an adverse affect on the sales of *Vytorin* and *Zetia*.

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Following the announcements of the ENHANCE and SEAS clinical trial results, sales of *Vytorin* and *Zetia* declined in 2008 and 2009 in the United States. These issues concerning the ENHANCE and SEAS clinical trials have had an adverse effect on sales of *Vytorin* and *Zetia* and could continue to have an adverse effect on such sales. If sales of such products are materially adversely affected, the Company's business, cash flow, results of operations, financial position and prospects could also be materially adversely affected. In addition, unfavorable outcomes resulting from the litigation concerning the sale and promotion of these products could have a material adverse effect on the Company's business, cash flow, results of operations, financial position and prospects.

An arbitration proceeding commenced by Centocor against Schering-Plough may result in the Company's loss of the rights to market *Remicade* and *Simponi*.

A subsidiary of the Company is a party to a Distribution Agreement with Centocor, now a wholly owned subsidiary of Johnson & Johnson, under which the Schering-Plough subsidiary has rights to distribute and commercialize the rheumatoid arthritis treatment *Remicade* and *Simponi*, a next-generation treatment, in certain territories.

Under Section 8.2(c) of the Distribution Agreement, If either party is acquired by a third party or otherwise comes under Control (as defined in Section 1.4 [of the Distribution Agreement]) of a third party, it will promptly notify the other party not subject to such change of control. The party not subject to such change of control will have the right, however not later than thirty (30) days from such notification, to notify in writing the party subject to the change of Control of the termination of the Agreement taking effect immediately. As used herein Change of Control shall mean (i) any merger, reorganization, consolidation or combination in which a party to this Agreement is not the surviving corporation; or (ii) any person (within the meaning of Section 13(d) and Section 14(d)(2) of the Securities Exchange Act of 1934), excluding a party's Affiliates, is or becomes the beneficial owner, directly or indirectly, of securities of the party representing more than fifty percent (50%) of either (A) the then-outstanding shares of common stock of the party or (B) the combined voting power of the party's then-outstanding voting securities; or (iii) if individuals who as of the Effective Date [April 3, 1998] constitute the Board of Directors of the party (the Incumbent Board) cease for any reason to constitute at least a majority of the Board of Directors of the party; provided, however, that any individual becoming a director subsequent to the Effective Date whose election, or nomination for election by the party's shareholders, was approved by a vote of at least a majority of the directors then comprising the Incumbent Board shall be considered as though such individual were a member of the Incumbent Board, but excluding, for this purpose, any such individual whose initial assumption of office occurs as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents by or on behalf of a person other than the Board; or (iv) approval by the shareholders of a party of a complete liquidation or the complete dissolution of such party.

Section 1.4 of the Distribution Agreement defines Control to mean the ability of any entity (the Controlling entity), directly or indirectly, through ownership of securities, by agreement or by any other method, to direct the manner in which more than fifty percent (50%) of the outstanding voting rights of any other entity (the Controlled entity), whether or not represented by securities, shall be cast, or the right to receive over fifty percent (50%) of the profits or earnings of, or to otherwise control the management decisions of, such other entity (also a Controlled entity).

On May 27, 2009, Centocor delivered to Schering-Plough a notice initiating an arbitration proceeding to resolve whether, as a result of the proposed Merger, Centocor is permitted to terminate the Distribution Agreement and related agreements. As part of the arbitration process, Centocor will take the position that it has the right to terminate the Distribution Agreement on the grounds that, in the Merger, Schering-Plough and the Schering-Plough subsidiary party to the Distribution Agreement were (i) acquired by a third party or otherwise come[ing] under Control (as defined in Section 1.4) of a third party and/or (ii) undergoing a Change of Control (as defined in Section 8.2(c)). A hearing in the arbitration is scheduled to commence in late September 2010. Sales of *Remicade* and *Simponi* included in the Company's results for the post-Merger period were \$430.7 million and \$3.9 million, respectively. Sales of *Remicade*

recognized by Schering-Plough in 2009 prior to the Merger were \$1.9 billion.

The Company is vigorously contesting Centocor's attempt to terminate the Distribution Agreement as a result of the Merger. However, if the arbitrator were to conclude that Centocor is permitted to terminate the Distribution Agreement as a result of the Merger and Centocor in fact terminates the Distribution Agreement, the

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Company's subsidiary would not be able to distribute *Remicade* or *Simponi*. In addition, in the arbitration, Centocor is claiming damages, in an amount to be determined, that result from Merck's alleged non-termination of the Distribution Agreement. If Centocor were to prevail in the arbitration, Merck could be liable for the net damages, including any offsets or mitigation, that the arbitration panel finds Centocor incurred as a result of non-termination and the Company would suffer an impairment charge. An unfavorable outcome in the arbitration would have a material adverse effect on the Company's financial position, liquidity and results of operations.

Finally, due to the uncertainty surrounding the outcome of the arbitration, the parties may choose to settle the dispute under mutually agreeable terms but any agreement reached with Centocor to resolve the dispute under the Distribution Agreement may result in the terms of the Distribution Agreement being modified in a manner that may reduce the benefits of the Distribution Agreement to the Company.

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.

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

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

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

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

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

The Company is increasingly dependent on sophisticated information technology and infrastructure. Any significant breakdown, intrusion, interruption or corruption of these systems or data breaches could have a material adverse effect on our business. In addition, the Company currently is proceeding with a multi-year implementation of an enterprise wide resource planning system, which includes modification to the design, operation and documentation of its internal controls over financial reporting, and intends to implement the resource planning system in the United States in 2010. Any material problems in the implementation could have a material adverse effect on the Company's business.

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, 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.

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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 safety 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 have 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 European Medicines Agency (EMEA) and the 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 claims for its products.

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

Future sales of key animal health products could be adversely impacted by a number of risk factors including certain risks that are specific to the animal health business. For example, the outbreak of disease carried by animals, such as Bovine Spongiform Encephalopathy (BSE) 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 multiple jurisdictions, such as the United States and European states within the EU, could result in restricted access to, or transport or use of, such materials. If the Company loses access to sufficient sources of such materials, or if tighter restrictions are imposed on the use of such materials, the Company may not be able to conduct research activities as planned and may incur additional development costs.

The development, manufacturing and marketing of biologics are subject to regulation by the FDA, the EMEA 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

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procedures, is required for human vaccine candidates and FDA approval is required for the release of each manufactured 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.

There currently is no process in the United States for the submission or approval of generic biologics based upon abbreviated data packages or a showing of sameness to another approved biologic, but there is public dialogue at the FDA and in Congress regarding the scientific and statutory basis upon which such products, known as biosimilars or follow-on biologics, could be approved and marketed in the United States. The Company cannot be certain when Congress will create a statutory pathway for the approval of biosimilars, and the Company cannot predict what impact, if any, the approval of biosimilars would have on the sales of Company products in the United States. In Europe, however, the EMEA has issued guidelines for approving biological products through an abbreviated pathway, and biosimilars have been approved in Europe. If a biosimilar version of one of the Company's products were approved in Europe, it could have a negative effect on sales of the product.

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 2010, President Obama's administration proposed significant changes to the U.S. international tax laws, including changes that would limit U.S. tax deductions for expenses related to un-repatriated

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foreign-source income and modify the U.S. foreign tax credit rules. We cannot determine whether these proposals will be enacted into law or what, if any, changes may be made to such proposals prior to their being enacted into law. If these or other changes to the U.S. international tax laws are enacted, they could have a significant impact on the financial results of the Company.

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

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

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

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

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

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

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

- identifying and eliminating redundant and underperforming operations and assets; and

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

Integration efforts between the two companies will also divert management attention and resources. An inability to realize the full extent of, or any of, the anticipated benefits of the Merger, as well as any delays encountered in the integration process, could have an adverse effect on the Company's business and results of operations, which may affect the value of the shares of Company common stock.

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

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

anticipated benefits.

The Company will incur significant transaction and merger-related transition costs in connection with the Merger.

The Company will incur significant costs in connection with consummating the Merger and integrating the operations of the two companies, with a significant portion of such costs being incurred through the first year after completion of the Merger. The Company continues to assess the magnitude of these costs, and additional unanticipated costs may be incurred in the integration of the businesses of the two legacy companies. Although the Company believes that the elimination of duplicative costs, as well as the realization of other efficiencies related to the integration of the businesses, will offset incremental transaction and Merger-related costs over time, no assurance can be given that this net benefit will be achieved in the near term, or at all.

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The Company's debt obligations incurred to finance the Merger could adversely affect its business.

While the Company's financing strategy for the Merger was focused on preserving financial strength and flexibility to continue to invest in the Company's business and key growth drivers post-merger, debt obligations incurred to finance the Merger could affect the Company's flexibility in planning for, or reacting to, changes in its business and the industry in which it operates, thereby placing it at a competitive disadvantage compared to competitors that have less indebtedness. Further, if the Company decides to retire or pay down indebtedness early it may be required to dedicate a substantial portion of its cash flow from operations to do so, thereby reducing the availability of its cash flow for other purposes, including business development efforts and mergers and acquisitions.

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.

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 will be significant due to the fact that the majority of Schering-Plough's legacy operations are outside the United States. 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.

As discussed below, the Venezuelan economy was recently determined to be hyperinflationary which requires the Company to remeasure its local currency operations there to U.S. dollars which remeasurement will be recorded in the first quarter of 2010. In addition, the Venezuelan government recently devalued its currency. These actions will have an adverse effect on the Company's results of operations, financial position and cash flows.

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.

Cautionary Factors that May Affect Future Results

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

This report, including the Annual Report, and other written reports and oral statements made from time to time by the Company may contain so-called forward-looking statements, all of which are based on management's current expectations and are subject to risks and uncertainties which may cause results to differ materially from those set forth in the statements. One can identify these forward-looking statements by their use of words such as expects, plans, will, estimates, forecasts, projects and other words of similar meaning. One can also identify them by the fact that they do not relate strictly to historical or current facts. These statements are likely to address the Company's growth strategy, financial results, product development, product approvals, product

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potential, and development programs. One must carefully consider any such statement and should understand that many factors could cause actual results to differ materially from the Company's forward-looking statements. These factors include inaccurate assumptions and a broad variety of other risks and uncertainties, including some that are known and some that are not. No forward-looking statement can be guaranteed and actual future results may vary materially. The Company does not assume the obligation to update any forward-looking statement. The Company cautions you not to place undue reliance on these forward-looking statements. Although it is not possible to predict or identify all such factors, they may include the following:

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

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

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

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

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

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

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

The arbitration proceeding involving the Company's right to distribute *Remicade* and *Simponi*.

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.

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

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Item 2. Properties.

The Company's corporate headquarters is located in Whitehouse Station, New Jersey. The Company's U.S. commercial operations are headquartered in Upper Gwynedd, Pennsylvania. The Company's U.S. pharmaceutical business is conducted through divisional headquarters located in Upper Gwynedd and Whitehouse Station, New Jersey. The Company's vaccines business is conducted through divisional headquarters located in West Point, Pennsylvania. Merck's Animal Health global headquarters is located in Boxmeer, the Netherlands. Principal U.S. research facilities are located in Rahway, Kenilworth, Summit and Union, New Jersey, West Point, Palo Alto, California, and Nebraska (Animal Health). Principal research facilities outside the U.S. are located in the Netherlands and Scotland. The Company also has production facilities for human health products at 14 locations in the United States and Puerto Rico. Outside the United States, through subsidiaries, the Company owns or has an interest in manufacturing plants or other properties in Australia, Canada, Japan, Singapore, South Africa, and other countries in Western Europe, Central and South America, and Asia.

Capital expenditures for 2009 were \$1.5 billion compared with \$1.3 billion for 2008. In the United States, these amounted to \$981.6 million for 2009 and \$946.6 million for 2008. Abroad, such expenditures amounted to \$479.0 million for 2009 and \$351.7 million for 2008.

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 Company is involved in various claims and legal proceedings of a nature considered normal to its business, including product liability, intellectual property, and commercial litigation, as well as additional matters such as antitrust actions.

Vioxx Litigation

Product Liability Lawsuits

As previously disclosed, individual and putative class actions have been filed against Old Merck in state and federal courts alleging personal injury and/or economic loss with respect to the purchase or use of *Vioxx*. All such actions filed in federal court are coordinated in a multidistrict litigation in the U.S. District Court for the Eastern District of Louisiana (the MDL) before District Judge Eldon E. Fallon. A number of such actions filed in state court are coordinated in separate coordinated proceedings in state courts in New Jersey, California and Texas, and the counties of Philadelphia, Pennsylvania and Washoe and Clark Counties, Nevada. As of December 31, 2009, the Company had been served or was aware that it had been named as a defendant in approximately 9,100 pending lawsuits, which include approximately 19,400 plaintiff groups, alleging personal injuries resulting from the use of *Vioxx*, and in approximately 44 putative class actions alleging personal injuries and/or economic loss. (All of the actions discussed in this paragraph and in Other Lawsuits below are collectively referred to as the *Vioxx* Product Liability Lawsuits.) Of these lawsuits, approximately 7,350 lawsuits representing approximately 15,525 plaintiff groups are or are slated to be in the federal MDL and approximately 10 lawsuits representing approximately 10 plaintiff groups are included in a coordinated proceeding in New Jersey Superior Court before Judge Carol E. Higbee.

Of the plaintiff groups described above, most are currently in the *Vioxx* Settlement Program, described below. As of December 31, 2009, 80 plaintiff groups who were otherwise eligible for the Settlement Program have not participated and their claims remain pending against Old Merck. In addition, the claims of approximately 275 plaintiff groups who are not eligible for the Settlement Program remain pending against Old Merck. A number of these 275 plaintiff groups are subject to various motions to dismiss for failure to comply with court-ordered deadlines. Since December 31, 2009, certain of these plaintiff groups have since been dismissed. In addition, the

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claims of over 35,600 plaintiffs had been dismissed as of December 31, 2009, the vast majority of which were dismissed as a result of the settlement process discussed below.

On November 9, 2007, Old Merck announced that it had entered into an agreement (the Settlement Agreement) with the law firms that comprise the executive committee of the Plaintiffs Steering Committee (PSC) of the federal *Vioxx* MDL, as well as representatives of plaintiffs counsel in the Texas, New Jersey and California state coordinated proceedings, to resolve state and federal myocardial infarction (MI) and ischemic stroke (IS) claims filed as of that date in the United States. The Settlement Agreement applies only to U.S. legal residents and those who allege that their MI or IS occurred in the United States. The Settlement Agreement provided for Old Merck to pay a fixed aggregate amount of \$4.85 billion into two funds (\$4.0 billion for MI claims and \$850 million for IS claims).

Interim and final payments have been made to certain qualifying claimants. It is expected that the remainder of the full \$4.85 billion will be distributed in the first half of 2010. The Company has completed making payments into the settlement funds.

There are two U.S. *Vioxx* Product Liability Lawsuits currently scheduled for trial in 2010. Old Merck has previously disclosed the outcomes of several *Vioxx* Product Liability Lawsuits that were tried prior to 2010.

Of the cases that went to trial, the *McDarby* matter was resolved in the fourth quarter of 2009, leaving only two unresolved post-trial appeals: *Ernst v. Merck* and *Garza v. Merck*.

As previously reported, in September 2006, Old Merck filed a notice of appeal of the August 2005 jury verdict in favor of the plaintiff in the Texas state court case, *Ernst v. Merck*. On May 29, 2008, the Texas Court of Appeals reversed the trial court's judgment and issued a judgment in favor of Old Merck. The Court of Appeals found the evidence to be legally insufficient on the issue of causation. Plaintiff filed a motion for rehearing *en banc* in the Court of Appeals. On June 4, 2009, in response to plaintiff's motion for rehearing, the Court of Appeals issued a new opinion reversing the jury's verdict and rendered judgment for Old Merck. On September 8, 2009, plaintiff filed a second motion for rehearing *en banc*, which the Court of Appeals denied on November 19, 2009. On December 7, 2009, plaintiff filed another motion for rehearing, which the Court of Appeals again denied. Plaintiff filed a petition for review with the Supreme Court of Texas on February 3, 2010.

As previously reported, in April 2006, in *Garza v. Merck*, a jury in state court in Rio Grande City, Texas returned a verdict in favor of the family of decedent Leonel Garza. The jury awarded a total of \$7 million in compensatory damages to Mr. Garza's widow and three sons. The jury also purported to award \$25 million in punitive damages even though under Texas law, in this case, potential punitive damages were capped at \$750,000. In May 2008, the San Antonio Court of Appeals reversed the judgment and rendered a judgment in favor of Old Merck. In December 2008, the Court of Appeals, on rehearing, vacated its prior ruling and issued a replacement. In the new ruling, the court ordered a take-nothing judgment for Old Merck on the design defect claim, but reversed and remanded for a new trial as to the strict liability claim because of juror misconduct. In January 2009, Old Merck filed a petition for review with the Texas Supreme Court. The Texas Supreme Court granted Old Merck's petition for review and oral argument was held on January 20, 2010.

Other Lawsuits

Approximately 190 claims by individual private third-party payors were filed in the New Jersey court and in federal court in the MDL. On September 15, 2009, Old Merck announced it had finalized a settlement agreement, which it had previously disclosed, to resolve all pending lawsuits in which U.S.-based private third-party payors (TPPs) sought reimbursement for covering *Vioxx* purchased by their plan members. Certain other claimants participated in the resolution as well. The agreement provided that Old Merck did not admit wrongdoing or fault. Under the settlement agreement, Old Merck paid a fixed total of \$80 million. This amount includes a settlement fund that will be divided

among the TPPs (insurers, employee benefit plans and union welfare funds) participating in the resolution in accordance with a formula that is based on product volume and a provision for potential payment of attorneys' fees. In return, the settling TPPs will dismiss their lawsuits and release their claims against Old Merck. Stipulated dismissals of the settled TTP actions were filed in New Jersey and the MDL in December 2009. Old Merck recorded a charge of \$80 million in the second quarter of 2009 related to the settlement and paid the

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\$80 million in the fourth quarter of 2009. Since the settlement, one additional TPP case has been filed which is pending in the MDL proceeding.

Separately, there are also still pending in various U.S. courts putative class actions purportedly brought on behalf of individual purchasers or users of *Vioxx* and seeking reimbursement of alleged economic loss. In the MDL proceeding, 33 such class actions remain. In 2005, Old Merck moved to dismiss a master complaint that includes these cases, but the MDL court has not yet ruled on that motion.

On March 17, 2009, the New Jersey Superior Court denied plaintiffs' motion for class certification in *Martin-Kleinman v. Merck*, a putative consumer class action. Plaintiffs moved for leave to appeal the decision to the New Jersey Supreme Court on November 6, 2009. On January 12, 2010, the New Jersey Supreme Court denied plaintiff's request for appellate review of the denial of class certification.

On June 12, 2008, a Missouri state court certified a class of Missouri plaintiffs seeking reimbursement for out-of-pocket costs relating to *Vioxx*. The plaintiffs do not allege any personal injuries from taking *Vioxx*. The Missouri Court of Appeals affirmed the trial court's certification of a class on May 12, 2009, and the Missouri Supreme Court denied Old Merck's application for review of that decision on September 1, 2009. Trial has been set for April 11, 2011. In addition, in Indiana, plaintiffs have filed a motion to certify a class of Indiana *Vioxx* purchasers in a case pending before the Circuit Court of Marion County, Indiana; discovery in that case is ongoing. Briefing is complete on plaintiffs' motion to certify a class of Kentucky *Vioxx* purchasers before the Circuit Court of Pike County, Kentucky. A hearing on this matter was held on February 26, 2010. A judge in Cook County, Illinois has consolidated three putative class actions brought by *Vioxx* purchasers. The plaintiffs in those actions recently voluntarily dismissed their lawsuits.

Plaintiffs also filed a class action in California state court seeking certification of a class of California third-party payors and end-users. The trial court denied the motion for class certification on April 30, 2009, and the Court of Appeal affirmed that ruling on December 15, 2009. On January 25, 2010, plaintiffs filed a petition for review with the California Supreme Court.

Old Merck has also been named as a defendant in twenty-one separate lawsuits brought by government entities, including the Attorneys General of thirteen states, five counties, the City of New York, and private citizens (who have brought *qui tam* and taxpayer derivative suits). These actions allege that Old Merck misrepresented the safety of *Vioxx* and seek: (i) recovery of the cost of *Vioxx* purchased or reimbursed by the government entity and its agencies; (ii) reimbursement of all sums paid by the government entity and its agencies for medical services for the treatment of persons injured by *Vioxx*; (iii) damages under various common law theories; and/or (iv) remedies under various state statutory theories, including state consumer fraud and/or fair business practices or Medicaid fraud statutes, including civil penalties. Nine of the thirteen cases are pending in the MDL proceeding, two are subject to conditional orders transferring them to the MDL proceeding, and two were remanded to state court. One of the lawsuits brought by the counties is a class action filed by Santa Clara County, California on behalf of all similarly situated California counties.

Old Merck's motion for summary judgment was granted in November 2009 in a case brought by the Attorney General of Texas that was scheduled to go to trial in early 2010. The Texas Attorney General did not appeal. In the Michigan Attorney General case, Old Merck is currently seeking appellate review of the trial court's order denying Old Merck's motion to dismiss. The trial court has entered a stay of proceedings (including discovery) pending the result of that appeal. Finally, the Attorney General actions in the MDL described in the previous paragraph are in the discovery phase. The Louisiana Attorney General case is currently scheduled for trial in the MDL court on April 12, 2010.

Shareholder Lawsuits

As previously disclosed, in addition to the *Vioxx* Product Liability Lawsuits, Old Merck and various current and former officers and directors are defendants in various putative class actions and individual lawsuits under the federal securities laws and state securities laws (the *Vioxx* Securities Lawsuits). All of the *Vioxx* Securities Lawsuits pending in federal court have been transferred by the Judicial Panel on Multidistrict Litigation (the JPML) to the U.S. District Court for the District of New Jersey before District Judge Stanley R. Chesler for inclusion in a nationwide MDL (the Shareholder MDL). Judge Chesler has consolidated the *Vioxx* Securities

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Lawsuits for all purposes. The putative class action, which requested damages on behalf of purchasers of Old Merck stock between May 21, 1999 and October 29, 2004, alleged that the defendants made false and misleading statements regarding *Vioxx* in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, and sought unspecified compensatory damages and the costs of suit, including attorneys' fees. The complaint also asserted claims under Section 20A of the Securities and Exchange Act against certain defendants relating to their sales of Old Merck stock and under Sections 11, 12 and 15 of the Securities Act of 1933 against certain defendants based on statements in a registration statement and certain prospectuses filed in connection with the Old Merck Stock Investment Plan, a dividend reinvestment plan. On April 12, 2007, Judge Chesler granted defendants' motion to dismiss the complaint with prejudice. Plaintiffs appealed Judge Chesler's decision to the U.S. Court of Appeals for the Third Circuit. On September 9, 2008, the Third Circuit issued an opinion reversing Judge Chesler's order and remanding the case to the District Court. Old Merck filed a petition for a writ of certiorari with the United States Supreme Court on January 15, 2009, which the Supreme Court granted on May 26, 2009. Oral argument was held on November 30, 2009 and a decision is expected in the first half of 2010. While the petition for certiorari was pending, plaintiffs filed their Consolidated and Fifth Amended Class Action Complaint in the District Court. Old Merck filed a motion to dismiss that complaint on May 1, 2009, following which the District Court proceedings were stayed pending the outcome of the Supreme Court appeal. The motion to dismiss in the District Court has been withdrawn without prejudice to Old Merck's right to re-file such a motion pending the outcome of the Supreme Court appeal.

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

In addition, as previously disclosed, various putative class actions filed in federal court under the Employee Retirement Income Security Act (ERISA) against Old Merck and certain current and former officers and directors (the *Vioxx* ERISA Lawsuits) and, together with the *Vioxx* Securities Lawsuits and the *Vioxx* Derivative Lawsuits described below, the *Vioxx* Shareholder Lawsuits) have been transferred to the Shareholder MDL and consolidated for all purposes. The consolidated complaint asserts claims for breach of fiduciary duty on behalf of certain of Old Merck's current and former employees who are participants in certain of Old Merck's retirement plans. The complaint makes similar allegations with respect to *Vioxx* to the allegations contained in the *Vioxx* Securities Lawsuits. On July 11, 2006, Judge Chesler granted in part and denied in part defendants' motion to dismiss the ERISA complaint. On October 19, 2007, plaintiffs moved for certification of a class of individuals who were participants in and beneficiaries of Old Merck's retirement savings plans at any time between October 1, 1998 and September 30, 2004 and whose plan accounts included investments in the Old Merck Common Stock Fund and/or Old Merck common stock. On February 9, 2009, the court denied the motion for certification of a class as to one count and granted the motion as to the remaining counts. The court also excluded from the class definition those individuals who (i) were not injured in connection with their investments in Old Merck stock and (ii) executed post-separation settlement agreements that released their claims under ERISA. On March 23, 2009, Judge Chesler denied defendants' motion for judgment on the pleadings. On May 11, 2009, Judge Chesler entered an order denying plaintiffs' motion for partial summary judgment against certain individual defendants, which had been filed on December 24, 2008.

As previously disclosed, on October 29, 2004, two individual shareholders made a demand on Old Merck's Board to take legal action against Mr. Raymond Gilmartin, former Chairman, President and Chief Executive Officer, and other

individuals for allegedly causing damage to Old Merck with respect to the allegedly improper marketing of *Vioxx*. In December 2004, the Special Committee of the Board of Directors retained the Honorable John S. Martin, Jr. of Debevoise & Plimpton LLP to conduct an independent investigation of, among other things, the allegations set forth in the demand. Judge Martin's report was made public in September 2006.

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Based on the Special Committee's recommendation made after careful consideration of the Martin report and the impact that derivative litigation would have on Old Merck, the Board rejected the demand. On October 11, 2007, two shareholders filed a shareholder derivative lawsuit purportedly on Old Merck's behalf in state court in Atlantic County, New Jersey against current and former officers and directors of Old Merck. Plaintiffs alleged that the Board's rejection of their demand was unreasonable and improper, and that the defendants breached various duties to Old Merck in allowing *Vioxx* to be marketed. The parties reached a proposed settlement and, on February 8, 2010, the court issued an order preliminarily approving the settlement, requiring that notice of the proposed settlement be made to Merck's shareholders, and setting a hearing to consider final approval of the settlement on March 22, 2010. On February 9, 2010, Merck notified shareholders of the proposed settlement and its terms. Under the proposed settlement, Merck has agreed to make certain corporate governance changes and supplement policies and procedures previously established by the Company, and has agreed to pay an award of fees and expenses to plaintiffs' attorneys in an amount to be determined by the court, not to exceed \$12.15 million. In addition, Merck, the plaintiffs and the individual defendants will exchange full, mutual releases of all claims that were, or could have been, asserted in the derivative actions. The proposed settlement does not constitute an admission of liability or wrongful conduct by Merck or by any of the defendants named in the actions. If approved by the court, this proposed settlement will also resolve the federal consolidated shareholder derivative action described below.

As previously disclosed, various shareholder derivative actions filed in federal court were transferred to the Shareholder MDL and consolidated for all purposes by Judge Chesler (the *Vioxx* Derivative Lawsuits). On May 5, 2006, Judge Chesler granted defendants' motion to dismiss on the grounds that plaintiffs had failed to demonstrate that demand should be excused and denied plaintiffs' request for leave to amend their complaint. Plaintiffs appealed, arguing that Judge Chesler erred in denying plaintiffs' leave to amend their complaint with documents acquired by stipulation of the parties. On July 18, 2007, the United States Court of Appeals for the Third Circuit reversed the District Court's decision on the grounds that Judge Chesler should have allowed plaintiffs to seek leave to amend their complaint using the documents acquired by stipulation, and remanded the case for the District Court's consideration of whether, even with the additional materials, plaintiffs' proposed amendment would be futile. Plaintiffs filed their brief in support of their request for leave to amend their complaint, along with their proposed amended complaint, on November 9, 2007. The Court denied the motion on June 17, 2008, and again dismissed the case. One of the plaintiffs appealed Judge Chesler's decision to the United States Court of Appeals for the Third Circuit. Oral argument on the appeal was held on July 15, 2009. On November 10, 2009, before any decision was issued, the appeal was stayed pending approval of a settlement reached in the derivative action pending in the New Jersey Superior Court that would resolve all state and federal shareholder derivative claims relating to *Vioxx*.

International Lawsuits

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

In November 2006, the Superior Court in Quebec authorized the institution of a class action on behalf of all individuals who, in Quebec, consumed *Vioxx* and suffered damages arising out of its ingestion. On May 7, 2009, the plaintiffs served an introductory motion for a class action based upon that authorization, and the case remains in preliminary stages of litigation. On May 30, 2008, the provincial court of Queen's Bench in Saskatchewan, Canada entered an order certifying a class of *Vioxx* users in Canada, except those in Quebec. Old Merck appealed the certification order and, on March 30, 2009, the Court of Appeal granted Old Merck's appeal and quashed the certification order. On October 22, 2009, the Supreme Court of Canada dismissed plaintiffs' appeal application and decided not to review the judgment of the Saskatchewan Court of Appeal. On July 28, 2008, the Superior Court in Ontario denied Old Merck's motion to stay class proceedings in Ontario and decided to certify an overlapping class of *Vioxx* users in Canada, except those in Quebec and Saskatchewan, who allege negligence and an entitlement to elect to waive the tort. On February 13, 2009, the Ontario Divisional Court dismissed the appeal from the order denying the

stay and, on May 15, 2009, the Ontario Court of Appeal denied leave to appeal. On October 22, 2009, the Supreme Court of Canada dismissed Old Merck's application and decided not to review the judgment of the Ontario Court of Appeal. After the Court of Appeal for Saskatchewan quashed the multi-jurisdictional certification order entered in that province, Old Merck applied to the Ontario Court of Appeal for leave to appeal from the

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Ontario certification order. Leave to appeal was granted, the appeal was filed on May 20, 2009 and, in accordance with the court's decision, Old Merck sought leave to appeal to the Divisional Court, which was denied on December 7, 2009. These procedural decisions in the Canadian litigation do not address the merits of the plaintiffs' claims and litigation in Canada remains in an early stage.

A trial in a representative action in Australia commenced on March 30, 2009, in the Federal Court of Australia. The named plaintiff, who alleges he suffered an MI, seeks to represent others in Australia who ingested *Vioxx* and suffered an MI, thrombotic stroke, unstable angina, transient ischemic attack or peripheral vascular disease. On March 30, 2009, the trial judge entered an order directing that, in advance of all other issues in the proceeding, the issues to be determined during the trial are those issues of fact and law in the named plaintiff's individual case, and those issues of fact and law that the trial judge finds, after hearing the evidence, are common to the claims of the group members that the named plaintiff has alleged that he represents. The trial in this representative action concluded on June 25, 2009, and the trial judge reserved decision.

Insurance

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

Investigations

As previously disclosed, Old Merck has received subpoenas from the DOJ requesting information related to Old Merck's research, marketing and selling activities with respect to *Vioxx* in a federal health care investigation under criminal statutes. This investigation includes subpoenas for witnesses to appear before a grand jury. As previously disclosed, in March 2009, Old Merck received a letter from the U.S. Attorney's Office for the District of Massachusetts identifying it as a target of the grand jury investigation regarding *Vioxx*. Further, as previously disclosed, investigations are being conducted by local authorities in certain cities in Europe in order to determine whether any criminal charges should be brought concerning *Vioxx*. The Company is cooperating with these governmental entities in their respective investigations (the *Vioxx* Investigations). The Company cannot predict the outcome of these inquiries; however, they could result in potential civil and/or criminal remedies.

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

Reserves

As discussed above, on November 9, 2007, Old Merck entered into the Settlement Agreement with the law firms that comprise the executive committee of the PSC of the federal *Vioxx* MDL as well as representatives of plaintiffs' counsel in the Texas, New Jersey and California state coordinated proceedings to resolve state and federal MI and IS claims filed as of that date in the United States. In 2007, as a result of entering into the Settlement Agreement, Old Merck recorded a pretax charge of \$4.85 billion which represents the fixed aggregate amount to be paid to plaintiffs qualifying for payment under the Settlement Program.

There are two U.S. *Vioxx* Product Liability Lawsuit trials scheduled for trial in 2010. The Company cannot predict the timing of any other trials related to the *Vioxx* Litigation. The Company believes that it has meritorious defenses to the

Vioxx Product Liability Lawsuits, *Vioxx* Shareholder Lawsuits and *Vioxx* Foreign Lawsuits (collectively the *Vioxx* Lawsuits) and will vigorously defend against them. In view of the inherent difficulty of predicting the outcome of litigation, particularly where there are many claimants and the claimants seek indeterminate damages, the Company is unable to predict the outcome of these matters, and at this time cannot reasonably estimate the possible loss or range of loss with respect to the *Vioxx* Lawsuits not included in the

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Settlement Program. The Company has not established any reserves for any potential liability relating to the *Vioxx* Lawsuits not included in the Settlement Program, other than a reserve established in connection with the resolution of the shareholder derivative lawsuits discussed above, or the *Vioxx* Investigations. Unfavorable outcomes in the *Vioxx* Litigation could have a material adverse effect on the Company's financial position, liquidity and results of operations.

Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable. As of December 31, 2008, Old Merck had an aggregate reserve of approximately \$4.379 billion (the *Vioxx* Reserve) for the Settlement Program and future legal defense costs related to the *Vioxx* Litigation.

During 2009, Merck spent approximately \$244 million in the aggregate in legal defense costs worldwide, including approximately \$54 million in the fourth quarter of 2009, related to (i) the *Vioxx* Product Liability Lawsuits, (ii) the *Vioxx* Shareholder Lawsuits, (iii) the *Vioxx* Foreign Lawsuits, and (iv) the *Vioxx* Investigations (collectively, the *Vioxx* Litigation). In addition, during 2009, Old Merck paid an additional \$4.1 billion into the settlement funds in connection with the Settlement Program. Also, during 2009, Merck recorded \$75 million of charges, including \$35 million in the fourth quarter, solely for its future legal defense costs for the *Vioxx* Litigation. Consequently, as of December 31, 2009, the aggregate amount of the *Vioxx* Reserve was approximately \$110 million, which is solely for future legal defense costs for the *Vioxx* Litigation. Some of the significant factors considered in the review of the *Vioxx* Reserve were as follows: the actual costs incurred by the Company; the development of the Company's legal defense strategy and structure in light of the scope of the *Vioxx* Litigation, including the Settlement Agreement and the expectation that certain lawsuits will continue to be pending; the number of cases being brought against the Company; the costs and outcomes of completed trials and the most current information regarding anticipated timing, progression, and related costs of pre-trial activities and trials in the *Vioxx* Litigation. The amount of the *Vioxx* Reserve as of December 31, 2009 represents the Company's best estimate of the minimum amount of defense costs to be incurred in connection with the remaining aspects of the *Vioxx* Litigation; however, events such as additional trials in the *Vioxx* Litigation and other events that could arise in the course of the *Vioxx* Litigation could affect the ultimate amount of defense costs to be incurred by the Company.

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

Other Product Liability Litigation

Fosamax

As previously disclosed, Old Merck is a defendant in product liability lawsuits in the United States involving *Fosamax* (the *Fosamax* Litigation). As of December 31, 2009, approximately 978 cases, which include approximately 1,356 plaintiff groups, had been filed and were pending against Old Merck in either federal or state court, including one case which seeks class action certification, as well as damages and/or medical monitoring. In these actions, plaintiffs allege, among other things, that they have suffered osteonecrosis of the jaw, generally subsequent to invasive dental procedures, such as tooth extraction or dental implants and/or delayed healing, in association with the use of *Fosamax*. In addition, plaintiffs in approximately five percent of these actions allege that they sustained stress and/or low energy femoral fractures in association with the use of *Fosamax*. On August 16, 2006, the JPML ordered that the *Fosamax* product liability cases pending in federal courts nationwide should be transferred and consolidated into one multidistrict litigation (the *Fosamax* MDL) for coordinated pre-trial proceedings. The *Fosamax* MDL has been transferred to Judge John Keenan in the U.S. District Court for the Southern District of New York. As a result of the JPML order, approximately 771 of the cases are before Judge Keenan. Judge Keenan issued a Case Management Order (and various amendments thereto) setting forth a schedule governing the proceedings which focused primarily upon resolving the class action certification motions in 2007 and completing fact discovery in an initial group of 25 cases by October 1, 2008. Briefing and argument on plaintiffs' motions for certification of medical monitoring classes

were completed in 2007 and Judge Keenan issued an order denying the motions on January 3, 2008. On January 28, 2008, Judge Keenan issued a further order dismissing with prejudice all class claims asserted in the first four class action lawsuits filed against Old Merck that sought personal injury damages and/or medical monitoring relief on a class wide basis. *Daubert* motions were filed

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in May 2009 and Judge Keenan conducted a *Daubert* hearing in July 2009. On July 27, 2009, Judge Keenan issued his ruling on the parties' respective *Daubert* motions. The ruling denied the Plaintiff Steering Committee's motion and granted in part and denied in part Old Merck's motion. The first MDL trial *Boles v. Merck* began on August 11, 2009, and ended on September 2, 2009. On September 11, 2009, the MDL court declared a mistrial in *Boles* because the eight person jury could not reach a unanimous verdict and, consequently, the *Boles* case is set to be retried on June 2, 2010. The second MDL case set for trial *Flemings v. Merck* was scheduled to start on January 12, 2010, but Judge Keenan granted Old Merck's motion for summary judgment and dismissed the case on November 23, 2009. The next MDL case set for trial *Maley v. Merck* is currently scheduled to start on April 19, 2010. Old Merck filed a motion for summary judgment in *Maley*, which the MDL court granted in part and denied in part on January 27, 2010 and, as a result, the Company expects that the trial will commence as currently scheduled on April 19. On February 1, 2010, Judge Keenan selected a new bellwether case *Judith Graves v. Merck* to replace the *Flemings* bellwether case, which the MDL court dismissed when it granted summary judgment in favor of Old Merck. The MDL court has set the *Graves* trial to begin on September 13, 2010. A trial in Alabama is currently scheduled to begin on May 3, 2010 and a trial in Florida is currently scheduled to begin on June 21, 2010.

In addition, in July 2008, an application was made by the Atlantic County Superior Court of New Jersey requesting that all of the *Fosamax* cases pending in New Jersey be considered for mass tort designation and centralized management before one judge in New Jersey. On October 6, 2008, the New Jersey Supreme Court ordered that all pending and future actions filed in New Jersey arising out of the use of *Fosamax* and seeking damages for existing dental and jaw-related injuries, including osteonecrosis of the jaw, but not solely seeking medical monitoring, be designated as a mass tort for centralized management purposes before Judge Higbee in Atlantic County Superior Court. As of December 31, 2009, approximately 189 cases were pending against Old Merck in the New Jersey coordinated proceeding. On July 20, 2009, Judge Higbee entered a Case Management Order (and various amendments thereto) setting forth a schedule that contemplates completing fact discovery in an initial group of 10 cases by February 28, 2010, followed by expert discovery in five of those cases, and a projected trial date of July 12, 2010 for the first case to be tried in the New Jersey coordinated proceeding.

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

As of December 31, 2008, the Company had a remaining reserve of approximately \$33 million solely for its future legal defense costs for the *Fosamax* Litigation. During 2009, the Company spent approximately \$35 million and added \$40 million to its reserve. Consequently, as of December 31, 2009, the Company had a reserve of approximately \$38 million solely for its future legal defense costs for the *Fosamax* Litigation. Some of the significant factors considered in the establishment of the reserve for the *Fosamax* Litigation legal defense costs were as follows: the actual defense costs incurred thus far; the development of the Company's legal defense strategy and structure in light of the creation of the *Fosamax* MDL; the number of cases being brought against the Company; and the anticipated timing, progression, and related costs of pre-trial activities in the *Fosamax* Litigation. The Company will continue to monitor its legal defense costs and review the adequacy of the associated reserves. Due to the uncertain nature of litigation, the Company is unable to reasonably estimate its costs beyond the third quarter of 2010. The Company has not established any reserves for any potential liability relating to the *Fosamax* Litigation. Unfavorable outcomes in the *Fosamax* Litigation could have a material adverse effect on the Company's financial position, liquidity and results of operations.

NuvaRing

Beginning in May 2007, a number of complaints were filed in various jurisdictions asserting claims against the Company's subsidiaries Organon USA, Inc., Organon Pharmaceuticals USA, Inc., Organon International (collectively, Organon), and Schering-Plough arising from Organon's marketing and sale of *NuvaRing*, a combined hormonal contraceptive vaginal ring. The plaintiffs contend that Organon and Schering-Plough 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 venued in Missouri and in New Jersey state court. Other cases are pending in other states.

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Vetsulin

On December 28, 2009, Schering-Plough Animal Health was named as a defendant in a putative class action lawsuit filed in the U.S. District Court for the Northern District of Ohio. In that lawsuit, entitled *Friedman v. Schering-Plough Animal Health*, the individual plaintiff seeks to represent a class of people who purchased *Vetsulin* for their household pets and the suit alleges the *Vetsulin* was contaminated or improperly manufactured. *Vetsulin* is an insulin product administered to diabetic dogs and cats. Plaintiff seeks compensatory and punitive damages based on theories of negligence, violation of consumer sales practices acts, breach of warranty, and product liability due to allegedly defective manufacturing. Merck intends to defend this lawsuit vigorously.

Commercial Litigation

AWP Litigation and Investigations

As previously disclosed, Old Merck was joined in ongoing litigation alleging manipulation by pharmaceutical manufacturers of Average Wholesale Prices (AWP), which are sometimes used in calculations that determine public and private sector reimbursement levels. The complaints allege violations of federal and state law, including fraud, Medicaid fraud and consumer protection violations, among other claims. The outcome of these litigations and investigations could include substantial damages, the imposition of substantial fines, penalties and injunctive or administrative remedies. In 2002, the JPML ordered the transfer and consolidation of all pending federal AWP cases to federal court in Boston, Massachusetts. Plaintiffs filed one consolidated class action complaint, which aggregated the claims previously filed in various federal district court actions and also expanded the number of manufacturers to include some which, like Old Merck, had not been defendants in any prior pending case. In May 2003, the court granted Old Merck's motion to dismiss the consolidated class action and dismissed Old Merck from the class action case. Old Merck and many other pharmaceutical manufacturers are defendants in similar complaints pending in federal and state court including cases brought individually by a number of counties in the State of New York. Fifty of the county cases have been consolidated in New York state court. Old Merck was dismissed from the Suffolk County case, which was the first of the New York county cases to be filed. In addition to the New York county cases, as of December 31, 2008, Old Merck was a defendant in state cases brought by the Attorneys General of eleven states, all of which are being defended. In February 2009, the Kansas Attorney General filed suit against Old Merck and several other manufacturers. AWP claims brought by the Attorney General of Arizona against Old Merck were dropped in 2009. The court in the AWP cases pending in Hawaii listed Old Merck and others to be set for trial in mid-2010.

In 2009, Schering-Plough reached settlements of claims relating to AWP. In August 2009, Schering-Plough and five other pharmaceutical companies settled all claims brought on behalf of the Alabama Medicaid program for a combined total of \$89 million. In addition, in July 2009, Schering-Plough reached a settlement with the Relator, acting on behalf of the United States in a non-intervened AWP *qui tam* action pending in the U.S. Federal District Court of Massachusetts and with the States of California and Florida for a combined total of \$69 million. That settlement resolved all claims brought on behalf of the Medicaid programs for the States of California and Florida and has been approved by the U.S. District Court for the District of Massachusetts and held to be preclusive of all claims for the federal share of any alleged Medicaid overpayment in all remaining states consistent with applicable precedent. In January 2010, the U.S. District Court for the District of Massachusetts held that a unit of Schering-Plough and eight other drugmakers overcharged New York City and 42 New York counties for certain generic drugs. The court has reserved the issue of damages and any penalties for future proceedings.

The Company continues to respond to litigation brought by certain states and private payors and to investigations initiated by the Department of Health and Human Services, the Department of Justice and several states regarding AWP. The Company is cooperating with these investigations.

Centocor Distribution Agreement

On May 27, 2009, Centocor, now a wholly owned subsidiary of Johnson & Johnson, delivered to Schering-Plough a notice initiating an arbitration proceeding to resolve whether, as a result of the Merger, Centocor is permitted to terminate the Company's rights to distribute and commercialize *Remicade* and *Simponi*. Sales of *Remicade* and *Simponi* included in the Company's results for the post-Merger period were \$430.7 million and \$3.9 million, respectively. Sales of *Remicade* recognized by Schering-Plough in 2009 prior to the Merger were

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\$1.9 billion. The arbitration process involves a number of steps, including the selection of independent arbitrators, information exchanges and hearings, before a final decision will be reached. A hearing in the arbitration is scheduled to commence in late September 2010. An unfavorable outcome in the arbitration would have a material adverse effect on the Company's financial position, liquidity and results of operations. For more information about this matter, see Item 1A. Risk Factors above.

Governmental Proceedings

As previously disclosed, in February 2008, Old Merck entered into a Corporate Integrity Agreement (CIA) with the U.S. Department of Health and Human Services Office of Inspector General (HHS-OIG) for a five-year term. The CIA requires, among other things, that Old Merck maintain its ethics training program and policies and procedures governing promotional practices and Medicaid price reporting. Further, as required by the CIA, Old Merck has retained an Independent Review Organization (IRO) to conduct a systems review of its promotional policies and procedures and to conduct, on a sample basis, transactional reviews of Old Merck's promotional programs and certain Medicaid pricing calculations. Old Merck is also required to provide regular reports and certifications to the HHS-OIG regarding its compliance with the CIA.

Similarly, as previously disclosed by Schering-Plough, in 2004 Schering-Plough entered into a CIA with HHS-OIG for a five-year term, and in August 2006, it entered into an addendum to the CIA also effective for five years. The requirements of Old Merck and Schering-Plough CIAs are similar, although not identical. Failure to comply with the CIAs requirements can result in financial penalties or exclusion from participation in federal health care programs. The Company believes that its promotional practices and Medicaid price reports meet the requirements of each of the CIAs.

Vytorin/Zetia Litigation

As previously disclosed, the legacy companies have received several letters from the House Committee on Energy and Commerce, its Subcommittee on Oversight and Investigations (O&I), and the Ranking Minority Member of the Senate Finance Committee, collectively seeking a combination of witness interviews, documents and information on a variety of issues related to the ENHANCE clinical trial, the sale and promotion of *Vytorin*, as well as sales of stock by corporate officers. In addition, as previously disclosed, since August 2008, Old Merck and Schering-Plough received three additional letters each from O&I, including identical letters dated February 19, 2009, seeking certain information and documents related to the SEAS clinical trial. As previously disclosed, the legacy companies received subpoenas from the New York State Attorney General's Office and a letter from the Connecticut Attorney General seeking similar information and documents, and on July 15, 2009, the legacy companies announced that they reached a civil settlement with the Attorneys General representing 35 states and the District of Columbia to resolve a previously disclosed investigation by that group into whether the legacy companies violated state consumer protection laws when marketing *Vytorin* and *Zetia*. As part of the settlement, the legacy companies agreed to reimburse the investigative costs of the 35 states and the District of Columbia which totaled \$5.4 million, and to make voluntary assurances of compliance related to the promotion of *Vytorin* and *Zetia*, including agreeing to continue to comply with the Food, Drug and Cosmetic Act, the U.S. Food and Drug Administration Amendments Act, and other laws requiring the truthful and non-misleading marketing of pharmaceutical products. The settlement did not include any admission of misconduct or liability by the legacy companies. Furthermore, as previously disclosed, in September 2008, the legacy companies received letters from the Civil Division of the DOJ informing them that the DOJ is investigating whether their conduct relating to the promotion of *Vytorin* caused false claims to be submitted to federal health care programs. The Company is cooperating with these investigations and responding to the inquiries.

As previously disclosed, the legacy companies have become aware of or been served with approximately 145 civil class action lawsuits alleging common law and state consumer fraud claims in connection with the MSP Partnership's

sale and promotion of *Vytorin* and *Zetia*. Certain of those lawsuits alleged personal injuries and/or sought medical monitoring. The lawsuits against Old Merck and Schering-Plough were consolidated in a single multi-district litigation docket before Judge Cavanaugh of the District of New Jersey, *In re Vytorin/Zetia Marketing Sales Practices and Products Liability Litigation*. On August 5, 2009, Old Merck and Schering-Plough jointly announced that their cholesterol joint venture, entered into agreements to resolve, for a total fixed amount of \$41.5 million, these civil class

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action lawsuits. The MSP Partnership recorded these charges in the second quarter of 2009. On February 9, 2010, Judge Cavanaugh granted final approval of the settlements.

Also, as previously disclosed, on April 3, 2008, an Old Merck shareholder filed a putative class action lawsuit in federal court in the Eastern District of Pennsylvania alleging that Old Merck and its Chairman, President and Chief Executive Officer, Richard T. Clark, violated the federal securities laws. This suit has since been withdrawn and re-filed in the District of New Jersey and has been consolidated with another federal securities lawsuit under the caption *In re Merck & Co., Inc. Vytorin Securities Litigation*. An amended consolidated complaint was filed on October 6, 2008, and names as defendants Old Merck; Merck/Schering-Plough Pharmaceuticals, LLC; and certain of the Company's current and former officers and directors. Specifically, the complaint alleges that Old Merck delayed releasing unfavorable results of the ENHANCE clinical trial regarding the efficacy of *Vytorin* and that Old Merck made false and misleading statements about expected earnings, knowing that once the results of the *Vytorin* study were released, sales of *Vytorin* would decline and Old Merck's earnings would suffer. On December 12, 2008, Old 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. On September 2, 2009, the court issued an opinion and order denying the defendants motion to dismiss this lawsuit, and on October 19, 2009, Old Merck and the other defendants filed an answer to the amended consolidated complaint. 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 on September 15, 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. On December 10, 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. On September 2, 2009, the court issued an opinion and order denying the defendants' motion to dismiss this lawsuit, and on September 17, 2009, the defendants filed a motion for reconsideration of the court's September 2, 2009 opinion and order denying the motion to dismiss. The motion for reconsideration was fully briefed on October 13, 2009 and a decision remains pending. The defendants filed an answer to the consolidated amended complaint on November 18, 2009.

As previously disclosed, on April 22, 2008, a member of an Old Merck ERISA plan filed a putative class action lawsuit against Old Merck and certain of the Company's current and former officers and directors alleging they breached their fiduciary duties under ERISA. Since that time, there have been other similar ERISA lawsuits filed against Old Merck in the District of New Jersey, and all of those lawsuits have been consolidated under the caption *In re Merck & Co., Inc. Vytorin ERISA Litigation*. A consolidated amended complaint was filed on February 5, 2009, and names as defendants Old Merck and various current and former members of the Company's Board of Directors. The plaintiffs allege that the ERISA plans' investment in Old Merck stock was imprudent because Old Merck's earnings are dependent on the commercial success of its cholesterol drug *Vytorin* and that defendants knew or should have known that the results of a scientific study would cause the medical community to turn to less expensive drugs for cholesterol management. On April 23, 2009, Old 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. On September 1, 2009, the court issued an opinion and order denying the defendants' motion to dismiss this lawsuit. On November 9, the plaintiffs moved to strike certain of the defendants' affirmative defenses. That motion was fully briefed on December 4, 2009 and is pending before the court.

There is a similar consolidated, putative class action ERISA lawsuit currently pending in the District of New Jersey, filed by a member of a Schering-Plough ERISA plan against Schering-Plough and certain of its current and former officers and directors, alleging they breached their fiduciary duties under ERISA, and under the caption *In re Schering-Plough Corp. ENHANCE ERISA Litigation*. The consolidated amended complaint was filed on October 1, 2009 and names as defendants Schering-Plough, various current and former members of Schering-Plough's Board of

Directors and current and former members of committees of Schering-Plough's Board of Directors. On November 6, 2009, the Company and the other defendants filed a motion to dismiss this lawsuit on the grounds that the plaintiffs failed to state a claim for which relief can be granted. The plaintiffs' opposition to the

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motion to dismiss was filed on December 16, 2009, and the motion was fully briefed on January 15, 2010. A decision remains pending.

On November 5, 2009, a stockholder of the Company filed a shareholder derivative lawsuit, *In re Local No. 38 International Brotherhood of Electrical Workers Pension Fund v. Clark* (*Local No. 38*), in the District of New Jersey, on behalf of the nominal defendant, the Company, and all shareholders of the Company, against the Company; certain of the Company's officers, directors and alleged insiders; and certain of the predecessor companies' former officers, directors and alleged insiders for alleged breaches of fiduciary duties, waste, unjust enrichment and gross mismanagement. A similar shareholder derivative lawsuit, *Cain v. Hassan*, was filed by a Schering-Plough stockholder and is currently pending in the District of New Jersey. An amended complaint was filed on May 13, 2008, by the Schering-Plough stockholder on behalf of the nominal defendant, Schering-Plough, and all Schering-Plough shareholders. The lawsuit is against Schering-Plough, Schering-Plough's then-current Board of Directors, and certain of Schering-Plough's current and former officer, directors and alleged insiders. The plaintiffs in both *Local No. 38* and *Cain v. Hassan* allege that the defendants withheld the ENHANCE study results and made false and misleading statements, thereby deceiving and causing harm to the Company and Schering-Plough, respectively, and to the investing public, unjustly enriching insiders and wasting corporate assets. The defendants in *Local No. 38* intend to move to dismiss the plaintiff's complaint. The defendants in *Cain v. Hassan* moved to dismiss the amended complaint on July 14, 2008, and that motion was fully briefed on October 15, 2008. A decision remains pending.

The Company intends to defend the lawsuits referred to in this section. Unfavorable outcomes resulting from the government investigations or the civil litigations could have a material adverse effect on the Company's financial position, liquidity and results of operations.

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

Securities and Class Action Litigation

Federal Securities Litigation

Following Schering-Plough's announcement on February 15, 2001 that the FDA had been conducting inspections of its manufacturing facilities in New Jersey and Puerto Rico and had issued reports citing deficiencies concerning compliance with current Good Manufacturing Practices, and had delayed approval of *Clarinex*, several lawsuits were filed against Schering-Plough and certain named officers. These lawsuits allege that the defendants violated the federal securities law by allegedly failing to disclose material information and making material misstatements. Specifically, they allege that Schering-Plough failed to disclose an alleged serious risk that a new drug application for *Clarinex* would be delayed as a result of these manufacturing issues, and they allege that the Company failed to disclose the alleged depth and severity of its manufacturing issues. These complaints were consolidated into one action in the U.S. District Court for the District of New Jersey, and a consolidated amended complaint was filed on October 11, 2001, purporting to represent a class of shareholders who purchased shares of Schering-Plough stock from May 9, 2000 through February 15, 2001. The complaint sought compensatory damages on behalf of the class. On February 18, 2009, the court signed an order preliminarily approving a settlement agreement under which Schering-Plough would provide for a settlement fund in the amount of \$165 million to resolve all claims by the class, which funds were placed in escrow at that time. The vast majority of the settlement was covered by insurance. On December 31, 2009, the District Court granted final approval of the settlement. The settlement is due to be consummated after the expiration of the appeal period from that final approval decision.

ERISA Litigation

On March 31, 2003, Schering-Plough was served with a putative class action complaint filed in the U.S. District Court in New Jersey alleging that Schering-Plough, its Employee Savings Plan (the Plan) administrator, several current and former directors, and certain former corporate officers breached their fiduciary obligations to certain participants in the Plan. The complaint seeks damages in the amount of losses allegedly

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suffered by the Plan. The complaint was dismissed on June 29, 2004. The plaintiffs appealed. On August 19, 2005 the U.S. Court of Appeals for the Third Circuit reversed the dismissal by the District Court and the matter has been remanded back to the District Court for further proceedings. On September 30, 2008, the District Court entered an order granting in part, and denying in part, the named putative class representative's motion for class certification. Schering-Plough thereafter petitioned the U.S. District Court of Appeals for the Third Circuit for leave to appeal the class certification decision. Schering-Plough's petition was granted on December 10, 2008. On December 21, 2009, the Third Circuit vacated the District Court's order and remanded the case for further proceedings consistent with the court's ruling.

K-DUR Antitrust Litigation

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. Following the commencement of an administrative proceeding by the United States Federal Trade Commission (the FTC) alleging anti-competitive effects from those settlements (which has been resolved in Schering-Plough's favor), alleged class action suits were filed in federal and state courts on behalf of direct and indirect purchasers of K-DUR against Schering-Plough, Upsher-Smith and Lederle. These suits claim violations of federal and state antitrust laws, as well as other state statutory and common law causes of action. These suits seek unspecified damages. In February 2009, a special master recommended that the U.S. District Court for the District of New Jersey dismiss the class action lawsuits on summary judgment. The U.S. District Court judge has not yet ruled on the recommendation.

Third-party Payor Actions

As discussed above, in July 2004, in connection with the settlement of an investigation with the DOJ and the U.S. Attorney's Office for the Eastern District of Pennsylvania, Schering-Plough entered into a five-year CIA. The CIA was amended in August 2006 in connection with the \$435 million settlement of an investigation by the State of Massachusetts involving certain of Schering-Plough's sales, marketing and clinical trial practices and programs (Massachusetts Investigation). Several purported class action litigations have been filed following the announcement of the settlement of the Massachusetts Investigation. Plaintiffs in these actions seek damages on behalf of third-party payors resulting from the allegations of off-label promotion and improper payments to physicians that were at issue in the Massachusetts Investigation. The actions have been consolidated in a multidistrict litigation in federal District Court for the District of New Jersey. In July 2009, the District Court dismissed the consolidated class action complaint but granted plaintiffs leave to refile. In September 2009, plaintiffs filed amended complaints, and the Company's motion to dismiss those complaints is pending.

Vaccine Litigation

As previously disclosed, Old Merck is a party to individual and class action product liability lawsuits and claims in the United States involving pediatric vaccines (e.g., hepatitis B vaccine) that contained thimerosal, a preservative used in vaccines. As of December 31, 2009, there were approximately 200 thimerosal related lawsuits pending in which Old Merck is a defendant, although the vast majority of those lawsuits are not currently active. Other defendants include other vaccine manufacturers who produced pediatric vaccines containing thimerosal as well as manufacturers of thimerosal. In these actions, the plaintiffs allege, among other things, that they have suffered neurological injuries as a result of exposure to thimerosal from pediatric vaccines. There are no cases currently scheduled for trial. The Company will defend against these lawsuits; however, it is possible that unfavorable outcomes could have a material adverse effect on the Company's financial position, liquidity and results of operations.

Old Merck has been successful in having cases of this type either dismissed or stayed on the ground that the action is prohibited under the National Childhood Vaccine Injury Act (the Vaccine Act). The Vaccine Act prohibits any person

from filing or maintaining a civil action (in state or federal court) seeking damages against a vaccine manufacturer for vaccine-related injuries unless a petition is first filed in the United States Court of Federal Claims (hereinafter the Vaccine Court). Under the Vaccine Act, before filing a civil action against a vaccine manufacturer, the petitioner must either (a) pursue his or her petition to conclusion in Vaccine Court and then timely

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file an election to proceed with a civil action in lieu of accepting the Vaccine Court's adjudication of the petition or (b) timely exercise a right to withdraw the petition prior to Vaccine Court adjudication in accordance with certain statutorily prescribed time periods. Old Merck is not a party to Vaccine Court proceedings because the petitions are brought against the United States Department of Health and Human Services.

The Company is aware that there are approximately 5,000 cases pending in the Vaccine Court involving allegations that thimerosal-containing vaccines and/or the *M-M-R II* vaccine cause autism spectrum disorders. Not all of the thimerosal-containing vaccines involved in the Vaccine Court proceeding are Company vaccines. The Company is the sole source of the *M-M-R II* vaccine domestically. The Special Masters presiding over the Vaccine Court proceedings held hearings in three test cases involving the theory that the combination of *M-M-R II* vaccine and thimerosal in vaccines causes autism spectrum disorders. On February 12, 2009, the Special Masters issued decisions in each of those cases, finding that the theory was unsupported by valid scientific evidence and that the petitioners in the three cases were therefore not entitled to compensation. Two of those three cases are currently on appeal. The Special Masters have held similar hearings in three different test cases involving the theory that thimerosal in vaccines alone causes autism spectrum disorders. Decisions have not been issued in this second set of test cases. The Special Masters had previously indicated that they would hold similar hearings involving the theory that *M-M-R II* alone causes autism spectrum disorders, but they have stated that they no longer intend to do so. The Vaccine Court has indicated that it intends to use the evidence presented at these test case hearings to guide the adjudication of the remaining autism spectrum disorder cases.

Patent Litigation

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

In February 2007, Schering-Plough received a notice from a generic company indicating that it had filed an ANDA for *Zetia* and that it is challenging the U.S. patents that are listed for *Zetia*. Prior to the Merger, the Company marketed *Zetia* through a joint venture, MSP Singapore Company LLC. On March 22, 2007, Schering-Plough and MSP Singapore Company LLC filed a patent infringement suit against Glenmark Pharmaceuticals Inc., USA and its parent corporation (Glenmark). The lawsuit automatically stays FDA approval of Glenmark's ANDA until October 2010 or until an adverse court decision, if any, whichever may occur earlier. The trial in this matter is scheduled to commence on May 3, 2010.

As previously disclosed, in February 2007, Old Merck received a notice from Teva Pharmaceuticals, Inc. (Teva), a generic company, indicating that it had filed an ANDA for montelukast and that it is challenging the U.S. patent that is listed for *Singulair*. On April 2, 2007, Old Merck filed a patent infringement action against Teva. A trial in this matter was held in February 2009. On August 19, 2009, the court issued a decision upholding the

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validity of Old Merck's *Singulair* patent and ordered that Teva's ANDA could not be approved prior to expiry of Old Merck's exclusivity rights in August 2012. Teva had appealed the decision, however, in January 2010, Teva withdrew its appeal of the trial court's decision upholding the validity of Old Merck's *Singulair* patent. In addition, in May 2009, the United States Patent and Trademark Office granted a petition by Article One Partners LLC to reexamine Old Merck's *Singulair* patent. On December 15, 2009, the United States Patent and Trademark Office issued a notice indicating that it will allow the claims of the Company's *Singulair* patent. Product exclusivity is accordingly expected to be maintained until August 2012.

In May 2005, the Federal Court of Canada Trial Division issued a decision refusing to bar the approval of generic alendronate on the grounds that Old Merck's patent for weekly alendronate was likely invalid. This decision cannot be appealed and generic alendronate was launched in Canada in June 2005. In July 2005, Old Merck was sued in the Federal Court of Canada by Apotex Corp. (Apotex) seeking damages for lost sales of generic weekly alendronate due to the patent proceeding. In October 2008, the Federal Court of Canada issued a decision awarding Apotex its lost profits for its generic alendronate product for the period of time that it was held off the market due to Old Merck's lawsuit. In June 2009, the trial court decision was upheld in part and both companies sought leave to appeal to the Supreme Court of Canada. In January 2010, the Supreme Court of Canada declined to hear the appeal, leaving intact the decision that Apotex is entitled to damages for the discrete period of time that its market entry was postponed due to the litigation launched by Old Merck.

As previously disclosed, in September 2004, Old Merck appealed a decision of the Opposition Division of the European Patent Office (EPO) that revoked the Company's patent in Europe that covers the once-weekly administration of alendronate. On March 14, 2006, the Board of Appeal of the EPO upheld the decision of the Opposition Division revoking the patent. On March 28, 2007, the EPO issued another patent in Europe to Old Merck that covers the once-weekly administration of alendronate. Under its terms, this new patent is effective until July 2018. Old Merck has sued multiple parties in European countries asserting its European patent covering once-weekly dosing of *Fosamax*. Decisions have been rendered in the Netherlands and Belgium invalidating the patent in those countries. Old Merck has appealed these decisions. Oppositions have been filed in the EPO against this patent. In a hearing held March 17-19, 2009, the Opposition Division of the EPO issued an appealable decision revoking this patent. Old Merck has appealed the decision.

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

In October 2008, the U.S. patent for dorzolamide, covering both *Trusopt* and *Cosopt*, expired, after which Old Merck experienced a significant decline in U.S. sales of these products. The Company is involved in litigation proceedings of the corresponding patents in Canada and Great Britain and Germany. In November 2009, the trial court in Great Britain issued a decision finding Old Merck's *Cosopt* patent invalid. In Canada a trial was held in December 2009 regarding the Company's Canadian *Trusopt* and *Cosopt* patents. The Company is awaiting a decision.

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

Old Merck and AstraZeneca received notice in January 2006 that IVAX Pharmaceuticals, Inc. (IVAX), subsequently acquired by Teva, had filed an ANDA for esomeprazole magnesium. The ANDA contains Paragraph IV challenges to patents on *Nexium*. In March 2006, Old Merck and AstraZeneca sued Teva in the U.S. District Court in New Jersey. On January 7, 2010, AstraZeneca, Old Merck and Teva/IVAX entered into a settlement agreement which provides that Teva/IVAX will not bring its generic esomeprazole product to market in the United States until May 27, 2014. In addition, in January 2008, Old Merck and AstraZeneca sued Dr. Reddy's Laboratories (Dr. Reddy's) in the District Court in New Jersey based on Dr. Reddy's filing of an ANDA for

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esomeprazole magnesium. The trial, which had been scheduled for January 2010 with respect to both IVAX's and Dr. Reddy's ANDAs, has been postponed and no new trial date has been set. Also, Old Merck and AstraZeneca received notice in December 2008 that Sandoz Inc. (Sandoz) had filed an ANDA for esomeprazole magnesium. The ANDA contains Paragraph IV challenges to patents on *Nexium*. In January 2009, Old Merck and AstraZeneca sued Sandoz in the District Court in New Jersey based on Sandoz's filing of an ANDA for esomeprazole magnesium. In addition, Old Merck and AstraZeneca received notice in September 2009 that Lupin Ltd. (Lupin) had filed an ANDA for esomeprazole magnesium. The ANDA contains Paragraph IV challenges to patents on *Nexium*. In October 2009, Old Merck and AstraZeneca sued Lupin in the District Court in New Jersey based on Lupin's filing of an ANDA for esomeprazole magnesium.

In January 2009, Old Merck received notice from Sandoz that it had filed an ANDA and that it was challenging five Old Merck patents listed in the FDA Orange Book for *Emend*. In February 2009, Old Merck filed a patent infringement suit against Sandoz. The lawsuit automatically stays FDA approval of Sandoz's ANDA until July 2011 or until an adverse court decision, if any, whichever may occur earlier. The case is scheduled to go to trial in December 2010.

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

In October 2009, Old Merck received notice from Teva Parenteral Medicines (TPM) that it filed an ANDA for caspofungin acetate and that it was challenging five patents listed in the FDA Orange Book for *Cancidas*. On November 25, 2009, the Company filed a patent infringement suit against TPM. The lawsuit automatically stays FDA approval of TPM's ANDA until April 2012 or until an adverse court decision, if any, whichever may occur earlier.

In November 2009, Schering received notice from Apotex that it filed an ANDA for mometasone furoate nasal spray and that it was challenging two patents listed in the FDA Orange Book for *Nasonex*. On December 18, 2009, Schering filed a patent infringement suit against Apotex. The lawsuit automatically stays FDA approval of Apotex's ANDA until May 2012 or until an adverse court decision, if any, whichever may occur earlier.

In November 2009, Schering-Plough received notice from Mylan that it filed an ANDA for ezetimibe/simvastatin and that it was challenging two patents listed in the FDA Orange Book for *Vytorin*. On December 16, 2009, Schering-Plough filed a patent infringement suit against Mylan. The lawsuit automatically stays FDA approval of Mylan's ANDA until May 2012 or until an adverse court decision, if any, whichever may occur earlier.

In July 2007, Schering and its licensor, Cancer Research Technologies, Limited (CRT), received notice from Barr Laboratories (Barr) (now a subsidiary of Teva) that Barr had filed an ANDA for *Temodar* and that it was challenging CRT's patent for temozolomide. In July 2007, Schering and CRT filed a patent infringement action against Barr. In January 2010, the court issued a decision finding the CRT patent unenforceable on grounds of prosecution laches and inequitable conduct. Schering and CRT are in the process of appealing the decision.

In January 2009, Schering and its licensor, Millennium, received notice from Teva that it filed an ANDA for eptifibatid and that it was challenging three Millennium patents listed in the FDA Orange Book for *Integrilin*. On February 18, 2009, Schering and Millennium filed patent infringement actions against Teva. The lawsuit automatically stays FDA approval of Teva's ANDA until August 2011 or until an adverse court decision, if any, whichever may occur earlier.

In May 2009, Schering, Bayer Schering Pharma AG, and Bayer Healthcare Pharmaceuticals received notice from Teva that it filed an ANDA for vardenafil and that it was challenging Bayer's patent listed in the FDA Orange Book for *Levitra* (vardenafil). On June 30, 2009, Schering and Bayer filed a patent infringement action against Teva. The lawsuit automatically stays FDA approval of Teva's ANDA until November 2011 or until an adverse court decision, if any, whichever may occur earlier.

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Legal Proceedings Related to the Merger

In connection with the Merger, separate class action lawsuits were brought against Old Merck and Schering-Plough challenging the Merger and seeking other forms of relief. As previously disclosed, both lawsuits have been settled pending court approval.

These settlements, if approved by the court, will resolve and release all claims that were or could have been brought by any shareholder of Old Merck or Schering-Plough challenging any aspect of the proposed merger, including any merger disclosure claims.

Other Litigation

French Matter

Based on a complaint to the French competition authority from a competitor in France and pursuant to a court order, the French competition authority has obtained documents from a French subsidiary of the Company relating to *Subutex*, one of the products that the subsidiary markets and sells. Any resolution of this matter adverse to the French subsidiary could result in the imposition of civil fines and injunctive or administrative remedies. On July 17, 2007, the Juge des Libertés et de la Détention ordered the annulment of the search and seizure on procedural grounds. On July 19, 2007, the French authority appealed the order to the French Supreme Court. On May 20, 2009, the French Supreme Court overturned that annulment and remanded the case to the Paris Court of Appeal on the basis that the Juge des Libertés et de la Détention had not examined each document to assess whether it should have been seized and whether it had been lawfully seized. The case is now pending before the Paris Court of Appeal.

In April 2007, the competitor also requested interim relief, a portion of which was granted by the French competition authority in December 2007. The interim relief required the Company's French subsidiary to publish in two specialized newspapers information including that the generic has the same quantitative and qualitative composition and the same pharmaceutical form as, and is substitutable for, *Subutex*. In February 2008, the Paris Court of Appeal confirmed the decision of the French competition authority. In January 2009, the French Supreme Court confirmed the decision of the French competition authority.

Other

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

Environmental Matters

The Company 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

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any reduction for anticipated recoveries of cleanup costs from former site owners or operators or other recalcitrant potentially responsible parties.

As previously disclosed, approximately 2,200 plaintiffs have filed an amended complaint against Old 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 and soil contamination found at the site of a former Old Merck subsidiary in Merced, California. Old Merck intends to defend itself against these claims.

In management's opinion, the liabilities for all environmental matters that are probable and reasonably estimable have been accrued and totaled \$161.8 million and \$89.5 million at December 31, 2009 and 2008, 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 \$170.0 million in the aggregate. Management also does not believe that these expenditures should result in a material adverse effect on the Company's financial position, results of operations, liquidity or capital resources for any year.

Executive Officers of the Registrant (ages as of February 1, 2010)

RICHARD T. CLARK Age 63

November 2009 Chairman, President and Chief Executive Officer, Merck & Co., Inc. (formerly Schering-Plough Corporation)

April 2007 Chairman, President and Chief Executive Officer, Old Merck

May 2005 Chief Executive Officer and President, Old Merck

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

ADELE D. AMBROSE Age 53

November 2009 Senior Vice President and Chief Communications Officer, Merck & Co., Inc. (formerly Schering-Plough Corporation) responsible for the Global Communications organization

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

April, 2005 On sabbatical

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

STANLEY F. BARSHAY Age 70

November 2009 Executive Vice President and President, Consumer Health Care, Merck & Co., Inc. (formerly Schering-Plough Corporation) responsible for the Consumer Health Care organization. Mr. Barshay will retire effective April 1, 2010.

Prior to November 2009, Mr. Barshay was Chairman, Consumer Health Care, Schering-Plough Corporation since June 2003

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RICHARD S. BOWLES III Age 58

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

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

JOHN CANAN Age 53

November 2009 Senior Vice President and Global Controller, Merck & Co., Inc. (formerly Schering-Plough Corporation) responsible for the Company's global control organization including all accounting, controls, external reporting and financial standards and policies

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

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

WILLIE A. DEESE Age 54

November 2009 Executive Vice President and President, Merck Manufacturing Division (MMD), Merck & Co., Inc. (formerly Schering-Plough Corporation) responsible for the Company's global manufacturing, procurement, and distribution and logistics functions

January 2008 Executive Vice President and President, MMD, Old Merck responsible for the Company's global manufacturing, procurement, and distribution and logistics functions

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

January 2004 Senior Vice President, Global Procurement

KENNETH C. FRAZIER Age 55

November 2009 Executive Vice President and President, Global Human Health, Merck & Co., Inc. (formerly Schering-Plough Corporation) 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, Old Merck responsible for the Company's marketing and sales organizations worldwide, including the global pharmaceutical and vaccine franchises

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

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

MIRIAN M. GRADDICK-WEIR Age 55

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November 2009 Executive Vice President, Human Resources, Merck & Co., Inc. (formerly Schering-Plough Corporation) responsible for the Global Human Resources organization

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

September 2006 Senior Vice President, Human Resources, Old Merck

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

BRIDGETTE HELLER Age 48

Effective March 1, 2010 Executive Vice President and President, Consumer Health Care, Merck & Co., Inc. (formerly Schering-Plough Corporation) responsible for the Consumer Health Care organization

Prior to March 1, 2010, Ms. Heller was President, Johnson & Johnson's Baby Global Business Unit (2007-2010) and Global President for Baby, Kids and Wound Care (2005-2007).

Prior to joining Johnson & Johnson, Ms. Heller was founder and managing partner at Heller Associates from 2004 to 2005.

PETER N. KELLOGG Age 53

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

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

PETER S. KIM Age 51

November 2009 Executive Vice President and President, Merck Research Laboratories, Merck & Co., Inc. (formerly Schering-Plough Corporation) (since January 2003) responsible for the Company's research and development efforts worldwide

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

January 2003 President, Merck Research Laboratories, Old Merck responsible for the Company's research and development efforts worldwide

RAUL E. KOHAN Age 57

November 2009 Executive Vice President and President, Animal Health, Merck & Co., Inc. (formerly Schering-Plough Corporation) responsible for the Company's Animal Health organization

October 2008 Senior Vice President and President, Intervet/Schering-Plough Animal Health, Schering-Plough Corporation

October 2007 Deputy Head, Animal Health and Senior Vice President, Corporate Excellence and Administrative Services, Schering-Plough Corporation.

February 2007 Senior Vice President and President, Animal Health, Schering-Plough Corporation

Prior to February 2007, Mr. Kohan was Group Head of Global Specialty Operations and President, Animal Health, Schering-Plough Corporation (since 2003).

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BRUCE N. KUHLIK Age 53

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

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

August 2007 Senior Vice President and General Counsel, Old Merck responsible for legal, communications, and public policy functions and The Merck Company Foundation (a not-for-profit charitable organization affiliated with the Company)

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

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

MICHAEL ROSENBLATT Age 62

December 2009 Executive Vice President and Chief Medical Officer, Merck & Co., Inc. (formerly Schering-Plough Corporation) the Company's primary voice to the global medical community on critical issues such as patient safety and will oversee the Company's Global Center for Scientific Affairs

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

J. CHRIS SCALET Age 51

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

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

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

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

MERVYN TURNER Age 63

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November 2009 Chief Strategy Officer and Senior Vice President, Emerging Markets Research & Development, Merck Research Laboratories, Merck & Co., Inc. (formerly Schering-Plough Corporation) responsible for leading the formulation and execution of the Company's long term strategic plan and additional responsibilities in Licensing & External Research within Merck Research Laboratories

November 2008 Chief Strategy Officer and Senior Vice President, Worldwide Licensing and External Research, Merck Research Laboratories, Old Merck

October 2002 Senior Vice President, Worldwide Licensing and External Research, Old Merck

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 SGP prior to the Merger, and then MRK after the Merger. 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⁽¹⁾

	Year	4th Q	3rd Q	2nd Q	1st Q
2009	\$ 0.26	\$ 0.065	\$ 0.065	\$ 0.065	\$ 0.065
2008	\$ 0.26	\$ 0.065	\$ 0.065	\$ 0.065	\$ 0.065

Common Stock Market Prices

2009	4th Q	3rd Q	2nd Q	1st Q
High	\$ 38.42	\$ 28.68	\$ 25.12	\$ 24.42
Low	\$ 27.97	\$ 24.34	\$ 21.67	\$ 16.32
2008				
High	\$ 18.48	\$ 22.32	\$ 20.72	\$ 27.73
Low	\$ 12.76	\$ 17.51	\$ 13.86	\$ 14.41

⁽¹⁾ In each of 2009 and 2008, Old Merck paid quarterly cash dividends per common share of \$0.38 for an annual amount of \$1.52.

As of January 31, 2010, there were approximately 176,000 shareholders of record.

Equity Compensation Plan Information

The following table summarizes information about the options, warrants and rights and other equity compensation under the Company's legacy Merck and legacy Schering-Plough equity plans as of the close of business on December 31, 2009. The table does not include information about tax qualified plans such as the MSD Employee Savings and Security Plan and the Schering-Plough Employees' Savings Plan.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders ⁽¹⁾	313,784,854 ⁽²⁾	\$ 43.01	134,004,583
Equity compensation plans not approved by security holders ⁽³⁾			
Total	313,784,854	\$ 43.01	134,004,583

⁽¹⁾ Includes options to purchase shares of Company Common Stock and other rights under the following shareholder-approved plans: the Merck Sharp & Dohme 1996, 2001, 2004 and 2007 Incentive Stock Plans, the Merck & Co., Inc. 1996, 2001 and 2006 Non-Employee Directors Stock Option Plans, and the Schering-Plough Corporation 1997, 2002 and 2006 Stock Incentive Plans.

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- (2) *Excludes approximately 7,453,426 shares of restricted stock units and 3,695,024 performance share units (assuming maximum payouts) under the Merck Sharp & Dohme 2004 and 2007 Incentive Stock Plans and 7,665,296 shares of restricted stock units and 475,077 performance share units (excluding accrued dividends) under the Schering-Plough Corporation 2006 Stock Incentive Plan. Also excludes 350,473 shares of phantom stock deferred under the Merck & Co., Inc. Deferral Program.*
- (3) *The table does not include information for equity compensation plans and options and other warrants and rights assumed by the Company in connection with mergers and acquisitions and pursuant to which there remain outstanding options or other warrants or rights (collectively, Assumed Plans), which include the Rosetta Inpharmatics, Inc. 1997 and 2000 Employee Stock Option Plans. A total of 69,934 shares of Merck Common Stock may be purchased under the Assumed Plans, at a weighted average exercise price of \$37.90. No further grants may be made under any Assumed Plans.*

Table of Contents**Performance Graph**

The following graph assumes a \$100 investment on December 31, 2004, and reinvestment of all dividends, in each of the Company's Common Shares, the S&P 500 Index, and a composite peer group of the major U.S.-based pharmaceutical companies, which are: Abbott Laboratories, Bristol-Myers Squibb Company, Johnson & Johnson, Eli Lilly and Company, and Pfizer Inc.

Comparison of Five-Year Cumulative Total Return*
Merck & Co., Inc., Composite Peer Group and S&P 500 Index

	End of Period Value	2009/2004 CAGR**
MERCK	\$ 170	11%
PEER GRP.***	104	1
S&P 500	102	0

	2004	2005	2006	2007	2008	2009
MERCK	100.00	100.91	115.48	131.36	85.26	169.87
PEER GRP.	100.00	93.24	105.85	107.91	96.21	103.80
S&P 500	100.00	104.91	121.46	128.13	80.73	102.10

* *The Performance Graph reflects Schering-Plough's stock performance from December 31, 2004 through the close of the Merger and New Merck's stock performance from November 3, 2009 through December 31, 2009. Assumes the cash component of the merger consideration was reinvested in New Merck stock at the closing price on November 3, 2009.*

** *Compound Annual Growth Rate*

*** *On October 15, 2009, Wyeth and Pfizer Inc. completed its previously announced merger (the Pfizer/Wyeth Merger) where Wyeth became a wholly-owned subsidiary of Pfizer Inc. As discussed, on November 3, 2009, Old Merck and Schering-Plough completed the Merger (together with the Pfizer/Wyeth Merger, the Transactions) where Old Merck (subsequently renamed Merck Sharp & Dohme Corp.) became a wholly-owned subsidiary of Schering-Plough (subsequently renamed Merck & Co., Inc.). As a result of the Transactions, Wyeth and Old Merck 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 Old Merck have been permanently removed from the peer group index.*

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Recent Sale of Unregistered Securities

Between November 3, 2009 and January 22, 2010, the Company inadvertently issued a total of approximately 834,000 unregistered shares of common stock to certain former directors and former employees of Old Merck upon the exercise of stock options they held. The aggregate of the exercise prices paid in connection with the stock option exercises was approximately \$26.6 million.

In addition, on January 8, 2010, the Company inadvertently issued a total of approximately 66,000 unregistered shares of common stock to certain former senior employees of Old Merck upon the vesting of performance share units they held.

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)

	2009 ⁽¹⁾	2008 ⁽²⁾	2007 ⁽³⁾	2006 ⁽⁴⁾	2005 ⁽⁵⁾
Results for Year:					
Sales	\$27,428.3	\$23,850.3	\$24,197.7	\$22,636.0	\$22,011.9
Materials and production costs	9,018.9	5,582.5	6,140.7	6,001.1	5,149.6
Marketing and administrative expenses	8,543.2	7,377.0	7,556.7	8,165.4	7,155.5
Research and development expenses	5,845.0	4,805.3	4,882.8	4,782.9	3,848.0
Restructuring costs	1,633.9	1,032.5	327.1	142.3	322.2
Equity income from affiliates	(2,235.0)	(2,560.6)	(2,976.5)	(2,294.4)	(1,717.1)
U.S. Vioxx Settlement Agreement charge			4,850.0		
Other (income) expense, net	(10,669.5)	(2,318.1)	(75.2)	(503.2)	(232.0)
Income before taxes	15,291.8	9,931.7	3,492.1	6,341.9	7,485.7
Taxes on income	2,267.6	1,999.4	95.3	1,787.6	2,732.6
Net income	13,024.2	7,932.3	3,396.8	4,554.3	4,753.1
Net income attributable to noncontrolling interests	122.9	123.9	121.4	120.5	121.8
Net income attributable to Merck & Co., Inc.	12,901.3	7,808.4	3,275.4	4,433.8	4,631.3
Preferred stock dividends	2.1				
Net income available to common shareholders	12,899.2	7,808.4	3,275.4	4,433.8	4,631.3
Basic earnings per common share available to common shareholders	\$5.67	\$3.65	\$1.51	\$2.03	\$2.10
Earnings per common share assuming dilution available to common shareholders	\$5.65	\$3.63	\$1.49	\$2.02	\$2.10
Cash dividends declared	3,599.8	3,250.4	3,310.7	3,318.7	3,338.7
Cash dividends paid per common share	\$1.52 ⁽⁶⁾	\$1.52	\$1.52	\$1.52	\$1.52
Capital expenditures	1,460.6	1,298.3	1,011.0	980.2	1,402.7
Depreciation	1,654.3	1,445.1	1,752.4	2,098.1	1,544.2
Average common shares outstanding (millions)	2,268.2	2,135.8	2,170.5	2,177.6	2,197.0
Average common shares outstanding assuming dilution (millions)	2,273.2	2,142.5	2,189.8	2,184.1	2,199.2

Year-End Position:

Working capital	12,677.9	\$4,793.9	\$2,787.2	\$2,507.5	\$7,806.9
Property, plant and equipment, net	18,273.5	11,999.6	12,346.0	13,194.1	14,398.2
Total assets	112,089.7	47,195.7	48,350.7	44,569.8	44,845.8
Long-term debt	16,074.9	3,943.3	3,915.8	5,551.0	5,125.6
Total equity	61,492.6	21,167.1	20,591.4	19,965.8	20,384.9

Year-End Statistics:

Number of stockholders of record	175,600	165,700	173,000	184,200	198,200
Number of employees	100,000	55,200	59,800	60,000	61,500

- (1) 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 increased materials and production costs as a result of the amortization of intangible assets and inventory step-up. Also included in 2009, is a gain on the sale of Merck's interest in Merial Limited, the favorable impact of certain tax items, the impact of restructuring actions and additional legal defense costs.
- (2) 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, additional legal defense costs and an expense for a contribution to the Merck Company Foundation.
- (3) Amounts for 2007 include the impact of the U.S. Vioxx Settlement Agreement charge, restructuring actions, a civil governmental investigations charge, an insurance arbitration settlement gain, in-process research and development expense resulting from an acquisition, additional Vioxx legal defense costs, gains on sales of assets and product divestitures, as well as a net gain on the settlements of certain patent disputes.
- (4) Amounts for 2006 include the impact of restructuring actions, in-process research and development expenses resulting from acquisitions, additional Vioxx legal defense costs and the adoption of a new accounting standard requiring the expensing of stock options.
- (5) Amounts for 2005 include the impact of the net tax charge primarily associated with the American Jobs Creation Act repatriation, restructuring actions and additional Vioxx legal defense costs.
- (6) Amount reflects dividends paid to common shareholders of Old 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**

On November 3, 2009, Merck & Co., Inc. (Old Merck) and Schering-Plough Corporation (Schering-Plough) completed their previously-announced merger (the Merger). In the Merger, Schering-Plough acquired all of the shares of Old Merck, which became a wholly-owned subsidiary of Schering-Plough and was renamed Merck Sharp & Dohme Corp. Schering-Plough continued as the surviving public company and was renamed Merck & Co., Inc. (New Merck or the Company). However, for accounting purposes only, the Merger was treated as an acquisition with Old Merck considered the accounting acquirer. Accordingly, the accompanying financial statements reflect Old Merck's stand-alone operations as they existed prior to the completion of the Merger. The results of Schering-Plough's business have been included in New Merck's financial statements only for periods subsequent to the completion of the Merger. Therefore, New Merck's financial results for 2009 do not reflect a full year of legacy Schering-Plough operations. References in this report and in the accompanying financial statements to Merck for periods prior to the Merger refer to Old Merck and for periods after the completion of the Merger to New Merck.

The Company is a global health care company that delivers innovative health solutions through its medicines, vaccines, biologic therapies, and consumer and animal 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 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, 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 preventative 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's professional representatives communicate the effectiveness, safety and value of its pharmaceutical and vaccine products to health care professionals in private practice, group practices and managed care organizations. The Company also has animal health operations that discover, develop, manufacture and market animal health products, including vaccines. The Company's professional representatives communicate the safety and value of the Company's animal health products to veterinarians, distributors and animal producers. Additionally, the Company has consumer health care operations that develop, manufacture and market Over-the-Counter (OTC), foot care and sun care products, which are sold through wholesale and retail drug, food chain and mass merchandiser outlets in the United States and Canada.

Overview

As discussed above, the Merger was completed on November 3, 2009. In the Merger, Old Merck shareholders received one share of common stock of New Merck for each share of Old Merck stock that they owned, and Schering-Plough shareholders received 0.5767 of a share of common stock of New Merck and \$10.50 in cash for each share of Schering-Plough stock that they owned. The consideration in the Merger was valued at \$49.6 billion in the aggregate. Schering-Plough was Old Merck's long-term partner in the Merck/Schering-Plough cholesterol partnership (the MSP Partnership). The cash portion of the consideration was funded with a combination of existing cash, including proceeds from the sale of Old Merck's interest in Merial Limited, the sale or redemption of investments and the issuance of debt.

The combined company has a research and development pipeline with greater depth and breadth and many promising drug candidates, a significantly broader portfolio of medicines and an expanded presence in key international markets,

particularly in high-growth emerging markets. The Company anticipates that the efficiencies gained from the Merger will allow it to invest in promising pipeline candidates, as well as strategic external research and development opportunities.

The combination increased the Company's pipeline of early, mid- and late stage product candidates, including a significant increase in the number of potential medicines the Company has in Phase III development to

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19 candidates. Additionally, a number of candidates are currently under review in the United States and internationally.

The Merger also is expected to accelerate the expansion into therapeutic areas that Old Merck has focused on in recent years with the addition of Schering-Plough's established presence and expertise in oncology, neuroscience and novel biologics. Further, the Merger is expected to broaden the Company's commercial portfolio with leading franchises in key therapeutic areas, including cardiovascular, respiratory, oncology, neuroscience, infectious diseases, immunology and women's health. Additionally, the combined company is expected to realize potential benefits from its animal health business and portfolio of consumer health brands, including *Claritin*, *Coppertone* and *Dr. Scholl's*. Many of the legacy Schering-Plough's products are expected to have long periods of marketing exclusivity and, by leveraging the combined company's expanded product offerings, the Company expects to benefit from additional revenue growth opportunities. For example, the combined company is expected to have expanded opportunities for life-cycle management through the introduction of potential new combinations and formulations of existing products of the two legacy companies. Also, the Company will have an expanded global presence and a more geographically diverse revenue base. Schering-Plough's significant international presence will accelerate Old Merck's own international growth efforts.

During 2009, revenue increased 15% driven largely by the incremental sales resulting from the inclusion of the post-Merger results of legacy Schering-Plough products, such as *Remicade*, a treatment for inflammatory diseases, *Temodar*, a treatment for certain types of brain tumors, *Nasonex* nasal spray, an inhaled nasal corticosteroid for the treatment of nasal allergy symptoms, and *PegIntron* for treating chronic hepatitis C, as well as the recognition of revenue from sales of *Zetia* and *Vytorin*, cholesterol modifying medicines. Prior to the Merger, sales of *Zetia* and *Vytorin* were recognized by the MSP Partnership and the results of Old Merck's interest in the MSP Partnership were recorded in *Equity income from affiliates*. As a result of the Merger, the MSP Partnership is now wholly-owned by the Company and therefore revenues from these products for the post-Merger period are reflected in *Sales*. Additionally, the Company recognized sales in the post-Merger period from legacy Schering-Plough animal health and consumer health care products. Also contributing to the sales increase was growth in *Januvia* and *Janumet* for the treatment of type 2 diabetes, *Isentress*, an antiretroviral therapy for the treatment of HIV infection, *Singulair*, a medicine indicated for the chronic treatment of asthma and the relief of symptoms of allergic rhinitis, *Varivax*, a vaccine to help prevent chickenpox (varicella), and *Pneumovax*, a vaccine to help prevent pneumococcal disease. These increases were partially offset by lower sales of *Fosamax* for the treatment and prevention of osteoporosis. *Fosamax* and *Fosamax Plus D* lost market exclusivity for substantially all formulations in the United States in February 2008 and April 2008, respectively. Revenue was also negatively affected by lower sales of *Gardasil*, a vaccine to help prevent cervical, vulvar and vaginal cancers, precancerous or dysplastic lesions, and genital warts caused by human papillomavirus (HPV) types 6, 11, 16 and 18, *Cosopt/Trusopt*, ophthalmic products which lost U.S. market exclusivity in October 2008, and lower revenue from the Company's relationship with AstraZeneca LP (AZLP). Other products experiencing declines include *RotaTeq*, a vaccine to help protect against rotavirus gastroenteritis in infants and children, *Zocor*, the Company's statin for modifying cholesterol and *Primaxin* for the treatment of bacterial infections.

As a result of the Merger, the Company expects to achieve substantial cost savings across all areas, including from consolidation in both sales and marketing and research and development, the application of the Company's lean manufacturing and sourcing strategies to the expanded operations, and the full integration of the MSP Partnership.

In February 2010, the Company announced the first phase of a new global restructuring program (the Merger Restructuring Program) in conjunction with the integration of the legacy Merck and legacy Schering-Plough businesses. This Merger Restructuring Program is intended to optimize the cost structure of the combined Company. As part of the first phase of the Merger Restructuring Program, by the end of 2012, the Company expects to reduce its total workforce by approximately 15% across all areas of the Company worldwide. The Company also plans to eliminate 2,500 vacant positions as part of the first phase of the program. These workforce reductions will primarily

come from the elimination of duplicative positions in sales, administrative and headquarters organizations, as well as from the consolidation of certain manufacturing facilities and research and development operations. The Company will continue to hire new employees in strategic growth areas of the business during this period. Certain actions, such as the ongoing reevaluation of manufacturing and research and development facilities

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worldwide have not yet been completed, but will be included later in 2010 in other phases of the Merger Restructuring Program. In connection with the first phase of the Merger Restructuring Program, separation costs under the Company's existing severance programs worldwide were recorded in the fourth quarter of 2009 to the extent such costs were probable and reasonably estimable. The Company recorded pretax restructuring costs of \$1.5 billion, primarily employee separation costs, related to the Merger Restructuring Program in the fourth quarter of 2009. This first phase of the Merger Restructuring Program is expected to be completed by the end of 2012 with the total pretax costs estimated to be \$2.6 billion to \$3.3 billion. The Company estimates that approximately 85% of the cumulative pretax costs relate to cash outlays, primarily related to employee separation expense. Approximately 15% of the cumulative pretax costs are non-cash, relating primarily to the accelerated depreciation of facilities to be closed or divested.

The Company expects this first phase of the Merger Restructuring Program to yield annual savings in 2012 of approximately \$2.6 billion to \$3.0 billion. These anticipated savings relate only to the first phase of the Merger Restructuring Program and therefore are only a portion of the estimated \$3.5 billion of incremental annual savings originally disclosed when the Merger was announced. The Company expects that additional savings will be generated by subsequent phases of the Merger Restructuring Program that will be announced later this year, as well as by non-restructuring related activities, such as procurement savings initiatives. These cost savings, which are expected to come from all areas of the Company's pharmaceutical business, are in addition to the previously announced ongoing cost reduction initiatives at both legacy companies.

As a result of the Merger, the Company obtained a controlling interest in the MSP Partnership and it is now owned 100% by the Company. Accordingly, the Company was required to remeasure Merck's previously held equity interest in the MSP Partnership at its merger-date fair value and recognize the resulting gain in earnings. As a result, the Company recorded a gain of \$7.5 billion recognized in *Other (income) expense, net* in 2009. Also during 2009, Old Merck sold its 50% interest in Merial Limited (Merial) to sanofi-aventis for \$4 billion in cash. The sale resulted in the recognition of a \$3.2 billion gain reflected in *Other (income) expense, net* in 2009. See Note 10 to the consolidated financial statements.

Earnings per common share (EPS) assuming dilution for 2009 were \$5.65, which reflect a net impact of \$2.40 resulting from gains related to the MSP Partnership and the sale of Merial, partially offset by increased expenses from the amortization of purchase accounting adjustments, restructuring and merger-related costs. EPS in 2009 were also affected by the dilutive impact of shares issued in the Merger.

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 operations may be affected by technological advances of competitors, industry consolidation, patents granted to competitors, competitive combination products, new products of competitors, 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 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 displacement, even for products protected by patents. For example, the number of

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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.

Global efforts toward healthcare cost containment continue to exert pressure on product pricing and access. In addressing cost containment pressure, the Company makes a continuing effort to demonstrate that its medicines provide value to patients and to those who pay for healthcare. In addition, pricing flexibility across the Company's product portfolio has encouraged growing use of its medicines and mitigated the effects of increasing cost pressures on individual medicines.

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

The Company anticipates that the worldwide trend toward cost containment will continue, resulting in ongoing pressures on healthcare budgets. In the United States, major healthcare reform has been introduced and passed in both houses of Congress. A final revised bill which unifies both versions may be considered and adopted into law. The impact of such actions, as well as budget pressures on governments in the United States and other nations, cannot be predicted at this time. As the Company continues to successfully launch new products, contribute to healthcare debates and monitor reforms, its new products, policies and strategies should enable it to maintain a strong position in the changing economic environment.

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

Access to Medicines

The Company is also committed to improving access to medicines and enhancing the quality of life for people around the world. To cite just one example, The African Comprehensive HIV/AIDS Partnerships in Botswana, a partnership between the government of Botswana, the Bill & Melinda Gates Foundation and The Merck Company Foundation/Merck & Co., Inc., is supporting Botswana's response to HIV/AIDS through a comprehensive and sustainable approach to HIV prevention, care, treatment, and support.

To further catalyze access to HIV medicines in developing countries, the Company makes no profit on the sale of its current HIV/AIDS medicines in the world's poorest countries and those hardest hit by the pandemic, and offers its HIV/AIDS medicines at significantly reduced prices to medium-income countries. In February 2007, Old Merck announced that it had again reduced the price of *Stocrin* in the least developed countries of the world and those hardest hit by the pandemic. Through these and other actions, the Company is working independently and with partners in both the public and private sectors to address the most critical barriers to access to medicines in the developing world. Addressing these barriers requires investments in education, training and health infrastructure and to improve capacity in developing countries achieved through increased international assistance and sustainable financing.

In addition, Old Merck has committed to providing *RotaTeq*, its vaccine to help protect against rotavirus gastroenteritis in infants and children, to the Global Alliance for Vaccines and Immunization-eligible countries at

prices at which it does not profit. Also, in 2009, Old Merck and The Wellcome Trust established the MSD Wellcome Trust Hilleman Laboratories, a joint venture in India to develop vaccines for millions of people in some of the poorest areas of the world.

Government Regulation

The pharmaceutical industry is subject to regulation by regional, country, state and local agencies around the world. Of particular importance is the U.S. Food and Drug Administration (FDA) in the United States, which administers requirements covering the testing, approval, safety, effectiveness, manufacturing, labeling, and marketing of prescription pharmaceuticals. In many cases, the FDA requirements have increased the amount of

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time and resources necessary to develop new products and bring them to market in the United States. In 1997, the Food and Drug Administration Modernization Act (the FDA Modernization Act) was passed and was the culmination of a comprehensive legislative reform effort designed to streamline regulatory procedures within the FDA and to improve the regulation of drugs, medical devices, and food. The legislation was principally designed to ensure the timely availability of safe and effective drugs and biologics by expediting the premarket review process for new products. A key provision of the legislation is the re-authorization of the Prescription Drug User Fee Act of 1992, which permits the continued collection of user fees from prescription drug manufacturers to augment FDA resources earmarked for the review of human drug applications. This helps provide the resources necessary to ensure the prompt approval of safe and effective new drugs.

In the United States, the government expanded access for senior citizens to prescription drug coverage by enacting the Medicare Prescription Drug Improvement and Modernization Act of 2003, which was signed into law in December 2003. Prescription drug coverage began on January 1, 2006. This legislation supports the Company's goal of improving access to medicines by expanding insurance coverage, while preserving market-based incentives for pharmaceutical innovation. At the same time, the legislation has helped control the cost of prescription drug costs through competitive pressures and by encouraging the appropriate use of medicines. As mentioned above, in the United States major healthcare reform has been introduced and passed in both houses of Congress. A final revised bill which unifies both versions may be considered and adopted into law. The U.S. Congress also considered, and may consider again, proposals to increase the government's role in pharmaceutical pricing in the Medicare program. These proposals may include removing the current legal prohibition against the Secretary of the Health and Human Services intervening in price negotiations between Medicare drug benefit program plans and pharmaceutical companies. They may also include mandating the payment of rebates for some or all of the pharmaceutical utilization in Medicare drug benefit plans. In addition, Congress may again consider proposals to allow, under certain conditions, the importation of medicines from other countries.

For many years, the pharmaceutical industry has been under federal and state oversight with the approval process for new drugs, drug safety, advertising and promotion, drug purchasing and reimbursement programs, and formularies. The Company believes that it will continue to be able to conduct its operations, including the introduction of new drugs to the market, in this regulatory environment.

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

Initiatives in some states seek rebates beyond the minimum required by Medicaid legislation, in some cases for patients beyond those who are eligible for Medicaid. Under the Federal Vaccines for Children entitlement program, the U.S. Centers for Disease Control and Prevention (CDC) funds and purchases recommended pediatric vaccines at a public sector price for the immunization of Medicaid-eligible, uninsured, Native American and certain underinsured children. Old Merck was awarded a CDC contract in 2009 for the supply of pediatric vaccines for the Vaccines for Children program.

Outside the United States, the Company encounters similar regulatory and legislative issues in most of the countries where it does business. There, too, the primary thrust of governmental inquiry and action is toward determining drug safety and effectiveness, often with mechanisms for controlling the prices of or reimbursement for prescription drugs and the profits of prescription drug companies. The EU has adopted directives concerning the classification, labeling,

advertising, wholesale distribution and approval for marketing of medicinal products for human use. The Company's policies and procedures are already consistent with the substance of these directives; consequently, it is believed that they will not have any material effect on the Company's business.

In January 2008, the European Commission (EC) launched a sector inquiry in the pharmaceutical industry under the rules of EU competition law. As part of this inquiry, Old Merck's offices in Germany were inspected by the authorities beginning in January 2008. The preliminary report of the EC was issued on November 28, 2008, and following the public consultation period, the final report was issued in July 2009. The final report confirmed that there has been a decline in the number of novel medicines reaching the market and instances of delayed market entry of generic medicines and discussed industry practices that may have contributed

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to these phenomena. While the EC has issued further inquiries with respect to the subject of the investigation, the EC has not alleged that the Company or any of its subsidiaries have engaged in any unlawful practices.

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

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, and there has been an increasing attention to privacy and data protection issues with the potential to affect directly the Company's business, including recently enacted laws and regulations in the United States and internationally requiring notification to individuals and government authorities of security breaches involving certain categories of personal information.

Operating Results

Sales

Worldwide sales totaled \$27.4 billion for 2009, an increase of 15% compared with 2008. Foreign exchange unfavorably affected global sales performance by 2%. The revenue increase over 2008 largely reflects incremental sales resulting from the inclusion of the post-Merger results of legacy Schering-Plough products such as *Remicade*, *Temodar*, *Nasonex* nasal spray, and *PegIntron*, as well as the recognition of revenue from sales of *Zetia* and *Vytorin*. Prior to the Merger, sales of *Zetia* and *Vytorin* were recognized by the MSP Partnership and the results of Old Merck's interest in the MSP Partnership were recorded in *Equity income from affiliates*. As a result of the Merger, the MSP Partnership is now wholly-owned by the Company and therefore revenues from these products for the post-Merger period are reflected in *Sales*. Additionally, the Company recognized sales in the post-Merger period from legacy Schering-Plough animal health and consumer healthcare products. Also contributing to the sales increase was growth in *Januvia* and *Janumet*, *Isentress*, *Singulair*, *Varivax* and *Pneumovax*. These increases were partially offset by lower sales of *Fosamax* and *Fosamax Plus D*, which lost market exclusivity for substantially all formulations in the United States in February 2008 and April 2008, respectively. Revenue was also negatively affected by lower sales of *Gardasil*, *Cosopt/Trusopt*, which lost U.S. market exclusivity in October 2008, and lower revenue from the Company's relationship with AZLP. Other products experiencing declines include *RotaTeq*, *Zocor* and *Primaxin*.

Domestic sales increased 8% compared with 2008, while foreign sales rose 24%, driven primarily by incremental sales resulting from the inclusion of the post-Merger results of legacy Schering-Plough products. The domestic sales increase was also driven by higher sales of *Januvia*, *Janumet*, *Isentress* and *Singulair*. These increases were partially offset by lower sales of *Fosamax* and *Fosamax Plus D*, *Cosopt/Trusopt*, *Gardasil* and *RotaTeq*. Foreign sales growth reflects the strong performance of *Januvia*, *Janumet* and *Isentress*, partially offset by lower sales of *Fosamax* and *Fosamax Plus D*, and vaccines. Foreign sales represented 47% of total sales in 2009.

Worldwide sales totaled \$23.9 billion for 2008, a decline of 1% compared with 2007. Foreign exchange favorably affected global sales performance by 3%. The revenue decline over 2007 largely reflects lower sales of *Fosamax* and *Fosamax Plus D*. Also contributing to the decline were lower sales of *Zocor*, *Vasotec/Vaseretic* and sales of certain vaccines, including hepatitis and Haemophilus influenzae type b (HIB) vaccines. Partially offsetting these declines were higher sales of *Januvia*, *Janumet*, *Isentress*, *Cozaar/Hyzaar*, *RotaTeq* and *Singulair*. Foreign sales represented 44% of total sales for 2008.

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(\$ in millions)	2009	2008	2007
Pharmaceutical:			
<i>Bone, Respiratory, Immunology and Dermatology</i>			
Singular	\$ 4,659.7	\$ 4,336.9	\$ 4,266.3
Fosamax	1,099.8	1,552.7	3,049.0
Propecia	440.3	429.1	405.4
Remicade	430.7		
Arcoxia	357.5	377.3	329.1
Nasonex	164.9		
Clarinet	100.6		
Asmanex	37.0		
<i>Cardiovascular</i>			
Vytorin	440.8	84.2	84.3
Zetia	402.9	6.4	6.5
Integrilin	45.9		
<i>Diabetes and Obesity</i>			
Januvia	1,922.1	1,397.1	667.5
Janumet	658.4	351.1	86.4
<i>Infectious Disease</i>			
Isentress	751.8	361.1	41.3
Primaxin	688.9	760.4	763.5
Cancidas	616.7	596.4	536.9
Invanz	292.9	265.0	190.2
Crixivan/Stocrin	206.1	275.1	310.2
PegIntron	148.7		
Avelox	66.2		
Rebetol	36.1		
<i>Mature Brands</i>			
Cozaar/Hyzaar	3,560.7	3,557.7	3,350.1
Zocor	558.4	660.1	876.5
Vasotec/Vaseretic	310.8	356.7	494.6
Proscar	290.9	323.5	411.0
Claritin Rx	71.1		
Proventil	26.2		
<i>Neurosciences and Ophthalmology</i>			
Maxalt	574.5	529.2	467.3
Cosopt/Trusopt	503.5	781.2	786.8
Remeron	38.5		
Subutex/Suboxone	36.3		
<i>Oncology</i>			
Emend	313.1	259.7	201.7
Temodar	188.1		
Caelyx	46.5		
Intron A	38.4		

<i>Vaccines</i> ⁽²⁾			
ProQuad/M-M-R II/Varivax	1,368.5	1,268.5	1,347.1
Gardasil	1,118.4	1,402.8	1,480.6
RotaTeq	521.9	664.5	524.7
Pneumovax	345.6	249.3	233.2
Zostavax	277.4	312.4	236.0
<i>Women's Health and Endocrine</i>			
Follistim/Puregon	96.5		
NuvaRing	88.3		
Other Pharmaceutical ⁽³⁾	1,294.9	922.9	1,136.6
	25,236.5	22,081.3	22,282.8
Other segment revenues ⁽⁴⁾	2,114.0	1,694.1	1,848.1
Total segment revenues	27,350.5	23,775.4	24,130.9
Other ⁽⁵⁾	77.8	74.9	66.8
	\$ 27,428.3	\$ 23,850.3	\$ 24,197.7

- (1) Sales of legacy Schering-Plough products only reflect results for the post-Merger period through December 31, 2009. Sales of MSP Partnership products Zetia and Vytorin represent sales for the post-Merger period through December 31, 2009. Prior to the Merger, sales of Zetia and Vytorin were primarily recognized by the MSP Partnership and the results of Old Merck's interest in the MSP Partnership were recorded in Equity income from affiliates. Sales of Zetia and Vytorin in 2008 and 2007 reflect Old Merck's sales of these products in Latin America which was not part of the MSP Partnership.
- (2) These amounts do not reflect sales of vaccines sold in most major European markets through the Company's joint venture, Sanofi Pasteur MSD, the results of which are reflected in Equity income from affiliates. These amounts do, however, reflect supply sales to Sanofi Pasteur MSD.
- (3) Other pharmaceutical primarily includes sales of other human pharmaceutical products, including products within the franchises not listed separately.
- (4) Reflects other non-reportable segments, including animal health and consumer health care, and revenue from the Company's relationship with AZLP primarily relating to sales of Nexium, as well as Prilosec. Revenue from AZLP was \$1.4 billion, \$1.6 billion and \$1.7 billion in 2009, 2008 and 2007, respectively.
- (5) Other revenues are primarily comprised of miscellaneous corporate revenues, third-party manufacturing sales, sales related to divested products or businesses and other supply sales not included in segment results.

Table of Contents**Pharmaceutical Segment Revenues***Bone, Respiratory, Immunology and Dermatology*

Worldwide sales of *Singulair*, a leukotriene receptor antagonist for the chronic treatment of asthma and for the relief of symptoms of allergic rhinitis, grew 7% reaching \$4.7 billion in 2009 primarily driven by favorable pricing and strong performance in Japan and Asia Pacific. Global sales of *Singulair* rose 2% to \$4.3 billion in 2008, reflecting higher sales outside the United States, including volume growth in Europe and Japan and the positive effect of foreign exchange, partially offset by lower sales domestically. *Singulair* continues to be the number one prescribed product in the U.S. respiratory market. U.S. sales of *Singulair* were \$3.0 billion in 2009. The patent that provides U.S. marketing exclusivity for *Singulair* expires in August 2012. The Company expects that within the two years following patent expiration, it will lose substantially all U.S. sales of *Singulair*, with most of those declines coming in the first full year following patent expiration. In addition, the patent for *Singulair* will expire in a number of major European markets in August 2012 and the Company expects sales of *Singulair* in those markets will decline significantly thereafter.

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, decreased 29% in 2009 to \$1.1 billion and declined 49% in 2008 to \$1.6 billion. Since substantially all formulations of these medicines have lost U.S. market exclusivity, the Company is experiencing significant declines in sales in the United States within the *Fosamax* product franchise and the Company expects such declines to continue.

International sales of *Remicade*, a treatment for inflammatory diseases, were \$430.7 million for the post-Merger period through December 31, 2009. *Remicade* is marketed by the Company outside of the United States (except in Japan and certain Asian markets). Products that compete with *Remicade* have been launched over the past several years. In October 2009, the EC approved *Simponi* (golimumab), a once-monthly subcutaneous treatment for certain inflammatory diseases. The Company has launched *Simponi* in Canada, Germany and Denmark; launches in other international markets are ongoing or planned. See Note 12 to the consolidated financial statements for a discussion of arbitration proceedings involving *Remicade/Simponi*.

Global sales of *Nasonex* nasal spray, an inhaled nasal corticosteroid for the treatment of nasal allergy symptoms, were \$164.9 million for the post-Merger period through December 31, 2009.

Global sales of *Clarinex* (marketed as *Aerius* in many countries outside the United States), a non-drowsy antihistamine, were \$100.6 million for the post-Merger period through December 31, 2009.

Other products included in the Bone, Respiratory, Immunology and Dermatology franchise include among others, *Propecia*, a product for the treatment of male pattern hair loss; *Arcoxia*, for the treatment of arthritis and pain; and *Asmanex*, an orally inhaled steroid for asthma.

Cardiovascular

Sales of *Zetia*, a cholesterol absorption inhibitor, and *Vytorin*, a combination product containing the active ingredients of both *Zetia* and *Zocor* were \$402.9 million and \$440.8 million respectively, for the post-Merger period through December 31, 2009. Prior to the Merger, sales of these products were recognized by the MSP Partnership and the results of Old Merck's interest in the MSP Partnership were recorded in *Equity income from affiliates*. As a result of the Merger, the MSP Partnership is now wholly-owned by the Company and therefore revenues from these products are now reflected in *Sales*. For a discussion of the performance of *Zetia* and *Vytorin* prior to the closing of the Merger (see Selected Joint Venture and Affiliate Information below).

Global sales of *Integrilin* Injection, a legacy Schering-Plough product for the treatment of patients with acute coronary syndrome, which is sold by the Company in the United States and Canada, were \$45.9 million for the post-Merger period through December 31, 2009.

In June 2009, launches of *Tredaptive* began in international markets and as of December 31, 2009, Merck had launched *Tredaptive* in 20 countries including most major European markets. *Tredaptive* is a lipid-modifying therapy for patients with mixed dyslipidemia and primary hypercholesterolemia. *Tredaptive*, also known by the trademark of *Cordaptive* in certain countries, is now approved in 45 countries outside the United States. In the United States, it remains investigational.

Table of Contents*Diabetes and Obesity*

Global sales of *Januvia*, Merck's dipeptidyl peptidase-4 (DPP-4) inhibitor for the treatment of type 2 diabetes, were \$1.9 billion in 2009, \$1.4 billion in 2008 and \$667.5 million in 2007. *Januvia* was approved by the FDA in October 2006 and by the EC in March 2007. DPP-4 inhibitors represent a class of prescription medications that improve blood sugar control in patients with type 2 diabetes by enhancing a natural body system called the incretin system, which helps to regulate glucose by affecting the beta cells and alpha cells in the pancreas. During 2009, *Januvia* received regulatory approval in Japan and China.

In 2009, the EC approved the restricted first line use of *Januvia* for the treatment of type 2 diabetes. With this approval, sitagliptin is indicated to improve glycemic control when diet and exercise alone do not provide adequate glycemic control and when metformin is inappropriate due to contraindications or intolerance. Sitagliptin is now the only diabetes treatment in the DPP-4 inhibitor class to have a restricted first line indication in the EU.

Worldwide sales of *Janumet*, Merck's oral antihyperglycemic agent that combines sitagliptin (Merck's DPP-4 inhibitor, *Januvia*) with metformin in a single tablet to target all three key defects of type 2 diabetes, were \$658.4 million in 2009 compared with \$351.1 million in 2008 and \$86.4 million in 2007. *Janumet* was initially approved as an adjunct to diet and exercise to improve blood sugar control in adult patients with type 2 diabetes who are not adequately controlled on metformin or sitagliptin alone, or in patients already being treated with the combination of sitagliptin and metformin. In February 2008, FDA approval to market *Janumet* as an initial treatment for type 2 diabetes was received. In July 2008, *Janumet* was approved for marketing in the EU, Iceland and Norway.

In 2009, the EC approved the use of *Januvia* tablets and *Janumet* tablets as add-on to insulin for the treatment of type 2 diabetes. Sitagliptin is now the only diabetes treatment in the DPP-4 inhibitor class to have an indication for use as add-on to insulin in the EU. In the United States, a supplemental New Drug Application concerning the use of *Januvia* and *Janumet* in combination with insulin has been accepted by the FDA and is currently under review.

Infectious Disease

Worldwide sales of *Isentress*, an antiretroviral therapy for the treatment of HIV infection, were \$751.8 million in 2009, \$361.1 million in 2008 and \$41.3 million in 2007. Sales growth in 2009 reflects positive performance in the United States, as well as internationally due in part to strong 2008 launches in certain countries, including France, Spain and Italy. *Isentress* is now available in all major international markets. In October 2007, the FDA granted *Isentress* accelerated approval for use in combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment-experienced adult patients who have evidence of viral replication and HIV-1 strains resistant to multiple antiretroviral agents. *Isentress* was the first medicine to be approved in the class of antiretroviral drugs called integrase inhibitors. *Isentress* works by inhibiting the insertion of HIV DNA into human DNA by the integrase enzyme. Inhibiting integrase from performing this essential function limits the ability of the virus to replicate and infect new cells. In January 2009, the FDA granted traditional approval to *Isentress* following review of the 48 week data from the BENCHMRK 1 & 2 clinical trials. In July 2009, the FDA approved an expanded indication for *Isentress* to include use in the treatment of adult patients starting HIV-1 therapy for the first time (treatment naïve), as well as in treatment-experienced adult patients.

In September 2009, *Isentress* was granted an expanded license from the EC for use in combination with other antiretroviral medicinal products for the treatment of HIV-1 infection in adult patients, including treatment-naïve adult patients, as well as treatment-experienced adult patients. The Commission's decision is applicable to the 27 countries that are members of the EU, as well as Iceland and Norway. Additionally, in October 2009, Merck announced that *Isentress* is now indicated for use in treatment-naïve adults in Canada.

Sales of *Primaxin*, an anti-bacterial product, declined 9% in 2009 to \$688.9 million as compared with 2008. These results reflect competitive pressures and also reflect supply constraints. Patents on *Primaxin* have expired worldwide

and multiple generics have been approved in Europe. Accordingly, the Company is experiencing a decline in sales of this product and the Company expects the decline to continue. Sales of *Primaxin* were essentially flat in 2008 as compared with 2007.

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Worldwide sales of *PegIntron* for treating chronic hepatitis C were \$148.7 million for the post-Merger period through December 31, 2009.

Other products contained in the Infectious Diseases franchise include among others, *Cancidas*, an anti-fungal product; *Crixivan* and *Stocrin*, antiretroviral therapies for the treatment of HIV infection; *Avelox*, a fluoroquinolone antibiotic for the treatment of certain respiratory and skin infections; and *Invanz* for the treatment of certain infections.

Mature Brands

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

Global sales of *Cozaar*, and its companion agent *Hyzaar* (a combination of *Cozaar* and hydrochlorothiazide), for the treatment of hypertension, were \$3.6 billion in 2009 which are comparable to sales in 2008 reflecting the unfavorable effect of foreign exchange, offset by strong performance of both products in the United States and of *Hyzaar* in Japan (marketed as *Preminent*). Global sales of *Cozaar* and *Hyzaar* grew 6% to \$3.6 billion in 2008 driven by strong performance of *Hyzaar* in Japan, as well as by the positive effect of foreign exchange. *Cozaar* and *Hyzaar* are among the leading medicines in the angiotensin receptor blocker class. The patents that provide U.S. market exclusivity for *Cozaar* and *Hyzaar* expire in April 2010. In addition, the patent for *Cozaar* will expire in a number of major European markets in March 2010. *Hyzaar* lost patent protection in a number of major European markets in February 2010. The Company anticipates a significant decline in future *Cozaar/Hyzaar* sales since there are multiple sources of generics expected for these medicines at the time of patent expiry.

Worldwide sales of *Zocor*, a statin for modifying cholesterol, declined 15% in 2009 and 25% in 2008. *Zocor* lost U.S. market exclusivity in June 2006 and has also lost market exclusivity in all major international markets.

Other products contained in the Mature Brands franchise include among others, prescription *Claritin* for the treatment of seasonal outdoor allergies and year-round indoor allergies; *Vasotec/Vaseretic* for hypertension and/or heart failure; and *Proscar*, a urology product for the treatment of symptomatic benign prostate enlargement.

Neurosciences and Ophthalmology

Sales of *Cosopt* and *Trusopt*, Merck's largest-selling ophthalmic products, declined 36% to \$503.5 million in 2009 as compared with 2008. The patent that provided U.S. market exclusivity for *Cosopt* and *Trusopt* expired in October 2008. *Cosopt* has also lost market exclusivity in a number of major European markets. *Trusopt* will lose market exclusivity in a number of major European markets in April 2012 and the Company expects sales in those markets to decline significantly thereafter. Sales of *Cosopt* and *Trusopt* declined 1% in 2008 as compared with 2007.

Saphris (asenapine), Merck's sublingual tablet for acute treatment of schizophrenia in adults and acute treatment of manic or mixed episodes associated with bipolar I disorder, was approved by the FDA in August 2009 and a full launch is underway. The Company has filed two supplemental New Drug Applications with the FDA for *Saphris* as an adjunct to therapy in patients with mania and for maintenance therapy in patients with schizophrenia. The application for asenapine is also under review in the EU.

The Company's muscle relaxant reversal drug, *Bridion*, is currently approved in 44 countries, including Japan, and has been launched in 28 countries around the world.

During 2009, *Saflutan* (tafluprost) was launched in a number of countries including the United Kingdom and Spain, and additional launches in other countries are expected over the next year, pending regulatory approvals. *Saflutan* is a preservative free, synthetic analogue of the prostaglandin F₂ for the reduction of elevated intraocular pressure in

appropriate patients with primary open-angle glaucoma and ocular hypertension. Tafluprost is in Phase III development in the United States. In April 2009, Old Merck and Santen Pharmaceutical Co., Ltd. (Santen) announced a worldwide licensing agreement for tafluprost (see Research and Development Update below).

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Also, during 2009, Old Merck divested its U.S. marketing rights to the *Timoptic* product franchise to Aton Pharma, Inc. The *Timoptic* product franchise includes ophthalmic products to treat elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma.

Oncology

Sales of *Temodar*, a treatment for certain types of brain tumors, were \$188.1 million for the post-Merger period through December 31, 2009. *Temodar* lost patent exclusivity in the EU in 2009. In January 2010, the Company announced that the U.S. District Court for the District of Delaware ruled against the Company in a patent infringement suit against Teva Pharmaceuticals USA Inc. (see Note 12 to the consolidated financial statements). The decision is being appealed. The effects of the ruling are uncertain while this matter is under appeal.

Other products in the Oncology franchise include *Emend* for the treatment of chemotherapy induced nausea and vomiting; and *Caelyx* for the treatment of ovarian cancer, metastatic breast cancer and Kaposi's sarcoma. Marketing rights for *Caelyx* return to Johnson & Johnson as of December 31, 2010.

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 included 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, declined 20% to \$1.1 billion in 2009 and declined 5% to \$1.4 billion in 2008. *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 and vaginal cancers, precancerous or dysplastic lesions, and genital warts caused by HPV types 6, 11, 16 and 18. *Gardasil* is also approved in the United States for use in boys and men ages 9 through 26 years of age for the prevention of genital warts caused by HPV types 6 and 11. Sales performance in 2009 was driven largely by declines in the United States which continue to be affected by the saturation of the 13 to 18 year-old female cohort due to rapid early uptake, and ongoing challenges to vaccinating the 19 to 26 year-old female age group. Sales in 2009 include \$51 million of revenue as a result of government purchases for the U.S. Centers for Disease Control and Prevention's (CDC) Strategic National Stockpile. In 2008, sales performance reflects lower sales domestically, partially offset by growth outside the United States. Sales in 2007 include initial purchases by many states through the CDC Vaccines for Children program. The Company is a party to certain third party license agreements with respect to *Gardasil* (including a cross-license and settlement agreement with GlaxoSmithKline). As a result of these agreements, the Company pays royalties on worldwide *Gardasil* sales of 21% to 27% which vary by country and are included in *Materials and production costs*.

In October 2009, the FDA approved *Gardasil* for use in boys and men, making *Gardasil* the only HPV vaccine approved for use in males. Later in October 2009, Merck announced that the CDC's Advisory Committee on Immunization Practices (ACIP) supports the permissive use of *Gardasil* for boys and men ages 9 to 26, which means that *Gardasil* may be given to males ages 9 to 26 to reduce the likelihood of acquiring genital warts. The ACIP also voted to recommend that funding be provided for the use of *Gardasil* in males through the Vaccines for Children program.

In January 2009, the FDA issued a second complete response letter regarding the supplemental Biologics License Application (sBLA) for the use of *Gardasil* in women ages 27 through 45. The FDA completed its review of the response that Old Merck provided in July 2008 to the FDA's first complete response letter issued in June 2008 and recommended that Old Merck submit additional data when the 48 month study has been completed. The initial sBLA included data collected through an average of 24 months from enrollment into the study, which is when the number of pre-specified endpoints had been met. Merck provided a response to the FDA in the fourth quarter of 2009. This was a

Class 2 Response which generally carries a 6-month review time from the point that the FDA has accepted the file. The complete response letter does not affect current indications for *Gardasil* in females ages 9 through 26.

Global sales of *RotaTeq*, a vaccine to help protect against rotavirus gastroenteritis in infants and children, recorded by Merck declined 21% in 2009 to \$521.9 million reflecting moderate impact from competition in the

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United States, with a greater impact in the public sector. Worldwide sales of *RotaTeq* grew 27% in 2008 to \$664.5 million primarily driven by the continued uptake in the United States and successful launches around the world. Sales in 2008 included purchases of \$54 million to support the CDC Strategic National Stockpile.

Old Merck has received regulatory approvals in the United States and certain other markets to increase its manufacturing capacity for the Company's varicella zoster virus (VZV)-containing vaccines. The Company is manufacturing bulk varicella and is producing doses of *Varivax* and *Zostavax*. *ProQuad*, a pediatric combination vaccine to help protect against measles, mumps, rubella and varicella, one of the VZV-containing vaccines, is currently not available for ordering; however, orders have been transitioned, as appropriate, to *M-M-R II* and *Varivax*. Total sales as recorded by Merck for *ProQuad* were \$9.5 million in 2008 and \$264.4 million in 2007. Merck anticipates that some *ProQuad* will be available in the U.S. market in 2010.

Merck's sales of *Varivax*, a vaccine to help prevent chickenpox (varicella), were \$1.0 billion in 2009, \$924.6 million in 2008 and \$854.9 million in 2007. *Varivax* is the only vaccine available in the United States to help protect against chickenpox due to the unavailability of *ProQuad*. Sales for 2009 reflect \$64 million in revenue as a result of government purchases for the CDC's Strategic National Stockpile. In 2007, *Varivax* benefited from the ACIP's June 2006 second dose recommendation. Merck's sales of *M-M-R II*, a vaccine to help protect against measles, mumps and rubella, were \$331.4 million in 2009, \$334.4 million in 2008 and \$227.8 million in 2007. Sales of *Varivax* and *M-M-R II* were affected by the unavailability of *ProQuad*. Combined sales of *ProQuad*, *M-M-R II* and *Varivax* increased 8% in 2009 and declined 6% in 2008.

Sales of *Zostavax*, a vaccine to help prevent shingles (herpes zoster), recorded by Merck were \$277.4 million in 2009, \$312.4 million in 2008 and \$236.0 million in 2007. Sales in all of these years were affected by supply issues. While normal shipping schedules for *Zostavax* in the United States were resumed in June 2009 and the Company anticipates that *Zostavax* will be available in 2010 in the United States, customers will likely experience back orders of *Zostavax* throughout the year. International launches of *Zostavax* will be delayed until 2011. The vaccine is the first and only medical option for the prevention of shingles.

Sales of *Pneumovax*, a vaccine to help prevent pneumococcal disease, were \$345.6 million for 2009 compared with \$249.3 million for 2008 and \$233.2 million for 2007. The increase in 2009 is due to favorable pricing in the United States and higher demand associated with the flu pandemic.

In September 2009, Old Merck announced that it had entered into an exclusive agreement with CSL Biotherapies (CSL), a subsidiary of CSL Limited, to market and distribute *Afluria*, CSL's seasonal influenza (flu) vaccine, in the United States, for the 2010/2011-2015/2016 flu seasons. Under the terms of the agreement, the Company will assume responsibility for all aspects of commercialization of *Afluria* in the United States. CSL will supply *Afluria* to Merck and will retain responsibility for marketing the vaccine outside the United States. *Afluria* is indicated for the active immunization of persons age 6 months and older against influenza disease caused by influenza virus subtypes A and type B present in the vaccine.

Efforts to resolve manufacturing issues related to HIB-containing vaccines, *PedvaxHIB* and *Comvax* have been ongoing since December 2007. In January 2010, *PedvaxHIB* became fully available in the United States for routine vaccination as well as for booster dose catch-up vaccination. The timing of availability outside the United States is dependent upon local regulatory requirements. The market return of *Comvax* will be dependent upon the supply situation for both the Company's HIB-containing vaccine and hepatitis B vaccine.

The pediatric/adolescent formulation of *Vaqta*, a vaccine against hepatitis A, is currently available. Because the Company is continuing to prioritize the pediatric/adolescent formulation, Merck anticipates the adult formulation will not be available in 2010. Outside of the United States, the supply of *Vaqta* is limited and availability will vary by

region. The pediatric/adolescent formulation of *Recombivax HB*, a vaccine against hepatitis B, became available in December 2009. The Company does not anticipate availability of the adult formulation in the first half of 2010. The Company anticipates the dialysis formulation will become available before the end of 2010.

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Women's Health & Endocrine

Global sales of *Follistim/Puregon*, a fertility treatment, were \$96.5 million for the post-Merger period through December 31, 2009. *Follistim/Puregon* lost market exclusivity in the EU in August 2009. Worldwide sales of *NuvaRing*, a contraceptive product, were \$88.3 million for the post-Merger period through December 31, 2009.

In January 2010, Merck received EC approval of *Elonva*. *Elonva* is indicated for controlled ovarian stimulation in combination with a GnRH antagonist for the development of multiple follicles in women participating in an assisted reproductive technology program. With the EC approval, Merck receives marketing authorization for *Elonva* with unified labeling valid in all European Union Member States. *Elonva* is the first in the class of sustained follicle stimulant. Due to its ability to initiate and sustain multiple follicular growth for an entire week, a single subcutaneous injection of the recommended dose of *Elonva* may replace the first seven injections of any daily recombinant follicle stimulating hormone (rFSH) preparation in a controlled ovarian stimulation treatment cycle.

Other

In January 2010, the Company, AZLP and Teva Pharmaceuticals, Inc. (which acquired IVAX Pharmaceuticals, Inc.) entered into a settlement agreement to resolve patent litigation with respect to esomeprazole (*Nexium*) which provides that Teva/IVAX will not bring its generic esomeprazole product to market in the United States until May 27, 2014. During 2008, Old Merck and AZLP entered into a similar agreement with Ranbaxy Laboratories Ltd. (Ranbaxy) which provides that Ranbaxy will not bring its generic esomeprazole product to market in the United States until May 27, 2014. The Company faces other challenges with respect to outstanding patent infringement matters for esomeprazole (see Note 12 to the consolidated financial statements).

Animal Health

Global sales of Animal Health products, which include livestock, poultry, companion animal and aquaculture products that prevent and treat animal diseases, totaled \$494.2 million for the post-Merger period through December 31, 2009. Animal Health sales are affected by intense competition and the frequent introduction of generic products.

Consumer Health Care

Global sales of Consumer Health Care products, which include OTC, foot care and sun care products, were \$149.2 million for the post-Merger period through December 31, 2009. Consumer Health Care product sales are affected by competition, frequent competitive product introductions and consumer spending patterns. Consumer Health Care products include *Dr. Scholl's* foot care products, *Claritin* non-drowsy antihistamines; *MiraLAX*, a treatment for occasional constipation; and *Coppertone* sun care products.

In December 2009, Merck announced that the FDA approved *Zegerid* OTC for over-the-counter treatment of frequent heartburn. Under an agreement with Santarus, Inc. a specialty pharmaceutical company that developed and currently markets prescription *Zegerid*, Schering-Plough Healthcare Products, the consumer healthcare division of Merck, is responsible for the development, manufacturing and commercialization of *Zegerid* OTC products for heartburn-related indications in the United States and Canada.

Table of Contents**Costs Expenses and Other**

(\$ in millions)	2009	Change	2008	Change	2007
Materials and production	\$ 9,018.9	62%	\$ 5,582.5	-9%	\$ 6,140.7
Marketing and administrative	8,543.2	16%	7,377.0	-2%	7,556.7
Research and development	5,845.0	22%	4,805.3	-2%	4,882.8
Restructuring costs	1,633.9	58%	1,032.5	*	327.1
Equity income from affiliates	(2,235.0)	-13%	(2,560.6)	-14%	(2,976.5)
U.S. Vioxx Settlement Agreement charge				*	4,850.0
Other (income) expense, net	(10,669.5)	*	(2,318.1)	*	(75.2)
	\$ 12,136.5	-13%	\$ 13,918.6	-33%	\$ 20,705.6

* 100% or greater.

Materials and Production

In 2009, materials and production costs were \$9.0 billion compared with \$5.6 billion in 2008. Materials and production costs include expenses related to the sale of legacy Schering-Plough products in the post-Merger period. Additionally, these costs were unfavorably affected by \$1.5 billion of amortization of purchase accounting adjustments to Schering-Plough's inventories and \$0.8 billion of expense for the amortization of intangible assets recognized in the Merger. Also included in materials and production costs in 2009 were \$115.2 million of costs associated with restructuring activities, substantially all of which represents accelerated depreciation associated with the planned sale or closure of manufacturing facilities. (See Note 4 to the consolidated financial statements.)

In 2008, materials and production costs declined 9% compared with a 1% decline in sales primarily reflecting lower restructuring costs. Included in materials and production costs in 2008 were \$123.2 million of restructuring costs comprised of \$88.7 million of accelerated depreciation and \$34.5 million of other costs, primarily asset write-offs. This compares with restructuring costs of \$483.1 million in 2007 representing \$460.6 million of accelerated depreciation and \$22.5 million of asset impairments.

Gross margin was 67.1% in 2009 compared with 76.6% in 2008 and 74.6% in 2007. The additional amortization expense as a result of the Merger in 2009 and restructuring charges reflected in all periods as noted above had an unfavorable impact of 8.8 percentage points in 2009, 0.5 percentage points in 2008 and 2.0 percentage points in 2007. Gross margin in 2008 reflects changes in product mix, including the decline in *Fosamax* and *Fosamax Plus D* sales as a result of the loss of U.S. market exclusivity in 2008, and manufacturing efficiencies. Gross margin in 2007 reflects a slight unfavorable impact from changes in product mix and the positive impact of manufacturing efficiencies.

Marketing and Administrative

Marketing and administrative expenses increased 16% in 2009 driven largely by the inclusion of expenses related to Schering-Plough activities in the post-Merger period. Additionally, \$370.7 million of merger-related costs were recognized in 2009 consisting of transaction costs directly related to the Merger (including advisory and legal fees) and integration costs. These increases were partially offset by initiatives to reduce the cost base, which were in place prior to the consummation of the Merger. Separation costs associated with sales force reductions have been incurred and are reflected in *Restructuring costs* as discussed below. In addition, marketing and administrative expenses benefited from foreign exchange. Marketing and administrative expenses in 2009 and 2008 included \$75 million and

\$62 million, respectively, of additional reserves solely for future *Vioxx* legal defense costs. Expenses in both 2009 and 2008 also reflect \$40 million of additional reserves solely for future legal defense costs for *Fosamax* litigation. (See Note 12 to the consolidated financial statements for more information on *Vioxx* and *Fosamax* litigation related matters).

Marketing and administrative expenses declined 2% in 2008 as compared with 2007. Included in marketing and administrative expenses in 2008 and 2007 were \$62 million and \$280 million, respectively, of additional reserves solely for future *Vioxx* legal defense costs. Also included in these costs in 2008 was \$40 million of additional reserves solely for future legal defense costs for *Fosamax* litigation. In addition, marketing and

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administrative expenses for 2007 included a \$455 million gain from an insurance arbitration award related to *Vioxx* product liability litigation coverage. In addition to lower expenses for future legal defense costs, the decline in marketing and administrative expenses in 2008 as compared with 2007 also reflects efforts to reduce the cost base.

Research and Development

Research and development expenses increased 22% in 2009 as compared with 2008, due in part to the incremental expenditures associated with the inclusion of Schering-Plough's results in the post-Merger period. Additionally, expenses in 2009 reflect \$231.6 million of costs associated with restructuring activities, including the closure or sale of research facilities in connection with the 2008 Restructuring Program, substantially all of which represent accelerated depreciation. (See Note 4 to the consolidated financial statements.) In addition, research and development expenses in 2009 as compared with 2008 reflect an increase in development spending in support of the continued advancement of the research pipeline, including investments in late-stage clinical trials.

Research and development expenses declined 2% in 2008 compared with 2007. Expenses in 2008 reflect \$128.4 million of costs related to restructuring activities. Expenses in 2007 reflect \$325.1 million of in-process research and development expense related to the NovaCardia acquisition. Research and development expenses in 2008 compared with 2007 reflect an increase in development spending in support of the continued advancement of the research pipeline.

Share-Based Compensation

Total pretax share-based compensation expense was \$415.5 million in 2009, \$348.0 million in 2008 and \$330.2 million in 2007. At December 31, 2009, there was \$521.8 million of total pretax unrecognized compensation expense related to nonvested stock option, restricted stock unit and performance share unit awards which will be recognized over a weighted average period of 1.5 years. For segment reporting, share-based compensation costs are unallocated expenses.

Restructuring Costs

Restructuring costs were \$1.6 billion, \$1.0 billion and \$327.1 million for 2009, 2008 and 2007, respectively. Of the restructuring costs recorded in 2009, \$1.4 billion related to the Merger Restructuring Program, \$178.2 million related to the 2008 Restructuring Program and \$38.7 million related to the legacy Schering-Plough Productivity Transformation Program. Of the restructuring costs recorded in 2008, \$735.5 million related to the 2008 Restructuring Program and the remainder were associated with the 2005 Restructuring Program. In 2009, 2008 and 2007, separation costs of \$1.4 billion, \$957.3 million and \$251.4 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 3,525 positions in 2009 (most of which related to the 2008 Restructuring Program), 5,800 positions in 2008 (of which approximately 1,750 related to the 2008 Restructuring Program and 4,050 related to the 2005 Restructuring Program) and 2,400 positions in 2007. These position eliminations are comprised of actual headcount reductions, and the elimination of contractors and vacant positions. Also included in restructuring costs are curtailment, settlement and termination charges on pension and other postretirement benefit plans 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* costs and *Research and development* expenses.

Equity Income from Affiliates

Equity income from affiliates reflects the performance of the Company's joint ventures and partnerships. The decline in 2009 was primarily driven by lower equity income from the MSP Partnership, which is now wholly-owned by the Company as a result of the Merger and therefore its results are reflected in the consolidated results of the Company beginning on the date of the Merger, and decreased equity income from Merial due to the sale of Old Merck's interest in September 2009, partially offset by higher partnership returns from AZLP. In 2008, the decline in equity income

from affiliates reflects decreased equity income from the MSP Partnership and lower partnership returns from AZLP, partially offset by higher equity income from Merial and SPMSD. The decrease in equity income from the MSP Partnership in 2008 was primarily the result of lower revenues of *Vytorin* and *Zetia* following the announcements of the ENHANCE and SEAS clinical trial results. The lower partnership returns from AZLP in

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2008 were primarily attributable to the first quarter 2008 partial redemption of Old Merck's interest in certain AZLP product rights, which resulted in a reduction of the priority return and the variable returns which were based, in part, upon sales of certain former Astra USA, Inc. products. The higher equity income from Merial in 2008 primarily reflects higher sales of biological products. The increase in equity income from SPMSD in 2008 was largely attributable to higher sales of *Gardasil* in joint venture territories outside of the United States. (See Selected Joint Venture and Affiliate Information below.)

U.S. Vioxx Settlement Agreement Charge

On November 9, 2007, Old Merck entered into an agreement (the Settlement Agreement) with the law firms that comprise the executive committee of the Plaintiffs Steering Committee of the federal multidistrict *Vioxx* litigation as well as representatives of plaintiffs counsel in state coordinated proceedings to resolve state and federal myocardial infarction (MI) and ischemic stroke (IS) claims filed as of that date against Old Merck in the United States. Under the Settlement Agreement, Old Merck paid an aggregate fixed amount of \$4.85 billion into two funds for qualifying claims consisting of \$4.0 billion for qualifying MI claims and \$850 million for qualifying IS claims that entered into the resolution process (Settlement Program), of which \$750 million was paid into such funds in 2008 and the remainder in 2009. As a consequence of the Settlement Agreement, a pretax charge of \$4.85 billion was recorded in 2007. (See Note 12 to the consolidated financial statements).

Other (Income) Expense, Net

Included in other (income) expense, net in 2009 was a \$7.5 billion gain related to Merck's previously held interest in the MSP Partnership. As a result of the Merger, the Company obtained a controlling interest in the MSP Partnership and it is now owned 100% by the Company. Previously, the Company had a noncontrolling interest. A business combination in which an acquirer holds a noncontrolling equity investment in the acquiree immediately before obtaining control of that acquiree is referred to as a step acquisition. The acquirer is required to remeasure its previously held equity interest in the acquiree at its acquisition-date fair value and recognize the resulting gain or loss in earnings. Additionally during 2009, a \$3.2 billion gain was recognized on the sale of Old Merck's interest in Merial (see Note 10 to the consolidated financial statements). Also included in other (income) expense, net in 2009 was \$231 million of investment portfolio recognized net gains, and an \$80 million charge related to the settlement of the *Vioxx* third-party payor litigation in the United States (see Note 12 to the consolidated financial statements). Included in other (income) expense, net in 2008 was an aggregate gain on distribution from AZLP of \$2.2 billion (see Note 10 to the consolidated financial statements), a gain of \$249 million related to the sale of the remaining worldwide rights to *Aggrastat*, a \$300 million expense for a contribution to the Merck Company Foundation, \$117 million of investment portfolio recognized net losses and a \$58 million charge related to the resolution of an investigation into whether Old Merck violated state consumer protection laws with respect to the sales and marketing of *Vioxx*. Merck experienced a decline in interest income in 2009 as compared with 2008 primarily as a result of lower interest rates and a change in the investment portfolio mix toward cash and shorter-dated securities in anticipation of the Merger. Merck recognized higher interest expense in 2009 largely due to \$174 million of commitment fees and incremental interest expense related to the financing of the Merger.

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

Table of Contents*Segment Profits*

<i>(\$ in millions)</i>	2009	2008	2007
Pharmaceutical segment profits	\$ 15,714.6	\$ 14,110.3	\$ 14,558.7
Other non-reportable segment profits	1,735.1	1,691.0	2,027.6
Other	(2,157.9)	(5,869.6)	(13,094.2)
Income before income taxes	\$ 15,291.8	\$ 9,931.7	\$ 3,492.1

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

Pharmaceutical segment profits rose 11% in 2009 largely driven by the inclusion of legacy Schering-Plough results in the post-Merger period. Pharmaceutical segment profits decreased 3% in 2008 largely driven by lower sales of *Fosamax* and *Fosamax Plus D*, *Zocor* and decreased equity income from the MSP Partnership.

Taxes on Income

The effective income tax rate was 14.8% in 2009, 20.1% in 2008 and 2.7% in 2007. The 2009 effective tax rate reflects the favorable impacts of increased income in lower tax jurisdictions, which includes the favorable impact of the MSP Partnership gain, and higher expenses in certain jurisdictions including the amortization of purchase accounting adjustments and restructuring costs. The effective income tax rate in 2009 also benefited from 2009 tax settlements, including the previously announced settlement with the Canada Revenue Agency (*CRA*). These favorable impacts were partially offset by the unfavorable effect of the gain on the sale of Old Merck's interest in Merial being taxable in the United States at a combined federal and state tax rate of approximately 38.0%. The net favorable impact of the above items on the 2009 effective tax rate was approximately 7 percentage points. The 2008 effective tax rate reflects a net favorable impact as compared with the statutory rate of approximately 3 percentage points, which includes favorable impacts relating to tax settlements that resulted in a reduction of the liability for unrecognized tax benefits of approximately \$200 million, the realization of foreign tax credits and the favorable tax impact of foreign exchange rate changes during the fourth quarter, particularly the strengthening of the Japanese yen against the US dollar, partially offset by an unfavorable impact resulting from the AZLP gain being fully taxable in the United States at a combined federal and state tax rate of approximately 36.3%. In the first quarter of 2008, Old Merck decided to distribute certain prior years' foreign earnings to the United States which will result in a utilization of foreign tax credits. These foreign tax credits arose as a result of tax payments made outside of the United States in prior years that

became realizable in the first quarter based on a change in Old Merck's decision to distribute these foreign earnings. The 2007 effective tax rate reflects the reduction of domestic pretax income primarily resulting from the U.S. *Vioxx* Settlement Agreement charge and the related change in mix of domestic and foreign pretax income.

Net Income and Earnings per Common Share

Net income available to common shareholders was \$12.9 billion in 2009 compared with \$7.8 billion in 2008 and \$3.3 billion in 2007. Earnings per common share assuming dilution available to common shareholders (EPS) were \$5.65 in 2009 compared with \$3.63 in 2008 and \$1.49 in 2007. The increases in net income and earnings per share in 2009 were largely driven by the gain associated with the MSP Partnership recognized in conjunction with the Merger, as well as the gain recorded on the sale of Old Merck's interest in Merial, partially offset by incremental charges associated with the Merger, including the amortization of intangible assets and

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inventory step-up and the recognition of merger-related costs. EPS in 2009 was also affected by the dilutive impact of shares issued in the Merger. The increases in net income and earnings per share in 2008 as compared with 2007 are primarily attributable to the gain on distribution from AZLP in 2008 and the impacts in 2007 of the U.S. *Vioxx* Settlement Agreement and civil governmental investigations charges. In addition, the increases reflect the positive impact of certain tax items, lower in-process research and development costs and lower expenses for legal defense costs, partially offset by higher restructuring costs and lower equity earnings in 2008, as well as the recognition in 2007 of an insurance arbitration gain.

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 earnings per share 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 are certain purchase accounting items related to the Merger, restructuring activities, merger-related 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 earnings per share 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.

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

<i>(\$ in millions)</i>	2009	2008	2007
Pretax income as reported under GAAP	\$ 15,292	\$ 9,932	\$ 3,492
Increase (decrease) for excluded items:			
Purchase accounting	2,286		
Restructuring activities	1,981	1,284	810
Merger-related costs	544		
Other items:			
Gain related to the MSP Partnership	(7,530)		
Gain on Merial	(3,163)		
Gain on distribution from AZLP		(2,223)	
U.S. <i>Vioxx</i> settlement agreement charge			4,850
Civil governmental investigations charge			671
Insurance arbitration gain			(455)
	9,410	8,993	9,368
Taxes on income as reported under GAAP	2,268	1,999	95
Tax (benefit) expense on excluded items	(390)	(472)	2,134
Non-GAAP taxes on income	1,878	1,527	2,229
Non-GAAP net income	\$ 7,532	\$ 7,466	\$ 7,139
	2009	2008	2007
EPS assuming dilution as reported under GAAP	\$ 5.65	\$ 3.63	\$ 1.49
EPS impact of excluded items	(2.40)	(0.21)	1.71
Non-GAAP EPS assuming dilution	\$ 3.25	\$ 3.42	\$ 3.20

Purchase Accounting Adjustments

Non-GAAP income and non-GAAP EPS exclude certain amounts recorded in connection with the Merger (see Note 3 to the consolidated financial statements). These amounts include the amortization of intangible assets and inventory step-up.

Restructuring Activities

Non-GAAP income and non-GAAP EPS exclude restructuring activities, including restructuring activities related to the Merger (see Note 4 to the consolidated financial statements). These amounts include employee separation costs

and accelerated depreciation associated with facilities to be sold or closed. The Company has undertaken restructurings of different types during the covered periods and therefore these charges should not to 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.

Merger-Related Costs

Non-GAAP income and non-GAAP EPS exclude transaction costs associated directly with the Merger, as well as integration costs. These costs are excluded because management believes that these costs are unique to the Merger transaction and are not representative of ongoing normal business activities. Integration costs associated with the Merger will occur over several years, however, the impacts within each year will vary as the integration progresses.

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

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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 include, among other items, the gain on the fair value adjustment of Merck's existing interest in the MSP Partnership as a result of the Merger, the gain on the divestiture of the interest in Merial, the gain on a distribution from AZLP and certain legal settlements.

Research and Development

A chart reflecting the Company's current research pipeline as of February 12, 2010 is set forth in Item 1. Business Research and Development above.

Research and Development Update

In connection with the Merger, the Company is assessing its pipeline to identify the most promising, high-potential compounds for development. The Company has completed the prioritization of its clinical development programs. The Company is continuing to work on the prioritization of its value adding programs related to currently marketed products and to its preclinical/discovery programs. The Company anticipates that the full prioritization process will be completed by the first half of 2010. In connection with this process, the Company may recognize non-cash impairment charges for the cancellation of certain legacy Schering-Plough pipeline programs that were measured at fair value and capitalized in connection with the Merger. These non-cash impairment charges, which are anticipated to be excluded from the Company's non-GAAP earnings, could be material to the Company's future GAAP earnings.

The Company currently has a number of candidates under regulatory review in the United States and internationally. Additionally, the Company has 19 drug candidates in Phase III development.

MK-6621, vernakalant (IV), is an investigational candidate for the treatment of atrial fibrillation currently undergoing regulatory review in the EU. In April 2009, Old Merck and Cardiome Pharma Corp. (Cardiome) announced a collaboration and license agreement for the development and commercialization of vernakalant which provides Merck exclusive rights outside of the United States, Canada and Mexico to the intravenous formulation of vernakalant (see below). Vernakalant (oral) is currently in Phase II development. Merck has exclusive global rights to the oral formulation of vernakalant for the maintenance of normal heart rhythm in patients with atrial fibrillation.

SCH 418131, MFF, is a combination of two previously approved drugs for the treatment of asthma: mometasone (*Asmanex*) and formoterol (*Foradil*). The Company is aiming to create a new option for patients by bringing these two key treatments together. In July 2009, Schering-Plough announced that it had filed a New Drug Application (NDA) with the FDA for MFF. MFF is also currently under regulatory review in the EU.

SCH 900121, NOMAC/E2, is an oral contraceptive that combines a selective progestin with estradiol, the estrogen that women produce naturally. The drug is currently under regulatory review in the EU. It is in Phase III development for the U.S. market.

SCH 900274, *Saphris*, asenapine, a central nervous system compound for bipolar I disorder and schizophrenia, is currently undergoing regulatory review in the EU. The FDA approved *Saphris* in August 2009.

SCH 900616, *Bridion*, sugammadex, is a medication designed to rapidly reverse the effects of certain muscle relaxants used as part of general anesthesia to ensure patients remain immobile during surgical procedures. It differs from other reversal agents that can only be administered once the muscle relaxant begins to wear off. *Bridion* has received regulatory approval in the EU, Australia, New Zealand and Japan, and is under regulatory review in other markets, including the United States. Prior to the Merger, Schering-Plough received a complete response letter from the FDA for *Bridion*. Following further communication from the FDA, the Company is assessing the agency's feedback in order

to determine a new timetable for response.

SCH 503034, boceprevir, is a hepatitis C protease inhibitor currently under development. Boceprevir is fully enrolled in its Phase III program, which the Company expects to conclude in mid-2010. The Company expects to submit an NDA to the FDA for boceprevir by the end of 2010 for both treatment-experienced and treatment-naïve patients with hepatitis C.

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

SCH 697243, an allergy immunotherapy sublingual tablet (AIT) for grass pollen allergy, is being developed by the Company. In November 2009, SCH 697243 met the primary endpoint in a Phase III study of adult subjects in the United States with a history of grass pollen induced rhinoconjunctivitis with or without asthma. The investigational grass AIT treatment is designed to work by inducing a protective immune response against grass pollen allergy and providing sustained prevention of allergy symptoms, treating both the symptoms and the underlying cause of the disease.

SCH 039641, an AIT for ragweed allergy, is also in Phase III development for the U.S. market.

SCH 530348, vorapaxar, is a thrombin receptor antagonist or antiplatelet protease activated receptor-1 inhibitor being studied for the prevention and treatment of thrombosis. In November 2009, Merck announced completion of patient enrollment of more than 26,000 patients in the TRA 2°P-TIMI 50 clinical trial, a Phase III, randomized, double-blind, placebo-controlled, multinational study. The trial will assess the ability of SCH 530348 to prevent major cardiovascular events when added to current antiplatelet regimens (aspirin or aspirin plus an ADP inhibitor) in patients who have previously experienced a heart attack or stroke or who have peripheral arterial disease. SCH 530348 is also being studied in the treatment of patients with acute coronary syndrome in the ongoing Phase III Thrombin Receptor Antagonist for Clinical Event Reduction in Acute Coronary Syndrome trial, led by the Duke Clinical Research Institute. The Company anticipates filing an NDA for vorapaxar with the FDA in 2011.

MK-2452, tafluprost, is a preservative free, synthetic analogue of the prostaglandin F₂ for the reduction of elevated intraocular pressure in appropriate patients with primary open-angle glaucoma and ocular hypertension. In April 2009, Old Merck and Santen announced a worldwide licensing agreement for tafluprost (see below).

As previously disclosed, Old Merck submitted for filing an NDA with the FDA for MK-0653C, ezetimibe combined with atorvastatin, which is an investigational medication for the treatment of dyslipidemia, and the FDA refused to file the application. The FDA has identified additional manufacturing and stability data that are needed and the Company is assessing the FDA's response and anticipates filing in 2011.

MK-0431C, a candidate currently in Phase III clinical development, combines *Januvia* with pioglitazone, another type 2 diabetes therapy. The Company continues to anticipate filing an NDA for MK-0431C with the FDA in 2011.

MK-0822, odanacatib, is an oral, once-weekly investigational treatment for osteoporosis. Osteoporosis is a disease which 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 September 2009, data from a Phase IIB clinical study of odanacatib were presented at the 31st Annual Meeting of the American Society for Bone and Mineral Research which showed that when stopping treatment after two years the increases in lower back (lumbar spine) bone mineral density (BMD) were reversed over the next year, while BMD at the hip (femoral neck) remained above levels observed at the start of the study. Additionally, three years of treatment with odanacatib 50 mg demonstrated increases in BMD at key fracture sites and minimal impact on the formation of new bone as measured by biochemical markers of bone turnover. Odanacatib is currently in Phase III clinical trials and is being evaluated in a large-scale, global outcomes study to determine its effects on vertebral, hip and non-vertebral fractures. The

Company continues to anticipate filing an NDA with the FDA in 2012.

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

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MK-0524A is a drug candidate that combines extended-release (ER) niacin and a novel flushing inhibitor, laropiprant. MK-0524A has demonstrated the ability to lower LDL-cholesterol (LDL-C or bad cholesterol), raise HDL-cholesterol (HDL-C or good cholesterol) and lower triglycerides with significantly less flushing than traditional extended release niacin alone. High LDL-C, low HDL-C and elevated triglycerides are risk factors associated with heart attacks and strokes. In April 2008, Old Merck received a non-approvable action letter from the FDA in response to its NDA for MK-0524A. At a meeting to discuss the letter, the FDA stated that additional efficacy and safety data were required and suggested that Old Merck wait for the results of the Treatment of HDL to Reduce the Incidence of Vascular Events (HPS2-THRIVE) cardiovascular outcomes study, which is expected to be completed in 2012. The Company anticipates filing an NDA with the FDA for MK-0524A in 2012. MK-0524A has been approved in more than 45 countries outside the United States for the treatment of dyslipidemia, particularly in patients with combined mixed dyslipidemia (characterized by elevated levels of LDL-C and triglycerides and low HDL-C) and in patients with primary hypercholesterolemia (heterozygous familial and non-familial) and is marketed as *Tredaptive* (or as *Cordaptive* in certain countries). *Tredaptive* should be used in patients in combination with statins, when the cholesterol lowering effects of statin monotherapy is inadequate. *Tredaptive* can be used as monotherapy only in patients in whom statins are considered inappropriate or not tolerated.

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

MK-0859, anacetrapib, is an inhibitor of the cholesteryl ester transfer protein that has shown promise in lipid management by raising HDL-C and reducing LDL-C without raising blood pressure. In November 2009, Merck announced that in a Phase IIb study in 589 patients with primary hypercholesterolemia or mixed hyperlipidemia treated with anacetrapib as monotherapy or co-administered with atorvastatin, there were persistent lipid effects in the higher dose arms in both the monotherapy and co-administration treatment groups eight weeks after stopping active therapy with anacetrapib. The effect of CETP inhibition on cardiovascular risk has yet to be established. A Phase III trial, titled DEFINE, is ongoing to further evaluate the safety and efficacy of anacetrapib in patients with coronary heart disease. The Company anticipates filing an NDA with the FDA beyond 2015.

As previously disclosed, in 2009, Old Merck announced it was delaying the filing of the U.S. application for telcagepant (MK-0974), the Company's investigational calcitonin gene-related peptide (CGRP)-receptor antagonist for the intermittent treatment of acute migraine. The decision was based on findings from a Phase IIa exploratory study in which a small number of patients taking telcagepant twice daily for three months for the prevention of migraine were found to have marked elevations in liver transaminases. The daily dosing regimen in the prevention study was different than the dosing regimen used in Phase III studies in which telcagepant was intermittently administered in one or two doses to treat individual migraine attacks as they occurred. Other studies with telcagepant for the acute, intermittent treatment of migraine continue. Following meetings with regulatory agencies at the end of 2009, Merck is planning to conduct an additional safety study as part of the overall Phase III program for telcagepant. The results of this study will inform planned filings for approval.

SCH 900395, acadesine, is a potential first-in class adenosine regulating agent for ischemia reperfusion-injury in patients undergoing heart bypass surgery. Patient enrollment in the RED CABG Phase III clinical trial was initiated in 2009.

SCH 417690, vicriviroc, for the treatment of HIV infection (treatment experienced) was evaluated in two Phase III studies in this patient population, and it was announced in January 2010 that the primary efficacy endpoint was not met. Merck will not submit an NDA to the FDA for vicriviroc in treatment-experienced HIV-infected patients at this time but will continue to evaluate vicriviroc as first-line therapy for treatment-naïve patients.

As previously disclosed, in 2007, Cubist Pharmaceuticals, Inc. (Cubist) entered into a license agreement with Old Merck for the development and commercialization of Cubicin (daptomycin for injection, MK3009) in Japan. Merck will develop and commercialize Cubicin through its wholly-owned subsidiary, Banyu Pharmaceutical Co., Ltd. Cubist commercializes Cubicin in the United States. MK-3009 is currently in Phase III development.

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MK-4305 is an orexin receptor antagonist, a potential new approach to the treatment of chronic insomnia, currently in Phase III development.

SCH 900962, *Elonva*, corifollitropin alpha injection, which has been approved in the EC for controlled ovarian stimulation in combination with a GnRH antagonist for the development of multiple follicles in women participating in an assisted reproductive technology program, is currently in Phase III development in the United States.

Merck has terminated the internal clinical development program for esmirtazapine (SCH 900265) for hot flashes and insomnia for strategic reasons.

As previously disclosed, in 2009, Old Merck announced that preliminary results for the pivotal Phase III study of rolofylline (MK-7418), its investigational medicine for the treatment of acute heart failure, showed that rolofylline did not meet the primary or secondary efficacy endpoints. Old Merck terminated the clinical development program for rolofylline.

In-Process Research and Development

In connection with the Merger, the Company recorded the fair value of human and animal health research projects underway at Schering-Plough. Approximately \$5.0 billion of the consideration transferred in the Merger was allocated to Pharmaceutical segment IPR&D projects and \$1.3 billion was allocated to Animal Health operating segment IPR&D projects.

Some of the more significant projects include *Bridion*, vorapaxar and boceprevir, all of which are in Phase III clinical development, as well as an ezetimibe/atorvastatin combination product. These projects are discussed in further detail above. Also, as noted above, the Company expects to file NDAs with the FDA in 2010 for boceprevir and in 2011 for vorapaxar and the ezetimibe/atorvastatin combination product.

The fair values of identifiable intangible assets related to IPR&D were determined by 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 discount rates which range from 12% to 15%. Actual cash flows are likely to be different than those assumed.

Additional research and development will be required before any of the 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, 2009, the estimated costs to complete projects in Phase III development for human health and the analogous stage of development for animal health were approximately \$1.6 billion. All of the IPR&D projects 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, will 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 as a result of the Company's portfolio prioritization process or otherwise, then the Company will not realize the future cash flows it has estimated and recorded as IPR&D on the Merger date, and the Company may also not recover the research and development expenditures made since the Merger to further develop that program. If such circumstances were to occur, the Company's future operating results could be adversely affected.

Acquisitions, Research Collaborations and License Agreements

Merck continues to remain focused on augmenting its internal efforts by capitalizing on growth opportunities that will drive both near- and long-term growth. During 2009, transactions across a broad range of therapeutic categories, as well as early stage technology transactions were completed. Merck is actively

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monitoring the landscape for growth opportunities that meet the Company's strategic criteria. Highlights from these activities include:

In December 2009, Merck and Avecia Investments Limited announced a definitive agreement under which Merck would acquire the biologics business of the Avecia group for a total purchase price of \$180 million. Avecia Biologics is a contract manufacturing organization with specific expertise in microbial-derived biologics. Under the terms of the agreement, Merck would acquire Avecia Biologics Limited (Avecia) and all of its assets, including all Avecia's process development and scale-up, manufacturing, quality and business support operations located in Billingham, United Kingdom. This transaction closed on February 1, 2010, and accordingly, the results of operations of the acquired business will be included in Merck's results of operations beginning as of the acquisition date.

In July 2009, Old Merck and Portola Pharmaceuticals, Inc. (Portola) signed an exclusive global collaboration and license agreement for the development and commercialization of betrixaban (MK-4448), an investigational oral Factor Xa inhibitor anticoagulant currently in Phase II clinical development for the prevention of stroke in patients with atrial fibrillation. In return for an exclusive worldwide license to betrixaban, Old Merck paid Portola an initial fee of \$50 million at closing, which was recorded as research and development expense. Portola is eligible to receive additional cash payments totaling up to \$420 million upon achievement of certain development, regulatory and commercialization milestones, as well as double-digit royalties on worldwide sales of betrixaban, if approved. The Company will assume all development and commercialization costs, including the costs of Phase III clinical trials. Portola retained an option (a) to co-fund Phase III clinical trials in return for additional royalties and (b) to co-promote betrixaban with Merck in the United States. The term of the agreement commenced in August 2009 and, unless terminated earlier, will continue until there are no remaining royalty payment obligations in a country, at which time the agreement will expire in its entirety in such country. The agreement may be terminated by either party in the event of a material uncured breach or bankruptcy of a party. The agreement may be terminated by Merck in the event that the parties or Merck decide to cease development of betrixaban for safety or efficacy. In addition, Merck may terminate the agreement at any time upon 180 days prior written notice. Portola may terminate the agreement in the event that Merck challenges any Portola patent covering betrixaban. 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 betrixaban and, in the case of termination for cause by Merck, certain royalty obligations.

In April 2009, Old Merck, Medarex, Inc. (Medarex) and Massachusetts Biologic Laboratories (MBL) of the University of Massachusetts Medical School announced an exclusive worldwide license agreement for CDA-1 and CDB-1 (MK-3415A) (also known as MDX-066/MDX-1388 and MBL-CDA1/MBL-CDB1), an investigational fully human monoclonal antibody combination developed to target and neutralize *Clostridium difficile* toxins A and B, for the treatment of *C. difficile* infection. CDA-1 and CDB-1 were co-developed by Medarex and MBL. Under the terms of the agreement, Merck gained worldwide rights to develop and commercialize CDA-1 and CDB-1. Medarex and MBL received an aggregate upfront payment of \$60 million upon closing, which was recorded as research and development expense, and are potentially eligible to receive additional cash payments up to \$165 million in the aggregate upon achievement of certain milestones associated with the development and approval of a drug candidate covered by this agreement. Upon commercialization, Medarex and MBL will also be eligible to receive double-digit royalties on product sales and milestones if certain sales targets are met. The term of the agreement commenced on the closing date and, unless terminated earlier, will continue until there are no remaining royalty payment obligations in a country, at which time the agreement will expire in its entirety in such country. Either party may terminate this agreement for uncured material breach by the other party, or bankruptcy or insolvency of the other party. Merck may terminate this agreement at any time upon providing 180 days prior written notice to Medarex and MBL.

Also, in April 2009, Old Merck and Santen Pharmaceutical Co., Ltd. (Santen) announced a worldwide licensing agreement for tafluprost (MK-2452), a prostaglandin analogue under investigation in the United States. Tafluprost, preserved and preservative-free formulations, has received marketing approval for the reduction of elevated

intraocular pressure in open-angle glaucoma and ocular hypertension in several European and Nordic countries as well as Japan and has been filed for approval in additional European and Asia Pacific markets. Under the terms of the agreement, Old Merck paid a fee, which was capitalized and will be amortized to *Materials and*

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production costs over the life of the underlying patent, and will pay milestones and royalty payments based on future sales of tafluprost (both preserved and preservative-free formulations) in exchange for exclusive commercial rights to tafluprost in Western Europe (excluding Germany), North America, South America and Africa. Santen will retain commercial rights to tafluprost in most countries in Eastern Europe, Northern Europe and Asia Pacific, including Japan. Merck will provide promotion support to Santen in Germany and Poland. If tafluprost is approved in the United States, Santen has an option to co-promote it there. The agreement between Old Merck and Santen expires on a country-by-country basis on the last to occur of (a) the expiry of the last to expire valid patent claim; or (b) the expiration of the last to expire royalty. Merck may terminate the agreement at any time upon 90 days prior written notice and also at any time upon 60 days prior written notice if Merck determines that the product presents issues of safety or tolerability. In addition, Merck may terminate the agreement in the event that any of the enumerated agreements between Santen and the co-owner/licensor of certain intellectual property terminate or expire and this materially adversely affects Merck. If either Merck or Santen materially breaches the agreement and fails to cure after receiving notice, then the non-breaching party may terminate the agreement. The agreement provides for termination by the non-insolvent party due to bankruptcy by the other party. Finally, the agreement will terminate if, during the term, Merck develops or commercializes a competitive product (as that term is defined in the agreement).

In addition, in April 2009, Old Merck and Cardiome Pharma Corp. (Cardiome) announced a collaboration and license agreement for the development and commercialization of vernakalant (MK-6621), an investigational candidate for the treatment of atrial fibrillation. The agreement provides Merck with exclusive global rights to the oral formulation of vernakalant (vernakalant (oral)) for the maintenance of normal heart rhythm in patients with atrial fibrillation, and provides a Merck affiliate, Merck Sharp & Dohme (Switzerland) GmbH, with exclusive rights outside of the United States, Canada and Mexico to the intravenous (IV) formulation of vernakalant (vernakalant (IV)) for rapid conversion of acute atrial fibrillation to normal heart rhythm. Under the terms of the agreement, Old Merck paid Cardiome an initial fee of \$60 million upon closing, which was recorded as research and development expense. In addition, Cardiome is eligible to receive up to \$200 million in payments based on achievement of certain milestones associated with the development and approval of vernakalant products (including \$15 million for submission for regulatory approval in Europe of vernakalant (IV), which Old Merck paid in 2009 as a result of that submission, and \$20 million for initiation of a planned Phase III program for vernakalant (oral)) and up to \$100 million for milestones associated with approvals in other subsequent indications of both the intravenous and oral formulations. Also, Cardiome will receive tiered royalty payments on sales of any approved products and has the potential to receive up to \$340 million in milestone payments based on achievement of significant sales thresholds. Cardiome has retained an option to co-promote vernakalant (oral) with Merck through a hospital-based sales force in the United States. Merck will be responsible for all future costs associated with the development, manufacturing and commercialization of these candidates. Merck has granted Cardiome a secured, interest-bearing credit facility of up to \$100 million that Cardiome may access in tranches over several years commencing in 2010. Cardiome's co-development partner in North America, Astellas Pharma U.S., Inc., submitted an NDA with the FDA for Kynapid (vernakalant hydrochloride) Injection in December 2006 that included results from two pivotal Phase III clinical trials. In December 2007, the Cardiovascular and Renal Drugs Advisory Committee recommended that the FDA approve vernakalant (IV) for rapid conversion of atrial fibrillation. In August 2008, the FDA issued an Approvable action letter requesting additional information. A Phase IIb double-blind, placebo-controlled, randomized, dose-ranging clinical trial in patients at risk of recurrent atrial fibrillation showed that, at the 500 mg dose, vernakalant (oral) significantly reduced the rate of atrial fibrillation relapse as compared to placebo. This agreement continues in effect until the expiration of Cardiome's co-promotion rights and all royalty and milestone payment obligations. This agreement may be terminated in the event of insolvency or a material uncured breach by either party. Additionally, the collaboration may be terminated by Merck in the event that Merck determines (in good faith) that it is not advisable to continue the development or commercialization of a vernakalant product as a result of a serious safety issue. In addition, Merck may terminate the agreement at any time upon 12 months prior written notice. Cardiome may terminate the agreement in the event that Merck challenges any Cardiome patent covering vernakalant. 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

vernakalant and in some cases continuing royalty obligations.

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In March 2009, Old Merck acquired Inmed Inc.'s (Inmed) portfolio of follow-on biologic therapeutic candidates and its commercial manufacturing facilities located in Boulder, Colorado. Under the terms of the agreement, Old Merck paid Inmed an aggregate of \$130 million in cash to acquire all rights to the Boulder facilities and Inmed's pipeline of follow-on biologic candidates. Inmed's follow-on biologics portfolio includes two clinical candidates: MK-4214, an investigational recombinant granulocyte-colony stimulating factor (G-CSF) that will be evaluated for its ability to prevent infections in patients with cancer receiving chemotherapy, and MK-6302, a pegylated recombinant G-CSF designed to allow for less frequent dosing. The transaction was accounted for as a business combination; 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 Inmed's follow-on biologics portfolio (MK-4214 and MK-6302) and an indefinite-lived intangible asset was recorded. The fair value was determined based upon the present value of expected future cash flows of new product candidates resulting from Inmed's follow-on biologics portfolio adjusted for the probability of their estimated technical and marketing success utilizing an income approach reflecting appropriate risk-adjusted discount rates. The ongoing activity related to MK-4214 and MK-6302 is not expected to be material to the Company's research and development expense. The remaining net assets acquired were not material and there were no other milestone or royalty obligations associated with the acquisition. This transaction closed on March 31, 2009, and accordingly, the results of operations of the acquired business have been included in Merck's results of operations beginning April 1, 2009.

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 new 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 and RNAi. Further, Merck moved to diversify its portfolio by creating a new division, Merck BioVentures, which has the potential to harness the market opportunity presented by biological medicine patent expiries by delivering high quality follow-on biologic products to enhance access for patients worldwide. The Company will continue to pursue appropriate external licensing opportunities.

The integration plans for research and development are focused on integrating the research operations of the legacy companies, including providing an effective transition for employees, realizing projected merger synergies in the form of cost savings and revenue growth opportunities, and maintaining momentum in the Company's late-stage pipeline. During 2009, Merck continued implementing a new model for its basic research global operating strategy at legacy Merck Research Laboratories sites. The new model will align franchise and function as well as align resources with disease area priorities and balance capacity across discovery phases and allow the Company to act upon those programs with the highest probability of success. Additionally, across all disease area priorities, the Company's strategy is designed to expand access to worldwide external science and incorporate external research as a key component of the Company's early discovery pipeline in order to translate basic research productivity into late-stage clinical success.

The Company's clinical pipeline includes candidates in multiple disease areas, including anemia, atherosclerosis, cancer, diabetes, heart disease, hypertension, infectious diseases, inflammatory/autoimmune diseases, migraine, neurodegenerative diseases, ophthalmics, osteoporosis, psychiatric diseases, respiratory disease and women's health. The Company supplements its internal research with an aggressive licensing and external alliance strategy focused on the entire spectrum of collaborations from early research to late-stage compounds, as well as new technologies.

Table of Contents**Selected Joint Venture and Affiliate Information**

To expand its research base and realize synergies from combining capabilities, opportunities and assets, in previous years Old Merck formed a number of joint ventures. (See Note 10 to the consolidated financial statements.)

Merck/Schering-Plough Partnership

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

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

As a result of the Merger, the MSP Partnership is now owned 100% by the Company. The results of the MSP Partnership through the date of the Merger are reflected in *Equity income from affiliates*. The results from sales of MSP Partnership products after the Merger have been consolidated with Merck's results.

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

(\$ in millions)	2009		Total	2008	2007
	Pre-Merger	Post-Merger			
Vytorin	\$ 1,689.5	\$ 370.6	\$ 2,060.1	\$ 2,360.0	\$ 2,779.1
Zetia	1,697.7	370.3	2,068.0	2,201.1	2,407.1
	\$ 3,387.2	\$ 740.9	\$ 4,128.1	\$ 4,561.1	\$ 5,186.2

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

Following the previously announced ENHANCE and SEAS clinical trial results (discussed below), sales of *Vytorin* and *Zetia* declined in 2009 and 2008.

As previously disclosed, in January 2008, the legacy companies announced the results of the Effect of Combination Ezetimibe and High-Dose Simvastatin vs. Simvastatin Alone on the Atherosclerotic Process in Patients with Heterozygous Familial Hypercholesterolemia (ENHANCE) clinical trial, an imaging trial in 720 patients with heterozygous familial hypercholesterolemia, a rare genetic condition that causes very high levels of LDL bad cholesterol and greatly increases the risk for premature coronary artery disease. As previously reported, despite the fact that ezetimibe/simvastatin 10/80 mg (*Vytorin*) significantly lowered LDL bad cholesterol more than simvastatin 80 mg alone, there was no significant difference between treatment with ezetimibe/simvastatin and simvastatin alone on the pre-specified primary endpoint, a change in the thickness of carotid artery walls over two years as measured by ultrasound. The Improved Reduction in High-Risk Subjects Presenting with Acute Coronary Syndrome (IMPROVE-IT) trial is underway and is designed to provide cardiovascular outcomes data for ezetimibe/simvastatin in patients with acute coronary syndrome. No incremental benefit of ezetimibe/

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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.

On July 21, 2008, efficacy and safety results from the Simvastatin and Ezetimibe in Aortic Stenosis (SEAS) study were announced. SEAS was designed to evaluate whether intensive lipid lowering with *Vytorin* 10/40 mg would reduce the need for aortic valve replacement and the risk of cardiovascular morbidity and mortality versus placebo in patients with asymptomatic mild to moderate aortic stenosis who had no indication for statin therapy. *Vytorin* failed to meet its primary end point for the reduction of major cardiovascular events. In the study, patients in the group who took *Vytorin* 10/40 mg had a higher incidence of cancer than the group who took placebo. There was also a nonsignificant increase in deaths from cancer in patients in the group who took *Vytorin* versus those who took placebo. Cancer and cancer deaths were distributed across all major organ systems. The Company believes the cancer finding in SEAS is likely to be an anomaly that, taken in light of all the available data, does not support an association with *Vytorin*. In August 2008, the FDA announced that it was investigating the results from the SEAS trial. In December 2009, the FDA announced that it had completed its review of the data from the SEAS trial as well as a review of interim data from the Study of Heart and Renal Protection (SHARP) and IMPROVE-IT trials. Based on currently available information, the FDA indicated it believed it is unlikely that *Vytorin* or *Zetia* increase the risk of cancer-related death. The SHARP trial is expected to be completed in 2010. The IMPROVE-IT trial is scheduled for completion in 2013. In the IMPROVE-IT trial, a blinded interim efficacy analysis will be conducted by the Data Safety Monitoring Board for the trial when approximately 50% of the endpoints have been accrued. That interim analysis is expected to be conducted in 2010.

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

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

The results from Old Merck's interest in the MSP Partnership through the completion of the Merger are recorded in *Equity income from affiliates*. Equity income was \$1.2 billion in 2009, \$1.5 billion in 2008 and \$1.8 billion in 2007.

The financial statements of the MSP Partnership for 2008 are included in Item 15. (a) (2) Financial Statement Schedules below.

AstraZeneca LP

In 1982, Old Merck entered into an agreement with Astra AB (Astra) to develop and market Astra's products under a royalty-bearing license. In 1993, Old 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 Old 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, Old Merck and Astra completed the restructuring of the ownership and operations of the joint venture whereby Old 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 (the AstraZeneca merger), became the exclusive distributor of the products for which KBI retained rights.

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While maintaining a 1% limited partner interest in AZLP, Merck has consent and protective rights intended to preserve its business and economic interests, including restrictions on the power of the general partner to make certain distributions or dispositions. Furthermore, in limited events of default, additional rights will be granted to the Company, including powers to direct the actions of, or remove and replace, the Partnership's chief executive officer and chief financial officer. Merck earns ongoing revenue based on sales of current and future KBI products and such revenue was \$1.4 billion, \$1.6 billion and \$1.7 billion in 2009, 2008 and 2007, 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, variable returns based, in part, upon sales of certain former Astra USA, Inc. products, and a preferential return representing Merck's share of undistributed AZLP GAAP earnings. These returns aggregated \$674.3 million, \$598.4 million and \$820.1 million in 2009, 2008 and 2007, respectively. The AstraZeneca merger triggered a partial redemption in March 2008 of Old Merck's interest in certain AZLP product rights. Upon this redemption, Old Merck received \$4.3 billion from AZLP. This amount was based primarily on a multiple of Old Merck's average annual variable returns derived from sales of the former Astra USA, Inc. products for the three years prior to the redemption (the Limited Partner Share of Agreed Value). A pretax gain of \$1.5 billion on the partial redemption was recorded in 2008. The partial redemption of Old Merck's interest in the product rights did not result in a change in Old Merck's 1% limited partnership interest.

In conjunction with the 1998 restructuring, Astra purchased an option (the Asset Option) for a payment of \$443.0 million, which was recorded as deferred income, to buy Old Merck's interest in the KBI products, excluding the gastrointestinal medicines *Nexium* and *Prilosec* (the Non-PPI Products). AstraZeneca can exercise the Asset Option in the first half of 2010 at an exercise price of \$647 million which represents the net present value as of March 31, 2008 of projected future pretax revenue to be received by Old Merck from the Non-PPI Products (the Appraised Value). On February 26, 2010, AstraZeneca notified the Company that it was exercising the Asset Option. Old Merck also had the right to require Astra to purchase such interest in 2008 at the Appraised Value. In February 2008, Old Merck advised AstraZeneca that it would not exercise the Asset Option, thus the \$443.0 million remains deferred but will be recognized when the Asset Option is consummated. In addition, in 1998, Old Merck granted Astra an option (the Shares Option) to buy Old Merck's common stock interest in KBI and, therefore, Old Merck's interest in *Nexium* and *Prilosec*, exercisable two years after Astra's exercise of the Asset Option. Astra can also exercise the Shares Option in 2017 or if combined annual sales of the two products fall below a minimum amount provided, in each case, only so long as AstraZeneca's Asset Option has been exercised in 2010. The exercise price for the Shares Option is based on the net present value of estimated future net sales of *Nexium* and *Prilosec* as determined at the time of exercise, subject to certain true-up mechanisms.

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

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

interest through the redemption date was settled. As a result of these transactions, Old Merck received net proceeds from AZLP of \$2.6 billion in 2008.

Table of Contents*Merial Limited*

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

On September 17, 2009, Old Merck sold its 50% interest in Merial to sanofi-aventis for \$4 billion in cash. The sale resulted in the recognition of a \$3.2 billion gain reflected in *Other income (expense), net* in 2009.

Also, in connection with the sale of Merial, Old Merck, sanofi-aventis and Schering-Plough signed a call option agreement. Under the terms of the call option agreement, following the closing of the Merger, sanofi-aventis has an option to require the Company to combine its Intervet/Schering-Plough Animal Health business with Merial to form an animal health joint venture that would be owned equally by the Company and sanofi-aventis. As part of the call option agreement, the value of Merial has been fixed at \$8 billion. The minimum total value received by the Company and its affiliates for contributing Intervet/Schering-Plough to the combined entity would be \$9.25 billion (subject to customary transaction adjustments), consisting of a floor valuation of Intervet/Schering-Plough which is fixed at a minimum of \$8.5 billion (subject to potential upward revision based on a valuation exercise by the two parties) and an additional payment by sanofi-aventis of \$750 million. Based on the valuation exercise of Intervet/Schering-Plough and the customary transaction adjustments, if Merial and Intervet/Schering-Plough are combined, a payment may be required to be paid by either party to make the joint venture equally owned by the Company and sanofi-aventis. This payment would true-up the value of the contributions so that they are equal. Any formation of a new animal health joint venture with sanofi-aventis is subject to customary closing conditions including antitrust review in the United States and Europe. Prior to the closing of the Merger, the agreements provided Old Merck with certain rights to terminate the call option for a fee of \$400 million. The recognition of the termination fee was deferred until the fourth quarter of 2009 when the conditions that could have triggered its payment lapsed.

Sales of joint venture products were as follows:

<i>(\$ in millions)</i>	2009⁽¹⁾	2008	2007
Fipronil products	\$ 783.9	\$ 1,053.0	\$ 1,033.3
Biological products	524.5	789.7	674.9
Avermectin products	341.4	511.8	478.4
Other products	199.7	288.2	262.2
	\$ 1,849.5	\$ 2,642.7	\$ 2,448.8

⁽¹⁾Amounts for 2009 include sales until the September 17, 2009 divestiture date.

Sanofi Pasteur MSD

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

Sales of joint venture products were as follows:

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<i>(\$ in millions)</i>	2009	2008	2007
Gardasil	\$ 549.2	\$ 865.3	\$ 476.0
Influenza vaccines	249.4	229.9	232.5
Other viral vaccines	112.1	105.1	86.8
Hepatitis vaccines	44.2	72.6	72.9
RotaTeq	42.2	28.4	15.7
Other vaccines	591.5	583.5	554.1
	\$ 1,588.6	\$ 1,884.8	\$ 1,438.0

Table of Contents*Johnson & Johnson^oMerck Consumer Pharmaceuticals Company*

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

Sales of joint venture products were as follows:

(\$ in millions)	2009	2008	2007
Gastrointestinal products	\$ 202.0	\$ 210.7	\$ 218.5
Other products	1.2	1.4	1.2
	\$ 203.2	\$ 212.1	\$ 219.7

Capital Expenditures

Capital expenditures were \$1.5 billion in 2009, \$1.3 billion in 2008 and \$1.0 billion in 2007. Expenditures in the United States were \$981.6 million in 2009, \$946.6 million in 2008 and \$788.0 million in 2007. Expenditures during 2009 included \$801.5 million for production facilities, \$161.2 million for research and development facilities, \$33.6 million for environmental projects, and \$464.3 million for administrative, safety and general site projects, of which approximately 25% represents capital investments related to a multi-year initiative to standardize the Company's information systems.

Depreciation expense was \$1.7 billion in 2009, \$1.4 billion in 2008 and \$1.8 billion in 2007 of which \$1.0 billion, \$1.0 billion and \$1.4 billion, respectively, applied to locations in the United States. Total depreciation expense in 2009, 2008 and 2007 included accelerated depreciation of \$348.6 million, \$216.7 million and \$460.6 million, respectively, associated with restructuring activities (see Note 4 to the consolidated financial statements).

Analysis of Liquidity and Capital Resources

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

Selected Data

(\$ in millions)	2009	2008	2007
Working capital	\$ 12,677.9	\$ 4,793.9	\$ 2,787.2
Total debt to total liabilities and equity	15.6%	13.2%	11.9%
Cash provided by operations to total debt	0.2:1	1.1:1	1.2:1

The \$18 billion cash portion of the consideration for the Merger was funded with a combination of existing cash, including the proceeds from the sale of Old Merck's interest in Merial discussed above, the sale or redemption of short-term investments and the issuance of debt. In preparation for the Merger, during 2009, Old Merck closed an underwritten public offering of \$4.25 billion senior unsecured notes as discussed below. Additionally, a significant portion of the long-term investments as of December 31, 2008 were liquidated in anticipation of the Merger.

Cash provided by operating activities, which was \$3.4 billion in 2009, \$6.6 billion in 2008 and \$7.0 billion in 2007, continues to be the Company's primary source of funds to finance operating needs, capital expenditures, treasury stock purchases and dividends paid to shareholders. Cash provided by operating activities in 2009 reflects \$4.1 billion of payments into the *Vioxx* settlement funds and a \$660 million payment made in connection with the previously disclosed settlement with the CRA. Cash provided by operating activities in 2008 reflects \$2.1 billion received in connection with a partial redemption of Old Merck's partnership interest in AZLP, representing a

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distribution of Old Merck's accumulated earnings on its investment in AZLP since inception. Cash provided by operating activities in 2008 was also affected by a \$675 million payment made in connection with the previously disclosed resolution of investigations of civil claims by federal and state authorities relating to certain past marketing and selling activities and \$750 million of payments into the *Vioxx* settlement funds. Cash provided by operating activities for 2007 reflects the payment made under a previously disclosed settlement with the Internal Revenue Service (IRS).

Cash provided by investing activities was \$3.2 billion in 2009 compared with cash used by investing activities of \$1.8 billion in 2008. The change was primarily driven by the release of restricted cash primarily due to the release of pledged collateral for certain *Vioxx*-related matters, lower purchases of securities and other investments and proceeds from the 2009 disposition of Old Merck's interest in Merial. These increases in cash used by investing activities were partially offset by the use of cash to fund the Merger, as well as by a 2008 distribution from AZLP representing a return of Old Merck's investment in AZLP. Cash used by investing activities in 2008 was \$1.8 billion compared with \$2.8 billion in 2007. The lower use of cash by investing activities primarily reflects a distribution from AZLP in 2008 and a \$1.1 billion payment in 2007 in connection with the December 2006 acquisition of Sirna Therapeutics, Inc., partially offset by higher net purchases of securities and other investments, higher capital expenditures and an increase in restricted assets.

Cash used by financing activities was \$1.6 billion in 2009 compared with \$5.5 billion in 2008 reflecting the 2009 issuance of \$4.25 billion senior unsecured notes, no purchases of treasury stock and lower payments on debt, partially offset by a net decrease in short-term borrowings. Cash used in financing activities was \$5.5 billion in 2008 compared with \$4.9 billion in 2007 reflecting higher purchases of treasury stock, lower proceeds from the exercise stock options and higher payments on debt in connection with the settlement of a note due to Astra, partially offset by a net increase in short-term borrowings. Dividends paid to stockholders were \$3.2 billion in 2009 and \$3.3 billion in 2008 and 2007.

At December 31, 2009, the total of worldwide cash and investments was \$10.0 billion, including \$9.6 billion of cash, cash equivalents and short-term investments, and \$432.3 million of long-term investments. In addition, the Company has \$290 million of cash and investments restricted under certain collateral arrangements as discussed below. Working capital levels are more than adequate to meet the operating requirements of the Company.

In August 2008, Old Merck executed a \$4.1 billion letter of credit agreement with a financial institution, which satisfied certain conditions set forth in the U.S. *Vioxx* Settlement Agreement (see Note 12 to the consolidated financial statements). Old Merck pledged collateral to the financial institution of approximately \$5.1 billion pursuant to the terms of the letter of credit agreement. Although the amount of assets pledged as collateral was set by the letter of credit agreement and such assets are held in custody by a third party, the assets were managed by Old Merck. Old Merck considered the assets pledged under the letter of credit agreement to be restricted. The letter of credit amount and required collateral balances declined as payments (after the first \$750 million) under the Settlement Agreement were made. As of December 31, 2008, \$3.8 billion was recorded within *Deferred income taxes and other current assets* and \$1.3 billion was classified as *Other assets*. During 2009, all remaining payments into the *Vioxx* settlement funds were made pursuant to the U.S. *Vioxx* Settlement Agreement. Accordingly, the letter of credit agreement was terminated and the collateral was released.

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

amounts had been previously accrued for.

As previously disclosed, in October 2006, the CRA issued Old Merck a notice of reassessment containing adjustments related to certain intercompany pricing matters. In February 2009, Old Merck and the CRA negotiated a settlement agreement in regard to these matters. In accordance with the settlement, Old Merck paid an additional tax of approximately \$300 million (U.S. dollars) and interest of approximately \$360 million (U.S. dollars) with no

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additional amounts or penalties due on this assessment. The settlement was accounted for in the first quarter of 2009. Old Merck had previously established reserves for these matters. A significant portion of the taxes paid is expected to be creditable for U.S. tax purposes. The resolution of these matters did not have a material effect on financial position or liquidity, other than with respect to the associated collateral as discussed below.

In addition, in July 2007 and November 2008, the CRA proposed additional adjustments for 1999 and 2000, respectively, relating to other intercompany pricing matters. The adjustments would increase Canadian tax due by approximately \$312 million (U.S. dollars) plus \$314 million (U.S. dollars) of interest through December 31, 2009. It is possible that the CRA will propose similar adjustments for later years. The Company disagrees with the positions taken by the CRA and believes they are without merit. The Company intends to contest the assessments through the CRA appeals process and the courts if necessary. Management believes that resolution of these matters will not have a material effect on the Company's financial position or liquidity.

In connection with the appeals process for the matters discussed above, during 2007, Old Merck pledged collateral to two financial institutions, one of which provided a guarantee to the CRA and the other to the Quebec Ministry of Revenue representing a portion of the tax and interest assessed. As a result of the settlement noted above, guarantees required to appeal the disputes were reduced or eliminated and approximately \$960 million of associated collateral was released. Certain of the cash and investments continue to be collateralized for guarantees required to appeal other Canadian tax disputes. The collateral is included in *Deferred income taxes and other current assets* and *Other assets* in the Consolidated Balance Sheet and totaled approximately \$290 million and \$1.2 billion at December 31, 2009 and 2008, respectively.

The IRS is examining Old Merck's 2002 to 2005 federal income tax returns. 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 1999 through 2009.

During the second quarter of 2007, the IRS completed its examination of Schering-Plough's 1997-2002 federal income tax returns. The Company is seeking resolution of an issue raised during this examination through the IRS administrative appeals process. In July 2007, Schering-Plough made a payment of \$98 million to the IRS pertaining to the 1997-2002 examination. The Company's income tax returns remain open with the IRS for the 1997-2009 tax years. During 2008, the IRS commenced its examination of the 2003-2006 federal income tax returns. This examination is expected to be completed in 2010. 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 2002 through 2009.

The Company's contractual obligations as of December 31, 2009 are as follows:

Payments Due by Period

<i>(\$ in millions)</i>	Total	2010	2011 - 2012	2013 -2014	Thereafter
Purchase obligations	\$ 3,734.9	\$ 2,380.8	\$ 730.4	\$ 523.0	\$ 100.7
Loans payable and current portion of long-term debt	1,362.3	1,362.3			
Long-term debt	15,329.1		2,378.5	3,966.5	8,984.1
Interest related to debt obligations	9,665.4	778.3	1,422.1	1,243.3	6,221.7
Unrecognized tax benefits ⁽¹⁾	324.0	324.0			

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Operating leases	944.8	281.6	393.4	195.1	74.7
	\$ 31,360.5	\$ 5,127.0	\$ 4,924.4	\$ 5,927.9	\$ 15,381.2

(1) As of December 31, 2009, the Company's Consolidated Balance Sheet reflects liabilities for unrecognized tax benefits, interest and penalties of \$5.7 billion, including \$324.0 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 2010 can not be made.

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Purchase obligations consist primarily of goods and services that are enforceable and legally binding and include obligations for minimum inventory contracts, research and development and advertising. Amounts reflected for research and development obligations do not include contingent milestone payments. Loans payable and current portion of long-term debt also reflects \$298.2 million of long-dated notes that are subject to repayment at the option of the holders on an annual basis. Required funding obligations for 2010 relating to the Company's pension and other postretirement benefit plans are not expected to be material. However, the Company currently anticipates contributing approximately \$950 million and \$50 million, respectively, to its pension plans and other postretirement benefit plans during 2010.

On June 25, 2009, Old Merck closed an underwritten public offering of \$4.25 billion senior unsecured notes consisting of \$1.25 billion aggregate principal amount of 1.875% notes due 2011, \$1.0 billion aggregate principal amount of 4.00% notes due 2015, \$1.25 billion aggregate principal amount of 5.00% notes due 2019 and \$750 million aggregate principal amount of 5.85% notes due 2039. 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 the redemption prices specified in each notes associated prospectus. Proceeds from the notes were used to fund a portion of the cash consideration of the Merger.

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

Also, in connection with the Merger, on March 8, 2009, Old Merck entered into a financing commitment letter with JPMorgan Chase Bank, N.A. and J.P. Morgan Securities Inc. (collectively JPMorgan), under which JPMorgan committed to provide \$7 billion of financing. On May 6, 2009, Old Merck entered into a \$3 billion 364-day senior unsecured interim term loan facility (the bridge loan facility); a \$3 billion 364-day asset sale revolving credit facility (the asset sale facility); and a \$1 billion 364-day corporate revolving credit facility (the incremental facility). In connection with the above \$4.25 billion offering, the bridge loan facility was terminated and the commitment of the lenders under the 364-day asset sale facility was reduced. Upon completion of the sale of Merial to sanofi-aventis (see Note 10 to the consolidated financial statements), the asset sale facility was terminated. The incremental facility is available to backstop commercial paper and for general corporate purposes. This facility has not been drawn on and will expire in November 2010. Merck has incurred commitment fees of approximately \$150 million associated with these facilities which are being amortized over the commitment period.

In April 2009, Old Merck amended its \$1.5 billion, 5-year revolving credit facility maturing in April 2013 to allow the facility to remain in place after the Merger. The Company's existing \$2.0 billion credit facility maturing in August 2012 remains outstanding. These facilities provide backup liquidity for the Company's commercial paper borrowing facility and are for general corporate purposes. The Company has not drawn funding from either facility.

Also, in connection with the Merger, effective as of November 3, 2009, New Merck executed a full and unconditional guarantee of the then existing debt of Old Merck and Old Merck executed a full and unconditional guarantee of the then existing debt of New Merck (excluding commercial paper), including for payments of principal and interest.

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 positive outlook, respectively. These ratings continue to allow access to the capital markets and flexibility in obtaining funds on competitive terms. The Company continues to maintain a conservative financial profile. The Company places its cash and investments in instruments that meet high credit quality standards, as specified in its investment policy guidelines. These guidelines also limit the amount of credit exposure to any one issuer. Despite this strong financial profile, certain contingent events, if realized, which are discussed in Note 12 to the

consolidated financial statements, could have a material adverse impact on the Company's liquidity and capital resources. The Company does not participate in any off-balance sheet arrangements involving unconsolidated subsidiaries that provide financing or potentially expose the Company to unrecorded financial obligations.

In November 2009 and February 2010, the Board of Directors declared a quarterly dividend of \$0.38 per share on the Company's common stock for the first and second quarter of 2010, respectively, and declared a

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quarterly dividend of \$3.75 per share on the 6% mandatory convertible preferred stock for the first and second quarter of 2010, respectively.

In November 2009, the Board of Directors approved purchases over time of up to \$3.0 billion of Merck's common stock for its treasury. No purchases of treasury stock were made in 2009. Old Merck purchased \$2.7 billion and \$1.4 billion of treasury stock in 2008 and 2007, respectively, under a previous program approved by Old Merck's Board of Directors in July 2002.

Financial Instruments Market Risk Disclosures

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

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

Foreign Currency Risk Management

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

The objective of the revenue hedging program is to reduce the potential for longer-term unfavorable changes in foreign exchange to decrease the U.S. dollar value of future cash flows derived from foreign currency denominated sales, primarily the euro and Japanese yen. To achieve this objective, the Company will partially hedge 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 sales hedged as it gets closer to the expected date of the forecasted foreign currency denominated sales, such that it is probable the hedged transaction will occur. The portion of sales hedged is based on assessments of cost-benefit profiles that consider natural offsetting exposures, revenue and exchange rate volatilities and correlations, and the cost of hedging instruments. The hedged anticipated sales are a specified component of a portfolio of similarly denominated foreign currency-based sales transactions, each of which responds to the hedged 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 cash flows of the hedged foreign currency sales. Conversely, if the U.S. dollar weakens, the options' value reduces to zero, but the Company benefits from the increase in the value of the anticipated foreign currency cash flows. The Company also utilizes 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 c