

Edgar Filing: MERCK & CO INC - Form 10-K405

MERCK & CO INC
Form 10-K405
March 21, 2002

As filed with the Securities and Exchange Commission on March 21, 2002

=====

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D. C. 20549

FORM 10-K

(MARK ONE)

Annual Report Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934
For the Fiscal Year Ended December 31, 2001

or

Transition Report Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934
For the transition period from _____ to _____

Commission File No. 1-3305

MERCK & CO., INC.
One Merck Drive
Whitehouse Station, N. J. 08889-0100
(908) 423-1000

Incorporated in New Jersey

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

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

Title of Each Class	Name of Each Exchange on which Registered
Common Stock (\$0.01 par value)	New York and Philadelphia Stock Exchanges

Number of shares of Common Stock (\$0.01 par value) outstanding as of
February 28, 2002: 2,271,094,459.

Aggregate market value of Common Stock (\$0.01 par value) held by
non-affiliates on December 31, 2001 based on closing price on February 28, 2002:
\$139,327,000,000.

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 [X]. No _____

Indicate by check mark if disclosure of delinquent filers pursuant to Item

Edgar Filing: MERCK & CO INC - Form 10-K405

405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [X]

Documents Incorporated by Reference:

Document	Part of Form 10-K
-----	-----
Annual Report to stockholders for the fiscal year ended December 31, 2001	Parts I and II
Proxy Statement for the Annual Meeting of Stockholders to be held April 23, 2002	Part III

PART I

Item 1. Business.

Merck & Co., Inc. (the "Company") is a global research-driven pharmaceutical company that discovers, develops, manufactures and markets a broad range of human and animal health products, directly and through its joint ventures, and provides pharmaceutical benefit services through Merck-Medco Managed Care, L.L.C. ("Merck-Medco"). The Company's operations are principally managed on a products and services basis and are comprised of two reportable segments: Merck Pharmaceutical, which includes products marketed either directly or through joint ventures, and Merck-Medco. Merck Pharmaceutical products consist of therapeutic and preventive agents, sold by prescription, for the treatment of human disorders. Merck-Medco revenues are derived from the filling and management of prescriptions and health management programs.

The following table shows the sales of various categories of the Company's products and services:

(\$ in millions)	2001	2000	1999
-----	-----	-----	-----
Atherosclerosis	\$ 7,179.6	\$ 5,805.2	\$ 5,093.2
Hypertension/heart failure	4,255.6	4,629.1	4,563.8
Anti-inflammatory/analgesics	2,630.5	2,251.7	578.5
Osteoporosis	1,759.2	1,275.3	1,043.1
Respiratory	1,375.7	862.2	501.8
Vaccines/biologicals	1,022.4	952.0	860.0
Anti-bacterial/anti-fungal	795.4	783.3	772.3
Ophthalmologicals	672.2	656.2	670.0
Human immunodeficiency virus ("HIV")	411.0	528.8	664.4
Anti-ulcerants	354.2	849.4	913.9
Other Merck products	891.2	1,629.7	1,820.6
Merck-Medco	26,368.7	20,140.3	15,232.4
-----	-----	-----	-----
Total	\$47,715.7	\$40,363.2	\$32,714.0
=====	=====	=====	=====

Human health products include therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. Among these are atherosclerosis products, which include Zocor (simvastatin) and

Edgar Filing: MERCK & CO INC - Form 10-K405

Mevacor (lovastatin); hypertension/heart failure products, which include Cozaar (losartan potassium), Hyzaar (losartan potassium and hydrochlorothiazide), Prinivil (lisinopril), Vasotec (enalapril maleate) and Vaseretic (enalapril maleate and hydrochlorothiazide); anti-inflammatory/analgesics, of which Vioxx (rofecoxib), an agent that specifically inhibits COX-2, is the largest-selling; an osteoporosis product, Fosamax (alendronate sodium), for treatment and prevention of osteoporosis; a respiratory product, Singulair (montelukast sodium), a leukotriene receptor antagonist; vaccines/biologicals, of which M-M-R II (measles, mumps and rubella virus vaccine live), Varivax (varicella virus vaccine live), a live virus vaccine for the prevention of chickenpox, and Recombivax HB (hepatitis B vaccine [recombinant]) are the largest-selling; anti-bacterial/anti-fungal products, of which Primaxin (imipenem and cilastatin sodium), Noroxin (norfloxacin) and Cancidas (caspofungin acetate) are the largest-selling; ophthalmologicals, of which Timoptic (timolol maleate), Timoptic-XE (timolol maleate ophthalmic gel forming solution), Trusopt (dorzolamide hydrochloride ophthalmic solution) and Cosopt (dorzolamide hydrochloride and timolol maleate ophthalmic solution) are the largest selling; HIV products, which include Crixivan (indinavir sulfate), a protease inhibitor for the treatment of human immunodeficiency viral infection in adults; and anti-ulcerants, which include Pepcid (famotidine).

Other Merck products include sales of Proscar (finasteride), which provides for the treatment of symptomatic benign prostatic hyperplasia in men with enlarged prostates, Maxalt (rizatriptan benzoate), an anti-migraine treatment, Propecia (finasteride), which treats male pattern hair loss and Aggrastat (tirofiban hydrochloride), a platelet blocker for treatment of acute coronary syndrome, and other human pharmaceuticals; continuing sales to divested businesses; pharmaceutical and animal health supply sales to the Company's joint ventures; and supply sales to AstraZeneca LP. Also included in this category are rebates and discounts on the Company's pharmaceutical products.

Merck-Medco primarily includes Merck-Medco sales of non-Merck products and Merck-Medco pharmaceutical benefit services, principally sales of prescription drugs through managed prescription drug programs, as well as services provided through programs to manage patient health and drug utilization.

In January 2002, the Company announced plans to establish Merck-Medco as a separate, publicly-traded company. The Company plans an initial public offering of a portion of the new company by mid-2002, subject to market conditions. Alternatives for the distribution of the remaining shares in the new company are under evaluation. The full separation of Merck-Medco should be completed within 12 months of the initial public offering, subject to receipt of an Internal Revenue Service ruling that such an event would be tax-free to shareholders and to other customary conditions.

On January 10, 2001, the Antiviral Advisory Committee of the U.S. Food and Drug Administration ("FDA") recommended that the FDA clear Cancidas, the Company's investigational intravenous anti-fungal medicine, for marketing. On January 26, 2001, the FDA cleared Cancidas for marketing in the United States for the treatment of invasive aspergillosis in patients who do not respond to or are intolerant of other anti-fungal therapies. In February 2001, the once-weekly formulation of Fosamax was approved for treatment to increase bone mass in men with osteoporosis. In November 2001, the FDA cleared Invanz (ertapenem sodium), a new once-a-day injectable antibiotic, for marketing in the United States for the treatment of adults with the following moderate to severe infections caused by susceptible strains of the designated organisms: complicated intra-abdominal infections, complicated skin and skin structure infections, community acquired

Edgar Filing: MERCK & CO INC - Form 10-K405

pneumonia, complicated urinary tract infections, and acute pelvic infections.

In June 2000, Merck-Medco commenced providing pharmaceutical benefit management services for the UnitedHealth Group, one of the largest managed care organizations in the United States.

In November 2000, the Company formed a new subsidiary, Merck Capital Ventures, LLC, to invest up to \$100 million in capital in private Internet and other emerging businesses that focus on areas related to the commercialization, distribution and delivery of pharmaceuticals and related health care services.

Acquisitions -- In November 1999, the Company acquired SIBIA Neurosciences, Inc., a publicly-held California based biotechnology firm, which engages in the discovery and development of novel small molecule therapeutics for the treatment of neurodegenerative, neuropsychiatric and neurological disorders.

In June 2000, Merck-Medco acquired ProVantage Health Services, Inc., a publicly-held Wisconsin based health care benefits management and health information company that provided pharmacy benefit services to approximately five million people.

In July 2001, the Company acquired Rosetta Inpharmatics, Inc., a publicly-held Washington based informational genomics company that designs and develops unique technologies to efficiently analyze gene data to predict how medical compounds will interact with different kinds of cells in the body.

Joint Ventures -- In 1982, the Company entered into an agreement with Astra AB ("Astra") to develop and market Astra products in the United States. In 1993, the Company's total sales of Astra products reached a level that triggered the first step in the establishment of a joint venture business carried on by Astra Merck Inc. ("AMI"), in which the Company and Astra each owned a 50% share. This joint venture, formed in November 1994, developed and marketed most of Astra's new prescription medicines in the United States including Prilosec (omeprazole), 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, the Company and Astra completed the restructuring of the ownership and operations of the joint venture whereby the Company acquired Astra's interest in AMI, renamed KBI Inc. ("KBI"), and contributed KBI's operating assets to a new U.S. limited partnership named Astra Pharmaceuticals, L.P. ("the Partnership"), in which the Company maintains a limited partner interest. The Partnership, renamed AstraZeneca LP, became the exclusive distributor of the products for which KBI retained rights. The Company earns certain Partnership returns as well as ongoing revenue based on sales of current and future KBI products. The Partnership returns include a priority return provided for in the Partnership Agreement, variable returns based, in part, upon sales of certain former Astra USA, Inc. products, and a preferential return representing the Company's share of undistributed Partnership GAAP earnings. In conjunction with the 1998 restructuring, for a payment of \$443.0 million, Astra purchased an option to buy the Company's interest in the KBI products, excluding the Company's interest in the gastrointestinal medicines Prilosec and Nexium (esomeprazole magnesium). The Company also granted Astra an option ("the Shares Option") to buy the Company's common stock interest in KBI, at an exercise price based on the net present value of estimated future net sales of Prilosec and Nexium.

Edgar Filing: MERCK & CO INC - Form 10-K405

In April 1999, Astra merged with Zeneca Group Plc, forming AstraZeneca AB ("AstraZeneca"). As a result of the merger, Astra was required to make two one-time payments to the Company totaling approximately \$1.8 billion for the relinquishment of certain rights, including rights to future Astra products with no existing or pending U.S. patents at the time of the merger. This merger also triggers a partial redemption of the Company's limited partner interest in 2008. Furthermore, as a result of the merger, AstraZeneca's option to buy the Company's interest in the KBI products is exercisable in 2010 and the Company has obtained the right to require AstraZeneca to purchase such interest in 2008. In addition, the Shares Option is exercisable two years after Astra's purchase of the Company's interest in the KBI products.

In 1989, the Company formed a joint venture with Johnson & Johnson to develop, market and manufacture consumer health care products in the United States. In April 1995, the joint venture obtained FDA clearance in the United States for marketing Pepcid AC (famotidine), an over-the-counter form of the Company's ulcer medication Pepcid. This 50% owned joint venture was expanded into Europe in 1993, and into Canada in 1996. The European extension currently markets and sells over-the-counter pharmaceutical products in France, Germany, Italy, Spain and the United Kingdom.

Effective April 1992, the Company, through the Merck Vaccine Division, and Connaught Laboratories, Inc. (now Aventis Pasteur), an affiliate of Aventis A.G., agreed to collaborate on the development and marketing of combination pediatric vaccines and to promote selected vaccines in the United States. The research and marketing collaboration enables the companies to pool their resources to expedite the development of vaccines combining several different antigens to protect children against a variety of diseases, including Haemophilus influenzae type b, hepatitis B, diphtheria, tetanus, pertussis and poliomyelitis.

In 1994, the Company, through the Merck Vaccine Division, and Pasteur Merieux Connaught (now Aventis Pasteur) formed a joint venture to market human vaccines in Europe and to collaborate in the development of combination vaccines for distribution in the European Union ("EU") and the European Free Trade Association. The Company and Aventis Pasteur contributed, among other things, their European vaccine businesses for equal shares in the joint venture, known as Pasteur Merieux MSD, S.N.C. (now Aventis Pasteur MSD, S.N.C.). The joint venture is subject to monitoring by the EU, to which the partners made certain undertakings in return for an exemption from European Competition Law, effective until December 2006. The joint venture is active, directly or through affiliates in Belgium, Denmark, Italy, Germany, Spain, France, Austria, Ireland and the United Kingdom, and through distributors in the rest of Europe.

In 1997, the Company and Rhone-Poulenc S.A. combined their respective animal health and poultry genetics businesses to form Merial Limited ("Merial"), a fully-integrated animal health company, which is a stand-alone joint venture, equally 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. In December 1999, Rhone-Poulenc S.A.'s interest in Merial was acquired by Aventis S.A., a corporation formed by the merger of Rhone-Poulenc S.A. and Hoechst A.G.

In May 2000, the Company and Schering-Plough Corporation ("Schering-Plough") entered into agreements to create separate partnerships to develop and market in the United States new prescription medicines in the cholesterol-management and respiratory therapeutic areas. These partnerships are pursuing the development and marketing of Zetia (ezetimibe), an investigational cholesterol absorption inhibitor discovered by Schering-Plough, as a once-daily monotherapy and in co-administration with statins; Zetia as a once-daily

Edgar Filing: MERCK & CO INC - Form 10-K405

combination tablet with Zocor; and a once-daily combination tablet of Singulair and Claritin, Schering-Plough's nonsedating antihistamine, for the treatment of allergic rhinitis and asthma. In December 2001, the Company and Schering-Plough announced the worldwide expansion (excluding Japan) of the cholesterol-management partnership.

Also in December 2001, an entity of the Merck/Schering-Plough Pharmaceuticals partnership submitted a New Drug Application ("NDA") to the FDA for Zetia tablets, to be administered alone or with statins for the reduction of elevated cholesterol levels. On February 28, 2002, the FDA accepted for standard review the NDA for Zetia tablets, to be administered alone or with a statin for the reduction of elevated cholesterol levels (hypercholesterolemia).

4

In February 2001, Merck-Medco, Advance PCS and Express Scripts, Inc. announced the signing of an agreement to form RxHub. RxHub will be an electronic exchange enabling physicians to link with participating pharmacies, prescription benefit managers and health plans. RxHub is designed to operate as a utility for the conduit of information among all parties engaging in electronic prescribing. Merck-Medco owns one-third of the equity in RxHub.

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

In addition, particularly in the area of human pharmaceutical products, legislation enacted in all states allows, encourages or, in a few instances, in the absence of specific instructions from the prescribing physician, mandates the use of "generic" products (those containing the same active chemical as an innovator's product) rather than "brand-name" products. Governmental and other pressures toward the dispensing of generic products have significantly reduced the sales of certain of the Company's products no longer protected by patents, such as Vasotec, Vaseretic, Pepcid and Mevacor, and slowed the growth of certain other products.

Merck-Medco's pharmacy benefit management business is highly competitive. Merck-Medco competes with other pharmacy benefit managers, insurance companies and other providers of health care and/or administrators of health care programs. Merck-Medco competes primarily on the basis of its ability to design and administer innovative programs that help plan sponsors provide high-quality, affordable prescription drug care and health management services to health plan members. Merck-Medco dispenses prescription drugs from its national network of mail service pharmacies, manages prescriptions dispensed through a national network of participating retail pharmacies and implements health management programs to help its members with some chronic conditions better understand their conditions and comply with their prescribed drug

Edgar Filing: MERCK & CO INC - Form 10-K405

therapies.

Distribution -- The Company sells its human health products primarily to drug wholesalers and retailers, hospitals, clinics, government agencies and managed health care providers such as health maintenance organizations and other institutions. The Company's professional representatives communicate the effectiveness, safety and value of the Company's products to health care professionals in private practice, group practices and managed care organizations. Merck-Medco sells its pharmaceutical benefit management services to corporations, labor unions, insurance companies, Blue Cross/Blue Shield organizations, government agencies, federal and state employee plans, health maintenance and other similar organizations.

Raw Materials -- Raw materials and supplies are normally available in quantities adequate to meet the needs of the Company's business.

Government Regulation and Investigation -- The pharmaceutical industry is subject to global regulation by regional, country, state and local agencies. Of particular importance is the FDA in the United States, which administers requirements covering the testing, approval, safety, effectiveness, manufacturing, labeling and marketing of prescription pharmaceuticals. In many cases, the FDA requirements have increased the amount of time and money necessary to develop new products and bring them to market in the United States. In 1997, the Food and Drug Administration Modernization Act 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

5

applications. This helps provide the resources necessary to ensure the prompt approval of safe and effective new drugs.

In recent years, an increasing number of legislative proposals have been introduced or proposed in Congress and in some state legislatures that would effect major changes in the health care system, either nationally or at the state level. Such legislative initiatives introduced in Congress include prescription drug benefit proposals for Medicare beneficiaries. Although a reform bill has not been enacted at the federal level, some states have passed reform legislation and further federal and state developments are expected. Although the Company is well positioned to respond to evolving market forces, it cannot predict the outcome or effect of legislation resulting from these reform efforts.

For many years, the pharmaceutical industry and the pharmacy benefits management business have been under federal and state oversight with the new drug approval system, drug safety, advertising and promotion, drug purchasing and reimbursement programs and formularies variously under review. The Company believes that it will continue to be able to conduct its operations, including the introduction of new drugs to the market, in this regulatory environment. One type of federal initiative to contain federal health care spending is the prospective or "capitated" payment system, first implemented to reduce the rate of growth in Medicare reimbursement to hospitals. Such a system establishes in advance a flat rate for reimbursement for health care for those patients for whom the payer is fiscally responsible. This type of payment system and other

Edgar Filing: MERCK & CO INC - Form 10-K405

cost containment systems are now widely used by public and private payers and have caused hospitals, health maintenance organizations and other customers of the Company to be more cost-conscious in their treatment decisions, including decisions regarding the medicines to be made available to their patients. The Company continues to work with private and federal employers to slow increases in health care costs. Further, the Company's efforts to demonstrate that its medicines can help save costs in other areas, and pricing flexibility across its product portfolio, have encouraged the use of the Company's medicines and have helped offset the effects of increasing cost pressures.

Also, federal and state governments have pursued methods to directly reduce the cost of drugs for which they pay. For example, federal legislation requires the Company to pay a specified rebate for medicines reimbursed by Medicaid, and also to pay rebates similar to the Medicaid rebate for outpatient medicines purchased by certain Public Health Service entities and "disproportionate share" hospitals (hospitals meeting certain criteria), and minimum discounts of 24% off of a defined "non-federal average manufacturer price" for the Veterans' Administration, Federal Supply Schedule and certain other federal sector purchasers of medicines.

Initiatives in some states seek rebates beyond the minimum required by Medicaid legislation, in some cases for patients beyond those who are eligible for Medicaid. Under the Federal Vaccines for Children entitlement program, the U.S. Centers for Disease Control and Prevention ("CDC") funds and purchases recommended pediatric vaccines at a public sector price for the immunization of Medicaid-eligible, uninsured, native American and certain underinsured children. The Company was awarded CDC contracts in 2001 for the supply of six pediatric vaccines for this program (and monovalent components of such vaccines).

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 prescription drugs and the profits of prescription drug companies. The EU has adopted directives concerning the classification, labeling, advertising, wholesale distribution and approval for marketing of medicinal products for human use. The Company's policies and procedures are already consistent with the substance of these directives; consequently, it is believed that they will not have any material effect on the Company's business.

In addition, certain countries within the EU, recognizing the economic importance of the research-based pharmaceutical industry and the value of innovative medicines to society, are working with industry and the European Commission on proposals for market deregulation.

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. Although it is difficult to predict the ultimate effect of these activities and legislative, administrative and regulatory

requirements and proposals, the Company believes that its development of new and improved products should enable it to compete effectively within this environment.

There are extensive federal and state regulations applicable to the practice of pharmacy and the administration of managed health care programs.

Edgar Filing: MERCK & CO INC - Form 10-K405

Each state in which Merck-Medco operates a pharmacy has laws and regulations governing its operation and the licensing of and standards of professional practice by its pharmacists. These regulations are issued by an administrative body in each state (typically, a pharmacy board), which is empowered to impose sanctions for noncompliance. The policies and procedures of the Company comply with these regulations.

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 date of grant and 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.

Patent portfolios developed for products introduced by the Company normally provide market exclusivity. Basic patents are in effect for the following major products in the United States: Aggrastat, Cancidas, Chibroxin (norfloxacin), Cosopt, Cozaar, Crixivan, Fosamax, Hyzaar, Invanz, Maxalt, PedvaxHIB (Haemophilus b conjugate vaccine), Primaxin, Propecia, Proscar, Recombivax HB, Singulair, Trusopt, Vioxx and Zocor.

In 2001, several U.S. product patents expired, including Mevacor, Prinivil, Prinzide (lisinopril and hydrochlorothiazide) and Vaseretic. The product patent for Prilosec (which is supplied exclusively to AstraZeneca LP) in the United States also expired in 2001. In the aggregate, domestic sales of these products, as well as Pepcid, for which market exclusivity expired in 2001, represent 10% of the Company's human health sales for 2001. The Company expects a significant decline in the sales of these products in 2002 as a result of the loss of market exclusivity. With the exception of Prilosec, for which the Company has U.S. rights only, a decline is also expected in the Company's European sales for these products in the years 2002 through 2005 upon the loss of market exclusivity in European countries throughout this period. European sales of these products represent 1% of the Company's human health sales for 2001.

The Company filed a supplemental new drug application with the FDA for Prinivil, in accordance with the provisions of the FDA Modernization Act of 1997 (the "Modernization Act"). Pursuant to the Modernization Act, the FDA granted an additional six months of market exclusivity, commencing December 2001, in the United States to Prinivil and Prinzide for all their uses, based upon pediatric studies performed by the Company. The FDA also granted an additional six months of market exclusivity in the United States to Singulair from its February 2012 patent expiration until August 2012, and Zocor from its December 2005 basic patent expiration until June 2006, in response to supplemental new drug applications the Company filed on pediatric studies. The market exclusivity which commenced in the United States for product patents for Prilosec in April 2001, and Mevacor in July 2001, pursuant to the Modernization Act, expired in October 2001 and December 2001, respectively. Market exclusivity in the United States also expired for Pepcid in April 2001. The Modernization Act, which was passed in 1997, 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 reauthorized until October 1, 2007 by the "Best Pharmaceuticals for Children Act" passed in January 2002.

While the expiration of a product patent normally results in a loss of market exclusivity for the covered product, commercial benefits may continue to be derived from: (i) later-granted patents on processes and intermediates

Edgar Filing: MERCK & CO INC - Form 10-K405

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, market exclusivity that may be available under federal law. The effect of product patent expiration 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.

7

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.

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 2001 on patent and know-how licenses and other rights amounted to \$125.5 million. The Company also paid royalties amounting to \$522.8 million in 2001 under patent and know-how licenses it holds.

Research and Development

The Company's business is characterized by the introduction of new products or new uses for existing products through a strong research and development program. Approximately 11,900 people are employed in the Company's research activities. Expenditures for the Company's research and development programs were \$2.5 billion in 2001, \$2.3 billion in 2000 and \$2.1 billion in 1999 and will be approximately \$2.9 billion in 2002. The Company maintains its ongoing commitment to research over a broad range of therapeutic areas and clinical development in support of new products. Total expenditures for the period 1992 through 2001 exceeded \$16.7 billion with a compound annual growth rate of 10%.

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. Projects related to human health are being carried on in various fields such as bacterial and viral infections, cardiovascular functions, cancer, diabetes, pain and inflammation, kidney function, obesity, mental health, the nervous system, ophthalmic research, prostate therapy, the respiratory system, fungal diseases, bone diseases, endoparasitic and ectoparasitic diseases, companion animal diseases and production improvement.

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 may be marketed in the United States, recorded data on preclinical and clinical experience are included in the NDA or the biological Product License Application to the FDA for the required approval. The development of certain other products

Edgar Filing: MERCK & CO INC - Form 10-K405

is also subject to government regulations covering safety and efficacy in the United States and many foreign countries. 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.

New product candidates resulting from this research and development program include Arcoxia (etoricoxib), a second COX-2 specific inhibitor potentially useful for the treatment of osteoarthritis, rheumatoid arthritis, acute pain, chronic pain and dysmenorrhea, for which the Company filed an NDA with the FDA on August 8, 2001. The Company plans to submit an expanded NDA for Arcoxia to the FDA in order to include new efficacy data that will better position the product to compete successfully in the coxib class, where there already are three entrants. Accordingly, on March 13, 2002, the Company withdrew the original U.S. NDA for the investigational medicine. The Company is submitting the additional efficacy data to support a new indication for ankylosing spondylitis, which is a chronic, inflammatory disorder primarily involving the spine. In addition to the indications listed above, the Company is seeking an indication for acute gouty arthritis. Timing of the expanded submission has not been determined. The regulatory process for Arcoxia outside the United States continues uninterrupted.

Other products in development include an oral compound potentially useful for treatment of chemotherapy-induced emesis; an oral compound potentially useful for the treatment of depression and other neuropsychiatric diseases; a compound potentially useful for the treatment of diabetes and diabetic dyslipidemia; a compound potentially useful for the treatment of anxiety; a compound potentially useful for the treatment of Chronic Obstructive Pulmonary Disease and asthma; a compound potentially useful to treat AIDS; and certain new vaccines including a Human Papillomavirus vaccine ("HPV"), potentially useful to prevent HPV infection; a rotavirus vaccine potentially useful for the prevention of infant diarrhea and dehydration caused by rotavirus; and a vaccine potentially useful for the prevention and treatment of human immunodeficiency virus.

All product or service marks appearing in type form different from that of the surrounding text are trademarks or service marks owned by or licensed to Merck & Co., Inc., its subsidiaries or affiliates (including Zetia, a trademark owned by an entity of the Merck/Schering-Plough Pharmaceuticals partnership). Cozaar and Hyzaar are registered trademarks of E.I. du Pont de Nemours and Company, Wilmington, DE. Claritin is a trademark of Schering Corporation and Prilosec and Nexium are trademarks of the AstraZeneca group.

Employees

At the end of 2001, the Company had 78,100 employees worldwide, with 50,400 employed in the United States, including Puerto Rico. Approximately 30% of worldwide employees of the Merck Pharmaceutical and Merck-Medco segments are represented by various collective bargaining groups.

Environmental Matters

The Company believes that it is in compliance in all material respects with applicable environmental laws and regulations. In 2001, the Company incurred capital expenditures of approximately \$197.5 million for environmental protection facilities. Capital expenditures for this purpose are forecasted to exceed \$500.0 million for the years 2002 through 2006. In addition, the Company's operating and maintenance expenditures for environmental protection facilities were approximately \$88.7 million in 2001. Expenditures for this

Edgar Filing: MERCK & CO INC - Form 10-K405

purpose for the years 2002 through 2006 are forecasted to approximate \$520.0 million. The Company is also remediating environmental contamination resulting from past industrial activity at certain of its sites. Expenditures for remediation and environmental liabilities were \$34.2 million in 2001, and are estimated at \$137.0 million for the years 2002 through 2006. These amounts do not consider potential recoveries from insurers or 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. 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 those provided should result in a materially adverse effect on the Company's financial position, results of operations, liquidity or capital resources.

Cautionary Factors that May Affect Future Results (Cautionary Statements Under the Private Securities Litigation Reform Act of 1995)

This report and other written reports and oral statements made from time to time by the Company may contain so-called "forward-looking statements," all of which are subject to risks and uncertainties. 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 approvals and development programs, as well as the proposed initial public offering, and eventual divestiture of our Medco subsidiary. One must carefully consider any such statement and should understand that many factors could cause actual results to differ 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. Although it is not possible to predict or identify all such factors, they may include the following:

- .. Generic competition as product patents for several products have recently expired in the United States and other countries, including product patents for Mevacor (U.S. - 2001), Prinivil and Prinzide (U.S. - 2001) and Vaseretic (U.S. - 2001). In addition, the product patent for Prilosec, which is supplied exclusively to AstraZeneca LP, also expired in 2001.
- .. 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 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 pharmaceutical, vaccine and/or pharmaceutical benefits management businesses.
- .. Efficacy or safety concerns with respect to marketed products, whether or not scientifically justified, leading to product recalls, withdrawals or declining sales.
- .. Legal factors, including product liability claims, antitrust litigation and governmental investigations, 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. In the United States, federal and state governments have pursued legislative and regulatory initiatives regarding patient privacy, including recently issued federal privacy regulations concerning health information, which could affect the Company's operations, particularly at Merck-Medco.
- .. Changes in tax laws including changes related to the taxation of foreign earnings, as well as the impact of legislation capping and ultimately repealing Section 936 of the Internal Revenue Code (relating to earnings from the Company's Puerto Rican operations).
- .. Changes in accounting standards promulgated by the American Institute of Certified Public Accountants, the Financial Accounting Standards Board or the Securities and Exchange Commission that are adverse to the Company.
- .. The risk that the initial public offering of our Medco subsidiary may not be completed due to economic and stock market conditions generally and specifically as such conditions may impact the pharmacy benefit manager industry. Additionally, if the initial public offering is completed, the Company may not complete the divestiture of its remaining interest in Medco due to, among other reasons, the failure to obtain an Internal Revenue Service ruling that the divestiture to stockholders would be treated as a tax free distribution, or the failure to meet other customary conditions.
- .. 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.

Geographic Area and Segment Information

The Company's operations outside the United States are conducted primarily through subsidiaries. Sales of the Company's human health products by subsidiaries outside the United States were 37% of the Company's human health sales in 2001, and 36% and 40% in 2000 and 1999, respectively.

The Company's worldwide business is subject to risks of currency fluctuations, governmental actions and other governmental proceedings abroad.

Edgar Filing: MERCK & CO INC - Form 10-K405

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.

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

Financial information about geographic areas and operating segments of the Company's business is incorporated by reference to page 37 of the Company's 2001 Annual Report to stockholders.

10

Item 2. Properties.

The Company's corporate headquarters is located in Whitehouse Station, New Jersey. The Company's pharmaceutical business is conducted through divisional headquarters located in Rahway, New Jersey and West Point, Pennsylvania. Principal research facilities for human health products are located in Rahway and West Point. The Company also has production facilities for human health products at nine locations in the United States and Puerto Rico. Branch warehouses provide services throughout the country. Outside the United States, through subsidiaries, the Company owns or has an interest in manufacturing plants or other properties in Australia, Canada, countries in Western Europe, Central and South America, Africa and Asia. Merck-Medco operates its primary businesses through its headquarters located in Franklin Lakes, New Jersey, and through owned or leased facilities in various locations throughout the United States.

Capital expenditures for 2001 were \$2,724.7 million compared with \$2,727.8 million for 2000. In the United States, these amounted to \$2,128.6 million for 2001 and \$2,139.6 million for 2000. Abroad, such expenditures amounted to \$596.1 million for 2001 and \$588.2 million for 2000.

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

Item 3. Legal Proceedings.

The Company, including Merck-Medco, is party to a number of antitrust suits, certain of which have been certified as class actions, instituted by most of the nation's retail pharmacies and consumers in several states, alleging conspiracies in restraint of trade and challenging the pricing and/or purchasing practices of the Company and Merck-Medco, respectively. A significant number of other pharmaceutical companies and wholesalers have also been sued in the same or similar litigation. These actions, except for several actions pending in state courts, have been consolidated for pre-trial purposes in the United States District Court for the Northern District of Illinois. In 1996, the Company and

Edgar Filing: MERCK & CO INC - Form 10-K405

several other defendants finalized an agreement to settle the federal class action alleging conspiracy, which represents the single largest group of retail pharmacy claims. Since that time, the Company has entered into other settlements on satisfactory terms. In October 2001, the Judicial Panel on Multi-District Litigation ("Panel") determined that consolidated pretrial proceedings in federal district court in Chicago were substantially completed. The Panel ordered that all of the federal antitrust conspiracy cases, several of which have not been settled by the Company, be returned to the federal district courts in which each case was originally filed. The cases have now been returned to those courts for further proceedings. The Company has not engaged in any conspiracy and no admission of wrongdoing was made nor included in any settlement agreements. While it is not feasible to predict the final outcome of the remaining proceedings, in the opinion of the Company, such proceedings should not ultimately result in any liability which would have a materially adverse effect on the financial position, liquidity or results of operations of the Company.

In June 2001, the Company received a notice from the Federal Trade Commission ("FTC") advising the Company that the FTC had closed its investigation into pricing practices, which commenced in 1996. The Company has been advised by the U.S. Department of Justice that it is investigating marketing and selling activities of the Company and other pharmaceutical manufacturers. The Company will be working with the government to respond appropriately to informational requests.

In a continuing worldwide dispute between the Company and Pharmacia Corporation ("Pharmacia") over competing claims to the patent rights to the class of compounds that include rofecoxib, the active ingredient in Vioxx, the federal district court in Washington, D.C. recently dismissed a Pharmacia claim for damages for the Company's sale of Vioxx. Pharmacia may seek an appeal of this decision. The Company has also received favorable decisions regarding the patent status of Vioxx from courts in the United Kingdom, Holland and Spain, while receiving no adverse decisions in any country. In addition, in February 2002, the Board of Appeal at the European Patent Office revoked, in its entirety, the Pharmacia European patent that has been the basis of patent infringement suits involving

11

Vioxx in European countries. As a result, Merck will maintain exclusive patent rights in Europe for Vioxx. The Company also noted that a number of federal and state lawsuits, involving individual claims as well as purported class actions, have been filed against the Company with respect to Vioxx. Some of the lawsuits also name as defendants Pfizer Inc. and Pharmacia, which market a competing product. The lawsuits include allegations regarding gastrointestinal bleeding and cardiovascular events. The Company believes that these lawsuits are completely without merit and will vigorously defend them.

From time to time, generic manufacturers of pharmaceutical products file Abbreviated New Drug Applications ("ANDAs") with the FDA seeking to market generic forms of Company products prior to the expiration of relevant patents owned by the Company. Generic pharmaceutical manufacturers have submitted ANDAs to the FDA seeking to market in the United States a generic form of Fosamax and Prilosec prior to the expiration of the Company's (and AstraZeneca's in the case of Prilosec) patents concerning these products. The generic companies' ANDAs include allegations of non-infringement, invalidity and unenforceability of the patents. One manufacturer has received FDA approval to market a generic form of Prilosec. The Company has filed patent infringement suits in federal court against companies filing ANDAs for generic alendronate, and AstraZeneca and the Company have filed patent infringement suits in federal court against companies

Edgar Filing: MERCK & CO INC - Form 10-K405

filings ANDAs for generic omeprazole. In the case of alendronate, 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. A trial in the United States with respect to the alendronate daily product concluded in November 2001 and the Company is awaiting a ruling; no trial involving the alendronate weekly product is expected before 2003. In the case of omeprazole, a trial in the United States commenced in December 2001. 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.

The Company is a party to a number of proceedings brought under the Comprehensive Environmental Response, Compensation and Liability Act, commonly known as Superfund. These proceedings seek to require the operators of hazardous waste disposal facilities, transporters of waste to the sites and generators of hazardous waste disposed of at the sites to clean up the sites or to reimburse the government for cleanup costs. The Company has been made a party to these proceedings as an alleged generator of waste disposed of at the sites. In each case, the government alleges that the defendants are jointly and severally liable for the cleanup costs. Although joint and several liability is alleged, these proceedings are frequently resolved so that the allocation of cleanup costs among the parties more nearly reflects the relative contributions of the parties to the site situation. The Company's potential liability varies greatly from site to site. For some sites the potential liability is de minimis and for others the costs of cleanup have not yet been determined. While it is not feasible to predict the outcome of many of these proceedings brought by federal or state agencies or private litigants, in the opinion of the Company, such proceedings should not ultimately result in any liability which would have a materially adverse effect on the financial position, results of operations, liquidity or capital resources of the Company. The Company has taken an active role in identifying and providing for these costs and such amounts do not include any reduction for anticipated recoveries of cleanup costs from insurers, former site owners or operators or other recalcitrant potentially responsible parties.

There are various other legal proceedings, principally product liability and intellectual property suits involving the Company, which are pending. While it is not feasible to predict the outcome of these proceedings, 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 which would have a materially adverse effect on the financial position, liquidity or results of operations of the Company.

Merck-Medco

Seven plaintiffs, from six pharmaceutical benefit plans for which Merck-Medco is the pharmaceutical benefit manager, have sued Merck-Medco and the Company in federal court. The suits, which are similar to claims against other pharmaceutical benefit managers in other pending cases, allege that Merck-Medco should be treated as a "fiduciary" under the provisions of the Employee Retirement Income Security Act ("ERISA"). Plaintiffs have not yet formally sought class-action status.

The amended complaints in the lawsuits also allege that the Company and Merck-Medco have violated ERISA by using Merck-Medco to increase the Company's market share and by entering into certain "prohibited transactions" with each other that favor the Company's products. The plaintiffs have demanded that Merck-Medco

Edgar Filing: MERCK & CO INC - Form 10-K405

and the Company turn over any unlawfully obtained profits to a trust to be set up for the benefit plans. A motion for summary judgment filed by Merck-Medco has been withdrawn for procedural reasons without prejudice to being refiled.

In addition, a complaint against Merck-Medco and the Company has recently been filed by one Northwest Airlines plan participant, purportedly on behalf of the plan and similarly-situated self-funded plans. Class action status has not yet been sought, and Northwest Airlines is not a party to the lawsuit. The complaint relies on many of the same theories as the litigation discussed above.

Merck-Medco and the Company believe that these cases are without merit, Merck-Medco is not a "fiduciary" within the meaning of ERISA and the Company has not violated ERISA. Merck-Medco and the Company intend to vigorously defend these claims.

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

Not applicable.

13

Executive Officers of the Registrant (as of March 15, 2002)

RAYMOND V. GILMARTIN -- Age 61

June, 1994 -- Chairman of the Board (since November, 1994), President and Chief Executive Officer

DAVID W. ANSTICE -- Age 53

March, 2001 -- President, The Americas and U.S. Human Health -- responsible for one of the two prescription drug divisions comprising U.S. Human Health, as well as the Company's prescription drug business in Canada and Latin America, and the Company's joint venture relationship with Schering-Plough

January, 1997 -- President, Human Health-The Americas -- responsible for the Company's human health business in the United States, Canada and Latin America

PAUL R. BELL -- Age 56

April, 1997 -- President, Human Health-Asia Pacific -- responsible for the Company's prescription drug business in the Far East, Australia, New Zealand and Japan

March, 1994 -- Vice President, Merck Sharp & Dohme Australia and New Zealand

RICHARD T. CLARK -- Age 56

January, 2000 -- President, Merck-Medco Managed Care, L.L.C. (Merck-Medco), a wholly-owned subsidiary of the Company

Edgar Filing: MERCK & CO INC - Form 10-K405

June, 1997 -- Executive Vice President/Chief Operating Officer,
Merck-Medco

April, 1997 -- Senior Vice President, Quality and Commercial Affairs,
Merck Manufacturing Division (MMD)

May, 1996 -- Senior Vice President, North American Operations, MMD

CELIA A. COLBERT -- Age 45

January, 1997 -- Vice President, Secretary (since September, 1993) and
Assistant General Counsel (since November, 1993)

CAROLINE DORSA -- Age 42

September, 1999 -- Vice President and Treasurer -- responsible for the
Company's treasury and tax functions and for providing financial
support for the Asia Pacific Division

February, 1999 -- Vice President and Treasurer -- responsible for the
Company's treasury and tax functions

January, 1997 -- Vice President and Treasurer (since January, 1994)

14

KENNETH C. FRAZIER -- Age 47

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

January, 1999 -- Vice President and Deputy General Counsel

January, 1997 -- Vice President, Public Affairs (since April, 1994) and
Assistant General Counsel -- responsible for public affairs, corporate
legal activities and The Merck Company Foundation

DOUGLAS A. GREENE -- Age 57

May, 2000 -- Executive Vice President, Clinical Sciences and Product
Development, Merck Research Laboratories

Prior to May, 2000, Dr. Greene served as Chief, Division of
Endocrinology & Metabolism at the University of Michigan School of
Medicine since 1991 and as Director, Center for Clinical Investigation
and Therapeutics since 1998

RICHARD C. HENRIQUES JR. -- Age 46

November, 2000 -- Vice President, Controller -- responsible for the
Corporate Controller's Group and providing financial
support for U.S. Human Health, Canada and Latin America (The Americas)
and the Merck Vaccine Division

February, 1999 -- Vice President, Controller -- responsible for the
Corporate Controller's Group and providing financial support for The
Americas

Edgar Filing: MERCK & CO INC - Form 10-K405

January, 1998 -- Vice President & Controller, The Americas

January, 1997 -- Controller, The Americas

BERNARD J. KELLEY -- Age 60

December, 1993 -- President, Merck Manufacturing Division

PETER S. KIM -- Age 43

February, 2001 -- Executive Vice President, Research and Development, Merck Research Laboratories

Prior to February, 2001, Dr. Kim served as Member of the Whitehead Institute (1985 - 2001), Professor of Biology at the Massachusetts Institute of Technology (1988 - 2001), and Investigator of the Howard Hughes Medical Institute (1990 - 2001)

15

JUDY C. LEWENT -- Age 53

February, 2001 -- Executive Vice President and Chief Financial Officer -- responsible for financial and corporate development functions, internal auditing, corporate licensing, the Company's joint venture relationships, and Merck Capital Ventures, LLC, a wholly-owned subsidiary of the Company

November, 2000 -- Senior Vice President and Chief Financial Officer -- responsible for financial and corporate development functions, internal auditing, corporate licensing, the Company's joint venture relationships, and Merck Capital Ventures, LLC

January, 1997 -- Senior Vice President (since January, 1993) and Chief Financial Officer (since April, 1990) -- responsible for financial and corporate development functions, internal auditing and the Company's joint venture relationships

ADEL MAHMOUD -- Age 60

May, 1999 -- President, Merck Vaccines

November, 1998 -- Executive Vice President, Merck Vaccines

Prior to November, 1998, Dr. Mahmoud was the John H. Hord Professor and Chairman, Department of Medicine and Physician-in-Chief, Case Western Reserve University and University Hospitals of Cleveland (1987-1998)

EDWARD M. SCOLNICK -- Age 61

December, 1999 -- Executive Vice President, Science and Technology and President, Merck Research Laboratories (MRL) -- responsible for worldwide research function, computer resources and corporate licensing

September, 1994 -- Executive Vice President (since January, 1993), Science and Technology and President, MRL (since May, 1985) -- responsible for worldwide research function and activities of Merck Manufacturing Division (since December, 1993), computer resources (since January, 1993) and corporate licensing

Edgar Filing: MERCK & CO INC - Form 10-K405

BRADLEY T. SHEARES -- Age 45

March, 2001 -- President, U.S. Human Health -- responsible for one of the two prescription drug divisions comprising U.S. Human Health (USHH)

July, 1998 -- Vice President, Hospital Marketing and Sales, USHH

May, 1996 -- Vice President, Anti-Infectives Therapeutic Business Group, USHH

16

JOAN E. WAINWRIGHT -- Age 41

January, 2001 -- Vice President, Public Affairs

June, 2000 -- Vice President, Corporate Communications, Public Affairs

Prior to June, 2000, Ms. Wainwright was Deputy Commissioner for Communications at the U.S. Social Security Administration (1994 - 2000)

PER WOLD-OLSEN -- Age 54

January, 1997 -- President, Human Health-Europe, Middle East & Africa -- responsible for the Company's prescription drug business in Europe, the Middle East and Africa and worldwide human health marketing

September, 1994 -- President, Human Health-Europe -- responsible for the Company's European prescription drug business

WENDY L. YARNO -- Age 47

December, 1999 -- Senior Vice President, Human Resources

June, 1999 -- Vice President, Human Resources

January, 1999 -- Vice President, Worldwide Human Health Marketing

November, 1997 to January, 1999, Ms. Yarno was Vice President, Women's Health Care, Johnson & Johnson, Ortho-McNeil Pharmaceutical (manufacturer of pharmaceuticals)

January, 1995 to November, 1997 -- Vice President, Hypertension and Heart Failure Therapeutic Business Group, U.S. Human Health

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. There are no family relationships among the officers listed above.

17

PART II

Item 5. Market for Registrant's Common Equity and Related Stockholder Matters.

The information required for this item is incorporated by reference

Edgar Filing: MERCK & CO INC - Form 10-K405

to pages 23 and 40 of the Company's 2001 Annual Report to stockholders.

Item 6. Selected Financial Data.

The information required for this item is incorporated by reference to the data for the last five fiscal years of the Company included under Results for Year and Year-End Position in the Selected Financial Data table on page 40 of the Company's 2001 Annual Report to stockholders.

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

The information required for this item is incorporated by reference to pages 13 through 23 of the Company's 2001 Annual Report to stockholders.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

The information required for this item is incorporated by reference to pages 20 (under the caption "Analysis of Liquidity and Capital Resources") to 22 of the Company's 2001 Annual Report to stockholders.

Item 8. Financial Statements and Supplementary Data.

(a) Financial Statements

The consolidated balance sheet of Merck & Co., Inc. and subsidiaries as of December 31, 2001 and 2000, and the related consolidated statements of income, retained earnings, comprehensive income and cash flows for each of the three years in the period ended December 31, 2001 and the report dated January 22, 2002 of Arthur Andersen LLP, independent public accountants, are incorporated by reference to pages 24 through 37 and page 38, respectively, of the Company's 2001 Annual Report to stockholders.

(b) Supplementary Data

Selected quarterly financial data for 2001 and 2000 are incorporated by reference to the data contained in the Condensed Interim Financial Data table on page 23 of the Company's 2001 Annual Report to stockholders.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

On February 26, 2002, the Board of Directors of the Company and its Audit Committee dismissed Arthur Andersen LLP ("Arthur Andersen" or "AA") as the Company's independent public accountants and engaged PricewaterhouseCoopers LLP ("PwC") to serve as the Company's independent public accountants for the fiscal year 2002. The appointment of PwC is subject to stockholder ratification at the Company's 2002 Annual Meeting of Stockholders to be held in April.

Arthur Andersen's reports on the Company's consolidated financial statements for each of the years ended 2001, 2000 and 1999 did not contain an adverse opinion or disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope or accounting principles.

During the years ended December 31, 2001, 2000 and 1999 and through March 21, 2002, there were no disagreements with Arthur Andersen on any matter of accounting principle or practice, financial statement disclosure, or auditing scope or procedure which, if not resolved to AA's satisfaction, would have caused them to make reference to the subject matter in connection with their report on the Company's consolidated financial statements for such years; and there were no reportable events as defined in Item 304(a)(1)(v) of Regulation S-K.

Edgar Filing: MERCK & CO INC - Form 10-K405

The Company provided Arthur Andersen with a copy of the foregoing disclosures. Attached as Exhibit 16 is a copy of AA's letter, dated March 21, 2002, stating its agreement with such statements.

During the years ended December 31, 2001 and 2000 and through the date of the Board's decision, the Company did not consult PwC with respect to the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on the Company's consolidated financial statements, or any other matters or reportable events as set forth in Items 304(a)(2)(i) and (ii) of Regulation S-K.

PART III

Item 10. Directors and Executive Officers of the Registrant.

The required information on directors and nominees is incorporated by reference to pages 7 (beginning with the caption "Election of Directors") through 10 of the Company's Proxy Statement for the Annual Meeting of Stockholders to be held April 23, 2002. Information on executive officers is set forth in Part I of this document on pages 14 through 17. The required information on compliance with Section 16(a) of the Securities Exchange Act of 1934 is incorporated by reference to page 30 (under the caption "Section 16(a) Beneficial Ownership Reporting Compliance") of the Company's Proxy Statement for the Annual Meeting of Stockholders to be held April 23, 2002.

Item 11. Executive Compensation.

The information required for this item is incorporated by reference to page 13 (under the caption "Compensation of Directors"), and pages 15 (beginning with the caption "Compensation and Benefits Committee

18

Report on Executive Compensation") to 22 of the Company's Proxy Statement for the Annual Meeting of Stockholders to be held April 23, 2002.

Item 12. Security Ownership of Certain Beneficial Owners and Management.

The information required for this item is incorporated by reference to pages 14 (under the caption "Security Ownership of Directors and Executive Officers") to 15 of the Company's Proxy Statement for the Annual Meeting of Stockholders to be held April 23, 2002.

Item 13. Certain Relationships and Related Transactions.

The information required for this item is incorporated by reference to page 13 (under the caption "Relationships with Outside Firms") and pages 22 (under the caption "Indebtedness of Management") to 23 of the Company's Proxy Statement for the Annual Meeting of Stockholders to be held April 23, 2002.

PART IV

Item 14. Exhibits, Financial Statement Schedules, and Reports on Form 8-K.

(a) Documents filed as part of this Form 10-K

1. Financial Statements

The following consolidated financial statements and report of

Edgar Filing: MERCK & CO INC - Form 10-K405

independent public accountants are incorporated herein by reference to the Company's 2001 Annual Report to stockholders, as noted on page 18 of this document:

Consolidated statement of income for the years ended December 31, 2001, 2000 and 1999

Consolidated statement of retained earnings for the years ended December 31, 2001, 2000 and 1999

Consolidated statement of comprehensive income for the years ended December 31, 2001, 2000 and 1999

Consolidated balance sheet as of December 31, 2001 and 2000

Consolidated statement of cash flows for the years ended December 31, 2001, 2000 and 1999

Notes to consolidated financial statements

Report of independent public accountants

2. Financial Statement Schedules

Schedules are omitted because they are either not required or not applicable.

Financial statements of affiliates carried on the equity basis have been omitted because, considered individually or in the aggregate, such affiliates do not constitute a significant subsidiary.

3. Exhibits

Exhibit Number	Description	Method of Filing
-----	-----	-----
2.1 --	Master Restructuring Agreement dated as of June 19, 1998 between Astra AB, Merck & Co., Inc., Astra Merck Inc., Astra USA, Inc., KB USA, L.P., Astra Merck Enterprises, Inc., KBI Sub Inc., Merck Holdings, Inc. and Astra Pharmaceuticals, L.P. (Portions of this Exhibit are subject to a request for confidential treatment filed with the Commission)	*

19

Exhibit Number	Description	Method of Filing
-----	-----	-----
3(a) --	Restated Certificate of Incorporation of Merck & Co., Inc. (September 1, 2000)	Incorporated by r Form 10-Q Quart for the period

Edgar Filing: MERCK & CO INC - Form 10-K405

3 (b)	--	By-Laws of Merck & Co., Inc. (as amended effective February 25, 1997)	September 30, 2001 Incorporated by reference Form 10-Q Quarterly Report for the period March 31, 1997
10 (a)	--	Executive Incentive Plan (as amended effective February 27, 1996)	Incorporated by reference Form 10-K Annual Report for the fiscal year ended December 31, 1995
10 (b)	--	Base Salary Deferral Plan (as adopted on October 22, 1996, effective January 1, 1997)	Incorporated by reference Form 10-K Annual Report for the fiscal year ended December 31, 1995
10 (c)	--	1991 Incentive Stock Plan (as amended effective February 23, 1994)	Incorporated by reference Form 10-K Annual Report for the fiscal year ended December 31, 1993
10 (d)	--	1996 Incentive Stock Plan (as amended November 24, 1998)	Incorporated by reference Form 10-Q Quarterly Report for the period June 30, 1999
10 (e)	--	2001 Incentive Stock Plan (as amended and restated February 26, 2002)	Filed with this document
10 (f)	--	Non-Employee Directors Stock Option Plan (as amended and restated February 24, 1998)	Incorporated by reference Form 10-K Annual Report for the fiscal year ended December 31, 1997
10 (g)	--	1996 Non-Employee Directors Stock Option Plan (as amended April 27, 1999)	Incorporated by reference Form 10-Q Quarterly Report for the period June 30, 1999
10 (h)	--	2001 Non-Employee Directors Stock Option Plan (adopted April 24, 2001)	Incorporated by reference Form 10-Q Quarterly Report for the period June 30, 2001
10 (i)	--	Supplemental Retirement Plan (as amended effective January 1, 1995)	Incorporated by reference Form 10-K Annual Report for the fiscal year ended December 31, 1994
10 (j)	--	Retirement Plan for the Directors of Merck & Co., Inc. (amended and restated June 21, 1996)	Incorporated by reference Form 10-Q Quarterly Report for the period June 30, 1996
10 (k)	--	Plan for Deferred Payment of Directors' Compensation (amended and restated as of January 1, 2002)	Filed with this document

20

Exhibit Number	Description	Method of Filing	
-----	-----	-----	
10 (l)	--	Limited Liability Company Agreement of Merck Capital Ventures, LLC (Dated as of November 27, 2000)	Incorporated by reference Form 10-K Annual Report for the fiscal year ended December 31, 2000

Edgar Filing: MERCK & CO INC - Form 10-K405

10 (m)	--	Amended and Restated License and Option Agreement dated as of July 1, 1998 between Astra AB and Astra Merck Inc.	*
10 (n)	--	KBI Shares Option Agreement dated as of July 1, 1998 by and among Astra AB, Merck & Co., Inc. and Merck Holdings, Inc.	*
10 (o)	--	KBI-E Asset Option Agreement dated as of July 1, 1998 by and among Astra AB, Merck & Co., Inc., Astra Merck Inc. and Astra Merck Enterprises Inc.	*
10 (p)	--	KBI Supply Agreement dated as of July 1, 1998 between Astra Merck Inc. and Astra Pharmaceuticals, L.P. (Portions of this Exhibit are subject to a request for confidential treatment filed with the Commission)	*
10 (q)	--	Second Amended and Restated Manufacturing Agreement dated as of July 1, 1998 among Merck & Co., Inc., Astra AB, Astra Merck Inc. and Astra USA, Inc.	*
10 (r)	--	Limited Partnership Agreement dated as of July 1, 1998 between KB USA, L.P. and KBI Sub Inc.	*
10 (s)	--	Distribution Agreement dated as of July 1, 1998 between Astra Merck Enterprises Inc. and Astra Pharmaceuticals, L.P.	*
10 (t)	--	Agreement to Incorporate Defined Terms dated as of June 19, 1998 between Astra AB, Merck & Co., Inc., Astra Merck Inc., Astra USA, Inc., KB USA, L.P., Astra Merck Enterprises Inc., KBI Sub Inc., Merck Holdings, Inc. and Astra Pharmaceuticals, L.P.	*
12	--	Computation of Ratios of Earnings to Fixed Charges	Filed with this d
13	--	2001 Annual Report to stockholders (only those portions incorporated by reference in this document are deemed "filed")	Filed with this d
16	--	Letter from Arthur Andersen LLP to the Securities and Exchange Commission dated March 21, 2002	Incorporated by r Form 8-K/A Amen Current Report dated March 21,
21	--	List of subsidiaries	Filed with this d
23	--	Consent of Independent Public Accountants	Contained on page this Report
24	--	Power of Attorney and Certified Resolution of Board of Directors	Filed with this d
99	--	Letter from Registrant to the Securities and Exchange Commission relating to Arthur Anderson LLP	Filed with this d

* Incorporated by reference to Form 10-Q Quarterly Report for the period ended June 30, 1998

Edgar Filing: MERCK & CO INC - Form 10-K405

None of the instruments defining the rights of holders of long-term debt of the Company and its subsidiaries (Exhibit Number 4) are being filed since the total amount of securities authorized under any of such instruments taken individually does not exceed 10% of the total assets of the Company and its subsidiaries on a consolidated basis. The Company agrees to furnish a copy of such instruments to the Commission upon request.

Copies of the exhibits may be obtained by stockholders upon written request directed to the Stockholder Services Department, Merck & Co., Inc., P.O. Box 100--WS 3AB-40, Whitehouse Station, New Jersey 08889-0100 accompanied by check in the amount of \$5.00 payable to Merck & Co., Inc. to cover processing and mailing costs.

(b) Reports on Form 8-K

During the three-month period ended December 31, 2001, the Company furnished three Current Reports on Form 8-K under Item 9 -- Regulation FD Disclosure:

- (1) Report dated and furnished October 18, 2001, regarding earnings for third quarter and certain supplemental information.
- (2) Report dated and furnished October 24, 2001, regarding an updated presentation to investors.
- (3) Report dated December 11, 2001 and furnished December 12, 2001, regarding the Company's business briefing to analysts.

22

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

MERCK & CO., INC.

Dated: March 21, 2002

By RAYMOND V. GILMARTIN
(Chairman of the Board,
President and Chief Executive Officer)

By CELIA A. COLBERT
Celia A. Colbert
(Attorney-in-Fact)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signatures	Title	Date
RAYMOND V. GILMARTIN	Chairman of the Board, President and Chief Executive Officer; Principal Executive Officer; Director	March 21, 2002

Edgar Filing: MERCK & CO INC - Form 10-K405

JUDY C. LEWENT	Executive Vice President and Chief Financial Officer; Principal Financial Officer	March 21, 2002
RICHARD C. HENRIQUES JR.	Vice President, Controller; Principal Accounting Officer	March 21, 2002
LAWRENCE A. BOSSIDY	Director	March 21, 2002
WILLIAM G. BOWEN	Director	March 21, 2002
JOHNNETTA B. COLE	Director	March 21, 2002
NIALL FITZGERALD	Director	March 21, 2002
WILLIAM N. KELLEY	Director	March 21, 2002
HEIDI G. MILLER	Director	March 21, 2002
EDWARD M. SCOLNICK	Director	March 21, 2002
THOMAS E. SHENK	Director	March 21, 2002
SAMUEL O. THIER	Director	March 21, 2002

Celia A. Colbert, by signing her name hereto, does hereby sign this document pursuant to powers of attorney duly executed by the persons named, filed with the Securities and Exchange Commission as an exhibit to this document, on behalf of such persons, all in the capacities and on the date stated, such persons including a majority of the directors of the Company.

By CELIA A. COLBERT
Celia A. Colbert
(Attorney-in-Fact)

23

Exhibit 23

CONSENT OF INDEPENDENT PUBLIC ACCOUNTANTS

As independent public accountants, we hereby consent to the incorporation by reference in this Form 10-K of our report dated January 22, 2002 included in the Company's Annual Report to stockholders for the fiscal year ended December 31, 2001, into the Company's previously filed Registration Statements on Form S-8 (Nos. 33-21087, 33-21088, 33-36101, 33-40177, 33-51235, 33-53463, 33-64273, 33-64665, 333-23293, 333-23295, 333-91769, 333-30526, 333-31762, 333-40282, 333-52264, 333-53246, 333-56696, 333-72206 and 333-65796), on Form S-4 (Nos. 33-50667 and 333-61982) and on Form S-3 (Nos. 33-39349, 33-60322, 33-51785, 33-57421, 333-17045, 333-36383, 333-77569 and 333-72546). It should be noted that we have not audited any financial statements of the Company subsequent to December 31, 2001 or performed any audit procedures subsequent to the date of our report.

ARTHUR ANDERSEN LLP

New York, New York
March 21, 2002

EXHIBIT INDEX

Exhibit Number -----	Description -----	Method of Filing -----
2.1 --	Master Restructuring Agreement dated as of June 19, 1998 between Astra AB, Merck & Co., Inc., Astra Merck Inc., Astra USA, Inc., KB USA, L.P., Astra Merck Enterprises, Inc., KBI Sub Inc., Merck Holdings, Inc. and Astra Pharmaceuticals, L.P. (Portions of this Exhibit are subject to a request for confidential treatment filed with the Commission)	*
3(a) --	Restated Certificate of Incorporation of Merck & Co., Inc. (September 1, 2000)	Incorporated by reference to Form 10-Q Quarterly Report for the period ended September 30, 2000
3(b) --	By-Laws of Merck & Co., Inc. (as amended effective February 25, 1997)	Incorporated by reference to Form 10-Q Quarterly Report for the period ended March 31, 1997
10(a) --	Executive Incentive Plan (as amended effective February 27, 1996)	Incorporated by reference to Form 10-K Annual Report for the fiscal year ended December 31, 1995
10(b) --	Base Salary Deferral Plan (as adopted on October 22, 1996, effective January 1, 1997)	Incorporated by reference to Form 10-K Annual Report for the fiscal year ended December 31, 1996
10(c) --	1991 Incentive Stock Plan (as amended effective February 23, 1994)	Incorporated by reference to Form 10-K Annual Report for the fiscal year ended December 31, 1994
10(d) --	1996 Incentive Stock Plan (as amended November 24, 1998)	Incorporated by reference to Form 10-Q Quarterly Report for the period ended June 30, 1999
10(e) --	2001 Incentive Stock Plan (as amended and restated February 26, 2002)	Filed with this document

Edgar Filing: MERCK & CO INC - Form 10-K405

10(f) --	Non-Employee Directors Stock Option Plan (as amended and restated February 24, 1998)	Incorporated by reference to Form 10-K Annual Report for the fiscal year ended December 31, 1997
10(g) --	1996 Non-Employee Directors Stock Option Plan (as amended April 27, 1999)	Incorporated by reference to Form 10-Q Quarterly Report for the period ended June 30, 1999
10(h) --	2001 Non-Employee Directors Stock Option Plan (adopted April 24, 2001)	Incorporated by reference to Form 10-Q Quarterly Report for the period ended June 30, 2001
10(i) --	Supplemental Retirement Plan (as amended effective January 1, 1995)	Incorporated by reference to Form 10-K Annual Report for the fiscal year ended December 31, 1994

Exhibit Number -----	Description -----	Method of Filing -----
10(j) --	Retirement Plan for the Directors of Merck & Co., Inc. (amended and restated June 21, 1996)	Incorporated by reference to Form 10-Q Quarterly Report for the period ended June 30, 1996
10(k) --	Plan for Deferred Payment of Directors' Compensation (amended and restated as of January 1, 2002)	Filed with this document
10(l) --	Limited Liability Company Agreement of Merck Capital Ventures, LLC (Dated as of November 27, 2000)	Incorporated by reference to Form 10-K Annual Report for the fiscal year ended December 31, 2000
10(m) --	Amended and Restated License and Option Agreement dated as of July 1, 1998 between Astra AB and Astra Merck Inc.	*
10(n) --	KBI Shares Option Agreement dated as of July 1, 1998 by and among Astra AB, Merck & Co., Inc. and Merck Holdings, Inc.	*
10(o) --	KBI-E Asset Option Agreement dated as of July 1, 1998 by and among Astra AB, Merck & Co., Inc., Astra Merck Inc. and Astra Merck Enterprises Inc.	*
10(p) --	KBI Supply Agreement dated as of July 1, 1998 between Astra Merck Inc. and Astra Pharmaceuticals, L.P. (Portions of this Exhibit are subject to a request for confidential treatment filed with the Commission)	*
10(q) --	Second Amended and Restated Manufacturing Agreement dated as of July 1, 1998 among Merck & Co., Inc., Astra AB, Astra Merck Inc. and Astra USA, Inc.	*
10(r) --	Limited Partnership Agreement dated as of July 1, 1998 between KB USA, L.P. and KBI Sub Inc.	*
10(s) --	Distribution Agreement dated as of July 1, 1998 between Astra Merck Enterprises Inc. and	*

Edgar Filing: MERCK & CO INC - Form 10-K405

		Astra Pharmaceuticals, L.P.	
10(t)	--	Agreement to Incorporate Defined Terms dated as of June 19, 1998 between Astra AB, Merck & Co., Inc., Astra Merck Inc., Astra USA, Inc., KB USA, L.P., Astra Merck Enterprises Inc., KBI Sub Inc., Merck Holdings, Inc. and Astra Pharmaceuticals, L.P.	*
12	--	Computation of Ratios of Earnings to Fixed Charges	Filed with this document
13	--	2001 Annual Report to stockholders (only those portions incorporated by reference in this document are deemed "filed")	Filed with this document
16	--	Letter from Arthur Andersen LLP to the Securities and Exchange Commission dated March 21, 2002	Incorporated by reference to Form 8-K/A Amendment No. 1 Current Report on Form 8-K dated March 21, 2002
21	--	List of subsidiaries	Filed with this document
23	--	Consent of Independent Public Accountants	Contained on page 24 of this Report

Exhibit

Number	Description	Method of Filing
-----	-----	-----
24	-- Power of Attorney and Certified Resolution of Board of Directors	Filed with this document
99	-- Letter from Registrant to the Securities and Exchange Commission relating to Arthur Andersen LLP	Filed with this document

* Incorporated by reference to Form 10-Q Quarterly Report for the period ended June 30, 1998

None of the instruments defining the rights of holders of long-term debt of the Company and its subsidiaries (Exhibit Number 4) are being filed since the total amount of securities authorized under any of such instruments taken individually does not exceed 10% of the total assets of the Company and its subsidiaries on a consolidated basis. The Company agrees to furnish a copy of such instruments to the Commission upon request.