

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

FORM 10-K

(MARK ONE)



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

For the Fiscal Year Ended December 31, 2012

or



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

For the transition period from _____ to _____

Commission File No. 1-6571

Merck & Co., Inc.

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:

Title of Each Class

Name of Each Exchange
on which Registered

Common Stock (\$0.50 par value)

New York Stock Exchange

Number of shares of Common Stock (\$0.50 par value) outstanding as of January 31, 2013: 3,022,367,538.

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

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

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐

(Do not check if a smaller reporting company)

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

Documents Incorporated by Reference:

Document

Part of Form 10-K

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

Part III

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PART I

Item 1. Business.

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

For financial information and other information about the Company’s segments, see Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and Item 8. “Financial Statements and Supplementary Data” below.

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Overview

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

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

Beginning with the Company’s sales performance in its largest markets during 2012, despite the adverse effects of the U.S. *Singulair* patent expiry which caused a significant and rapid decline in U.S. *Singulair* sales, sales in the United States were relatively flat compared to the prior year reflecting strong growth of key brands including *Januvia* (sitagliptin) and *Janumet* (sitagliptin/metformin HCl), treatments for type 2 diabetes, *Zostavax* (Zoster Vaccine Live), a vaccine to help prevent shingles (herpes zoster), *Gardasil* (Human Papillomavirus Quadrivalent [Types 6, 11, 16 and 18] Vaccine, Recombinant), a vaccine to help prevent certain diseases caused by four types of human papillomavirus (“HPV”), *Victrelis* (boceprevir), a treatment for chronic hepatitis C, and *Isentress* (raltegravir), an antiretroviral therapy for use in combination therapy for the treatment of HIV-1 infection. Turning to Europe and Canada, the Company continues to experience positive volume growth trends for many of its key

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

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

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

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

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

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

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

from various actions, including the Merger Restructuring Program discussed below, previously announced ongoing cost reduction activities, as well as from non-restructuring-related activities. As of the end of 2012, the Company had achieved its projected \$3.5 billion in annual net cost savings from these activities since the merger with Schering-Plough Corporation (“Schering-Plough”) (the “Merger”).

The global restructuring program that was initiated in conjunction with the integration of the legacy Merck and legacy Schering-Plough businesses (the “Merger Restructuring Program”) is intended to optimize the cost structure of the combined company. The workforce reductions associated with this plan relate to the elimination of positions in sales, administrative and headquarters organizations, as well as from the sale or closure of certain manufacturing and research and development sites and the consolidation of office facilities. The Company recorded total pretax restructuring costs of \$951 million in 2012, \$1.8 billion in 2011 and \$1.8 billion in 2010 related to this program. Costs associated with the Company’s restructuring actions are included in *Materials and production costs*, *Marketing and administrative expenses*, *Research and development expenses* and *Restructuring costs*. The restructuring actions under the Merger Restructuring Program are expected to be substantially completed by the end of 2013, with the exception of certain actions, principally manufacturing-related. Subsequent to the Merger, the Company has rationalized a number of manufacturing sites worldwide. The remaining actions under this program will result in additional manufacturing facility rationalizations, which are expected to be substantially completed by 2016. The Company now expects the estimated total cumulative pretax costs for this program to be approximately \$7.2 billion to \$7.5 billion. The Company estimates that approximately two-thirds of the cumulative pretax costs relate to cash outlays, primarily related to employee separation expense. Approximately one-third of the cumulative pretax costs are non-cash, relating primarily to the accelerated depreciation of facilities to be closed or divested. The Company expects the Merger Restructuring Program to yield annual savings by the end of 2013 of approximately \$3.5 billion to \$4.0 billion and annual savings upon completion of the program of approximately \$4.0 billion to \$4.6 billion.

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

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

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

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