

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, 2015

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.

2000 Galloping Hill Road
Kenilworth, N. J. 07033
(908) 740-4000

Incorporated in New Jersey

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

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

<u>Title of Each Class</u>	<u>Name of Each Exchange on which Registered</u>
Common Stock (\$0.50 par value)	New York Stock Exchange
1.125% Notes due 2021	New York Stock Exchange
1.875% Notes due 2026	New York Stock Exchange
2.500% Notes due 2034	New York Stock Exchange

Number of shares of Common Stock (\$0.50 par value) outstanding as of January 31, 2016: 2,775,258,591.

Aggregate market value of Common Stock (\$0.50 par value) held by non-affiliates on June 30, 2015 based on closing price on June 30, 2015: \$160,710,000,000.

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 24, 2016,
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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The EU has adopted directives and other legislation concerning the classification, labeling, advertising, wholesale distribution, integrity of the supply chain, enhanced pharmacovigilance monitoring and approval for marketing of medicinal products for human use. These provide mandatory standards throughout the EU, which may be supplemented or implemented with additional regulations by the EU member states. The Company's policies and procedures are already consistent with the substance of these directives; consequently, it is believed that they will not have any material effect on the Company's business.

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

Operating Results

Sales

Worldwide sales were \$39.5 billion in 2015, a decline of 6% compared with 2014 including a 6% unfavorable effect from foreign exchange. The acquisition of Cubist in 2015, the divestiture of MCC in 2014, as well as product divestitures and the termination of the Company's relationship with AstraZeneca LP (AZLP) also in 2014, as discussed below, had a net unfavorable impact to sales of approximately 3%. In addition, sales performance in 2015 reflects declines in *PegIntron* and *Vitreliis*, medicines for the treatment of HCV, *Remicade*, a treatment for inflammatory diseases, *Pneumovax 23*, a vaccine to help prevent pneumococcal disease, *Nasonex*, an inhaled corticosteroid for the treatment of nasal allergy symptoms and *Vytorin*, a cholesterol modifying medicine. These declines were partially offset by volume growth in *Keytruda*, an anti-PD-1 therapy; *Januvia* and *Janumet*, for the treatment of type 2 diabetes, *Gardasil/Gardasil 9*, vaccines to help prevent certain diseases caused by certain types of human papillomavirus (HPV), *Noxafil*, for the prevention of invasive fungal infections, *Simponi*, a once-monthly subcutaneous treatment for inflammatory diseases, *Implanon/Nexplanon*, single-rod subdermal contraceptive implants, *Invanz*, for the treatment of certain infections, *Dulera* Inhalation Aerosol, a combination medicine for the treatment of asthma, and *Bridion*, a medication for the reversal of two types of neuromuscular blocking agents used during surgery, as well as volume growth in Animal Health products and higher third-party manufacturing sales.

In January 2015, the Company acquired Cubist, which contributed sales of \$1.3 billion to Merck's revenues in 2015. In 2014, the Company divested certain ophthalmic products in several international markets (most of which closed on July 1, 2014). In addition, on October 1, 2014, the Company divested its MCC business including the prescription rights to Claritin and Afrin. The sales decline in 2015 attributable to these divestitures was approximately \$1.9 billion of which \$1.5 billion related to the Consumer Care segment and \$400 million related to the Pharmaceutical segment. Also, in 2014, the Company sold the U.S. marketing rights to *Saphris*, an antipsychotic indicated for the treatment of schizophrenia and bipolar I disorder in adults, which resulted in revenue of \$232 million. Additionally, the Company's relationship with AZLP terminated on June 30, 2014; therefore, effective July 1, 2014, the Company no longer records supply sales to AZLP. These supply sales were \$463 million in 2014 through the termination date and were reflected in the Alliances segment.

Sales in the United States were \$17.5 billion in 2015, an increase of 3% compared with \$17.1 billion in 2014. The increase was driven primarily by the acquisition of Cubist, as well as higher sales of *Keytruda*, *Gardasil/Gardasil 9*, *Januvia/Janumet*, *Zetia*, a cholesterol modifying medicine, and higher third-party manufacturing sales. These increases were partially offset by the 2014 divestiture of MCC, the termination of the Company's relationship with AZLP in 2014, revenue recognized in 2014 in connection with the sale of the U.S. marketing rights to *Saphris*, as well as lower sales in 2015 of *Pneumovax 23* and *Nasonex*.

International sales were \$22.0 billion in 2015, a decline of 13% compared with \$25.2 billion in 2014. Foreign exchange unfavorably affected international sales performance by 11% in 2015. Excluding the unfavorable effect of foreign exchange, the sales decrease reflects the divestiture of MCC, as well as lower sales in the Pharmaceutical segment, largely reflecting declines in Europe and Japan, partially offset by growth in the emerging markets. Sales in Europe declined 19% in 2015, to \$7.7 billion, including a 14% unfavorable effect from foreign exchange. Excluding the unfavorable effect from foreign exchange, the decline was driven primarily by lower sales of *Remicade*, as well as lower sales of products for the treatment of HCV and from product divestitures and ongoing generic erosion and fiscal austerity measures in this region, partially offset by growth in *Simponi*, *Keytruda*, and *Januvia/Janumet*. Sales in Japan declined 23% in 2015, to \$2.6 billion, of which 11% was due to the unfavorable effect of foreign exchange. The sales decline was largely driven by product divestitures and the ongoing impacts of the loss of market exclusivity for several products, including *Cozaar* and *Hyzaar*, treatments for hypertension, as well as lower sales of *PegIntron* and *Januvia*.