COMPANY PROFILE

Merck & Co., Inc.

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COMPANY OVERVIEW

Merck & Co., Inc. (Merck & Co. or 'the company'), known as Merck Sharp & Dohme (MSD) outside the US and Canada, is a healthcare company. The company delivers health solutions through its prescription medicines, vaccines, biologic therapies and animal health products. The company sells prescription medicine and pharmaceutical products for the treatment of cardiovascular, cancer, immune disorders, infectious, respiratory and women's diseases, and diabetes. It commercializes products to drug wholesalers and retailers, hospitals, government agencies and managed health care providers. It also sells Vaccine products that include preventive pediatric, adolescent and adult vaccines to physicians, wholesalers, physician distributors and government entities. Apart from this, Merck & Co. manufactures and markets animal health products, including vaccines and sells to veterinarians, distributors and animal producers. The company has operations across the world. Merck & Co. is headquartered in Kenilworth, New Jersey, the US.

The company reported revenues of (US Dollars) US$40,122 million for the fiscal year ended December 2017 (FY2017), an increase of 0.8% over FY2016. In FY2017, the company's operating margin was 16.5%, compared to an operating margin of 12.2% in FY2016. In FY2017, the company recorded a net margin of 6%, compared to a net margin of 9.8% in FY2016.

The company reported revenues of US$10,037.0 million for the first quarter ended March 2018, a decrease of 3.8% over the previous quarter.

KEY FACTS

Head Office	Merck & Co., Inc. 2000 Galloping Hill Road Kenilworth New Jersey Kenilworth New Jersey USA
Phone	1 908 7404000
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Web Address	www.merck.com
Revenue / turnover (USD Mn)	40,122.0
Financial Year End	December
Employees	69,000
New York Stock Exchange Ticker	MRK

SWOT ANALYSIS

Merck & Co., Inc. (Merck & Co. or 'the company') known as Merck Sharp & Dohme (MSD) outside the US and Canada, is one of the leading healthcare companies in the world. The company has a wide pharmaceutical products portfolio in different therapeutic areas, which helps in enhancing its brand image in the pharmaceutical industry. However, healthcare reform in the US could negatively impact the company's profitability.

Strength	**Weakness**
Strong research and development programs Worldwide presence Business performance of innovative health segment	Patent infringement litigation Significant reliance on key products
Opportunity	**Threat**
Promising product pipeline Strategic acquisition to strengthen Merck & Co.'s portfolio Product approvals likely to help the company in catering to unmet medical needs	Uncertainty in global economic conditions together with austerity measures being taken by certain governments Negative events in the animal health industry Intense competition

Strength

Strong research and development programs

Merck & Co. manages diverse research and development (R&D) programs. In FY2017, approximately 12,650 people were employed in the company's research activities, and had an R&D expense of US$10.2 billion in FY2017. Merck & Co. maintains a number of long-term exploratory and fundamental research programs in biology and chemistry as well as research programs directed toward product development. The company operates research facilities in New Jersey, Pennsylvania, California, Massachusetts and Nebraska, the US, Switzerland and China. Its expertise in R&D enabled it to generate a strong patent portfolio. As of February 2018, Merck had 10 programs in Phase II, 20 programs in Phase III and three programs under review. The company's r&d network operates and collaborates with biomedical ecosystem including in the US. The company's strong R&D program helps in increasing its productivity and improving the probability of success by prioritizing R&D resources on candidates the company believes are capable of providing unambiguous, promotable advantages to patients and payers and delivering the maximum value of its approved medicines and vaccines through new indications and new formulations.

Worldwide presence

Merck & Co's wide geographic operations helps in mitigating various risks associated with dependence

on select region. The company has operations spread across North America, Europe, Middle East and Africa (EMEA), Asia Pacific, Japan, Latin America and other countries. It sells its products in more than 150 countries spanning across the Americas, Asia-Pacific, Europe, Middle East and Africa. The company generated more than 50% of its revenue from outside the US. In FY2017, Merck & Co generated 28.6% of company's total revenue from EMEA, followed by Asia Pacific with 10.8%, Japan with 7.8%, Latin America with 5.8%, and Other countries with 3.5%. The company operates research facilities in the US, Switzerland and China. Wide geographic presence enables the company to serve a wide customer base, which result in improved top line performance.

Business performance of innovative health segment

Merck & Co's Pharmaceutical segment was the major contributor to its revenue stream. Strong performance of the segment enabled the company in achieving overall growth in revenue. Growth in revenue enhances the company's ability to provide higher returns to its shareholders and also increases its ability to allocate adequate funds for future growth initiatives. In FY2017, the company's pharmaceutical segment accounted for 88.2% of the company's total revenue and reported a year-on-year growth of 0.7%. The growth was due to increase the sales of Keytruda and Zepatier, the newly launched products of the company. In FY2017, Keytruda recorded the revenue of US$3,809 million as compared to US$1,402 million in FY2016. Similarly, Zepatier recorded the revenue of US$$1,660 million during the year as compared to US$555 million in FY2016. Kentruda is an anti-PD-1 therapy useful for the treatment of adult and pediatric patients with cHL refractory. Zepatier is useful or the treatment of adult patients with chronic hepatitis C virus (HCV) genotype (GT) 1 or GT4 infection.

Weakness

Patent infringement litigation

Merck & Co was involved in several litigations related to infringement of patents. The company's certain products are involved in such patent infringement litigation in the US such as Noxafil and NuvaRing. It also faces patent infringement litigations with companies such Ono Pharmaceutical and Bristol-Myers Squibb Co. The manufacturer of pharmaceutical product files abbreviated NDAs with the FDA to market generic forms of the company's products prior to the expiration of company's patents. The company is engaged with BMS and Ono in worldwide litigation patent infringement litigation related to the use of Keytruda, an anti-PD-1 antibody for the treatment of cancer. In 2017, the company settled the litigation and made paid of US$625 million to BMS. It will pay royalties on the worldwide sales of Keytruda for a non-exclusive license to market Keytruda in any approval market. As per the settlement, Merck will pay royalties of 6.5% on net sales of Keytruda in 2017 through 2023 and 2.5% on net sales in 2024 through 2026.

Significant reliance on key products

The company's ability to generate profits and operating cash flow depends largely upon the continued profitability of the company's key products, such as Januvia, Janumet, Keytruda, Gardasil/Gardasil 9 and Isentress. As a result, any event that adversely affects any of these products or the markets for any of these products could have a significant impact on the company's results of operations and cash flows.

These events could include loss of patent protection, increased costs associated with manufacturing, generic or over-the-counter availability of the company's product or a competitive product, the discovery of previously unknown side effects, results of post-market trials, and increased competition from the introduction of new, more effective treatments and discontinuation or removal from the market of the product for any reason. If any of these events had a material adverse effect on the sales of certain products, such an event could result in a material non-cash impairment charge. Thus, the company's reliance on its key products to generate a significant amount of profits and cash flows could have a negative impact on its results of operations. For example, in 2018, the company's sales of Zepatier and Zostavax will be affected by increasing competition and declining patient volumes.

Opportunity

Promising product pipeline

A pipeline of new products will complement the Merck & Co's portfolio, besides strengthening its market presence. The company focuses on developing strong pipeline for some major areas such as oncology and immune-oncology, neuroscience, infectious disease and vaccines, cardiometabolic disease and immunology. As of February 2018, the company had ten programs in Phase II, 20 programs in Phase III and three programs under review. Under Phase III, the company's products include MK-7655A (relebactam+imipenem/cilastatin) for bacterial infections; MK-3475 Keytruda for cancer; MK-7339 Lynparza for pancreatic and prostate cancer, MK-5618 for thyroid cancer; V920 - Ebola vaccine; MK-1242 (vericiguat) for heart failure; V212 (inactivated VZV vaccine) for herpes zoster; and MK-1439 (doravirine) and MK-1439A (doravirine/lamivudine/tenofovir disoproxil fumarate) for HIV. Successful development of these products may help Merck & Co in its revenue growth.

Strategic acquisition to strengthen Merck & Co.'s portfolio

The company has acquired various businesses in the recent past, which are highly complementary to its portfolio. For instance, in February 2018, the company's subsidiary acquired Viralytics, an Australian publicly traded company focused on oncolytic immunotherapy treatments for a range of cancers to expand the company's immuno-oncology pipeline. As part of the acquisition, Viralytics will become a wholly-owned subsidiary of Merck and the company will gain full rights to cavatak (CVA21), Viralytics's investigational oncolytic immunotherapy. Cavatak is based on Viralytics's proprietary formulation of an oncolytic virus (Coxsackievirus Type A21) that has been shown to preferentially infect and kill cancer cells. In October 2017, the company acquired Rigontec GmbH (Rigontec), a company specialized in RIG-I therapeutics for cancer and tumors. RGT100, Rigontec's lead candidate is in Phase I development evaluating treatment in patients with various tumors and cancer. The new therapy, immuno-oncology approach of engaging the innate immune system to eliminate cancer cells will complement Merck's current pipeline. In March 2017, Merck Animal Health, a division of the company, acquired a controlling interest in Vallee, a leading privately-held producer of animal health products in Brazil. Vallee has an extensive portfolio of more than 100 products spanning parasiticides, anti-infectives and vaccines. Vallee's portfolio includes products for livestock, horses, and companion animals. Merck Animal Health has a broad portfolio of products to protect against some of the most important pathogens affecting livestock. The complementing portfolio of Vallee would further strengthen Merck & Co.'s animal health business portfolio and also its presence in Latin America. Thus, these acquisitions of complementary

businesses are likely to strengthen the company's product portfolio.

Product approvals likely to help the company in catering to unmet medical needs

Merck & Co. has received approvals for a number of products over the recent past. For instance, in June 2018, the company received FDA approval for keytruda, the company's anti-PD-1 therapy, for the treatment of adult and pediatric patients with refractory primary mediastinal large B-cell lymphoma (PMBCL), or who have relapsed after two or more prior lines of therapy. In December 2017, the company received FDA approval for Steglatro (ertugliflozin) tablets, an oral sodium-glucose cotransporter 2 (SGLT2) inhibitor, the fixed-dose combination Steglujan (ertugliflozin and sitagliptin) tablets, and the fixed-dose combination Segluromet (ertugliflozin and metformin hydrochloride) for the treatment of type 2 diabetes. In November 2017, Merck & Co. received FDA approval of PREVYMIS (letermovir). PREVYMIS is used for the prevention of Cytomegalovirus (CMV) infection and diseases in adult allogeneic stem cell transplant patients. In January 2017, Merck & Co. received approval from European Commission (EC) of KEYTRUDA for the first-line treatment of metastatic NSCLC in adults whose tumors have high PD-L1 expression (TPS of 50% or more) with no EGFR or ALK positive tumor mutations. Thus, these product approvals are likely to help the company in catering to unmet medical needs. In May 2017, the company received FDA approval Isentress HD for the treatment of HIV-1 infection patients who are treatment-naïve or whose virus has been suppressed on an initial regimen of Isentress 400 mg given twice daily. In July 2017, the company again received EC approval for Isentress 600 mg film-coated for the treatment f HIV-1 infection in patients who are treatment-naïve or who are virologically suppressed on an initial regimen of Isentress 400 mg twice daily.

Threat

Uncertainty in global economic conditions together with austerity measures being taken by certain governments

The uncertainty in global economic conditions may result in a further slowdown that could affect Merck & Co.'s business by reducing the prices that drug wholesalers and retailers, hospitals, government agencies and managed health care providers may be able or willing to pay for the company's products or by reducing the demand for the company's products, which could in turn negatively impact its sales and result in a material adverse effect on its business, cash flow, results of operations, financial position and prospects. Global efforts toward health care cost containment continue to exert pressure on product pricing and market access. In many international markets, government-mandated pricing actions have reduced prices of generic and patented drugs. The company anticipates these pricing actions and other austerity measures will continue to negatively affect revenue performance in 2018. If credit and economic conditions worsen, the resulting economic and currency impacts in the affected markets and globally could have a material adverse effect on the company's results.

Negative events in the animal health industry

Future sales of key animal health products could be adversely affected by a number of risk factors. For example, the outbreak of disease carried by animals, such as Bovine Spongiform Encephalopathy or mad cow disease, could lead to their widespread death and precautionary destruction as well as the reduced

consumption and demand for animals, which could adversely impact the company's results of operations. Also, the outbreak of any highly contagious diseases near the company's main production sites could require the company to immediately halt production of vaccines at such sites or force the company to incur substantial expenses in procuring raw materials or vaccines elsewhere. Other risks specific to animal health include epidemics and pandemics, government procurement and pricing practices, weather and global agribusiness economic events. As the animal health segment of the company's business becomes more significant, the impact of any such events on future results of operations would also become more significant. This in turn may have a negative impact on the company's future results of operations.

Intense competition

Merck & Co. faces intense competition from its competitors for products, which could lead to non-cash impairment charges. The company faces competition from lower-cost generic products that creates risk of biosimilar products and the company may not be able protect its patents right. In some countries, patent protection is significantly weaker than in the US or in the EU. The company also faces competition while launching of any new product of competitor in the market. The competitor's product may be safer or more effective, more convenient to use, more effectively marketed and sold than the company’s products. This could have a material adverse effect on its business, cash flow, results of operations, financial position and prospects. Some of the major competitors of Merck & Co. include AbbVie Inc, Amgen Inc, Bristol-Myers Squibb Co, Eli Lilly and Co and F. Hoffmann-La Roche Ltd.