

COMPANY PROFILE

# Bayer Healthcare Pharmaceuticals

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## COMPANY OVERVIEW

Bayer HealthCare Pharmaceuticals, (Bayer Healthcare or 'the company'), a subsidiary of Bayer AG is involved in development and commercialization of drugs in cardiovascular and blood diseases, oncology, ophthalmology and women's healthcare. The company offers cardiovascular and blood disorder treatment drugs, women healthcare products, contraceptives, erectile dysfunction medicines, testosterone deficiency treatment and ophthalmology products. It also offers oncology products, hematology drug, multiple sclerosis treatment drugs, diabetes treatment drugs, drugs for treatment of infectious diseases (respiratory tract infections, urinary-tract infections, serious skin infections), diagnostic imaging equipment and contrast agents. Bayer Pharma offers its products under brands such as Adalat, Adempas, Aleve, Adengo, Nebido, Xarelto, Xofigo, Yasmin, YAZ among others. It operates through its research and development facilities in Germany, France, China and the US. Bayer HealthCare is headquartered in Berlin, Germany.

## KEY FACTS

<b>Head Office</b>	Bayer Healthcare Pharmaceuticals Mullerstr 178 Berlin Berlin Berlin Berlin DEU
<b>Phone</b>	49 30 4681111
<b>Fax</b>	49 30 46815305
<b>Web Address</b>	<a href="http://www.pharma.bayer.com/">www.pharma.bayer.com/</a>
<b>Revenue / turnover (EUR Mn)</b>	16,847.0
<b>Revenue (USD Mn)</b>	18,993.7
<b>Financial Year End</b>	
<b>Employees</b>	99,762
<b>Ticker</b>	

## SWOT ANALYSIS

Bayer HealthCare Pharmaceuticals (Bayer HealthCare or 'the company'), a pharmaceutical business division of Bayer, primarily focuses on the development and commercialization of drugs for cardiovascular and blood diseases, oncology, ophthalmology and women's healthcare. The company's strong portfolio of pharmaceutical products, strategic alliance, global footprint and focus on research and development are its major strengths. Lawsuits is a cause of concern. But, the company finds growth opportunities from Agreements and collaborations, product approvals and positive outlook for the global pharmaceutical industry. However, growing parallel trade, intellectual property risk and regulatory controls could hamper the future business prospects of the company.

<p><b>Strength</b></p> <p>Strong portfolio of pharmaceutical products Strategic Alliance Global footprint Focus on research and development</p>	<p><b>Weakness</b></p> <p>Lawsuits</p>
<p><b>Opportunity</b></p> <p>Agreements and collaborations Product approvals Positive outlook for the global pharmaceutical industry</p>	<p><b>Threat</b></p> <p>Regulatory controls Growing parallel trade Intellectual property risk</p>

### Strength

Strong portfolio of pharmaceutical products

Bayer Healthcare has a strong portfolio of branded pharmaceuticals products. The company's range of cardiovascular products includes the anticoagulant Xarelto, Adalat to treat hypertension and coronary heart disease, and Aspirin Cardio for secondary prevention of heart attacks. The product portfolio in women's healthcare comprises contraceptives such as YAZ/Yasmin/Yasminelle, Mirena, Diane-35, Jaydess/Skyla, and Kyleena, among others. The company also offers specialty pharmaceuticals that are mainly prescribed by specialist physicians, including Kogenate for people with hemophilia A, Betaferon/ Betaseron to treat multiple sclerosis, the cancer drugs Nexavar, Stivarga (regorafenib) and Xofigo (radium-223 dichloride), the eye medicine Eylea (aflibercept), and Ventavis and Adempas to treat two forms of pulmonary hypertension. The company's pharmaceutical products are primarily distributed through wholesalers, pharmacies and hospitals. A strong portfolio of branded pharmaceutical products drives Bayer Pharma's growth.

Strategic Alliance

Bayer Healthcare has strategic partnerships and alliances which help it in developing new drugs and

keeping its pipeline robust. For instance, with Evotec, it has a research collaboration to identify and validate development candidates in endometriosis; while with ImmunoGen, it has a partnership in the field of antibody-drug conjugates (ADCs) for novel tumor therapies. The company has a development and marketing collaboration in the field of soluble guanylate cyclase (sGC) modulation with Merck & Co.; while with Novartis, it is engaged in the development of a targeted antibiotic inhalation therapy for lung infections. With Janssen Research & Development, a Johnson & Johnson company, Bayer Pharma is engaged in the development of Xarelto. The company also has research collaboration with academic institutions. For instance, with Ludwig Boltzmann Institute, Bayer Pharma has an alliance for lung vascular research; while with Broad Institute, it has a strategic partnership in the field of genome and drug research in cardiology aimed at using findings from human genetics to develop new cardiovascular therapies and in the field of oncology to identify and develop active ingredients that target tumor-specific gene alterations. With University of Oxford, the company has a strategic alliance for the development of novel gynecological therapies.

#### Global footprint

Bayer Healthcare has geographically diversified operations. It has production locations in Europe, the US, Latin America and Asia, while its R&D facilities are located in Germany, Norway, Finland and the US. The company's revenues are also geographically diversified. The company classifies its operations into four segments, namely Europe/Middle East/Africa, North America, Asia Pacific and Latin America. In FY2017, Europe/Middle East/Africa segment accounted for 38.2% of the company's total revenues, followed by North America with 29%; Asia Pacific with 21.8%; and Latin America with 11%.

#### Focus on research and development

Bayer Healthcare puts strong focus on its research and development (R&D) activities. Innovation based strategies enables the company to stay abreast of the changes in the industry and provides it with 'first mover' advantage by launching products ahead of competition. The company's R&D initiatives are focused on cardiovascular diseases, hemophilia, ophthalmology, oncology, Gynecology and radiology. The company conducts research and development activities at Germany, the US, Japan, China, Finland and Norway. The company employed 8,138 employees on various research activities. R&D activities. In FY2017, the company transferred ten new molecular entities from research pipeline into preclinical development through various clinical trials with several drug candidates from research and development pipeline as well as developed a new molecular entity (NME) as a new chemical or biological substance. It entered into strategic alliances with various partners such as universities, governmental agencies, start-ups, suppliers and industry. The company also invests in venture capital funds that finance life science start-up companies, and other projects. As of December 2017, Bayer owned around 48,100 valid patents and patent applications worldwide relating to over 4,700 protected inventions. In FY2017, the company spent EUR2,888 million on research activities.

### **Weakness**

#### Lawsuits

The company is exposed to numerous lawsuits for instance, January 2018, the company had

approximately 2,900 US lawsuits filed users under brand Mirena that alleged personal injuries after consumption of Mirena including perforation of the uterus, ectopic pregnancy or idiopathic intracranial hypertension and seek compensatory and punitive damages. In the same month, the five Canadian lawsuits was filed against the company seeking class action certification, Further 22,000 recipients of Xarelto, an oral anticoagulant for the treatment and prevention of blood clots, had been served upon Bayer alleging personal injuries from the use of Xarelto, including gastrointestinal, cerebral or other bleeding and death and seek compensatory and punitive damages; and 16,100 users of Essure, had been served upon Bayer alleging personal injuries from the use of Essure, including perforation, pain, bleeding, hysterectomy, weight gain, depression, nickel sensitivity and unwanted pregnancy. Such lawsuits against some of Bayer Pharma's products may dent its brand image.

## Opportunity

### Agreements and collaborations

The company has formed various agreements and collaborations that are likely to enhance its product pipeline. For instance in July 2018, Bayer Animal Health GmbH signed a global license agreement with Mitsui Chemicals Agro, Inc. to expand its strong parasiticide portfolio for companion animals with new compounds derived from MCAG's (Mitsui Chemicals Agro) chemical library. In June 2018, Bayer and MD Anderson cancer center collaborated on development of novel cancer treatments to improve the development of novel targeted treatments based on patient or tumor characteristics. In March 2018, the company and The Nature Conservancy Brazil entered into an agreement to support farmers in restoring native vegetation on their farms in Brazil.

### Product approvals

Bayer Healthcare received approvals for its various products in the recent past. For instance, in July 2018, Seresto, a drug to reduce the risk of canine leishmaniosis via transmission by sand flies has been approved by the national authorities in many European countries. In February 2018, the Chinese State Food and Drug Administration (CFDA) approved Eylea (aflibercept solution for injection into the eye) the first anti-VEGF drug for the treatment of visual impairment due to diabetic macular edema. In December 2017, the CFDA approved Stivarga (regorafenib) tablets for the second-line treatment of patients with hepatocellular carcinoma. In 2017, the US FDA approved Xarelto 10 mg once daily for the extended treatment of venous thromboembolism; copanlisib (Aliqopa) 60 mg vial for injection for the treatment of adult patients with relapsed follicular lymphoma after two prior systemic therapies; and Stivarga (regorafenib) for the second-line systemic treatment of hepatocellular carcinoma. In August 2017, the European Commission granted marketing authorization for Stivarga (regorafenib) for the treatment of adult patients with hepatocellular carcinoma who have been previously treated with Nexavar (sorafenib). In June 2017, the Ministry of Health, Labour and Welfare in Japan granted marketing authorization for Stivarga (regorafenib) tablets for the second-line treatment of unresectable hepatocellular carcinoma. These approvals would enhance Bayer Pharma's effort to bring innovative treatments to the market in the field of hemophilia. These product approvals may help Bayer Pharma in its revenue growth.

### Positive outlook for the global pharmaceutical industry

The company could benefit from the growing global pharmaceutical industry. According to an in-house research report, the market already realized a strong growth in past and is aiming for further positive result in coming future. In 2017, the global pharmacy market had total revenues US\$1,066.5 billion, where Asia Pacific led the market with revenues of US\$291 billion. The global market is further expected to grow at a CAGR of 5.9% during 2017-22 to reach value of US\$1,423.6 billion by the end of 2022. In FY2017, the US accounted for 37.6% of the global pharmaceutical market followed by Asia Pacific (27.3%). Major factors driving the growth include increased specialty drug innovation, greater patient access to medicines in developing countries and reduced impact from patent expiry dates. Apart from these, the global pharmaceutical market is projected to be strongly influenced by positive global GDP growth, innovations and the introduction of new products, wider access to healthcare services and rising funding. The company provides various solutions to pharmaceutical industries. Thus, positive outlook of global pharmaceutical industry may help in increasing demand for the company's products.

## Threat

### Regulatory controls

Pharmaceutical product prices are subject to regulatory controls in many markets. Some governments intervene directly in setting prices. In addition, in some markets major purchasers of pharmaceutical products have the economic power to exert substantial pressure on prices. Price controls as well as price pressure from generic manufacturers as a result of government reimbursement systems favoring less expensive generic pharmaceuticals over brand-name products diminish Bayer Pharma's earnings from its pharmaceutical products and could potentially render the market introduction of a new product unprofitable. This, in turn, could have a negative impact on Bayer Pharma's profitability.

### Growing parallel trade

The rising trend of parallel trade in pharmaceutical products in the EU countries could impact considerably the company's ability to effectively leverage revenue generating opportunities. Parallel traders exploit the differential pricing mechanisms in various EU countries by buying drugs from countries where they are cheap and reselling them in countries where they are priced higher; thereby denying the company its legitimate right to leverage the differential pricing to increase its profitability. It is estimated that parallel trade accounts for close to 10% of total pharmaceutical sales in the EU.

### Intellectual property risk

The company's intellectual property rights could be challenged, invalidated, or infringed by its competitors. The company has strong R&D activity which allowed it to develop several new technologies. The company's intellectual property includes patents, trademarks, industrial design rights and various trade secrets. Currently, the company has several issued and pending patents applications worldwide. Failure to meet the requirements in securing its technology could adversely hamper the company's competitive position. Similarly, the company could face infringement claims and incur additional costs that would affect its profitability.

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