COMPANY PROFILE

AstraZeneca PLC

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COMPANY OVERVIEW

AstraZeneca PLC (AstraZeneca or 'the company') is global biopharmaceutical company involved in developing, manufacturing and marketing prescription pharmaceuticals. The company provides drugs for three therapeutic areas including oncology, cardiovascular and metabolic disease (CVMD) and respiratory, while selectively pursuing therapies in autoimmunity, infection and neuroscience. The company has three strategic R&D centers located in Gaithersburg, the US; Gothenburg, Sweden; and Cambridge, the UK. Major brands of the company include Faslodex, Zoladex, Tagrisso, Iressa,Symbicort, Pulmicort, Lynparza, Nexium, and Onglyza. The company primarily operates across the Americas, Europe and Asia. AstraZeneca is headquartered in London, the UK.

The company reported revenues of (US Dollars) US$22,465 million for the fiscal year ended December 2017 (FY2017), a decrease of 2.3% over FY2016. In FY2017, the company's operating margin was 16.4%, compared to an operating margin of 21.3% in FY2016. In FY2017, the company recorded a net margin of 13.4%, compared to a net margin of 15.2% in FY2016.

The company reported revenues of US$5,155.0 million for the second quarter ended June 2018, a decrease of 0.4% over the previous quarter.

KEY FACTS

Head Office	AstraZeneca PLC 1 Francis Crick Avenue Cambridge Biomedical Campus London W2 6BD London England London England GBR
Phone	44 20 73045000
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Web Address	www.astrazeneca.com
Revenue / turnover (USD Mn)	22,465.0
Financial Year End	December
Employees	61,100
London Stock Exchange (LON) Ticker	AZN

SWOT ANALYSIS

AstraZeneca (or 'the company') is a UK-based global biopharmaceutical company. The company is engaged in the development manufacture, and marketing of prescription biopharmaceuticals in primarily in the therapeutic areas of cardiovascular, gastrointestinal, neuroscience, oncology, respiratory, inflammation, and infection. The company's wide product portfolio across various therapeutic areas enables it to cater to the needs of its customer base in diverse markets. However, uncertain R&D outcomes, influx of generics and government regulations are likely to affect AstraZeneca's sales growth and operating profit margin.

Strength	**Weakness**
Significant R&D capabilities and manufacturing and supply resources Wide product portfolio across various therapeutic areas	Substantial debt Product recalls
Opportunity	**Threat**
Acquisitions likely to increase the market share of AstraZeneca Collaborations to develop novel immuno-oncology therapeutic area Aging global population and increasing unmet medical needs Initiatives to expand breadth and depth of patient offering in respiratory therapeutic area	Influx of generics Government regulations Uncertain R&D Outcomes

Strength

Significant R&D capabilities and manufacturing and supply resources

AstraZeneca has significant research and development (R&D) capabilities. The company's small molecule sites are located in the UK (Cambridge and Macclesfield), Sweden (Molndal), the US (Gaithersburg, Maryland and Waltham, Massachusetts), Japan (Osaka) and China (Shanghai). Its biologics sites are located in the UK (Cambridge) and in the US (Gaithersburg, Maryland and Mountain View, California). Its Gaithersburg, Maryland site focuses on late-stage development for small molecules and biologics across its entire portfolio. The company also has its R&D facility in China (Shanghai).

In FY2017, AstraZeneca spent US$5.4 billion on its R&D activities. The company also has significant manufacturing and supply resources. Its principal small molecule manufacturing facilities are in the UK (Avlon and Macclesfield), Sweden (Gartuna and Sodertalje), the US (Newark, Delaware; Westborough, Massachusetts; and West Chester, Ohio), China (Wuxi and Taizhou), Russia (Vorsino), France (Reims

and Dunkerque), Japan (Maihara), Australia (North Ryde), Indonesia (Jakarta), Egypt (Cairo), Puerto Rico (Canovanas), Germany (Wedel), Mexico (Lomas Verdes), Brazil (Cotia) and Argentina (Buenos Aires). The company operates sites for the manufacture of APIs in the UK and Sweden, complemented by the use of external sourcing. Its principal tablet and capsule formulation sites are in the UK, Sweden, Puerto Rico and the US. AstraZeneca also has major formulation sites for the global supply of parenteral and/ or inhalation products in Sweden, France, Australia and the UK. For biologics, its principal commercial manufacturing facilities are in the US (Frederick, Maryland and greater Philadelphia, Pennsylvania), the UK (Speke), and the Netherlands (Nijmegen) with capabilities in process development, manufacturing and distribution of biologics, including global supply of MAbs and influenza vaccines. AstraZeneca's significant R&D capabilities and manufacturing and supply resources help it in manufacturing its product efficiently that caters to unmet needs of its large customer base.

Wide product portfolio across various therapeutic areas

AstraZeneca has a strong product portfolio. It offers its products across various therapeutic areas, namely, cardiovascular and metabolic; oncology; respiratory, inflammation and autoimmunity; infection; neuroscience; and gastrointestinal.

In the cardiovascular therapeutic area, the company manufactures drugs such as Atacand/Atacand HCT/Atacand Plus for the treatment of hypertension and symptomatic heart failure; Brilinta/Brilique (ticagrelor), an oral antiplatelet for acute coronary syndromes (ACS); and Crestor 2 (rosuvastatin calcium), a statin for dyslipidaemia and hypercholesterolemia. For metabolic diseases, AstraZeneca manufactures diabetes treatment drugs like Byetta (exenatide injection), an injectable medicine indicated to improve blood sugar (glucose) control.

In oncology, the company's drugs, among others, include Arimidex (anastrozole), an aromatase inhibitor used to treat breast cancer; and Caprelsa (vandetanib), a kinase inhibitor indicated to treat aggressive and symptomatic medullary thyroid cancer (MTC) in patients with unresectable locally advanced or metastatic disease. In the respiratory, inflammation and autoimmunity therapeutic area, AstraZeneca's products include Accolate (zafirlukast), an oral leukotriene receptor antagonist used for the treatment of asthma; and Rhinocort (budesonide), a nasal steroid used as a treatment for allergic rhinitis (hay fever), perennial rhinitis and nasal polyps, among others.

In the area of infection, the company's products include Synagis (palivizumab), a humanised MAb used to prevent serious lower respiratory tract disease caused by RSV in paediatric patients at high risk of acquiring RSV disease; Cubicin (daptomycin) to treat serious infections in hospitalized patients; and Merrem/Meronem (meropenem) to treat serious infections in hospitalized patients. In neuroscience, AstraZeneca manufactures drugs such as Seroquel IR (an immediate release formulation of quetiapine fumarate), an atypical antipsychotic generally approved for the treatment of schizophrenia and bipolar disorder (mania, depression and maintenance); and Naropin (ropivacaine), an anaesthetic for surgical anaesthesia and acute pain management. In gastrointestinal therapeutic area, the company's drugs include Entocort (budesonide), a locally-acting corticosteroid used to treat inflammatory bowel disease; and Losec/Prilosec (omeprazole) used for the short- and long-term treatment of acid-related diseases.

A wide product portfolio across various therapeutic areas enables AstraZeneca to cater to the needs of its customer base in diverse markets. The company also has a well-diversified revenue stream from its

product categories. In FY2017, the company generated 36% of its total revenues from cardiovascular and metabolic products, followed by respiratory (23%); other disease areas (21%) and oncology products (20%). A well-diversified revenue stream offsets the company's exposure to the risks associated with a particular business in various therapeutic markets it serves.

Weakness

Substantial debt

AstraZeneca has substantial debt, which may adversely affect its operations and may further weaken its financial position. The company reported total debt of US$17,807 million during FY2017, representing an annual increase of 5.9%. The significant increase in debt limits its ability to obtain additional financing in future for working capital, and for other strategic initiatives.

Product recalls

Product recalls have a negative impact on the company’s brand image and may also result in decrease in customers’ confidence in the company, which in turn affect its profitability. In May 2017, the company voluntarily recalled one lot of professional (physician) sample bottles containing eight tablets of BRILINTA (ticagrelor) 90mg tablets as a precautionary measure, as it might contain RAMPIC (lesinurad) 200 mg tablets.

Opportunity

Acquisitions likely to increase the market share of AstraZeneca

AstraZeneca has been strengthening its business division through acquisitions and divestitures since the past few years. For instance, in May 2016, AstraZeneca completed the acquisition of the core respiratory business of Takeda Pharmaceutical Company Limited (Takeda) which includes the expansion of rights to roflumilast (marketed as Daliresp in the US and Daxas in other countries), the only approved oral PDE4 inhibitor for the treatment of chronic obstructive pulmonary disease (COPD) and also provide AstraZeneca with access to other marketed respiratory medicines and early pipeline products.

In February 2016, AstraZeneca completed the transaction to acquire a majority equity stake in Acerta Pharma, a privately-owned biopharmaceutical company based in the Netherlands and US. This provides the company with irreversible oral Bruton's tyrosine kinase (BTK) inhibitor, acalabrutinib (ACP-196), currently in Phase II/III development for B-cell blood cancers and in Phase I/II clinical trials in multiple solid tumours. Expanding further into B-cell cancers, acalabrutinib is estimated to reach potential peak-year sales in excess of $5 billion globally.

Earlier, AstraZeneca acquired all the outstanding shares of ZS Pharma, a biopharmaceutical company based in San Mateo, California for $90 per share. This transaction is likely to strengthen AstraZeneca’s cardiovascular and metabolic disease (CVMD) portfolio with the addition of the potassium-binding compound ZS-9 (sodium zirconium cyclosilicate), a potential best-in-class treatment for hyperkalaemia, a

condition associated with increased mortality in patients with chronic kidney disease (CKD), diabetes mellitus (DM), and chronic heart failure (CHF). Such acquisitions and alliances could help AstraZeneca expand its market share and provide it with a competitive edge.
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Collaborations to develop novel immuno-oncology therapeutic area

AstraZeneca has formed new collaborations with other pharmaceutical companies. For instance, in October 2017, the company and MedImmune entered into clinical trial collaboration in early lung cancer with Incyte Corporation. Under the agreement, the companies would conduct a Phase III trial to evaluate Imfinzi and epacadostat in patients with locally-advanced (Stage III), unresectable non-small cell lung cancer (NSCLC) disease which is not progressed following platinum-based chemotherapy along with radiation therapy (CRT).
In July 2017, AstraZeneca and Merck entered into strategic oncology collaboration to develop and commercialize the potential of Lynparza, the world’s first and leading PARP and MEK inhibitors in combination with PD-L1/PD-1 medicines for the treatment of multiple cancer types. Earlier, the company entered into an agreement with Heptares Therapeutics, a wholly-owned subsidiary of Sosei Group Corporation, under which AstraZeneca would acquire exclusive global rights to develop, manufacture and commercialize the adenosine A2A receptor antagonist, HTL-1071, a small molecule immuno-oncology candidate, and potential additional A2A receptor-blocking compounds. AstraZeneca would explore the assets across a range of cancers, including in combination with its existing portfolio of immunotherapies. By combining the pioneering A2A receptor programme with the strength of AstraZeneca's oncology portfolio, the company hopes to develop novel treatments with the potential to transform the lives of patients. Previously, the company formed a collaboration with Peregrine Pharmaceuticals to evaluate the safety and efficacy of Peregrine's investigational phosphatidylserine (PS)-signalling pathway inhibitor, bavituximab, in combination with its AstraZeneca's investigational anti-PD-L1 immune checkpoint inhibitor, durvalumab (MEDI4736). According to AstraZeneca, the combination therapy in immuno-oncology has the potential to be a novel and effective approach to treat cancer. The partnership with Peregrine provides AstraZeneca with an opportunity to explore a novel combination that could deliver important clinical benefit to patients across a range of cancers.

Aging global population and increasing unmet medical needs

The world population is expected to rise from its current level of some seven billion to reach nine billion by 2050. In addition, the number of people who can access healthcare continues to increase, particularly among the elderly. Globally, it is estimated that between 2000 and 2050, the number of people aged 60 years and over will increase from 605 million to two billion. Developing markets now represent approximately 85% of the world population and over 20% of the world's pharmaceutical revenues. Faster-developing economies, such as China, India and Brazil, offer new growth opportunities for the pharmaceutical industry. As AstraZeneca provides its biopharmaceutical products in several therapeutic areas across various countries, it is likely to benefit from rapidly aging population and its increasing demand for healthcare products and services. AstraZeneca has taken several initiatives to expand breadth and depth of patient offering in respiratory therapeutic area.
In October 2017, the company partnered with International Diabetes Federation, the World Heart Federation and Primary Care Diabetes Europe,to build momentum for tangible policy changes addressing

outcomes for all people with type-2 diabetes.
In July 2017, the company partnered with Merck & Co., Inc., to co-develop and co-commercialise its Lynparza (olaparib) for multiple cancer types. Lynparza is an innovative, first-in-class oral poly ADP ribose polymerase (PARP) inhibitor currently approved for BRCA-mutated ovarian cancer in multiple lines of treatment. By 2030, AstraZeneca anticipates that the number of people dying from cardiovascular diseases will reach 23.3 million a year, while deaths from cancer will continue rising, to an estimated 13.1 million annually.

Initiatives to expand breadth and depth of patient offering in respiratory therapeutic area

AstraZeneca entered an agreement with Abbott, to develop companion diagnostic tests to identify patients with severe asthma who are most likely to benefit from the investigational biological therapy, tralokinumab. As mentioned by AstraZeneca, to date, no companion diagnostic blood tests have been approved for use in asthma. Under the terms of the agreement, Abbott would develop and commercialize diagnostic tests to measure serum levels of the proteins periostin and DPP4 (dipeptidyl peptidase-4), which have been identified as potential predictive biomarkers of up-regulated IL-13 in severe asthma. The tests would be developed in conjunction with AstraZeneca's Phase III trial of tralokinumab, a potential treatment for patients with severe, inadequately controlled asthma, developed by MedImmune. Periostin has been previously described as a potential biomarker for asthma1, and DPP4 is a novel and promising predictive biomarker identified by MedImmune. This partnership with Abbott to develop companion diagnostics for tralokinumab is an important step in delivering on AstraZeneca's ambition to bring innovative options for patients who continue to suffer with severe asthma. The company anticipates that physicians would ultimately use these tests to better identify patients likely to benefit from tralokinumab to bring their condition under control.

Threat

Influx of generics

Pharmaceutical industry across the world is expected to report patent expiries of a large number of innovative drugs in the next few years. Over the last couple of years, the looming arrival of the "patent cliff" has been haunting the pharmaceutical industry, and it is expected to continue until 2018 with the exposure of sales of prescription drugs worth over US$290 billion to generic competition. As the demand for pharmaceuticals grows, governments are exerting increasing pressure on doctors to prescribe cheaper generic medicines. As a result, pharmaceutical manufacturers will be under pressure to develop generic medicines. This makes companies undertake changes in their operations such as deploying the scale and international sourcing capabilities to secure lower prices and better margins on generics in a way in which legislation typically does not permit branded products. An increase of generic penetration will have a direct effect on the prescription medicines. Influx of generics into the market could affect the company’s revenue.

Government regulations

The company operates in a highly regulated industry, where a variety of statutes and regulations are in place for the testing, manufacture and sale of pharmaceutical products. The company has to obtain

regulatory approvals before commercializing its products. The company's products, research and development activities and manufacturing processes are subject to various local, state, federal, foreign and transnational laws and regulations. In the US, the FDA; in Europe, the European Medicines Agency (EMA); and in China, the State Food and Drug Administration (SFDA) of China regulate the manufacture, safety and quality of pharmaceutical products, the commercialization of new pharmaceutical products, and labelling and record keeping procedures. Receiving marketing approval for new pharmaceutical drugs and medical devices from these regulatory agencies is time consuming and expensive. Failure to comply with the present or future regulations related to clinical, laboratory and manufacturing practices may result in delayed approval of drugs, product recalls, and cancellation of permission to produce or sell the drugs. With several products under development, the company faces challenges from its competitors, which have obtained regulatory approvals for marketing. The company's financial position could also be affected due to its inability to obtain or retain regulatory approvals on a timely basis, as this will delay the commercialization of its products.

Uncertain R&D Outcomes

Adverse or inconclusive results from preclinical testing or clinical trials may substantially delay or halt the development of the company's various product candidates, consequently affecting its timeliness for profitability. The outcome of clinical trials is always a subject of uncertainty. After the discovery of a new compound, substantial amount of money and a great deal of time need to be invested to successfully launch a new product. Moreover, it may become necessary to discontinue clinical development if the effectiveness of a drug is not proven as initially expected, or if serious adverse effects arise. Pharmaceuticals are subject to legal restrictions in every country and authorization from regulatory authorities is a prerequisite for a product launch in every country. It is difficult to accurately foresee when approvals for a new product could be obtained.