COMPANY PROFILE

Amgen, Inc.

REFERENCE CODE: 8632C7AC-1633-4198-8551-BB79570C668D
PUBLICATION DATE: 24 Dec 2015
www.marketline.com

MarketLine

TABLE OF CONTENTS

COMPANY OVERVIEW

Amgen (or 'the company') is a biotechnology company engaged in the discovery, development, manufacture, and marketing of innovative human therapeutics. The company mainly focuses in the areas of cancer, kidney disease, rheumatoid arthritis and other serious illnesses. It primarily operates in the US where it is headquartered in Thousand Oaks, California. Amgen employed about 17,900 people as on December 31, 2014.

The company recorded revenues of $20,063 million during the financial year ended December 2014 (FY2014), an increase of 7.4% over FY2013. The operating profit of the company was $6,191 million in FY2014, an increase of 5.5% over FY2013. The net profit of the company was $5,158 million in FY2014, an increase of 1.5% over FY2013.

KEY FACTS

Head Office	Amgen, Inc. One Amgen Center Drive Thousand Oaks California 91320 1799 USA
Phone	1 805 447 1000
Fax	1 805 447 1010
Web Address	http://www.amgen.com
Revenue / turnover (USD Mn)	20,063.0
Financial Year End	December
Employees	17,900
NASDAQ Ticker	AMGN

SWOT ANALYSIS

Amgen (or 'the company') is a pioneering biotechnology company engaged in the discovery, development, manufacture and marketing of human therapeutics. The company's focus and increased investment on R&D has helped it in strengthening its portfolio of human therapeutics further. However, cost containment measures and healthcare reforms could affect Amgen's sales growth and profitability.

Strengths	**Weaknesses**
Significant performance across product portfolio driving Amgen's profitability Strong collaborative arrangements helping Amgen in keeping its product pipeline robust Focus and increased investment on R&D	Significant debt obligations may impact the company's financial flexibility Alleged involvement in misbranding activities
Opportunities	**Threats**
Launch and approvals for new products likely to strengthen Amgen's product portfolio further Neuroscience collaboration with Novartis for Alzheimer's disease and migraine programs Research collaboration and license agreement with Kite Pharma	Cost containment measures may affect sales growth Intensifying competition from biosimilars

Strengths

Significant performance across product portfolio driving Amgen's profitability

Amgen's performance has strengthened over the years. The company recorded revenues of $20,063 million during the financial year ended December 2014 (FY2014), representing a compound annual growth rate (CAGR) of 8% between 2012and 2014. Amgen's performance in FY2014 was driven by strong execution across the portfolio. On a year-to-year basis, during FY2014, its product sales grew by 6.3% in the US, and by 11.2% in rest of the world.

Neulasta (pegfilgrastim) and Neupogen (filgrastim) sales grew in FY2014 with an established track record of efficacy and safety in the oncology setting. Notably, Neulasta represents more than 75% of the company's filgrastim business. Sensipar/Mimpara (cinacalcet), the company's therapy for patients with secondary hyperparathyroidism on dialysis, generated sales of $1.1 billion in FY2014.

Furthermore, Nplate (romiplostim) and Vectibix (panitumumab) continued to grow, while Aranesp (darbepoetin alfa) remained an important therapy in use by physicians for the treatment of anemia.

Due to strong sales performance by products, Amgen's operating and net profits have recorded double-digit CAGR growth during FY2012-14. The company's operating profit in FY2014 was $6,191 million, representing a compounded annual growth rate (CAGR) of 5% between FY2012 and FY2014. In FY2014, Amgen's net profit was $5,158 million, increasing at a CAGR of 9% between 2012 and 2014.

Strong collaborative arrangements helping Amgen in keeping its product pipeline robust

Amgen has strong collaborative arrangements, for the research and development (R&D), manufacture and/or commercialization of products and/or product candidates. For instance, the company has collaborative arrangements with Bayer HealthCare Pharmaceuticals (Bayer), AstraZeneca and Kirin-Amgen (K-A).

As a result of its acquisition of Onyx, Amgen is party to a collaboration with Bayer to jointly develop and commercialize Nexavar (sorafenib) worldwide, except in Japan. The rights to develop and market Nexavar in Japan are reserved to Bayer. In all countries outside of the US, except Japan, Amgen receives 50% of net profits on sales of Nexavar after deducting certain Bayer related costs.

The company is in a collaboration with AstraZeneca to jointly develop and commercialize certain monoclonal antibodies from its (Amgen's) clinical inflammation portfolio, including brodalumab, AMG 139, AMG 157, AMG 181, AMG 557 and AMG 570. The agreement covers the worldwide development and commercialization of these antibodies, except for certain Asian countries for brodalumab and Japan for AMG 557 and AMG 570, which are licensed to other third parties.

K-A, a 50:50 joint venture of Amgen with Kirin Holdings Company, granted an exclusive license to Amgen to manufacture and market G-CSF and pegfilgrastim in the US, Europe, Canada, Australia, New Zealand, Mexico, all Central and South American countries and certain countries in Asia and the Middle East.

Strong collaborative arrangements help Amgen in keeping its product pipeline robust.

Focus and increased investment on R&D

Amgen's R&D activities focus on novel human therapeutics for the treatment of grievous illness in the areas of oncology, hematology, inflammation, bone health, nephrology, cardiovascular and general medicine including neuroscience. Amgen's discovery research programs may therefore yield targets that lead to the development of human therapeutics delivered as large molecules, small molecules, or other combination or new modalities. The company has gained significant expertise in the discovery and development of protein therapeutics. Through techniques such as PEGylation and glycosylation, Amgen has enhanced the clinical profile of its lead products by increasing potency and duration of action.

The company has major R&D centers in several locations throughout the US and in the UK. Amgen also has smaller research centers and development facilities in Canada, Germany, China, Japan, Switzerland and other countries.

The company's R&D spend was $4,297 million in FY2014, representing a compound annual growth rate (CAGR) of 10% between FY2010 and FY2014. The increase in R&D expense for 2014 was driven primarily by increased costs of $326 million associated with Onyx across all categories of R&D spend, as well as increased costs associated with other later stage clinical program support.

Focus and increased investment on R&D has helped Amgen further strengthen its portfolio of human therapeutics.

Weaknesses

Significant debt obligations may impact the company's financial flexibility

Amgen has a significant level of indebtedness. The company reported an increased total debt of $30,715 million in FY2014, compared to $13,362 million in FY2010. As a result, Amgen's debt to equity ratio increased from 0.5 in FY2010 to 1.1 in FY2014. Consequently, the company had to spend pay more on interest repayments. For instance, the company recorded interest expenses of $1,071 million in FY2014, compared to $604 million in FY2010. High debt may affect Amgen's financial flexibility to fund its expansion.

Alleged involvement in misbranding activities

During 2012, Amgen finalized a settlement agreement with the US government, 49 states and the District of Columbia related to certain promotional practices related to the drugs Aranesp, Epogen, Neupogen, Neulasta, Enbrel and Sensipar as alleged in the unsealed qui tam complaints. The company was guilty to a single misdemeanor count of misbranding Aranesp by promoting it in a way that was different from the dosages in the label. In connection with entering into the settlement agreement, the company also entered into a Corporate Integrity Agreement with the Office of Inspector General of the US Department of Health and Human Services that requires Amgen to maintain its corporate compliance program and to undertake a set of defined corporate integrity obligations for a period of five years. Due to the breadth of the statutory provisions and the absence of guidance in the form of regulations or court decisions addressing some of Amgen’s practices, it is possible that in the future Amgen’s practices might be further challenged under anti-kickback or similar laws.

Hence, involvement in such activities may dent Amgen's brand image.

Opportunities

Launch and approvals for new products likely to strengthen Amgen’s product portfolio further

Amgen, in March 2015, launched Neulasta delivery kit in the US. The delivery kit includes a specially designed single-use prefilled syringe co-packaged with the new on-body injector for Neulasta. As stated by Amgen, this injection system allows cancer patients who are at high risk of infection undergoing chemotherapy to receive Neulasta automatically, and at the appropriate time following chemotherapy, without having to return to the doctor's office.

Amgen has also received approvals for several of its products in the recent past. For instance, in April 2015, the FDA approved Amgen's Corlanor (ivabradine) to reduce the risk of hospitalization for worsening heart failure in patients with stable, symptomatic chronic heart failure. Many heart failure patients are repeatedly admitted to the hospital, which could cause a great burden on the patient and on healthcare resources. As reported by the company, heart failure costs an estimated $31 billion in the US each year, with the majority of the cost related to hospitalizations. By 2030, the cost of heart failure in the US is expected to increase almost 127% totaling $70 billion. Hence, the approval of Corlanor as an innovative therapeutic option would help Amgen address a major unmet need for these patients in the US.

In August 2015, the FDA approved Amgen's new cholesterol-lowering medication Repatha (evolocumab). Repatha is a human monoclonal antibody that inhibits proprotein convertase subtilisin/kexin type 9 (PCSK9), a protein that reduces the liver's ability to remove low-density lipoprotein cholesterol (LDL-C, or 'bad' cholesterol), from the blood. Repatha is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of LDL-C; and as an adjunct to diet and other LDL-lowering therapies for the treatment of patients with homozygous familial hypercholesterolemia (HoFH), who require additional lowering of LDL-C. With the approval of Repatha in the US as patients and physicians would have a new treatment option to lower LDL cholesterol.

Launch and approvals for new products is likely to strengthen Amgen's product portfolio further.

Neuroscience collaboration with Novartis for Alzheimer's disease and migraine programs

Amgen, in September 2015, announced neuroscience collaboration with Novartis in the areas of Alzheimer's disease and migraine. The collaboration accelerates Amgen's potential entry into Alzheimer's disease by teaming up with Novartis on a differentiated and genetically validated Alzheimer's disease program directed at genetically predisposed individuals at risk of developing Alzheimer's disease. The collaboration would also enable Amgen to focus on the commercialization of its migraine programs in the US, Canada and Japan, while leveraging Novartis' strong commercial capabilities in neuroscience throughout Europe and other markets worldwide.

The agreement combines each company's BACE (beta-site APP-cleaving enzyme-1) programs targeting Alzheimer's disease into a global co-commercialization and co-development arrangement. Novartis' Phase 1/2a BACE inhibitor (CNP520) would be the lead molecule and each company's pre-clinical BACE inhibitor programs would be potential follow-ons. CNP520 is an oral drug designed to prevent the production of different forms of amyloid and has the potential to prevent, slow or delay the symptoms associated with Alzheimer's disease. It is currently in Phase 1/2a trials.

Amgen would make upfront and milestone payments, and would be responsible for disproportional R&D costs for an agreed-upon period followed by a 50:50 cost and profit share arrangement. As part of the collaboration, Novartis received global co-development rights and commercial rights outside the US, Canada and Japan to the investigative molecules in Amgen's migraine portfolio program. This includes AMG 334 in Phase 3 and AMG 301 in Phase 1, as well as an option to commercialize an additional early-stage Amgen molecule in these territories. In exchange for territory rights, Novartis would fund disproportional amounts of global R&D expenses for an agreed-upon period on the migraine programs and pay Amgen double-digit royalties on sales.

Hence, Amgen’s collaboration with Novartis on BACE inhibition would provide it (Amgen) with a strategic focus on genetically validated drug candidates, while the collaboration on migraine creates an opportunity for it to rapidly advance AMG 334 on a global scale.

Research collaboration and license agreement with Kite Pharma

In January 2015, Amgen and Kite Pharma entered into a strategic research collaboration and license agreement to develop and commercialize the next generation of novel Chimeric Antigen Receptor (CAR) T cell immunotherapies based on Kite's engineered autologous cell therapy (eACT) platform and Amgen's extensive array of cancer targets. Under the terms of the agreement, Amgen will contribute cancer targets, and Kite would leverage its proprietary CAR platform, research and development and manufacturing capabilities, and expertise. Kite would be responsible for conducting all preclinical research and cell manufacturing and processing through Investigational New Drug (IND) filing. Each company would then be responsible for clinical development and commercialization of their respective CAR therapeutic candidates, including all related expenses.

Kite Pharma is a clinical-stage biopharmaceutical company engaged in the development of novel cancer immunotherapy products, with a primary focus on eACT designed to restore the immune system's ability to recognize and eradicate tumors. Kite's leading CAR T Cell therapy platform would help the company to advance its new promising therapeutic approach to fight cancer.

Threats

Cost containment measures may affect sales growth

Sales of all of Amgen's principal products are dependent on the availability and extent of coverage and reimbursement from third-party payers, including government healthcare programs and private insurance plans. Governments and private payers may regulate prices, reimbursement levels and/or access to the products to control costs or to affect levels of use of the products. Amgen relies in large part on the reimbursement for its principal products through government programs such as Medicare and Medicaid in the US and similar programs in foreign countries and a reduction in the coverage and/or reimbursement for its products could have a material adverse effect on the product sales, business and results of operations.

In the US, there is an increased focus by the federal government and others on analyzing the impact of various regulatory programs on the federal deficit, which could result in increased pressure on federal programs to reduce healthcare costs.

Cost containment measures and healthcare reforms resulting in drug price reduction could affect Amgen's sales growth and profitability.

Intensifying competition from biosimilars

Amgen faces increased competition in Europe from biosimilars. To the extent that governments adopt more permissive approval frameworks and competitors are able to obtain broader marketing approval for biosimilars, Amgen’s products will become subject to increased competition. Expiration or successful challenge of applicable patent rights could trigger such competition, and Amgen could face more litigation regarding the validity and/or scope of its patents. Its products may also experience greater competition from lower-cost biosimilars that come to market as branded products that compete with its products lose patent protection.

In the European Union (EU), the European Commission (EC) has granted marketing authorizations for several biosimilars pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued since 2005. In In addition, in an effort to spur biosimilar utilization and/or increase potential healthcare savings, some European countries, such as France, have considered and may adopt biosimilar uptake measures such as requiring physician prescribing quotas or automatic substitution by pharmacists of biosimilars for the corresponding reference products. Some EU countries may impose automatic price reductions upon market entry of the second or third biosimilar competitor. Amgen's inability to compete effectively with such competitors could reduce its sales, which could have a material adverse effect on its business and results of operations.