COMPANY PROFILE

Sanofi

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COMPANY OVERVIEW

Sanofi (or 'the group'), formerly Sanofi-Aventis, is a France-based international pharmaceutical group engaged in the research, development, manufacture and marketing of healthcare products. It offers biopharmaceuticals, human vaccines and animal and consumer health products. The group operates in more than 100 countries. It is headquartered in Paris, France, and employed 113,719 people as of December 31, 2011.

The group recorded revenues* of E33,389 million ($46,490.8 million**) during the financial year ended December 2011 (FY2011), an increase of 3.2% over FY2010. The operating profit of the group was E5,731 million ($7,979.8 million**) in FY2011, a decrease of 12.3% over FY2010. The net profit was E5,693 million ($7,926.9 million**) in FY2011, an increase of 4.1% over FY2010.

*Net sales.

**Calculated using a constant conversion rate of E1 = $1.3924 for the year ended December 31, 2011.

KEY FACTS

Head Office	Sanofi 54, Rue La Boetie 75008 Paris FRA
Phone	33 1 53 77 40 00
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Web Address	http://en.sanofi.com/
Revenue / turnover (EUR Mn)	33,389.0
Financial Year End	December
Employees	113,719
Euronext Ticker	SAN
New York Ticker	SNY

SWOT ANALYSIS

Sanofi (or 'the group'), formerly Sanofi-Aventis, is an international pharmaceutical group engaged in the research, development, manufacture and marketing of healthcare products. It offers biopharmaceuticals, human vaccines and animal and consumer health products. Sanofi is a dominant player in the diabetes market via its Lantus (insulin glargine) franchise. The continued strong performance of Lantus has enhanced the group's leadership position in the diabetes market. However, generic competition for its major brands could result in significant decline in sales.

Strengths	**Weaknesses**
Genzyme provides Sanofi strong position in niche rare disease therapy area Continued strong performance of Lantus enabling Sanofi to sustain leadership position in diabetes market Sanofi Pasteur's dominant position in global vaccine market Addition of Chattem provides Sanofi with platform for Rx-OTC switch in the US	Setback in Multaq development program for patients with permanent atrial fibrillation Major drugs' loss of market exclusivity affecting sales growth
Opportunities	**Threats**
Increased sales growth from emerging markets could reduce Sanofi's reliance on traditional markets Acquisition of Pluromed likely to enhance Sanofi's biosurgery portfolio	Claims of possible link between Lantus and increased cancer risk could affect its sales Healthcare cost containment pressures leading to drug pricing controls

Strengths

Genzyme provides Sanofi strong position in niche rare disease therapy area

The $20.1 billion acquisition of Genzyme, a US-based Orphan Drug major provides Sanofi with a strong platform to diversify away from its blockbuster-centric growth model to specialist niche markets. In April 2011, Sanofi completed the acquisition of Genzyme after a hostile takeover bid and a series of enhanced tender offers.

Genzyme has developed a position as the global leader in lysomal storage disorder enzyme replacement therapies (LSDs). By specializing in such niche indications as Gaucher disease (Cerezyme; imiglucerase alpha), Fabry's disease (Fabrazyme; agalsidase beta), and Pompe disease

(Myozyme; alglucosidase alpha), Genzyme can effectively operate in a competition-free environment. In addition, Genzyme has also expanded its focus into other therapy areas, including end-stage renal disease and oncology, through its own acquisition strategy.

Through its strong focus on rare genetic diseases, key products in Genzyme's portfolio are naturally aligned to a much reduced risk of competitive threat via the potential designation of Orphan Drug status (providing a period of 10 years exclusivity in the EU and seven years in the US). Not only does Orphan Drug status allow Genzyme to operate in a competition free market, but has also allowed the company to establish very strong (and necessary) relationships with patients, physicians and health insurance companies on a global scale, thereby enhancing Genzyme's entrenched position in a specific niche disease market prior to the entry of any future competition. Furthermore, there is a very low risk factor to the likelihood of companies with biosimilar capabilities launching biosimilar versions of Genzyme's LSDs, given the entrenched position of Genzyme brands, the small size of market and highly specialized sales force to support commercialization. Therefore, the reduced competitive threat allows Genzyme for the effective extension of a product's lifecycle.

Continued strong performance of Lantus enabling Sanofi to sustain leadership position in diabetes market

Sanofi is a dominant player in the diabetes market via its Lantus (insulin glargine) franchise. Lantus is the world’s leading insulin brand in terms of both sales and units and is available in over 70 countries worldwide. The three leading countries for sales of Lantus in 2011 were the US, France and Japan, which are the largest pharmaceutical markets in the world. Global sales of Lantus were recorded at E3,916 million (approximately $5,453 million) in 2011, reflecting an impressive CAGR of 13% during 2009–11. In addition, Lantus represented 11.7% of the group’s consolidated revenues in 2011. Thus, Lantus’ leadership position in insulin market enhances Sanofi’s top-line growth.

Sanofi Pasteur's dominant position in global vaccine market

Sanofi Pasteur, Sanofi's vaccine business, is one of the leading vaccine companies in the world in terms of sales. In the US, Sanofi Pasteur is the market leader in the segments where it competes. In addition, Sanofi Pasteur is a world leader in the production and marketing of influenza vaccines. Sales of the influenza vaccines Fluzone and Vaxigrip/Mutagrip have more than tripled since 1995 and annual supply reached more than 200 million doses in 2011. Sanofi Pasteur represents an integral element of Sanofi's diversified operating model which would become increasingly important in light of the company's strategic objectives to promote diversity across its business. As efforts to contain public sector pharmaceutical spending continue to intensify in established markets, vaccines are easily positioned as being the most cost effective form of intervention in the relevant disease areas. This has increased the flexibility in pricing of vaccines which also benefit from limited exposure to generic competition. Furthermore, there is significant unmet demand for vaccines in emerging markets.

Addition of Chattem provides Sanofi with platform for Rx-OTC switch in the US

Chattem is a major consumer health player in the US, producing and distributing branded consumer health products, toiletries and dietary supplements across various market segments. Chattem has grown each year for over 140 years. Its historic presence enabled the group to launch Allegra over-the-counter (OTC) in 2011 and has proven to be the most successful OTC launch in the US. Chattem's well-known brands include Gold Bond, Icy Hot, ACT, Cortizone-10, Selsun Blue and Unisom.

Currently, Chattem manages the Allegra brand, and acts as the platform for Sanofi over-the-counter and consumer healthcare products in the US. The acquisition of Chattem in 2010 strengthened Sanofi's position in the world's consumer healthcare arena, and particularly in the US market. Thus, addition of Chattem provides Sanofi with platform for conversion of prescription medicines to over-the-counter products (OTC).

Weaknesses

Setback in Multaq development program for patients with permanent atrial fibrillation

Sanofi announced its decision in July 2011 to discontinue Multaq's PALLAS Phase IIIb trial in patients with permanent atrial fibrillation (AF). The group discontinued the PALLAS trial in patients with permanent AF, different from the population with non-permanent AF for which Multaq is currently approved. The decision follows recommendations from the study's operations committee and the data monitoring committee which observed a significant increase in cardiovascular events in the dronedarone arm.

AF affects almost 10% of the very elderly (80–89 years), and is already a major public health issue. According to industry estimates, it is projected to increase as the population of industrialized countries ages. In the US alone, it is estimated to affect 2.5 million people, while across the EU the figure is expected to be around 4.5 million. Men are at greater risk of developing the AF than women, and many patients with the condition have underlying cardiovascular conditions such as hypertension, coronary heart disease, heart failure and valvular heart disease. Thus, the failure of Multaq in advanced clinical trial in patients with permanent AF could affect Sanofi's ability to tap significant commercial opportunity in the global AF market.

Major drugs' loss of market exclusivity affecting sales growth

Sanofi is already experiencing the initial downward 'drag' on revenues caused by emerging generic competition to certain brands, most notably insomnia offering Stilnox/Ambien (zolpidem), which lost US patent exclusivity in 2007, and allergic rhinitis drug Allegra/Telfast (fexofenadine), which lost patent protection in 2006.

In addition, pediatric exclusivity for Aprovel and Plavix which contribute significantly to the group's net income expired in the US in March 2012 and May 2012, respectively, and the compound patent of Aprovel expired in most of the European Union in August 2012. Also, the US market exclusivity

of Eloxatin expired in August 2012, pursuant to settlement agreements. In addition, in 2011, there was only one generic product of enoxaparin sodium (Lovenox) marketed in the US. The introduction of a second generic in the US market in 2012 is likely to decrease the group’s sales from this product.

Opportunities

Increased sales growth from emerging markets could reduce Sanofi's reliance on traditional markets

Central to Sanofi's current strategy is the goal of increased growth from markets in rest of the world (RoW) and, in particular, emerging markets. Closely tied to this strategy is further diversification of the company's healthcare offering beyond branded prescription pharmaceuticals to expand its presence in generics and OTC products and build upon its industry-leading position in vaccines. Sanofi is well positioned in a number of the fastest growing emerging markets (i.e. the BRIC countries) and also possesses a significant 'base' business of integrating into a bespoke territorial sales and marketing strategy in order to maximize competitive performance.

Moreover, 30% of Sanofi’s 2011 sales were from emerging markets, where it has enhanced its offerings in high growth market segments such as generics and consumer health care by completing 17 transactions and investing a total of approximately E3.7 billion (approximately $5.2 billion) in acquisitions over the last three years. In addition, in FY2011, Sanofi achieved E10 billion (approximately $13.9 billion) sales in emerging markets, including 65% in non-BRIC countries (BRIC being Brazil, Russia, India and China) demonstrating its significant geographic reach. Thus, deeper penetration into emerging markets could help Sanofi reduce its dependence on mature traditional markets such as the US and EU.

Acquisition of Pluromed likely to enhance Sanofi’s biosurgery portfolio

In March 2012, Sanofi entered in to a definitive agreement to acquire Pluromed, a US-based manufacturer of disposable medical devices for surgery. Pluromed has developed a proprietary polymer technology, called Rapid Transition Polymers (RTP), pioneering the use of injectable plugs to improve the safety, efficacy of medical interventions. Its products are used in cardiac and vascular surgery, prostate, kidney and liver surgery, plastic reconstructive surgery and trauma/battlefield applications.

Pluromed’s LeGoo represents a major advancement in surgical technology because of its ability to control bleeding without clamps or snares that can injure the blood vessels. With this acquisition, Sanofi could commercialize LeGoo, the FDA approved and CE marked gel for temporary endovascular occlusion of blood vessels during surgical procedures. Thus, with this acquisition, Sanofi could strengthen its biosurgery portfolio and also enhance its top-line growth by commercialization of the FDA approved LeGoo.

Threats

Claims of possible link between Lantus and increased cancer risk could affect its sales

In 2009, four registry studies were published investigating a possible relationship between insulin analogues, in particular Lantus, and the risk of cancer. In addition, the European Medical Agency (EMEA) has issued a statement which asserts that on the basis of the currently available data, the relationship between Lantus and cancer cannot be confirmed nor excluded.

To study the link between Lantus and cancer, three epidemiological studies (two retrospective cohort studies and one case-control study) have been launched, including the Northern European Study which compares the risk of cancer in adults prescribed insulin glargine versus those prescribed human insulin, and other types of insulin, and in all users of insulin combined. The results of the Northern European database study of Insulin and cancer risk are under review by health authorities and are expected to be presented to scientific conferences in 2012. In addition, the US study compares the risk of breast, prostate and colon cancer (each considered separately) in glargine users versus human NPH insulin users. The study is expected to complete in 2012. Further, the International study of Insulin and cancer, being carried out in the UK, France and Canada, would assess the association of breast cancer with the use of insulins. The study results are expected by end 2012.

Furthermore, in January 2011, the FDA updated its ongoing safety review of Lantus. In addition to the analysis of the four registry analyses published in 2009, the FDA also reviewed results from a five-year diabetic retinopathy clinical trial in patients with type 2 diabetes. Based on these data, the FDA has not concluded at this time that Lantus increases the risk of cancer. However, the FDA review remains ongoing. If a link can be determined, sales of Lantus would be significantly negatively impacted.

Healthcare cost containment pressures leading to drug pricing controls

In many countries the prices of pharmaceutical products are controlled by law. Governments may also influence prices through their control of national healthcare organizations, which can bear a large part of the cost of supplying medicines to consumers. In the recent years, there have been cutbacks in health care spending in major economies. The ongoing financial crisis and its resultant drag on economic growth continue to impact the debt burden of many economies, most notably in Europe. Recent government healthcare reforms in countries such as France, Spain and Germany may restrict pricing and reimbursement. In the US, there are currently no government price controls over private sector purchases, but federal law requires pharmaceutical manufacturers to pay rebates on certain medicines to be eligible for reimbursement under several state and federal healthcare programs. Those rebates increased in 2011 as the health reform law, the Affordable Care Act (ACA), came into effect. Thus, the pressure to control healthcare costs is expected to continue in 2012 and beyond.