Genentech, Inc.

Company Profile

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COMPANY OVERVIEW

Genentech, a wholly-owned member of the Roche Group, is one of the leading biotechnology companies. The company is engaged in the discovery, development, manufacture and commercialization of medicines to address significant unmet medical needs. The company sells its biotechnology products to wholesalers, specialty distributors or directly to hospital pharmacies and specialist physicians in private practice. The company primarily operates in the US. It is headquartered in South San Francisco, California and employed 11,186 people as of December 2008.

The company recorded revenues of $13,418 million during the financial year (FY) ended December 2008, an increase of 14.4% over FY2007. Increase in revenues was majorly due to higher sales of its oncology products. The operating profit of the company was $5,329 million during FY2008, an increase of 26% over FY2007. The net profit was $3,427 million in FY2008, an increase of 23.8% over FY2007.

KEY FACTS

Head Office	Genentech, Inc. 1 DNA Way South San Francisco California 94080 4990 USA
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Revenue / turnover (USD Mn)	13,418.0
Financial Year End	December
Employees	11,186

SWOT ANALYSIS

Genentech, a wholly-owned member of the Roche Group, is one the leading biotechnology companies engaged in the discovery, development, manufacture and commercialization of biotherapeutics for medical conditions in the areas of oncology, immunology, disorders of tissue growth and repair, neuroscience, and infectious disease. The company's specialization in mAb therapies has provided a competitive advantage over its rivals, as the mAb product segment is expected to perform well on the markets during the forecast period (2007-13). However, healthcare cost containment measures affecting the price of Genentech's mAb products could have a negative impact on the company's profit growth.

Strengths	**Weaknesses**
Specializing in mAb therapies—the most attractive product segment out to 2013 Genentech has 'locked out' competition by developing first-to-market therapies with strong clinical data supporting the marketed products efficacy Science-driven culture Strong forecast profit growth	Over-reliance on the 'core' portfolio to drive growth, with the majority of product launches over the forecast period viewed as lifecycle management strategies, with a lack of mechanistic diversity being introduced to the company's portfolio
Opportunities	**Threats**
Extensive indication broadening strategy for a number of key mAb products owing to the 'broad spectrum nature' of their mode of action Developing new technologies, focusing on small molecule therapies Ocrelizumab – increasing profitability	Risk of Genentech and Roche becoming 'victims of their own success': how long will healthcare providers which are struggling to contain costs be prepared to pay for expensive mAb products? Emergence of small molecule targeted therapies in oncology providing comparable efficacy to mAbs

Strengths

Specializing in mAb therapies—the most attractive product segment out to 2013

Monoclonal antibody therapeutics (mAbs) are forecast to be the fastest growing product type (excluding vaccines, which have omitted due to market size) out to 2013. To this end they are the most attractive product segment compared to small molecules and therapeutic proteins (Datamonitor, Monoclonal Antibodies Report Update 2008, DMHC2427, June 2008). Critically, small molecules

face the brunt of generic competition with a very small amount of 'biosimilar' competition threatening only the oldest and simplest members of the therapeutic protein class. Datamonitor expects the mAb class to be totally insulated from material generic competition to 2013 by virtue of regulatory, intellectual property and technology barriers.

In terms of positive forces, or 'growth drivers', mAbs have the advantage of primarily addressing high unmet need therapy areas such as oncology and I&I. In addition, mAbs have opened up an entirely novel 'target space' of extracellular signaling pathways (examples including CD20 (Rituxan), VEGF (Avastin) and HER2 (Herceptin)) to therapeutic modulation and such innovative mechanistic approaches are rewarded in the market by no or very low levels of direct competition.

MAbs, with their insulation from the negative force of generic competition combined with high exposure for the twin positive forces of high unmet need and 'novel target space', are expected to be the fastest growing of the 3 types, and command the highest revenue per product. In contrast, small molecules face an unattractive combination of forces with high exposure to generic competition, no major focus on areas of highest unmet need and little access to novel target space conspiring to make this product set the slowest growing to 2013 and having the lowest average revenue per product. Therapeutic proteins appear to stand halfway between mAbs and small molecules in terms of commercial attractiveness. In fact, the major dynamic impacting the therapeutic protein class is the sales cannibalization of first-generation products by their successor second-generation products.

Genentech has 'locked out' competition by developing first-to-market therapies with strong clinical data supporting the marketed products efficacy

Genentech's leading products and the 3 key growth drivers out to 2013 effectively operate in a competition-less environment. Termed the 'big three', Avastin, Herceptin and Rituxan are established as the gold standards in their respective fields of colorectal cancer, HER2 positive breast cancer and non-Hodgkin's lymphoma. This position is likely to remain the same out to 2013 with no other competitors able to demonstrate superior efficacy to Genentech's 'big three'. Clinical trial design is a big factor with Genentech choosing strict unrivaled endpoints. Obtaining first-to-market position is a key factor also in Genentech's current and forecast position, for example Rituxan (marketed in 1997 for NHL and targeting the CD20 protein) preceded the launches of two other mAbs that target the same protein and treat the same disorder: Biogen IDEC's Zevalin (ibritumomab tiuxetan) in 2002 and GSK's Bexxar (tositumomab) in 2003. Despite Bexxar and Zevalin offering a new method of treating NHL (both mAbs are radio-labeled conjugates), Rituxan had already been marketed for 5 years before the appearance of Zevalin and in that time had accrued significant safety and efficacy data as well as a strong brand. This almost impenetrable brand of Rituxan is likely to remain out to 2013 with the chimeric mAb forecast to retain its gold-standard status with further sales increases forecast.

Science-driven culture

Genentech's strategy of operating as a science-driven biotechnology company has enabled the company to develop and launch truly innovative therapeutics that target areas of high unmet need and thus has rewarded the company with high historical sales growth and such a culture within the

company will translate into further sales growth out to 2013. Instead of specializing in therapy areas and more specifically developing therapeutics that target diseases with high populations and thus high profits, Genentech are a 'disease pathway innovator' and have launched products, such as the big three of Avastin, Herceptin and Rituxan, which have changed the standard of care in their respective fields by targeting specific disease pathways (i.e. by targeting the proteins of VEGF, HER2 and CD20 respectively). Supporting Genentech's self proclaimed 'science-driven culture' is the company's active 'Postdoc Program'. This scheme provides Genentech with a steady flow of young scientists with diverse backgrounds. Genentech hire post-graduate students for a maximum of 4 years for these scientists to work in the laboratory working purely on the discovery of novel targets. The success of the scheme for each candidate is measured by the number of publications and the ability to obtain an academic or industry permanent position thereafter. Genentech's 'Postdoc Program' helps to keep Genentech's basic science group intellectually vibrant and technically current.

Strong forecast profit growth

In addition to a very strong portfolio of anticancer mAbs, forecast to drive double-digit ethical sales growth, Genentech has a superior set of operating ratios. The company has controlled its operating costs over the historical period and as a result achieved an exceedingly impressive operating profit growth: a 2001-07 CAGR of 74.8%. Over the forecast period, Genentech's operating profit growth is set to remain in double figures, albeit it at a slower rate than the historical figure (12.8%). Genentech's extensive indication broadening strategy, particularly in the case of the company's key strategic product, Avastin (with numerous Phase III trials ongoing exploring the potential of expanding its indications), is an efficient way of generating sales growth and lowering expenditure. As Phase III trials are the most expensive to conduct, one would expect Genentech's R&D expenditure to be higher (as a proportion of total revenues). However, the indication-broadening Phase III trial expense is offset by the lack of the combined expense of Phase I and Phase II trials as Avastin's safety profiles are known. Thus, such trials are not required.

Weaknesses

Over-reliance on the 'core' portfolio to drive growth, with the majority of product launches over the forecast period viewed as lifecycle management strategies, with a lack of mechanistic diversity being introduced to the company's portfolio

Given the robustness of Genentech's 2007–13 outlook, it is difficult to identify any major weaknesses in the Genentech business model.

Genentech's core portfolio (currently marketed products, prior to 2007, which will not face patent expiry out to 2013) will derive the majority of the company's total absolute growth: 96.6% of Genentech's forecast total absolute growth from 2007–13. In fact, Genentech is exhibiting an over-reliance on 3 products—Avastin, Herceptin and Rituxan—with these 3 therapeutics generating 85.0% of the company's absolute core growth. While the growth is strong, the distinct lack of late-stage pipeline contribution to total ethical sales will concern Genentech. Genentech's launch portfolio is forecast to generate a small 1.9% of 2007–13 total absolute growth. When Genentech's pipeline is

scrutinized further, the lack of mechanistic diversity is clear amongst the late stage launch products of ocrelizumab and pertuzumab. The launch of ocrelizumab (which like Rituxan is a CD20-targeting mAb) can be viewed as a second-generation Rituxan (ocrelizumab differs by being humanized as opposed to Rituxan being chimeric). Pertuzumab in the short term will be used in conjunction with Herceptin, one of Genentech's 'big three', to maintain and possibly add to the revenues of the HER2+ breast cancer treatment (however, the long-term prospects of pertuzumab are promising).

Genentech's strategy of developing pipeline products that maintain their position within their markets, instead of developing and manipulating new areas, over the next 6 years at least, is a potential weakness.

Opportunities

Extensive indication broadening strategy for a number of key mAb products owing to the 'broad spectrum nature' of their mode of action

Genentech is operating a broad indication strategy for a number of its key mAb products. The majority of Genentech's sales growth will come from its core product segment with the primary momentum for this sales expansion coming from an ambitious indication-broadening strategy for mAb products such as Avastin and Rituxan. By utilizing this strategy, Genentech is maximizing the returns on the investment made on these therapies in the initial R&D stages, although Rituxan is an in-licensed product from Biogen Idec. Instead of developing new molecular entities and progressing them through Phase I–III trials and subsequent regulatory filing, by expanding indications of already marketed products with a wealth of safety data, and most importantly with Rituxan and Avastin patient and physician brand confidence can be used to generate extra sales revenue in a shorter space of time and theoretically from less investment.

Developing new technologies, focusing on small molecule therapies

Genentech has stated that it intends to develop more small molecule therapies after witnessing strong sales uptake of its only small molecule therapy, the in-licensed Tarceva. In recent years Genentech signed numerous deals with small molecule players in order to fill their pipeline with such potential therapies.

Ocrelizumab – increasing profitability

While focusing on mAbs is a strong strategy as they are the technology type with the highest forecast sales growth out to 2013 (DMHC2427), by populating its pipeline with early-stage small molecule therapies Genentech recognizes the value of establishing itself as multi-technology player and not as a 'one-trick pony'.

Threats

Risk of Genentech and Roche becoming ‘victims of their own success’: how long will healthcare providers which are struggling to contain costs be prepared to pay for expensive mAb products?

Despite its current and forecast success, Genentech does face a number of long-term threats. Perhaps most importantly, the company could emerge as a ‘victim of its own success’, particularly if increasingly cost-conscious healthcare providers begin to make a concerted protest at paying high prices for therapeutics that are deemed highly necessary to patients.

Emergence of small molecule targeted therapies in oncology providing comparable efficacy to mAbs

On the technology front, another threat is the emergence of more efficacious small molecule targeted cancer drugs, which would offer obvious benefits in terms of cost (typically cheaper to manufacture than biologics) and delivery (orally available). To date, these products have not impacted Genentech revenue streams; the CML (chronic myeloid leukemia) market for Novartis’s highly successful Gleevec is not one where Genentech is present, while AstraZeneca’s Iressa failed to demonstrate the same survival benefits that Genentech’s own small molecule Tarceva did. However, this trend does not rule out future successes, with GlaxoSmithKline’s Tykerb (lapatinib) emerging as a potential threat to Herceptin. Currently approved for Herceptin non-responders, GSK has recently filed with the FDA and EMEA for Tykerb to be used as a first-line therapy.