Strategic Report



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# Background

### History

Genentech, Inc. (NYSE: DNA) is a biotechnology company that discovers, develops, manufactures, and commercializes biotherapeutic drugs. Genentech was founded in 1976 by venture capitalist Robert A. Swanson and biochemist Dr. Herbert W. Boyer. In the early 1970s, Boyer and geneticist Stanley Cohen pioneered a new scientific field called recombinant DNA technology.

In 1977, Genentech produced the first human protein (somatostatin) in a microorganism (E. coli bacteria). In 1980, they went public and raised \$35 million. They marketed their first recombinant DNA drug in 1982: human insulin (licensed to Eli Lilly and Company). The Company currently manufactures and commercializes 11 biotechnology products in the United States.

### Products

#### Rituxan

Genentech's best selling drug is Rituxan, a chimeric monoclonal antibody, which treats low-grade non-Hodgkin's lymphoma. It has also been approved for additional uses, such as the treatment of relapsed patients and of bulky disease. Almost 300,000 patients have been prescribed Rituxan throughout the world.

The drug was developed and is co-promoted by Genentech and Biogen IDEC. Biogen IDEC, based in Cambridge, MA, also produces drugs for multiple sclerosis and chronic plaque psoriasis. Genentech is responsible for worldwide manufacturing and domestic sales of Rituxan. They pay Biogen IDEC a share of the profits and reimburse them for certain expenses. These payments are estimated to be 30% of domestic sales in 2004. Rituxan had sales of \$1.49 billion in 2003 and \$1.16 billion in 2002. Sales are predicted to reach \$1.8 billion in 2004.<sup>1</sup>

#### Avastin

Recently (February 26, 2004), the FDA approved Genentech's Avastin as a firstline treatment of metastatic colorectal cancer. This drug is designed to stop blood vessel growth and oxygen supply to cancerous tumors. Genentech is currently conducting clinical trials to test if Avastin is effective in combination with various chemotherapies or for treating breast cancer, renal cell cancer, or non-small cell lung cancer. Analysts predict that Avastin could reach over \$1.5 billion in sales for colorectal cancer. This potential could increase to \$2-\$3 billion is Avastin is approved for other uses.

<sup>&</sup>lt;sup>1</sup> Goldman Sachs Analyst Report

# Herceptin

Another big seller for Genentech is Herceptin, an antibody formulated for the treatment of metastatic breast cancer. Sales were \$425 million in 2003 and \$385 million in 2002. Genentech is currently conducting 4 clinical trials with over 10,000 patients to find other uses for Herceptin. Sales potential could reach \$1 billion if Herceptin can safely and effectively treat adjuvant breast cancer.

## Xolair

Xolair is used to treat severe persistent asthma in adults and adolescents. Genentech has formed a partnership with Novartis to promote and sell Xolair. Currently, the company is conducting trials to test Xolair's effectiveness in treating peanut allergy and allergic rhinitis. Sales potential is expected to be \$300-\$500 million.

# Raptiva

Genentech developed Raptiva with XOMA Limited, a Berkeley, CA biopharmaceutical company focusing on cancer, immunologic and inflammatory disorders. The drug treats moderate-to-severe psoriasis in adults. Sales are expected to reach \$500 million.

# Human Growth Hormone/Thrombolytics/Pulmozyme

The markets for these drugs are very mature and growth is expected to be minimal. Examples are Nutropin Depot, a long-acting growth hormone for the treatment of growth failure in children; and Protropin, a growth hormone for the treatment of inadequate endogenous growth hormone secretion or growth hormone deficiency in children. Sales should be very stable and should provide steady cash flow.



#### **Research & Development**

With over \$1.5 billion in cash and investments and 2003 revenues of more than \$3.3 billion, Genentech reinvested approximately 22 percent of its revenues into research and development (R&D) in 2003 – significantly more than the pharmaceutical industry average. To balance resource use with the strongest likelihood of success, Genentech moves only the most promising of its products into clinical development.

#### Pipeline

Genentech's devotion to R&D is quite apparent as its development pipeline continues to grow, now numbering approximately 20 projects in three therapeutic focus areas – oncology, immunology, and vascular medicine. The pipeline also includes a category for projects outside of these focus areas, in the realm of specialty biotherapeutics. Four products with combined sales potential of over \$2 billion are supposed to complete Phase III, the final phase before FDA approval, in 2004-2005.

Specifically, Genentech is continuously studying and developing therapies for a variety of cancers, including four of the most common – lung, breast, prostate, and colon. In 2003, Genentech realized almost \$2 billion in revenues from marketed oncology products, and they are focused on becoming the industry leader in cancer therapies.

The company's current successful drugs are mainly oncology-related. Products in development are particularly innovative, meaning they are of higher risk. Genentech may wish to focus on developing some less risky drugs, in order to better balance their portfolio.

Genentech also develops medicines outside of their three focus areas (oncology, immunology, and vascular medicine), provided they address unmet medical needs and utilize the company's areas of expertise. One such project moving through the development pipeline is a potential new indication for use of Nutropin Depot in adults with growth hormone deficiency. (The product is already approved and marketed for use with children who are deficient in growth hormone.)

#### Manufacturing

Genentech has a long history of manufacturing protein-based drugs, which is one of their strengths. Their original plant is located in South San Francisco and has a capacity of 96,000 liters. This plant is mainly used for mammalian cell manufacturing. Another plant was built in Vacaville, California in 1999 which added 144,000 liters to the overall capacity. Vacaville is used to produce monoclonal antibody drugs, including Rituxan, Herceptin, Raptiva, Xolair, and Avastin. Genentech also has a plant in Spain,

where they plan to begin manufacturing Rituxan. The company has also contracted Lonza, a Swiss manufacturing company, to begin producing Rituxan in their Portsmouth, New Hampshire plant.

#### Growth

Genentech's success is predicated on its ability to recruit and retain highly qualified and motivated people in all areas of the company. Of the more than 5,200 Genentech employees, more than 80 percent have college degrees and more than 20 percent hold advanced degrees, including Ph.D.s and M.D.s.

In terms of sources of growth, the near-term growth driver is the increasing revenue of oncology products. Medium-term growth drivers are several Phase III pipeline projects that could contribute significantly to growth, depending on clinical trial outcomes and FDA approval. Finally, several projects in late-stage development and a steady project flow from research, along with some alliances moving into development, could help drive earnings per share in the longer term.

Management has recently outlined their future growth plans with the Horizon 2010 strategy. Genentech's main goal is to become an industry leader in treating cancer, immunological diseases and angiogenic disorders. Specifically, they desire to become number one in U.S. oncology sales by 2010, build a leading immunology franchise, and develop biotherapeutics for disorders of tissue growth and repair. This new plan follows their previous 5X5 plan, which set out 5 goals hoped to be achieved by 2005. To this day, the 5X5 growth plan has been extremely successful, which creates high hopes for Horizon 2010.

# **Financial Analysis**

# Market Capitalization and Stock Price

Genentech closed at a near 4 year high of \$108.48 on April 15, 2004. The recent surge in stock price is a result of the FDA approval of Avastin, the new colorectal cancer drug. Year to date, market capitalization has increased 15%. The market size of the company has been growing rapidly since a low in 2002. Genentech's current market capitalization is \$57 billion.



The dramatic increase in market capitalization corresponds to a similar increase in the stock price. The stock price has risen over 200% in the past year, and is up over 15% year to date.



| (in thousands)           | 2003         | %    | 2002         | %    | 2001         | %    |
|--------------------------|--------------|------|--------------|------|--------------|------|
| Revenues                 |              |      |              |      |              |      |
| Product sales            | \$ 2,621,490 | 79%  | \$ 2,163,665 | 84%  | \$ 1,742,897 | 85%  |
| Royalties                | 500,903      | 15%  | 365,550      | 14%  | 264,475      | 13%  |
| Contract revenue         | 177,934      | 5%   | 54,443       | 2%   | 36,660       | 2%   |
| Total operating revenues | 3,300,327    | 100% | 2,583,658    | 100% | 2,044,032    | 100% |

# **Financial Statements Overview**

In the past few years, Genentech has seen very strong revenue growth: 24% between 2001 and 2002, 21% between 2002 and 2003. In 2003, product sales accounted for 79% of total revenue as opposed to 84% in 2002. With such a strong pipeline and the recent approval of Avastin, this revenue line has the most potential for future growth.

| 2003      | %  | 2002   | %   | 2001  | %  |
|-----------|--|--|---|---|--|
|           |  |  |   |   |  |
| 480,123   | 15% \$   | 441,630  | 17% \$  | 354,442   | 17%  |
| 721,970   | 22%  | 623,482  | 24%   | 526,230   | 26%  |
| 794,845   | 24%  | 546,276  | 21%   | 446,906   | 22%  |
| 457,457   | 14%  | 350,725  | 14%   | 246,657   | 12%  |
| 154,344   | 5%   | 155,713  | 6%  | 321,816   | 16%  |
| (113,127) | -3%  | 543,905  | 21%   | -   | 0%   |
| ,495,612  | 76% 2  | 2,661,731  | 103%  | 1,896,051   | 93%  |
| 1         | 2003<br>480,123<br>721,970<br>794,845<br>457,457<br>154,344<br>(113,127)<br>,495,612 | 2003 %   480,123 15% \$   721,970 22% \$   794,845 24% \$   457,457 14% \$   154,344 5% \$   (113,127) -3% \$   ,495,612 76% 2 | 2003%2002480,12315%\$ 441,630721,97022%623,482794,84524%546,276457,45714%350,725154,3445%155,713(113,127)-3%543,905,495,61276%2,661,731 | 2003 % 2002 %   480,123 15% \$ 441,630 17% \$   721,970 22% 623,482 24%   794,845 24% 546,276 21%   457,457 14% 350,725 14%   154,344 5% 155,713 6%   (113,127) -3% 543,905 21%   ,495,612 76% 2,661,731 103% | 2003 % 2002 % 2001   480,123 15% \$ 441,630 17% \$ 354,442   721,970 22% 623,482 24% 526,230   794,845 24% 546,276 21% 446,906   457,457 14% 350,725 14% 246,657   154,344 5% 155,713 6% 321,816   (113,127) -3% 543,905 21% -   ,495,612 76% 2,661,731 103% 1,896,051 |

Cost of sales has fallen from 17% of total revenue in 2001 and 2002 to 15% of total revenue in 2003. This indicates an improvement in management and efficient production. Research and development (R&D) costs have also fallen as a percentage of total sales, from 26% to 22% between 2001 and 2003. This percentage is declining because overall revenues have been rising quite dramatically. In absolute terms, R&D expenditures are rising, from \$623 million in 2002 to \$721 million in 2003. Nevertheless, this level of spending may not be sufficient to compete with larger biotechs (i.e. Amgen) and pharmaceutical companies. For example, in 2003, Amgen spent \$1,655 million for research and development. The largest pharmaceutical company, Pfizer, spent \$7,131 million on R&D in 2003. It is clearly not logical to compare Genentech with the largest pharmaceutical company in the industry. However, it should be obvious that if Genentech wishes to growth aggressively, R&D spending must be dramatically increased.

| Consolidated Statements of Income |          |        |           |      |       |         |
|-----------------------------------|----------|--------|-----------|------|-------|---------|
| (in thousands)                    | 2003     | 3      | 2002      | 2    |       | 2001    |
| Total operating revenues          | \$ 3,300 | ,327   | \$ 2,583, | ,658 | \$ 2, | 044,032 |
| Total costs and expenses          | 2,495    | ,612   | 2,661,    | ,731 | 1,    | 896,051 |
| Net income                        | \$ 562   | ,527 💲 | \$ 63,    | ,787 | \$    | 150,236 |

Genentech earned \$562 million in 2003. This seems to be a dramatic improvement over earnings in 2002; however, the 2002 net income number is slightly misleading. The company was forced to take a \$543 million charge related to special litigation issues, which decreased pre-tax net income by that amount. Since this charge is not related to operations, Genentech has actually been generating solid income from operations. (Note: Net income is positive in 2002 because of non-operating revenues.)

# **Ratio Analysis**

## **Key Numbers**

| Bristol-Myers         |           |           |              |             |           |  |  |  |
|-----------------------|-----------|-----------|--------------|-------------|-----------|--|--|--|
|                       | Genentech | Squibb    | Novo Nordisk | Biogen Idec | Amgen     |  |  |  |
| Annual Sales (\$mil.) | 2,799.40  | 20,894.00 | 4,501.00     | 679.2       | 8,356.00  |  |  |  |
| Employees             | 6,226     | 44,000    | 18,800       | 3,727       | 12,900    |  |  |  |
| Market Cap (\$mil.)   | 56,782.30 | 47,529.60 | 16,032.20    | 18,893.90   | 75,600.80 |  |  |  |

Genentech is the second smallest of the above five competitors in terms of sales and employees; however, it is the second-largest in terms of market capitalization. The market values Genentech so highly because it sees tremendous growth potential.

# Profitability

|                            | 1         | Bristol-Myers |              |             |        |          |
|----------------------------|-----------|---------------|--------------|-------------|--------|----------|
|                            | Genentech | Squibb        | Novo Nordisk | Biogen Idec | Amgen  | Industry |
| Gross Profit Margin        | 93.40%    | 67.44%        | 78.07%       | 62.22%      | 88.15% | 82.52%   |
| Operating Margin           | 24.44%    | 22.47%        | 24.05%       |             | 36.99% | 16.08%   |
| Net Profit Margin          | 21.80%    | 14.87%        | 18.31%       |             | 27.04% | -0.25%   |
| Return on Equity           | 9.40%     | 31.70%        | 19.30%       |             | 11.70% | 1.50%    |
| Return on Assets           | 7.00%     | 11.30%        | 14.10%       | -9.20%      | 8.60%  | -0.74%   |
| Return on Invested Capital | 8.80%     | 17.00%        | 18.70%       | -11.00%     | 10.10% | -0.39%   |

Genentech has reasonable profitability margins in relation to key competitors and the rest of the industry. With a gross profit margin of 93.40% (which is profit after accounting for the cost of goods sold), Genentech is significantly ahead of the curve. This shows that they are producing their products very efficiently, compared with their competitors. They are also strong in net profit margin (which is net income divided by total revenue), although not quite as strong as Amgen. While ahead of the industry

in terms of return on equity, assets, and invested capital, Genentech is much weaker than its key competitors, except for Biogen IDEC. These measures indicate the ability to produce profits with each dollar of equity, assets, and invested capital.

#### Valuation

|                       | Genentech | Squibb | Novo Nordisk | Biogen Idec | Amgen | Industry |
|-----------------------|-----------|--------|--------------|-------------|-------|----------|
| Beta                  | 1.18      | 0.44   | 0.59         | 0.97        | 0.48  | 0.8      |
| Price/Earnings Ratio  | 94.1      | 15.41  | 18.83        |             | 34.95 |          |
| Price/Sales Ratio     | 20.3      | 2.27   | 3.56         | 27.76       | 9.04  | 9.75     |
| Price/Book Ratio      | 8.71      | 4.86   | 3.75         | 2.68        | 3.9   | 4.46     |
| Price/Cash Flow Ratio | 62.55     | 12.19  | 14.58        | -23.23      | 25.68 | 110.65   |

Genentech's current beta of 1.18 shows that the company bears 118% of the risk of the overall stock market, i.e. 1% increase in the price of the market is expected to coincide with 1.18% increase in Genentech's stock price. This signals that Genentech is riskier than the market. On the whole, Genentech is an extremely overvalued company. With a P/E ratio of 94.1, each dollar of Genentech's earnings costs an investor almost three times as much as a dollar of Amgen's earnings. Genentech's price to sales, book and cash flow ratios are also quite large. This means that each dollar of sales, book value (common stock equity) and cash flow is over-priced in relation to competitors and the market.

#### Management Effectiveness

| Bristol-Myers              |           |        |              |             |       |          |  |
|----------------------------|-----------|--------|--------------|-------------|-------|----------|--|
|                            | Genentech | Squibb | Novo Nordisk | Biogen Idec | Amgen | Industry |  |
| Days of Sales Outstanding  | 78.78     | 62.82  | 59.35        | 167.42      | 43.42 | 66.16    |  |
| Inventory Turnover         | 0.4       | 4.3    | 1            | 1           | 1.6   | 1.5      |  |
| Days Cost of Goods Sold in |           |        |              |             |       |          |  |
| Inventory                  | 841       | 84     | 354          | 372         | 229   | 238      |  |
| Asset Turnover             | 0.4       | 0.8    | 0.9          | 0.1         | 0.3   | 0.3      |  |
| Net Receivables Turnover   |           |        |              |             |       |          |  |
| Flow                       | 4.9       | 6.3    | 6.4          | 3.2         | 9.5   | 6.2      |  |

All of Genentech's turnover ratios are very low. This is not a good indicator of efficient operations. Inventory turnover measures the efficiency of inventory management. Genentech's inventory turnover is 0.4, which is significantly below the industry average of 1.6. Asset turnover measures how efficiently a company uses its assets to generate sales. Genentech's asset turnover of 0.4 is slightly above industry average, but still below two of its key competitors.

## Financial

|                   | -         | Bristol-Myers |              |             |       |          |
|-------------------|-----------|---------------|--------------|-------------|-------|----------|
|                   | Genentech | Squibb        | Novo Nordisk | Biogen Idec | Amgen | Industry |
| Current Ratio     | 3.16      | 1.58          | 2.45         | 4.54        | 3.3   | 3.73     |
| Leverage Ratio    | 1.34      | 2.81          | 1.36         | 1.35        | 1.35  | 1.53     |
| Total Debt/Equity | 0.06      | 0.88          | 0.07         | 0.13        | 0.16  | 0.26     |

DNA has a current ratio of 3.16, meaning that they have 3.16 times as much current assets as current liabilities. Such a level indicates that they will have no trouble meeting these current liabilities. With DNA's low level of debt, it is logical that their leverage ratio is only 1.34. As a company becomes more highly levered, the risk of bankruptcy increases and the company become more unstable as a whole. Genentech's total debt/equity ratio is also very low as they are not highly levered.

## Growth

|                            |           | Bristol-Myers |              |             |        |          |
|----------------------------|-----------|---------------|--------------|-------------|--------|----------|
| _                          | Genentech | Squibb        | Novo Nordisk | Biogen Idec | Amgen  | Industry |
| 12-Month Revenue Growth    | 24.30%    | 15.30%        | 26.60%       | 68.00%      | 51.30% | 35.50%   |
| 12-Month Net Income Growth | 856.40%   | 50.30%        | 42.60%       |             |        |          |
| 12-Month EPS Growth        | 858.30%   | 48.60%        | 45.50%       |             |        |          |

Although significantly behind Amgen, Genentech has seen decent revenue growth in the past twelve months. With a vastly improved net income in 2003, growth in both this category and EPS is tremendous.

# Porter's Five-Forces Analysis

## **Market Definition**

Genentech operates in the biotechnology industry. Traditionally, biotechnology companies focused exclusively on mapping and analyzing genes, creating new drugs from plant, animal and human proteins, and investigating cures for cancer, heart disease and other uncured ailments. Pharmaceutical companies tend to focus more on chemical-based products. Today, this breakdown is not as clearly defined. Biotech companies are much smaller than pharmaceutical companies, and are therefore mainly R&D-driven. They usually lack the marketing ability of their pharma competitors.

Numerous strategic alliances have linked biotech companies with pharmaceutical partners. In 1990, Genentech reached a deal with Swiss-based pharmaceutical company Roche Holdings. Under the agreement, Roche paid \$2.1 billion for 60% of Genentech, which included issuance of new shares that gave Genentech \$500 million in fresh capital. Since this deal, many pharmaceutical companies have shown interest in similar biotech-partnerships. While there are still differences between biotech and pharma companies, it is assumed that the final market for drugs is an all-encompassing market.

In 2003, global pharmaceutical sales reached \$491.8 billion, growing 9% from the previous year.<sup>2</sup> Almost 90% of global sales in 2003 occurred in North America, Europe and Japan. With the fastest rate, North American drug sales grew 11% to \$229.5 billion, close to half of total sales worldwide.

| Region                     | 2003 Sales (\$bn) | % Global sales<br>(\$) | % Growth (constant \$) |
|----------------------------|-------------------|------------------------|------------------------|
| North America              | 229.5             | 49%                    | +11%                   |
| European Union             | 115.4             | 25                     | 8                      |
| Rest of Europe             | 14.3              | 3                      | 14                     |
| Japan                      | 52.4              | 11                     | 3                      |
| Asia, Africa and Australia | 37.3              | 8                      | 12                     |
| Latin America              | 17.4              | 4                      | 6                      |
| TOTAL                      | \$466.3bn         | 100%                   | +9%                    |

## 2003 Pharmaceutical Sales by Region

Source: IMS World Review 2004

<sup>&</sup>lt;sup>2</sup> http://www.ims-global.com/insight/news\_story/0403/news\_story\_040316.htm

#### Internal Rivalry

Rivalry determines the extent to which price or non-price competition erodes the profitability of firms in the biotech industry. While Genentech does have a fair number of competitors, there are not very many direct competitors for its drugs, as a result of FDA patents. At least initially, a patent will prevent other companies from releasing a drug with a similar structure. However, competitors are still allowed to release drugs that have similar effects or treat similar diseases. For example, Genentech's Avastin and ImClone's Erbitux both treat colorectal cancer, but by different methods. After patent expiration, companies in this industry begin to see intensified competition due to the entrance of generic drug makers. This entrance always reduces a firm's market share and profitability.

The drug industry as a whole is exhibiting strong growth. Sales have been growing steadily for many years. Consumers will always need drugs, and as research cures more diseases, the overall market for drugs will be expanding. In terms of costs, all firms in the industry face huge costs for R&D, although these costs do not differ dramatically from firm to firm. However, in terms of sales and marketing, the larger pharmaceutical companies have a significant advantage. This explains the strategic alliances between biotech and pharma companies.

Genentech does not currently have excess production capacity. Actually, many analysts are worried that insufficient capacity may be a problem in upcoming years. However, in general, companies in this business cannot simply expand output to steal business from rivals. Success in this industry is directly tied to R&D success.

#### Entry

There are significant barriers for companies attempting to enter the biotech/pharma industry. They are regulation, experience, and capital-related. Most importantly, patent and intellectual property (IP) law poses the biggest threat to potential entrants. Since products in this industry are protein/chemical-based and easily reproduced by competitors, the patent is needed to ensure technological innovation: the majority of a firm's capital investment must take place before a product is produced and marketed, and thus the patent is the only way that a firm can protect its IP and earn a return on its significant R&D investment. A typical patent protects IP for 20 years from the date of patent filing. However, in this industry, firms are required to disclose product information long before a product is actually brought to market. Since this industry produces products that are vital for the health and safety of consumers, the Food and Drug Administration (FDA) is heavily involved in regulation. In addition to the R&D

investments required, firms must also invest in clinical trials to satisfy the FDA that products are safe and effective.<sup>3</sup>

The long amount of time between patent filing and product introduction means that drug companies actually receive a period of patent protection much shorter than 20 years. Since FDA approval requires 8.5 years on average, a typical company will only benefit from patent protection for 11.5 before generic producers can enter.<sup>4</sup> Under the Waxman-Hatch Act of 1984, generic drugs can be approved if they have the same active ingredient and are bioequivalent to the branded product. Since extensive clinical trials are not required, these generic producers can begin selling the same day that the patent expires since all preparation can be completed before the patent expires.

Luckily, these generic rules do not apply to biotechnology products. Since biotechs usually produced protein-based drugs, as opposed to pharmaceutical companies who produce chemical-based drugs, short bioequivalency studies are usually not sufficient to receive FDA approval. It is expected that the FDA will issue guidance in the next 1-2 years, governing the pathway for obtaining approval of generic biologic drugs.<sup>5</sup>

Another significant barrier to entry is the intense experience/capital requirement. A huge investment is required in R&D before entry can occur. Genentech has also spent a significant amount of capital in constructing manufacturing plants. Specialized knowledge is also required for developing and producing drugs. Both of these barriers are prohibitive to entry.

#### Substitutes and Complements

The top-selling drugs that Genentech produces perform very specific functions, and the market has a relatively small number of substitutes. Since cancer drugs are especially difficult to create, there are few blockbuster drugs in this category of drug. However, rival drugs still do exist, and Genentech must keep an eye out to make sure they retain sizeable market share. Genentech's top selling drugs are predicted to be: Rituxan (\$1.75 billion), Herceptin (\$475 million), Xolair (\$156 million), and Raptiva (\$74 million).

Recently, the FDA approved Genentech's newest drug, Avastin, which treats colorectal cancer. Analysts predict this has the potential to be a blockbuster drug because it is the first humanized monoclonal antibody in the market for colorectal cancer. Colorectal cancer is the second most common form of cancer in the US, after lung cancer, and has a higher mortality rate than either breast or prostate cancer. Recently, this type of cancer has received much attention by the media, as celebrity sufferers

<sup>&</sup>lt;sup>3</sup> Bruce Lehman, "The Pharmaceutical Industry and the Patent System", International Intellectual Property Institute, 2003.

<sup>&</sup>lt;sup>4</sup> http://www.pacificresearch.org/pub/hpp/2002/hpp\_02-09.html

<sup>&</sup>lt;sup>5</sup> Goldman Sachs Analyst Report

such as Sharon Osbourne and the late husband of Katie Couric have made their cases public. The approval of Avastin is particularly unique as it is a first-line treatment. In the past, novel treatments, such as Avastin, were only approved for second-line use.

| Compound     | Type of action                   | Developers          | Phase (colorectal |
|--------------|----------------------------------|---------------------|-------------------|
|              |                                  |                     | cancer)           |
| ABX-EGF      | MAb, EGFR                        | Abgenix, Amgen      | III               |
| Canvaxin     | therapeutic vaccine              | CancerVax           | III               |
| IGN101       | MAb, EpCAM vaccine               | igeneon             | III               |
| Genasense    | bcl-2 antisense inhibitor        | Genta, Aventis      | II                |
| (oblimersen) |                                  |                     |                   |
| Oncophage    | personalised therapeutic vaccine | Antigenics          | II                |
| Theratope    | mucin vaccine                    | Biomira, Merck KGaA | II                |

#### Late-stage biological therapies for colorectal cancer

Source: IMS LifeCycle R&D Focus

It is clear that the predicted success of Avastin has caused many other companies to prepare for entry. Since researchers are beginning to understand that this cancer is not a single biological entity, but a group of subclasses, it is probable that many chemically different treatments will enter the market in the next few years. This will increase competition for Genentech's Avastin.

The company's current top-selling drug, Rituxan, treats non-Hodgkin's Lymphoma. There are no close substitutes, which explains its success in the market. Xolair treats people with severe allergy-related asthma. While the market for this drug may be small, people with asthma and allergies may turn to normal prescription allergy medications before learning about Xolair. Thus, Xolair may face few substitutes for those with the severest of allergy-related asthma, but generally, stiff competition is had from heavily marketed drugs like Allegra and Zyrtec.

Another drug with intense competition is Raptiva, which treats moderate to severe psoriasis. The psoriasis market is heating up because many are unsatisfied with current treatments. Analysts estimate this to be a \$5 billion industry, so biotech firms are keeping a close eye on possibilities for entry with an effective drug. Raptiva is a minor player in this market, compared to Amgen's Enbrel, Abbott's Humira, and Biogen IDEC's Amevive. This market should continue to have steady competition and provide many substitutes for Raptiva. Raptiva will need to differentiate itself as being more effective if it is to remain profitable.

As far as complements, there are few drugs that work together to achieve multiple purposes. More generally, if health care costs in general were to fall, the demand for Genentech's (as well as other companies') prescription drugs would increase.

#### **Supplier Power**

Biotechnology firms produce their own protein structures and so for the most part do not have to contract out production. Thus, there is limited supplier power. Genentech has recently expanded its production potential by attaining the approval for construction of another production facility in California. Genentech has established alliances with other biotechnology companies such as Alagen. Many biotechnology companies engaged in the production of similar drugs have begun to enter into this practice to conserve resources as well as to enhance the production of specific drugs.

Due to the rapid growth of Genentech and the increase in demand for their recently approved drugs, Genentech will need significant expansion over the next few years. Nevertheless, there is little to no supplier power currently in the market. As the market continues to expand, however, there is the potential for supplier power growth, due to the limited number of biotechnology manufacturing facilities.

#### **Buyer Power**

Although biotech drugs are sold primarily to patients and the general public who have a need for the specific drugs, HMOs and PPOs have significant influence over these consumer choices. This influence stems from the reimbursement policies of the HMO and PPOs, as they will only reimburse their clients a certain percentage of a drug's cost. The role of Medicare in the market has increased due to aging baby boomers as well current economic factors.

Medicare has recently made two significant changes affecting the biotech market and the administration and distribution of drugs. It has lowered the reimbursement percentage for drugs administered in physician's offices, which has the potential to create temporary disruptions in the market. To offset this, beginning in 2005, reimbursement percentages for treatments and drugs outside of the doctor's office will increase and continue to increase for several years. Medicare has also begun to pressure the FDA to extend generic prescription laws to biotech drugs, due to their rising costs. Currently, the production and approval time for a generic drug is under one year. If the FDA does change its policies, the HMOs and PPOs will exert more power and control over the market as generics will become the common drug taken by patients. Thus, HMOs and PPOs are the companies exerting the most substantial buyer power, however due to the necessity of the drugs, this is not a significant threat to biotechs, as of yet.

# Summary

| Force                       | Threat to Profits |
|-----------------------------|-------------------|
| Internal Rivalry            | Medium            |
| Entry                       | Low               |
| Substitutes and Complements | Medium            |
| Supplier Power              | Low               |
| Buyer Power                 | Low-Medium        |

## Strategic Recommendation

PAC Consulting, LLP has concluded that Genentech is a financially and operationally healthy company with a bright future. They have a very strong pipeline with 20 drugs in development. Avastin's release in February added a third drug to Genentech's already strong oncology portfolio.

In analyzing the biotech and pharmaceutical industry as a whole, we have found that growth and investment in R&D are the main keys to success. While Genentech is performing well, we believe that its current small size in relation to Amgen and other pharmaceutical companies may pose a challenge to future growth and continued success.



Even though Genentech invested the largest percentage of their sales dollars in R&D, we believe this overall level is not enough to compete with larger companies. Genentech should look to expand its size and R&D spending. We also believe that it would be advantageous to expand its portfolio beyond oncology drugs. A more diversified pipeline will encourage more stable growth in the future. Our first recommendation is that Genentech raise cash with a secondary offering of common stock. Since the current stock price is very high, a significant amount of cash could be raised this way. These funds can be used to expand research and development.

Genentech's recent performance has encouraged a dramatic increase in market capitalization. Therefore, our second recommendation is that Genentech capitalize on this overvaluation and pursue an acquisition strategy. We advise that Genentech finance possible acquisitions with all or mostly stock deals.

We suggest that Genentech look at one or more of the following as possible acquisition targets: Celltech, Gilead Sciences, MedImmune or Genzyme. We picked these companies because they are relatively cheap, have strong growth potential and/or generate most of their revenues from nononcology related drugs.

#### 1. Celltech

| Key Numbers           |          | <u>Financial</u>                 |        |
|-----------------------|----------|----------------------------------|--------|
| Annual Sales (\$mil.) | 531.2    | Current Ratio                    | 1.43   |
| Market Cap (\$mil.)   | 2,151.40 | Leverage Ratio                   | 1.6    |
| Profitability         |          | Total Debt/Equity                | 0.14   |
| Net Profit Margin     | 1.37%    | <u>Per Share Data (\$)</u>       |        |
| <u>Valuation</u>      |          | Revenue Per Share                | 3.98   |
| Price/Sales Ratio     | 3.89     | Fully Diluted Earnings Per Share | 0.06   |
| Price/Earnings Ratio  | 258.33   | Growth                           |        |
| Price/Book Ratio      | 2.52     | 12-Month Revenue Growth          | 14.00% |
|                       |          | 36-Month Revenue Growth          | 71.40% |

Celltech Group plc is a European biotechnology company engaged in drug discovery and development. Celltech partners with major pharmaceutical or biotechnology companies, retaining comarketing rights, profit sharing arrangements or substantial royalties. The Company offers an extensive late-stage product pipeline that includes products for arthritis, Crohn's disease and other inflammatory diseases.

We think that Celltech would be a good acquisition target for a number of reasons. First, their pipeline will do much to diversify that of Genentech, as they make drugs for arthritis, bowel and inflammatory diseases. Genentech's partnership with Europe-based Roche should give Genentech some experience in dealing with a European company. Finally, we think that Celltech is undervalued. Celltech has little debt and strong revenue growth. While it is currently not producing much earnings, its strong late-stage pipeline and low price to sales and book ratios make it a good target.

| Key Numbers           |           | <u>Financial</u>                 |        |
|-----------------------|-----------|----------------------------------|--------|
| Annual Sales (\$mil.) | 867.9     | Current Ratio                    | 6.81   |
| Market Cap (\$mil.)   | 12,097.90 | Leverage Ratio                   | 1.55   |
| Profitability         |           | Total Debt/Equity                | 0.34   |
| Gross Profit Margin   | 89.42%    | Per Share Data (\$)              |        |
| Net Profit Margin     | -8.30%    | Revenue Per Share                | 4.06   |
| Valuation             |           | Fully Diluted Earnings Per Share | -0.36  |
| Price/Sales Ratio     | 13.94     | <u>Growth</u>                    |        |
| Price/Book Ratio      | 12.07     | 12-Month Revenue Growth          | 85.90% |
| Price/Cash Flow Ratio | -235.79   | 36-Month Revenue Growth          | 67.60% |

# 2. Gilead Sciences

Gilead Sciences, Inc. focuses on the care of patients suffering from life-threatening diseases worldwide. The Company has six products that are marketed in the United States, all of which are also marketed worldwide. These products are Viread and Emtriva for the treatment of HIV; Hepsera for the treatment of chronic hepatitis B infection; AmBisome, an antifungal agent, and Vistide for the treatment of cytomegalovirus (CMV) retinitis. Hoffmann-La Roche markets Tamiflu for the treatment of influenza, under a royalty-paying collaborative agreement with the Company.

We have chosen Gilead because they are currently marketing and developing drugs for the treatment of HIV. We think these drugs will fit well with Genentech's cancer drug product portfolio. Gilead has a significant amount of sales revenue and sales growth. While this company is quite large – a market cap of over \$12 billion – we believe that it still presents a good opportunity to Genentech. It has a small amount of debt and is predicted to have positive EPS in 2004.

| J. Meanninune         |          |                                  |        |
|-----------------------|----------|----------------------------------|--------|
| Key Numbers           |          | <u>Financial</u>                 |        |
| Annual Sales (\$mil.) | 1,054.30 | Current Ratio                    | 2.82   |
| Market Cap (\$mil.)   | 5,994.70 | Leverage Ratio                   | 1.64   |
| <b>Profitability</b>  |          | Total Debt/Equity                | 0.4    |
| Net Profit Margin     | 17.38%   | <u>Per Share Data (\$)</u>       |        |
| Return on Equity      | 10.80%   | Revenue Per Share                | 4.25   |
| Valuation             |          | Fully Diluted Earnings Per Share | 0.72   |
| Price/Sales Ratio     | 5.68     | <u>Growth</u>                    |        |
| Price/Earnings Ratio  | 33.54    | 12-Month Revenue Growth          | 24.40% |
| Price/Cash Flow Ratio | 25.42    | 36-Month Revenue Growth          | 26.10% |

#### 3. MedImmune

MedImmune, Inc. is a global biotechnology company that concentrates on infectious diseases, immune system disorders and cancer. The Company's core competencies are in the areas of monoclonal antibodies and vaccines. MedImmune's main products include Synagis, Ethyol and CytoGam. Synagis prevents serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients. Ethyol is an agent used to prevent certain unwanted side effects of chemotherapy and radiation therapy used to treat cancer. While MedImmune makes oncology drugs, they are not related directly to those Genentech makes. We think that MedImmune's product will greatly diversify Genentech's portfolio.

MedImmune is a medium sized company, with decent returns on equity and EPS. It has low debt, strong revenue growth, and is priced relatively cheaply in relation to its sales revenue.

| 4. Genzyme            |           |                                  |        |
|-----------------------|-----------|----------------------------------|--------|
| Key Numbers           |           | <u>Financial</u>                 |        |
| Annual Sales (\$mil.) | 1,713.90  | Current Ratio                    | 3.38   |
| Market Cap (\$mil.)   | 10,602.70 | Leverage Ratio                   | 1.7    |
| <b>Profitability</b>  |           | Total Debt/Equity                | 0.49   |
| Gross Profit Margin   | 76.93%    | <u>Per Share Data (\$)</u>       |        |
| Net Profit Margin     | -3.94%    | Revenue Per Share                | 7.58   |
| Valuation             |           | Fully Diluted Earnings Per Share | -0.42  |
| Price/Sales Ratio     | 6.19      | <u>Growth</u>                    |        |
| Price/Book Ratio      | 3.61      | 12-Month Revenue Growth          | 28.90% |
| Price/Cash Flow Ratio | 114.44    | 36-Month Revenue Growth          | 22.20% |
|                       |           |                                  |        |

Genzyme Corporation is a global biotechnology company with a broad product portfolio, focused on rare genetic disorders, renal disease and osteoarthritis and includes an array of diagnostic products and services. Genzyme researches novel approaches for treating cancer, heart disease and other areas of unmet medical need. In September 2003, the Company acquired SangStat Medical Corporation, a global biotechnology company focused on immunology that is working to discover, develop, and market therapeutic products in the autoimmune, hematology/oncology and immunosuppression areas. According to Genentech's Horizon 2010 strategy, the company hopes to establish itself in the immunology market. We think that the acquisition of Genzyme will fit well with that plan.

While Genzyme is currently losing money, we like the relatively low price/sales and price/book ratios. As a fairly large company, Genzyme has strong sales revenue at over \$1.7 billion with equally strong sales revenue growth.

# Conclusions

Our analysis of Genentech shows a strong biotechnology company with good opportunities for future growth. They have been very successful in the past and seem to be at an inflection point. We believe that an aggressive growth-through-acquisition strategy will allow Genentech to experience strong earnings growth in the future. We are certain that a dramatically increased R&D effort is requisite for this to happen. Our recommendation is to acquire one or more of the four aforementioned companies.