



EMCC case studies

Biomedical healthcare sector: Biogen Idec, Denmark

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Background

Biogen Idec was formed in 2003 from the merger of two companies, Biogen Inc., founded in 1978, and IDEC Pharmaceuticals Corporation, founded in 1985. Today, it is one of the largest biotechnology companies in the world. Biogen Idec covers the entire value chain, from R&D to worldwide sales. The company is currently represented in 26 European countries, Japan, Canada, Australia and New Zealand and operates a global distribution network covering more than 90 countries. The corporate headquarters is located in Cambridge, MA.

Biogen Idec develops and produces drugs for the treatment of multiple sclerosis (MS), psoriasis, cancer and other diseases and has several leading products on the market. One of the leading products is Avonex, used for the treatment of patients with relapsing forms of MS. This product is the most prescribed product in MS worldwide, with close to 130,000 patients on therapy.

Biogen Idec's other main products are:

- Rituxan for the treatment of non-Hodgkin's lymphomas, NHL (cancer treatment).
- Tysabri for the treatment of relapsing forms of multiple sclerosis.
- Zevalin for the treatment of patients with relapsed or refractory low-grade, follicular or transformed B-cell NHL, including patients with Rituxan refractory NHL.
- Fumaderm for the treatment of severe psoriasis. Fumaderm was acquired with the purchase of Fumapharm AG in June 2006.

Avonex and Rituxan represented approximately 94% of Biogen Idec's total revenues in 2006. In addition to the revenues from the sales of the company's five main products, the company also receives royalty revenues on sales, by licensees, of a number of products covered under patents controlled by Biogen Idec.

Biogen Idec sees process sciences and manufacturing as its own key strengths. In particular, the company has expertise in protein expression in mammalian cells and process sciences capability for cell culture and downstream processing. Biogen Idec is one of only a few biotechnology companies in the world with its own licensed and dedicated biological bulk-manufacturing facilities, of which it has three. These facilities include a large-scale manufacturing plant in Research Triangle Park, North Carolina. The plant has 90,000 litres of bioreactor capacity and is one of the largest biologic manufacturing facilities of its kind in the world. This facility has received industry recognition for its exceptional design, innovative modular construction methods and strong safety record.

The company also operates other licensed manufacturing facilities in the US and has one of the leading capacities for biologics manufacturing in the biotechnology industry. An additional manufacturing facility is being built in Hillerød, Denmark, due to a need for increased production capacity, following the approval of a new drug (Tysabri) and a healthy looking pipeline. When the facility in Denmark goes operational in 2009, Biogen Idec will have nearly 200,000 litres of capacity for the manufacture of biologics. This represents sufficient manufacturing capacity for Biogen Idec's own growing pipeline of products, as well as the products of potential partners. Furthermore, the increased production capacity ensures sufficient production planning flexibility.¹

¹ Danish Trade Council website, <http://www1.eksportraadet.dk/focusDK/1004/html/chapter03.htm>

Biogen Idec in Denmark

Biogen Idec has been present in Denmark since 1999, when the company's Nordic marketing and sales office was established in Copenhagen. The Hillerød production facility represents the company's largest investment outside of the US, and is one of only three similar facilities in the world – in fact, the facility in Hillerød is the only facility of this kind in Europe.

In 2005, Biogen Idec decided to consolidate its European production-related activities by moving its packaging facility and quality control lab from the Netherlands to Hillerød. As a result, in addition to the manufacturing facility for biologics and buildings for support functions, the production site in Hillerød now hosts the company's administration, a quality control lab and a packaging facility.

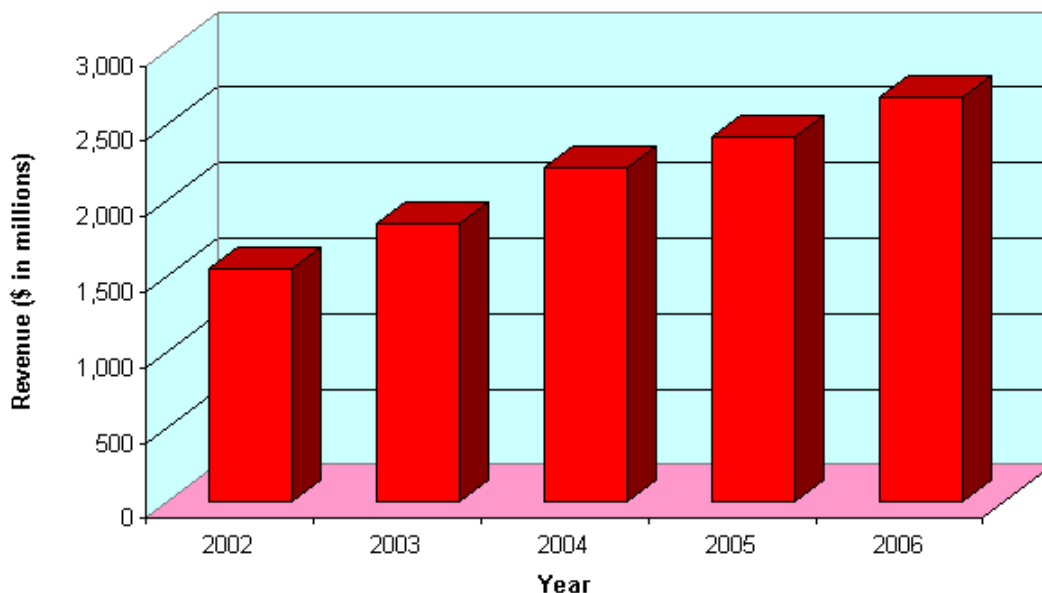
The Danish division of Biogen Idec currently employs around 200 people, working primarily in the quality control lab and the packaging facility. However, the number of employees will increase to 400 in 2009, once the manufacturing facility becomes operational.

Facts about the company

Key figures

In recent years, Biogen Idec has experienced a steady increase in revenues. In 2006, total revenues amounted to US \$2,683 million – an 11% increase compared to 2005.

Figure 1: *Revenues (2002–2006)*



The company has close to 4,000 employees in over 21 countries, and this number is expected to grow in the coming years.

Training and working conditions

Biogen Idec does not pay the highest wages in the industry – and it does not aim to do so. Rather, the company seeks to offer employees an attractive combination of a meaningful career (including opportunities for continued training and

education), attractive wages and good working conditions (including retirement benefits, health insurance, healthy food free of charge and a motivating environment).

R&D

Biogen Idec has established two Centres of Excellence for its research effort: one at its corporate headquarters in Cambridge, MA and the other in San Diego, CA. This research capability is supplemented by selective alliances with other companies and academic research groups. The company's R&D budget exceeds US\$750 million. There are 750 employed in R&D, including approximately 300 in discovery research. Over 20 products are currently in clinical development, addressing a variety of key medical needs. The company's research in key areas, such as oncology, immunology and neurobiology, is supplemented by additional discovery and development efforts aimed at extending the use of Biogen Idec's existing products to other diseases. In 2007, the company expected to allocate 27% to 29% of total revenue to R&D.

Biogen Idec's key R&D strengths are: ²

- Strong R&D fundamentals.
- Focused drug discovery efforts.
- Strong link between discovery research, clinical development and strategic business units.

Strategy

Biogen Idec displayed strong operational, commercial and financial performance in 2006. However, new market opportunities and the challenges of the next decade have led the company's management to adopt a new strategy called '2015 Vision'. According to the strategy, the company intends to:

- Grow the company's core therapeutic areas.
- Advance Biogen Idec into new therapeutic areas.
- Expand the company's global footprint.
- Further develop people and culture.
- Bring valuable products to Biogen Idec's patients.

In terms of expanding Biogen Idec's core therapeutic areas, the company advanced three drug programmes into late-stage clinical trials during 2006. The company is also seeking to grow its current core therapeutic areas and to obtain greater value from the company's existing portfolio via 'lifecycle management' (expanding the use of the company's existing therapies). For instance, Rituxan, an antibody cancer treatment, is being targeted at other indications with high medical needs that are currently unmet. This includes rheumatoid arthritis, for which Rituxan was recently launched, multiple sclerosis and, potentially, lupus.

² Biogen Idec, Presentation: Research & Development Day 2007,
http://www.corporate-ir.net/media_files/irol/14/148682/Biogen_RD_Day.pdf

In addition to investigating Biogen Idec's core products for their potential use in other indications, the company intensified its business development efforts in 2006. Significant operating cost savings, created through a restructuring implemented primarily in 2005, have enabled the company to allocate approximately US\$200 million per year of R&D investment for business development and external research opportunities.³

The importance of partnerships

Partnerships and alliances are key elements in Biogen Idec's business strategy. According to Jim Mullen, president and Chief Executive Officer for Biogen Idec, the ability to enhance the company's pipeline through partnerships will be an important driver in the future growth of the company.⁴ Biogen Idec aims to in-license half of its pipeline by 2010.

Many of the company's products on the market have been developed in cooperation with other companies. The list of collaborators includes:

- Genentech Inc.
- Elan Corporation PLC.
- Fumapharm AG.
- Mitsubishi Pharma Corporation.
- Seikagaku Corporation.

Risk factors

In their fiscal report for 2006, the company identifies a range of risk factors. In terms of products and product development, the company is substantially dependent on revenues from its two principal products, Avonex and Rituxan. A decline in sales from either of these two products would adversely affect the company. In general, Biogen Idec's long-term success depends on the successful development and commercialisation of new products from the company's research and development activities. If the company is unable to introduce new products to the market successfully or is unable to expand the indicated uses of approved products, the results of operations would be adversely affected.

Partners and other collaborators also constitute a risk. For instance, Biogen Idec depends on collaborators for both product and royalty revenue and for the clinical development of future products. These two important parts of the business are outside of the company's full control, making the company vulnerable to negative changes affecting its collaborators. Biogen Idec also relies on third parties to provide services connected to the manufacture of its products. If a third party does not provide products in sufficient quantities and on a timely and cost-effective basis, the company's business could be harmed.

The company's business involves environmental risks, which include the risk of contamination or injury. Biogen Idec has implemented an extensive health and safety programme in order to minimise these risks. Finally, international sales and operations are subject to the risks of doing business abroad (economic problems that disrupt foreign healthcare payment systems, fluctuations in currency exchange rates, the imposition of governmental controls, etc.).

³ Biogen Idec, *Patients are our purpose*. 2006 annual report, http://library.corporate-ir.net/library/14/148/148682/items/244239/BIOGENIDEC_AR06_FINAL.pdf

⁴ Biogen Idec website, <http://www.biogenidec.com/site/strategic-alliances.html>

Social values

Community involvement and dialogue with key stakeholders (e.g. scientists, healthcare personnel, authorities, patients, other companies, neighbours and educational institutions) is a priority for Biogen Idec. In 2004 in the US, support for the community included financial support for science education and community service programmes, grants from the Biogen Idec Foundation and educational grants to medical schools, hospitals and community-based, healthcare-related organisations. Employees also volunteer to help raise funds for social agencies and provide direct services in the community. In the autumn of 2005, *BusinessWeek* magazine selected Biogen Idec as the ‘Most generous in-kind’ corporate giver and the second ‘Most generous cash giver’ based on gifts as a percentage of pre-tax profits.⁵

Biogen Idec also works actively to promote an interest in the natural sciences among students. Among the main initiatives is the creation of a Community Lab in the US (see details below).

Biogen Idec’s Community Lab

Located within Biogen Idec’s own research buildings in Cambridge, MA and San Diego, CA, the Community Lab is designed to help transform today’s young students into the discoverers of tomorrow. The Community Lab operates teaching laboratories that are open to local middle and high school students and teachers. All programmes are offered at no cost to the community.

A unique aspect of the Community Lab programme is that it takes students out of the classroom and brings them into a working environment where science is applied every day. By giving students a chance to interact with scientists and by providing an opportunity to do science using sophisticated equipment, the Community Lab can have an impact on a larger number of students. The Community Lab aims at promoting an active interest in the natural sciences among young people and – not least – sparking an interest in a science-based career.

Scientists and teachers lead the instruction and offer insights on working at Biogen Idec. In addition, the company’s employees volunteer as lab assistants, speakers and mentors. Throughout the academic school year, the Community Lab hosts class visits, professional development seminars for teachers and student mentoring.

Source: *Biogen Idec website*: <http://www.biogenidec.com/site/community-lab.html>

Challenges

Hiring and retaining staff

For the Danish division of Biogen Idec, the most important challenge is to recruit people so that the manufacturing facility can become operational. The company has to find a significantly large number of potential employees, in order to be able to pick the 400 employees that have the right skills and motivation. This is very difficult, since unemployment in Denmark for all skills levels is low and demand is high. The competitive situation on the job market makes it necessary for the company to put extra effort into the recruitment of employees.

⁵ Biogen Idec website, <http://www.biogenidec.com/site/community-relations.html>

Hiring employees in other countries could help the company in its recruitment efforts. However, Paul Coleman, the managing director of Biogen Idec in Denmark (2001–2007), thinks that it is currently too difficult to get employees from other countries into Denmark, as immigration rules are very strict. Paul Coleman is also concerned about the Danish integration policy's ability to move immigrants that are living in Denmark from unemployment and into the labour force. Both policies need to be revised to ensure sufficient supply of human capital for companies in Denmark.

Retaining qualified personnel is also vital. According to Paul Coleman, the key to retaining people is in getting them to understand that they have a future in the company, and offering them an environment and culture that supports their individual development.

Competition from countries outside the EU

Competition from countries such as India and China poses a serious threat to companies in Europe and North America. According to Paul Coleman, Europe can't compete with Asia when it comes to low-value-added production. Instead, Europe has to challenge its competitors on intellectual skills and ideas. This requires support for start-ups, venture capital and adequate protection of intellectual property rights. Entrepreneurship is also important and one of the main problems in Denmark is the lack of entrepreneurs. A possible explanation for this is the entrepreneurial culture in Denmark. There is simply no tolerance for failure. In other countries, failure is a natural part of the start-up process.

Stimulating innovation is thus an important challenge for the company. Among the main initiatives in this regard is the Biogen Idec Innovation Incubator (bi³), see details below.

Biogen Idec Innovation Incubator (bi³)

bi³ offers the opportunity for entrepreneurial scientists to rapidly convert novel biological insights into life-saving and life-changing therapeutics.

With this initiative, Biogen Idec offers a comprehensive set of resources and services to ensure rapid start-up and quick progression to the clinic.

- **Funding:** bi³ supplies the financial resources necessary to convert drug prototypes into development candidates that can quickly enter the clinic, in return for pre-negotiated option rights for Biogen Idec.
- **Facility:** bi³ offers state-of-the-art laboratory space, office space and shared equipment in an access-controlled environment adjacent to Biogen Idec's headquarters in Cambridge, Massachusetts.
- **Focus:** bi³ provides important resources that allow founders to stay focused on the science. bi³ companies have access to Biogen Idec's drug discovery expertise, core facilities, scientific services and world-class technology. bi³ supplies all the business and administrative support required to manage day-to-day company operations.

With these resources in hand, founders are able to successfully demonstrate the therapeutic potential of a drug candidate and realise significant economic benefits in only 2 to 3 years.

Source: *Biogen Idec website*, <http://www.biogenidec.com/bi3>

Regulatory field

Biotechnology is a highly regulated industry and Biogen Idec's business is subject to extensive governmental regulation and oversight. Hence, changes in legislation could negatively affect revenues and profitability. One example is legislation that could ease the entry of generics into the marketplace and the importation of lower-cost competing drugs from other jurisdictions.

Another challenge is changes in the extent of reimbursement for citizens who buy drugs. The industry depends to a significant extent on reimbursement from third-party payers (government health administration authorities, private health insurers and other organisations). In the US, many of Biogen Idec's products are subject to increasing price pressures from government health administration authorities, reflecting government efforts to reduce healthcare expenses. The company has encountered similar issues in most other countries. In the EU and in some other international markets, governments provide healthcare at low cost to consumers and regulate pharmaceutical prices, patient eligibility or reimbursement levels to control costs in the government-sponsored healthcare system. According to Biogen Idec's financial report for 2006, the global biotechnology and pharmaceutical industries within North America, Europe and Japan have witnessed a slow down of growth due to changing regulation and managed care markets.⁶

A related issue is that when a new medical product is approved, the availability of government and private reimbursement for that product is uncertain, as is the amount for which that product will be reimbursed. This means that the company cannot predict the availability or amount of reimbursement for its product candidates, making it impossible to estimate the demand for, and thus the profitability of, new products before they enter the market.⁷

IPR

Inadequate protection and enforcement of the company's intellectual property rights means that competitors may take advantage of the company's development efforts or its acquired technology. In addition, there is considerable uncertainty within the biotechnology industry about the validity, scope and enforceability of many issued patents and, to date, there is no consistent policy regarding the breadth of claims allowed in biotechnology patents. Uncertainty over intellectual property in the biotechnology industry has been the source of litigation, which is inherently costly and unpredictable.⁸

Skills needs

The quality of the Danish workforce is very high. However, due to the highly specialised production at Biogen Idec, low- and medium-skilled employees may need additional training to meet the specific needs of the company. Such training is primarily conducted in partnerships with universities and technical schools.

The availability and quality of researchers is an important factor in global competition. However, the number of PhDs in Denmark is stagnating, and the current level of PhD students is considered by the company, to be completely inadequate to ensure a sufficient number of scientists for R&D activities in the country. As a result, according to the company, there is a serious need for efforts at national level to ensure that more people enter relevant PhD programmes.

⁶ Biogen Idec, Patients are our purpose. 2006 annual report,
http://library.corporate-ir.net/library/14/148/148682/items/244239/BIOGENIDEC_AR06_FINAL.pdf

⁷ Biogen Idec Inc. Annual report on form 10-K for the year ended December 31, 2006,
<http://library.corporate-ir.net/library/14/148/148682/items/240081/BIIB200610K.pdf>

⁸ Ibid.

Location decisions

A number of factors were pertinent when making the decision to construct the new manufacturing facility in Denmark:

- There is a productive business environment in Denmark. The public administration is trying to help companies and they are highly responsive to business needs.
- The quality of the workforce is high.
- There is a productive trade union environment. Trade unions are open and orientated towards dialogue. For instance, in December 2006, Biogen Idec Denmark managed to sign one single collective agreement which covered agreement with five trade unions.
- The Danish authorities were very helpful when Biogen Idec was considering locating its new facility in Denmark.
- Copenhagen Capacity, the official inward investment agency of Greater Copenhagen, served as the single entry point for Biogen Idec and communication between Biogen Idec and all persons and institutions in Denmark went through Copenhagen Capacity.⁹
- In countries, such as Ireland, that already have a large biotechnology industry and many large, foreign companies, Biogen Idec is just a 'small fish' in the sea. In Denmark, the company is a 'big fish', making it possible for the company to have an impact at regional and national policy level.
- The opportunity to locate in the Danish-Swedish Medicon Valley cluster.
- A well-developed infrastructure. For instance, Copenhagen Airport is the largest in Northern Europe, and was rated the best airport in Europe in 2004 in terms of service level.

Cooperation between Biogen Idec and Copenhagen Capacity started in March 2000, when Copenhagen Capacity and Invest in Denmark were invited to give a presentation of the opportunities in Copenhagen/Medicon Valley. There then followed 14 months of research, where Biogen benchmarked different locations in Europe on a large number of variables. During this period, Copenhagen Capacity worked closely with Biogen Idec and provided the company with extensive information and calculations. This close cooperation between Copenhagen Capacity and Biogen Idec was critical to the company's decision to locate its manufacturing facility in Hillerød.

Infrastructure

In Denmark, the transport infrastructure is fundamentally effective, but is being put under increasing pressure. Trains are often delayed and every day thousands of people are stuck in traffic jams. In short, there is an increasing problem with the transport of human capital – especially in the Greater Copenhagen area. This has a negative effect on companies that are already located there and may also influence future location decisions of companies who might consider moving their activities to Denmark.

Biomanufacturing

Today's protein-based drugs and monoclonal antibody therapeutics typically face dosing requirements of up to 1,000-fold higher than earlier first-generation biologics. With sales of such biologics accelerating and with a pipeline of additional drugs in late-stage development, biomanufacturing capability and capacity has become a critical issue for all companies. Biogen Idec's manufacturing capacity and know-how make the company a potential collaborator for the co-development of innovative therapeutics.

⁹ Copenhagen Capacity website, 'Biogen Idec invests USD 340 in Copenhagen', <http://www.copcap.com/composite-8316.htm>

Conclusion

Biogen Idec is a global biomedical company covering all parts of the value chain – from R&D to manufacturing and sales. The executive management points to the following main challenges for the company in the years to come:

- Hiring and retaining staff.
- Protection of IPR.
- Increasing competition.
- Changes in public regulation.
- Meeting skills needs.

Locating the company's European manufacturing facility in Denmark was decided mainly on the grounds of Denmark's productive business environment, the high quality of the workforce, the Medicon Valley cluster and a well-developed infrastructure. Cooperation with and support from Copenhagen Capacity also played a crucial role for the choice of the Greater Copenhagen area. Hence, regions that want to attract biomedical companies like Biogen Idec might want to consider focusing on these issues in their efforts to provide an attractive alternative to other regions.

Sources

Interview

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