

EMCC case studies

Biomedical healthcare sector: Berlin-Brandenburg cluster, Germany

Background

Key facts

Industry and product development

BioTOP initiative

Main changes and challenges

Competitive advantages

Weaknesses and threats

Workforce

Conclusion

Sources



Background

The biotechnology cluster in the Berlin-Brandenburg region was established on the basis of a federal initiative in 1996. That year the German Federal Ministry of Education and Research (BMBF) announced a competition for regions across Germany to show what scientific, economic and political resources they could offer to start catching up with the US in the field of biotechnology. On this basis, the state governments of Berlin and Brandenburg launched the BioTOP initiative, leading to the establishment of a biotechnology infrastructure in Berlin-Brandenburg and the creation of an organisation (BioTOP) dedicated to promoting and facilitating the development of the biotechnology industry in the region.¹

Part of the reason for the BioTOP initiative was the strong interest of key local government actors in accelerating economic growth in Berlin after the unification process. Berlin is not an industrial city and, at local government level, there was an explicit interest in facilitating the development of new industries, such as the biotechnology industry.

The Berlin-Brandenburg region already had an outstanding scientific research environment and a wide-ranging medical sector with a long tradition when the BioTOP initiative was launched. But since 1996, more than 120 new biotech companies have been founded, six biotechnology parks have been established and expanded, and existing research facilities have been able to further consolidate their position. This positive development suggests that the BioTOP initiative has had a big impact on the development of the regional biotechnology industry. The BioTOP initiative was supplemented in 2005 with the approval of a master plan for the development of biotechnology and biomedicine in Berlin-Brandenburg up to 2010.

Key facts

The Berlin-Brandenburg biotechnology cluster is the biggest biotechnology cluster in Germany, and is among the leading biotechnology clusters in Europe. The cluster consists of 174 biotechnology companies, five universities, three technical universities and more than 20 research institutes with a total of 350 work groups. More than half of the biotech companies are spin-offs from the universities and research institutes.

The cluster is undergoing positive development. In 2006, biotechnology companies in the Berlin region continued their positive growth trend of previous years, and the 174 biotechnology companies currently employ 3,427 people – an increase of 7% compared to 2005. An additional indicator of the cluster's leading position is that the merger of the Berlin-based Bayer-Schering Pharma created the world's 7th largest biotechnology company.

Of the 174 biotechnology companies, 76% work in the field of biomedicine. The distribution of companies according to market segments (some companies work in several segments) and the changes in the number of companies within each segment in the period 2001–2006 are shown in Figure 1.

BioTOP, Biotech report 2006/2007, http://www.biotop.de/download/Biotech-BerlinBrandenburg-2007.pdf

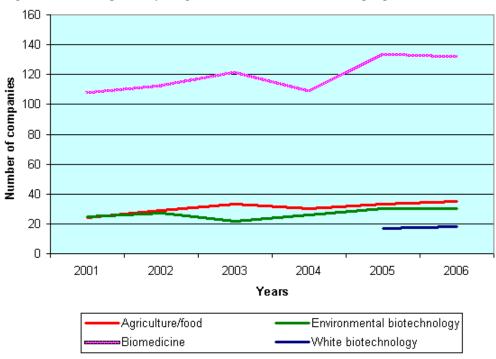


Figure 1: Market segments of companies in the Berlin-Brandenburg region, 2001–2006

Source: BioTOP, Biotech report 2006/2007, http://www.biotop.de/download/Biotech-BerlinBrandenburg-2007.pdf

12 new biotechnology companies were registered in 2006, while eight companies went out of business. Two of them left the region, three ceased operations and three discontinued biotechnology. There were no insolvencies involved. The 12 new companies created 66 new jobs, while 58 jobs were lost due to the closures.

In terms of employee numbers, the cluster has experienced very positive developments since 1996 (see Figure 2).

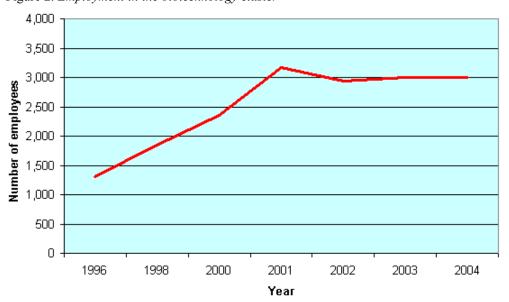


Figure 2. Employment in the biotechnology cluster

Source: BioTOP, Biotech report 2006/2007, http://www.biotop.de/download/Biotech-BerlinBrandenburg-2007.pdf

In comparison to other industries in the region, biotechnology showed above-average growth of 7% in 2006. A strongly growing core of 70 companies contributed most to this positive trend, creating 274 new jobs

The majority of biotechnology companies in the cluster are small companies (1-10 employees). Companies with 11-50 employees account for 31% of biotechnology companies, while those with more than 50 employees account for 8% of the total. The largest companies experienced the strongest growth in the number of employees in 2006.²



Figure 3: Distribution of companies by size (number of employees)

Source: BioTOP, Biotech report 2006/2007, http://www.biotop.de/download/Biotech-BerlinBrandenburg-2007.pdf

Although large companies are few in number, they account for the largest share of employees in the cluster (47%).

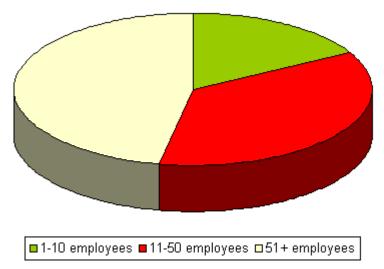


Figure 4: Share of employees by company size

Source: BioTOP, Biotech report 2006/2007, http://www.biotop.de/download/Biotech-BerlinBrandenburg-2007.pdf

² BioTOP, Biotech report 2006/2007, http://www.biotop.de/download/Biotech-BerlinBrandenburg-2007.pdf

Industry and product development

The regional biotechnology industry has developed very well overall. M&A (mergers and acquisitions) activities and increased international cooperation have generated important impulses for growth and expansion in the cluster. Moreover, in 2006, a number of important new cooperation contracts were signed between biotechnology and pharmaceutical companies. Examples include the strategic alliance between Pfizer and NOXXON Pharma AG, the research and development partnership between Centocor Inc. and Epigenomics (a Berlin-based molecular diagnostics company) and the cooperation between Baxter and Jerini (a pharmaceutical company focusing on the discovery, development and commercialisation of novel peptide-based drugs).

In terms of product development, a number of important milestones were reached in 2006 and the pipeline has been strengthened – the regional development pipeline grew by 27% overall. A total of 27 companies have 93 product developments in the preclinical and clinical trial phase, of which 57 are currently preclinical and 16 are in Phase I. A total of 20 products are in Phase II/III. At least two admissions were expected in 2007.

BioTOP initiative

BioTOP Berlin-Brandenburg has been a 'one-stop agency' for all matters concerning biotechnology in the area since its establishment. BioTOP started out as a virtual organisation, and it was not until 1997/1998 that it was formally established. BioTOP is not a membership organisation and hence receives no fees from companies. Instead, funds for the not-for-profit organisation come from local government (60%), industry (10%) and income generated from various projects (30%). There are currently 7-8 persons working at BioTOP.

The overall objective of BioTOP is to coordinate all regional activities in biotechnology by networking with all key players and to initiate specific projects in order to turn Berlin-Brandenburg into a globally leading industry site, known as a competence centre for biotechnology. A main element in this is to transform scientific potential into products by supporting companies with the commercialisation of their scientific discoveries. However, the organisation also acts as a forum for discussion and collaboration. In this regard, the organisation is playing the role of a moderator and facilitator, rather than the role of a decision maker.

The key services provided by BioTOP include:

- Technology transfer between science and industry.
- Initiation and support of networks.
- Support for technology-oriented start-ups.
- Funding support for innovative projects.
- Building and coordination of scientific and interdisciplinary networks, and establishing contacts between experts from all disciplines.
- Design and organisation of events.
- Public relations work for the Berlin-Brandenburg biotech region.

For several years, one of the main priorities for BioTOP has been to support start-ups by identifying potential sources of funding (e.g. the Fit for Finance initiative), helping with the development of business plans, etc. However, support for commercialisation is also high on the agenda.

BioTOP is part of a larger organisational network, headed by the TSB Technology Foundation Berlin – an independent regional organisation that sponsors science and research in selected technology sectors, promotes concrete innovative projects and conducts strategic dialogues on technology policy matters in Berlin. In terms of formal external relations, the organisation is a member of Bio Deutschland³, Council of European Bioregions⁴ and Scanbalt⁵.

Main changes and challenges

Transformation of the healthcare market

According to Dr Kai Uwe Bindseil, managing director of BioTOP, the healthcare market is changing. This change is triggered, in large part, by the growing number of elderly people in Europe, expanding the market for products targeted at this segment.

Also, chronic diseases and a focus on lifestyle-related diseases (obesity) constitute expanding markets. Further opportunities include personalised medicine and orphan drugs.⁶

Weak venture capital market

According to BioTOP's annual assessment report, most companies in 2006 successfully managed to finance their operations through cooperation agreements and milestone payments, license transactions, development commissions and, last but not least, sales revenues from services rendered and product sales. However, for several years, the sector has been characterised by a weak venture capital market, and start-ups in particular have been struggling to get the necessary funding for their research. In particular, access to seed financing capital is very limited – not least when it comes to companies that are working with biopharmaceuticals in the early phases of development, when investment needs are pronounced and the level of risk is high.

At the European level, the different funding opportunities, such as the European Framework Programmes, are not really geared towards supporting R&D in companies. The instruments are too complex and the chances of getting the needed funds are limited. Such funding mechanisms are probably more interesting for research institutions. At the federal level, however, there is a range of interesting funding mechanisms. The Go-Bio programme is targeted at scientists who need support for establishing their own biotechnology company. Another programme is BioChancePlus, dedicated to companies in the post start-up phase. Finally, there is also a range of regional schemes which provide funding for R&D in the biomedical sector.

Bio Deutschland website, http://www.biodeutschland.org/

⁴ Council of European Bioregions website, http://www.cebr.net/

⁵ Scanbalt website, http://www.scanbalt.org/

^{6 &#}x27;Orphan drugs' are medicinal products intended for the diagnosis, prevention or treatment of life-threatening or very serious diseases affecting fewer than five in 10,000 persons in the community. These drugs are called 'orphans' because the pharmaceutical industry has little interest, under normal market conditions, in developing and marketing products intended for only a small number of patients suffering from very rare conditions. Source: European Commission website, http://ec.europa.eu/health/ph_threats/non_com/rare_6 en.htm

BioTOP, Biotech report 2006/2007, http://www.biotop.de/download/Biotech-BerlinBrandenburg-2007.pdf

⁸ Go-Bio website, http://www.go-bio.de/

While these initiatives are important, according to Dr Bindseil, the one thing that would truly have an impact on the development of biomedical companies is significant change in the venture capital landscape.

Segmentation of SMEs

In the Berlin-Brandenburg area, SMEs belong to one of two groups: SMEs focusing on product development (e.g. in the areas of biopharmaceuticals and diagnostics), and a relatively large group of SMEs focusing on providing services or instruments to companies in the biomedical sector, medical devices or 'traditional' pharmaceuticals. Often the service companies are biomedical companies that were previously involved in product development that have decided to change their business strategy and focus on providing services instead of developing new products. This 'service track' is characterised by stable growth and companies in this segment are becoming increasingly profitable.

In terms of financing needs and risks, these two types of companies are very different. Companies involved in drug development need considerable funding and face considerable risks during the development process, while the funding needs and risks associated with the provision of services is less extensive. In the last couple of years, it has been very difficult to get venture capital, and the change of business strategy in the sector could be a response to this.

Importance of regenerative medicines and therapies

In recent years, the significance of regenerative medicine has increased rapidly worldwide. Stem cell research has become a highly competitive field internationally, and there has been a need to concentrate forces in this area at the regional level. In response to this challenge, the Berlin-Brandenburg Centre for Regenerative Therapies (BCRT) was established in 2007. The entre specialises in using the findings of basic research in regenerative medicine for clinical applications.

The BCRT is a joint initiative of Europe's largest university hospital, the Charité, and Germany's leading research organisation, the Helmholtz Association. Together with 23 new research teams, scientists from these two institutions are working under one roof at the Charité Campus Virchow Hospital in order to develop clinical applications and products. With the establishment of the centre and the concentration of relevant scientific expertise in one place, it has been possible to focus the skills that are available in the region.

Need for cross-disciplinary thinking and organisation

Crossing the boundaries between disciplines and individual research facilities is one of the main challenges when it comes to promoting innovation in the biomedical sector. This point has been incorporated in the organisational set-up of the Berlin-Brandenburg Centre for Regenerative Therapies (see Figure 5).

BioTOP, BioTOPics_30 regenerative medicine in Berlin-Brandenburg, 2006, http://www.biotop.de/biotopics/pdf/biotopics30_en.pdf

Regenerative Therapies Translational Technologies Cell and Factor Delivery · Applied Cell Biology · Bioreactors · Preclinical Testing F2 **Immune System** Cardio-Nervous Liver Musculoskeletal Adoptive Immune Cell Therapy vascular System Therapy System Imaging Mechano Biology System **Biological Healing Potential** Immune Regulation Molecular Basis **Business Development - Education** 19 new Investigator Groups Ethics - Communication **Bio-Engineering** Biomaterial Delevopment - Scaffold Engineering - BioInterface Engineering - Cellular Engineering - Drug Delivery Systems Genomics · Proteomics · BioInformatics · Cell Biology · Immune Methods

Figure 5: Organisation of the Berlin-Brandenburg Centre for Regenerative Therapies

Source: BioTOP, BioTOPics_30 Regenerative Medicine in Berlin-Brandenburg, 2006, http://www.biotop.de/biotopics/pdf/biotopics30_en.pdf

The organisational set-up of the centre provides an opportunity for real and intense interdisciplinary cooperation. The vital progressive feature of this centre is that it enables scientists to transcend the borders between specialties within Charité and to jointly tackle projects that are important to all disciplines, such as cell sorting, cell banking and cell imaging, so that everyone benefits.

Regulatory field

The main barriers for bringing innovative medicines to the market include national regulation and particularly the rules for the reimbursement of medical costs. In Germany the rules are not very flexible compared to, for instance, the US. Innovative and expensive medicines are not reimbursed to the same extent as traditional medicines. This is a problem for small companies that develop innovative medicines, since they will not be able to profit from those medicines in the short term.

Innovation challenge

BioTOP has identified a range of barriers to product development in the biomedical area: 10

- No understanding of the market value of discoveries.
- Difficult to assess the importance to the clinical sector of a certain product.
- Lack of data to validate discoveries.

BioTOP, Handlungsfeld Biotechnologie/Biomedizin Status April 2007, http://www.health-capital.net/download/hf-05-themen-2007-04.pdf

- Discoveries do not by themselves lead to new products.
- Development of products is not of interest for scientific institutions, since they lack the financial means for further development.
- Lack of partners for further development of products.
- Lack of knowledge of starting up businesses among potential entrepreneurs.

These barriers need to be overcome in order to ensure that the level of innovation in the cluster remains high. In terms of cluster initiatives aimed at promoting innovation, Dr Bindseil points to the 'Innovationsoffensive Life Sciences TOP-50' initiative. This initiative runs from 2006–2008 and involves a screening of biotech and biomedical research projects. The projects are assessed by a panel consisting of scientists and representatives of venture capital, who assist selected research projects by designing a work plan and by providing support for the commercialisation of research results.

Relocation of activities

There are no significant large-scale manufacturing activities in the Berlin-Brandenburg any more, but near-shore outsourcing to Central and Eastern Europe or offshore outsourcing to other regions, such as Asia, is not perceived to be a big problem. Some R&D companies are moving to Asia, but most of the Berlin-based R&D-intensive companies are staying in the cluster. Some Asian companies are in fact moving small-scale manufacturing activities and R&D activities to Europe.

One example is the Korean company FCB (Future Cell Bank)-Pharmicell, which in 2006 decided to establish a laboratory facility for the production of adult stem cells under Good Manufacturing Practice conditions in Berlin. ¹¹

In general, while Asian companies tend to locate their European headquarters in continental Europe, US companies often locate their European headquarters in the UK, primarily for language reasons.

Competitive advantages

There is a range of factors that make the cluster in Berlin-Brandenburg an attractive location for companies in the biomedical healthcare sector.

Scientific potential is business potential

One of the main strengths of the cluster is its scientific potential. The cluster has the highest density of universities, research institutes and hospitals in Germany and therefore possesses a unique concentration and variety of research and education. The sheer size of the cluster also matters. Companies in the sector tend to move to big (in terms of the number of companies and research institutions) clusters. This move is also often recommended by venture capital – in fact, moving to a large cluster often makes it easier for companies to attract venture capital.

BioTOP website, Pharmicell Europe GmbH: Company launch in Berlin-Brandenburg, http://www.biotop.de/news/archiv detail e.asp?ID=2202

University of Potsdam – BioMedTech website, http://www.mba-biomedtech.de/index.php?article_id=8&clang=1

Around 50% of all the companies in the cluster originate from local research institutions. In Dr Bindseil's words, the research intensity in the region is also a benefit for the cluster, in terms of numbers of companies and the level of innovation.

Strong infrastructure

The availability of suitable laboratory and office spaces is often mentioned as one of the success factors responsible for the growth of the Berlin-Brandenburg Bioregion. Compared to other clusters in Europe, there is a high spatial concentration of biotechnology parks, which offer low rent and a full range of services. The parks differ in their offers and strategic focus and provide good conditions for newcomers. More than half of the companies in the cluster use the infrastructure provided by a publicly or privately managed park. ¹³

Scientific networks

Biotechnology is highly diverse and this is reflected in the numerous thematic networks between companies and scientific institutions in the region. These networks are vital for the success of the cluster, since close cooperation between partners from science and industry ensures effective technology transfer and speeds up the conversion of the results of basic research into wide-ranging applications. The list of thematic networks includes networks in Bioinformatics, Functional Genomics, Personalised Medicine, Nutrigenomics, Regenerative Medicine and Tumour Diagnostics.¹⁴

Proximity to authorities

Most of the relevant German authorities have their headquarters in Berlin-Brandenburg, and this closeness to the authorities is important for biomedical companies. It is a highly regulated sector with complex and resource-demanding approval processes, and therefore the ability to work closely with the different public authorities is a must.

Proximity is also an issue for young companies that can benefit from collaborating with scientific institutions in the region. With the high density of research institutions in the cluster, the cluster becomes the natural focal point for young, innovative companies.

Human resources

The Berlin-Brandenburg region is home to 6 million people, who are not only potential customers but also form a pool of highly qualified potential employees. The availability of well-educated staff is a key priority when companies look for places to locate their activities. Due to the number and high quality of regional research institutions and educational institutions in the area, the Berlin-Brandenburg biotechnology cluster is able to provide the human resources needed for high-level R&D activities.

Living conditions and cost levels

According to Dr Bindseil, Berlin is among the five most interesting cities in the world, and this is also important for companies in deciding where to locate their business. They need to be able to attract top scientists and high level managers to this place, and perhaps even live there themselves. Moreover, living expenses are low and, although the infrastructure is exceptional, the costs of establishing R&D facilities in Berlin are significantly lower than elsewhere in the world.

Kompetenznetze Deutschland website, http://www.kompetenznetze.de/navi/en/Kompetenznetze/biotop-berlin-brandenburg.html

¹⁴ Ibid.

Weaknesses and threats

According to Dr Bindseil, the main weakness of the cluster is that Berlin is not a financial centre like, for instance, London. The financial centre of Germany is Frankfurt. This is a problem in terms of finding venture capital (institutions with venture capital are concentrated in Frankfurt). Also, Germany's federal structure makes it difficult for foreign companies to find their way in the German biotechnology landscape. There are many regional centres and thus many potential places to set up biotechnology businesses. Smaller countries, such as Denmark, have only one 'centre' (i.e. the Greater Copenhagen area), making it easier for companies to navigate. However, measures have been implemented in order to support companies considering moving to the Berlin-Brandenburg region. Among the key initiatives is the establishment of the Business Location Centre Berlin-Brandenburg, which provides sector-specific support to biotechnology companies.

Business Location Centre Berlin-Brandenburg

The Business Location Centre Berlin-Brandenburg provides information about foreign trade to Berlin-based companies, and information about Berlin as an economic location to foreign companies considering moving to Berlin.

According to the centre, Berlin-Brandenburg offers the following opportunities for life science companies:

- Close collaboration and cooperation between science and business.
- Proximity to European growth markets.
- Affordable labour costs, flexible working hours.
- Best business support conditions in Europe.
- An important sales and test market for new therapies and technological innovations.
- An optimal infrastructure for new companies and start-ups.
- A strong support industry in the surrounding region.
- Quick, non-bureaucratic authorisation procedures.
- The centre of healthcare policy decision-making in Germany.

Source: Business Location Centre Berlin-Brandenburg website, http://www.blc.berlin.de/en/B/iv/seite0.jsp?nav1=open&nav2=open

Workforce

Recruitment

The demographic situation is a concern for companies in the cluster, since the decreasing size of the European population reduces the pool of potential employees. However, Berlin is an attractive city for young people, and this ensures that there is always a large pool of young people from which to recruit.

The sector is research intensive, and therefore the major concern in the sector is to attract top-level scientists. One major challenge for biomedical companies is that scientists do not find the biotechnology industry, and drug development in particular, as attractive as they did some years ago. In the 1990s, the sector was considered a 'fast track' to success and wealth, but negative developments in the sector after the bursting of the 'technology bubble' in 2000 changed the

perception of the sector. The sector is no longer perceived to be a fast way to get wealthy, and thus is not as attractive as other sectors. At the moment there is no lack of scientists in Berlin, but there is a constant risk of 'brain drain' from Europe to the US – especially when it comes to top-class scientists.

Skills needs

Whereas the threat of a lack of top scientists is a concern, according to Dr Bindseil, the most important present skills deficit in the biotechnology sector today exists at management level. The majority of managers have a scientific background, and they lack knowledge of, and experience with, the management of a biotech company. On the other hand, managers need to have an in-depth understanding of scientific issues in the field of biotechnology. Therefore, people with a pure management background are not considered to be suitable alternatives.

Over the years, managers in the sector have gained more managerial experience through 'learning by doing'. Formal training programmes focusing on the management of biotechnology companies have been established – one example is the MBA BioMedTech programme at the University of Potsdam.

The MBA BioMedTech programme at the University of Potsdam

The MBA BioMedTech offered at the University of Potsdam is a part-time MBA programme that has been created for managers in the fields of biotechnology and medical technology. The fundamental objective of the MBA BioMedTech is to expand the personal and professional perspectives of the participants.

Managers educated in science or engineering are trained in all fields of current management studies and learn how these are interlinked. In addition to looking at various practical solutions and questions, particular importance is given to analytical and strategic thinking. The MBA programme introduces the participants to general management issues, in combination with sector-specific management issues, within biotechnology and medical technology.

The MBA BioMedTech is adapted to the requirements of professionals and companies by combining distance learning and on-site training modules. This ensures maximum flexibility for the participants. The majority of the on-site modules take place during weekends.

Source: University of Potsdam, BioMedTech website, http://www.mba-biomedtech.de/index.php?article_id=1&clang=1

In terms of the specific skills needs at managerial level, business developers often lack experience in international markets or clinical development.

In addition to the need to enhance management skills in the sector, there is currently a lack of lab technicians in the region, and companies need to focus their training efforts on this specific staff category. However, young, small companies are often not motivated to invest in the education of lab technicians. The education of lab technicians takes three years; small, young companies do not have the resources for training and lack a long-term perspective in their approach to training.

Stimulating interest in science and technology

A range of different initiatives have been launched in order to stimulate interest in science and new technologies among young people and to give new impetus to science teaching at educational institutions. In November 2006, the Berlin-Brandenburg Learning Laboratory Network GenaU (the German acronym stands for 'Joining Together for Scientific-Technological Instruction') got underway. GenaU is a network of extramural scientific-technological learning sites at

research institutions, universities and museums in Berlin and Brandenburg. The learning laboratories give young people an opportunity to experiment on their own. Their offers include further education for teachers and events for students.¹⁵

Conclusion

The success of the Berlin-Brandenburg bioregion depends on the cluster's ability to attract a substantial number of innovative biotech companies to the region and to offer them a strong infrastructure. The establishment of networks for cooperation between research and industry has been considered vital for the competitiveness of companies in the region and the cluster as a whole. Positive developments in the cluster, and the intensive collaboration between the many regional actors, gives an indication of the success of BioTOP in meeting those challenges.

However, the cluster faces a range of challenges:

- Closing the critical gap between science and industry.
- Securing funding for product development.
- Promoting and supporting innovation and commercialisation.
- Employing the right people.

The challenges facing the cluster are developed further in the following SWOT analysis.

SWOT analysis

The following strengths, weaknesses, opportunities and threats can be identified for the Berlin-Brandenburg biotechnology cluster.

Strengths	Weaknesses	Opportunities	Threats
Many high-quality research institutions and research-	Commercialisation of scientific discoveries	Transformation of the healthcare market	Weak venture capital market for biotechnology
intensive companies	Difficult to get funding	 Providing biotech services 	Recruitment problems
• Strong infrastructure and networks	Small, young companies do not invest in staff training	Regenerative therapies	Extensive regulation, national healthcare systems
• Living conditions and cost level	Skills gaps		Berlin is not a financial centre
• Closeness to public authorities			Complex governance structure

 $^{^{15} \} Bio Top, \textit{Biotech report 2006/2007}, \\ \textbf{http://www.biotop.de/download/Biotech-BerlinBrandenburg-2007.pdf}$

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