

## Bio Germany: Building on its strengths



### Area Development Site and Facility Planning

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The nation's biotech industry is meeting the challenges of sustaining viability and growth.

The advanced biotechnology sector in Germany, home to 82 million people, operates as one of the strongest in Europe. While in the past it has been called the "most densely populated Kindergarten in the biotech world," these days it's being promoted by "good grades."

Many of the nation's biotechs have achieved numerous milestones and triumphs in the global marketplace thanks to the researchers who've earned acclaim for their scientific innovations. They co-exist and collaborate with numerous well-established pharmaceutical manufacturing and marketing companies, including Aventis Pharma, Bayer AG, GlaxoSmithKline GmbH, Pfizer GmbH, and Lilly Deutschland GmbH.

Despite these successes the young industry's future here could be at a crossroad, as questions have recently erupted concerning the ability of some players to sustain viability and growth - even with solid government support.

### Foundation for Commercial Activity

A bit of historical background is helpful in understanding what's happening today in the German biotech sector. As evidenced by antigenetic activism, repressive regulations, and little investment capital for the industry, even into the 1980s biotechnology was not something the German people were overwhelmingly interested in learning about or investing in. However, that commercial "desert landscape" began to green up in the early 1990s. A watershed moment occurred in 1993, when Germany amended its Genetic Engineering Act (passed three years prior) to facilitate commercialization of biotechnology.

Then something amazing happened. The nation's biotech infrastructure was created almost overnight by one visionary federal government program named BioRegio. Established in 1995 by the German Ministry of Education and Research, this national competition encouraged regions to cultivate and nurture new biotech firms. Of the 17 areas that took up the challenge, by 1996 three had actually succeeded: Heidelberg, Munich, and the Rhineland. The "runners-up" regions continued with their plans to jumpstart biotech work by securing funds from state governments and other sources. According to a 2002 article in *The Scientist*, a news journal for life scientists, those regions each received DM 50 million over five years. The funds were used to "hire scientists, fund research projects, build incubator facilities, and establish central offices."

Even though the tide of opinion was changing, in the late 1990s the majority (75 percent) of German biotech investment was still made abroad - mostly in America. The related industry of pharmaceuticals, however, was booming at home. By 1997 Germany ranked as the world's fourth-largest producer of pharmaceuticals after the United States, Japan, and France.

BioRegio sparked interest in biotechnology like nothing else before it. Vital partnerships were established among universities, research centers, and biotech startups, and government and private financial aid - including venture capital monies - began to flow into the fledgling industry. Public, political, and scientific viewpoints began to shift to the positive side. Finally biotechnology became an exciting entrepreneurial activity for Germans. The contest remains a model program for other nations seeking to jumpstart their weak or nonexistent biotechnology sectors.

Related to BioRegio's success, the Association of German Biotech Companies (VBU) was formed in late 1996 with 55 members. Two years later, half of the member firms were no more than five years old, and 45 percent had 10 or fewer employees.

According to an E&Y report, at the end of 1999 the sector really showed off its newfound strength by increasing its company numbers by 25 percent over the previous year. "The still-young industry in Germany reached a milestone. With 279 ELISCOs [small and medium-sized companies which commercialize modern biotechnology], Germany narrowly overtook Great Britain in the total number of biotech companies," explains the study. These ELISCOs "form the heart of the German biotech industry and are the driving force behind the growth of the country's life sciences industry. The better established ELISCOs, such as Evotec OAI, GPC Biotech, LION Bioscience, MediGene, or MorphoSys have been able to assert themselves against international competition."

By the end of 2002, E&Y says the sector supported 360 firms and 13,400 employees. However, quantity isn't the determining factor when assessing any industry's health. Since a number of these biotechs are spin-offs of universities and research centers, some concerns arise about the depth of business experience possessed by executives who were pulled from the world of academia rather than the world of business.

### Insights from 2003 E&Y Biotech Report

Fast forward to this year. Just last month E&Y released "At the Crossroad: German Biotechnology Report 2003." This fourth report in a series describes the current situation - and current mood - of Germany's biotech industry and focuses on "core biotech enterprises" - firms which predominately develop or use modern biotech methods.

In contrast to past years of "strong dynamic growth," E&Y believes the nation is "at a crossroad and will have to prove its sustainability and endurance." What's the prognosis? The authors contend today's situation in Germany is characterized by a "clearly shrinking volume" of venture capital financings, reduced growth rate in net losses based on cost-saving programs, and an increasing number of products in Phase I.

And the upshot is ". . .the industry is facing an acid test which, in the years to come, will separate the successful from the unsuccessful companies, particularly affecting firms which are essentially eligible for financing with business models that will not receive financing. . ."

Last year marked the first time the total number of German core biotech firms did not increase. In 2002 there were 360 of them compared to 365 the previous year, points out the study. This is connected to "the expected consolidation wave." Also, for the first time the number of firms going out of business (30) outnumbered new formations (25). In contrast, the growth rate was 20 percent in 2000 and 25 percent in 1999.

"Altogether," notes E&Y, "the decrease in the number of companies still represents less than 10 percent of all core biotech enterprises. So the expected substantial breakdown in the number of firms has not yet occurred." Not unexpectedly, then, the German core biotech industry lost 1,000 employees in the past year, decreasing from 14,408 workers in 2001 to 13,400 in 2002. About half of the employees in 2002 were engaged in R&D work.

Regarding financing and capital markets, E&Y notes venture capital was the primary source of equity available for the German biotech industry in the past year. "The total

amount of invested venture capital - about euro200 million is slightly greater than the level in 1999. . . Altogether, compared to the year 2001, capital invested into the biotech industry has been reduced by more than 50 percent. In contrast to the year 2000, the worldwide 'boom year' in equity financing, the German biotech industry has had access to less than a sixth of the equity raised at that time."

On the positive side, "the number of active substances in Phase I clinical development increased by 25 percent, although the total number of active substances in the clinical development stage has not changed," states the study. "Like last year, there are 60 products in clinical development. . . However, we are still awaiting the first product derived from R&D efforts of a German biotech company to reach the market."

The regional distribution of core biotech companies did not change from 2001 to 2002. The leading German federal states are Bavaria (85 firms), Baden-Wurttemberg (67 firms), North Rhine-Westphalia (42 firms), and Berlin (26). A three-year analysis shows that "among the five strongest states Baden-Wurttemberg and Lower Saxony had an increase in the number of enterprises despite the current situation." The key business areas of the study's sample companies were, in order of prominence, therapeutics, molecular diagnostics, drug delivery, food (including diagnostics), tissue engineering, bioinformatics, transgenic plants, and fine chemicals.

According to Dr. Julia Schuler, project manager of this E&Y report, current major players in Germany's biotech scene include public companies Qiagen, LION Bioscience, Evotec OAI, GPC Biotech, MediGene, and Morphosys; private companies Cellzome, febit, Graffinity Pharmaceuticals, 4SC, apovia, Axxima Pharmaceuticals, Curacyte, Micromet, Morphochem, Scil, Willex, Xantos, Xerion, atugen, Epigenomics, NOXXON, JERINI, metaGen Pharmaceuticals, Zentaris, DeveloGen, amaxa, Artemis Pharmaceuticals, Aliga Pharmaceutical, Cardion, DIREVO Biotech, and Paion; plus "new exciting startups" such as Pieris Proteolab, elbion, Cenix Bioscience, GeneBridges, Lynkeus Biotech, SiREEN, G2M Cancer Drugs, Phenion, and Avontec.

### Support Beyond BioRegio

BioRegio was just the beginning of major government-funded biotech programs seeking to boost the industry.

The BioFuture competition funds individual young as well as experienced scientists, giving them the chance to start a scientific career or to set up a company in Germany. Funded by euro55 million, the BioFuture Prize has been awarded to 38 outstanding researchers thus far. Eight firms were founded thanks to the prize money, and five winners have received positions at German universities.

Since 1999 BioChance grants have supported at least 52 young German startups. These monies enable companies to expand their scope of research and broaden their product pipeline, thus reducing the risk of failure. Then there's BioProfile, which asks regions to create a unique local cluster in one strategic area of biotechnology. It differs from BioRegio as it seeks to broaden the scope of German biotechnology and focus on areas such as bioinformatics as well as agricultural and environmental biotechnology.

In 2001 the federal government launched its new, comprehensive DM1.85 billion "Biotechnology Research and Technology" framework program that set annual allocations for biotech and genetic engineering from 2001 to 2005. Its activities are designed to support new biotechnology companies doing research, support young scientists, encourage greater cooperation between science and industry, plus extend biological safety research and reorient biotechnology toward sustainability.

That same year the government also began funding the new National Genome Research Network to the tune of DM350 million over a three-year period. The initiative supports centers of excellence in genome research and the establishment of disease-oriented functional genomics networks. It also promotes activities in proteomics and bioinformatics as well as projects focused on the ethical, social, and legal aspects of genome research. Specifically, the network funds the Max Planck Institute for Molecular Genetics in Berlin (DM19 million) plus four other (Helmholtz) genome research centers: the German Cancer Research Centre in Heidelberg (DM50 million), the Biotechnology Research Centre in Braunschweig (DM15 million), the Research Centre for Health and the Environment in Munich (DM42 million), and the Max Delbrück Centre for Molecular Medicine in Berlin (DM7 million).

Germany's biotech industry also is supported by numerous incubators as well as industry and technology parks. For example, L-Bank (state bank of Baden-Württemberg) operates state-of-the-art parks for life science companies built near well-known universities and research facilities. They include:

- \* Tübingen/Reutlingen Technology Parks: Dozens of new life-science companies have developed rapidly as a result of the cooperation between Tübingen University, hospitals, and research facilities.
- \* Gottmadingen Industrial Park: This old industrial site near the Swiss border has been successfully revitalized over a period of just 10 years, and today is a fast-growing commercial and logistics center.
- \* Karlsruhe Technology Park: A leading center for high-tech companies and other

innovative enterprises located in the Karlsruhe Technology Region, its internationally renowned for a famous technical university and many research facilities.

In fact, the state of Baden-Wurttemberg, located in the southwest of Germany adjoining France and Switzerland, has developed into one of the nation's most prominent biotech locations. Its powerful bioscience research infrastructure includes six universities, eight polytechnic engineering schools, and 16 private or public research institutes. Some 3,700 people work in Baden-Wurttemberg's biotechnology sector. The state is home to 400 companies operating in the fields of biotech/pharma, optics/precision mechanics, and medical technology, including 140 biotech R&D firms.

### Other Biotech Hot Spots

While there are 18 biotech centers in Germany - some more growth-oriented than others - the major clusters are found in a handful of regions:

\* Munich (Bavaria), the venture-capital metropolis, is home to 120-plus biotechs and small pharmaceutical firms. It also boasts Garching Innovation, the technology transfer division of the Max Planck Society; the Genetic Research Center (Genzentrum) at the University of Munich; and the Life Science Center (Freising-Weihenstephan) specializing in research on agro and food biotechnology.

\* The Cologne/Duesseldorf (North Rhine-Westphalia) area is home to the Max Planck Institute for Plant Research (Zuchtungsforschung).

\* The Heidelberg (Baden-Wurttemberg) region's University of Heidelberg houses the European Molecular Biology Laboratory and a noted center for cancer research. Not surprisingly, numerous well-known universities and public research institutes are situated in those areas. Here too are found production facilities with global impact; i.e., companies Boehringer Ingelheim, Rentschler Biotechnologie, and BioReliance Manufacturing (all in Baden-Wurttemberg); ProBioGen and Alpha Bioverfahrenstechnik (both in Berlin); and Strathmann Biotec (Hamburg).

According to Boston consulting group A.T. Kearney and BioCom, the Berlin-Brandenburg area in particular is renowned as a biotech locale in Germany as well as in all Europe. The region (not one of the original BioRegio winners) has experienced incredible growth during the past years and presently is home to more than 160 biotech companies directly employing about 3,200 workers. Moreover, 250 other "work groups" are engaged in biotech activity at local scientific institutions: five universities, three technical universities, as well as 20-plus major research institutes. They represent the highest density of scientific R&D found anywhere in Germany. In

total, the regional biotech industry employs about 10,000 people.

Companies in Berlin-Brandenburg work primarily in the biotech areas of genomics, proteomics, biohybrid technologies, tissue engineering, bioinformatics, and nutrigenomics. Not surprisingly, over half of them are spin-offs of universities and research centers that are said to produce 10 to 20 biotech business startups annually. A major facility here is the Robert-Koch Institute, an important research/reference facility of the Federal German Ministry of Health for biomedical sciences and gene technology. It is named after Robert Koch, a Berlin bacteriologist who received the 1905 Nobel Prize for Medicine for his pioneering achievements in tuberculosis research.

Besides the scientific environment, a suitable technical infrastructure (lab/office space found at seven biotechnology parks) supports the Berlin bioregion's success. In fact, more than half of the region's 160 firms do business from operations located in one of these private or public facilities. Other attractors include existence of a thriving biotech cluster, a low cost of living, attractive commercial rental rates, and a pool of highly skilled workers. Moreover, "red tape" is not as thick here in the capital region, meaning official permits are generally obtained faster, smoothing the way for medical advances.

What are a few Greater Berlin biotech organizations working on? The German Human Genome Project, cofunded by the federal government, seeks to identify and characterize the structure, function, and regulation of human genes. It joined the international Human Genome Project in 1995. Proteome Factory AG specializes in proteomics and target validation. Its proteomic key technology platform significantly increases the chances of identifying new drug targets in emerging disease and "biomarkers" of disease. (Finding biomarkers significantly enhances the opportunities for individual disease treatment.)

BioGenes GmbH offers highly sophisticated services in biochemistry and immunology for research and development for biotech and pharmaceutical firms worldwide. And the Research Institute of Molecular Pharmacology conducts R&D to identify and characterize biological macromolecules representing drug targets. It's also a national network of 77 research institutes, museums, and scientific service institutions.

### **[Sidebar]**

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1995.

**[Sidebar]**

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**[Sidebar]**

Baden-Wurttemberg

In the first quarter of 2003, the state of Baden-Wurttemberg, Germany's leading life sciences and biotech location in the southwest, founded BIOPRO Baden-Wurttemberg GmbH, a nonprofit organization charged with promoting, strengthening, and combining all statewide biotech activities. BIOPRO Baden-Wurttemberg focuses on international as well as marketing/promotion activities and internal statewide economic development programs for the biotech branch members. Dedicated partnering programs between biotech, pharma, and medtech are being carried out under its supervision. Other targets for partnering programs are currently under investigation. BIOPRO Baden-Wurttemberg serves a centralized contact for all information, investment, and business relocation requests on an international level.

**[Sidebar]**

NOTE: For more information about Ernst & Young's "German Biotechnology Report 2003," contact E&Y's German Health Sciences BioTeam: [biotech@de.ey.com](mailto:biotech@de.ey.com)

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