



Healthcare in Bavaria



Invest in Bavaria – The agency that pulls the strings

Invest in Bavaria is the business promotion agency of the Bavarian Ministry of Economic Affairs. Our international team is there to offer you confidential assistance with setting up a new business or expanding your present facilities in Bavaria. We will provide you with information, help you find a suitable site and arrange contacts with government agencies as well as local partners and networks. Our service is of course free of charge.

Comprehensive one-stop service

Our services range from the initial steps to set up a business operation, the identification of the optimal location in Bavaria to arranging contacts with potential employees and customers. We provide interested companies with business data and information on public support and incentive schemes. Invest in Bavaria facilitates initial contacts to relevant public administration departments, industry and business associations as well as key networks.

Network to networks

In view of the key importance of networks we provide detailed information on and networking opportunities through the Bavarian State Government's so-called Cluster initiative. Known officially as "Alliance Bavaria Innovative", the program aims to create and foster the formation of state-wide networks comprising companies, research institutions and organisations and public administration in 19 key industry sectors. Cluster spokesmen and managers create platforms that enable industry and science to forge new and intensify existing ties.

International outlook for the benefit of our customers

One indicator for Invest in Bavaria's international outlook are our language capabilities: aside from German, the team offers fluency in English, French, Spanish, Chinese, Japanese, and Russian. Our multilingual website provides information and data in German, English, French, Japanese, Chinese and Korean. Moreover, 20 Bavarian representative offices worldwide, from Moscow to São Paulo, from California to Tokyo, assist Bavarian companies abroad and foreign companies interested in Bavaria.

Promoting a strong location

Aside from the acquisition of and support for inward investors, Invest in Bavaria also promotes and markets Bavaria as a top business location. We take part in major trade fairs and industry conferences, organize seminars, company and location visits for investors and initiate targeted promotion campaigns as well as journalists' briefing to promote Bavaria - and Invest in Bavaria's range of services. With some success: major investment projects such as Merck & Co.'s (MSD Merck, Sharp & Dohme) new headquarters near Munich for its EMEA and Canada business, the decision by Linde to relocate its group headquarters to Munich, the opening of the new GE Healthcare Commercial Center in Munich or the move to Bavaria of Sandoz's HQ testify to our team's competence and commitment.

Preface



Martin Zeil
Minister of Economic Affairs,
Infrastructure, Transport and
Technology
State of Bavaria

The life sciences are one of the major sectors in Bavaria's high-performing business community. The sector is comprised of such global players as Siemens, GE Healthcare, Beckman Coulter, Novartis, Roche, Daiichi-Sankyo and MorphoSys. One key reason why these companies have set up R & D, production and other facilities in the state is to work with Bavaria's Europe-leading scientific community, which includes 11 Max-Planck-Institutes, the 3 centers maintained by the Helmholtz Society and 10 Fraunhofer institutes. World-class basic and applied research is also carried out by the state's 11 universities and 17 universities of applied sciences. Many of the graduates of these top-ranked institutions of higher education go on to work for the above companies and for the large number of life sciences SMEs in Bavaria.

Among the customers for the advanced products and services emanating from Bavaria's life sciences community are the state's health care facilities, whose reputation for excellence of treatment partially stems from these items. This reputation attracts many thousands of patients from around the world to Bavaria each year. These patients join local residents in being treated at the state's 400 hospitals and 350 centers of palliative medicine and rehabilitation. Others find cures for their ailments and wellness for body and soul at the state's more than 50 spas and clinics.

The high level of performance achieved by Bavaria's highly diverse life sciences sector stems from the close working relationships existing among the state's companies, research institutes and health care facilities. This level makes the industry a centerpiece of the state government's economic development efforts. This networking has been greatly furthered by Bavaria's Clusters Initiative, which was launched in 2006 to forge and foster ties between the state's business, especially its high-tech companies and academic communities, so as to ease and expedite the process of turning research findings into market-making products and services. To further this process, the state government has enacted policies improving the conditions under which R & D is conducted. These, in turn, have greatly increased the efficiency, effectiveness and thus output of research operations in the state, and have accordingly helped Bavaria remain one of the world's centers of advanced technologies.

To enable investors to profit from these technologies, the state government has set up a world-spanning network of representative offices located in 20 cities. These offices work closely with Invest in Bavaria, the state's business promotion agency, and with sector and regional networks in locating the sites and providing the expert services needed by investors to grow in the state.

Provided free of charge and for each step in the investment process, these services put each and every investor in touch with the organizations, clusters and networks, and associations capable of turning plans into completed projects.

This brochure will show you why Bavaria is such a great place to do business, and how our state's edges over competitors and efficiencies of structure and infrastructure make it the ideal base for your operations in the fields of biotechnologies, medical technologies and pharmaceuticals. Profit from these opportunities!

Martin Zeil
Minister of Economic Affairs, Infrastructure, Transport and Technology
State of Bavaria

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Overall design

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Bavaria Set to Become World's No. 1 Healthcare Location

An overview

No other German state has pursued such an ambitious and determined life sciences policy as Bavaria over the last 15 years. The Free State's biotechnology and medtech-sector is now the largest and most dynamic in Germany. This is all the more remarkable as conditions in Bavaria were not the best at the start of the European life sciences boom in the mid-1990s. But what exactly has driven the region's success? Which companies have developed there? And what have politicians done to create such a favourable climate? An insight into the bits and pieces that have shaped the location.

The right environment for the industry

The state of Bavaria has made life sciences (comprised of medtech, biotechnology and genetic engineering) one of the thrusts of its high-tech campaign. To that end, the state government

provided funds – in addition to those already budgeted – amounting to some EUR 80 million during the period 2000–2005. These funds stemmed from out-of-budget sources. This support complements the generous funding supplied for many years by dedicated technology development programs to research & development projects in that area.

There are certain conditions that innovative companies look for: first class research institutions to act as development partners and to generate spin-offs; local venture capitalists prepared to invest long-term; potential collaboration with major pharmaceutical businesses and, above all, political support. Bavaria offers conditions that are unique in Germany for three of these four requirements. Munich, for example, is home to nearly half of all German venture capital companies

Biotech Cluster in Bavaria

- **BioTech region Munich:** *The Munich metropolitan area is home to a uniquely powerful group of research facilities: Max Planck institutes, the Helmholtz Center in the city, and those maintained by Munich's top-ranked universities – LMU and TU. These institutes include the world-renowned Gene Center and the CeNS. The Center for Nanosciences is one of the world's leaders in the development and application of nanobiotechnologies. The universities also maintain research hospitals. Located in the Munich's southernmost district of **Großhadern** and the adjoining community of **Martinsried**, the Life Sciences Campus forms the core of Munich's BioTech region. The campus is home to nearly half of the region's biotechs, to the IZB center of innovation and incubation, to Max Planck Institutes, to the Helmholtz Society's center, to the Gene Center, to the majority of LMU's departments of sciences, and to the Großhadern research hospital.*
- *One of Europe's major centers of green (plant-derived) biotechnologies is **Freising-Weihenstephan**, a town to the north of Munich, this campus is home to a large number of research institutes, many affiliated with universities, and to an incubation center. It all adds up to a great place to develop advanced products and services.*
- **BioRegion Regensburg** *has all of the elements of a successful region: its BioPark incubation and development center, the government of the Eastern Bavaria region, and the local university and university of applied sciences. The latter specializes in fluorescent bioanalytics, molecular diagnostics, biofunctional surfaces, sensors and applied biomedicine.*
- **BioRegion Franconia:** *The region is home to three nodes of biotechnological development. Thanks to its internationally renowned university and its investigations into the fundamentals of biotechnologies and their use as medicines and applications in clinical situations, Würzburg is a national and international-level hub of research. The city's BioMed is a center of biotechnological and medical innovation and incubation.*
- **BioRegion Straubing:** *Its Center of Expertise in Regenerative Raw Materials is the main venue of Bavaria's R & D in this area. Many of the materials and technologies developed at the center are turned into products and processes by the companies profiting from the operating advantages accruing from being located in the BioCampus Straubing-Sand, which is comprised of an industrial park, a riverside port and the BioCubator (the new incubation center for renewable materials companies).*

“The Munich biotech cluster has a leading position in Europe”

Interview with Hanns-Peter Wiese and Holger Reithinger, Partners of Global Life Science Ventures



Hanns-Peter Wiese (l.) and Dr. Holger Reithinger (r.) are partners in the Global Life Science Ventures GmbH, an early-stage investor with a focus on Life Sciences, based in Munich and Zug in Switzerland.

How do you assess the quality of the biotech/healthcare companies in Bavaria in a national and international comparison?

Reithinger: As an internationally active investor, we have also supported several companies in Bavaria. With 350 life-science compa-

nies and seven stock-exchange-listed biotech companies, the Munich biotech cluster has a leading position in Europe. In a national comparison, the Bavarian companies have historically had a certain head start because of the start-ups scene rooted in Munich and the high quality of the research in biomedicine.

What site advantages do you see in Bavaria?

Wiese: The decisive factor is the presence of numerous renowned universities and non-

university research institutions, which make Bavaria one of the most important research sites in the world. A lasting culture of innovation has been created here in the cooperation between institutes, biotech companies, pharmaceutical, chemical industry and politics. The biotech region of Munich, in particular, has established itself as one of the leading international biotech sites due to the location of scientific institutions and biotech companies. Even large groups such as Roche, Amgen, MSD Merck, Sharp & Dohme, SKB SmithKline Beecham and GE Healthcare have recognised these site advantages and are active in research here.

In what areas of the life sciences do you see the declared strengths of Bavarian companies?

Reithinger: At the sites at Munich, Regensburg and Würzburg, the focus is upon red biotechnology. There, new companies are continually being founded and financed, whereas the site at Nuremberg/Erlangen is more devoted to medical technology due to the presence of Siemens.

and the state investment company BayernKapital provides young Bavarian biotech and medtech

Medtech-Cluster in Bavaria

- **Erlangen and Nuremberg** are among the world's leading experts in imaging processes (including X-rays), physical-based medical techniques, research into viruses and pharmaceuticals and in other areas of MT.
- **Munich's hospitals** and institutes (a number of both affiliated with the city's universities) are world leaders in minimally-invasive and ICT-based processes, and in other areas of medical care and technologies.
- **Regensburg** is the hub of a network setting up telemedical links between university-run and other hospitals, and is the home of the Center for Applied Biomedicine.
- Research into biomaterials, implants and magneto-resonance imaging is conducted by a **consortium** comprised of the **Universities of Erlangen-Nuremberg and Bayreuth-Würzburg**.

firms with high levels of risk capital compared to the national average. On top of their previous efforts BayernKapital launched an additional fund of EUR 30 million for start-ups in April 2009. A large proportion of this money is invested in local biotech and medtech companies while the Bavarian State Government has been channeling significant sums into Bavarian research for many years. These efforts have resulted in an extremely successful and concentrated research environment – not only all around Munich, but also in Regensburg, Nuremberg/Erlangen and Würzburg.

Bavaria's biotech cluster includes a large number of high-performance research institutes of

national and international reputation. Many of these institutes form part of the state's large universities. Others operate independently, or are associated with networks of fundamental and applied research. Some of the most promising innovations come from the highly regarded Max-Planck Institutes. They focus on basic research and enrich the area through spin-offs or partnerships with existing companies. In general, it is fair to say that the wellspring of the development of Bavaria's biotech community into a world leader was the founding and maintenance of a large number of institutes. The fruits of their research have made them famous throughout Germany and the world. Many of the state's biotechs started out as institute spin-offs.

350 company strong life sciences community

The ongoing support provided by the state government to the life science industry is paying off handsomely. As of today, Bavaria's more than 350 company strong life sciences community is by far the most important in Germany and one of the three largest in Europe. This size comes with a commensurate level of output. Bavaria's biotechs are also Germany's leaders in the creation of products which have made it to the clinical testing phase and beyond. Therapeutics and diagnostics predominate among these products.

Seven publicly-listed biotechs are headquartered in Bavaria. They join the major operations that have been set up in Bavaria by international life sciences

“The number of new companies has been constantly increasing”

Interview with Prof. Dr. Horst Domdey, Managing Director of Bio^M



Prof. Dr. Horst Domdey, Managing Director of Bio^M, Martinsried, as well as Spokesman of „Cluster Biotechnologie Bayern“

The financing of young biotech companies always represents a great challenge. What is the current situation like in Bavaria?

The financing of young start-up companies is actually pretty good. We have a number of effective pre-seed programs; we have the (Federal) Hightech-Founders Fund and the (Bavarian) Seed Fund, so that the number of newly started companies has been constantly increasing in the past years. On the other hand there are not enough “instruments” on the market for the first real VC round and for longterm financing of drug developing companies. What could help here would be a fund of funds comparable to examples in other European countries.

The Free State of Bavaria recognised biotechnology as a future industry early on. What measures by the State Government had and now have the biggest influence on Bavaria as a site for biotech?

In the past many people assumed that the state of Bavaria had poured hundreds of millions of Euros

into this new high-tech industry. But that was not the case. Instead the Bavarian Government supported the corresponding science and the technology with huge amounts of money about 500 Mio. EUR, i.e., this money did not go into the biotech industry but into the academic life science institutes, mainly new buildings. These institutes and their scientists then became the solid basis for the high number of excellent spin-offs which now form the pillars of the exceptionally strong and successful Bavarian biotech industry – which itself attracted almost 2,5 bn EUR of private money in the last years.

Where do you see Bavaria as a site in 10 years?

I can only hope for a positive development which is justified on the basis of the current dynamic developments. As we see good news from Bavarian companies raising more than 100 Mio. EUR at the stock exchange in these times of crisis I am quite certain that these hopes come true.

giants such as Amgen, Astellas, Biogen-Idec, Baxter, Bristol-Myers Squibb, GlaxoSmithKline, Novartis, Roche Diagnostics, Daiichi-Sankyo and Sandoz as well as a large number of CROs (contract research organizations). Including other service providers to the life science industry such as specialized patent attorneys, they form a community that constitutes a tremendous source of customers, products and technology development partners.

Government agencies

To assist entrepreneurs in the process of setting up and growing of biotech firms, the state of

Bavaria has established three agencies: Bio^M AG (responsible for greater Munich), BioMed Würzburg and BioPark Regensburg GmbH. In addition to providing customized services, these agencies put companies and their founders in touch with dedicated networks.

MedTech-Sector

Bavaria is a part of Germany's medtech sector – the second largest in the world after that of the USA. Nearly 150,000 people work in this line of business in Germany alone. More than half of all medtech sales are of products which are no more than three years old. Bavaria's

“Bavaria will grow into a leading site in Europe and beyond”

Interview with Prof. Dr. Michael Nerlich, Head of the Department of Emergency Surgery at the University Clinic Regensburg



Prof. Dr. med. Michael Nerlich is Head of the Department of Emergency Surgery at the University Clinic Regensburg and Chairman of the executive committee of the Forum MedTech Pharma and Spokesman Cluster Medical Technology.

The Medical Technology Cluster in Bavaria started its work almost exactly three years ago. Can you draw a short interim balance of the extent to which the companies, research institutions and hospitals involved have benefited from this so far?

A multitude of personal consultations, and mediations of contact and collaboration at regional, national and international level have been established. We have organised 65 events on current technical subjects and for making contacts with around 4,500 visitors: lots of positive feedback about business contacts and collaborations that arose at these. 10 cluster fund projects (company, research institutions, hospitals) with a funding volume of 5 million EUR have been backed. From a study on the state of training and further training we developed a further training programme with 230 participants at 13 events, crash courses, basic courses and seminars. An EU project for the utilisation of innovations potentials of clinics in the industry, with a volume of 2.3 million EUR has been approved – a European cooperation with 11 partners in 7 countries. And we have a very good rating in the external intermediate evaluation after 2 ½ years.

Which other measures by the Free State have the greatest influence on the medical technology site of Bavaria?

General investment in training and further training, in universities and clinical centres, in the financing of start-ups, in telematics and in frameworks for clinical studies are generally important for medical technology. The board members have already had a similar conversation with minister of state Dr. Heubisch. Otherwise, very important general conditions for approval, refunding and re-financing are extremely difficult to influence by measures at regional government level.

Where do you see medical technology in Bavaria in ten years?

Due to embedding in healthcare, medical technology is now already much less affected by general crises. Because of the existence of important basic requirements such as critical mass of small and medium-sized businesses, global players, excellent interdisciplinary research and clinical application and constant further networking, medical technology in Bavaria will certainly continue to grow into a leading site in Europe and beyond.

“The Munich area has a strong attraction for international skilled personnel”

Interview with Dr. Ulrich Dauer, CEO of 4SC AG



Dr. Ulrich Dauer is a founding member and CEO of the 4SC AG. Previously, he held a management position with the U.S. company, Tripos, a leading provider of screening libraries, software and systems integration in the life sciences.

As the CEO of 4SC, what is your experience of Bavaria as a company site?

The site at the IZB in Martinsried near Munich is ideal for our company, because it has an infrastructure that supports innovation. The geographical proximity to other researching biotech companies and to academic institutions such as the Max-Planck Institute, the Gene Centre, the Ludwig-Maximilian University and numerous university hospitals enables an intensive exchange of information between our researchers and renowned academic institutions and clinics.

What do you regard as the major advantages of being based in Bavaria?

In Bavaria, the promotion and preservation of companies with innovative technologies has been on the agenda of Bavarian regional policy for a long time, and this – together with targeted support programmes such as e.g. the Bavarian Research Foundation – ensure the attractiveness of the site for researching companies. At the same time, soft site factors like first-class education and leisure facilities ensure that the Munich area in particular has a strong attraction for international skilled personnel.

workforce – nearly 20,000 – accounts for roughly 20% of the German medtech total. These highly-qualified staff members account for more than 60% of Germany’s electronics-based medtech devices and some 30% of its products as a whole. The customer base in this sector is truly international: 70% of the sales recorded by Bavaria’s medtech industry stem from abroad. This high international visibility makes Bavaria’s medtech sector admired around the world. The same is true for healthcare in Bavaria: Its reputation is attributable to the breadth and excellence of the health care provided, and to such patient-pleasing factors as the large number of facilities attending to their well-being.

The sector shows a breadth matched by few in Europe. Its core is comprised of 250 companies. While most of them are SMEs (small and medium-sized enterprises), the state is home to the headquarters and major operations of a number of global players, with this referring to their sales and including pharmaceuticals: Siemens Medical Solutions, Baxter, Fresenius Medical Care,

GlaxoSmithKline, Novartis Pharma, Roche and General Electric. General Electric maintains its European Research Center in Munich’s northern suburb of Garching.

The market-making products manufactured by these companies stem from their close working relationships with Bavaria’s scientific community in the areas of medical devices, imaging, data processing, minimally-invasive surgical methods, and regenerative medicine.

Conclusion:

Healthcare in Bavaria is clearly a resounding success, founded on concerted cooperation between industry, politics and research. A look at the product pipeline and upcoming announcements from some Bavarian firms nevertheless suggests the area can hope for even greater success in years to come. Much will be decided in the immediate future. Positive news would send out a particularly strong message in the current economic crisis, now gradually beginning to affect Bavarian companies’ financing.

Investing in Health

**By Juliane Quaranta (Investment Manager) and Michael Thiess (CEO)
SANEMUS AG, Munich**

From healthcare to the healthcare industry

Germany has the largest health market in Europe. Healthcare – also in the Free State of Bavaria – is thus one of the growth drivers in the economy. With 4.4 million employees and a health expenditure volume of 253 billion Euros, the healthcare industry is one of the most important German industries. The most important factors driving growth in the German health market are the changed awareness of health on the part of individuals, progress in medical technology and demographic changes.

Where are the growth markets?

Medical technology is a dynamic and highly innovative industry. Around a third of its sales are generated by Bavarian medical technology manufacturers with products that are less than three years old. According to information from the European Patent Office in Munich, medical technology tops the list of registered inventions. The networking of medical technologies and hospital systems with IT is, however, becoming ever more important. The aim is networked healthcare provision that creates intelligent networks and makes possible the development and marketing of regional centres of excellence (clusters). The use of information and communication technologies in healthcare provision (e-health) not only decisively improves the quality of provision, but also increases efficiency and effectiveness. A concrete example is the introduction of the electronic health card as the foundation stone for the building-up of a standardised telematics infrastructure. For several years, different companies have been working on the introduction of an electronic patient file.

Bavaria as Healthcare Site Number One

Scientific and entrepreneurial expertise is being bundled in fundamental research and medical technology. Around 20 special research fields are working on (bio-)medical questions at Bavarian universities. In the framework of its future and high tech offensives, the government is providing around 430 million Euros for college medicine and health research. More than 250 mostly small-to-

medium-sized medical technology companies are located in Bavaria. In addition, more than 60% of all electrical medical equipment and 30% of the entire medical technology in Germany are produced in Bavaria. Globally leading pharmaceutical companies like Roche, Novartis and Pfizer are represented in Bavaria. Bayern Kapital GmbH, subsidiary of LfA Förderbank Bayern, supplies venture capital to young, innovative technology companies, normally together with other investors. Smaller venture capital companies, Business Angels, Family Offices and individual private investors are possible partners. Other cooperation partners include the ERP start-up funds from the KfW and High-Tech Gründerfonds, supported by the national government. Bayern Kapital is currently looking after a total of seven investment funds with an investment volume of around 190 million Euros. A large proportion of the companies assisted have been able to achieve a successful market position with an investment from Bayern Kapital.

The Free State provides 700,000 Euros as additional funding for the field of telemedicine. Modern technologies are promoted which – independent from the electronic health card – offer substantial advantages in the treatment and healthcare provision of patients.

Conclusion

In our opinion, medical technology will continue to be an essential driving aspect of the health industry in the years to come. This will above all be a matter of promoting innovations that improve the quality of healthcare provision and increase its efficiency and effectiveness. Networking technologies and concepts in the field of e-health are another substantial growth market. The constantly growing demands of healthcare require networked thinking and new organisational and communication structures that network all agencies/organisations involved in the provision process together with each other. In both cases, there still exists a great deal of potential for (further) developments and thus promising opportunities for successful investments.

Top ten in the field of technology

Number of applications to the European Patent Office in 2007

Source: BVMed - Bundesverband Medizintechnologie e.V. (German Medical Technology Association)

Flourishing Hospital Landscapes in Bavaria

By Dr. Holger Bengs and Matthias Heitmann

For flourishing landscapes to continue to bloom in the future, they must be cultivated. The stagnation caused by the global financial crisis is hardly noticeable at all in the hospital landscape of the Free State of Bavaria.

In its hospital planning, the regional government pursues the aim of modernising its comprehensive healthcare and to adapt it to the changing general conditions and requirements. This plan is produced in close cooperation with the BKG (the Bavarian Hospital Association) and the health insurance schemes.

Fine-Meshed Provision Network

Since the beginning of state support of hospitals in 1972 under Franz-Josef Strauß, the Free State together with the district authorities has invested around 18.6 billion EUR into the clinics and thus created a provision structure that enjoys a high reputation far beyond the region's borders for its level of performance. Around 350 acute in-patient clinics are assigned to different care levels within the graduated provision system: hospitals in the first provision level are for basic on-the-spot healthcare. Establishments in the second level also carry out main supra-regional tasks in diagnosis and treatment. Hospitals in the third level offer a

comprehensive range of health services and have the medical-technical facilities necessary for this.

As well as demographic changes, the plans must take into account the patients' lengths of stay, which have been decreasing for years, and the results of medical-technical progress, and also some special factors that are typical for Bavaria. For example, in comparison with other states in Germany, the Free State possesses many hospitals; added to which, two thirds of all hospital beds belong to the public authorities. In its implementation of the necessary adjustments, the Free State has benefited from its economic prosperity. Due to decades of intensive investment, the Bavarian healthcare system also already possesses a highly developed infrastructure that can be developed upon.

Making the System Fit for the Future

And this development has gained further impetus with the national government's current Economic Stimulus Plan II. The annual hospital building plan for 2009 contained 96 larger construction projects. In addition, another subsidy programme, amounting to 70 million EUR, has been launched under the title "Saving Energy in Hospitals". This focuses upon the improvement of heat insulation, efficient energy management and self-sufficient energy production.

The Bavarian healthcare system possesses a highly developed infrastructure.

Photo: © hospital of the university Munich



"Although funding for investment in Bavarian clinics has not yet reached the necessary level, the Bavarian hospital "landscape", with its outstanding medical care, nevertheless continues to be in a comprehensively good condition", confirms Eduard Fuchshuber, head of Policy and Public Relations of the Bavarian Hospital Association. He sees a growing danger, however, in the shortage of skilled nursing and medical staff. He says that this problem not only affects the present healthcare situation, but also training, and that it is making it much more difficult to guarantee sufficient provision throughout the region: "The shortage of skilled personnel sharpens the differences in provision between the regions. That might not affect Munich much", says Fuchshuber.

Bavaria's Landscape of Innovation

Bavaria in the top league for biotechnology and pharmaceutical research

By Matthias Heitmann and Dr. Holger Bengs

Since the 1960s, the Bavarian research infrastructure has been systematically extended. Bavaria now offers an excellent research landscape, with 11 universities, 17 technical colleges, 11 Max-Planck institutes, 9 establishments of the Fraunhofer Society and 3 large-scale research establishments. In addition, the government has substantially strengthened innovation in important industries and promising fields of technology, with the Zukunft Bayern and High-Tech campaigns, and developed the Free State into one of the most attractive and high-performance technological sites in Europe.

European Metropolitan Region Munich (EMM)

Since the 90s, the Munich area has changed into one of the leading European innovation clusters for the biotechnological and pharmaceutical industry. As well as about 350 companies, eight prestigious research institutions have also located in the region. With two elite universities, three Max-Planck institutes, the Helmholtz Zentrum München – the German Research Center for Environmental Health – and the technical colleges of Munich and Weihenstephan, the region offers conditions for the linking of research and industry that are to be found nowhere else in Germany. The research driven forward in these centres ranges from molecular biology to nanotechnology to the researching of cardiovascular illnesses and infectious diseases and also places emphasis upon an interdisciplinary approach.

The development of the university hospital in Großhadern and of the Max-Planck Institute for Biochemistry in Martinsried is regarded as initial catalysts for the rapid development of the biotechnology cluster. In the late 80s and early 90s, the first companies settled in the area, in the form of Mikrogen, Micromet, Morpho-



Bavarian BioTech Regions

Sys and MediGene. The Innovation and Start-up Centre for Biotechnology IZB Martinsried/Freising, founded in 1995, is now one of the largest centres for biomedical research and is highly respected around the world. In addition to the institutions already named, the Martinsried campus also includes, among others, the Max-Planck Institute for Neurobiology, the Gene Center of the Ludwig-Maximilians-University of Munich, the Center For Integrated Protein Science Munich (CIPSM), the Munich Center For Neurosciences Brain and Mind LMU and Graduate School of Systemic Neurosciences (GSN-LMU) and the Bernstein Center. On top of this, nearly half of all biotech companies have set up sites in Bavaria.

The immediately neighbouring location of Freising-Weihenstephan has developed into a competence cluster for green biotechnology in Europe. The



Bavaria is the only German region to play a leading role in Europe's top league for biotechnology and pharmaceutical research.

Photo: © Frank Oppermann - Fotolia.com

Center of Life and Food Sciences of the Technische Universität München, the Research Centrum for Milk and Foodstuffs, the Fachhochschule Weihenstephan, the Weihenstephan State Dairy and the Bavarian regional offices for natural resources, life sciences and horticulture, and for forestry and agricultural engineering are all based here among others.

Bavarian BioTech Regions

As well as the Munich/Martinsried bio-tech region and the Martinsried-Großhadern campus, three other Bavarian bio-regions contribute to a research landscape that is unique in Germany. The "Bio-Region Regensburg" is a combination of BioPark, East Bavarian Region, university and technical college specialising in fluorescent bio-analysis, molecular diagnostics, bio-functional surfaces, sensor technology and applied biomedicine. The "BioRegion Franken" represents a further location. With its university, Würzburg enjoys the reputation of a scientific centre for research in the life sciences, in which nationally and internationally important activities are developing in medical and clinical research and in biotechnology. The site of Erlangen-Nuremberg offers outstanding expertise in the field of medical technology and virological and pharmaceutical research, while Bayreuth places emphasis on applied biochemistry and material research. In addition, the "BioRegion Straubing" concentrates activities on everything to do with the subject of renewable raw materials. Many new companies have settled in the industrial park, in the port, in the start-up centre or in the new BioCubator business centre for renewable primary products.

The outstanding site conditions of the Bavarian biotechnology cluster have also attracted

"global players" in the pharmaceutical industry to Bavaria: for example, Aventis and GlaxoSmithKline are present in the region, as well as General Electric Healthcare (GEHC), the US-American pharmaceutical company Merck, Sharp & Dohme (MSD), Bristol-Myers Squibb and the Japanese group Daiichi-Sanyko, with important research institutions and branches. In addition, the Upper Bavarian town of Penzberg is home to the Roche Group's biggest biotechnological research, development and production centre within Europe. Research, development and production are carried out here in the two business fields of pharmaceuticals and diagnostics.

Further Development of the Innovation Landscape

New companies founded by large pharmaceutical and biotech companies and spin-offs from university research institutions in particular benefit from the close cooperation between research and industry. Almost every second German, stock-exchange-listed biotech company has its headquarters in Bavaria, and around half of all German products in the clinical phase originate in the Free State. Numerous research associations contribute to the further development of the region and to the strengthening of scientific and economic dynamism: for example, the Bavarian Research Alliance (BayFOR GmbH), founded in 2006 for the promotion of science and research, supports Bavarian researchers and developers in organising, applying for and carrying out European research projects. The Bavarian genome research network BayGene, in which the universities of Munich, Regensburg, Würzburg and Erlangen are currently working on projects in functional genome research and in which collaborations with industry are being promoted, is a further important step with which the Federal Republic would like to secure a leading place in global and national economic and scientific competition. Similar aims are also being pursued by BayImmuNet, founded in 2008. This network, which is the only one of its kind in Germany, supports the faster transition of immunotherapeutic approaches into clinical application. With the alliance "Bayern Innovativ", the Bavarian government wants to further spur on the overall development of Bavaria as a site for business and science.

It is in keeping with the international importance of Bavaria as a biotechnology site that in November 2010 the BIO-Europe will be held in Munich for what is already the second time since 2001. It is the most important international partnering conference in Europe for the biotechnology industry and will bring further impetus to the region.

Approval of Medicines: A Science in Itself

By Matthias Heitmann and Dr. Holger Bengs

Out of the thousands of substances that are put forward as medicinal active ingredients, usually only a single one makes it through the final exam. The process from the initial tests to approval as a medicine is very complex and can last up to twelve years. It is not just for outsiders that this selection process is a science in itself.

From the Hit to the Test Object

There are very good reasons for this complexity in medicine approval; after all, it must be ensured that protection against risks and defence against health hazards are guaranteed in each case. Pharmaceutical quality, therapeutic effectiveness and the harmlessness of the active ingredient are examined in many test phases. Approval is only possible at all if the benefit is clearly predominant in the risk-benefit analysis.

Unlike medical-technical developments, the career of an active ingredient first begins with the conclusion that it has a positive effect on an illness-relevant target structure in the human body. In order to rule out pure "flukes" at this early stage, a pharmaceutical "lead" is developed out of this "hit". A long-drawn-out process then follows, in which this rough diamond is processed until it reaches readiness for testing.

The Test Phases

In the preclinical phase, the mode of action and half-life of the substance are first tested in vitro on cell cultures and later in vivo in the animal model. Only if it passes this first tough test successfully, can multi-phase clinical studies on people be started. In phase 0 (not stipulated), the effectiveness of the substance is first analysed in sub-therapeutic doses in order to be able to draw conclusions about tolerance and pharmacodynamics. In phase I of the clinical studies, the effective ingredient is then administered in therapeutic doses.

Phase II, randomised and controlled if possible, is devoted in two sub-steps to the therapy



Before the launch of a new drug extensive testing needs to be conducted. Regional peculiarities play an important role in the approval procedure.

Photo: © Catalin Stefan - Fotolia.com

concept ("proof of concept") and optimal dosing ("dose finding"). The more clearly the positive effects of the substance emerge here, the more manageable the number of subjects normally required to take part in the final approval study (phase III) – this can be 200, but also even 10,000.

Approvals Regionally Limited

If the positive results can be confirmed here too, approval for the entire European Union can be applied for from the European Medicines Agency (EMA) in the framework of a centralised and standardised procedure. Alternatively, approval can also take place in a decentralised way in individual EU states by means of reciprocal acknowledgement. But even this EU-certificate is still not a licence with global validity. Approval in other countries, such as in the USA or in Japan, is subject to particular, sometimes more stringent conditions. But it is generally the case that if an active ingredient manages to reach clinical phase III, then the chances are good that it will be granted approval onto the market.

“Regenerative methods will supplement transplantation medicine”

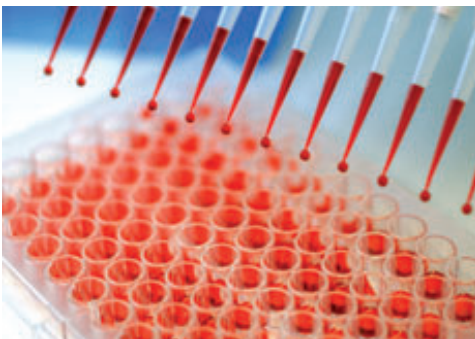
Interview with Dr. Med. Matthias Schieker, manager of the Laboratory for Experimental Surgery and Regenerative Medicine, “ExperiMed”, on the state of research and the potential of regenerative medicine.

What is regenerative medicine about, particularly in your area of expertise, experimental surgery?

Regenerative medicine is devoted to the development of methods for repairing damaged or sick tissue using the body’s own regeneration of tissues. In “tissue engineering”, cells, e.g. stem cells, are removed from a patient and then tissue structures are grown from these in the laboratory, in order to then implant them again. In experimental surgery, these procedures are being developed for bones, cartilage and sinews.

How far has your research in these areas progressed?

In 2005, we founded the Laboratory for Experimental Surgery and Regenerative Medicine, “ExperiMed”, from the tissue engineering work group for bone. To date, we have been carrying out fundamental research, mostly in the areas of bone and sinew, and are pursuing the aim of developing therapy strategies to their clinical application. A large number of concrete areas of application are, however, now emerging in the field of regenerative medicine: in future, cell-based therapies will play an important role in heart surgery, neurosurgery and orthopaedics/ accident surgery, and in the treatment of liver and kidney diseases and diabetes mellitus. With respect to orthopaedics, I am convinced that regenerative methods will replace the currently common transplantation of bone from the body itself.



In Germany, regenerative medicine is now promoted as an important field of research.

Photo: © BioM



What is the public acceptance of such methods like?

I think that acceptance has risen over the past few years. This is due to the fact that the public is now better informed about the advantages and possibilities than was previously the case; but the researchers and medical scientists have also learnt how to communicate this potential better. As further studies confirm the applicability and efficiency of experimental methods, readiness to use them to heal illnesses and defects will grow.

What is your assessment of Germany as a research site?

In Germany, regenerative medicine is now being recognised and also promoted as an important field of research. One example is the “Research Alliance for Cell-Based Regeneration of the Musculoskeletal System in Old Age” (ForZebRA) – supported by the Bavarian Research Foundation – in which university and industrial partners are investigating degenerative diseases such as osteoporosis, arthrosis and degeneration of sinews, in order to develop innovative therapy options. This demonstrates that one can receive sponsorship in Germany in the field of regenerative medicine, if one proposes exciting projects.

Herr Dr. Schieker, thank you very much for the conversation.

The interview was conducted by Matthias Heitmann, Dr. Holger Bengs – Biotech Consulting, Frankfurt a.M.

Dr. Med. Matthias Schieker is manager of the Laboratory for Experimental Surgery and Regenerative Medicine, “ExperiMed”, on the state of research and the potential of regenerative medicine.

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Symbiosis between Diagnostics and Medicine Development

Bavaria Makes Progress in Fundamental Research for Personalised Medicine

The knowledge that the same treatment can have entirely different chances of success for different people has already been gaining recognition in medicine for a long time. The reasons for this are also being slowly uncovered. Progress in molecular diagnostics allows an ever more targeted and individual treatment of patients. Personalised medicine also plays an important role in Bavaria as a site, in fundamental research at universities and institutes as well as in application in companies. Here, diagnostics and the development of medicines are combined. Doctors and researching companies benefit from this as well as patients.

According to tests, medicines do not function optimally in at least a third of patients. Some even become worse after taking the active ingredients. This proportion of patients is astonishingly high, at around 15%. The difficult task now consists of finding out for which half the medicines will work – and for which half they will not. Research has made enormous progress here during the past few years. In Bavaria, researchers from different fields of medicine have contributed to making sure that medicines have their desired effect in more than two thirds of cases. New molecular-diagnostic methods here enable more accurate research into the causes of illnesses.

Genetic Causes of Illnesses

The progress in genome research contributes to a better understanding of illnesses. In this field, Prof. Dr. Thomas Meitinger from the Institute for Human Genetics at the Helmholtzzentrum München is tracking down illness-related special features in the genes of humans and mice. The intention is to find the genetic causes of complex illnesses in genome-wide DNA and RNA studies, especially in the field of neurology and cardiology.

The Institute for Epidemiology of Prof. Dr. H.-Erich Wichmann (see interview box) is also located at the Helmholtz-Zentrum. It deals with methodical questions concerning the quantification of small risks, with the effects of particles and air pollutants upon the lungs and the cardiovascular system, and also with the regional distribution and development of respiratory illnesses and allergies. A new focus of the institute is the molecular analysis of complex illnesses (e.g. asthma, type 2 diabetes, heart attack). The central aim is to use epidemiological methods to



The intention of the Helmholtzzentrum München is to find the genetic causes of complex illnesses in genome-wide DNA and RNA studies.

Photo: © Photodisc

investigate the role of environmental influences and genetic predisposition upon human health.

At the Weihenstephan site near Freising, Prof. Dr. Bernhard Küster of TU München and his interdisciplinary team are carrying out research to discover biomarkers. Biomarker research is an important part of personalised medicine, because it allows more accurate diagnosis of illnesses and thus a better provision of effective medicines. Küster is also a member of the "Excellence Cluster" CIPSM (Centre for Integrated Protein Science Munich), which deals

with the field of protein research within biotechnology and biomedicine.

The Entirety of the Proteins

Also participating in the CIPSM is Prof. Dr. Matthias Mann at the Max-Planck Institute of Biochemistry near Munich, who is conducting research into the proteome, which is the entirety of all proteins. Last year, one research group under his direction successfully decoded the complete proteome of an organism – baker's yeast – for the first time.

Dr. Henrik Daub, who is also active at the Max-Planck Institute of Biochemistry, has shown that research in such areas can also be the springboard for founding one's own company. Together with Prof. Dr. Axel Ullrich, he founded KINAXO Biotechnologies GmbH. The young entrepreneurs were supported in this by Garching Innovation GmbH, the technology transfer agency of the Max-Planck Society. The company was financed by High-Tech Gründerfonds, among others. Together with biotech and pharmaceutical companies, KINAXO develops and optimises spectrum-specific kinase

inhibitors. Protein kinases are assuming an important role in the regulation of the cell cycle, but were for a long time regarded as unsuitable targets for treatment with medicines (non-druggable targets). This has now changed. KINAXO is thus also contributing to improving the therapeutic characteristics of active ingredients.

Knowing What Helps

An already successfully applied example of successful interaction between diagnostics and medicine development is the breast cancer agent Herceptin from the biotechnology company Genentech, which now belongs to the Roche group. This medicine, however, only helps in a particular form of breast cancer, which occurs in 25% of patients. But this can be clarified with a biomarker test.

Penzberg in East Bavaria is an important site for Roche in personalised medicine – in which the Swiss group occupies a globally leading position. Because both the pharmaceutical and the diagnostics sections of Roche are represented in Penzberg, where around 4,500 employees are currently employed. In order to convey deeper insights into personalised medicine to its own employees, Roche has set up its own exhibition on this subject in a room adjoining the canteen.

Conclusion

The Munich area in particular, with its universities and research centres, is at the world forefront in fundamental research in many aspects of personalised medicine. The Free State of Bavaria has contributed a lot to this, but needs to continue to take care that it does not let things slide. Other regions are also active and want to shorten the gap. In competition for qualified employees and research funding, however, Bavaria continues to offer the best site conditions for a future-oriented subject like personalised medicine.

Penzberg in East Bavaria is an important site for Roche in personalised medicine.

Photo: © Roche



“By bundling resources even more can be achieved”

Interview with Prof. Dr. H.-Erich Wichmann, Helmholtz Institute of Epidemiology



Prof. H.-Erich Wichmann is director of the Institute of Epidemiology at Helmholtz Center Munich.

Prof. Wichmann, how do you judge the research landscape in Bavaria in the field of epidemiology?

In Bavaria, we can look back on a long epidemiological tradition. For 25 years, the Helmholtz Zentrum München has been conducting the major MONICA/KORA study in the Augsburg area. Almost 20,000 adults are being and have been regularly examined and interviewed. In addition to this, there are various illness registers in Bavaria, such as the region-wide cancer register (Erlangen), the stroke register (Erlangen) and the heart attack register (Augsburg). Also to be mentioned in this connection is the environmental epidemiological and provision epidemiological research in the Munich area. In future, the most important project will probably be the National Helmholtz Cohort, a very large epidemiological study with 200,000 adults across Germany, who will be observed for 20–30 years. The coordinating offices are in Munich and Heidelberg.

What is the cooperation like with researching companies in Bavaria?

The companies would actually be able to make good use of the epidemiological resources, because we are in a position to make statements about the congenital and acquired risks of many important illnesses and to provide bio-samples. The utilisation is still not very intensive, however. This is partly due to the fact that the researching companies have to date relied overwhelmingly upon their own resources. There is still a large unused potential here.

What possibilities does your area of research offer for closer interaction between diagnostics and medicine development?

Here one should mention the new project m4 “Personalised Medicine and Target-Oriented

Therapies” which might already be getting off to a start next year. It is about networking researching industry and biomedical resources in the Munich area more closely with each other. An important subject here is the bio-banks: collections of blood samples, tissue samples, urine etc. It is intended to make these resources more useful for diagnostics and medicine development. As well as this, the transfer of knowledge from research to industrial use is to be improved. In order to achieve this, an application has been made to the Federal Ministry of Research, which will be decided upon in January. Just the fact that people are getting together and writing an application is leading to them coming into conversation more often and the development of bilateral or trilateral activities.

What would you like politicians to do to improve site conditions in Bavaria?

Bavaria, particularly the site of Munich, is already in a very strong position as regards epidemiology and bio-banks. We are involved in the excellence initiatives, have universities that are very strong in research and important research institutions such as Helmholtz, Max-Planck-Institute etc. in a relatively small area. The disadvantage is that there has not yet been as much cooperation as would be desirable. By bundling resources, even more could be achieved. Interestingly, this is happening in other regions that have less to offer, sometimes very intensively. There they have recognised that they would have no chance without cooperation. Precisely because we in the Munich area are set up so broadly and have such a good basis, we perhaps do not yet see the necessity to cooperate clearly enough. I think that the politicians are certainly in a position to cause quite a lot of change in this respect by creating incentives for cooperation.

“Geographical proximity is very important”

Interview with Prof. Dr. Günther Wess, Helmholtz-Zentrum München

The task of translational research is to transfer knowledge from fundamental research over to practical application as quickly as possible, so that it can be used directly to help people in diagnosis and therapies. It is all about the translation of knowledge “between the laboratory and the sick-bed” – and also in the reverse direction, from the clinic to the researchers. Prof. Dr. Günther Wess, Scientific and Technical Managing Director of the Helmholtz-Zentrum München, still sees a great need for improvement.

What infrastructure conditions promote cooperation and the transfer of knowledge between the participants?

Geographical proximity is very important. Pure researchers and clinicians should work close to each other, in order to be able to exchange information and communicate at meetings more often. And they need a joint organisation and/or structure.

How can a shared structure be implemented?

By forming interdisciplinary teams with shared aims that cooperate on supported projects. By setting up translation centres, for example. Four such centres have been set up on the initiative of the Helmholtz Society, focussing on different types of illnesses: in Munich (lungs), Heidelberg (cancer), Brunswick (infections) and Berlin (cardiovascular). Here in Munich we have brought everything that we need together under one roof; an experimental and a clinical pneumologist work in close cooperation.

What must be done to make translational research in Germany more successful in future?

The attitude of the people involved needs to change; it is about a cultural shift towards more cooperation and exchanging of knowledge. Also, appropriate structures must be created that encourage working together. In German healthcare, we unfortunately have a complicated network of different levels such as national/regional govern-



ment, universities/clinics and non-university institutions such as the Helmholtz and Leibniz centres, among others. The various interest groups should look further than the end of their own nose. In the past few years, the Federal Ministry for Research has already taken initiatives for more partnership cooperation. But we still need more strategic investment in this direction.

In what area is translational research particularly important?

In my opinion it is particularly important for new therapy approaches in the field of personalised medicine; but also in the optimisation of already existing therapies and in the field of diagnostics.

Where is translational research already working out especially well in Germany?

At the four Helmholtz translation centres mentioned and at some health centres that have been initiated by the Federal Ministry for Research. These include the two research associations DZNE (for neurodegenerative diseases) and DZD (for diabetes). We must set up more such centres. There is a substantially higher level in the USA, where translational research enjoys much stronger priority and more money is invested. Of course, attractive conditions also draw talented people, and some emigrate from Germany to the USA.

Thank you very much for the conversation.

The interview was conducted by Bernd Frank

Prof. Dr. Günther Wess is an Honorary Professor at the Technische Universität München and since 2005 has been President and CEO of the Helmholtz-Zentrum München – German Research Centre for Environmental Health. Until 2004, Prof. Wess performed management functions in research and development as well as business management, e.g. at Hoechst, Aventis and Sanofi-Aventis.

“Innovation Made in Germany”

Molecular Biologics: Small and Medium-Sized Bavarian Biotech Companies at the Forefront

In Bavaria, young Biotech companies are working successfully on the development of new processes and technologies. In the Free State they find good conditions and are causing a stir, even internationally, with their innovative results. But the lack of venture capital is presenting a challenge for many researchers. Cooperation with large pharmaceutical companies offers one way out.

Difficult Capitalisation

Molecular biology deals with living organisms and life processes at the sub-cellular level. It serves as a fundamental science for parts of medicine and biotechnology. The overwhelming majority of Biotech companies work in the field of red biotechnology, probably the most lucrative segment in the biotech business. The industry has nevertheless been suffering from a lack of sufficient venture capital for years. This is reflected in the fact that the number of candidates in the decisive test phase III, the clinical testing of new medicines, has not increased in the past few years. “There are currently only a few venture capital companies that invest in life science”, says Dr. Peter Hanns Zobel, managing director of IZB GmbH. Claus Schalper, CEO of Pieris AG, adds: “In general, I see a substantial lack of investors taking part in the financing of the early phases, which is to say in the A and B rounds financing.” Many biotech companies seek a solution in cooperation with major pharmaceutical concerns. One advantage of this is that the partners from the pharmaceutical industry take over a part of the contingency risk.

Success Through Cooperation

Morphosys AG is one of the few companies of its size to already be operating profitably and to have one of the globally leading antibody



Woolmade Human Chromosome Set
Photo: © Torsten Naeser for BioM

technologies at its disposal. Dr. Simon Moroney, Chairman of Morphosys, says happily: “Morphosys has a range of partnerships with leading pharmaceutical companies, including a ten-year alliance with Novartis. These contracts generate assured turnovers of 400 million EUR”. The company also receives profit sharing and royalties from products that are created in cooperation. Its own sales department secures Morphosys marketing rights to resultant products in selected regions and the rights to the bilateral development of selected ranges. The substanti-

“We have a very close relationship with our tenants”

Interview with Dr. Peter Hanns Zobel, Managing Director of IZB GmbH



Dr. Peter Hanns Zobel is Managing Director of the Innovation and Founding Center for Biology (IZB) Martinsried and Weihenstephan.

Herr Dr. Zobel, what does the IZB now look like in Martinsried?

The IZB is currently in the process of expanding to a size of approx. 23,000 m² of rentable area. The site is thus among the most successful in Europe, on account of its size and the 55 companies located in Martinsried and Weihenstephan. Due to the massive relocation of the natural sciences of the Ludwig Maximilians University from the city centre to Martinsried and the two Max-Planck Institutes, an internationally respected Life Science Campus has been created.

Did the economic and financial crisis affect the IZB cluster?

Despite the crisis, the continued existence of the tenants is currently not endangered. The majority

of our tenants are experiencing moderate growth. In 2008, the tenants were able to gain more than 85 million Euros in the form of funding rounds. It was possible to gain funding in 2009, too; in the middle of November, 4SC AG was able to fully place a capital increase of 30 million EUR.

What support do you give, in concrete terms?

We have a very close relationship with our tenants. One example of this is the BTA training taking place from September 2010 under the umbrella of the IZB. We have been able to persuade the Chemieschule Elhardt, based in Munich, to teach 2 BTA classes from 2010, directly in the IZB, and hope that we have thereby solved a personnel problem not only for the tenants but also for the entire campus.

ally strengthened financial position accelerates the development of the company's own medication pipeline. Morphosys itself can finance the in-house development of medicines with revenues from other partnerships. “We have raised our investment from around 8 million EUR last year to 18-20 million EUR this year and are still

showing a solid profit”, emphasises Moroney. “That is why we are currently not dependent on external sources of money.” The partnership between Trion Pharma and Fresenius Biotech is also running successfully. Trion was created in 1998 as a spin-off of the Helmholtz-Zentrum Munich. Since then, both companies have been collaborating in the field of antibody development. There was no nerve-racking search for providers of venture capital for founder Horst Lindhofer. Fresenius now holds more than a quarter of Trion. While Trion is responsible for the designing of new molecules, process development and production, Fresenius monitors clinical development and possesses the global marketing rights to the antibodies developed by Trion. In the framework of the partnership, Trion is actively involved in all



Horst Lindhofer, Chairman of Trion Pharma

The building of the BioPark Regensburg
Photo: © Biopark Regensburg



stages of development up to market approval and possesses the Triomab® technology with the accompanying patents. Three antibody candidates developed together are currently in clinical studies. “The targeted stimulation of a concentrated immune response, as is triggered by Triomab® antibodies, has great potential for the treatment of a large number of illnesses”, emphasises Lindhofer. Trion has recently received a recommendation for approval for a new type of medicine against the adverse effects of cancer.

Pieris: The Next Generation

At the biotech company Pieris in Freising, research is already being conducted into the next generation of medicines. Anticalins, artificial



Claus Schalper,
CEO of Pieris

proteins, are smaller and more stable than antibodies and are effective for longer. “Due to the sup-shaped structure of the anticalins, Pieris can also address small molecules such as biologically active peptides, lipids and haptens, which is more difficult with antibodies”, stresses Claus Schalper. Because the Freising company secured the patents for the necessary technology early on for the whole of Europe and the USA, no other company is currently carrying out the research on the proteins. Pharmaceutical companies have recognised Pieris’ head start. “Our technology was at last validated in September 2009 by the concluding of a cooperation agreement with the US pharmaceutical company Alergan, which included an advance payment of 10 million USD to Pieris”, says Schalper. In addition to this, the world’s largest healthcare-dedicated investment firm has been won over in the form of Orbimed Advisors. “The most recent financial transaction was a successfully concluded B round financing in April 2008, with a total volume of 25 million EUR, which was offered by Orbimed”, says Schalper happily. Since being founded in 2001, Pieris has received over 40 million EUR of capital.



The Innovation and Founding Center for Biology (IZB) in Martinsried
Photo: © IZB

Site Advantages of Bavaria

“Innovation made in Germany is possible”, says Horst Lindhofer in summary. The success of companies such as Morphosys, Trion and Pieris is thus no coincidence. For 15 years, Bavaria has been promoting the establishing and consolidation of the life science industry in the Free State. In addition to the sites of the IZB (Innovation and Startup Centers for Biotechnology) in Martinsried and Weihenstephan, further research centres have been opened in Regensburg, Würzburg, Bayreuth and Straubing. For Peter Hanns Zobel of the IZB, these institutions



The Innovation and Entrepreneur Center (IGZ BioMed) in Würzburg
Photo: © IGZ

“Many investors want to be in the stock before that happens”

Interview with Dr. Simon Moroney, Founder and CEO of Morphosys



Dr. Simon Moroney is founder and CEO of MorphoSys. The Munich-based company is one of the world's leading biotechnology companies focusing on fully human antibodies.

MorphoSys is currently testing seven new active ingredients in clinical trials – either on its own or with partners from the pharmaceutical sector; another 30 are almost at the clinical phase. What kind of news can we expect from MorphoSys in 2010?

Besides the accelerating flow of new programs entering clinical trials in 2010 we are closing in on a very significant milestone for MorphoSys – the first clinical proof-of-concept for one of our HuCAL antibodies. Many investors, especially in the US, have told us that they see such an event looming, expect it to be a trigger for the share price, and want to be in the stock before that happens. With regard to new partnerships, we strive, amongst other initiatives, to sign new deals in the infectious disease space similar to the Daiichi Sankyo alliance we announced in October 2009.

If you analyse the current situation for biotech founders in Bavaria, what is better compared to the early days of MorphoSys? Is there anything you would improve?

When we founded the company back in 1992 there was no noteworthy biotech industry in Germany and only fragments of the infrastructure today's founders can potentially rely on.

The political climate for biotech in general was a disaster at that time. From this perspective today's entrepreneurs face much more favourable conditions. In terms of things that could be improved, I would point to the need for a different political approach to how financial losses are handled in research-stage companies. We, a selection of entrepreneurs and finance experts from the German biotech sector in collaboration with the industry association BioDeutschland, addressed this topic in an open letter to Chancellor Merkel. Additionally, we suggest tax credits for expenditure on research and development in small companies, to bring Germany into line with standard practice in several other European countries.

MorphoSys was founded in 1992. Which location factors determined the decision at that time for Bavaria and especially Munich?

In those early days of the company, the close interaction with our co-founder Prof. Andreas Plückthun was very important and one of our main considerations. At that time, he worked at the Max Planck Institute for Biochemistry in Martinsried before moving on to Switzerland. So the choice we made to found MorphoSys in Munich was a rather simple one, and was based on proximity to our co-founder and his lab.

are not competitors, but rather competence centres with their own strengths and weaknesses. The biotechnology cluster in which all the centres are combined is run by Bio^M Cluster Development GmbH. University research work and the commitment of regional providers of capital safeguard the technological capability

of Bavaria in the life science sector. Many newly founded life science companies have been financed by the Förderbank Bayern, Bayern Kapital or Bio^M AG. What remains decisive is that in the framework of cooperation agreements, the innovation partner keeps his independence and “founding spirit”.

“Bavaria is a technology-friendly site”

Interview with Dr. Joachim Eberle, Research and Development Manager at Roche Professional Diagnostics, Penzberg



Dr. Joachim Eberle is Head of Research and Development at Roche Professional Diagnostics, Penzberg

Roche is the worldwide number one in the field of in-vitro diagnostics. Roche has set up an important centre for diagnostics, development and production in Penzberg, Bavaria, a small city about 40 kilometers south of Munich. During the last three decades this facility has grown to 350,000 square metres making it one of the largest Biotech-Centres in Europe. What makes Penzberg special is that it is the only Roche site in the world at which research, development and production are carried out for diagnostics and pharmaceuticals.

Why did Roche select to settle at Penzberg, a former mining town in Bavaria?

That was based upon a very practical decision! Towards the end of the 1960s, the original factory premises were no longer expandable. An employee actually gave the management the decisive information that a former coal mine in Penzberg had been disused for several years. The rest is history – because since the laying of the foundation stone in 1972 the factory has developed into Roche’s biggest biotechnology factory in Europe on an area of 350,000 square metres.

Roche now employs around 4,500 employees in Penzberg. What distinguishes the site and the region?

For one the region is one of the most beautiful areas in Germany! Further our company has very good scientific links with the universities,

colleges and institutes in the region. Also, Bavaria is a technology friendly site. Business and politics communicate in partnership. Within the Roche Group, the Penzberg site plays an important role. Here, research, development and production of the two Roche divisions – Pharmaceuticals and Diagnostics are united under one roof. This is unique in the Roche world.

What does Penzberg contribute within the Roche group in the field of in-vitro diagnostics?

The whole value chain is present at the Penzberg site – research, development and production. For example new biomarkers for the diagnosis of infections, cancer or immune diseases are searched for here. They are incorporated in analysis systems which are used in large laboratories, hospitals and doctor’s practices. But Penzberg also supplies products to the research market. Almost everything that researchers need to investigate genetic material, cells, proteins or biochemical pathways is produced and evaluated at the site.

You have particularly extended your product portfolio in immunology and in laboratory diagnostics. What products were added?

Numerous research projects for improved diagnostics of rheumatoid arthritis, of metabolic syndrome, different cancers and cardiovascular complaints focus on the search for and fixing of new protein markers and their reading as single markers or in combination. For the overall biomarker programme, the diagnostics research unit makes a substantial contribution to the profiling of illnesses, patient groups and to therapy successes, by identifying and characterising suitable biomarkers with its test methods.

What challenges do you see in the short and medium term in the field of in-vitro diagnostics?

Medical research is continually opening up new or expanded possibilities of diagnosis. Let us take the biomarker programme as an example. Once they are identified, these markers must provide reliable statements as the basis of the therapy chosen by the doctor. The challenge then consists of identifying the most suitable markers.

How are you facing these challenges?

Our employees in the biomarker programme are looking for suitable markers from a diagnostic as well as pharmaceutical standpoint. We are well networked for this via international collaborations and use the most modern technologies for analysing markers or to find them internally using suitable experiments.

For groups like Roche, proximity to innovative small biotech companies is important, as well as their own in-house research. How important, for you, is closeness to the biotech cluster Martinsried/Weihenstephan and to all the research institutions based there?

It is now indispensable for research to maintain contacts with the best scientific institutions. It is also vital, however, to find well trained employees. These requirements are met thanks to the Bio Region of Munich.

Thank you very much for the interview.

The interview was conducted by Mathias Renz



The large area of Roche in Penzberg
Photo: © Roche

Ideal Conditions for Biotech Companies

MIKROGEN GmbH: 20 Years of Organic Growth

Bavaria offers a good infrastructure for companies producing gene technology products and has an established research landscape, including in the field of biotechnology. MIKROGEN GmbH, which has been based in Bavaria for 20 years, has benefited from this, as well as from the collaborations between established companies and start-ups regularly initiated by the Bavarian Research Foundation.



Good Site Conditions

Dr. Erwin Soutschek, one of the two managing directors of MIKROGEN, is certain that "the recruiting of employees and cooperation partners is made easier by the good site conditions and the image of the Munich Biotech-Region". This also makes approaching customers easier, says Soutschek, who also praises the "extremely constructive cooperation with the official authorities in different regions of Bavaria". "We have heard from partners that this does not always function as smoothly in other states of Germany", adds Soutschek.



Dr. Erwin Soutschek,
managing director, MIKROGEN

Spin-off from the LMU

Soutschek and Dr. Manfred Motz founded MIKROGEN GmbH together in 1989 as one of the first German start-ups in the field of biotechnology, following their doctorate in the field of medical microbiology at LMU Munich. Soutschek and Motz received 750,000 DM for the founding of the company from the BMBF's (Federal Ministry of Education and Research) TOU programme for the "promotion of the founding of technology-oriented companies". MIKROGEN brought its first products onto the market in 1991, and has been building up its own distribution in Germany since 1995. At the beginning of 2001, Soutschek and Motz strengthened their commitment to exports, including to Eastern Europe, and concluded a large number of distribution contracts with European partners. MIKROGEN first settled

in the Westend business park in Munich, and afterwards in Martinsried until 2005, and since then Neuried has been the company headquarters.

MIKROGEN emerged as the market leader of Europe in the field of laboratory diagnostics.
Photo: © Julián Rovagnati - Fotolia.com

European Market Leaders

MIKROGEN develops, produces and markets test systems for medical laboratory diagnostics in the field of bacterial and virus-induced infectious diseases and auto-immune diseases. The company is now the market leader in the field of medical laboratory diagnostics, especially in testing for Lyme disease, not only in Germany but also Switzerland, France, Sweden and the Netherlands. The technology platform of MIKROGEN is protected by patents in Germany, Europe and the USA. Soutschek states that sales in 2008 amounted to 11 million Euros; for 2009 he forecasts 12.5 million Euros, and expects sales of approx. 18 million Euros in three to four years.

US Market in its Sights

Since its founding, MIKROGEN has always grown organically from financing from its own profits. The company has not had an investor on board to date, but Soutschek assumes a need to acquire venture capital or a strategic investor in the short to medium term. "Our next important milestone is expansion into the USA. Capital in any form will help us to realise requirements such as the expansion of production premises made necessary by entry into the US market, and the employment of personnel who will see to the fulfilment of the regulatory requirements", explains Soutschek. The step will also be made easier by one of the state representations that Bavaria maintains abroad; these provide support that includes helping companies in their search for distributors on site.

The Sound of Light

Helmholtz Zentrum München: Making light audible

For over 40 years, the centre has been researching chronic illnesses and seeking a better understanding of the relationships between health and environment. The innovative linking of light and sound waves could facilitate the examination of tumours and coronary vessels in human beings.

Research at the Highest Level

Since 1964, the researchers at the Helmholtz Zentrum München have been working out basic principles and applications for the treatment of complex chronic illnesses. Originally founded as the Gesellschaft für Strahlenforschung (society for radiation research), it was renamed as the Helmholtz Zentrum München in 2008, in order to reflect the institution's strategic reorientation. The institute, Germany's biggest environmental centre since the 1990s, is bundling its activities

through this barrier and produced three-dimensional images of a six-millimetre-thick zebra fish. For this, the fish is irradiated with laser flashes. Fluorescent dyes inside the fish light up under the flashes, causing the immediately surrounding area to heat up and expand. Due to the high speed, an ultrasound echo is produced, which the researchers capture with special microphones. A computer then converts the sound wave pattern into a three-dimensional image. The result of the "multi-spectral optoacoustic tomography" (MSOT) is an image with a resolution of four hundredths of a millimetre. Vasilis Ntziachtistos, Director of the Institute of Biological and Medical Imaging at the Helmholtz Zentrum: "MSOT offers an enormous potential for biomedical research, the development of medicines and medical care." Biologists can follow the development of organs, cell functions and genes through deeper tissue

and thus the development of tumours and other biological processes, such as disease of coronary arteries. Pharmaceutical research can also be decisively accelerated by observing the molecular effects of new agents against cancer, over longer periods of time and in the framework of tests on animals.



Scientists of the Helmholtz Zentrum produced three-dimensional images of a six-millimetre-thick zebra fish.
Photo: © Helmholtz Zentrum München

in the health and environmental field and concentrating its research upon environmental health in the new millennium. The Helmholtz Zentrum now employs over 1,600 people, of which almost 1,300 are scientists and technical employees.

Audible Light

With a combination of light waves and ultrasound, the researchers at the Helmholtz Zentrum have now succeeded in making proteins that are several centimetres deep in living tissue visible. A detailed observation of cell functions or abnormal changes was previously impossible at a tissue thickness of more than half a millimetre. Scientists of the Helmholtz Zentrum have broken

A Strong Network

The Helmholtz Zentrum München does not work alone. A lively exchange takes place with internationally used experimental platforms, clinical cooperation groups and centres for translational medicine. Collaborations also exist with the Munich universities and other national and internationally leading institutes. Researchers at the Helmholtz Zentrum are regularly scientific articles published in international specialist magazines. In addition, the centre also supports spin-offs of young entrepreneurs. An important boost is thus given to cooperation between state research and industry in Germany.

To See More Clearly

Many Innovations in Imaging Come from Bavaria

Medical technology is regarded as an innovative and relatively crisis-resistant industry. A particularly exciting area in this broad field is imaging, which is to say the representation of the insides of the body in a form that can at least be interpreted by the medical personnel. Many people are already familiar with X-rays, ultrasound, and computer and magnetic resonance tomography (MRT) from their own examinations. But development is by no means over. The state of Bavaria is pushing innovation ahead – thanks to its research institutes and companies.

Market Leaders in Erlangen and Garching

The market for imaging is dominated by the biggest electronics companies – such as General Electric and Siemens – with their health-care divisions. Both also have important sites in Bavaria, at Garching near Munich (GE) and in Erlangen (Siemens). In addition to these, many small Bavarian companies are also active in the field of imaging. One centre for this sector is the Nuremberg region, with Siemens and the Institute of Medical Physics of Prof. Dr. Willi Kalender at the University of Erlangen-Nürnberg.

Especially in computer tomography, Kalender is a world-recognised expert. He is regarded as the inventor of spiral CT, which he introduced in 1989 and which is now the standard procedure of computer tomography. In the spiral procedure, the patient is pushed lengthways through the radiation planes at constant speed, while the radiation detector constantly rotates.

Siemens has also contributed to innovation in CT. In 2005, the company presented the dual-source computer tomograph. In this, two rotating x-ray emitters set at 90 degrees to each other work at the same time. This halves the recording time and thus the time that the patient has to spend in the CT. This is especially useful and helpful in the case of heart imaging. The

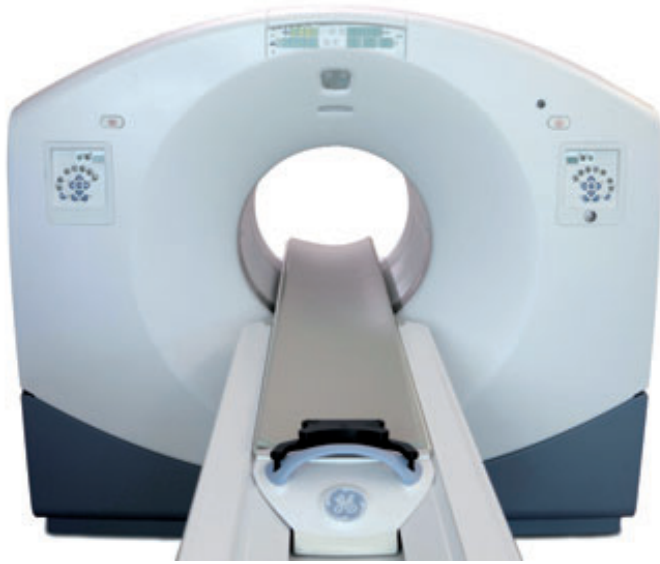
Nuremberg company Ziehm Imaging, on the other hand, has distinguished itself as a specialist in mobile x-ray solutions. The devices from Ziehm are intended to allow the visualisation of the finest tissue, vessel and bone structures, even during the operation.

MRT and PET Complement Each Other

Magnetic resonance tomography (MRT) has established itself as an alternative to computer tomography. Unlike in CT, the patient is not subjected to any exposure to radiation. Neither is it necessary to administer any contrast agents in order to image organs and tissue with high contrast. The technology is based upon magnetic fields and alternating electromagnetic fields in the radio frequency range. These are used to excite particular atom nuclei in the body into resonance. The different relaxation times of different tissues then provide the image contrast.

One leading researcher in the field of MRT is Prof. Dr. Peter Michael Jakob of the Chair for Experimental Physics V at the University of Würzburg. He sees a technology of the future in the combination of MRT and positron emission tomography (PET), which is frequently used to find tumours. He says that the combination of the two technologies provides the added value that one can determine the position of the tumours more accurately.

Another combination of different technologies is molecular imaging, which is being researched by, among others, GE Healthcare in its research centre in Garching. This process makes it possible to view the surface and inside of a body cell and to monitor the extent to which it changes or how cell processes take place. Defects caused by illnesses or a clinical intervention can also be represented. In addition, one can observe how a cell or a group of cells changes its state or its metabolism over a specific period of time. Doctors can quantify and interpret these changes,



The Discovery PET/CT 600 scanner by GE Healthcare is optimized for use in oncology.
Photo: © General Electric

and relate them to the progression of an illness or the condition of the patient, in order to guide the therapy appropriately. This is applied, for example, in the context of cancer or in cardiology or neurology screenings of high-risk patients in whom no symptoms of illness have yet occurred.

New Systems for Better Results

Molecular imaging is not restricted to a particular imaging process. It is true to say that hybrid systems such as combined PET/CT systems and SPECT/CT systems produce excellent results in the representation of radioactive molecules, but

MRT also has great potential. New scanners are proving useful above all for oncological examinations – because more than 90% of all PET/CT examinations take place here. Even the smallest lesions can be recognised due to the excellent spatial image resolution.

Despite the obvious presence of successful innovations, some university researchers would prefer a stronger involvement of the companies in fundamental research. One often receives the impression that research is only conducted when the subsidies are flowing. It is here also necessary for politicians to encourage companies to invest more in fundamental research. As well as this, the universities should also be prompted more to approach the companies.

Qualified Personnel as an Important Site Factor

The quality of Bavaria as a site depends very heavily on how easy it is here to find and keep qualified people. One hears from the universities that they would find better conditions abroad, but also in Baden-Württemberg. The Free State also requires suitable programmes for enticing people here from other sites. This is partly already succeeding, with the Excellence Initiative in Munich – although scientists are said to depart from this construct after only a few years. A long-term bond with the site of Bavaria would be much more important.

Conclusion

Bavaria has also achieved substantial research successes in imaging. This field benefits from outstanding site conditions in not just one but two regions: Munich and in particular Nuremberg/Erlangen. In future, the Free State should endeavour to attract highly-qualified scientists to its universities and to also keep them there for the long term. Then both established and new companies would be able to benefit from proximity to research institutions.



Qualified Personnel as an Important Site Factor in Bavaria.
Photo: © BioM

“We require suitable programmes for binding people to Bavaria”

Interview with Prof. Dr. Peter Jakob, University of Würzburg

Prof. Jakob, what innovations in the field of imaging do you regard as particularly trendsetting?

An interesting new development that will very probably become established in clinical routine is the combined imaging process using MR and PET, which opens up new kinds of perspectives. On the one hand, the MRT process displays anatomy excellently and on the other, the simultaneous PET imaging makes the metabolism in the cells visible by using weakly radioactive substances.

Where do you see Bavaria as a site in an international comparison?

In Bavaria we have very good sites, such as Erlangen, with Prof. Kalender (University of Erlangen) and Siemens as an equipment manufacturer. Siemens are also working actively on the MR-PET technology. The first MR-PET devices have already been delivered and are being tested in a clinical context. So we are definitely at the forefront nationally, as far as innovations in this field are concerned – and that also applies internationally.

What priority does research have at medical technology companies?

Of course, every company in the medical technology industry claims to be carrying out active research. The question is how seriously the companies really are about it. Often only the procedures and technologies that are already available are implemented, using the existing equipment platform. I, however, regard real fundamental research as meaning that companies are also carrying out intensive research into things for which the market value is not immediately recognisable. The companies certainly tend mostly to stay out of this form of research. I would therefore like them to make a greater contribution there as well.

Why is that obviously not happening enough?

Companies are always ready to enter into fundamental research if they can expect a 50% subsidy. One therefore sometimes receives the impression that research only occurs when subsidies are



Prof. Dr. Peter Jakob is Head of the Department of Experimental Physics 5 at the Institute of Physics, University of Würzburg.

flowing. Politicians also need to motivate companies to invest more into fundamental research. As well as this, the universities must also be encouraged to approach the individual companies more.

What strategic decisions are decisive for Bavaria as a site?

The quality of Bavaria as a site will depend strongly on whether it manages to gain qualified people and to keep them. The “high-carat” candidates sometimes find better conditions abroad, but also already in the neighbouring German state of Baden-Württemberg. These scientists will not feel bound to the site of Bavaria if they have the feeling that they would find higher incomes and better research conditions somewhere else. We therefore require suitable programmes for enticing people here from other sites and binding them to the site of Bavaria for the long term.

Is there also a structural problem here?

We basically have the problem that we in research – and especially at the universities – have no central structure. At the faculties there is generally a professor, a secretary and some assistants. Many of them usually have time-limited contracts – normally for six years. But those who want to achieve something in the long term need the option of retaining good scientists – who are perhaps not striving for a qualification - for the long term. Here, we are in the fortunate situation of having such a research centre that collects precisely these scientists. In future, we will need more of such “collecting vessels”, because these scientists and their know-how are eminently important for the implementation of future innovations.

Innovative Environment in Bavaria

An excellent location in which to relocate or found a medical technology company

Bavaria offers attractive site conditions for those founding new companies in the field of medical technical navigation and robotics. According to experts, this does not just depend on the hard factors such as subsidies and the options for regional networking. Soft factors such as the quality of life in the "holiday destination" of Bavaria are also said to play an important role in the choice of location.

Global players have their headquarters in Bavaria

Bavaria is positioned prominently in the growing medical technology market. The German medical products industry employs about 150,000 people and generates more than half of its sales with products that are no more than three years old. A good 20% of employees in the German medical product sector work in Bavaria – there are almost 20,000 highly qualified employees in the field of medical technology. This puts the region substantially above average compared with other states in Germany. More than 60% of Germany's production of electrical medical equipment and around 30% of its total medical-technical production takes place in Bavaria.

This is because high-sales medical technology companies and pharmaceuticals giants with big-

name medical technology divisions have their headquarters in Bavaria, or at least possess an important site there. Global players such as Siemens Medical Solutions, Baxter, Fresenius Medical Care, GlaxoSmithKline, BrainLab, Novartis Pharma, Roche and General Electric with its European research centre in Garching stand for the industry. In addition more than 250 small to medium-sized companies - many of which operate in the field of medical navigation and robotics - carry out research, development and other work in Bavaria.

Ideal research partners are available

"The most important site factors for healthcare companies active in the field of navigation/robotics are a comprehensive interdisciplinary research landscape and suitable industrial key personnel. In the area of university and private research, strong partners are needed in the fields of information technology, mechatronics, sensors, automation and medical application (esp. surgery). At an industrial level, manufacturers with experience in the fields of robot development, software development, embedded systems, electronics, control technology, imaging and image data processing are necessary," finds Dr. Matthias Schier from the Forum MedTech Pharma e.V.



Dr. Matthias Schier,
Forum MedTech Pharma e.V.



BrainLAB headquarters in Feldkirchen: Many high-sales medical technology companies have their headquarters or an important site in Bavaria.

Photo: © BrainLAB

Bavaria fits this profile of requirements to an outstanding degree. "Ideal research partners are available", in the form of the DLR (Germany's national research centre for aeronautics and space), medical technology and information technology faculties active in this field in Erlangen-Nuremberg and Munich, university hospitals in Munich, Erlangen-Nuremberg and Regensburg, and the Fraunhofer Institutes for Integrated Circuits ISS (Erlangen) and Reliability and Microintegration IZM (Munich). It is important for Schier that "as well as medical technology, the clusters for

satellite navigation, information and communication technology, sensors and power electronics, and mechatronics and automation can also make valuable contributions.”



Dr. Robert Klarner, Regional Branch Office Technology Marketing, German Aerospace Center (DLR)

This abundance of possible partners is extremely important because “the principle of geographical proximity” cannot be rated too highly, finds Dr. Robert Klarner of the DLR. Even in an era of Skype, the Internet and video-conferencing, he says that it is indispensable

to have direct contact to potential partners and customers. Prof. Dr. Tim Lüth, Holder of the Chair for Micro Technology and Medical Device Technology at the TU Munich, underlines this view: “The handling of development is particularly important in the case of medical equipment.” This, he says, cannot be represented by e-mail, “instead, for example, the supplier must visit the premises.” In the field of medical technology, nothing beats holding the item and trying it out. He says that this approach is also more efficient than constantly sending e-mails back and forth and that it protects innovations: “We have had the experience that arranging courses of action in direct personal conversations works well”, adds Lüth. The alternative is to specify requirements or characteristics in writing “and that can of course be copied and used elsewhere.”

Innovative environment in Bavaria

For Klarner and Lüth, spin-offs from universities and research institutions are especially promising of success because the new entrepreneurs can build upon relationships that have already been cultivated and upon shared technical foundations. Klarner calls this the “innovative milieu”, and says that it exists in an excellent form in Bavaria.

Also important are the institutionalised funding options, as provided via the so-called ESA incubators at DLR sites. The example of a non-invasive device for the treatment of tumours



Excellent research partners: Germany's national research centre for aeronautics and space (DLR) in Oberpfaffenhofen
Photo: © DLR



Prof. Dr. Tim Lüth,
TU Munich

shows how space technology can make a decisive contribution to the development of new medical devices: magnetic resonance tomography (MRT) for the location and diagnosis of cancerous tissue and high-intensity focussed ultrasound (HIFU) for “burning out” malignant cells are expected to open up a new approach to treatment. The software platform EuroSim, originally developed for the real-time simulation of satellites, was used for the solution of complex technical problems in designing the system. The ESA technical knowledge for the modelling of wave propagation was of decisive importance in ensuring that the MRT and HIFU technologies were optimally coordinated with each other.

Also important: High quality of life

Lüth sees potential for improvements, e.g. in the matter of patent law. Since the change in the law in 2003, patents no longer belong to the professors, but instead to the universities. Lüth sees this as having an “inhibiting effect on spin-offs.” This is, however, a fundamentally nation-wide problem. Schier sees potential in deregulation and improved financing in the hospital segment: “As in many areas of medical technology, the general conditions for the clinical evaluation of new technologies are not optimal - even in navigation and robotics – as regards regulatory requirements and with respect to financial equipment and the personnel resources of the hospitals”, he claims.

All in all, however, Bavaria is an excellent location in which to relocate or newly found a medical technology company, he says. “As well as the hard factors mentioned, the high quality of life in Bavaria is also a reason for this”, clarifies Lüth.

For More Quality of Life and Independence

Telemedicine and Homecare Growing in Importance

Living with more self-determination, being less dependent on constant visits to the doctor or hospital stays – telemedicine, homecare and ambient assisted living (AAL) can offer people more quality of life. The field of so-called e-health is about using medical and information technology in health care. Innovations are promising growth here, provided that the health service involved is also paid for, either by the insurance schemes or by the patients themselves.



The person must accept the technology, understand the handling and also want it for himself.

Photo: © Bio^M

Staying active and mobile in old age

In Germany today, between 16 and 17 million people are over 65 years old. The proportion of the population of this age will continue to grow, and is expected to already be over 20 million in the year 2030. There is also an increasing wish to continue to be active, to be independent, and to maintain social relationships. Frequent visits to doctors or even longer stays in hospitals or rehabilitation clinics can conflict with these expectations. It is therefore important, now and in the future, to expand the possibilities for looking

after patients in their natural living environment. Ambient assisted living (AAL), homecare and telemedicine applications are areas which are being developed. Telemedicine is regarded as an important field of innovation for medical and information technology in healthcare.

“Thinking based on the person”

Research results have shown that people who are still relatively fit, remain active in their social milieu and also participate in their own healthcare normally also stay healthy for longer. In order to promote “provision in one’s own home”, contact to doctors, medical personnel and carers from one’s own home must be simplified. The use of modern technology is here a central element. “Appropriate solutions must, however, always be developed based on the person – the patient – and not just the technology”, says Prof. Heinz Gerhäuser, Director of the Fraunhofer Institut for Integrated Circuits IIS in Erlangen. “The person must accept the technology, understand the handling and also want it for himself”. The Fraunhofer IIS carries out research and development in the field of software, microelectronics and information and communication technology.

Aiming at cost containment

Mobile technology for mobile people is a concern of Prof. Gerhäuser, who played a decisive role in the development of the “MP3” audio system. In healthcare, the need for in-patient treatment can be reduced with the use of suitable technology. The latter is also a matter of price. Even if the focus is on the improvement of the patients’ quality of life, the aim of cost containment in healthcare is also a factor in the application of homecare and telemonitoring. Expenditure will certainly continue to rise together with the growth of the proportion of old people in the population. New channels of treatment can also help to make good healthcare more affordable. Ideally,

telemedicine improves quality of life and at the same time lowers treatment costs compared with "conventional" methods. There are, however, no accurate figures about the telemedicine market and savings in healthcare or the growth potential of such care and treatment channels.

Lifesaver in an emergency

But there are numerous examples. Telemonitoring - the observation of patients outside medical establishments - is a very important segment of telemedicine. It comprises the remote examination, diagnosis and monitoring of the patient by the responsible doctor. In the case of chronically ill people – cardiac illnesses and diabetes are particular focuses – data goes from the measurement apparatus of the patient directly to the doctor or carer or to the closest telemedical centre, where they are stored and analysed. Such vital information can include weight, blood pressure and heart rate among others. If certain limit values are exceeded, the responsible medic receives a signal. In an emergency, a doctor or nurse can then visit the patient straight away. This can sometimes save lives. Also, with a device like a PDA (Personal Digital Assistant), information can be transmitted from the doctor to the patient, e.g. the reminder to take medication or the communication of a particular measure based upon the patient data already received.

Swift provision minimises subsequent damage to health

Aid can thus be provided swiftly in acute situations. But telemonitoring can contribute, in particular, towards preventing acute situations from arising in the first place, by providing early warnings – the early recognition of trends of deterioration in certain measurement values such as heart-rate, blood pressure, etc.. This also minimises subsequent damage to health that would lead to additional high costs. One area of application, for example, is the diagnosis and acute therapy of strokes. Here, every minute counts. That is why Bavaria has set up a network of 19 special stroke wards. Assisted by the telemedical connection of clinics to these centres, patients can be provided with care swiftly and regardless of their place of admission. Cardiovascular illnesses are by far the most frequent cause of death in Germany, and a much more frequent cause than cancer.

FitForAge – maintaining fitness

Prevention is therefore a keyword that has climbed a considerable distance up the priority ladder during the past few years. Especially in an

ageing society, it is central for an approach to achieving better health. The project "FitForAge", promoted by the Bavarian Research Foundation, involves capable partners from industry, research and universities. This also includes the Fraunhofer IIS with Prof. Gerhäuser: "The aim is for people to train their physical



Telemonitoring can sometimes save lives.
Photo: © Matthias-Balzer-pixelio.de

and mental fitness early. This will extend quality of life in the future". How fit someone is, he says, depends not so much on his calendar age as on his biological age. "The research association tries to find technical solutions to enable people to stay mobile and fit-for-work longer and – even when very old or as patients – to live with self-determination with as little outside help as possible", explains Prof. Gerhäuser.

Growth market "mobile health"

Companies that are active in the growth market for telemedical solutions are often to be encountered in Nuremberg-Erlangen medical technology cluster. This includes, for example, the Dr. Hein Gruppe, founded in 1999, which is cooperating with the mobile radio group Vodafone in the "mobile health" segment. The company is a member of the FitForAge association and offers, among things, technical solutions for the early recognition of strokes and heart attacks. "But no matter how much technology there is, people still need personal contacts, otherwise telemedical healthcare fails", says Managing Director Robert Setz. He expects substantial growth in such applications in future, especially in the area of optional additional services ("self-paying market"). This also affects his company, which is looking for a further investor to finance growth.

Partners:

www.invest-in-bavaria.com



www.biotech-bayern.de



www.medtech-pharma.de



www.bayern-international.de



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