The Medical Biotechnology Industry in Germany
Issue 2011/2012
A Global Medical Biotech Force

The German medical biotechnology industry is a significant global industry player. In fact, Germany is the world’s leading medical biotech nation behind the US. The industry’s strength comes from the presence of long-established and start-up companies alike. Industry, government, and the research sector are pulling in one direction to build on the thriving sector’s already strong market foundations.

Already home to Europe’s largest market for medical goods, Germany’s gradually aging population is a significant health care industry growth driver.

The number of people aged 65 years or older is expected to reach the 17.5 million mark by 2015 (equivalent to around one fifth of the total population of 82 million).

The resulting increased demand for health goods significantly enlarges the potential market for all medical biotechnology products, biopharmaceuticals, molecular diagnostics products, and regenerative medicine approaches.

With the largest amount of biotech companies in Europe, world-class research infrastructure, and internationally renowned scientists, Germany has firmly established itself as an international medical biotechnology hub.
The Industry in Numbers

The German biotechnology sector remained stable and demonstrated continuous turnover growth rates during the global economic downturn. Medical biotech company revenue increased by nearly 20 percent for the period 2007 through 2010. The German medical biotech market is mainly made up of small but highly innovative companies — generally one to fifty employees in size.

Market Segmentation
Medical biotechnology is the most important German biotechnology industry segment. Around 47 percent or some 400 of the biotech companies based in Germany develop new medicines or diagnostic tests in the fields of human and animal medicine. Approximately 35 percent of the remaining biotech firms undertake activities not particular to one specific sector. A significant number of these are companies providing services for the biotechnology industry and biotech firm suppliers. The rest of the firms are focused in the areas of bioinformatics, agricultural, and industrial biotechnology.

Biopharmaceuticals as Market Driver
In 2010, the German biopharmaceuticals market recorded sales of EUR 5.2 billion – an eight percent increase on the previous year. This is equivalent to 17 percent of the total pharmaceutical market. The German medical biotechnology sector is dominated by biopharmaceuticals (e.g., antibodies, protein and peptide therapeutics). Biopharmaceuticals are strongly represented in certain fields of therapy.

For example, their revenue share is 74 percent in immunology, 35 percent in the area of metabolism, 32 percent in oncology, and 23 percent in hematology.

Company Structure
The domestic medical biotechnology industry is largely characterized by small companies with a small number of employees. The vast majority of German biotech companies (more than 80 percent) have less than 50 employees; only 1.5 percent of all companies have grown out of the small and medium-sized enterprise category, employing more than 250 employees.

International Sales Potential
German medical biotechnology products and technology platforms are increasingly prized abroad, with international demand on the rise. Pharmaceutical and medical device industries closely connected with the biotechnology industry secure 63 percent and 62.5 percent of their revenues from exports respectively.
Europe’s Largest Health Economy

Stable Healthcare Consumer Market
Catering to the largest population in Europe (82 million), Germany’s health care sector is a highly attractive market with significant growth opportunities. A steady increase in life expectancy levels has resulted in a rise in chronic and age-related illnesses. Improved health awareness has further increased consumer demand for medical products and therapies. Germany ranks fourth internationally in terms of GDP health spend (11.6 percent). In 2010 around EUR 174.5 billion in funding was set aside for the statutory health insurance sector. From this budget, 15.5 percent was spent on medical treatment; 33.3 percent was allocated to hospital treatment; and 17.3 percent was spent on pharmaceuticals. With around 90 percent of the German population enrolled with a statutory health insurance provider, the statutory health insurance system plays a major role in the allocation of health care sector funds. The remaining 10 percent of the population opt for private health insurance. As such, Germany provides ready access to a stable market of health care consumers with a clear and adequately distributed expenditure system.

From Producer to Patient
Prescription drugs used in outpatient care are prescribed by the physician (i.e. general practitioner or office-based specialist) and dispensed by one of more than 20,000 pharmacies nationwide. The German pharmacy market is dominated by small, privately-owned pharmacies. Patients bear 10 percent of the price as co-payment, but no more than EUR 10 in total.

Drugs are usually purchased by the pharmacist from one of the wholesaler groups. Wholesaler and pharmacists margins are legally defined and calculated according to the ex-manufacturer price.

Reimbursement Scheme
Reimbursement is regulated by different guidelines subject to use in either of the out-patient or in-patient sectors. As a general rule, biologics treated as medical goods are reimbursable when covered by the catalogue of benefits applicable in the relevant sector. In the in-patient sector innovative products not yet covered by the relevant catalogue of benefits can obtain temporary reimbursement. They can also be used in the out-patient sector, however, patients have to bear the costs themselves.
German Biotech Research Excellence

Germany is home to a dynamic and vibrant biotechnology industry. Despite moderate economic forecasts, 2010 German biotech firm R&D expenditure maintained an overall high of EUR 1.02 billion.

Academic Excellence
The German biotech industry is exemplified by a highly innovative environment that places considerable value on technology and research resources. Germany’s research landscape is made up of 343 universities and over 330 research institutes who cooperate with companies to discover and bring new products to market. Leading German research associations such as the German Research Foundation, the Helmholtz Foundation, the Fraunhofer Association, the Leibniz Association, and the Max Planck Society can call upon an illustrious roll call of companies working at the cutting edge of biopharmaceutical research – and all of them based in Germany.

Public R&D Support
The German government will invest approximately EUR 5.5 billion in a program called the “Health Research Framework Programme of the Federal Government” in the period 2011-2014. The initiative focuses on research into major diseases and places particular emphasis on individualized therapy approaches, the health care industry and globally networked research efforts. This directive is just one manifestation of the German Federal Government’s “High-Tech Strategy” which includes biotechnology as one of the eight key technologies promoted.

Innovation Leader Germany
German patent figures pay testimony to the innovation work done in German science and industry; with almost one thousand biotech patent applications at the European Patent Office in 2010, Germany has the best record in Europe and is second only to the US globally. Germany is the European leader in terms of patents granted in the same year, with a 100 percent plus advantage over the UK and France. The country is also a leading nation in triadic patents. With 73 triadic patents per million inhabitants in 2008, Germany ranks fourth after Switzerland, Japan and Sweden respectively.

Leading German Research Associations

<table>
<thead>
<tr>
<th>Research Association</th>
<th>Profile</th>
<th>Annual Research Budget</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DFG</strong></td>
<td>The DFG is the central, self-governing research funding organization that promotes research at universities and other publicly financed research institutions in Germany.</td>
<td>EUR 2 billion</td>
</tr>
<tr>
<td><strong>Helmholtz Association</strong></td>
<td>The Helmholtz Association is a community of 16 scientific-technical and biological-medical research centres employing 28,000 staff.</td>
<td>EUR 2.8 billion (approximate)</td>
</tr>
<tr>
<td><strong>Fraunhofer Gesellschaft</strong></td>
<td>Germany’s Fraunhofer-Gesellschaft is Europe’s largest applied research institution. It employs a staff of 17,000 in 80 research units.</td>
<td>EUR 1.5 billion (of which around two thirds is generated from contract research)</td>
</tr>
<tr>
<td><strong>Leibniz Association</strong></td>
<td>The Leibniz Association is an interdisciplinary scientific community of 86 German research institutes. Twenty-five of these institutes are specialized in the field of life sciences.</td>
<td>EUR 1 billion (approximate)</td>
</tr>
<tr>
<td><strong>Max Planck Society</strong></td>
<td>More than 13,000 PhD students, postdoctorals, guest scientists and researchers, student assistants and other staff members work in the 80 research institutes of the Max Planck Society.</td>
<td>EUR 1.56 billion</td>
</tr>
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</table>
Growing Biopharmaceuticals Market

Five hundred sixteen biopharmaceuticals are currently in clinical development in Germany. Of these, monoclonal antibodies – with 242 projects in total – account for the main area of focus. The clinical development pipeline has achieved its highest growth levels specifically in phases II and III, an indicator which demonstrates accelerated progress in the development of the drug candidates.

Personalized Medicine: A New Age in Medicine

For patients, science and industry alike, the notion of a “personalized pill” promises a new world of health and prosperity. Finding and providing an individual cure for each and every single patient would help restore people to full health more effectively than ever before, and help increase health care system efficiency while making significant cost reductions. Small Dx companies are fast becoming the most sought after partners for big pharmaceutical concerns looking for companion diagnostics to match new biopharmaceutical therapeutics for joint development with major academic players.

This ideal scenario has already become a hands-on reality in Germany’s medical biotech sector, with individual industry clusters specializing in this area and government designing specific funding instruments in order to promote progress in both science and industry.

From 2011 to 2014 the German government will invest a total of EUR 5.5 billion in the support of the country’s life sciences research activities, with personalized medicine singled out as a major priority field.
BioM, the cluster organization entrusted with the task of cluster management for the biotech sector in Munich and Bavaria, was one of the recent winners of a federal government-supported competition which will see EUR 100 million flow into personalized medicine over the next five years. The Bavarian cluster has been awarded EUR 40 million in funding in order to support its innovative work. At the time of writing, 20 personalized medicine drugs are available in the German market; 16 of which require a corresponding diagnostic test and three which are biopharmaceuticals.

**Growth Driver:**

**Molecular Diagnostics**

Molecular diagnostics is the most promising in vitro diagnostics subsegment in Germany, with the country accounting for the largest IVD market in Europe and second only to the US globally. Molecular Dx already enjoys more than a 10 percent share of the entire German diagnostics market, but boasts a growth rate more than twice that of the entire IVD market as such.

A number of German companies are engaging the global markets successfully, the most prominent example being Qiagen, a spin-off from the University of Düsseldorf. The significant market opportunities are reflected in strong R&D activity, the government supporting some 20 science-industry partnerships with a grant program worth EUR 22 million.

**Innovative Approaches:**

**Regenerative Therapies**

Regenerative therapies are premised on the principle of the body curing itself by replacing damaged tissue or cells in order to restore original biological function.

New products building on regenerative medicine are at the cusp between medical devices and the biotechnology industry, and contribute significantly to the efficiency of classical medical devices. Successful examples of regenerative therapies are, for example, cell-coated implants.

Taking into account anticipated patient numbers for three exemplary areas of commercialization for regenerative medicine (skin replacement products for chronic wounds; cell therapies for repair of the liver; and repairing joints near bone defects), the estimated market potential in Germany is around EUR 150 million per year. Larger market value of more than EUR 1 billion annual revenue is forecast in the developing heart research sector (myocardial infarction and congestive heart indications).

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**Selected Investments in Personalized Medicine**

<table>
<thead>
<tr>
<th>Company</th>
<th>Field</th>
<th>Investor</th>
<th>Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carpegen/Systec</td>
<td>MDx</td>
<td>Federal Ministry of Education and Research</td>
<td>EUR 2 m</td>
</tr>
<tr>
<td>CureVac</td>
<td>MDx</td>
<td>Dievini Hopp BioTech holding</td>
<td>EUR 28 m</td>
</tr>
<tr>
<td>Lophius Bioscience</td>
<td>MDx, BM</td>
<td>S-Refit, High-Tech Gründerfonds, Bayern Kapital</td>
<td>EUR 2 m</td>
</tr>
<tr>
<td>MorphoSys/Proteros biostructures</td>
<td>MDx, THx</td>
<td>Federal Ministry of Education and Research</td>
<td>EUR 1 m</td>
</tr>
<tr>
<td>mtm laboratories</td>
<td>BM</td>
<td>HBM BioVentures, Wellington Partners, Gilde Healthcare Partners, National Technology Enterprises, Heidelberg Innovation, private Investors</td>
<td>EUR 8 m</td>
</tr>
<tr>
<td>PheneX Pharmaceuticals</td>
<td>MDx</td>
<td>EVP Capital, LBBW Venture Capital, Creathor Venture, Swiss Life, CD Venture, KfW, private Investors</td>
<td>EUR 6 m</td>
</tr>
<tr>
<td>Protagen</td>
<td>MDx, DM</td>
<td>MIG Fonds, S-Capital Dortmund, S-Venture Capital Dortmund, KfW</td>
<td>EUR 10 m</td>
</tr>
<tr>
<td>Synimmune</td>
<td>THx</td>
<td>Federal Ministry of Education and Research</td>
<td>EUR 3 m</td>
</tr>
</tbody>
</table>

Source: VentureCapital Magazine 2011
Innovation Infrastructure

Science and industry need to work in close harmony in order for innovations to be successful. German bioclusters are proving to be important new technology impulse givers in this respect.

Germany’s BioRegions

Germany’s biotech landscape has developed its own clearly defined regional contours. These so-called “BioRegions” act as platforms for industrial development, facilitating organic interaction between corporate and institutional actors. Each region boasts its own research capabilities and a clear and defined commercial orientation. More importantly, the different regions cooperate with each other as part of a network designed to leverage their respective individual strengths. Germany boasts more than 25 industry-relevant clusters, the largest of them settled around Berlin, Munich, the Rhine Neckar triangle (Heidelberg), Frankfurt, and Cologne. BioRegions help take ideas from the lab to the marketplace by providing access to a stimulating scientific environment, excellent infrastructure, ready access to capital, experienced management, and highly trained personnel.

Best Practice Example

The Biotechnology Cluster Rhine-Neckar (BioRN) was granted some EUR 40 million in order support bringing biotechnological innovations to industrial maturity as part of the Federal Ministry of Education and Research’s Leading Edge Cluster Competition. Consisting of over 100 partners from industry, science and politics, the cluster focuses on the areas of personalized medicine and cancer, with partners including the German Cancer Research Center (DKFZ), the University of Heidelberg, the Heidelberg University Hospital and the European Molecular Biology Laboratory (EMBL) as well as health care companies Roche (Mannheim), Abbott (Ludwigshafen), and Merck-Serono (Darmstadt).

More detailed BioRegion information can be found in the Germany Trade & Invest “BioRegions in Germany” publication.
Public and Private Sector Partnership

The German medical biotech industry is best characterized by a highly innovative environment that places considerable value on technology and research resources. This is reflected in the high number of collaborations – typical to the industry – along the entire value chain. Almost half of the partnerships identified are with research institutes.

Research Networks

Germany has established itself as a major R&D force by creating a broad platform of research universities, research organizations (such as the Fraunhofer Society and the Max Planck Society) and other public and private research facilities that work in close collaboration with interested partners. In the last three years, there has been a tremendous growth in product partnerships between German biotech companies and major international players. Global collaboration not only exists between research institutes, but also between research institutes and private companies as well as solely between private companies.

Global Best Practice: Max Planck Society

With 80 institutes the Max Planck Society is a major German source of biotech innovation with a tradition of global collaboration. The society’s “Max Planck Innovation” marketing unit currently oversees more than 1,170 inventions and has shareholdings in 15 companies. In the last 30 years more than 1,900 license agreements have been closed and, since 1990, more than 90 spin-offs followed through. The total proceeds for inventors, the Max Planck Institutes and the Max Planck Society currently amounts to about EUR 280 million.

Selected German Biotech Company Partnerships 2010

<table>
<thead>
<tr>
<th>Selected Partnerships</th>
<th>Product/Technology</th>
<th>Potential Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellzome and GlaxoSmithKline</td>
<td>Using Cellzome’s proprietary Epishere technology for epigenetic enzymes from four different classes</td>
<td>EUR 508 m</td>
</tr>
<tr>
<td>Pieris and Sanofi-Aventis</td>
<td>Discovery and development of two drug candidates using Pieris proprietary Anticalin Technology</td>
<td>EUR 270.5 m</td>
</tr>
<tr>
<td>DeveloGen (subsidiary of Evotec) and Medimmune (subsidiary of AstraZeneca)</td>
<td>Exclusive access to DeveloGen’s research program in the field of “Regeneration of insulin-producing Beta cells” in diabetes research</td>
<td>EUR 259 m</td>
</tr>
<tr>
<td>Priaxon and Boehringer Ingelheim</td>
<td>Worldwide R&amp;D collaboration into mdm2/p53-Inhibitors for cancer treatment using Priaxon’s expertise in the area of small molecule drug discovery</td>
<td>EUR 86 m</td>
</tr>
<tr>
<td>MediGen and Astellas Pharma Europa</td>
<td>Sale of European marketing and distribution rights for the Eligard treatment with 2% share of net sales for MediGene</td>
<td>at least EUR 25 m</td>
</tr>
<tr>
<td>MorphoSys and Xencor</td>
<td>Worldwide license and collaboration agreement for clinical antibody program MOR208 (Xm Ab 5574) for treatment of B-cell tumors</td>
<td>at least EUR 10 m</td>
</tr>
</tbody>
</table>

Source: Ernst & Young 2011
Dynamic Labor Market

Well-trained Labor Force
Highly skilled and specialized employees are a key feature of the German labor market and will remain so in the future. Nearly 50 national universities offer studies in life sciences and biomedical engineering. Each year, around 48,000 natural sciences and mathematics and 21,000 medicine students successfully graduate from German universities. Of the latter, around 9,000 have successfully obtained degrees in biology; 5,300 in chemistry; and 2,100 in pharmacy. Germany has proportionally more natural sciences graduates than the US or Japan.

World-Class Education Standards
Germany’s world-class education system ensures that the highest standards are always met. Eighty-four percent of the German population have been trained to university entrance level or possess a recognized vocational qualification – above the OECD average of 67 percent. German universities have introduced masters and bachelor degrees for improved international acceptance and comparison.

Dual Education System
Germany provides direct access to a highly qualified and flexible labor pool. The country’s dual education system – unique in combining the benefits of classroom-based and on-the-job training over a period of two to three years – is specifically geared to meet industry needs. The German Chambers of Industry and Commerce (IHK) ensure that exacting standards are adhered to, guaranteeing the quality of training provided across Germany.

Competitive Labor Costs
High productivity rates and steady wage levels make Germany an extremely attractive investment location. Labor cost increases have been the lowest in Europe in recent years, with a modest annual increase rate of 1.6 percent. German productivity rates are almost 10 percent greater than the average of the EU’s 15 core national economies, and almost one quarter higher than the OECD average. Highly flexible working practices such as fixed-term contracts, shift systems, and 24/7 operating permits contribute to enhance Germany’s international competitiveness as a suitable investment location for internationally active businesses.

Quality Biomanufacturing
Thanks to its favorable labor market conditions, Germany is at the cutting edge in biotechnology R&D and is a leading player in large and clinical scale production. Observance of the highest standards ensures optimum production quality. Companies who require a reliable and secure manufacturing process can do no better than Germany. The country’s biomanufacturing firms are world leaders in providing the optimal mix of diverse capabilities and efficient workflow.

European Labor Cost Growth 2001-2010

- **Germany**: 1.6%
- **France**: 2.1%
- **Netherlands**: 3.4%
- **Spain**: 3.6%
- **UK**: 4.1%
- **Poland**: 6.3%
- **Czech Rep.**: 6.8%
- **Slovak Rep.**: 7.7%
- **Hungary**: 8.3%

Annual average growth expressed as percentage of industry, construction and services. Source: Eurostat 2011
Creating Investment Stability

Sound and Secure Legal Framework
According to the World Economic Forum (WEF), Germany is one of the world’s best locations in terms of planning and operating security. Germany is also one of the world’s leading nations in terms of intellectual property protection and security from organized crime. German regulatory authorities are highly professional in their operations. The German legal system also counts as one of the world’s most efficient and independent. Social, economic, and political stability provides a solid base for corporate investment projects. Contractual agreements are secure and intellectual property is strictly protected in Germany.

Open and Transparent Markets
The German market is open for investment in practically all industry sectors, and business activities are free from regulations restricting day-to-day business. German law makes no distinction between Germans and foreign nationals regarding investments, available incentives or the establishment of companies. The legal framework for FDI in Germany favors the principle of freedom of foreign trade and payment. There are no restrictions or barriers to capital transactions or currency transfers, real estate purchases, repatriation of profits, or access to foreign exchanges.

World-Class Logistics Infrastructure
Germany’s infrastructure excellence is confirmed by a number of recent studies including the Swiss IMD’s World Competitiveness Yearbook and various UNCTAD investor surveys. According to the WEF’s Global Competitiveness Report 2011-2012, Germany boasts the world’s second best infrastructure.

Internationally Competitive Tax Conditions
Germany has developed one of the most competitive tax systems in the world. Significant company taxation reforms made in 2008 have resulted in a decrease of the corporate tax burden by around 25 percent. The overall average corporate tax burden has sunk to just below 30 percent, with a number of federal states providing even more competitive tax rates. Standard corporate income tax has also been reduced by ten percent to just 15 percent on all corporate taxable earnings.

International Legal System Efficiency Assessment 2010

<table>
<thead>
<tr>
<th>Country</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
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<tr>
<td>Finland</td>
<td>5.7</td>
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<td>Netherlands</td>
<td>5.3</td>
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<td>Germany</td>
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<td>UK</td>
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<tr>
<td>France</td>
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<td>USA</td>
<td>3.8</td>
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<td>Poland</td>
<td>2.9</td>
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<td>Czech Rep.</td>
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<td>Hungary</td>
<td>2.4</td>
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<tr>
<td>Slovak Rep.</td>
<td>2.4</td>
<td></td>
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</tbody>
</table>

(1 = extremely inefficient 7 = highly efficient)
Source: World Economic Forum 2011

Germany – The Most Attractive Business Location in Europe

Germany remains the most important location for US companies looking to expand in Europe according to the eighth AmCham Germany Business Barometer.

US investors consider Germany to have handled the global economic downturn in robust fashion, allowing the country to significantly improve its attractiveness as a place to do business. This can be attributed to changes made to the economic framework in recent years.

A large majority of US companies saw renewed growth in revenues in 2010, and most have an optimistic outlook for 2011.
Financing & Incentives in Germany

In Germany, investment projects can receive financial assistance through a number of different instruments. These instruments may come from private sources or consist of public incentives programs available to all companies – regardless of country of provenance. They fit the needs of diverse economic activities at different stages of the investment process.

Early Stage Investment Project Financing
Technologically innovative start-ups in particular have to rely solely on financing through equity such as venture capital (VC). Germany offers several public-private-partnership programs to support companies in the start-up phase. One example is the High-Tech Gründerfonds program: a partnership between government, the KfW development bank and industry (industry partners include BASF, Deutsche Telekom, Siemens, Daimler, Carl-Zeiss and Robert Bosch) which provides a total of EUR 272 million in venture capital funding to start-ups. The individual federal states also have specific funds directed to support innovative start-ups obtaining equity capital as well as funds supporting specific R&D programs in the form of grants and loans. R&D grants are also available at the federal level as well as through programs of the EU.

Later Stage Investment Project Financing
Debt financing is a central financing resource and the classic supplement to equity financing in Germany. It is available to established companies with a continuous cash flow. Loans can be borrowed for day-to-day business (working capital loans), can help bridge temporary financial gaps (bridge loans) or finance long-term investments (investment loans). Besides offers from commercial banks, investors can access publicly subsidized loan programs in Germany. These programs usually offer loans at attractive interest rates in combination with repayment-free start-up years, in particular for small and medium-sized companies. These loans are provided by the state-owned KfW development bank and also by regional development banks.

Cash Incentives for Investment Projects
When it comes to setting up production or service facilities, investors can count on a number of different public funding programs. These programs complement the financing of an investment project. Most important are cash incentives provided in the form of non-repayable grants applicable to co-finance investment-related expenditures such as new buildings, equipment or machinery. In Eastern Germany, investment grants are complemented by an investment allowance, which is usually allotted in the form of a tax credit but which can also be provided in the form of a tax-free cash payment.

Labor-related Incentives and R&D Project Grants
After the location-based investment has been initiated, companies can receive further subsidies for building up a workforce or the implementation of R&D projects. Labor-related incentives play a significant role in reducing the operational costs incurred by new businesses. The range of programs offered can be classified into three main groups: programs focusing on recruitment support, training support, and wage subsidies respectively. R&D project funding is made available through a number of different incentives programs targeted at reducing the operating costs of R&D projects. Programs operate at the regional, national, and European level and are wholly independent from investment incentives. At the national level, all R&D project funding has been concentrated in the so-called High-Tech Strategy to push the development of cutting-edge technologies. Substantial annual funding budgets are available for diverse R&D projects.
“Germany enjoys a clear advantage in its pool of highly trained and motivated specialists – essential for sustained high-quality work and company know-how retention. The country’s generous R&D funding also provides much-needed support in the early drug development stage right through to the clinical testing stage. In this respect, Germany is ideally set up to help companies develop their products for market success.”

Prof. Dr. Peter Buckel, CEO, SuppreMol

Best Practice Example
SuppreMol GmbH

In July 2011 SuppreMol GmbH, a German biopharmaceutical company pioneering therapeutics for the treatment of autoimmune diseases launched a phase II clinical trial of its lead product SM101 for the treatment of systemic lupus erythematosus (SLE). At present, SM101 is being developed in primary immune thrombocytopenia (ITP) - coagulation disorder - for which SuppreMol has been already granted orphan drug designation (ODD) in both the European Union (EU) and US.

With its own pipeline, SuppreMol is an exemplary case for the continuous growth of the clinical pipeline of German biotech companies in general. In 2010, there were 516 new drug candidates, which 417 candidates were undergoing the phase I and II testing, with the remaining 99 compounds in phase III testing.

Technology
SuppreMol’s unique treatment is based on the observation that inflammatory processes are further boosted by the interaction of the immune complexes with specific receptors on the surface of immune cells. SM101 modulates the activity of autoantibodies by substances competing with these cellular receptors, thereby hindering the autoantibodies from binding to them. As a result, the immune cells are down-regulated and are unable to maintain the autoimmune response.

Collaboration and Partnership
SuppreMol can look back on almost ten years of successful work. It was founded in the Munich Cluster in 2002 as a spin-off from the laboratory of Prof. Dr. Robert Huber (Nobel Prize winner in Chemistry in 1988) and his team at the Max Planck Institute for Biochemistry in Martinsried. The innovative technology platform enabled the firm to raise its first venture capital through its lead investors.

In 2010, SuppreMol counted among the top seven biotech companies in terms of venture capital financing (EUR 35 million). In order to advance the clinical development of its SM101 lead candidate, the German start-up has also been granted generous research funding by the German Federal Ministry of Education and Research (BMBF) as part of the biotechnology initiative in the field of personalized medicine.

As well as this, access to the Bio-M high-tech cluster’s clinical study centers makes a significant contribution to exploring further SM101 indications.

Profiting from German Excellence
The SuppreMol success story is a prime example of how a German start-up – implementing a novel approach – can make swift progress in order to make its treatment a commercial reality. This has been made possible by significant contribution made by fruitful collaboration between cutting-edge research and industry and a vibrant research landscape.

Moreover, the German government has also created the required conditions for boosting the market innovation potential of private companies. This landscape also creates ample opportunity for private investors thanks to the presence of innovative companies, investor-friendly market conditions and clear and transparent legal procedures. Germany’s innovative environment ensures that the country’s innovative power in medical science and industry will continue to flourish making new visions in diagnostics and therapeutics a reality for the patient.

Germany enjoys a clear advantage in its pool of highly trained and motivated specialists – essential for sustained high-quality work and company know-how retention. The country’s generous R&D funding also provides much-needed support in the early drug development stage right through to the clinical testing stage. In this respect, Germany is ideally set up to help companies develop their products for market success.”

Prof. Dr. Peter Buckel, CEO, SuppreMol

Best Practice Example
SuppreMol GmbH

In July 2011 SuppreMol GmbH, a German biopharmaceutical company pioneering therapeutics for the treatment of autoimmune diseases launched a phase II clinical trial of its lead product SM101 for the treatment of systemic lupus erythematosus (SLE). At present, SM101 is being developed in primary immune thrombocytopenia (ITP) - coagulation disorder - for which SuppreMol has been already granted orphan drug designation (ODD) in both the European Union (EU) and US.

With its own pipeline, SuppreMol is an exemplary case for the continuous growth of the clinical pipeline of German biotech companies in general. In 2010, there were 516 new drug candidates, which 417 candidates were undergoing the phase I and II testing, with the remaining 99 compounds in phase III testing.

Technology
SuppreMol’s unique treatment is based on the observation that inflammatory processes are further boosted by the interaction of the immune complexes with specific receptors on the surface of immune cells. SM101 modulates the activity of autoantibodies by substances competing with these cellular receptors, thereby hindering the autoantibodies from binding to them. As a result, the immune cells are down-regulated and are unable to maintain the autoimmune response.

Collaboration and Partnership
SuppreMol can look back on almost ten years of successful work. It was founded in the Munich Cluster in 2002 as a spin-off from the laboratory of Prof. Dr. Robert Huber (Nobel Prize winner in Chemistry in 1988) and his team at the Max Planck Institute for Biochemistry in Martinsried. The innovative technology platform enabled the firm to raise its first venture capital through its lead investors.

In 2010, SuppreMol counted among the top seven biotech companies in terms of venture capital financing (EUR 35 million). In order to advance the clinical development of its SM101 lead candidate, the German start-up has also been granted generous research funding by the German Federal Ministry of Education and Research (BMBF) as part of the biotechnology initiative in the field of personalized medicine.

As well as this, access to the Bio-M high-tech cluster’s clinical study centers makes a significant contribution to exploring further SM101 indications.

Profiting from German Excellence
The SuppreMol success story is a prime example of how a German start-up – implementing a novel approach – can make swift progress in order to make its treatment a commercial reality. This has been made possible by significant contribution made by fruitful collaboration between cutting-edge research and industry and a vibrant research landscape.

Moreover, the German government has also created the required conditions for boosting the market innovation potential of private companies. This landscape also creates ample opportunity for private investors thanks to the presence of innovative companies, investor-friendly market conditions and clear and transparent legal procedures. Germany’s innovative environment ensures that the country’s innovative power in medical science and industry will continue to flourish making new visions in diagnostics and therapeutics a reality for the patient.
Our Investment Project Consultancy Services

Germany Trade & Invest Helps You

Germany Trade & Invest’s teams of industry experts will assist you in setting up your operations in Germany. We support your project management activities from the earliest stages of your expansion strategy.

We provide you with all of the industry information you need – covering everything from key markets and related supply and application sectors to the R&D landscape. Foreign companies profit from our rich experience in identifying the business locations which best meet their specific investment criteria. We help turn your requirements into concrete investment site proposals; providing consulting services to ensure you make the right location decision. We coordinate site visits, meetings with potential partners, universities, and other institutes active in the industry. Our team of consultants is at hand to provide you with the relevant background information on Germany’s tax and legal system, industry regulations, and the domestic labor market. Germany Trade & Invest’s experts help you create the appropriate financial package for your investment and put you in contact with suitable financial partners. Incentives specialists provide you with detailed information about available incentives, support you with the application process, and arrange contacts with local economic development corporations.

All of our investor-related services are treated with the utmost confidentiality and provided free of charge.

### Strategy

#### Project Management Assistance

| Business opportunity analysis and market research | Market entry strategy support | Project partner identification and contact | Joint project management with regional development agency | Coordination and support of negotiations with local authorities |

### Evaluation

#### Location Consulting/Site Evaluation

| Identification of project-specific location factors | Cost factor analysis | Site preselection | Site visit organization | Final site decision support |

### Decision & Investment

#### Support Services

| Identification of relevant tax and legal issues | Project-related financing and incentives consultancy | Organization of meetings with legal advisors and financial partners | Administrative affairs support | Accompanying incentives application and establishment formalities |
The information contained in this brochure has been compiled from the following sources:
American Chamber of Commerce and Boston Consulting Group,
AmCham Business Barometer 2011, Frankfurt am Main, 2011.
BPI Bundesverband der Pharmazeutischen Industrie e.V. Pharma-Daten, Berlin, 2011.
Ernst & Young, Deutscher Biotechnologie-Report, Mannheim, 2011.
Eurostat 2011.
VfA and Boston Consulting Group, Medizinische Biotechnologie in Deutschland, München, 2010.
About Us

Germany Trade & Invest is the foreign trade and inward investment agency of the Federal Republic of Germany. The organization advises and supports foreign companies seeking to expand into the German market, and assists companies established in Germany looking to enter foreign markets.

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