Research Made In Germany

Europe's Largest Pharma Market is Regaining a Leading Position in R&D

In its role as the world's third largest market for medical drugs, Germany is a natural focus of international pharmaceutical corporations. Despite the €33 billion market size, as a R&D location Germany maintains a mixed reputation. Although research in Germany recognized as contributing high-end intellectual property to the international innovation chain, the pharmaceutical research landscape probably is too fragmented, processes too slow and market orientation of institutional research appears to be too limited, in order to quickly bring commercially successful products to the market.

Germany in brief

Population:	82,683,380
GDP (billion $, 2006):	2,631
GDP per capita in $ (2006):	31,950
Inflation (GDP deflator, 2006):	0.57 %
Expentiture on R&D in % of GDP (2006):	2.51 %

Source: OECD

But the time seems to be right to address the issues and to turn Germany into a promising R&D location again. Especially since recently several initiatives from the German government, university hospitals and research institutions. as well as private companies have created a momentum of change. While Germany captures 8 % market share in sales and 8 % in production, its share in terms of worldwide expenditures on R&D has been dropping from 9 % in 1981 to 6 % in 2005. In comparison to competing countries, investing up to 0.79 % (Switzerland) of their GDP in pharmaceutical R&D, Germany spends 0.16 % in this area, less than most of its direct competitors do.

In contrast to the downward sloping curve of the overall investments, there are a number of valid signs indicating that Germany has started to regain market share and importance within the global R&D arena. Present Business Expenditures on R&D (BERD) show a positive trend towards a share of 7 %, after hitting a low in the mid nineties of around 5 %.

Additional good news is coming from the university hospitals; despite the great need to become more efficient in the management of clinical study centers, Germany is the European country with the highest number of clinical studies, ranking worldwide number two behind the USA. Last but not least the recent successes are reaching the job market, bringing up the number of employees in R&D by 1.5 % p.a. – a growth rate, stronger than shown by Germany's peer countries.

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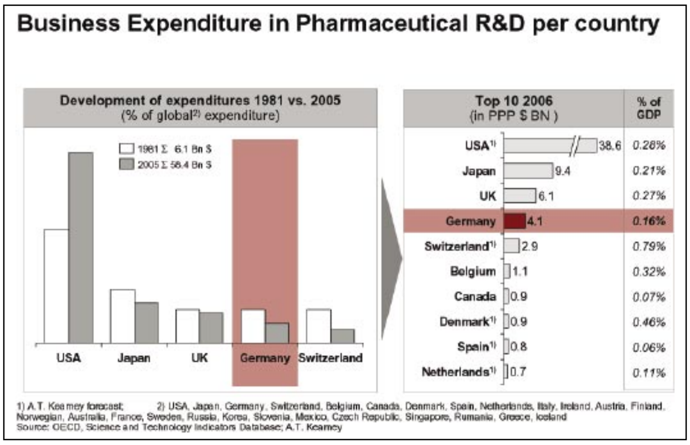
Growth By Innovation

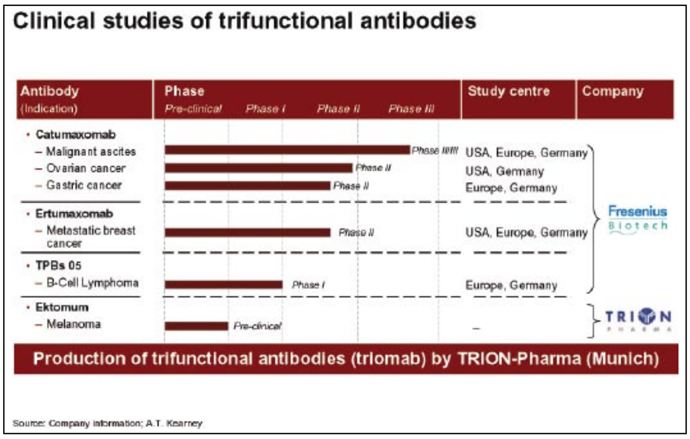
The message is well understood – innovation drives both economic growth and productivity. As one of the most sustainable, attractive and growing industry sectors, the pharmaceutical industry is showing its innovative strength. Health related patents registered at the European Patent Office account for more than 10% of patent registries, making them the most relevant product group to drive innovation. Awareness of this, politicians are increasingly paying more and more attention to the pharmaceutical industry, taking their chance to create employment and drive economic growth by supporting this future-oriented industry sector.

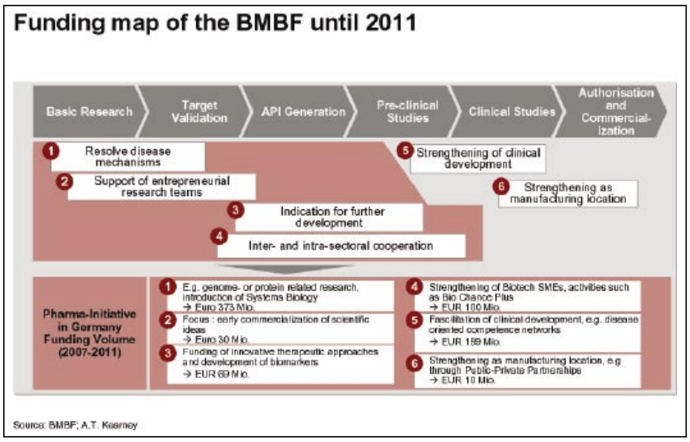
Recent Success Stories

A number of recent success stories indicate that Germany is on track in improving its R&D infrastructure. Being recognized for outstanding research successes in the past, the German government increased the funds spent on basic R&D in universities. The "Elite University Project", as well as a mixture of regional support programs on infrastructure and national competitions on quick commercialization of R&D results have touched the heart of the problem: inefficient management structures and a lack of professional corporations reduce the speed and value of commercialization. German researchers tend to invent and publish great ideas and scientific studies but are rather weak in developing and selling high potential/ high value commercial products.

This condition might take some time to change, but initiatives such as the "Pharma Initiative" from the Federal Ministry of Education and Research (BMBF) have corrected the incentive structures right: the program explicitly supports approaches that are setup to overcome fragmentation, inefficient management and white spots in the value chain, and strive to become profitable quickly after a limited initial period of public funding.







Before even having been rolled out completely, the program has already obtained a significant success by motivating local structures to form clusters that are managed by one single Cluster Management Company (CMC), which coordinates the local research offers. At the same time the CMC represents a profitable business model, prepared to stand alone after a five years period of public funding.

One example of such an initiative is the Tiger M Cluster in Munich, Southern Germany. In this approach, two German Elite Universities, two major non-profit research organization (MPI and Helmholtz center), a number of big pharma companies and a unique biotech scene located in the area around Martinsried came together in order to found the Tiger M corporation. Such a corporation has the potential to overcome the small but nasty local competition, fill gaps in the value chain, speed up commercialization processes and thus significantly increase the locally created value.

New Molecular Entities in Cancer Indications

Although not a result of the above initiative but still developed in the same region, the trifunctional antibody catumaxumab from Fresenius Biotech, which is targeting significant indications such as ovarian and stomach cancer, is the latest success story. Being developed and produced in Bavaria, it reaches out to capture the world markets in these indications of great medical need. Having filed the dossier in 2007 with the EMEA, Fresenius Biotech expects European market authorization in 2008. After the launch of the Colorectal Cancer antibody Erbitux by Darmstadt based Merck in 2003 and the launch of Bayer-Schering's Nexavar in 2007, this is the third example of how a German life science company is reinventing itself through the successful ramp-up of an oncology business. It can be expected that current government and cluster initiatives will reinforce this trend and will thereby help to lift the German pharmaceutical R&D scene to the next level.

Professional Clinical Trial Management

Comparable changes can be observed in clinical research, too. The German clinical trial offering was mainly driven by the presence of well recognized intellectual capacities and international opinion leaders in university hospitals, who attracted single clinical trials from the large pharmaceutical companies.

Incentivized by their share of third party opinion acquired, professors were not used to collaborate with colleagues inside and outside their organizations in order to market their clinical trial centers and patient potential actively. Neither did they collaborate to support large international pharma companies as well as small biotech players in finding the right patients in the right institution with the right physicians beyond their own department.

Fragmented landscapes for clinical studies are a nightmare for pharma managers who strive to conduct clinical trials successfully with a minimum of time, budget and complexity. Most international pharma players have recognized the huge improvement potential, implied in this inefficient form of clinical trial management and have initiated global competitions on preferred clinical partners. Extra scores are given for reduced complexity, in cases where there is only one contractual framework, one contact partner and a track record of successful trials and trustful cooperation.

Some German university hospitals have already addressed this by founding private Contract Research Outsourcing (CRO) structures within their organization, to be able to offer a central organization of clinical trials. The CROs make use of a network which often comprises additional hospitals and private practices that support the fast, efficient and successful fulfillment of clinical trials. Examples are the networks around the university hospitals in Hamburg (UKE) and Berlin (Charité). Most interesting is the fact that both UKE and Charité have not been as highly recognized by the scientific community and government as their competitors in Southern Germany.

A Brighter Future

All recent initiatives and success stories can only be seen as a first step into a brighter future – a future in which Germany can rebuild its strength in pharmaceutical R&D. The next steps have to follow and their success will depend on the ability to cooperate internationally to encounter the fierce international competition. This will benefit local cluster structures which are located close to borders (e.g. Biotech Region Freiburg/Basel, Mulhouse) or those who are in complementary areas with recognized international cluster regions such as Cambridge or Copenhagen.

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