

Picking new therapeutics

Establishing a technology-driven biotechnology pilot lab in China

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Inside a research lab at Bicoll

Case Study Bicoll

Most of the worldwide best selling pharmaceuticals are developed from active agents found in nature. Bicoll GmbH, Munich/Germany, is a biotechnology company that provides an innovative, fast and flexible approach to modern drug research — it takes advantage of the unique features found in natural active agents. For the development of new lead structures of medicinal targets, Bicoll focuses first of all on biologically active compounds from plants, because this source is most likely to provide active agents.

Bicoll uses its proprietary separation and isolation system BIFRAC N[®] to detect biologically active compounds. This process selects only high-quality active agents that have a high chance for further development into new therapeutics. Therefore, unlike other companies dealing with the drug-finding process, Bicoll does not waste any effort to generate data on molecules that have little chance of ever being successfully developed into pharmaceuticals. Another advantage is the fact that only small amounts of plant material are necessary for this process. Bicoll's technology shortens the long lasting and expensive process from discovery to pre-clinical testing by around one third. A process that can save up to two years in the developing cycle of a new drug means that patients can benefit faster from the new therapy and that companies can have two more years to exploit patent life.

Consequently, Bicoll's projects with partners may result in potential additional early sales and savings of well over € 1 million per day for the co-operating company. Thus, collaboration with Bicoll could benefit from bringing the drug faster to the patients and market. Bicoll leads the way in establishing a foreign, privately owned, and economically relevant biotechnology company in China. Although China is one of the most exciting emerging pharmaceutical markets, most Chinese pharmaceutical companies are state owned and their production processes still rely heavily on low-tech processes.

Assisted by the Delegation of German Industry and Commerce, Bicoll could deal with all the for-

mal (and informal) problems in setting up an initial infrastructure in Shanghai.

Bicoll also established contact with the German Investment and Development Company (DEG). DEG is one of Europe's largest development finance institutions specializing in long-term project and corporate financing for private sector investments in Asia, Latin America, Africa as well as Central and Eastern Europe. DEG has so far cooperated with more than 950 private enterprises and is



currently active in about 80 countries, having financed a total of more than 4.2 billion €. In addition, DEG, among other institutions, executes the **Public Private Partnership (PPP)** program of the **German Federal Ministry for Economic Development and Cooperation (BMZ)**. The program aims at joining hands with German private companies for the economic and social development in the partner country. Based on the growing global involvement of private economy in development projects, this program was started by the BMZ in 1999.

Basically any enterprise from the European community or one of its associated companies in a developing country can submit a proposal for a joint project. Partnership projects are expected to make a major contribution to national development and have a beneficial impact on the environment and social relations. The private enterprise acts as the project leader that transfers technology

and knowledge but benefits economically in the long run. In the People's Republic of China, DEG has carried out 27 of such PPP-projects with a total investment of more than 8 million € to date. DEG bears up to 50% of the total costs on a project, usually no more than 200,000 €. The DEG and Bicoll currently also working together in such kind of partnership in China.



Bicoll's ongoing PPP Project

So far, less than 5% of the more than 400,000 known species of plants have been systematically investigated for the pharmacological activity of their compounds. In many cases, those species containing interesting compounds for drug research and development have been exploited in the past, without any interest in their preservation. As for the fauna, a vast and careless harvest often has endangered or even extinguished the species.

For years now, the Chinese government has encouraged universities and research institutions to increase their outside funding. There is an increasing and continuous need for support from the non-governmental side to help reduce the risk of endangering the next generation's knowledge in general.

With the PPP-project, Bicoll supports to do research and simultaneously helps to preserve the plant species in South China. It demonstrates the economic value of preservation to local people thus making them more sensitive to the necessity of protecting biodiversity. The company will provide knowledge and technology. Furthermore, it will fund a unique educational program in China and train students. All project activities will be executed in compliance with the local Chinese requirements and guidelines.

Evaluation of Bicoll's PPP Project as a show-case

DEG bases its project cooperation on diverse criteria. The DEG departments of economy, development politics, environmental studies and other project-related fields examine the incoming proposals. In addition, outside expertise —if required— is used for the evaluation. The project company and DEG agree upon milestones that have to be achieved and presented in midterm and final reports before the agreed amount of money is transferred. Bicoll proposed to locate its project in the Zhangjiang Hi-Tech Park Pudong, Shanghai. The chosen location helped Bicoll to establish one of the most modern laboratories build-up in China. The safety standards are similar to those in Europe and North America.

Working hand in hand to implement the PPP Project

With DEG's commitment to carry 45% of the total costs, Bicoll could start a unique educational program. The program will help universities to provide lectures on a vast range of biology- and medicine-related topics. On excursions, Bicoll's experts will teach the students to recognize and document protected or endangered species without removing them from their local habitats. This contributes to the implementation of the »Convention on Biological Diversity« (Rio-Convention, 1992), thus supporting the country to benefit in a sustainable way from its biological richness in the long term.

Before active compounds are isolated in Bicoll's laboratories in Shanghai, taxonomists identify and catalogue each of the defined plant species that will be analyzed during the first year of the project. For the subsequent actual chemical analysis only small sample amounts are needed — which means that, besides the initial several hundred grams of the sample collection, no additional plant material has to be used. The scientific inventory generated during the identification process allows for an update of old surveys on the flora in Southern China with more accurate data. Since some of the surveys are more than 130 years old, the new information will have a major impact on the efforts towards protecting specific regions. Upon successful completion of the PPP-Project, Bicoll likes to make the data available to academic institutions all over the world through a database, which can be accessed via the Internet — Bicoll's BIFLORA®. To put this BIFLORA-database on a solid ground, Bicoll has started discussions with different partners for additional support.

For all further research steps towards new therapeutics, promising compounds will either be opti-

◀ Bicoll's research location in the Zhangjiang Hi-Tech-Park Pudong, Shanghai



Arundina stenopetala
(BIFLORA®)

mized towards a drug candidate with synthetic methods or be produced by biotechnological methods. Hereby, the rare natural sources only act as a lead structure supplier. Thus, Bicoll's innovative scientific approach does not threaten the existence of these species, but rather helps to preserve each investigated species and highlights the value of biodiversity in general.

It is vital to understand this difference to the classical approach because most of the herbs and other plants used in traditional medicine are nowadays collected in a non-regulated and often destructive manner. Consequently, a plant can be extinct by a sudden increase in the demand for a treatment, subsequently the natural compound. In contrast, Bicoll's approach does not use the plant species as the original resource for any further research. Unlike in the traditional Chinese herb medicine, the production of larger amounts of plant extracts will not be attempted — the scope is wider: the production of the future drug will be done locally at Bicoll in China with the latest technologies. Therefore, the Chinese population, too, will benefit from Bicoll's research.

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Conclusion

Bicoll's case has the potential of speeding up privatization and establishment of the biotechnology market in China. Furthermore, the educational project will create jobs for highly qualified employees and strengthen the position of academic institutes involved. Legal support of the Chinese government for Bicoll's activities highlights the political commitment to improve the domestic research deficiency.

Natural resources will be protected for the long term and the project will sensitize inhabitants to the necessity of such an effort.

Along the lines of BMZ's credo, Bicoll Biotechnology (Shanghai) Co. Ltd. serves as a role model in the local biotechnology industry by attracting foreign experts to light the flame of high-tech enterprises in China. Currently, already ten foreign and local experts are working for Bicoll in Shanghai.

Bicoll will benefit from the co-financing (55/45) by DEG thus speeding up its growth in China. This step is designed to position Bicoll among the forerunners of biotech companies in a constantly changing international landscape of modern drug development.

DEG — Deutsche Investitions- und Entwicklungsgesellschaft mbH

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Gute Aussichten für Biomedizin in der VR

*Dr. Stefanie Schmitt,
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Der chinesischen Biomedizin-Industrie werden offiziell Wachstumsraten von 15 bis 20% pro Jahr zugetraut. Der Output soll bis 2005 auf 5 Mrd. und bis 2015 auf 14 Mrd. US\$ steigen. Da es vielen Unternehmen am Investitionskapital fehlt, sind finanzstarke Partner gern gesehen. Umgekehrt suchen zahlreiche ausländische Firmen Biotech-Betriebe vor Ort, die ihre Produkte in der VR China vertreiben. Als gute Kontaktbörsen gelten die großen Pharma-Messen. Auch Anfragen bei Unternehmen in den High-Tech-Parks können hilfreich sein.

Die Bedeutung von Biomedizin-Produkten steigt. Zwischen 1989 und 2000 wurden 18 genetisch erzeugte Pharmazeutika für die kommerzielle Nutzung zugelassen. Der Outputwert belief sich im Jahr 2000 auf rd. 7,2 Mrd. RMB (100 RMB = rd. 12,78 Euro;

Jahresdurchschnittskurs 2000). Weitere 20 Präparate befänden sich im Entwicklungsstadium und durchliefen vorklinische oder klinische Versuchsreihen, so die Wochenzeitung »China Chemical Week«.

Biotechnologie gehört zu den Schlüsselbereichen, die im Verlauf des aktuellen Fünfjahresplans (2001 bis 2005) gefördert werden sollen. Die führenden Forschungsinstitute befinden sich unter der Chinese Academy of Sciences, der Academy of Military Medical Sciences und der Academy of Medical Sciences.

Insgesamt sollen sich über 300 Einrichtungen mit Biotech-Forschung befassen. Im Jahr 2001 hat das Ministry of Science and Technology Venture-Kapital für rd. 700 derartiger Projekte in Höhe von 1,2 Mrd. RMB bereitgestellt. Die meisten Mittel