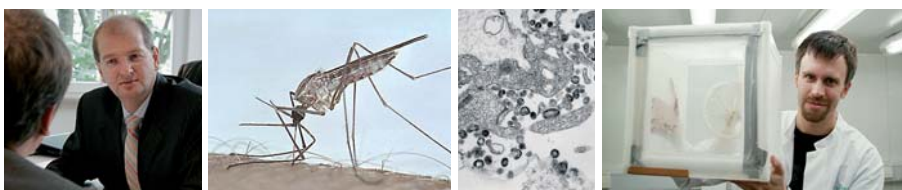


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Ascenion Information Letter
November 2008

Beyond Trust – Three Years of Collaboration with the Leibniz Association

When Ascenion started to cooperate with nine institutions from the Leibniz Association in 2005, the partners agreed that fostering relationships with researchers would be one of the most important tasks. "Scientists must believe that it is worthwhile sharing their results with Ascenion," they emphasised when asked for mid-term goals. Today, the question of trust is no longer an issue.



"Meanwhile, researchers are well aware of IP-relevant matters in their work and voluntarily approach Ascenion with their ideas and findings," says Prof. Dr Rolf Horstmann, Chairman of the Board of Directors of the Bernhard Nocht Institute for Tropical Medicine (BNI), one of the Leibniz institutions that chose Ascenion as marketing partner. "For us, the most significant outcome of working with Ascenion is that we identified the lack of translational research within our institution as a bottleneck in technology transfer. Typically, scientists design individual experiments and

end their projects once they have gained a new insight – which is fine if the objectives are to deepen our understanding on human diseases and compile new scientific publications. If the goal, however, is to advance these findings into medical applications, we need to go further and develop experimental settings that enable systematic screening for putative drug candidates", Horstmann points out. "Only then, we will be able to enter research projects into the drug discovery process, attract funding or get an industry partner on board," Dr Peter Ruile, COO of Ascenion confirms.

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Prof. Dr Rolf Horstmann,
Vorstandsvorsitzender des BNI und Leiter der Sektion
tropenmedizinische Grundlagenforschung

Supporting translational research

Therefore, the partners came up with a new tool to support technology transfer at the BNI: The institution set up a "translation fund" with an initial volume of 200,000 Euros per year, solely dedicated to financing the internal maturation of promising projects. The initiative met with a strong response from scientists and received a range of excellent applications. A project in the field of malaria was selected for funding. Ascenion is currently trying to attract funding from other sources for further projects, targeting Lassa fever, Chagas' disease or malaria. "All these projects hold strong potential", Dr Hinrich Habeck, Ascenion's Technology Manager at the Hamburg Office comments. "But given the philanthropic nature of these projects, there are only very few support programmes that come into question. Nevertheless, we hope to get at least one of them externally funded, e.g. by the Gates Foundation or the Wellcome Trust."



Looking at the detail

"The BNI example has offered us a major insight," Ruile adds: "Improving technology transfer means looking at the detail, case-by-case, and working individually with each partner to find appropriate solutions." Ascenion's partner institutions differ significantly in terms of structure, funding policy, research topics and commercial opportunities.

While the BNI focuses on diseases which mainly affect the poor, other institutions address key pharmaceutical markets such as cancer or cardiovascular diseases. "And these open different opportunities in terms of funding and commercialization," Ruile says. While the creation of an internal fund was most appropriate for the BNI, projects from other institutions were amenable to federal support programmes such as GO-Bio that provide prospective founders with funding for translational research. For another partner, a broad collaboration with industry is currently under negotiation.

The advantage of variety

"We have also learnt that the diversity and breadth of our partners' combined know-how and IP is an enormous plus," Dr Christian Stein, CEO of Ascenion adds. "We can easily connect experts from various institutions whenever a project requires complementary tools or expertise to take the next step." In addition, Ascenion has created new platforms for the exchange of experience and marketing of technologies to industry, e.g. the BioVaria. "These and further initiatives we have in mind can only work because we have gained a critical mass."

Down to figures

Summing up three years of collaboration with the Leibniz Association also means: 59 patent applications, 61 agreements with industry, 2 spin-off deals and a total of 370,000 Euros in returns from license fees. Taking into account all the groundwork required – building awareness, establishing

regular publication screens and clearing existing patent portfolios – these results are quite respectable.

"Yet for us, it is not the raw number of patents, deals or revenues that counts," Horstmann from the BNI emphasises. "It would certainly be great to feed our translation fund from commercial revenues someday. But in the first instance, we want to see our

results be translated into novel medicines. Being the only public research organisation in Germany that focuses on tropical diseases, we regard this as central to our mandate."



Outlook

That is why Horstmann wants to continue the chosen path with Ascenion. "We need to go ahead, see what works and adapt our strategy accordingly.

Ascenion is an excellent sparring partner in this process," he says. The other Leibniz institutions that started to work with Ascenion three years ago share Horstmann's positive evaluation of the partnership, as well as his ambition to carry on. Ascenion and its partners therefore applied for continued support from the Federal Ministry of Education and Research (BMBF), which co-funded the initial three years of collaboration to a total of 1.5 million Euros. "We hope to keep or even extend the number of our partner institutions", Stein says. "The critical mass of licensable technologies already accumulated is an important prerequisite in helping us to shape an increasingly effective and professional technology transfer landscape in Germany." Now, that the groundwork is done, Ascenion will focus on the development of new technology transfer tools to address the translational gap, which is certainly not confined to the BNI, but is a major hurdle to technology transfer in general. "One of our major objectives is to provide our partners with access to early drug discovery and drug development expertise", Stein continues. "Only then we will be able to make a real difference in technology transfer over the longer term."

Inventor Profile

Invention:	Temperature-sensitive liposomes for targeted drug delivery
Advantage:	The new liposomes can stably travel throughout the body for a long time, but will instantly release the drug they contain once heated to temperatures beyond 40° C. When combined with regional hyperthermia, the approach allows for specific delivery and accumulation of potent drugs at the tumour site which should increase the drug's efficacy and reduce side effects.
Inventors:	Dr Lars Lindner, Prof. Dr Hansjörg Eibl
Institute of origin:	Max Planck Institute for Biophysical Chemistry (Department of Phospholipids), Göttingen, Germany
Collaboration partners:	University Hospital Großhadern and Helmholtz Zentrum München, both Munich, Germany



Not being limited to what the pharmaceutical industry offers – that is one of the driving forces in Lars Lindner's professional life. As an oncologist, he is faced with the shortcomings of available therapeutics each day. At the same time, he is convinced that his new approach jointly developed with Prof. Eibl, specialist in phospholipids, and Prof. Issels, expert in regional hyperthermia (RHT), holds strong promise for many cancer patients. The idea was born in the late 1990s during Lindner's time as doctoral student in Prof. Eibl's lab in Göttingen.

Q: That was about 10 years ago. How have things progressed from there?

The idea and its potential benefit for patients seemed so compelling to me that I could not get it out of my mind. In order to further advance the approach, I moved to Munich, where I had the opportunity to work as physician, and, in parallel, as clinical researcher together with Prof. Issels and his team. We jointly explored the application of our thermo-sensitive liposomes in combination with regional hyperthermia and generated an impressive set of data that were really encouraging.

Q: When did you start thinking about commercializing your invention?

In a sense, right from the beginning. It has always been my vision to make the technology available for cancer patients – which means that you have to move it from the bench to market. The more tricky question was: how to make this transition?

Q: What is your strategy?

The idea is to set-up a new company: "Lipotherm". Together with colleagues, technology transfer professionals and a team of students in business economy, we have already outlined a business plan that won second prize in the 2006 Munich Business Plan Contest. It was an inspiring project. By bringing together different disciplines, we were able to effectively create a viable business concept. However, before building up our new venture, we need to complete pre-clinical studies and provide proof-of-concept in relevant animal models. Currently, we are in process of applying for appropriate funding.

Q: Why not simply out-licence your patent to big pharma?

Firstly, our technology is still at too early a stage to attract a big pharma partner. Secondly, our approach is to some extent "off the beaten track". Regional hyperthermia demonstrated impressive results in phase III studies and is becoming more established, but is still limited to a few clinical centres. Moreover, most of our work focuses on sarcoma which is an orphan indication. So, our approach does not very well fit into typical pharma marketing and business development strategies.

Q: Does that mean that your approach may miss market requirements?

No, we are addressing a very urgent medical need. I am convinced that the combination of our drug delivery technology with regional hyperthermia can substantially improve the safety and efficacy of some of the most common drugs – chemotherapeutics for instance. This makes it highly attractive, also from the commercial point of view. But there remains a long way to go. And at this stage of development, it needs a "champion", a person who has not only the knowledge and expertise that is required but also absolute commitment.

Q: Are you prepared to join the start-up team?

Sure – although I am open with regards to the position. I would probably not be an ideal CEO and I definitely want to keep in touch with patients. I also believe that the experience of day-to-day life in the clinic will be helpful in moving our new therapy towards the market. And vice versa: The understanding of professional drug development will certainly inspire my work as physician and clinical researcher.

Q: Looking back, what was most surprising for you along the way from the initial idea to the current stage?

Well, things take always longer than expected. And: There is a great difference between creating a new approach and validating it to industry standards. Most difficult for me was to find advice on drug development and regulatory issues, e.g. on how to design preclinical studies. Without the help of Ascenion and Max Planck Innovation and the contacts they provided, the progress up to now would not have been possible.

Q: Looking to the future – what are your short-term objectives?

I keep learning. Mid of this year, I have accepted a one-year position as PostDoc at the Laboratory for Experimental Surgical Oncology, Erasmus MC, in Rotterdam. My primary goal is to further improve my understanding of preclinical testing and translational research.

Q: This also means commuting between Rotterdam and Munich for one year. How does that all fit with your personal life?

Right, my schedule is quite dense. However, it takes exceptional personal commitment to translate an idea into an application – as we mentioned before. Nevertheless, I must admit that it would probably not be compatible with family life if my wife did not share my enthusiasm for clinical research and the potential benefit it holds for patients. Our 10-year vision is obvious: Having a new temperature-sensitive liposome approved and in widespread use for the treatment of cancer.

Lars Lindner is 36 years old, married, and has two children.

Spinning Innovation

Certus Pharmaceuticals – new shuttles for chemotherapies

Certus is the first spin-out from one of Ascenion's partner institutes to build its new venture in the US. Based in South San Francisco, California, co-founder and CSO Peter Scherrer has already attracted a group of experienced industry managers and drug discovery experts to the Certus Board of Directors. The team has just initiated Certus' first financing round. "They are perfectly set to exploit the potential of the innovative drug-delivery technologies that were developed at the MDC," Christian Stein, CEO of Ascenion comments.



Certus Pharmaceuticals key facts

Technology:	Novel drug delivery approaches based on charge-neutral nanoparticles or embolizing agents
Advantage:	Extends the therapeutic window of conventional drugs by increasing the drug accumulation in tumor, increasing their exposure time to the drugs (> 25 fold) and decreasing toxic side effects.
Products:	Two candidates under development: – a compound for the treatment of liver cancer – a nanoparticle containing the chemotherapeutic agent paclitaxel
Development Status:	Preclinical, first-in-man data from a physician-sponsored trial
Originating Institution:	Max Delbrück Center for Molecular Medicine, Berlin-Buch (MDC)

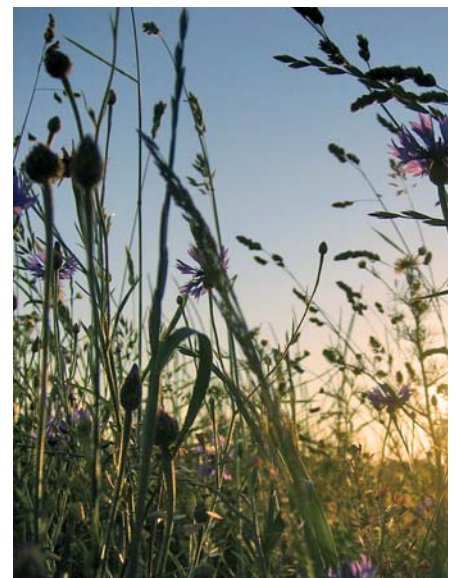
"We have carefully evaluated different routes of commercialization – on both sides of the Atlantic – and identified Certus as an ideal licensing partner." The potential of the technologies is enormous, medically as well as commercially. "Based on our technology

platforms, we hope not only to improve the safety and efficacy of chemotherapy for a large group of cancer patients but also to provide the first effective treatment option for patients suffering from liver cancer," Scherrer comments.

Protectimmun – stable dust against hay fever and asthma

Protectimmun is the second spin-off from Ascenion's partner institutions in the Leibniz Association that Ascenion has helped get off the ground – just two years after the partners started to collaborate with regards to IP protection and commercialization. Protectimmun's business concept is based on international studies demonstrating that children who regularly spent time in farm stables during their first year of life were virtually immune to hay fever and allergic asthma later in life. In light of this, scientists at the FZB and the Ruhr-University Bochum have developed procedures for extracting soluble components from stable dust that can be administered in aerosol form, e.g. as

a nose spray. Preclinical testing is ongoing and the team is about to initiate its first financing round. Furthermore, Protectimmun has recently identified the active components in stable dust and has expanded its patent position appropriately. "This further endorses our position in negotiating with investors," Marion Kauth, CEO of Protectimmun, comments. "And it is an important milestone on our way towards a safe and easily applicable medication that could effectively protect children from developing allergic respiratory diseases." With its approach, Protectimmun addresses an urgent medical need and an attractive market, since more and more children are suffering from these kinds of allergies.



Protectimmun key facts

Approach:	Using components of stable dust for the prevention of hay fever and allergic asthma
Advantage:	Potential to safely induce long-term immunity to hay fever and allergic asthma
Products:	Preventive nose spray
Development Status:	Preclinical
Originating Institutions:	Research Center Borstel (FZB), Ruhr-University Bochum



Founders of Protectimmun:
Prof. Dr Otto Holst, Dr Marion Kauth, Prof. Dr Albrecht Bufe

Turning Science into Business Opportunities

Killing bacteria is not enough

Sepsis – blood poisoning – is a severe form of infection that poses pressing problems in intensive care units. According to the Centers for Disease Control and Prevention, worldwide mortality rates range from 20% for sepsis up to > 60% for septic shock. “Sepsis develops when a patient’s immune system runs out of control in response to bacterial infection”, Prof. Klaus Brandenburg, scientist at the Research Center Borstel (FZB), explains. The most crucial components involved in that process are molecules at the outer membrane of Gram-negative bacteria, known as lipopolysaccharides (LPS) or endotoxins. “This means that killing the bacteria is not sufficient. The release of LPS resulting from bacterial destruction could even contribute further to the overstimulation of the patient’s immune system”, Brandenburg continues. His team has therefore developed a novel peptide with a two-fold mode of action: Firstly, it destroys bacteria and secondly, it neutralizes free LPS.

Supporting patentability

In the middle of last year, Brandenburg discussed his approach with Ascenion, the FZB’s commercialization partner. “We immediately grasped the peptide’s potential,” Dr Hinrich Habeck, Technology Manager at Ascenion comments. “But our IP analysis showed that a patent application based on available data would have had little prospect of success.”

So, they jointly developed a list of research required to support the peptide’s patentability. Just two months later, the results were complete. While preparing the patent application, the FZB and Ascenion also started to look for appropriate funding opportunities and potential collaboration partners.

Joining forces

Prof. Brandenburg has now teamed up with Prof. Matthias Hornef at the Medical School Hanover (MHH), Dr Tobias Schürholz at the RWTH Aachen University, and a CRO (Clinical Research Organisation). The joint objective is to identify a peptide suitable as a pharmaceutical lead and to develop it until proof-of-concept in animal models. While the MHH and RWTH bring in dedicated animal models to evaluate in-vivo binding, biological activity

and potential toxicity of a range of peptide variants, the CRO will initiate production and formal preclinical development to industry standards once the most promising candidate has been identified. A joint project proposal was filed by the FZB under the federal “Innovative Therapies” support programme in April 2008, just one day following the patent application. By October, the consortium had already received positive interim feedback with regards to funding.

“This is an excellent example of how rapidly and effectively things can progress when scientists, medical researchers and technology transfer professionals work hand in hand. I really enjoyed working with the team”, Habeck concludes. “I am confident that they will soon receive the funds they need to advance their project to initial proof-of-concept.”



Fostering Networks

In recent months, Ascenion has participated in a number of international events in order to exchange experience, market licensable technologies and help improve technology transfer standards across the globe.

From California...

This year’s BIO Annual Convention in San Diego, US, was very effective in establishing Ascenion as a premier point of access to life science IP emanating from public research institutions in Germany. During the event, Ascenion presented selected technologies to international business developers. Many of these onsite meetings triggered strong interest from industry and resulted in an ongoing transatlantic dialogue. “I have appreciated our communications at BIO and ever since then. I think you are in the top tier of business development people who were at BIO in terms of being responsive and follow-

ing up,” Judith I. Blakemore, U.S. Biotechnology Business Development Consultant, comments.

...to Japan

During this year’s Science and Technology in Society (STS) forum in Kyoto, Japan, over 750 delegates from 91 countries discussed key issues of environmental policy, energy development, food supply, communication technology, intellectual property and technology transfer. For the first time, young scientists were invited to contribute their views to the debate on the social impact of science and technology development.



“Overall, the meeting is becoming more influential in decision making,” Dr. Christian Stein, CEO of Ascenion comments, who joined the event as speaker. This was also reflected by the German delegation, which included the Ministry of Education and Research, Annette Schavan, as well as key decision makers from industry and public research. With regards to IP and technology transfer, a major conclusion was that a worldwide pro-innovation IP infrastructure was needed to drive the advancement of science and technology for global socio-economic development. “The focus was very much on infrastructure”, Stein emphasises. “So far, basic research seems to be a ‘technology-transfer-free area’ in most countries across the globe – which means that we first need to focus on education, building up technology transfer offices and the like.”

**BioVaria:
Germany’s top technologies**

The first BioVaria, held in Munich in May 2008, brought together more than 150 delegates from international biopharmaceutical companies and Germany’s top universities and research institutions. Around 50 patent-protected technologies including research tools, diagnostics and therapeutics were presented in 10-minute presentations and an all-day poster exhibition. This innovative meeting provided a comprehensive overview and ample opportunity to discuss technologies of interest face-to-face with the inventor. The event received outstanding feedback from participants who strongly encouraged the organisers to make it a regular event.

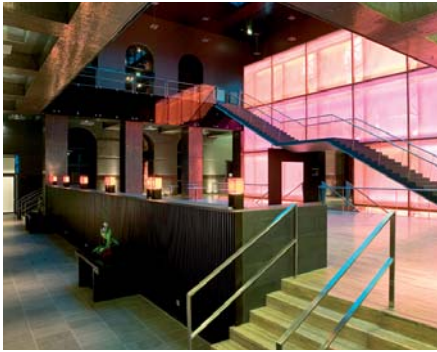
Save the date for BioVaria 2009

The next BioVaria will be held in Munich on May 8, 2009. A range of top-tier partners and sponsors have already signed up. Are you interested in joining us as presenting inventor, partner, sponsor or participant? Find further information at: www.biovaria.org

„Clearly a ‘missing link’ in the German conference scene ...”

„Very good gathering of academic opportunities from Germany ...”

„Plenty of valuable contacts... we had some specific follow-on discussions for concrete projects already.”



**3rd Biotech Workshop:
Learn from seasoned managers**

Ascenion and Max Planck Innovation are happy to announce their 3rd Biotech Workshop to be held on 4th-6th March, 2009 at the Evangelische Akademie Tutzing. In response to participants’ feedback from previous years, the organizers came up with a new format to provide even more space for networking and individual consulting. For the first time, entrepreneurs will be invited to present their business concepts at the beginning.

“The goal, however, is not to convince the audience through glossy presentations but rather to provide the basis for networking and fruitful discussions throughout the workshop”, Isabel von Korff, Technology Manager with Ascenion comments. Following their presentations, founders will have the opportunity to gain advice from experienced life-science executives, either in workshops or in individual coaching sessions. On the second day, business developers and experts from the financial community will join to introduce various financing vehicles. More details on the program will be made available in due course.

The workshop addresses entrepreneurs at Max Planck Institutes and Ascenion’s partner institutions. Are you interested? Please contact Isabel von Korff at korff@ascenion.de

Meet us at the forthcoming events:

- BIO-Europe, November 17-19, 2008, Mannheim / Heidelberg, Germany
- Doktorandencamp 2008, November 28-29, 2008, Headquarters of the Fraunhofer-Gesellschaft and Munich Business School, Munich, Germany
- Seminar on “IP Asset Management – from theory to practice”, February 10, 2009, Ludwig-Maximilian University, Munich, Germany
- BioTech Networkshop, March 4-6 2009, Tutzing, Germany
- BioVaria, May 8, 2009, Munich, Germany

News in Brief

In dialogue with the Wellcome Trust and HTGF



Ascenion invited representatives of the Wellcome Trust and the High-Tech Gründerfonds (HTGF) to learn about some of the most attractive projects from its portfolio. Inventors and founders from overall 13 different partner institutions or spin-offs presented their technologies and business concepts in individual meetings with both funds. The feedback was extremely positive from both sides.

Fund managers appreciated the opportunity to gain an overview of projects that were carefully pre-selected by Ascenion to meet their respective investment strategies. Some of the projects presented have already been shortlisted for follow-on discussions or selected for filing formal funding applications.

“Biting” Antibodies against cancer

Micromet’s BiTE® antibodies are designed to activate T cells, the body’s most potent “killer” cells, specifically against cancer cells. The approach, which is partly based on IP generated at the Max Delbrück Center for Molecular Medicine, has met major clinical milestones this year.

MT103, the most advanced BiTE® targeting B cell lymphomas, has entered a phase II clinical trial, and MT110, the first BiTE® against solid tumours, has entered a phase I trial.

PARF:

One idea – many applications

“PARF” (peptide associated with rheumatic fever) is a peptide that is present on certain pathogenic bacteria of the streptococcal family. It was discovered and described by HZI researchers who found out that PARF, through its interaction with human collagen, plays a crucial role in the development of rheumatic fever. A first-option contract relating to corresponding HZI IP has now

been mediated by Ascenion. Under the terms of the agreement, an undisclosed biopharmaceutical company obtains an exclusive option to use PARF in combination with its proprietary drug delivery technology.

The idea is to employ PARF as an anchor for the specific attachment of drug-delivery vehicles to extracellular matrices. As a result, the drug contained within the vehicles will be concentrated at the intended site of action, improving its efficacy and reducing side effects.

“It is an excellent idea to exploit the collagen-binding properties of PARF for targeted drug delivery,” Sabina Heim, Technology Manager with Ascenion, comments.

“Further applications include the development of novel diagnostics for the identification of bacteria that cause rheumatic fever or the generation of therapeutic or preventive vaccines.” Licences for PARF are still available in these areas.

Improving technology transfer in national genome research

With the expiry of the national genome research network (NGFN) at the end of last year, the Federal Ministry of Education and Research restructured its support programme for medical genome research in Germany. The new initiative called “Program of Medical Genome Research” will focus even more on widespread diseases and seek intense collaboration with industry. In order to accelerate the transfer of research findings into medical use a “KompetenzCenter Technology Transfer” was established as a successor to the “KTT” that coordinated technology transfer in the NGFN. Like the KTT, the KompetenzCenter will be managed by Ascenion and Max Planck Innovation. Key tasks include the coordination of all players involved in technology transfer, regular publication screens, IP asset management support if needed and, last but not least, increased PR work and education in order to raise awareness among scientists for IP-relevant issues.



New employee to support the KompetenzCenter



In May this year, Anja Kroke joined Ascenion to support the activities of the KompetenzCenter. She is responsible for communications and public relations and assists the team in operational tasks. Anja holds a degree in biology and, before joining Ascenion, gained widespread experience in PR, communication and project management from various positions with Edelman, Ernst & Young, Genius and the Hessen Agentur.

KompetenzCenter Technologietransfer

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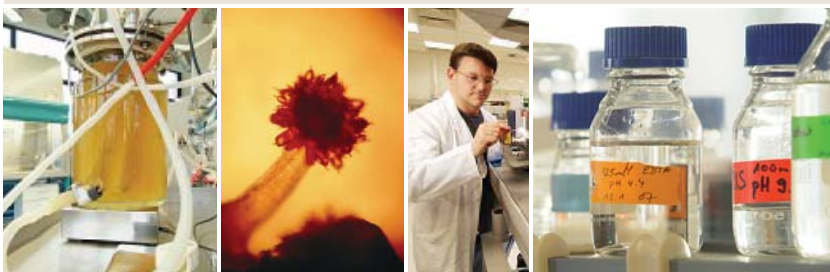
BioVaria is open free of charge to credentialed press.

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Latest Technology Offers

- New substances for treatment of HIV and HTLV infections [TO 13-00020](#)
- Specific CD8+ T cell repertoire in HIV long-term nonprogressors [TO 01-00748](#)
- Novel antibiotics for the treatment of Methicillin-resistant Staphylococcus aureus [TOs 10-00030, 10-00023](#)
- Antibiotic salts suitable for implant coating [TO 10-00028](#)
- New Macrolactin Antibiotic [TO 02-00115](#)
- Stabilized Etnangien derivative – antibiotic drug candidate from myxobacteria [TO 02-00236](#)
- New highly specific inhibitor of microbial hyaluronate lyase as adjuvant in cosmetic or pharmaceutical formulations [TO 10-00045](#)
- Novel antibiotics for the treatment of tuberculosis [TO 10-00006](#)

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Editorial

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