

THINK OVER. THINK AHEAD. THINK NEW. | Biotest AG 2014



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“We are an innovative company. The research and development work we are doing today will result in products and profits of tomorrow.”



THINK  
OVER.  
THINK  
AHEAD.  
THINK  
NEW.

## “2015 IS AN EXCITING AND IMPORTANT YEAR FOR EVERYONE AT BIOTEST.”

Biotest Group once again achieved record sales in 2014. What drove this positive growth?

DR RAMROTH: With sales up 16% to € 582 million, we significantly exceeded the goal we set for 2014. Strong sales in the fourth quarter drove this development in particular, when we benefited in Asia and elsewhere from high demand for our innovative products. In the US, sales of plasma also generated an increase in revenue.

DR EHMER: We expanded sales in most of our product groups. Our hepatitis B preparations and albumins in particular experienced higher demand worldwide. To be able to cover this rising demand, we doubled our production capacities for albumin in Dreieich last year.

DR FLOß: From the production point of view as well, 2014 was a successful year. We continued to streamline our processes in Dreieich and were able to increase our efficiency once again. This, and Dreieich's consistent operation at high capacity were the conditions for the significant sales increase.

In terms of profits, however, Biotest was not able to maintain the growth of the previous years. What were the reasons for this?

DR RAMROTH: One reason for the weaker profit development was reduced sales of our immunoglobulin Bivigam® in the US. Marketing of this product did not progress as we had planned due to strong competition. Political crises, such as in Russia, slowed down potential sales. With these developments, and the continued pressure on prices in various product areas and regions, the margins we had achieved in previous years were no longer achievable.

DR EHMER: We invested a great deal in our future in 2014. Based on the progress made in clinical studies, we once again expanded our research and development activities compared to the previous year. We moved up production of clinical testing materials that had originally been planned for the following year. We are an innovative company. The research we are doing today will result in products and profits of tomorrow. And even with these additional costs, we achieved an EBIT margin of 9%.

One of the most important research projects is Civacir®. What progress was made here?

DR EHMER: The interim data from our phase III study of Civacir® were certainly a highlight in 2014. The product is being investigated for the treatment of hepatitis C patients after a liver transplantation. The preliminary data show that Civacir® can markedly reduce the reinfection rate after transplantation. We will present the final results in the fourth quarter of 2015. Civacir® is therefore one of the crucial projects of the current financial year.

In April, you published first data from the TREAT 2b study with the monoclonal antibody tregalizumab (BT-061). None of the three tested dose groups showed a significant improvement versus the current standard of care. What do these results mean for Biotest?

DR EHMER: This initial data was disappointing for all of us: the management, employees, shareholders and investors. The data based on an analysis after 12 weeks' treatment of rheumatoid arthritis using tregalizumab (BT-061). The entire study is scheduled for 24 weeks and current patients are being treated in an extension phase, which could last up to six months. Therefore a large data set will be evaluated in the



“We are convinced of our approach and of the value of our products and projects, as they form the basis for our current and future success.”

DR BERNHARD EHMER

coming weeks which we will analyse and discuss at length with renowned experts in the field of rheumatoid arthritis and our cooperation partner, AbbVie. Only then, we will determine how to further proceed. It would be too soon to consider the project a failure at the current state.

However, the development with indatuximab ravtansine (BT-062) proceeded as planned...

DR RAMROTH: For this active agent, which is currently being tested in patients with multiple myeloma among others, study data will be available towards the end of 2015. If the outcome is positive, we expect that our partner ImmunoGen will decide to opt for a cooperation with us in terms of further development and marketing.

DR FLOß: The advances with monoclonal antibodies clearly prove our versatility: Biotest is outstandingly positioned with both plasma products and biotechnological medications.

Important clinical data and possible milestone payments – will 2015 pave the way for future years?

DR EHMER: Yes, the current year will, among others, decide Biotest's future direction. Turnover of one billion is our clear goal for 2020, which we can achieve just by doubling capacity within the scope of "Biotest Next Level". Besides the aforementioned

Civacir® and indatuximab ravtansine (BT-062) we are advancing our other research projects. If our studies for example with IgM concentrate, a product against severe bacterial infections, or BT-062 in the treatment of solid tumours demonstrate positive clinical data future growth will be triggered. Already now, 2015 is an exciting and important year for us.

As an international pharmaceutical company with production facilities in Germany and the USA, Biotest faces extensive regulatory and legal challenges. What does this mean for the company?

DR EHMER: We work in a highly regulated and ethical environment, which is why we are subject to continuous control by various regulatory authorities. Last year our US subsidiary in Boca Raton received a "Warning Letter" from the FDA. We immediately introduced measures to address the federal agency's expectations and we are making multiple adjustments in our quality processes in order to ensure state of the art quality control of our manufacturing processes. I want to state that our products sold in the USA are and were always safe, as patient safety is Biotest's first priority.

The stock exchange responded well to your 2014 business growth. The news about tregalizumab (BT-061), however, claimed for a significant setback. What can the shareholders expect from Biotest this year?

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“Biotest is perfectly positioned  
for both plasma-derived  
products and biotechnological  
medications.”

DR GEORG FLOß

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“We want to further increase our revenue in the current year with our core business.”

DR MICHAEL RAMROTH

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DR EHMER: We want to continue to grow in 2015 with our established products. Biotest is and remains a solid investment. Potential setbacks are part of the work of a researching pharmaceuticals company. Our pipeline is full and the other projects will provide great value. We will invest strongly in our research and development efforts again this year. These expenditures currently amount to 11.5% of our revenue, which is significantly higher than the industry average. We are convinced of our approach and of the value of our projects, as they form the basis for our current and future success. These efforts should also be reflected in our share price in the medium term.

DR RAMROTH: We want to further increase our revenue in the current year with our core business – probably in the low single-digit percentage range. We will invest more strongly in our research projects in 2015, with longer study duration with increasing capital requirements. Our EBIT development will be strongly influenced by the decisions regarding tregalizumab (BT-061). Without these effects, we

are aiming for EBIT in the vicinity of around € 50 million with our core business. If the tregalizumab development will be fully discontinued, EBIT could decline by EUR 25 – 30 million.

Dr Ehmer, you have been Chairman of the Board of Management at Biotest since 1 January 2015, following the long and successful leadership of Prof. Dr Schulz. What do you see as special about Biotest, what motivates you each day to do your work?

DR EHMER: Biotest products help people around the world. This shows how important the work is we do every day. I see it as a privilege and a strong personal motivation to be able to continue to shape the company's development in the future. I am fascinated by the great expertise and excellent teamwork of Biotest's employees. Everyone here works together to develop new products and make our existing ones better. That is why I support the company's approach of investing in research and development to ensure its long-term success – and being profitable at the same time.

Dr Bernhard Ehmer

Dr Michael Ramroth

Dr Georg Floß

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>  
7 / May

€ 0.57

dividend per ordinary share  
was paid by Biotest AG in 2014

€ 0.63

per share were paid by Biotest AG  
to holders of preference shares

>  
10 / November

“The preliminary data from  
our US Civacir® study is  
very promising. If it is confirmed,  
this could mean a  
breakthrough in treatment  
of hepatitis C.”

PROF. DR GREGOR SCHULZ





## FINANCIAL YEAR 2014 HIGHLIGHTS



27 / March

First treatment of a patient using indatuximab ravtansine (BT-062) against breast and bladder cancer in a phase I/IIa study.



7 / May

The Biotest AG annual shareholders' meeting resolves a dividend of € 0.57 per ordinary share (+ 14% compared with the previous year) and € 0.63 per preference share (+ 12.5% over the previous year).



9 / July

Dr Bernhard Ehmer was appointed as the new Chairman of the Board of Management of Biotest AG, replacing Prof. Dr Gregor Schulz as CEO effective 1 January 2015.



9 / September

Conclusion of patient recruitment for TREAT 2b, the largest study in the history of the Biotest company. Over 300 patients have been included in the study since November 2013. The monoclonal antibody tregalizumab (BT-061) against rheumatoid arthritis is being developed by Biotest in cooperation with AbbVie.



24 / October

At the World ADC specialist conference in San Diego, USA, the results of preclinical studies are presented, emphasising the potential of indatuximab ravtansine (BT-062) for solid tumours.



5 / November

Marketing authorisation of Albumin 20% is obtained for China, the world's second biggest market for medicinal products.



10 / November

Very good interim results of the phase III study with the hepatitis C hyperimmunoglobulin Civacir® in the USA. Preliminary data, presented at the conference of the American Association for the Study of Liver Disease (AASLD) in Boston, USA, show good efficacy for reinfection prophylaxis after liver transplantation. No reinfections were observed in the treatment group that received the highest Civacir® dosage.



12 / November

Biotest receives construction approval for extending production capacity at the Dreieich site.



18 / November

At the annual conference of the American College of Rheumatology in Boston, USA, Biotest presents new preclinical data on tregalizumab (BT-061), which confirm the treatment concept in mono- and combination therapy: pro-inflammatory cytokines, which are present in high concentration in patients with autoimmune diseases, and the co-medication methotrexate do not have any negative influence on the mechanism of action of tregalizumab (BT-061).



9 / December

Promising results for the efficacy of indatuximab ravtansine (BT-062) in combination with lenalidomide and dexamethasone in multiple myeloma are presented at the 56<sup>th</sup> annual conference of the American Society of Hematology. These results show clinical benefit in all patients and complete tumour remission in individual patients.



THINK OVER.  
THINK AHEAD.  
THINK NEW.

&gt;

For Biotest, thinking over represents our commitment to people, which is at the core of our entire business. The efforts of every employee, every development and every process step are intended to ease or save the lives of others. People are at the centre of our concerns, which is why we are also committed to further education, a work-family balance, training, and social and cultural community.

&gt;

At Biotest, thinking ahead means constantly questioning the status quo and – where possible – improving it. Biotest products have been helping patients around the world, in some cases for decades. We are nevertheless always working to develop them further, so that we can continue to optimise our product portfolio with new pharmaceutical forms, improved active agents or more efficient production processes.

&gt;

Thinking new for Biotest means constantly seeking out new ideas. When you are not progressing you are losing ground, especially in a constantly changing environment. We have already shown more than once in our long history that we are prepared to explore new and innovative avenues. Now for example with our monoclonal antibodies we are once again breaking new ground – with huge potential for the future.



## “NOVEL” PRINCIPLE WITH TARGET EFFECT – A NEW WAY TO FIGHT TUMOURS WITH INDATUXIMAB RAVTANSINE (BT-062)

The monoclonal antibodies point towards Biotest’s future. Complex names such as tregalizumab (BT-061), indatuximab ravtansine (BT-062) or simply BT-063 mark drugs that differ greatly from all current Biotest products both in how they are manufactured and in their areas of use.

These developments with their partly immense potential nearly failed to get to Biotest. In 2003 the company was in a state of reorganisation. The aim of the new Biotest CEO Prof. Dr Gregor Schulz, was for the group to focus on its core area, namely, production and marketing of plasma products. Diaclone SAS, its subsidiary in Besançon, France, which specialised in diagnostic antibodies, no longer fitted optimally into the portfolio. Prof. Schulz, however, recognised the potential of the precursor antibodies of BT-061, BT-062 and BT-063, secured the rights for therapeutic exploitation and provided for research to continue at Biotest. This would soon prove to be meaningful.

Currently, the development of indatuximab ravtansine (BT-062) is also interesting, since it is used in oncology where it could later make life easier for patients or even save their lives. BT-062 is one of the most complex Biotest projects. Only a competent interdisciplinary team could succeed in advancing this project to phase II in multiple myeloma, a new indication for Biotest.

Dr Christoph Uherek, who played a pivotal part in the preclinical development of indatuximab ravtansine (BT-062), describes working with the drug: “The special feature of monoclonal antibodies is that they can bind to certain protein structures on the surface of their target cells, known as receptors, on the classic lock and key principle. Our antibody BT-062 is the key that fits exactly into locks that occur particularly frequently on the cells of multiple myeloma, an aggressive bone marrow cancer.” This specific binding to the CD 138 receptor was discovered in early experiments with the BT-062 precursor B-B4. This meant that multiple myeloma cancer cells could be labelled reliably with the antibody (see illustration page 13).

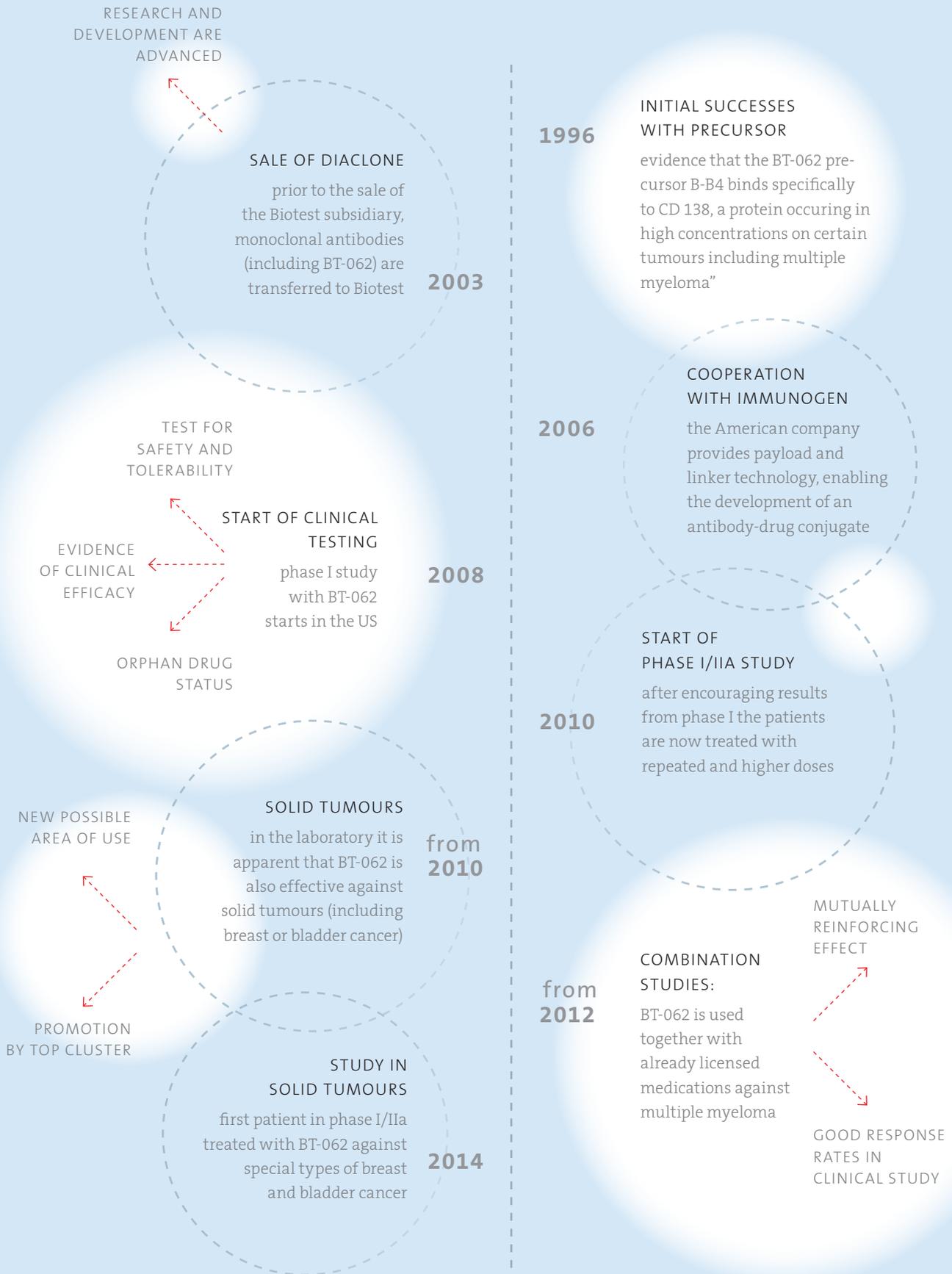
A further step was needed in order not only to recognise the tumour cells but also destroy them effectively: the addition of a potent cancer cell-killing agent that would get into the cancer cell together with the antibody after “docking” on it where it would cause the cancer cells to die. In 2006 Biotest concluded a cooperation agreement with the American biotech company ImmunoGen Inc., Waltham, MA, USA, to achieve this antibody-drug conjugate (ADC). ImmunoGen is one of the leading companies in ADC technology and has various cancer-cell killing agents designed for targeted delivery using antibodies. First, the antibody was chimaerised (see fact box), and the best product design was selected in extensive laboratory experiments. The first clinical study of this optimised drug started in 2008 in patients suffering from multiple myeloma. Dr Thomas Häder, who is in charge of the clinical development of BT-062, tells the story: “In this phase I study, the safety and tolerability of the drug were tested first. However, we were already able to draw encouraging conclusions about the efficacy of our product.”

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### CHIMAERISATION OF AN ANTIBODY

- > The development of a new drug begins in the laboratory: the first experiments and test at cellular level are performed in the proverbial test tube (in vitro)
  - > Suitable animal studies are the next step. In tumour models (usually in mice), the efficacy and tolerability of the drug are tested in a living body
  - > For use in humans, the antibody must be altered genetically so that its efficacy is maintained but no rejection reaction occurs in the human body
  - > To achieve this, the antibody is chimaerised – a large part of the mouse components is exchanged for the corresponding human elements
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DEVELOPMENT BT-062



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#### POSSIBLE USES OF BT-062

- > Indatuximab ravtansine (BT-062) is currently being tested in clinical studies for the treatment of multiple myeloma and also for different types of solid tumours such as breast and bladder cancer
- > The reason for this versatility is the fact that BT-062 binds to a special protein that is present particularly often on the cell surface of just these types of cancer
- > Multiple myeloma is a malignant and extremely aggressive cancer of the bone marrow for which there is so far no cure
- > Malignant solid tumours are cancers that originate in different organs and can spread throughout the body
- > Chemotherapy is often used for treatment. However, this has a range of sometimes severe side effects on account of its extensive action

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#### COOPERATION WITH IMMUNOGEN INC.

- > ImmunoGen Inc. with its headquarters in Waltham, Massachusetts (USA), is a biotech company founded in 1981, which is active especially in the development of targeted treatments for cancers
  - > With its own technology for using its potent cancer-cell killing agents with antibodies (antibody-drug conjugate, ADC), ImmunoGen develops medicines and has also outlicensed this technology to other pharmaceutical companies
  - > Since 2006 Biotest has been working together with ImmunoGen on the development of BT-062: Biotest supplies the antibody that binds specifically to tumour cells and ImmunoGen provides the technology for the cell-killing agent and its attachment to the antibody
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And even if market introduction was still far in the future at that time, decisions for marketing and sales were taken at this early stage. "Orphan Drug Status" was assigned to BT-062 both in the US and in Europe (see fact box page 17). The regulatory authorities hereby acknowledged that there is a great medical need for our product. Biotest thus obtains the possibility of exclusive marketing the later drug for certain periods.

Following the initial successes, the study programme was extended in subsequent years: in 2010 the first study with multiple doses of the drug started, and a combination study was initiated in 2012. In this study, BT-062 was given together with different products already licensed for the treatment of multiple myeloma. It was possible to show that combining the therapies led to a marked reinforcement of the effect while tolerability remained good.

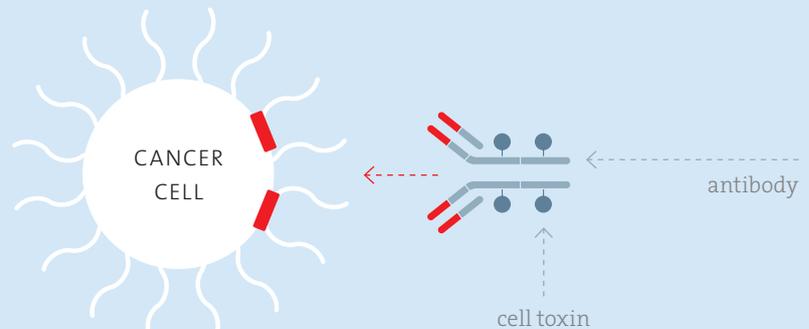
And a further exciting discovery was made in this period: preclinical data showed that BT-062 is also effective against different solid tumours such as breast cancer and bladder cancer. This was another milestone for Biotest. Thus, considerably more patients could benefit in future from treatment with BT-062. In 2014 the first patients with metastatic breast or bladder cancer were treated in a phase I/IIa study.

The project team under the direction of Dr Katrin Bernöster is currently preparing intensively for phase III in multiple myeloma: "Whether it is the transfer and upscaling of antibody and conjugate production, the clinical design of the phase III study or agreement of the further development programme with the authorities – 2015 will be crucial for fully raising the economic potential of this project and providing an effective and very well tolerated medication for many cancer patients." /.

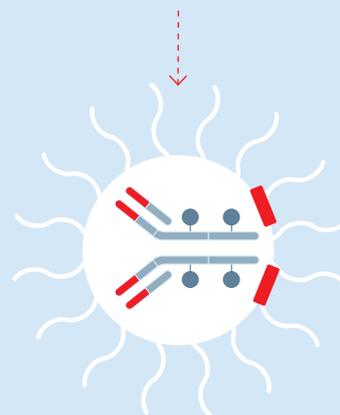
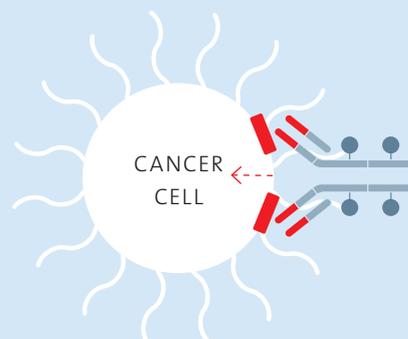
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MECHANISM OF ACTION BT-062

**STEP 1**

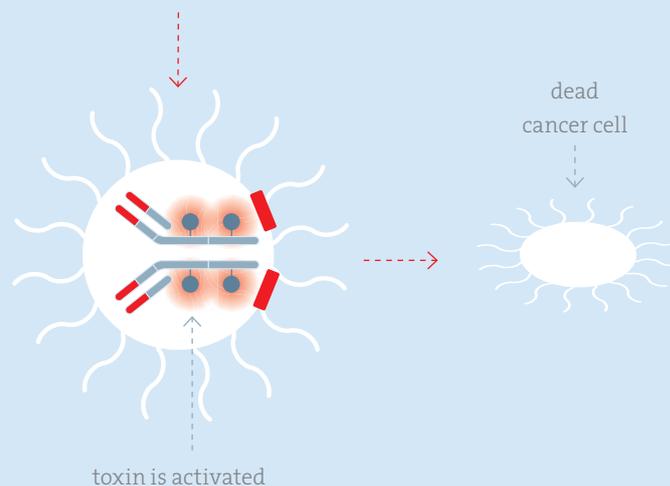
Indatuximab ravtansine (BT-062) is a so-called antibody-drug conjugate, a combination of a monoclonal antibody and highly effective cell toxin, which can target cancer cells and destroy them.

**STEP 2**

According to the lock and key principle, BT-062 binds exactly to the protein molecule that occurs particularly often on the surface of multiple myeloma cells. Through this binding, BT-062 is taken up by the cancer cell.

**STEP 3**

Inside the cancer cell, the toxin is released and activated. This prevents the cancer cell from dividing and it dies.





## CIVACIR® – AN INNOVATIVE APPROACH IN THE TREATMENT OF HEPATITIS C PATIENTS

2007 was a pioneering year for Biotest AG: in December Biotest took over the “Biologics” division of the American Nabi Biopharmaceuticals, thus obtaining an entry into the world’s biggest pharmaceutical market. And with the takeover, Biotest also secured a development project that is currently in the phase III of clinical testing: Civacir®.

The basic principle of its mechanism of action has not changed since 2007: Civacir® is what is known as a hyperimmunoglobulin, in which antibodies to neutralise the hepatitis C virus are present in high concentration and variety. When it was acquired, the candidate product was at clinical phase IIb. Over the years we have continued to improve the formulation and also the production process of Civacir®. Another milestone is imminent with the

publication of the crucial phase III results. Data from the ongoing phase III study were first presented at the international conference of the American Association for the Study of Liver Disease (AASLD) in 2014. Further interim results from the study, which were presented at the EASL conference in April 2015 in Vienna, Austria, are promising. More than two thirds of the patients have now been included in the study. The data presented in Vienna show that despite treatment of patients with modern virostatic drugs prior to transplantation, about one third of the patients are reinfected (control group). Only one reinfection was detected so far in patients who received Civacir® (5%). According to World Health Organisation (WHO) estimates, up to 150 million patients suffer from chronic hepatitis C worldwide. Three to four million people become infected annually with the




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### WHAT IS HEPATITIS C?

- > Hepatitis C is a liver disease caused by the hepatitis C virus (HCV). It can have both an acute and chronic course and lead to severe liver damage (including liver cirrhosis and liver cell cancer)
- > The virus is transmitted through the blood so the most frequent ways of infection are unsafe injections, inadequate sterilisation of medical equipment and contaminated blood transfusions
- > 130 to 150 million people worldwide have chronic hepatitis C infection, and 350,000 to 500,000 patients die annually of liver diseases attributable to HCV infection
- > Vaccination is not possible at present and treatment is with antiviral substances such as virostatic drugs
- > Approximately 15–30% of all patients with chronic HCV infection develop liver cirrhosis within 20 years and often require organ transplantation

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### WHAT DOES CIVACIR® DO?

- > Civacir® is a hyperimmunoglobulin developed by Biotest, which is used for the treatment of hepatitis C patients during and immediately after liver transplantation
  - > To produce Civacir® antibodies from hundreds of plasma donors who have a high level of antibodies to HCV are collected and processed. In this way, a broad range of antibodies against the different HCV variants is obtained
  - > Civacir® is able to neutralise the virus by binding to it. The ongoing clinical phase III study is investigating the use of Civacir® as reinfection prophylaxis after liver transplantation in HCV-infected patients. If this is successful, this will lead to cure of the patient
  - > At present there is no recognised standard therapy for reinfection prophylaxis after liver transplantation in HCV-infected patients. Currently available virostatic drugs are not used directly after the liver transplantation because of toxicities, problems with tolerability and drug-drug interactions
  - > Since Civacir® is an immunoglobulin that is produced from donor plasma, it is expected to possess very good tolerability with high efficacy at the same time
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FACTS

900

liver transplants  
in Germany

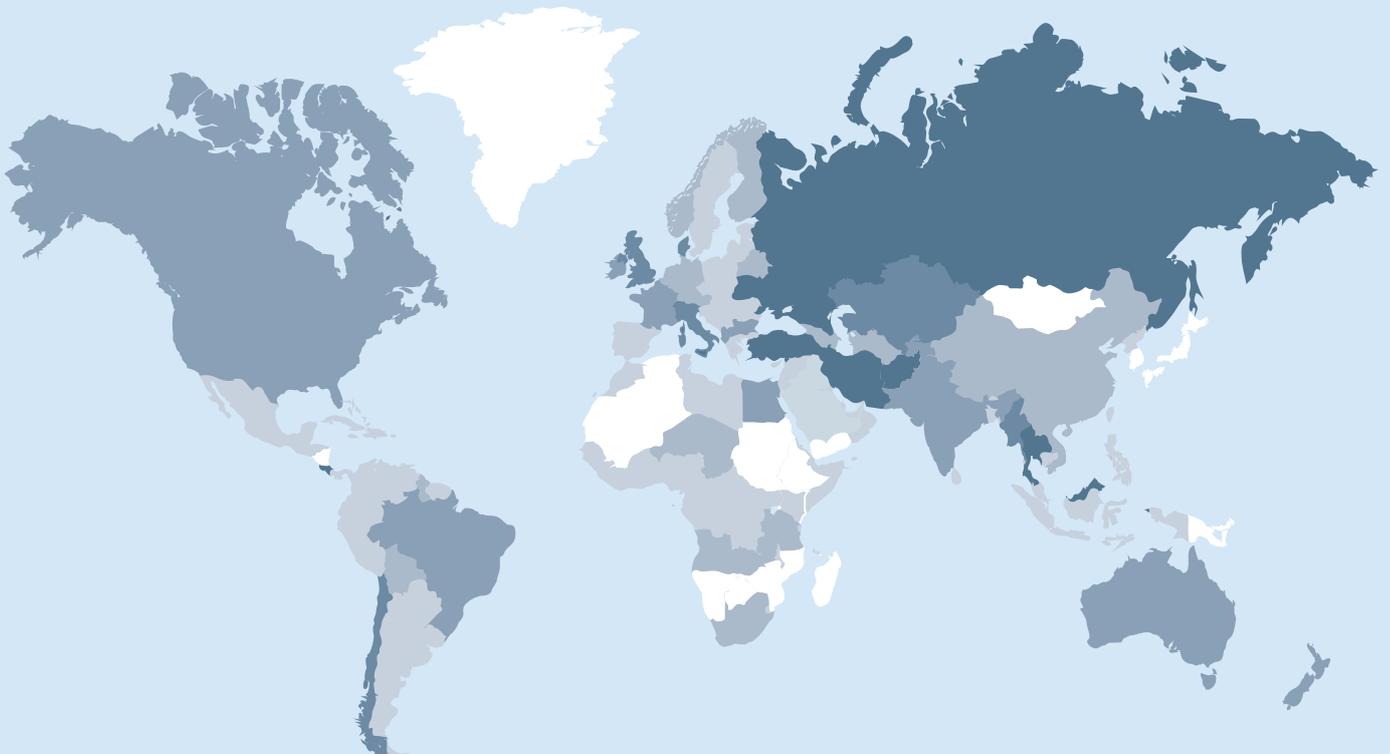
5,000

liver transplants  
in the EU

5,000

liver transplants  
in the US

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GLOBAL RISK OF A  
HEPATITIS C INFECTION



● risk higher than 1.0%

● risk 0.6–1.0%

● risk 0.4–0.5%

● risk 0.2–0.3%

● risk lower than 0.2%

○ no data available

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# 3-4

million new hepatitis C infections  
per year estimates the WHO

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hepatitis C virus (HCV) though the symptoms cannot always be classified directly and accordingly many infections are not even identified initially. In addition, the course of the disease often varies from patient to patient and so is sometimes diagnosed only after years. However, all hepatitis C patients have one thing in common: an increased risk of liver cirrhosis – the end stage of many liver diseases – or of developing liver cell cancer.

The liver is the most important organ in human metabolism. It produces vital proteins and also breaks down and eliminates metabolic products and toxic substances. The only alternative for patients suffering from severe liver disease because of hepatitis C is liver transplantation. Thus, chronic hepatitis C is the most frequent reason nowadays for transplantation of this vital organ.

Because of the limited availability of donor organs, not all patients worldwide can be given a new liver: 10,000 liver transplants are registered annually in the EU and US, about 900 of them in Germany. In high-risk regions for infection with hepatitis C such as North Africa and Asia, where medical healthcare is usually less well developed, the transplantation numbers are much lower. According to the WHO, over 350,000 people still die annually of liver disease caused by hepatitis C. The relatively high mortality rate is explained partially by the fact that patients in many regions have no access to expensive standard therapies.

Even transplantation does not offer the certainty that the hepatitis C virus is completely eliminated. In many patients, reinfection occurs on account of virus that is still present within four weeks after liver transplantation. The majority of these patients will need a new organ within only five years. Given the background of the extremely limited number of donor organs, this is a major problem. The reason for this reinfection is that even with treatment using current standard therapies and a reduction of the virus level, hepatitis C viruses can persist in the body. These cause a new onset of the disease. In the months after the transplantation the use of virostatic drugs, that are the medicines that should inhibit multiplication of the virus, is limited. The reasons are their toxicities, tolerability problems and drug-drug interactions. At present there is no recognised treatment to prevent hepatitis C reinfection after liver transplantation.

And this is where Civacir® comes onto the scene. The Biotest product is obtained from the blood plasma of hundreds of different donors who all have one thing in common: a naturally high level of antibodies that act to neutralise hepatitis C viruses. Since there are different HCV variants, Biotest ensures when selecting and combining Civacir® that it contains antibodies in great variety and adequate concentration. Dr Shailesh Chavan explains the benefit of Civacir®: “We thereby provide a broad

spectrum of antibodies that eliminate hepatitis C viruses in the body and thus can protect the new liver effectively from reinfection. And since we use natural raw materials that do not place additional stress on the immune system as virostatics, we can give our product directly from the day of transplantation without expecting complications or side effects as a result.”

The new standard treatment for patients who need liver transplantation because of hepatitis C infection could look like this in future: following diagnosis of chronic HCV infection with corresponding liver damage, brief treatment will reduce virus level in the patient’s body below a determined threshold. On the day of the liver transplantation, a ten-week treatment with Civacir® will start, which is intended to eliminate the virus in the body completely and protect the transplanted liver.

Before this new treatment possibility can become a reality, the final study phase III has to be concluded and marketing authorisation must be obtained. A phase III study with up to 84 patients at 23 sites is currently conducted in North America. These patients are due to have liver transplantation soon. Participation in the study is independent of the HCV variant, known as the virus genotype, with which the patient is infected. The study participants receive Civacir® in different doses over a ten-week period or are given the current standard therapy (no antiviral treatment) in the control group. In the 12<sup>th</sup> and 24<sup>th</sup> week after the end of treatment, the virus level is measured. If no further HCV is detectable, the therapy is regarded as successful. On the basis of interim results, which were presented at the EASL conference in Vienna in April 2015, HCV reinfection has been found so far in only one of the patients treated with Civacir® (5%), but in 32% of the patients in the control group. If these results are also confirmed after the conclusion of the study, this would be an important milestone for the treatment of transplant patients with hepatitis C.

The next step before market introduction would then be the licensing procedure with the appropriate authorities. Since Civacir® has “Orphan Drug Status” (see fact box), an accelerated licensing procedure should be used so that this important product might come on the market as early as 2017/2018. Through the Orphan Drug Status, exclusive marketing of Civacir® is ensured in addition for seven (USA) and ten years (Europe). Biotest would therefore help people throughout the world with another plasma protein product. /.

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#### ORPHAN DRUG DESIGNATION

- > The Orphan Drug Designation was introduced in 1983 in the US and in 2000 in the EU to promote the development of drugs for rare diseases
  - > Different stimuli are used to promote the development of drugs for the treatment of life-threatening or very severe rare diseases for which there is no treatment or only inadequate treatment options available today
  - > For Orphan Drug Status rare means a disease with fewer than 230,000 patients per year (EU) or 200,000 patients per year (USA)
  - > Recognition as an orphan drug is associated with the right, in the case of marketing authorisation, to market the product in question exclusively for ten years (EU) or seven years (USA). In addition, an acceleration licensing procedure is possible
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## MULTIFACETED COMMITMENT

Patient well-being has always guided our focus and our approach to our work, and is also the consideration that overwhelmingly orients our development. Our teams work every day to improve the lives of patients with our products. Naturally, we also take very seriously our responsibility towards our employees. For example, we see it as our duty to provide employees with an optimal work environment by offering training and continuing education opportunities, or with our company childcare facility. Our corporate responsibility is reflected among other things in our extensive social and cultural engagement.

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### APPRENTICESHIP, CONTINUING EDUCATION AND PROMOTION

“We currently employ 46 apprentices and two dual education students at our Dreieich location,” says Christina Konzelmann, Director for vocational training and job entry programmes at Biotest. “Training opportunities are extremely varied with us, ranging from chemistry and biology lab technician to

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# 46

apprentices work at the Biotest headquarters in Dreieich

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electronics technicians, business courses for office management and chemical technicians all the way to dual education courses. In October 2014, Biotest was awarded a certificate for the promotion of young talent by the German Employment Agency for its exemplary commitment to training. We also offer practical further and continuing education courses to our employees, such as courses in process engineering or business IT provided parallel to their jobs. These hands-on education opportunities are quite popular.”

Biotest also actively contributes to the education of future scientists. Dr Jörg Schüttrumpf, Research Director and Coordinator of Biotest’s university partnerships, explains: “We directly participate in education events at various universities, to share practical experiences with future scientists in lectures and seminars.” We also extend frequent invitations to information events at Biotest, and offer a look behind the scenes at the research and production efforts of a pharmaceutical company. We take advantage of this unique opportunity to present Biotest as an attractive employer in the region, and attract the attention of young talents to our company. “In addition, we award ten Germany Scholarships each year at Goethe University Frankfurt, thus serving as a mentor to support particularly dedicated students in a wide variety of project activities,” says Schüttrumpf.

Biotest promotes Bachelor, Master and doctoral studies and cooperates with universities and technical universities from all across Germany in this effort, in particular in the Rhine-Main region (including Frankfurt, Darmstadt, Mainz, Giessen, Marburg and Wismar). The company has already attracted numerous very well educated young skilled workers with its excellent support for thesis work and interesting entry-level positions. /

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“I like going to Biotest every morning, and look forward to learning something new and working with the team.”

ALEXANDRA SCHULZ

first-year  
office management apprentice

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“The apprenticeship at Biotest is multifaceted and very interesting. I like that we get to be hands-on. You’re right in the thick of things instead of just watching!”

DOGUS YASAR

first-year  
chemical technician apprentice

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“What I like about the apprenticeship at Biotest is that you don’t just get to know the different parts of the company and its activities when you’re at work, but you’re really a part of things. Supervisors’ and co-workers’ relationships with the apprentices are both friendly and professional, so you just like going to work every day.”

CARINA DEPTUCH

second-year  
biology lab technician apprentice

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# 80

children between the ages of eight months and six years find space in the Biotest daycare centre



“With our childcare facility, we provide a better work-family balance.”

HEINZ PÖTTER

## BIOTEST CHILDCARE FACILITY – OPENING SUMMER 2015

Management, HR directors and Works Council chairs discussed the idea of a company childcare facility in Dreieich for the first time in July 2012. It was quickly agreed that offering this facility would significantly improve employees’ work-family balance. A survey of interest showed overwhelming support. No sooner said than done: we were able to celebrate the groundbreaking for our company daycare on 14 November 2014, and in summer 2015 the first children will bring the new building to life with their laughter. The two-story building with a total surface area of around 1,200 square meters directly adjacent to the company premises will provide space for up to 80 children between the ages of eight months and six years.

“The childcare centre will welcome children from 6 AM to 6 PM, aligned with our flexible system of working hours, and will also be open during school holidays,” says Project Manager Heinz Pötter. This family-friendly approach is intended to attract the young, skilled workers that Biotest urgently needs in the coming years to support the expansion of its production facilities. Children of employees will have priority for acceptance, but extra capacity in the first few years means the facility will also be available to other parents in Dreieich: “We are working closely with the city government to be able to propose this comprehensive childcare offer to other families,” says Pötter.

## LAUGHTER BRINGS HAPPINESS!

Under the motto “Don’t stress about stress”, medical cabaret artist Dr Eckart von Hirschhausen paid us a visit to present an excerpt from his current programme, specifically tailored to Biotest. The event room was filled to capacity and our employees were delighted. The audience laughed heartily at the many humorous anecdotes from Dr von Hirschhausen, who included valuable ideas and inspiration for physical and mental health in his afternoon presentation. He addressed issues such as how to prevent stress, or when that is impossible, how to deal with it well. What role do fun, happiness and a sense of purpose play in our physical health? And if laughter is the best medicine, how can you laugh yourself silly more often?

Following his performance, employees could sign up for the seven-week online workshop “Try your luck at happiness” which offers additional possibilities for finding daily happiness and sharing it with others. Biotest employees from a wide range of departments took part, leading to cheerful discussions throughout the company in the hallways and at lunch breaks.





## GOETHE IS BACK!

Biotest has had a close relationship with Johann Wolfgang Goethe University Frankfurt for many years, via study grants, support for theses, event series and as an employer of the university's graduates. So it was natural for Biotest to contribute to the University's 100<sup>th</sup> anniversary celebration in 2014: under the motto "Goethe is back!", conceptual artist Prof. Ottmar Hörl created 400 different coloured statues of the famous Frankfurt poet and arranged them in the green spaces of the university campus. Biotest contributed funding for the installation's opening ceremony, thus helping among other things to create a real impact for these effigies in the colours of the historic faculties.

## HUMOUR HELPS HEAL

Biotest is also very conscious of people who might currently have less to laugh about – ill or injured patients. The company supports the HUMOUR HELPS HEAL Foundation founded by Dr Eckart von Hirschhausen, which sends professional clowns to hospitals to bring laughter to children of all ages. This is a source of hope and optimism for patients, because laughter is still the best medicine.

Apart from this sponsorship, Biotest supports numerous other patient organisations financially. This includes donations to the Deutsche Hämothilfegesellschaft zur Bekämpfung von Blutungskrankeiten e.V. (DHG), the World Federation of Hemophilia (WFH), the International Patient Organization for Primary Immunodeficiencies (IPOPI), the Deutsche Selbsthilfe Angeborene Immundefekte e.V. (dsai) and the European Haemophilia Consortium (EHC).

“Everyone who comes  
into contact with the Goethe  
installation becomes part of it.”

PROF. OTTMAR HÖRL



# 400

colorful Goethe statues decorated the  
Frankfurt University campus



“IT WAS CRUCIAL FOR BIOTEST’S SUCCESS IN RECENT YEARS, THAT WE HAD A CONSISTENT APPROACH SINCE 2003.”

Prof. Schulz was heading the company for twelve successful years. Under his leadership, the market capitalisation of Biotest AG increased from around € 50 million to almost € 1.0 billion today.

Prof. Schulz, Biotest is in a very good situation today. Looking back, what were the most important decisions on your tenure that made this development possible?

**PROF. SCHULZ:** It was crucial for Biotest’s success in recent years that we had a consistent approach since 2003 and we currently produce and market only medicines that are made from blood plasma or by biotechnology in the three indication areas of clinical immunology, haematology and intensive care medicine.

Apart from the sale of non-core business areas, an important decision during my term in office was the acquisition of Nabi Biopharmaceuticals in the US (2007), since high prices are paid for plasma proteins in the US and high quantities are needed.

Extremely important was a cooperation contract with AbbVie (formerly Abbott) on co-development and co-marketing of our monoclonal antibody tregalizumab (BT-061), which was concluded in 2011.

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“The value of our contract with AbbVie is about 500 million US dollars.”

PROF. DR GREGOR SCHULZ

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“The major expansion of our production capacity in Dreieich will be a significant challenge.”

PROF. DR GREGOR SCHULZ

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Finally, it was important in recent years for Biotest to expand the plasma protein pipeline by new developments, in addition to the clinical development of the three monoclonal antibodies.

Let us take a look into the future. What areas do you think will pose the greatest challenges to your successor in the coming years?

The political conditions in our core markets are becoming increasingly difficult. For example, in Germany we are still facing a price moratorium and compulsory discounts of 7%.

This means that my successor Dr Ehmer and all Biotest employees face the challenge of continuing to show a profit that satisfies our shareholders, despite high research and development costs. Because we have several products entering phase III clinical trials in the next few years, with very high development costs, it is essential for us to enter into partnerships for our large projects, such as the one we have successfully implemented with AbbVie for the BT-061 monoclonal antibodies.





DR BERNHARD EHMER

PROF. DR GREGOR SCHULZ

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“As a management team we will continue to execute Biotest’s existing strategy. We continue the clinical development of plasma proteins as well as monoclonal antibodies.”

DR BERNHARD EHMER

“It was important in recent years for Biotest to expand the plasma protein pipeline by new developments, in addition to the clinical development of the three monoclonal antibodies.”

PROF. DR GREGOR SCHULZ

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“Biotest has an exciting  
business model.”

DR BERNHARD EHMER

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The major expansion of our production capacity in Dreieich will be another significant challenge. As you know, we intend to invest more than € 250 million to more than double our production capacity. We received the building permit for this project in December 2014, and were able to begin construction excavation immediately. This major project is proceeding as planned, in terms of timing and budget. We expect to generate revenue from the capacity expansion starting in 2018.

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“We expect to generate revenue  
from the capacity expansion  
starting in 2018.”

PROF. DR GREGOR SCHULZ

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So the new Chairman of the Board, Dr Ehmer, still has plenty to do.

To conclude, a personal question: after devoting the past 12 years completely to Biotest, what are you planning next – new pharmaceutical projects, or simply enjoy retirement?

As you know, I have been a member of the Board of Partners and of the Supervisory Board of Merck KGaA, Darmstadt, Germany since the start of 2014, and several biotech companies have invited me to join their supervisory bodies, as well.

But of course I will also enjoy not to be subject to the pressures that the Chairman of the Board of a publicly traded company each day. Hopefully, I will have a little more time to enjoy my hobbies.



“Of course I will not be subject to the pressures that the Chairman of the Board of a publicly traded company each day.”

PROF. DR GREGOR SCHULZ

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Dr Ehmer, you were previously with Imclone, one of the pioneering firms in the field of monoclonal antibodies. Is it the antibodies, or what is it that particularly excites your interest at Biotest?

Biotest has an exciting business model. On one hand there is the core business, with essential, life-saving plasma proteins such as immunoglobulins and albumin, which Biotest offers in many countries. And on the other hand, the monoclonal antibodies in clinical development offer huge potential for treating diseases with high medical need.

Moreover a few special plasma proteins such as the hyper-immunoglobulin Civacir® are in advanced clinical studies. If results are positive, these therapies could lead to meaningful improvements for patients.

Also regarding the development of the monoclonal antibodies: will the focus shift at all under your leadership, and how do you plan to balance out opportunities and risks?

DR EHMER: As a management team we will continue to execute Biotest's existing strategy. We continue the clinical development of plasma proteins as well as monoclonal antibodies. We will consider most careful attention to the future opportunities and risks of individual projects and continue to rely on cooperation. Data from our various ongoing studies will help us to fine-tune our strategy.

Thank you for the interview!

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QUESTIONS WERE ASKED BY ANDREAS SCHMIDT,  
ANDREAS SCHMIDT CONSULTING

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## THE BIOTEST SHARE

The Biotest share was able to continue the successful development of the previous year in fiscal year 2014. Ordinary shares rose from their price of € 78.00 at end-2013, to € 89.30 one year later. The share thus rose + 14.5%, a significantly better performance than the SDAX which gained 5.9% in value over the same period. Both the Biotest share and the SDAX reached new record highs over the course of the year.

Biotest AG's preference shares also performed very well. On the last day of trading in fiscal year 2014, these securities closed at € 94.00 in Xetra trading, up 23.7% over the previous year's price of € 76.00. The securities thus significantly outperformed the SDAX index.

Biotest AG's solid and forward-looking orientation played a key role in the very positive evolution of the Biotest share price overall during the year. The company is already massively investing in research and development for the future.

Biotest AG is listed on the Prime Standard of Deutsche Börse AG, the segment with the highest transparency requirements. The preference shares have also been listed on the SDAX since 2007. This makes Biotest AG one of the 50 largest industrial securities under the MDAX. On 30 December 2014, the last day of trading in the fiscal year, Biotest's market capitalisation had increased by a total of around € 190 million in one year. Biotest AG's market capitalisation was € 1.21 billion at end-2014 (2013: € 1.02 billion). The average daily trading volume of Biotest preference shares on the Xetra electronic trading system in 2014 was 14,442 shares.

A key goal of the investor relations activities of Biotest AG is to fully inform the capital markets of our sustainable value creation strategy. Biotest also strengthens trust through a policy of honest, complete and prompt communication with investors and the public. In addition to published press releases, ad hoc announcements, and direct dialogue with investors, we are in close and continuous contact with analysts as well as the business and financial media.

Key elements of our capital market communication efforts include participation in international investor conferences, road shows and individual meetings with investors. The Investor Relations section of the Biotest website features current and detailed information aimed at existing shareholders as well as potential investors.

Stock analysts from various prestigious banks and securities firms monitor Biotest AG's development and publish regular research studies. In this context, the predicted target share price for Biotest preference shares was between € 94 and € 133. Recommendations were primarily "Buy" and "Accumulate". In addition to its positive performance on the market, the appeal of the stock is further enhanced by the consistent dividend policy of Biotest AG. Biotest seeks to allow its shareholders to participate appropriately in the company's success. To this end, significant investments in research and development as well as property, plant and equipment are analysed as part of the company's expansion efforts. The dividend has increased from year to year, or at least remained stable, since 2004. Also for the fiscal year 2014, an increased dividend of € 0.60 per ordinary share and € 0.66 per preference share was paid. /.

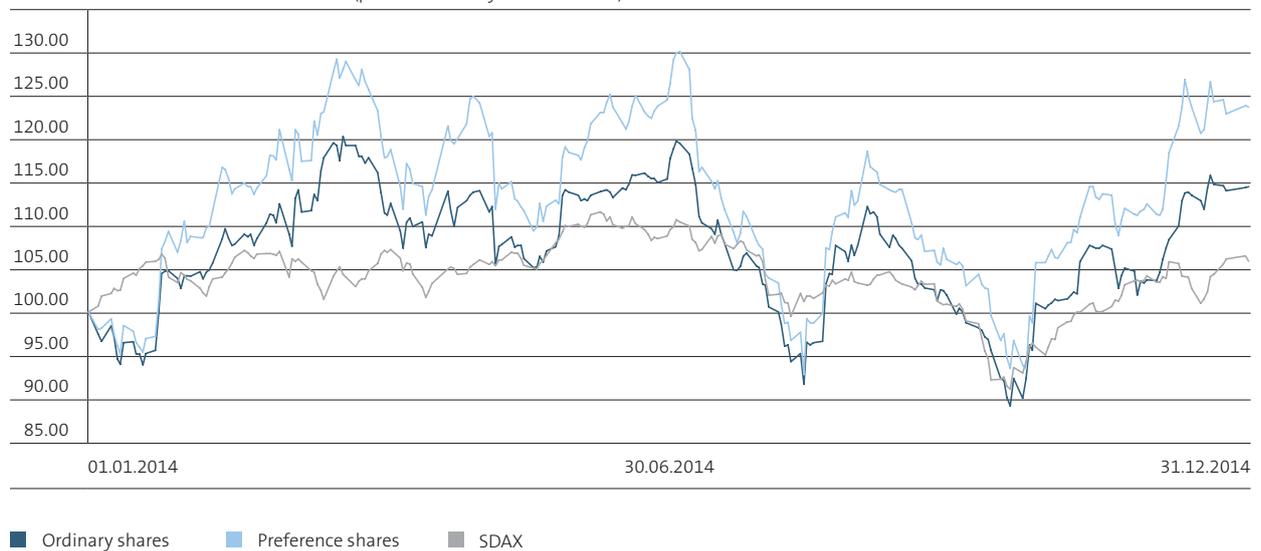
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“We are convinced of our innovative approach,  
as it forms the basis for future success.  
This development is also reflected in our share price.”

DR MICHAEL RAMROTH,  
Chief Financial Officer

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BIOTEST SHARE: PERFORMANCE 2014 (price at close of year 2013 = 100)

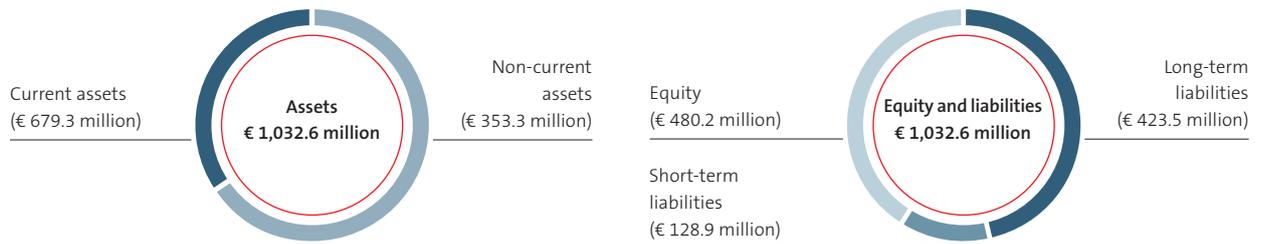


## 2014 AT A GLANCE

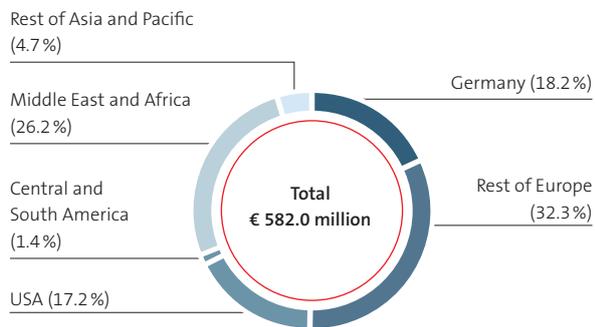
BIOTEST GOUP		2014	2013	Change in %
Revenue	in € million	582.0	500.8	16.2
thereof:				
Germany	in € million	106.0	93.4	13.5
Rest of world	in € million	476.0	407.4	16.8
thereof:				
Therapy	in € million	409.8	386.2	6.1
Plasma & Services	in € million	157.0	102.5	53.2
Other Segments	in € million	15.2	12.1	25.6
EBITDA	in € million	85.9	85.6	0.4
Operating profit (EBIT)	in € million	53.4	53.8	-0.7
EBIT in % of revenue	%	9.2	10.7	
Earnings before taxes	in € million	46.9	47.8	-1.9
Earnings after taxes	in € million	19.2	32.0	-40.0
Structure of expenses:				
Personnel expenses	in € million	138.2	126.2	9.5
Research and development costs	in € million	67.2	64.6	4.0
Research and development costs in % of revenue	%	11.5	12.9	
Capital expenditure in property, plant and equipment and intangible assets	in € million	47.1	42.9	9.8
Financing:				
Cash flow from operating activities	in € million	-11.4	-7.2	-58.3
Depreciation and amortisation	in € million	32.5	31.8	2.2
Equity (as of 31 December)	in € million	480.2	460.7	4.2
Equity ratio (as of 31 December)	%	46.5	52.0	
Balance sheet total (as of 31 December)	in € million	1,032.6	886.5	16.5
Employees (full-time equivalents as of 31 December)	amount	2,158	1,997	8.1
Earnings per share	€	1.46	2.57	-43.2

## FACTS & FIGURES 2014

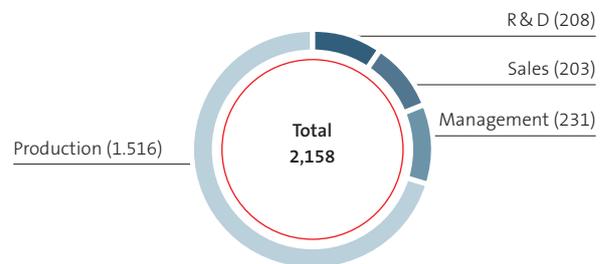
### BALANCE SHEET STRUCTURE



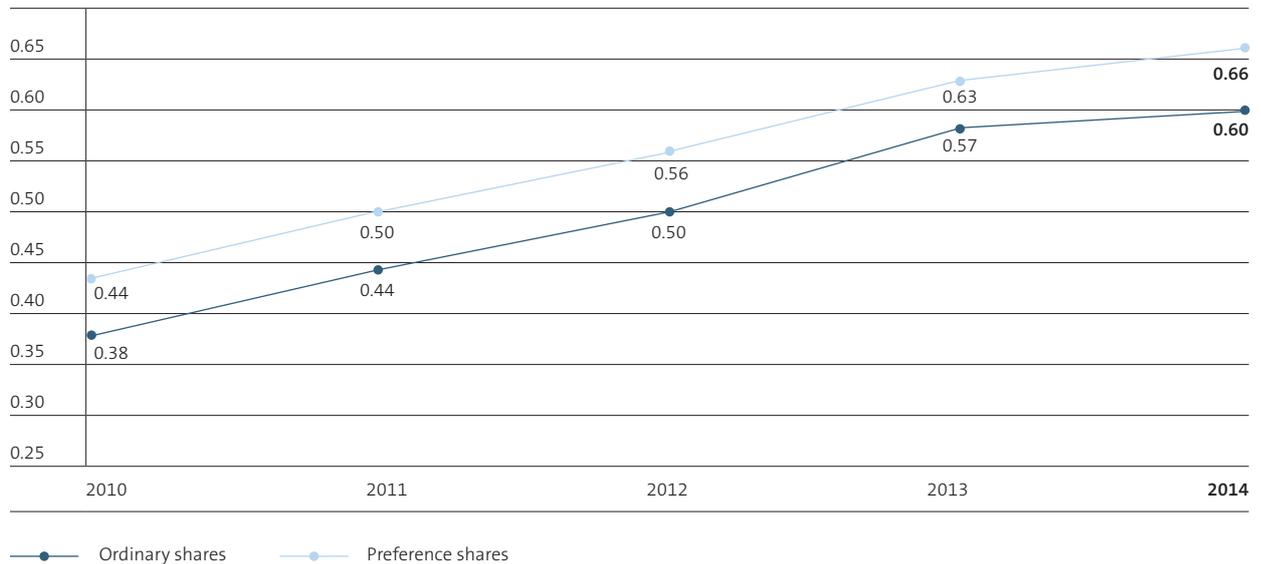
### REVENUE BY REGION



### EMPLOYEES (full time equivalents)



### DIVIDEND PER SHARE in €



## CONSOLIDATED STATEMENT OF INCOME

of the Biotest Group for the period from 1 January to 31 December 2014

in € million	2014	2013
Revenue	582.0	500.8
Cost of sales	-357.5	-293.2
<b>Gross profit</b>	<b>224.5</b>	<b>207.6</b>
Other operating income	7.0	12.6
Distribution costs	-74.2	-60.1
Administrative expenses	-31.6	-30.6
Research and development costs	-67.2	-64.6
Other operating expenses	-5.1	-11.1
<b>Operating profit</b>	<b>53.4</b>	<b>53.8</b>
Financial income	21.4	16.9
Financial expenses	-27.9	-23.9
<b>Financial result</b>	<b>-6.5</b>	<b>-7.0</b>
Income from associated companies	—	1.0
<b>Earnings before taxes</b>	<b>46.9</b>	<b>47.8</b>
Income tax	-27.7	-15.8
<b>Earnings after taxes</b>	<b>19.2</b>	<b>32.0</b>
Attributable to:		
<b>Equity holders of the parent</b>	<b>19.2</b>	<b>32.0</b>
<b>Non-controlling interests</b>	<b>—</b>	<b>—</b>
<b>Earnings per share in €</b>	<b>1.43</b>	<b>2.54</b>
<b>Additional dividend rights per preference share in €</b>	<b>0.06</b>	<b>0.06</b>
<b>Earnings per preference share in €</b>	<b>1.49</b>	<b>2.60</b>

## CONSOLIDATED STATEMENT OF FINANCIAL POSITION

of the Biotest Group as of 31 December 2014

in € million	31 December 2014	31 December 2013
<b>ASSETS</b>		
<b>Non-current assets</b>		
Intangible assets	50.2	48.1
Property, plant and equipment	282.3	254.9
Investments in associates	1.3	1.6
Other financial investments	5.2	0.2
Other assets	0.8	0.7
Deferred tax assets	13.5	18.5
<b>Total non-current assets</b>	<b>353.3</b>	<b>324.0</b>
<b>Current assets</b>		
Inventories	246.0	227.0
Trade receivables	181.6	118.5
Current income tax assets	4.6	1.0
Other assets	67.7	11.6
Cash and cash equivalents	179.4	204.4
<b>Total current assets</b>	<b>679.3</b>	<b>562.5</b>
<b>TOTAL ASSETS</b>	<b>1,032.6</b>	<b>886.5</b>
<b>EQUITY AND LIABILITIES</b>		
<b>Equity</b>		
Subscribed capital	33.8	33.8
Share premium	225.6	225.6
Retained earnings	201.5	169.2
Share of profit or loss attributable to equity holders of the parent	19.2	32.0
<b>Equity attributable to equity holders of the parent</b>	<b>480.1</b>	<b>460.6</b>
Non-controlling interests	0.1	0.1
<b>Total equity</b>	<b>480.2</b>	<b>460.7</b>
<b>Non-current liabilities</b>		
Provisions for pensions and similar obligations	77.5	59.1
Other provisions	6.3	5.4
Financial liabilities	325.8	226.2
Other liabilities	2.5	0.5
Deferred tax liabilities	11.4	7.8
Liabilities from deferred revenue	—	2.5
<b>Total non-current liabilities</b>	<b>423.5</b>	<b>301.5</b>
<b>Current liabilities</b>		
Other provisions	23.5	24.5
Current income tax liabilities	8.6	10.0
Financial liabilities	6.1	5.3
Trade payables	55.5	51.4
Other liabilities	32.7	26.2
Liabilities from deferred revenue	2.5	6.9
<b>Total non-current liabilities</b>	<b>128.9</b>	<b>124.3</b>
<b>Total liabilities</b>	<b>552.4</b>	<b>425.8</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>1,032.6</b>	<b>886.5</b>

## CONSOLIDATED CASH FLOW STATEMENT

of the Biotest Group for the period from 1 January to 31 December 2014

in € million	2014	2013
Earnings before taxes	46.9	47.8
Depreciation, amortisation and impairment of intangible assets and property, plant and equipment	32.5	31.8
Other non-cash income and expense items	4.9	—
Income from associated companies	—	-1.0
Losses from the disposal of fixed assets	0.4	0.2
Changes in pension provisions	-0.1	0.6
Financial result	6.5	7.0
<b>Operating cash flow before changes in working capital</b>	<b>91.1</b>	<b>86.4</b>
Changes in other provisions	-1.0	7.3
Changes in inventories, receivables and other assets	-70.3	-78.5
Changes in liabilities from deferred revenue	-6.9	-15.6
Changes in trade payables and other liabilities	0.9	9.3
<b>Cash flow from changes in working capital</b>	<b>-77.3</b>	<b>-77.5</b>
Interest paid	-5.6	-5.3
Taxes paid	-19.6	-10.8
<b>Cash flow from operating activities</b>	<b>-11.4</b>	<b>-7.2</b>
Cash received on the disposal of fixed assets	0.8	—
Payments for investments in fixed assets	-44.7	-42.9
Cash from the sale of discontinued operations	—	10.4
Payments for financial assets as part of the short-term financial planning	-59.7	—
Interest received	1.2	0.2
<b>Cash flow from investing activities</b>	<b>-102.4</b>	<b>-32.3</b>
Dividend payments for the previous year	-7.9	-6.2
Proceeds from the capital increase	—	73.7
Proceeds from the assumption of financial liabilities	100.5	222.0
Payments for the redemption of financial liabilities	-5.2	-102.6
<b>Cash flow from financing activities</b>	<b>87.4</b>	<b>186.9</b>
Cash changes in cash and cash equivalents	-26.4	147.4
Exchange rate-related changes in cash and cash equivalents	1.4	-0.2
Cash and cash equivalents on 1 January	204.4	57.2
<b>Cash and cash equivalents on 31 December</b>	<b>179.4</b>	<b>204.4</b>

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## FINANCIAL CALENDAR

### 11 AUGUST 2015

Half-year report 2015

### 10 NOVEMBER 2015

Nine-month report for 2015  
Analyst conference

## CONTACT

The 2014 annual report contains a comprehensive presentation of Biotest's development and prospects. It is available to download from the Biotest website.

At [www.biotest.de](http://www.biotest.de), you will also find comprehensive, up-to-date information about the company, its projects and markets. In the Investor Relations area, you will find all of our financial disclosures as well as our annual and interim reports.

If you have any questions, feel free to contact us directly:

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(Page 2, 23, 24, 25)

Frank Eidel, Berlin, Germany  
(Page 21 top)

Stephan Minx, Fürth, Germany  
(Cover, Page 6, 8, 16, 19, 24)

Thinkstock  
(Page 6)

### PRINTING

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Ober-Ramstadt, Germany

## KEY FIGURES

		2014	2013	2012*	2011*	2010*
Revenue	In € million	582.0	500.8	440.0	422.0	412.5
thereof:						
Germany	In € million	106.0	93.4	89.4	96.9	101.5
Rest of world	In € million	476.0	407.4	350.6	325.1	310.7
thereof:						
Therapy	In € million	409.8	386.2	330.9	324.7	303.4
Plasma & Services	In € million	157.0	102.5	97	87.9	101.0
Other Segments	In € million	15.2	12.1	12.1	9.4	8.1
EBITDA	In € million	85.9	85.6	76.1	72.4	69.8
Operating profit (EBIT)	In € million	53.4	53.8	44.7	41.6	42.9
EBIT in % of revenue	%	9.2	10.7	10.2	9.9	10.4
Earnings before taxes	In € million	46.9	47.8	36.5	28.6	28.4
Earnings after taxes	In € million	19.2	32.0	23.1	18.7	19.6
Structure of expenses:						
Personnel expenses	In € million	138.2	126.2	116.1	106.7	98.7
Research and development costs	In € million	67.2	64.6	51.4	49.4	49.0
Research and development costs in % of revenue	%	11.5	12.9	11.7	11.7	11.9
Capital expenditure in property, plant and equipment and intangible assets	In € million	47.1	42.9	34.5	26.7	31.1
Financing:						
Cash flow from operating activities	In € million	-11.4	-7.2	34.7	72.5	41.7
Depreciation and amortisation	In € million	32.5	31.8	31.4	30.8	26.9
Equity (as of 31 December)	In € million	480.2	460.7	369.4	346.7	307.6
Equity ratio (as of 31 December)	%	46.5	52.0	54.1	50.8	48.6
Balance sheet total (as of 31 December)	In € million	1,032.6	886.5	682.3	682.8	632.3
Employees (full-time equivalents as of 31 December)	amount	2,158	1,997	1,727	1,662	1,611
Earnings per share	€	1.46	2.57	1.94	1.57	1.64

\* Continuing Operations

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