

VALUE. QUALITY. PROGRESS. | Magazine for Annual Report 2016



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"It is our vision to consistently focus on customers in all we do. Customer satisfaction, process and solution orientation and responsibility belong to the core of our value-oriented guiding principles."

VALUE. QUALITY. PROGRESS.





DR GEORG FLOß Chief Operations Officer DR BERNHARD EHMER Chairman of the Board of Management DR MICHAEL RAMROTH Chief Financial Officer

"WE HAVE TAKEN A BIG STEP FORWARD IN OPTIMIZING OUR VALUE CREATION CHAIN."

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INTERVIEW WITH THE BOARD OF MANAGEMENT

In 2016 Biotest showed a growth in sales and EBIT. At the same time, the expansion project Biotest Next Level was consistently pursued, and important milestones were reached. Within the strategic re-alignment, Biotest decided to sell the US therapy and toll manufacturing business. The therapy business and toll manufacturing outside the US as well as plasma collection in the US and Europe are the group's core business and are reported as continuing operations. In the interview, the Board of Management reports on the details and background of the business development, progress regarding Biotest Next Level and future perspectives.

In its continuing operations, Biotest reached its business targets for 2016. Which key factors contributed to these results?

DR EHMER: Our employees did a very good job. All business areas of the company, from plasma collection to research & development, production and marketing & sales, contribute every day to Biotest's value creation and growth. In absolute terms, Germany and Europe are the most important markets for Biotest, representing 48% of the sales. Compared to 2015, the highest year-on-year growth rates were achieved in the US and in the region Other Asia and Pacific. In many countries of this region, we received new marketing authorisations in 2016, for instance for the products Fovepta[®], Zutectra[®], Hepatect[®], Cytotect[®] but also for Albiomin[®] and Intratect[®]. DR RAMROTH: The rise in earnings before interest and taxes (EBIT) from \in 37 million to \in 64 million is due to the growth in sales. In addition, we reduced costs. In research and development, we reduced costs by 38%, and in marketing and sales, by 11%. In future, we aim to continue reducing the risks and costs of development. After completion of the current studies in the area of monoclonal antibodies, Biotest will only pursue further activities with a partner.

An important strategic decision is the planned sale of the US therapy business and toll manufacturing business to ADMA Biologics Inc. How was this decision made, and what does it mean for the future?

DR EHMER: This transaction is part of the strategy to limit the Group's risks, utilize more widely expertise through partnerships and create additional options for further strategic development. In view of ADMA's expertise, we more widely are convinced to have found the right partner. With the interest in ADMA, Biotest receives access to new specialized products and can participate in the hyperimmunoglobulin business in the US. In the medium term, Biotest will also sell these products in selected markets in Europe, the Middle East, and Asia. Furthermore, in view of the current political situation in the US it is helpful to have a local partner.

DR FLOB: Biotest will continue to be active in the US with 22 plasma collection centres, and the company will receive two additional centers from ADMA as of 1 January 2019. Thus we focus our resources even more on the expansion project Biotest Next Level (BNL) at the Dreieich location and the successful further development of our network of plasma collection centres.

Speaking of Biotest Next Level: Higher profitability is an important goal that you hope to achieve in the medium to long term with this project. But how will the project affect short-term results?

DR RAMROTH: In the short term, the high start-up costs associated with the capital expenditure will adversely impact results over the next three to four years. After that, the capital expenditure will pay off. Expanding our portfolio and increasing capacities are important for increasing our future profits. Our goal is to considerably increase yields in production and to use our raw material plasma even more effectively. In the next step, five instead of the current three product lines are therefore to be obtained from plasma. In the expansion of our product range, we are focusing on the development of IgG Next Generation, IgM Concentrate and Fibrinogen. In 2016, we made significant progress in research and development, and we are optimistic that the new products will be ready for the market within the next few years. This is an important prerequisite for our planned substantial increase in sales and profitability.

DR FLOSS: In this context, it is also important that the BNL production plant is to be approved and certified by EU authorities as well as the U.S. Food and Drug Administration (FDA). As a result, we will be able to sell the drugs produced in Dreieich both in Europe and on the very attractive, high-price US market. As a company, this takes us a big step forward in optimising the value chain. What progress was achieved in 2016 with regard to Biotest Next Level?

DR EHMER: We are making very good overall progress with BNL. In the past year, we achieved all project goals. The production building is now complete, interior construction is progressing, and most of the equipment has been installed. The next step is to implement internal production and validation processes and to lay the foundation for sales of the new products beginning in 2019/2020.

<u>How is Biotest preparing for the planned doubling of capacities within BNL?</u>

DR FLOSS: We collaborate in a process-oriented, cross-departmental manner to successfully complete our construction and development projects. The integration of many new employees is another major task for the entire Group. We are well on the way to prepare for marketing the broadened product range and increasing sales from the additional production capacity from 2019/2020 on.

DR RAMROTH: In addition, the expansion of plasma collection centres is an important prerequisite for doubling our capacities, and we are on the right track in this respect. Last year, we opened six new plasmapheresis centres, two in Hungary and four in the US, which considerably enhanced our plasma collection network. Biotest plans to open additional centres in the US and Europe. This will ensure a sufficient supply of our most important raw material, human blood plasma.

"Important for increasing our future profits is the expansion of our product portfolio and our capacities."

DR MICHAEL RAMROTH

DR GEORG FLOß

"We are active in a highly dynamic market with great potential. We will take advantage of this opportunity!"

What does the future of Biotest look like? Where would the Group like to be in five years?

DR EHMER: Our products are very important for seriously ill people worldwide. By strengthening our product pipeline, doubling capacities and entering into strategic partnerships, we want to develop and market additional important products. With this we will meet the increasing demand for immunoglobulins and additional products to be able to offer suitable drugs to even more patients.

What is the course for an increasing demand for plasmaderived products?

DR FLOSS: There are multiple causes for this increase. Access to medical care and hence access to our products is increasing worldwide. The indications and treatment options in which our products are used are not yet well known in many countries. There is great potential in this area. The demographic development plays an important role as well. The population – and hence the number of patients – is growing. Therefore, we are active in a highly dynamic market. We will take advantage of this opportunity!

To manage the growth of Biotest in a future-oriented manner, you have initiated an internal change process. What guidelines are in place to support this process?

DR EHMER: To meet the new challenges within the Group, future-oriented working methods and competencies must be jointly developed and implemented. It is our vision to consistently focus on customers in all we do. Customer satisfaction, process and solution orientation and responsibility belong to the core of our value-oriented guiding principles. We intend to constantly improve our work and collaborate in a positive environment. In addition, it is essential to always challenge our actions and continuously improve them. In this process, it is important to take into account the different views and needs of our employees. Their dedicated efforts make us successful. As management team, we want to take this opportunity to thank our colleagues for their dedication. At Biotest, we want to continue to ensure a working environment in which all employees enjoy coming to work and contribute to our joint success. /.

Mr. Kaunoth for

Dr Bernhard Ehmer

Dr Michael Ramroth

Dr Georg Floß

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HIGHLIGHTS OF THE FINANCIAL YEAR 2016

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<u>14 January</u>: Pentaglobin[®] achieves impressive results in the treatment of patients with donor-specific antibodies following lung transplantation.

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<u>16 March</u>: IgM Concentrate shows an extraordinarily high reduction in mortality of over 50% in a patient subgroup with severe Community Acquired Pneumonia (sCAP).

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23 March: 2016 EBIT guidance raised by more than 10%

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<u>7 April:</u> Biotest opens new plasma collection centre in Györ, Hungary

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<u>23 May:</u> In a study Pentaglobin[®] shows a significant survival advantage in severe infections caused by multi resistant bacteria.

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<u>24 May:</u> Opening of a new plasma collection centre in Brookings, South Dakota, USA

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<u>27 July:</u> Biotest opens a new plasma collection centre in Clemson, South Carolina, USA

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<u>29 July</u>: Opening of the fifth Hungarian plasma collection centre in Szeged

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<u>28 September</u>: Biotest opens a new plasma collection centre in Vermillion, South Dakota, USA

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<u>3 November</u>: Starting in 2017, Biotest will sell a new recombinant factor VIII product in Germany and Switzerland as part of a cooperation agreement with Octapharma AG, Lachen, Switzerland.

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<u>4 November</u>: Changed tax assessments for 2005-2008 result in lower claims against Biotest AG – proceedings against Biotest AG are nearly completed.

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<u>8 November</u>: First patient in global clinical phase III study in the indication primary immunodeficiencies treated with IgG Next Generation

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<u>1 December</u>: Biotest opens a new plasma collection centre in Kearney, Nebraska, USA

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<u>6 December</u>: Promising study results for combined therapy with indatuximab ravtansine in advanced multiple myeloma



Spring 2016:

Very encouraging and positive study results for the products Pentaglobin[®] and IgM Concentrate

<u>29 July:</u>

Opening of the fifth plasma collection centre in Hungary





08 November:

First patient treated with IgG Next Generation in the indication primary immunodeficiency within a global clinical phase III study

Biotest

VALUE. QUALITY. PROGRESS.

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<u>Value</u>. Biotest covers all important steps of the value chain, from plasma collection to research and development, production and worldwide marketing. The name Biotest stands for a state-of-the-art pharmaceutical company that combines all processes and value-adding steps under a single roof. In future, Biotest intends to further increase this value, both by entering into new cooperation agreements with external partners and by further internal development. The Group is continuously optimising processes, changing the company culture and consistently implementing this culture in a customer-oriented manner.

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<u>Quality</u>. Meeting the highest quality standards is absolutely essential for Biotest in all parts of the value chain. Biotest operates in a highly ethical environment. Authorities in all countries have strict requirements for the manufacture of drugs. Biotest meets these requirements and additionally operates with high internal quality guidelines and controls that far exceed legal requirements. The name Biotest stands for state-of-the-art technology in the production of plasma-derived products and biotherapeutic drugs. Patient safety is the focus of all Biotest activities.

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<u>Progress.</u> More than 2,500 Biotest employees worldwide work on the advancement of the company. In research and development department they develop promising clinical studies. In the marketing and sales department, the focus is on expanding the worldwide distribution system. Progress is also visible at the Dreieich location, where the project Biotest Next Level is coming closer to completion every day. Progress: Progess is driven by the motivation to continuously increase value for patients and all external interest groups.

VALUE CREATION AT THE PLASMA COLLECTION CENTRES

In terms of sales, Biotest is among the six largest manufacturers of plasma-derived products worldwide. These products are used in patient treatment every day. Disorders of the immune and blood systems are treated with plasma-derived products. In emergency medicine, these products can save lives as well. For instance, intensive care physicians administer an IgM-containing product to treat serious bacterial infections. The raw material for the manufacture of plasma-derived products is human blood plasma, which is collected by plasma donations at plasmapheresis centres. Worldwide, Biotest operates 13 plasma collection centres in Europe and 22 in the US, thereby securing a long-term independent plasma supply.

> THE PLASMA DONATION PROCESS

- > IRegistration: First, donors check in at the reception. Donors are asked into the registration booth individually. Donors identify themselves in Europe with a donor ID card or official photo ID and are asked to complete a questionnaire in which they provide information on their health condition. Vital parameters are checked as well. An employee of the plasma centre measures blood pressure, pulse, body temperature and weight and determines the haemoglobin value, that is, the pigment in the red blood cells.
- II Medical examination: After the data is recorded, in Europe donors are medically cleared by a physician. They undergo a medical examination at regular intervals. The physician checks the recorded parameters and the completed questionnaire. Afterwards, the physician decides if the person is eligible to donate. This process ensures donor and product safety. Besides a number of criteria, each donation is tested for hepatitis B antigen and antibodies against human immunodeficiency virus HIV 1/2 and hepatitis C virus (serological testing). The donation is released for use only if the laboratory results are unobjectionable.
- > III Collection: Before collection, employees of a plasma centre re-check the donor's identity and then explain the donation procedure. Plasma donation is comparable to a blood donation with blood taken from a vein in the arm and transported to a plasmapheresis unit. In the unit, the cellular blood com-

ponents (red and white blood cells as well as platelets) are separated from the plasma. The cellular components are returned to the donor, while the plasma is separated. This process is called plasmapheresis. Since in plasma donation, the blood cells are returned to the body, it is much more gentle to the circulatory system than full blood donation. The body can replace the plasma within a few days. After the plasma collection, the donor receives for example in Germany and Hungary compensation in line with local legal regulation.

Donor candidates who have never donated plasma before first go through a shortened process: In addition to the steps at registration, their veins are checked, and they receive detailed medical information and an examination by the physician. No plasma is donated, but instead a blood sample is taken for the serological tests mentioned above. If the test results are negative, meaning everything is fine, the candidate can donate his or her first plasma donation.

V Further processing: To ensure that plasma contents remain intact, the plasma is frozen immediately after the donation and stored frozen at a maximum temperature of minus 25 degrees Celsius. Due to the high complexity of raw material collection, the plasma quarantine hold, manufacture, virus inactivation and virus removal steps, six to twelve months pass between the plasma donation and the release of the finished drug. /.

THE PLASMA DONATION PROCESS

THE BASIS OF BIOTEST'S BLOOD PLASMA PRODUCTS IS DONATED BLOOD PLASMA.

Comprehensive medical supervision and testing serves the safety of donors and the product.





Plasma collection is similar to the process of blood donation. The extraction and processing of blood plasma is subject to various legally binding regulations.



Since blood cells return to the body after separation of the blood plasma, plasma donation is typically much more gentle to the circulatory system than full blood donation.





Due to the complexity of plasma collection, treatment and further processing, up to 12 months pass between plasma donation and the release of the finished drug. > LOCATIONS OF THE BIOTEST PLASMA COLLECTION CENTRES WORLDWIDE

PLASMA CENTRE IN GYÖR, HUNGARY

The plasma centre in Györ is one of the most modern in Europe. With a floorspace of 750 m², it accommodates up to 35 donation chairs.





FACTS ABOUT TYPICAL BIOTEST PLASMA COLLECTION CENTRES

- > 25 to 40 employees, including physicians, quality assistants and nurses
- > 20,000 to 30,000 litres of plasma collected annually at each centre
- > About 30 donation chairs per centre
- > Open about 70 hours/week
- > 700 to 800 donors per week

35

PLASMA COLLECTION CENTRES

OF THE TOTAL OF 35 BIOTEST PLASMA COLLECTION CENTRES WORLDWIDE, SIX WERE NEWLY OPENED IN 2016.

STRATEGIC EXPANSION OF THE PLASMA COLLECTION CENTRES

Biotest plans to open additional plasma collection centres in the US and Europe in the future. US plasma has the advantage of being suitable for the manufacture of drugs worldwide. The U.S. authority for drug safety, FDA, requires that plasmaderived products administered in the US must be manufactured from US plasma only. In contrast, plasma-derived products in Europe may be manufactured from US plasma or EU plasma. In several Asian regions, only plasma protein products made from US plasma are approved.

The expansion of our plasma collection centres is strategically important for Biotest. The opening of new centres secures a sufficient supply of the important raw material blood plasma for the planned doubling of capacities. In future, Biotest plans to increase the percentage of plasma supplied by our own centres to about 70%.



BIOTEST PLASMA COLLECTION CENTRES MEET HIGHEST QUALITY STANDARDS

- > All donation centres, test laboratories, plasma storage areas and plasma transport companies are inspected and approved by the European Medicines Agency (EMA) or the FDA.
- > All centres have a GMP-compliant quality management system, which also includes a central quality assurance representative and a quality assistant on site.
- > All plasma donations are subject to a quarantine hold of 60 days. If safety-relevant information about the donor becomes known during this time, the relevant donations are not processed further.
- Biotest uses only plasma that meets the strict requirements of the European and US regulatory authorities.
- > The plasma used by Biotest derives exclusively from selected, tested donors.
- > Regular audits at the plasma collection centres are performed by the regulatory authorities of the federal states and administrative districts, the FDA, Biotest quality management and the Plasma Protein Therapeutics Association (PPTA).
- > The Biotest plasma collection centres are certified by the International Quality Plasma Program (IQPP).

CORE COMPETENCE IN RESEARCH AND DEVELOPMENT

The research and development of new medicines is a growth driver for the Group. Newly developed treatments may be of great advantage in the treatment of a disease. At the same time, innovative treatment solutions open new business areas for Biotest. In the past year, Biotest invested \in 48.7 million in research and development. An important research project is the development of the new immunoglobulin G product IgG Next Generation. In the long-term, it is planned to be the successor of Intratect[®].

Pivotal studies in order to obtain marketing approval in three different indications are planned for IgG Next Generation; two of the studies have already started, after submission to the relevant drug regulatory authorities and approved by the respective countries. These are a phase III study (no. 991) for treatment of patients with primary immunodeficiencies (PID) and a phase III study (no. 992) for the treatment of immune thrombocytopenia (ITP). To extend indications, an additional phase III study in chronic inflammatory demyelinating polyradiculoneuropathy (CIDP, no. 993) is planned for 2017.

IgG Next Generation is another step forward for Biotest: For IgG Next Generation, a new production process was developed with much higher yields and better product characteristics. With IgG Next Generation, Biotest aims to achieve international marketing authorisations in the US, Europe and additional countries. /.

"In 2016, we have reached important milestones in the development of our product IgG Next Generation."



DR GEORG FLOß

INDICATIONS FOR IgG NEXT GENERATION



IN THE LONG-TERM,

IgG NEXT GENERATION IS PLANNED

TO BE THE SUCCESSOR OF

THE PRODUCT INTRATECT[®].

ITP

> Immunothrombocytopenia (ITP) is an autoimmune disease characterised by the massive destruction of thrombocytes and associated with a greater tendency to bleed. ITP can be acute or chronic. Acute ITP is particularly common in children and typically heals within six months. The chronic form is typical for adults and is characterised by relapsing bleeding episodes.

PID

> Primary immunodeficiency (PID) is a group of more than 200 currently identified congenital and genetic disorders in which part of the body's immune system is missing or not working properly. According to estimates, at least 10 million children and adults suffer from PID worldwide. Characteristic for PID is the increased susceptibility to a multitude of pathogenic

CIDP

> Chronic inflammatory demyelinating polyradiculoneuropathy is an acquired disorder of the peripheral nervous system. The disorder is characterised by chronic or recurrent attacks of muscle weakness and sensory loss. CIDP can affect children or adults. Its reported prevalence is 0.5 per 100,000 children. In micro-organisms such as bacteria, viruses and fungi. Compared to people with a normal immune system, PID patients not only suffer from infection more frequently, but these infections may also last longer and be more difficult to treat. Patients with PID typically require life-long replacement therapy with immunoglobulins to

prevent repeat infections.

adults, studies show a prevalence of between one and eight cases per 100,000 inhabitants. Today, drug therapy with immunoglobulins is a well-established treatment method that must typically be administered over an extended time period to stabilise the patient clinically and functionally. 5

CLINICAL DEVELOPMENT OF NEW IMMUNOGLOBULINS

The clinical development of an immunoglobulin in established areas of indications is associated with a high likelihood of success and low risk. There are also many other diseases, particularly in neurology and dermatology, for which the efficacy of immunoglobulins is known from years of clinical experience, but few evidence-based clinical studies have been performed to prove it. In light of increasing worldwide demand, these areas are associated with very interesting economic opportunities in the development of immunoglobulins in the future. One of the reasons for this is that immunoglobulins as natural components of the blood are known for their efficacy and their good safety profile.

The requirements for marketing authorisation are precisely stipulated in guidelines issued by the European and US regulatory authorities. Unlike in other developments, companies do not need to conduct time-consuming and expensive programmes, some with multiple phase I, II and III studies, as the tolerability of immunoglobulins and their mode of action are already well known.

$40_{to}50$

is the minimum number of evaluable patients to participate in a immunoglobulin study.

The EMA and FDA guidelines require a pivotal study in patients with primary immunodeficiency (PID). In this study, various aspects, such as efficacy in a relevant number of patients, tolerability and pharmacokinetics must be investigated.

The recommended primary endpoint is the number of severe bacterial infections (less than one treatment per year). Bacterial infections include bacteraemia, sepsis, bacterial meningitis, osteomyelitis / septic arthritis, bacterial pneumonia and visceral small abscesses. Efficacy is verified in the context of an open-label study in which patients are treated for one year to rule out seasonal effects. The number of included patients should be based on statistic parameters; the guidelines state that at least 40 to 50 evaluable patients should be included in a study, of which about half should be children or adolescents. The study protocol must define specific diagnostic criteria for patient selection.

Another focus is on tolerability, product safety as well as the pharmacokinetic data. Pharmacokinetics is a subdiscipline of pharmacology and deals with drug resorption in the body, its distribution through the body, metabolisation and excretion.

The EMA additionally requires an ITP study for the new approval of an IVIG. In this indication, it must be shown that immunoglobulins have an immune-modulatory effect and can suppress the overreaction of the immune system. The clinical study is intended to show that in addition to immunoglobulin substitution and pathogen neutralisation in PID, aspects such as the inhibition of inflammation and immunomodulation work effectively. A list of indications is found in the infobox below.

DR BERNHARD EHMER

"The further development of immunoglobulins for new indications offers very interesting opportunities for growth."

FOLLOWING SUCCESSFUL PHASE III STUDIES FOR PID AND ITP, THE MARKETING AUTHORISATION INCLUDES THE FOLLOWING INDICATIONS:

- > Primary immunodeficiency (PID)
- > Secondary immunodeficiencies (SID) such as
 - Hypogammaglobulinaemia and recurrent bacterial infection in patients with chronic lymphocytic leukaemia
 - Hypogammaglobulinaemia and recurrent bacterial infection associated with multiple myeloma
 - Congenital AIDS and regularly recurring bacterial infections
 - Hypogammaglobulinaemia after allogenic hematopoietic stem cell transplantation
- > Primary immunothrombocytopenia (ITP)
- Guillain-Barré Syndrome (GBS), a nervous system disorder
- > Kawasaki syndrome, a vascular disorder in children





> DEVELOPMENT OF THE NEW, POLYCLONAL ANTIBODY PRODUCT IGM CONCENTRATE



"The development of IgM Concentrate as part of the Biotest Next Level project is currently one of the most important development projects of the Biotest Group." The development of the new, polyclonal antibody product IgM Concentrate is one of the most important research projects of the Biotest Group. It is an important component of the expansion of the product portfolio and part of the Biotest Next Level project.

The product is intended primarily for application in intensive care for patients with severe community acquired pneumonia (sCAP). Despite effective antibiotics, this disease presents a worldwide health problem, at mortality rates of 23-58%. In the context of the development, Biotest is targeting a novel treatment approach for severe pneumonia. The goal is to neutralise the pathogen causing pneumonia as well as the excessive inflammation triggered by the immune response. In sCAP, these processes otherwise lead to severe lung damage, sepsis with multiorgan failure and ultimately the death of the patient.

For this novel treatment approach, encouraging data on clinical efficacy was already collected in a phase II study in 2015. In view of a shortened artificial respiration period and a reduced mortality rate, a clearly positive trend could be observed in the phase II study. Groups of patients who particularly benefited from this treatment approach could be identified.

The results of the phase II study are taken as a basis in the planning of the phase III study. Biotest is coordinating the phase III study with regulatory agencies in Europe and the US. The clinical phase III study is expected to begin end of 2017 /.

DR BERNHARD EHMER

> INTERVIEW DR JÖRG SCHÜTTRUMPF

HEAD OF RESEARCH & DEVELOPMENT, ON RESEARCH AND DEVELOPMENT AT BIOTEST



DR JÖRG SCHÜTTRUMPF

Dr Schüttrumpf, you have been responsible for Research and Development at Biotest AG for almost five years now. In your opinion, what are the critical aspects of successful research and development?

DR SCHÜTTRUMPF: A thorough understanding of medical needs, good ideas and solid science are the starting points for research & development. To be successful, human and financial resources must also be secured throughout the multiple years of development. This means that the resources, size and strength of a well-managed company are therefore a fundamental requirement for success in research and development. Furthermore, goal-oriented collaboration in interdisciplinary teams is essential. We have to ensure intensive coordination with staff from Regulatory Affairs, Drug Safety, Project Management, Production, Legal and Patents as well as Marketing and Sales.

What is the range of activities of the Biotest Research and Development department?

DR SCHÜTTRUMPF: Our tasks start in the area of pre-clinical research, where we try to identify innovative treatment approaches. Next, we design test systems to characterise the products. A principal part of our work involves performing clinical trials on the safety and efficacy of our products in humans. In parallel to new developments, we also deal with our existing products, where we consider how we can affect the course of disease even more effectively and reduce side

effects. In addition, we perform continuous quality assurance for our product portfolio regarding product characteristics or viral and prion safety.

What challenges do you face as part of your activities?

DR SCHÜTTRUMPF: We must precisely analyse the needs of patients. Only if we are successful in doing so we can work toward optimising the effect of our drugs and develop them accordingly. Another major challenge is the time factor: The development cycles, which are several years long, require that we analyse and predict the needs of users and patients from a long-term perspective. During this time, many things can change and we have to adopt. Collaboration in interdisciplinary teams helps with this challenge.

What motivates you personally to work in pharmaceutical research and development?

DR SCHÜTTRUMPF: I personally find the ethical component enormously motivating. Every day, we actively develop drugs for people, many of whom currently have no treatment options at all. We aim to break new ground with our products, and I want to contribute to this effort. Compared to academic research, where I first worked after studying medicine, I think our company offers excellent conditions for truly making a difference. /. SCHEMATIC DESCRIPTION OF THE PRODUCTION PROCESS

DR GEORG FLOSS

"We are already working on adapting our processes, equipment and products to the requirements of the new production plant. This ensures that we meet the highest quality and safety requirements at all times."



Separation of human blood plasma into its individual protein components (fractions). These fractions are the basis of the Biotest product lines. In the purification, the unwanted components contained in the fractions are separated and rendered harmless. The goal is to obtain the high-purity plasma proteins, which are used in the production and processing process for the manufacturing of Biotest products. The routine production process intended for large scale production must generate over long time periods end products that consistently meet the highest quality and safety requirements. Largescale manufacturing of products can start only once this is ensured and the process is inspected and approved by a government agency.

VALUE CREATION IN BIOTEST PRODUCTION

The Biotest production is located at the Dreieich headquarters. In future, this location will become even more important for the company. By 2020, the company plans to double production capacities in Dreieich in the context of the Biotest Next Level (BNL) project.

The first step in the production of all Biotest products is the so called plasma fractionation. In this process, the supplied plasma is first thawed at low temperature.

Then the human blood plasma is separated into the individual protein components (fractions) by repeated precipitations with alcohol at different concentrations. The fractions containing the various proteins of the plasma are each generated by using large filter presses.

The further purification of the fractions, for instance for manufacturing immunoglobulin, is performed by means of cation exchange chromatography. This process ensures high purity while maintaining the natural antibody structure as well as their functionality. At a defined pH value, the positively charged IgG molecules bind to the negatively charged column matrix. All other, undesired molecules pass the column and are discarded. The IgG molecules are then gently released from the matrix and collected as a pure eluate.

Plasma production at Biotest includes four virus inactivation steps. The last step in this process is a nanofiltration (20 nm), which is performed to remove even smallest particles or viruses from the solution.

The protein fractions generated through plasma fractionation are the raw material for the Biotest product groups of immunoglobulins, hyperimmunoglobulins, factor VIII, IX and albumin. The various product groups include the individual products such as Intratect[®], Hepatect[®], Haemoctin[®], or Albiomin[®], which in turn are used for different indications. The applications include rare diseases such as immunodeficiency, prophylaxis of hepatitis B virus reinfection, clotting disorders and protein deficiency.

The throughput time from the plasma donation to the finished drugs is typically six to eight months.

PRODUCTION DATA

- > 1,800 employees work in the production of plasma proteins and in the plasma collection
- > The production site is in Dreieich, Germany
- > 1.3 million litres of blood plasma can be processed annually, with the capacity expansion in the context of Biotest Next level, the volume shall increase to more than 2.7 million litres annually
- > Potential expansion of the product portfolio and efficiency increases: In future, five instead of the current three product lines shall be obtained from a litre of plasma
- > Biotest currently manufactures 12 products for the indication areas haematology, clinical immunology and intensive care medicine



THE INTRATECT® MANUFACTURING PROCESS

Intratect[®] is a drug obtained from human blood plasma and contains immunoglobulins (antibodies) from more than one thousand plasma donors. The drug is administered to patients with a variety of infectious diseases, among others congenital immunoglobulin deficiency or Kawasaki syndrome. The latter is an inflammation of the blood vessels that typically affects children between the ages of two and five years and can be fatal if untreated.

In the manufacture of Intratect[®], it is essential for the natural antibody structure to be preserved unchanged to maintain their efficacy and immunobiological properties. At the same time, maximum purity and safety must be achieved, amongst others by inactivating any viruses that may be present. The Intratect procedure therefore includes four effective viral reduction steps. In the beginning, the so-called cryoprecipitate and clotting factors are separated, and fraction I/II/III is obtained via alcohol precipitation. Intratect[®] is manufactured from the subsequently separated fraction II. This is followed by treatment with octanoic acid / calcium acetate. This treatment serves as virus reduction but also as complete elimination of thrombogenic factors, meaning plasma proteins that may cause blood clots.

In the next step, the plasma runs through the solvent/detergent procedure, which has been globally established as an effective virus inactivation procedure. The mode of action is based on destruction of the viral envelope using a solvent and a detergent. An important advantage of the procedure is that plasma proteins are not affected.

The actual purification is then achieved through cation exchange chromatography. With this procedure, substances can be separated based on their charge and a purity of up to 100 percent immunoglobulins can be obtained.

Validation studies and test series prove the viral and prion safety of Intratect[®].



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"OUR INTERDISCIPLINARY PROJECT TEAMS ARE KEY FOR A SUCCESSFUL NEW PRODUCT."

>

INTERVIEW DR WOLFGANG MÖLLER

HEAD OF DEVELOPMENT PLASMA PROTEIN, ON BIOTEST PRODUCTION

Dr Wolfgang Möller, you have an academic background in biochemistry and years of experience as the Head of Development Plasma Proteins at Biotest. What is your personal motivation to work in the Production department of a pharmaceutical company?

DR WOLFGANG MÖLLER: I am motivated by developing the Biotest products and continuously improve the production processes. I feel that I have an interesting interface function in development, in which ethical and economic aspects must be reconciled. In addition, I am motivated by the challenge of making the production process as effective as possible, optimising quality and yields and minimising costs to make the drugs more affordable. After all, they are supposed to help as many people as possible.

What challenges do you face every day in the production of immunoglobulins?

DR WOLFGANG MÖLLER: Optimal tolerability of our products is an essential quality feature from the perspective of patients, treating physicians and us as the manufacturer. Therefore, it is a great challenge to preserve the tolerability of immunoglobulins throughout the production process and to separate undesired components which may be found in plasma, such as thrombogenic factors (factors that can cause blood clots). Another important task in the extraction of immunoglobulins is to achieve the maximum yield from the donated blood plasma. For ethical reasons, this is very important to us because the basis of our products is blood plasma which is donated by many volunteers. We do not take this willingness to donate plasma for granted, and we handle the donated plasma very responsibly. We try to use the donated plasma as effectively as possible. Achieving the maximum possible yield is important from an economic perspective as well, of course



DR WOLFGANG MÖLLER: In this industry, it takes an average of eight to ten years. But it always depends on the magnitude of the clinical studies. They may take many years, for instance if it is difficult to recruit patients. That differs by product.

What departments are involved in the development of new products?

DR WOLFGANG MÖLLER: When a new product is developed, we set up project groups that work specifically on the new product. These project groups consist of members from a multitude of departments such as Research and Development, Quality Control, Production but also Marketing. Marketing, for instance, is very closely involved in product development from the very beginning. Marketing staff members analyse the indications for which there is a high unmet medical need. Once an appropriate indication has been identified, the market environment is analysed. This supports the identification of unique selling points for a development project. A new product can become truly successful only if Biotest employees from a wide range of departments are involved and their broad range of knowledge can be incorporated into the process to bundle our expertise. This process has been successful in the past, and we continue to count on this type of teamwork in future as well. /.

What is unique about the production processes at Biotest?

DR WOLFGANG MÖLLER: It is an innovative achievement that Biotest manufactures not only immunoglobulin G-containing products but also immunoglobulin M-containing therapeutic agents, currently Pentaglobin[®] and in future IgM Concentrate. The production process we are designing for the production facility currently under construction within the Biotest Next Level expansion project is intended for the manufacture of both groups of products.

As part of BNL, Biotest has worked on the research and development of new products for some time. How long does it take from the idea for a new product to its launch in the market?

"Drug development as the interface between medical research and economic manufacture brings ethical and economic aspects in line with each other."

DR WOLFGANG MÖLLER

BIOTEST QUALITY SYSTEM IN PRODUCTION

All Biotest staff members in production work in strict compliance with Good Manufacturing Practices (GMP), which is a set of guidelines for the production of medicinal drugs, active agents, cosmetics, food and animal feed.

GMP regulations are specified in national and international policies and include requirements for hygiene, facilities, equipment, documentation, control, etc. Typically, the GMP guideline for the respective production location must be applied. However, if the site – for instance in Germany – also produces drugs to be delivered to another country – such as the US – the company must also comply with the GMP guidelines of that country. German and international authorities regularly verify compliance with GMP guidelines. The Darmstadt regional authority, for instance, performs annual inspections at the Dreieich site. In the past, Biotest always achieved very good results in official inspections.

Among other things, this is due to the strict quality management system which Biotest has established internally. This system ensures compliance with GMP guidelines along the entire value chain, from goods receipt to Production and Marketing and Sales. Specific processes are defined for this purpose. Critical work steps are monitored by a minimum of



two people, for instance. Raw materials, such as salts or solutions, are checked and examined. During the production process, employees continuously take samples and analyse them. Instructions and specifications for Biotest employees are worded clearly and comprehensibly to ensure that everyone knows exactly what to do.

Both the Biotest Quality Assurance department and specially trained employees who support the processes are responsible for the Biotest quality system. These employees perform regular inspections in the respective areas and check compliance with the quality systems. Furthermore, cooperating partners regularly carry out audits at Biotest.

Within the Biotest Group, the company has specified higher-level quality guidelines that must be followed by all employees.

The quality system itself is also analysed monthly by Biotest Quality Control. For this purpose, the department checks quality parameters, such as the number of deviations. These are compared to historic trend data, and any deviations are identified. The goal of this process is to continuously verify that the quality system works properly and is further developed as part of the continuous improvement process.

Biotest meets not only the strict quality requirements specified by the authorities but also voluntarily meets standards above and beyond those. One example is the QSEAL certificate, which Biotest was awarded by the PPTA. For this Biotest must meet very high quality standards, such as strict donor selection with regular donor examinations. In addition, Biotest uses only very high quality blood plasma from qualified collection centres.

Worldwide, more than one million people annually receive drugs made of human plasma. The safety, efficacy and quality of these drugs is absolutely essential. For Biotest, meeting highest quality standards is therefore one of the most important corporate goals.

OUR QUALITY REQUIREMENTS FOR PRODUCTS PRODUCED AT BIOTEST



The medicines manufactured by Biotest are based on a natural, biological raw material, meet the highest safety requirements and shall be highly effective.

"Biotest meets not only the strict quality requirements specified by the Paul-Ehrlich Institute and the U.S. Food & Drug Administration, but also meets even more rigorous quality standards."

DR BERNHARD EHMER

>

TAKING ADVANTAGE OF OPPORTUNITIES IN MARKETING AND SALES

The Biotest Group continuously expands its product range with new marketing authorisations and product launches. In the past financial year, the sales and marketing team achieved important progress once again. For instance, Biotest received marketing authorisations for various drugs in Brazil, includ-

BIOTEST FOR PATIENTS – EXPERIENCING FREEDOM AGAIN

Patient orientation is a key objective for Biotest. In addition to optimal efficacy, this includes good tolerability and a safe and easy application of Biotest products.

A good example is the follow-up care in hepatitis B-induced liver transplantation: A decisive factor for adequate function of the transplanted organ and longterm patient survival is graft protection from reinfection with the hepatitis B virus. For this purpose, Biotest developed the first subcutaneously applied hepatitis B immunoglobulin for the long-term treatment of patients after liver transplantation. It is administered using a safety syringe and simplifies treatment for the attending physician and the patient. Both the patient and the patient's family benefit: Instead of being administered via intravenous infusions, the product can be administered independently at home.

This means that the patient can be discharged from the hospital earlier and can start recovering at home in his or her family environment. Due to the syringe's safety mechanism, the patients family is protected from injury or infections. In the past, treatment could only be started six months after liver transplantation. In January 2016 Biotest received the marketing authorisation for use as early as one week after transplantation. ing Intratect[®] 50 g/l (5%), Fovepta[®] and Zutectra[®]. Albiomin[®] (20% and 5%) was sold for the first time in Switzerland, and Haemonine[®] was sold in Algeria for the first time as part of a public tender – just to mention a few marketing introductions. In addition, Biotest expanded its presence on markets such as Saudi Arabia, Libya, Bulgaria, Indonesia, Jordan, Australia, France, the Netherlands, Italy, Singapore and Oman. This proves once again that Biotest products are in demand worldwide and stand for high quality and safety.

Particularly good news for the marketing team are the most recent results of the SIPPET study* ("Survey of Inhibitors in Plasma-Products Exposed Toddlers") are. Their publication could impact the choice of product in the treatment of patients with severe haemophilia A. This inheritable disease leads to clotting disorder and is found predominantly in men.

The study answers a key question regarding the role played by the source of the factor VIII product. It shows that treating haemophilia A patients with recombinant factor VIII concentrates is associated with an 87% greater likelihood of the formation of inhibitors – antibodies against the administered factor VIII – than treatment with factor VIII gained from plasma, which contains the von Willebrand factor. This protein plays an important role in haemostasis.

One of Biotest's plasmatic products contains the physiological complex with the von Willebrand factor. The results of the published SIPPET study suggest that plasmatic products with this complex have a therapeutic advantage. /.

 * F. Peyvandi et. al., 2016. "A randomized trial of factor VIII and neutralizing antibodies in hemophilia A." N. Engl. J. Med., 2016; 374:2054–64 THE AFFILIATES TAKE OVER MARKETING AND DISTRIBUTION TASKS



BIOTEST MARKETS PRODUCTS ABROAD EITHER THROUGH ITS OWN COMPANIES OR IN COLLABORATION WITH LOCAL PARTNERS.

€ 553 million

in sales achieved by Biotest in 2016 – a growth of 3.5 % over the previous year

MARKETING AND SALES AT BIOTEST

- > In 2016, Biotest achieved sales of € 553 million an increase of 3.5% as compared to the previous year
- > Europe and the US are the most important markets for Biotest
- > In 2016, Biotest generated 80% of sales abroad
- > Worldwide, Biotest has 10 locations and collaborates with 75 distributors
- > Seven products are currently in the research pipeline
- > Biotest products are sold in more than 80 countries
- > Biotest counts on distribution cooperations
- Strategic cooperation is intended to achieve future competitive advantages

DR BERNHARD EHMER

"In 2016 as well, we were able to promote the international distribution of our products through new marketing authorisations and sales starts." 5

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SECURING VALUE CREATION IN THE LONG TERM WITH BIOTEST NEXT LEVEL

INTERVIEW DR MATHIAS BEHRMANN

BIOTEST PROJECT MANAGER

Which progress was achieved in 2016 and early 2017 with regard to Biotest Next Level?

DR MATHIAS BEHRMANN: For one thing, the shell and interior construction are mostly complete and we also started to install the first production equipment in the building. In addition, the infrastructure that supplies the building and production plants, such as ultrapure water generators, cooling units, hot water systems and the cooling water supply system, was installed and commissioned. Furthermore, a water laboratory was put into operation in which the sterile ultra-pure media needed for production will be continuously monitored. In this laboratory, a robot processes the numerous water samples by opening the sample vessels and automatically placing them in the various analysis systems, for instance to determine microbial counts.

What are the next important steps?

DR MATHIAS BEHRMANN: After completing the construction of the new production building, we must set up and adjust all internal processes, such as thawing and stirring times in the production vessels for the large-scale production. This is part of the subproject "BNL Completion", which we started in early 2017. In the past year, I made preparations for "BNL Completion" and set up schedules and resource plans, for instance, to prepare for the tasks to come.

What are some examples of internal processes that are part of the "BNL Completion" project phase?

DR MATHIAS BEHRMANN: The qualification and validation work for the production plants, for instance. For the former, Biotest must prove that the plants can achieve the required performance under real-life conditions. In the validation, we establish the production processes by manufacturing the first consistency lots. This production process is repeated several times because we must prove to the authorities that we can continuously generate the same flawless output.

"With BNL, we are greatly expanding our value chain."

DR MATHIAS BEHRMANN



Biotest

What is the biggest future challenge in the context of BNL?

DR MATHIAS BEHRMANN: We plan to have the new plants and processes inspected and approved by the Darmstadt regional authority in 2018 so we can receive the manufacturing license. Until 2019, we aim to collect all documents to be submitted to the Paul-Ehrlich Institute and the U.S. FDA to apply for the marketing authorisation of our new, next generation immunoglobulin product. For this purpose, we must simultaneously complete a wide variety of tasks, for instance the completion of the clinical studies for IgG Next Generation and compilation of the data of the consistency batches. This requires good coordination and very precise planning.

What opportunities are created by BNL?

DR MATHIAS BEHRMANN: As part of BNL, we generate added value for our patients in the form of new and even better products. These new products also benefit the company because we plan to sell IgM Concentrate and IgG Next Generation also in the US, a very high-priced market. Under profitability aspects, this makes very good sense for the company. As part of BNL, we are also restructuring our processes, increasing the exchange between employees and work together even better and more effectively. However, the project's most important opportunity is certainly the doubling of our production capacities – which represents huge progress. With BNL, we are considerably expanding our value chain.

BIOTEST NEXT LEVEL

- > Total investments of more than € 250 million at the Dreieich site
- > Creation of 300 new jobs
- > Doubling of the production capacity
- > Expansion of the product portfolio
- Increase of profitability through better yields in the production process
- > Project to be completed by 2020

> MILESTONES OF BIOTEST NEXT LEVEL

2017

- > Commissioning of the laboratories
- > Installation of all production plants

2018

- > Manufacturing licence by the Darmstadt regional authority
- > Manufacture of the consistency batches
- > Stability testing of the consistency batches for six months

2019

- > Submission of all data for the marketing authorisation of IgG Next Generation at Paul-Ehrlich Institute and FDA
- > Approval inspection by the U.S. FDA
- > Start-up of the production process

THE BIOTEST SHARE

In the 2016 financial year, the Biotest's ordinary and preference shares ranged widely and ended the year well above their lowest levels. Up to the beginning of February, weakening economic growth in China unsettled investors and led to considerable price declines on stock markets worldwide. The Biotest shares were unable to defy the negative overall market. The prices of the ordinary and preference shares decreased to a greater extent than the SDAX comparative index due to the after-effects of impairment in the third quarter of 2015. In early February 2016, ordinary and preference shares both reached their lowest prices for the year at € 10.30 and € 11.70 respectively. However, they had significantly recovered again by April, when they were temporarily up on the start of the year. This was amongst others due to the increase of the guidance for 2016. However, this price level could not be maintained over the rest of the year. The Xetra closing price of the ordinary share on 30 December 2016 was € 15.90, 15.0% below the closing price on 30 December 2015. Biotest's preference share ended the year at € 13.39 in Xetra trading, 13.1% below the closing price on 30 December 2015. Over the year 2016, the shares therefore performed worse than the SDAX comparative index (+2.8%).

Biotest AG is listed in the Prime Standard of Deutsche Börse AG, the segment with the highest transparency standards. The preference shares have been listed on the SDAX since 2007. Biotest AG is one of the 50 largest industry stocks below the MDAX. On 30 December 2016, the final trading day of the financial year, Biotest's market capitalisation reached € 579.5 million. On average, 56,451 Biotest preference shares were traded on the Xetra trading system per day in 2016. An important objective of Biotest AG's investor relations work is to provide the capital market with comprehensive information about the corporate strategy, which is focused on sustainable value growth. In addition, Biotest strengthens trust through a policy of providing honest, complete and timely information to investors and the public. As well as press and ad hoc releases and direct dialogue with investors, this also includes close and continuous communication with analysts and the economic and financial media.

The financial statements press conference in the spring and the press and analyst conference in the autumn, participation in international investor conferences, the hosting of road shows and individual meetings with investors are fixed components of the capital market communication. The Investor Relations pages of the Biotest website provide up-to-date and detailed information targeted at shareholders and potential investors alike.

Share analysts from various renowned banks and investment firms follow the performance of Biotest AG and publish regular research studies. At the end of the year, the forecasted price target for Biotest preference shares was between \notin 16.00 and \notin 25.00. Most of the recommendations were to "buy" or "hold".

After the exceptional year 2015, Biotest is returning to its long-term dividend policy. For the 2016 financial year, the Annual General Meeting will propose a dividend of \notin 0.05 per ordinary share and \notin 0.07 per preference share. /.

"We thank our investors for their trust and are confident that the progress in our Biotest Next Level expansion project will make our share an attractive investment."

> DR MICHAEL RAMROTH, Chief Financial Officer



OVERVIEW OF 2016

BIOTEST GROUP		2016*	2015*	Change in %
Revenue	in € million	553.1	534.6	3.5
thereof:				
Germany	in € million	108.3	123.3	-12.2
Rest of world	in € million	444.8	411.3	8.1
thereof:				
Therapy	in € million	346.8	359.6	-3.6
Plasma & Services	in € million	199.3	166.4	19.8
Other Segments	in € million	7.0	8.6	-18.6
EBITDA	in€million	86.8	59.3	46.4
Operating profit (EBIT)	in € million	63.9	37.3	71.3
EBIT in % of revenue	%	11.6	7.0	
Adjusted operating earnings (EBIT)**	in € million	112.9	110.7	2.0
Earnings before taxes	in € million	52.7	34.8	51.4
Earnings after taxes	in € million	34.5	27.0	27.8
Structure of expenses:				
Personnel expenses	in € million	156.0	138.0	13.0
Research and development costs	in € million	48.5	78.5	-38.2
Research and development costs in % of revenue	%	8.8	14.7	
Capital expenditure in property, plant and equipment and intangible assets	in € million	152.5	109.9	38.8
Financing:				
Cash flow from operating activities	in € million	74.7	55.8	33.9
Depreciation and amotisation	in€million		22.0	22.0
Equity (as of 31 December)	in€million	360.7	412.3	-12.5
Equity ratio (as of 31 December)	%	38.7	42.8	
Balance sheet total (as of 31 December)	in € million	932.8	962.7	-3.1
Employees (full-time equivalents as of 31 December)	amount	2,527	2,271	11.3
Earnings per share	€	0.86	0.67	28.4

Continuing Operations
** Derivation page 16 annual report Biotest AG

2016 FACTS & FIGURES

BALANCE SHEET STRUCTURE



REVENUE BY REGION*

EMPLOYEES (full time equivalents)



* Revenue in the continuing operations

DIVIDEND PER SHARE in €

	2016*	2015	2014	2013	2012
Ordinary shares	0.05	0.02	0.20	0.19	0.17
Preference shares	0.07	0.04	0.22	0.21	0.19

* A dividend of € 0.05 per ordinary share and € 0.07 per preference share for the financial year 2016 will be proposed to the annual shareholders' meeting.

CONSOLIDATED STATEMENT OF INCOME

of the Biotest Group for the period from 1 January to 31 December 2016

Revenue 5531 5446 Cost of sales -3496 -3257 Gross profit 2083 2089 Other operating income 4.0 2.6 Marketing and distribution costs -527 -531 Administative expenses -352 -330 Research and development costs -445.5 -725 Operating profit 63.9 337.3 Financial income -72 -3.6 Operating profit 63.9 37.3 Financial income -40.0 3.6 Financial result -12.6 -4.5 Income from joint ventures 1.4 2.0 Earnings after taxes -18.2 -7.8 Dircome taxes -18.2 -7.8 Earnings after taxes from continuing operations 34.5 22.0 Earnings after taxes from discontinued operations -80.2 -109.5 Earnings after taxes from discontinued operations -80.2 -109.5 Owhich from discontinued operations -0.1 - Of which from discontinued operations -0.1 - Of which from dis	in € million	2016	2015
Cost of sales349.6325.7Gross profit20.5206.9Other operating income4.02.6Marketing and distribution costs55.755.1Administrative expenses35.238.0Research and development costs48.578.5Operating profit6.8.33.73.3Operating profit6.8.33.73.3Operating profit26.6-42.9Financial expenses36.642.9Financial result12.64.5Income form joint ventures12.64.5Income form joint ventures12.64.5Earnings after taxes from continuing operations34.827.0Earnings after taxes from discontinued operations36.20.05.5Earnings after taxes from continuing operations4.5.82.5.7Introm taxes1.122.002.77Attributable to:	Revenue	553.1	534.6
Gross profit 203.5 208.9 Other operating income 4.0 2.6 Marketing and distribution costs -52.7 -59.1 Administrative expenses -35.2 -33.0 Research and development costs -48.5 -77.2 Operating expenses -7.2 -3.6 Operating profit 63.9 97.3 Financial income 24.0 38.4 Financial expenses -7.2 -3.6 Financial result -41.6 -44.5 Income from joint ventures 1.4 2.0 Earnings before taxes -18.2 -7.8 Income taxes -18.2 -7.8 Earnings after taxes from ontinuing operations -45.5 20.9 Earnings after taxes -45.7 -82.5 Of which from discontinued operations -80.2 -109.5 Earnings after taxes -0.17 -2.00 Of which from discontinued operations -80.2 -109.5 Non-controlling interests 0.1 - of which from discontinued operations -0.02 -00.02 Of which fro	Cost of sales		-325.7
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Research and development costs-44.5-72.5Other operating expenses-7.2-3.6Operating profit63.99.73.3Financial expenses-36.6-42.0Financial expenses-36.6-42.0Financial expenses-36.6-42.9Income from joint ventures1.42.0Earnings before taxes52.734.8Income taxes-18.2-7.8Earnings after taxes from continuing operations-80.2-10.95Earnings after taxes from discontinued operations-80.2-10.95Earnings after taxes from continuing operations-45.8-82.5Of which from continuing operations-45.8-82.5of which from continuing operations-45.8-82.5of which from continuing operations0.1-of which from continuing operationsEarnings after taxes-11.17-2.2.0of which from continuing operationsOf which from discontinued operationsOf which from continuing operationsOf which from discontinued operationsOf which from continuing operationsOf which from continuing operationsOf which from continuing operations- </td <td>Administrative expenses</td> <td>-35.2</td> <td>-33.0</td>	Administrative expenses	-35.2	-33.0
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Operating profit 63.9 37.3 Financial income 24.0 38.4 Financial expenses -36.6 -42.9 Financial result -12.6 -4.5 Income from joint ventures 1.4 2.0 Earnings before taxes 52.7 34.8 Income taxes -18.2 -7.8 Earnings after taxes from continuing operations -45.5 -10.9 Earnings after taxes from discontinued operations -80.2 -10.9 Earnings after taxes from discontinued operations -80.2 -10.9 Equity holders of the parent -45.8 -82.5 of which from continuing operations -34.4 27.0 of which from continuing operations -45.8 -82.5 Non-controlling interests -0.1 - of which from continuing operations -1.17 - of which from discontinued operations -0.1 - of which from discontinued operations -1.17 - of which from discontinued operations -0.2 - of which from discontinue	Other operating expenses	-7.2	-3.6
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Financial expenses -36.6 -42.9 Financial result -12.6 -44.5 Income from joint ventures 1.4 2.0 Earnings before taxes 52.7 34.8 Income taxes -18.2 -7.8 Earnings after taxes from continuing operations 34.5 27.0 Earnings after taxes from discontinued operations -80.2 -100.5 Earnings after taxes from discontinued operations -45.7 -82.5 Attributable to: -45.8 -82.5 Individual operations -10.1 - Individual operations -80.2 -109.5 Non-controlling interests 0.1 - In		24.0	38.4
Financial result -12.6 -4.5 Income from joint ventures 1.4 2.0 Earnings before taxes 52.7 34.8 Income taxes -18.2 -7.8 Income taxes -18.2 -7.8 Earnings after taxes from continuing operations 34.5 27.0 Earnings after taxes -45.7 -80.2 Attributable to: -45.8 -82.5 of which from continuing operations -80.2 -109.5 Non-controlling interests 0.01 - of which from discontinued operations -80.2 -109.5 Non-controlling interests 0.01 - of which from discontinued operations - - <td>Financial expenses</td> <td></td> <td>-42.9</td>	Financial expenses		-42.9
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of which from discontinued operations -2.03 -2.77	of which from continuing operations	0.88	0.69
	of which from discontinued operations	-2.03	-2.77

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

of the Biotest Group as of 31 December 2016

 in € million	31 December 2016	31 December 2015
ASSETS		
Non-current assets		
Intangible assets		44.7
Property plant and equipment		317.2
Investment property		-
Investments in joint ventures		3 5
Other accets		5.5
Other financial ascets		1.0
		0.8
		375.0
	405.0	575.9
Current assets		
Inventories	170.8	218.7
Trade receivables	163.8	173.9
Current income tax assets	5.7	5.8
Other assets	16.7	13.8
Other financial assets	12.2	120.8
Cash and cash equivalents	72.9	53.8
	442.1	586.8
Assets from discontinued operations	25.1	0.0
Total current assets	467.2	586.8
Total assets	932.8	962.7
EOUITY AND LIABILITIES		
Equity		
Subscribed capital		39.6
Share premium		219.8
Retained earnings		215.0
Share of profit or loss attributable to equity holders of the parent		
Faulty attributable to equity holders of the parent		412.2
Non-controlling interests		
		412.2
		412.5
Non-current liabilities		
Provisions for pensions and similar obligations		72.6
Other provisions		6.6
Financial liabilities		335.5
Other liabilities		2.2
Deferred tax liabilities	2.5	7.7
Total non-current liabilities	426.1	424.6
Current liabilities		
Other provisions	35.6	27.5
Current income tax liabilities	3.5	4.3
Financial liabilities	16.2	9.1
Trade payables	62.8	53.1
Other liabilities	27.9	31.8
Total current liabilities		125.8
Total liabilities	572.1	550.4
Total equity and liabilities	932.8	962.7
· · · · · · · · · · · · · · · · · · ·		552.7

CONSOLIDATED CASH FLOW STATEMENT

of the Biotest Group for the period from 1 January to 31 December 2016

in € million	2016	2015
Earnings before taxes	52.7	34.8
Depreciation, amortisation and impairment of intangible assets and property, plant and equipment	22.9	22.0
Other non-cash income and expense items	0.8	6.5
Income from joint ventures	-1.4	-2.0
Losses from the disposal of fixed assets	0.4	0.7
Changes in pension provisions	2.3	1.4
Financial result	12.6	4.5
Operating cash flow before changes in working capital	90.3	67.9
Changes in other provisions	8.8	2.5
Changes in inventories, receivables and other assets	24.6	29.8
Changes in liabilities from deferred revenue		-2.5
Changes in trade payables and other liabilities	-17.9	-20.5
Cash flow from changes in working capital	15.5	9.3
Interest paid	-10.6	-6.1
Taxes paid	-20.5	-15.3
Cash flow from operating activities from continuing operations	74.7	55.8
Cash flow from operating activities from discontinued operations	-8.8	-17.7
Cash flow from operating activities	65.9	38.1
Cash received on the disposal of fixed assets		0.1
Payments for investments in fixed assets	-143.9	-94.0
Cash received on the disposal of other financial assets	110.6	
Payments for investments in other financial assets		-60.1
Interest received	0.8	0.6
Cash flow from investing activities from continuing operations	-32.5	-153.4
Cash flow from investing activities from discontinued operations	-1.5	-6.7
Cash flow from investing activities	-34.0	-160.1
Dividend payments for the previous year	-1.2	-8.3
Payments into cash and cash equivalents from discontinued operations	-11.9	
Proceeds from the assumption offinancial liabilities	9.9	10.5
Payments for the redemption of financial liabilities	-10.4	-6.8
Cash flow from financing activities from continuing operations	-13.6	-4.6
Cash flow from financing activities from discontinued operations	11.9	-
Cash flow from financing activities	-1.7	-4.6
Cash changes in cash and cash equivalents	30.2	-126.6
Exchange rate-related changes in cash and cash equivalents	0.8	1.0
Cash and cash equivalents on 1 January	53.8	179.4
Cash and cash equivalents on 31 December	84.8	53.8
Less cash and cash equivalents at end of period from discontinued operations	11.9	
Cash and cash equivalents at end of period from continuing operations	72.9	53.8

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FINANCIAL CALENDAR CONTACT

10 MAY 2017 Three-month report for 2017

10 MAY 2017 Annual Shareholders' Meeting

14 AUGUST 2017 Half-year report for 2017

14 NOVEMBER 2017 Nine-month report for 2016 Analysts Conference The 2016 Annual Report contains a detailed presentation of the development and perspectives of Biotest. It is available for download

on the Biotest website.

On <u>www.biotest.com</u> you will also find comprehensive and current information on companies, projects and markets. You can view all financial announcements as well as the Annual Reports and interim reports in the Investor Relations section.

Please contact us if you have any questions:

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ACKNOWLEDGEMENTS

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CONCEPT AND DESIGN

Scheufele Hesse Eigler Kommunikationsagentur GmbH, Frankfurt am Main, Germany

EDITORIAL OFFICE AND PROJECT MANAGEMENT

cometis AG, Wiesbaden, Germany

PHOTOGRAPHY

Simone Kiefer, Dreieich, Germany (Cover, Page 2, 8, 14, 17, 18, 19, 25, 30)

Stephan Minx, Fürth, Germany (Page 21, 22, 23, 25)

Biotest (Page 7, 11, 12, 15, 18)

Getty Images (Page 11, top)

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PRINTING

Druckhaus Becker GmbH, Ober-Ramstadt, Germany

KEY FIGURES

		2016*	2015*	2014	2013	2012*
Revenue	in € million	553.1	534.6	582.0	500.8	440.0
thereof:						
Germany	in € million	108.3	123.3	106.0	93.4	89.4
Rest of world	in€million	444.8	411.3	476.0	407.4	350.6
thereof:						
Therapy	in € million	346.8	359.6	409.8	386.2	330.9
Plasma & Services	in € million	199.3	166.4	157.0	102.5	97
Other Segments	in € million	7.0	8.6	15.2	12.1	12.1
EBITDA	in € million	86.8	59.3	85.9	85.6	76.1
Operating profit (EBIT)	in € million	63.9	37.3	53.4	53.8	44.7
EBIT in % of revenue	%	11.6	7.0	9.2	10.7	10.2
Earnings before taxes	in€million	52.7	34.8	46.9	47.8	36.5
Earnings after taxes	in € million	34.5	27.0	19.2	32.0	23.1
Structure of expenses:	·					
Personnel expenses	in € million	156.0	138.0	138.2	126.2	116.1
Research and development costs	in € million	48.5	78.5	67.2	64.6	51.4
Research and development costs in % of revenue	%	8.8	14.7	11.5	12.9	11.7
Capital expenditure in property, plant and equipment and intangible assets	in € million	138.0	109.9	47.1	42.9	34.5
Financing:						
Cash flow from operating activities	in € million	74.7	55.8	-11.4	-7.2	34.7
Depreciation and amotisation	in € million		22.0	32.5	31.8	31.4
Equity (as of 31 December)	in € million	360.7	412.3	480.2	460.7	369.4
Equity ratio (as of 31 December)	%	38.7	42.8	46.5	52.0	54.1
Balance sheet total (as of 31 December)	in € million	932.8	962.7	1.032.6	886.5	682.3
Employees (full-time equivalents as of 31 December)	amount	2,527	2,271	2,158	1,997	1,727
Earnings per share	€	0.86	0.67	1.46	2.57	1.94

* Continuing Operations



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