

VISION. FOCUS. TEAM SPIRIT. | Magazine for Annual Report 2015



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"Biotest Next Level is a big change for all divisions of the company."

DR BERNHARD EHMER

# VISION. FOCUS. TEAM SPIRIT.



# "BY EXPANDING THE PORTFOLIO, WE WILL SIGNIFICANTLY IMPROVE OUR PROFITABILITY AND THEREBY INCREASE OUR COMPETITIVENESS."

.......

INTERVIEWS WITH THE BOARD OF MANAGEMENT

2015 was an eventful year for Biotest. Which events shaped the company the most, also with regard to sales and earnings performance?

DR EHMER: It was indeed a difficult year for all of us. We had to suffer unexpected setbacks concerning the results of the clinical phase II b study of tregalizumab (BT-061), the monoclonal antibody in clinical development in the indication rheumatoid arthritis. Then there were the extraordinary impairments in the third quarter. Both events led to a reformulation of our strategy. We want to increase our focus on the plasma protein business in the future. In this context, it is good that in the course of our expansion project Biotest Next Level we achieved all of our targets for 2015.

DR RAMROTH: Biotest still has rock-solid financing and continues to generate positive operating cash flows despite the extraordinary impairments in the 2015 financial year. The equity ratio was at healthy 42.8% at the end of the year and the expansion project Biotest Next Level and all development projects are financed. Last year was turbulent for us. However, we have taken this as a reason to reposition ourselves and to place a very strong focus on the plasma business.

DR EHMER: We want to concentrate even more on our end customers. Therefore we are planning to establish distribution and marketing partnerships outside of Europe. This also applies to the USA. At the start of 2016, we concluded an exclusive cooperation agreement with Kedrion Biopharma

through our US subsidiary Biotest Pharmaceuticals in order to expand the possibilities for distributing the immunoglobulin Bivigam®, which is produced there. Kedrion Biopharma intends to distribute 30% more units of Bivigam® in the first year than BPC did in the 2015 financial year.

Let's take a look at the future: What do you consider to be at the centre of the company's future development?

DR EHMER: This is clearly Biotest Next Level. In addition to doubling production capacity, the focus is mainly on expanding the product portfolio and thereby increasing profitability. Our goal is to produce five instead of three products from the plasma raw material in the future. As approximately 60% of the production costs account for the plasma raw material, expanding the portfolio will enable us to use the raw material more effectively, significantly improve our profitability and thereby increase our competitiveness.

DR FLOß: We are well on our way with Biotest Next Level. The costs and the progress of the implementation are well on target. We completed the shell of the new production facility in the autumn of 2015. We have hired new employees and recruited more trainees to support the installation and expansion of the facilities so that they can then be commissioned by qualified personnel. Further important measures for our future growth include focussing on the plasma business, stabilising the US business, implementing strict cost management and increasing our cooperation with partners.



"Biotest Next Level is the key to our future growth."

# Which changes occur within the project Biotest Next Level?

DR FLOG: The first steps are, of course, the new buildings that are being constructed in Dreieich. However, this is not the most important change leading the project to success. The new optimised production processes will result in higher efficiency, new products, global marketing authorisations and further possibilities for distribution.

DR RAMROTH: The sense of unity is a top priority at Biotest. We need to bundle our strengths and ideas to step forward with determination, both in Dreieich and with our colleagues all over the world. In this context, it is also important that many new employees are trained and integrated into the existing structures. Biotest intends to maintain a strong sense of unity in the future, too.

**DR EHMER:** We are aware that our employees are our assets and our most important resource. In accordance with our self-conception, each individual contributes to the company's overall success. I am convinced of the great professional expertise of Biotest employees and their good teamwork. This is the key aspect for the success of Biotest Next Level.

Biotest and ADMA Biologics announced last year that they intend to continue their cooperation. What are the opportunities for the future?

DR EHMER: Biotest and ADMA have been working together for many years and we will further continue our cooperation. The primary focus of our cooperation is on the product RSV (respiratory syncytial virus) hyperimmunoglobulin RI-002. Biotest is supporting the production process by providing plasma and services. We have acquired the distribution licence for Europe and other selected international markets. Following a successful phase III study, ADMA submitted an application of approval to the United States Food and Drug Administration (FDA) this year.

# Are further cooperations planned?

DR FLOß: Yes, we are seeking to form strategic partnerships with suitable partners in selected areas and specific business segments, in particular in our core business of plasma products. The exclusive cooperation agreement with Kedrion Biopharma Inc., that we signed in January 2016, is a good example for such a partnership. Being an established manufacturer and distributor on the US market with a well-developed marketing and distribution organisation, Kedrion Biopharma is an ideal partner for Biotest and will take over the distribution of Bivigam® in the USA until December 31, 2022. We also intend to form partnerships for the future development and marketing in the area of monoclonal antibodies following the achievement of relevant study end points in the respective studies.

"The market for plasma proteins is experiencing dynamic growth. Biotest Next Level will allow us to benefit from this even more in the future."

"New markets, new technologies and new products were and still are key to our growth strategy."

DR MICHAEL RAMROTH

One of the most important research projects is the development of IgM Concentrate. What significant progress was made here?

DR EHMER: The clinical phase II study of IgM Concentrate, an immunoglobulin product enriched with IgM, showed encouraging results for life-threatening pneumonia. The study was conducted in patients with severe community-acquired pneumonia (sCAP = severe Community Acquired Pneumonia). This group of patients has a high mortality rate and includes severely ill patients in intensive care units. We were able to identify a clear trend in terms of reducing the duration of artificial ventilation as well as mortality rates. Detailed analyses have shown encouraging results that will be used in the preparation of upcoming studies. We are currently preparing a clinical phase III on the basis of the results of the previous phase II study.

Dr Ramroth, could you give us an outlook on the future and the coming year in particular?

DR RAMROTH: Since we made the decision to expand in 2013, we have laid the foundation for our future growth with Biotest Next Level. The expansion of the product portfolio for the plasma business will lead to a considerable increase of the future earnings potential. New markets, new technologies and new products were and still are the key to our growth strategy. I predict good overall future business performance. The expected sales growth for 2016 is in the low single-digit percentage range. Despite the considerable costs for the expansion of our business and due to positive effects of our cooperation with Kedrion, our EBIT forecast is in the range of € 30 million.

Dr Bernhard Ehmer

Dr Michael Ramroth

Dr Georg Floß

# FINANCIAL YEAR 2015 HIGHLIGHTS

<u>3 February:</u> Biotest opens a plasma collection centre in Jacksonville, North Carolina, USA

13 April: Biotest opens a plasma collection centre in Conway, Arkansas, USA

23 April: Biotest presents positive interim results of Civacir® at the 50<sup>th</sup> International Liver Conference in Vienna, Austria

 $\underline{24 \text{ April:}}$  Biotest phase II b study with tregalizumab (BT-061) has not met the primary endpoint

<u>7 May:</u> The annual shareholders' meeting passes dividend distribution resolution of €  $0.20^*$  per ordinary share and €  $0.22^*$  per preference share

<u>24 June:</u> Biotest and AbbVie terminate their cooperation on tregalizumab (BT-061) after the phase II b study did not meet the primary endpoint

<u>30 June:</u> IgM Concentrate developed by Biotest shows encouraging results for life-threatening pneumonia

<u>15 July:</u> 1:3 share split, and a capital increase from company funds is carried out to realize, that each ordinary and preference share has a proportional amount of the share capital of € 1.00. The listing and portfolio holdings are adapted accordingly

<u>30 September:</u> Biotest and ADMA Biologics continue their cooperation on RSV (respiratory syncytial virus)-hyperimmunoglobulin RI-002 after completion of a phase III study and submission of the data to the FDA (United States Food and Drug Administration)

<u>6 October:</u> Start of the clinical trial in the phase II a study (no. 990) of the monoclonal antibody BT-063 in the lead indication Systemic Lupus Erythematosus (SLE)

20 October: Biotest incurs an extraordinary impairment of € 84 million

23 November: Biotest receives a positive recommendation from the European Committee for Medicinal Products for Human Use (CHMP) for the early use of Zutectra® after a liver transplantation

<u>1 December:</u> Start of phase III study with the fibrinogen concentrate for congenital fibrinogen deficiency

<u>10 December:</u> Initial operation of the new plasma goods receipt area and the new virological laboratories

<u>21 December:</u> Biotest receives the marketing authorisation for the early use of Zutectra® after a liver transplantation

<sup>\*</sup>  $\bullet$  0.60 per ordinary share and  $\bullet$  0.66 per preference share based on the old number of shares before the share split on July 15, 2015

# <u>7 May</u>

€ 0.20\*

Biotest AG paid a dividend of € 0.20\* per ordinary share in 2015

€ 0.22\*

Biotest AG distributed € 0.22\* per share to holders of preference shares





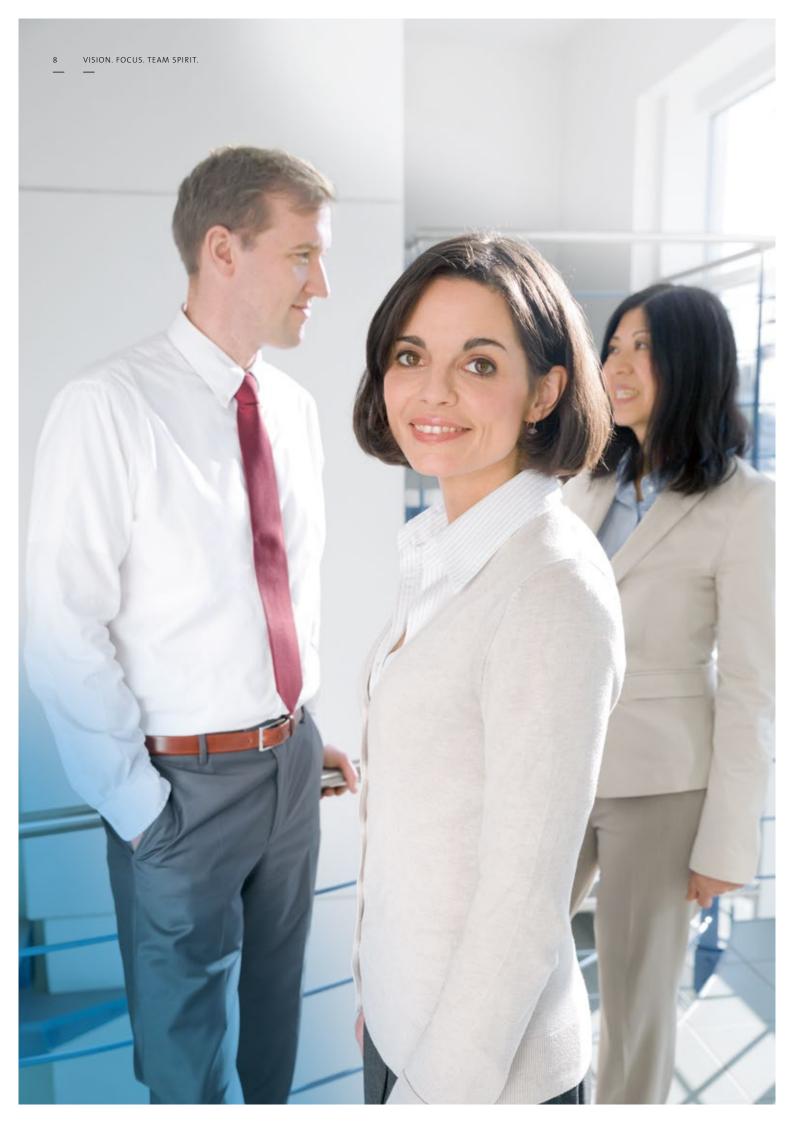
# 21 December



Biotest receives
the marketing approval for
the use of Zutectra® one
week after transplantation
for the European Union.









<u>Vision.</u> We have a clearly defined goal for the future. To us, Biotest Next Level first and foremost implies a new quality and profitability of our plasma protein business because from 2019/20. The new production process will enable us to produce not just three, but five products from one litre of the valuable raw material of plasma and to market them globally. Scaling effects and the doubling of capacity will contribute to higher profitability. This also opens up new prospects for up to 300 additional employees who will support our existing staff in reaching the goals within of Biotest Next Level.

>

<u>Focus.</u> With Biotest Next Level we are focusing on our longtime and successful core business. Biotest Next Level represents a further development of our product portfolio. We are using existing valuable resources in order to show profitable growth in the future. It is our goal to further strengthen our position on the global market with the clear aim of making pharmaceutical products made in Dreieich available to all important markets worldwide.

>

<u>Team Spirit</u>. Team spirit is an integral part of the Biotest corporate culture. Intensive cooperation on a national and international level is the precondition for the successful implementation of projects even with the dimension of Biotest Next Level. We support creative ideas from committed employees in order to benefit from innovation within the company.

# HEADING FOR THE NEXT LEVEL: GOALS FOR THE FUTURE

Biotest Next Level – three words that stand for many things: for an expansion of the product portfolio, an increase in efficiency, a transformation of the company and a cultural change. With Biotest Next Level, the company intends to expand the product range while increasing profitability at the same time. Concerning the expansion of its product portfolio, Biotest is focussing on the plasma business, a market that is showing significant growth and a great deal of potential. In order to expand production, Biotest is investing approximately € 250 million in the construction of a new production facility in Dreieich and is creating 300 new jobs with its Biotest Next Level project. By expanding the production facility in Dreieich, the company is clearly committing itself to the Rhine-Main region – the home of Biotest and one of the strongest economic areas in Europe.

average. With modern manufacturing facilities and production processes five instead of three products will be produced from the same amount of raw material in the future.

An authorisation and certification from EU-authorities and the United States Food and Drug Administration (FDA) as well as from the EU authorities is being pursued for the Biotest Next Level manufacturing facility. Just like the requirements of the European authorities, the requirements for the FDA certifica-

The project is the company's reaction to the global in-

crease in the demand for immunoglobulins. These are

pharmaceutical products that are used, for example, to treat

immunodeficiencies. These products account for the largest

Up to now, Biotest has an annual production capacity of

5.5 tonnes of immunoglobulins. The capacity is to increase to

13 tonnes per year after a more than doubling of the capacity.

The company has set itself a clear target with the Biotest Next

Level: an increase in sales and an increase in profitability above

percentage share of sales.

from the EU authorities is being pursued for the Biotest Next Level manufacturing facility. Just like the requirements of the European authorities, the requirements for the FDA certification are high. The American FDA authority certifies the entire manufacturing facility, just like the European EMA authority and the German authorities, the Paul Ehrlich Institute and the Darmstadt Regional Government Commission. In addition, the individual products undergo separate marketing authorisation procedures. The FDA is responsible for the review and marketing authorisation of drugs for the American market, while the EMA is in charge of marketing authorisations for the European market.

By means of changes to and adaptations of the production process as well as the necessary documentation and qualification, products can be produced in Germany and then be approved for global marketing and sales in the future. By expanding the German production site, the company will be able to further decrease costs, realise economies of scale and, as a result, increase profitability. By this Biotest intends to strengthen its international competitiveness and future growth.

"The expansion of the production capacity within Biotest Next Level will be realised by a strong Biotest team."

DR GEORG FLOß

# FROM THREE PRODUCTS TO FIVE

#### **ALBIOMIN®**

- > <u>Action</u>: Albiomin® is administered, for example, to patients with blood volume depletion. The depletion can have various causes, such as severe burns or sepsis. Albiomin® is used mostly in emergency or intensive care medicine.
- > <u>Status quo</u>: The pre-product for Albiomin® is produced by Biotest AG in Dreieich, Germany, or its subsidiary, Biotest Pharmaceuticals Corp. in Boca Raton, Florida, USA. The final product is then manufactured at the production facility in Dreieich and distributed on the German market and abroad.





## IgM CONCENTRATE

- > <u>Action:</u> This unique preparation contains high titres of IgM antibodies. IgM has neutralizing, immunomodulating, and anti-inflammatory properties and supports the immune system. Therefore the IgM Concentrate represents a promissing therapeutic option for the treatment of different diseases.
- > <u>Status quo</u>: The recently completed analysis of the clinical phase II study of IgM Concentrate, conducted in patients with severe community-acquired pneumonia (sCAP), shows a clear trend in mortality reduction in a defined subpopulation. On the basis of these encouraging results Biotest, is currently preparing a phase III clinical study which will be initiated in the course of 2016/2017. In addition, Biotest is evaluating other potential applications of this unique product.

## Igg NEXT GENERATION

- > <u>Action</u>: The product is used to treat primary immune deficiencies (PID), secondary antibody deficiency syndromes and some autoimmune diseases. Patients with primary or secondary antibody deficiency need immunoglobulins to maintain their immunological defences and reduce their risk of infection. PID patients require lifelong treatment. In case of autoimmune diseases, the immune system attacks the patient's own body. This can lead to severe disorders of individual organ functions or to the failure of organ systems (including the immune system). Immunoglobulins have an anti-inflammatory effect, prevent the disease from progressing and assist the restoration of organ functions.
- > <u>Status quo:</u> Two pivotal trials for the marketing authorisation are scheduled to start in 2016. One trial in PID and one in primary immune thrombocytopenia (ITP).

#### **FIBRINOGEN**

- > Action: Fibrinogen is a clotting factor that is produced in the liver. It plays a central role in haemostasis and wound healing. A deficiency of the body's own fibrinogen leads to an impairment of the blood's ability to coagulate (form clots), resulting in hemorrhaging or thrombosis.
- > <u>Status quo</u>: The clinical phase III trial for congenital fibrinogen deficiency could be completed at the beginning of 2017. Biotest is currently planning further development in acquired fibrinogen deficiency.

# HAEMOCTIN®

- > <u>Action</u>: Haemoctin® is used to treat a blood clotting disorder also known as haemophilia A. Patients who suffer from this condition bleed for a significantly longer time when they are injured. In the worst case, even minor injuries can cause patients to bleed to death.
- > <u>Status quo:</u> Biotest introduced the factor VIII product (Haemoctin®) for haemophilia patients back in 1993.

# REQUIREMENT FOR A NEW LEVEL: THE FDA CERTIFICATION

With Biotest Next Level, the company has set itself an important strategic goal: Biotest intends to expand the production facility in Dreieich and sell the preparations produced globally. Biotest distributes its products on all 6 continents by now. The company maintains 10 group locations worldwide and in addition cooperates with 75 distributors.

WHAT IS THE FDA?

- > The FDA (U.S. Food and Drug Administration) is the official food control and drug licensing authority in the United States of America
- > The authority reports to the U.S. Department of Health and Human Services and is responsible for protecting public health
- > It monitors the safety and efficacy of, for example, drugs, medical devices and food

# CERTIFICATION REQUIREMENTS

- > The quality management system must meet the requirements of the Code of Federal Regulations (CFR). The Code of Federal Regulations comprises the administrative regulations passed by the federal agencies. Key points include production and process controls, corrective and preventive measures, product development and management responsibility
- > The company must have an office in the USA. Otherwise, it must appoint an official representative, known as the FDA US agent. The representative manages the approval procedure in the USA
- > The drug must be assigned to a specific product class

To put the strategic goal "From Dreieich to the world" into practice, Biotest must accomplish several important requirements: First, the manufacturing location needs to be certified by the American authority FDA and by German national regulatory authorities, such as the Regional Government Commission in Darmstadt.

Then, the newly developed products that are produced in the new facility must obtain a separate marketing authorisation from the various regulatory authorities.

Biotest requires these certifications as the basis to produce medications in Germany and then distribute them globally.

In order to obtain the FDA approval for the manufacturing location, Biotest must undergo a long and demanding process. The requirements of the FDA are similar to those of the European authority, but there are some special characteristics. These must be integrated in the quality management system. "The FDA attaches great value to documentation during the production and quality control of a product," Peter Seith, one of the employees responsible for the FDA certification at Biotest, explains. "The FDA expects a high degree of detail to prove that the quality standards are met, especially with regard to risk management."

Right from the start Biotest must submit numerous documents to the authority, for example the results of clinical studies, information on the building, the production process and the manufacturing facilities. The authority then conducts an on-site inspection. This involves an analysis of three complete and consecutive production runs for one drug. Ultimately, the product must always show an identically high quality to prove a consistent high-quality production process.

Following the initial certification, the company generally will be subject to a follow-up inspection every two years. This serves as continous monitoring whether the regulatory requirements are fulfilled. The other national authorities also conduct follow-up inspections on a regular basis. //

# FROM DREIEICH TO THE WORLD



"Biotest is represented with its products all over the world. On one hand, we have >10 group locations, on the other hand, we are working with a total of >75 distributors on >6 continents." 5

# BIOTEST NEXT LEVEL: THE LARGEST PROJECT IN COMPANY HISTORY

In mid-2013 the first excavators drove onto the construction site in Dreieich. The first project, the construction of the seven-storey car park with 700 parking spaces, was started. The building was inaugurated in April 2014. Construction was completed after just seven months. The site of the former employee car park was then free for the new production building and the power centre.

Biotest contracted strong partners for the construction of the production building, for example Drees & Sommer. The company coordinated the construction of the new European Central Bank in Frankfurt/Main. A total of approximately 100 companies are involved in planning and implementing the project. The timetable for the completion of the project is ambitious, and its implementation requires excellent organisation. Project management has introduced a system that displays and reveals all the steps for each operating company by the day (Lean Site Management). This helps to avoid potential conflicts. Around 300 employees from various construction companies and service providers work on the construction site every day.

This may appear confusing to laypersons at first, but there is a strict schedule. While the excavators were still driving around the site in 2015 and the drywall builders were still at work on one side of the production building, skilled workers were already starting on the glazing and part of the interior fittings on the other side. Behind the lively activity there is a great deal

of precision and extensive planning. In the autumn of 2015 the shell was completed and a roofing ceremony was held. The time schedule was therefore perfectly met. The structural and technical installations are to be completed by mid-2017.

The surface area of the new building is roughly the size of a soccer field,  $60 \times 100$  metres, and the usable floor space of around  $31,750 \, \text{m}^2$  is spread across seven storeys. The ventilation control centre is located on an additional level on the roof. This level included, the new building rises more than thirty metres above ground.

The building will contain manufacturing facilities, systems for producing high-purity media, storage for plasma and products, offices, changing areas, a cafeteria, as well as laboratories for the quality control of raw materials and finished products. Slightly less impressive in terms of its size, but just as important is the new power centre, which is being built next to the production building. This is where the waste water from the production building will be collected and purified before being diverted into the public sewage network. Emergency power systems will secure the production facility against power failure. A total of 68,000 cubic metres of earth were moved and roughly 22,000 cubic metres of concrete were used for the entire construction project. With the concrete alone 10 Olympic swimming pools could have been filled.



A new logistics centre is also being planned that will allow the capacity of the incoming and outgoing goods to be doubled. The new plasma goods receipt and the new virological laboratories were already inaugurated and commissioned last year.

All newly created buildings are characterised by their environmentally friendly construction using low-pollution and low-emission materials and energy-efficient operation. This is achieved by using highly insulated exterior building elements for the facade, triple glazing, special high-performance insulating material and, ultimately, energy-efficient building technology as well.

The environmentally friendly energy concept will allow Biotest to save a significantly on energy costs, for example for heating and electricity. This way, everybody wins. The strict energy concept helps to preserve the environment and reduces the costs for Biotest: By exceeding the energy requirements for new buildings stipulated by the legislator, Biotest has qualified for low-interest loans from the KfW Bank Group.

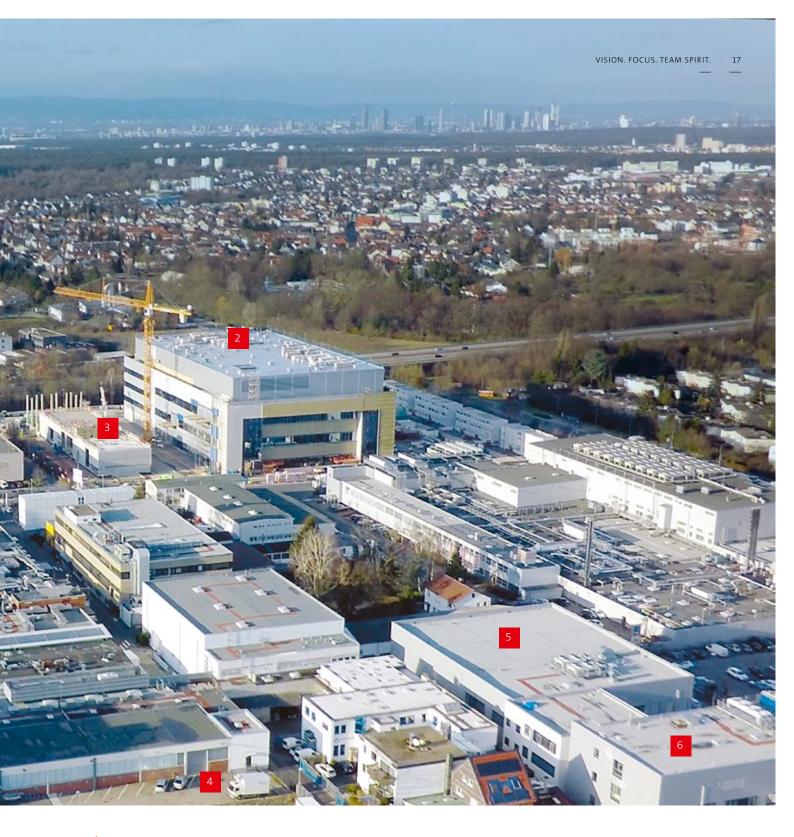
31,750 m<sup>2</sup>

of usable floor space is distributed across seven storeys.



"Biotest is planning to invest approximately € 250 million in the Dreieich location, thereby clearly committing itself to the Rhine-Main economic region."

DR BERNHARD EHMER



NEW BUILDINGS OF THE PRODUCTION EXPANSION OF BIOTEST NEXT LEVEL

- 1 Parking deck
- 2 Production building with plasma storage and quality control
- 3 Power centre
- 4 Planned logistics centre
- 5 Plasma goods receipt
- 6 Virological laboratories



# RESPONSIBILITY OF AND FOR EMPLOYEES

The construction site makes the transition of the company visible for everyone. In the course of the expansion, Biotest is adapting all internal processes to the double capacity. Approximately 300 new employees are needed in the different areas primarily chemical and pharmaceutical technicians, engineers and scientists. The Quality Assurance, Distribution and Human Resources departments also have a greater demand for new employees.

Biotest Next Level also implies that the company will be working on an even more global level in the future. The individual employees at the different locations will work together more closely and intensively. In this context, it is important to have a good network and good communication among the employees. Michael Moritz knows this very well. He is the manager of the Biotest Next Level project and thereby responsible for reaching the quality-, time-, and cost-targets.

#### MICHAEL MORITZ

"To me, Biotest Next Level is far more than just a project."



#### INTERVIEW WITH MICHAEL MORITZ

Project Manager, responsible for the new production facility and expansion of logistics

Mr. Moritz, you have been involved in the planning of Biotest Next Level right from the start and as the responsible project manager, you are at the heart of the action. How do you manage such a huge project?

MICHAEL MORITZ: There are more than 100 people actively involved in the project including Biotest employees and our partners of the project planning. In addition to that, there are roughly 300 construction site workers and around 80 contractors who will equip the new production facility from the individual laboratory device to the entire manufacturing facility. We are thinking in dimensions such as kilometres of piping and tonnes of stainless steel. We need more than 2,500 prefabricated components for the shell. Together with our partners, we have excellent expertise in the different specialist areas. Well-coordinated interdisciplinary communication with all parties involved and proactive management of quality, time and costs will be crucial for the success. This is made possible with the "Lean Site Management" project management tool. The entire building was planned using 3D simulation. The tool is also used to monitor the progress on the construction site. The continuous coordination of the project with "Lean Site Management" ensures that the construction project runs smoothly, i.e. the companies doing the work do not have to discuss who will work on what each day.".

What does Biotest Next Level mean to you personally?

MICHAEL MORITZ: I consider it an honour to manage this project. Its success will allow me to make an important contribution to shaping the future of Biotest. /.

# RECONCILING WORK





"For me as a young mother the compatibility of work and family is very important. I am very happy that Biotest offers such great working conditions."

HANNA ÉRI

Employee satisfaction and the compatibility of work and family are important aspects with regard to the planned company growth. Biotest wants to tie its employees to the company for the long term, e.g. by providing attractive jobs, employee benefits, further training and a good work-life balance. To make it easier for employees to combine work and family, Biotest opened a company daycare centre in summer 2015. The "BioNest" covers a surface area of 1,400 square metres, providing a generous amount of space for 80 children.

Hanna Éri, who has been working for Biotest for many years, appreciates the advantages of the new company daycare centre. She is originally from Hungary and was first employed at Biotest Hungaria Kft. She came to Germany to work in the financial department at the Group's headquarters in 2012. She has a two-year-old son. Every morning, she goes to work and her son Samu goes to the "BioNest" daycare centre 300 metres away. That is why it was easy for Hanna Éri to decide in favour of the Biotest daycare centre to take care of Samu.

The little towers and pillars of the daycare centre are impressive not only from the outside. The inside in particular is a real gem. The daycare centre is so nice that the mayor of Dreieich even called it the nicest one in town.

Hanna Éri's son Samu already has a favourite room at the day-care centre. It's called "the little explorer" and is equipped with microscopes and magnifying glasses. Samu is also very fond of the other rooms, for example the activity room, the long corridors where the children can ride on little vehicles, and the art room. There is even a very original play area for the little ones, with bubbling water columns and an illuminated ball pit. "The great advantage of the daycare centre is simply the fact that it is so close to my workplace," says Hanna Éri. "I only have to take one route in the morning. It's comfortable to know that Samu is nearby. So far I haven't had to check on my son during work, but it's a good feeling to know that I could go and see him any time."

Both the equipment of the daycare centre and its care concept are very different from those of other facilities. For example, the size of the groups at the "BioNest" is much smaller because the staff/child ratio is considerably above what is required by local laws. This allows staff to devote more attention to the children and to better adjust to their individual needs. Furthermore, the children and staff develop a closer relationship.

The daycare centre was planned and built by Matthias Wagner, an architect from Dreieich. He has a lot of experience with building daycare centres: He has designed and built more than 40 daycare centres all over Germany and bundled all of his experience in the "BioNest" daycare centre at Biotest.

Furthermore, the places at the daycare centre are not reserved for the children of Biotest employees exclusively. 20 places were also allocated to the town of Dreieich. "What's really unbeatable is the opening times of the daycare centre," says Hanna Éri. On workdays, the daycare centre is open from 6 a.m. to 6 p.m. It is never closed, except between Christmas and New Year — a dream for working parents.

# TO ME, BIOTEST NEXT LEVEL IMPLIES: ...







# DR THOMAS BECKER

Senior Director Haematology Corporate Marketing

"Biotest Next Level requires a new way of thinking."

# Mr. Becker, what does Biotest Next Level imply to you?

THOMAS BECKER: It is a great challenge, especially because Biotest has always been strongly rooted in Germany and is now taking the big leap towards globalisation — we now have to change our way of thinking and adopt to a more global approach. We also have to take the different correlations between markets into account as well as the specific demands of different countries.

# What does Biotest Next Level mean to you personally?

THOMAS BECKER: Biotest Next Level has many facets, is future-oriented and therefore very motivating. It is all the more special to be personally involved and to contribute to the success.

#### DR KATRIN BERNÖSTER

Head of the project management organisation

# "To me, Biotest Next Level means a multidisciplinary cooperation on a new working level."

# PETER SEITH Head of Quality Operations

"Biotest Next Level —
new pathways
in the production
with high-performance
chromatography."

# Mrs. Bernöster, what do you consider to be the greatest challenges of Biotest Next Level?

KATRIN BERNÖSTER: One of the challenges will be to integrate the large number of new employees into the existing procedures and the team in a short time. Biotest intends to hire up to 300 new employees. There should be sufficient space for the new employees so that they are able to develop their new ideas and offer some valuable input. This is a great opportunity. They will bring in new experiences and creativity, which will give new impulses.

# How will the project affect the further development of the organisation at Biotest?

KATRIN BERNÖSTER: Biotest Next Level will set new standards for the project management. We have always worked very closely together in teams at Biotest, but it will be even more intensive with Biotest Next Level. The tight schedule for the project requires to reach decisions even more quickly. Multidisciplinary teams need to be coordinated and complex projects must be linked. Biotest Next Level transforms the whole company. It's very exciting for all of us. /

# Mr. Seith, what measures is Biotest using to enhance the exchange of knowledge?

PETER SEITH: German employees have the opportunity to spend a few years in the USA to work at the Biotest location in Boca Raton, Florida. Our colleagues from the USA do the same and come to work at the Dreieich location for a few years. I managed a project in the USA myself. In the context of this project, I was responsible for the expansion of the manufacturing facilities at the location and supervised the marketing authorisation for Bivigam® that followed.

## What are the advantages?

PETER SEITH: Our global team becomes closer. Employees from other countries communicate with each other. They exchange ideas and come in contact with different cultures at the different locations. This helps to develop a greater understanding of each other. They form valuable personal contacts that advance the network and team building on a global level.

# Can you give a precise example of how the knowledge exchange works in practice?

PETER SEITH: During my stay in the USA, I was responsible for complying with the FDA requirements. In this context, I learned what is most important to the FDA auditors, for example the production steps required by the FDA and their documentation, and there is also a particular style of communicating with the FDA. I can now apply this knowledge in the context of the planned FDA certification of the manufacturing location in Dreieich.

# THE GROWTH MARKET OF PLASMA PROTEINS: WHERE THE HIDDEN POTENTIAL LIES

Immunoglobulins (i.v. and s.c. immunoglobulin G preparations) have the largest market volume of all plasma proteins, followed by human albumin and factor VIII preparations. Biotest generates almost one third of its sales with immunoglobulin products, including in particular Intratect®, a polyspecific immunoglobulin G (IgG).

There has been a great increase in the demand for immuno-globulins (lgG) over the past years. The forecasts for the coming years are optimistic. The USA has the greatest demand for plasma proteins, making up 40% of the global demand for immunoglobulin (lgG). Europe and Germany in particular are also important markets. The emerging markets will also play a more important role in the future. Many of these countries are seeing an increase in wealth, resulting in an improvement of the health system and access to medications.

"The demand for immunoglobulins has been increasing for years. We want to benefit from the high demand with Biotest Next Level."

DR MICHAEL RAMROTH

The estimated average annual growth of immunoglobulin (IgG) in the "Rest of World" area will be more than 10% by 2023. The estimated average annual growth rate up to 2023 is 6% for Europe and 4.5% for North America. The growth is supported by an expansion of the market due to the improved access to both medications and health care as well as the option of reimbursement. The fact that many patients have not been diagnosed correctly so far and that the possibility of treating patients with immunoglobulins is not sufficiently known to doctors in many cases can also lead to further growth. Demographic development will also play a role.

The per capita supply with intravenous immunoglobulins differs strongly from country to country. The USA and Australia have the highest per capita consumption. Significant fluctuations between industrial countries and emerging countries can be seen, although per capita consumption is comparatively low in some European countries, for example in Italy and Hungary.

Low per capita consumption generally implies that there is great potential for the future. Biotest sees this future potential in the emerging countries in particular.

The second largest market for plasma proteins is the albumin market. This market is generally price-driven and quality criteria such as "aluminium content" or "salt concentration" are considered only in individual cases. The demand for human albumin is currently slightly higher than the supply, which generally causes prices to increase in many countries, in particular in the Middle East.

The European and US markets for human albumin are roughly the same in terms of their importance. However, the largest growth potential is in the "Rest of World" area. China in particular is a very important market, as it is the largest market for albumin in the world. However, the import barriers are very high. For example, China can import only those products made from US plasma. Biotest is able to meet these requirements. During the last year, Biotest has prepared for the future distribution to China and also continued to expand its cooperation with the local partners. Overall, market researchers are predicting a global annual growth rate of 4% annually for the albumin market in the next five years.

# IgG-MARKET OFFERS GREAT POTENTIAL

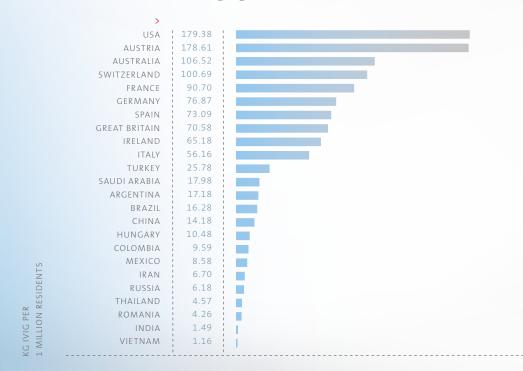
# AVERAGE ANNUAL GROWTH RATE OF IMMUNOGLOBULINS

The annual market volume is forecasted to increase from 170 tonnes to 270 tonnes by 2023



# PER CAPITA CONSUMPTION OF INTRAVENOUS IMMUNOGLOBULINS IN 2014

A lower per capita consumption generally indicates a higher growth potential for the future. Biotest sees this potential especially in the emerging countries.



# MARKET POSITION OF BIOTEST IN THE PLASMA INDUSTRY

Biotest is the only company in the world that offers an immunoglobulin M preparation with Pentaglobin®. Furthermore, Biotest has a 50 percent market share of the hepatitis B-market after liver transplantation. The company is achieving further growth due to the outstanding quality of Intratect®.

Biotest has a clear view of the company's development for the next ten years. The expansion of the portfolio in combination with the innovative products IgM Concentrate and Fibrinogen will guarantee further growth. Biotest will improve its competitiveness considerably with the broader product range, doubling of capacity and better yields in order to allow the company to assert itself successfully even in highly competitive areas.

The hyperimmunglobulins make a significant contribution to the company's profitability even today. This allows Biotest to position itself as a specialist supplier and the company has made further progress in this area over the last year. Biotest obtained marketing authorisation for Hepatect®, a drug developed for

prophylaxis of hepatitis B reinfection, in Norway, Finland and Iran. Zutectra® obtained marketing authorisation in December 2015 which represents another important success for the company. While treatment with Zutectra® could previously not be commenced until six months after a liver transplantation, the drug can be administered one week after the transplantation from now on. The successful further development of Zutectra® supports the role of Biotest as the world's leading provider of hepatitis B hyperimmunoglobulins. In contrast to other plasma companies, Biotest is investing a significant portion of its revenue in research and development and thus in the future of the company.

Biotest intends to have a share in the growth in the long term. Biotest Next Level and the associated expansion of the capacity, as well as the expansion of the product portfolio are the decisive prerequisites for this endeavour. The investments in manufacturing facilities and also the high expenses for research and development will pay off in the long run. /.

"Research and development is the best investment in Biotest's future."

DR BERNHARD EHMER

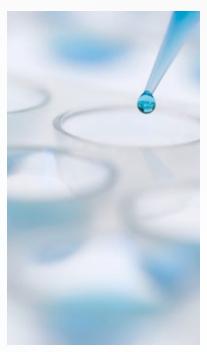


# RESEARCH AND DEVELOPMENT

## DR BERNHARD EHMER

# "The ongoing research and development of new plasma products is the future of tomorrow."



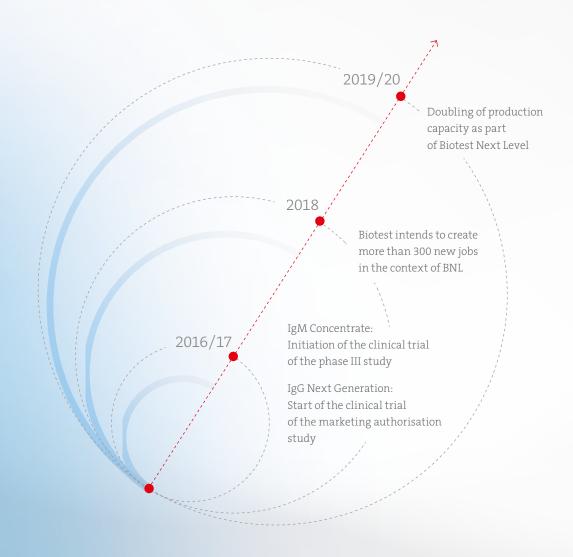


# LOOK INTO THE FUTURE

#### DR BERNHARD EHMER

"We already reached important goals and are now aiming to reach the next milestones. The positive mood spreads anywhere in the company.

The vision is clear: Biotest Next Level."



# BIOTEST NEXT LEVEL — A LOOK INTO THE FUTURE

Biotest has ambitious objectives for the company. In view of the innovative strength and great significance of the products, these objectives are realistic. Despite the growth, Biotest still places the patients' well-being at the centre of its thinking and actions.

Important goals have already been reached. At the same time, the Biotest team still has great challenges ahead of it. The final qualification measures for the manufacturing facilities and high-purity media systems are to start from mid-2017. The production of what are known as the stability batches is an important and time-consuming yet necessary step on the way to obtaining marketing authorisation for products from the US and European authorities.

With the implementation of Biotest Next Level, 2016 is going to be an exciting and determining year. Despite all the changes going on within the company, Biotest strongly sticks to its core principles and values which includes a target-oriented and conscientious way of working which never ceases to convince many customers. Needless to say, it is very important to Biotest that interactions with both customers and colleagues are characterised by a high level of mutual appreciation. These guiding principles serve as cornerstones for cooperation and the corporate culture.

The company's principles on cooperation are a crucial building block for the successful implementation of the Biotest Next Level project.



The spirit of optimism is noticable at the company. Biotest Next Level is present not only on the construction site, but in the minds of the employees. They are responsible for making progress. They plan the further project steps on the construction site. They are looking for support on the job market. They are working on the certifications for distributing the products and they will raise the company to a new level and make it stronger and even more profitable for the next decade – that is Biotest Next Level.

# THE BIOTEST SHARE

The Biotest share was not able to continue the successful development of the past three years in the 2015 financial year. The ordinary share recorded a closing price of € 18.70 after the 1:3 share split on 15 July 2015. The share thus performed below the SDAX benchmark. A similar picture appeared for the preference shares of Biotest AG. On 30 December 2015, the shares closed at € 15.40 in Xetra trading. The share price loss can be attributed in part to the fact, that the primary endpoint was not met of the II b study of tregalizumab (BT-061) and in part to the unscheduled impairments in the third quarter.

Biotest AG is listed in the Prime Standard of the German stock exchange (Deutsche Börse AG), the segment with the highest standards of transparency. The preference shares have been listed on the SDAX since 2007. Biotest AG is thus among the 50 industrial majors below the MDAX. On 30 December 2015, the last trading day of the financial year, Biotest market capitalisation reached a value of € 674 million. The average daily trading volume with Biotest preference shares in Xetra computer-based trading in 2015 was 61,647 shares.

In July 2015 Biotest AG carried out a 1:3 share split and a capital increase from company funds. For each Biotest share, each shareholder received two further share certificates without additional payment. The purpose of the share split is to promote share transactions and make them even more attractive to the broad investing public.

One important goal of investor relations of Biotest is to inform the capital market in detail about the company strategy that is geared to the sustainable increase in value. In addition, Biotest is strengthening trust by implementing an honest, exhaustive and real-time information policy towards investors and the public. Aside from press releases, ad-hoc reports and the direct dialogue with investors, this also includes the close and continuous exchange with analysts as well as the business and finance media.

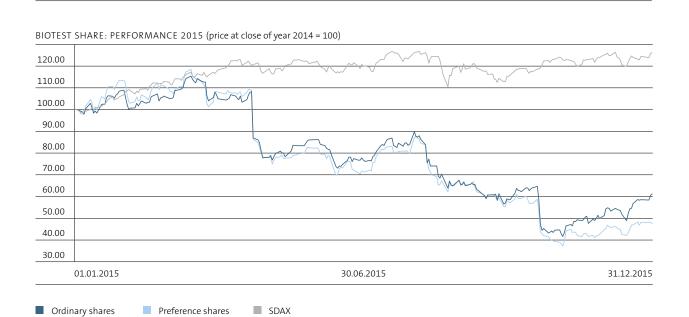
Participating in international investor conferences, carrying out road shows and having one-on-one conversations with investors are constant parts of the communication with the capital market including the press and analyst conference in spring and in autumn. The Investor Relations section of the Biotest website provides current and detailed information that is addressed to both existing shareholders and potential investors.

Sell side analysts from various renowned banks and securities companies constantly monitor the development of Biotest AG and publish regular research studies. The forecast target price for the Biotest preference shares was between € 15 and € 25 at the end of the year. Most of the recommendations were "Buy" or "Hold"

Biotest continues to retain to its dividend policy. The dividend has increased year after year or has at least remained at a constant level since the 2004 financial year. Because of the unscheduled depreciation and the rebound of the clinical study about tregalizumab (BT-061) for the financial year 2015, a dividend of  $\in$  0.02 per ordinary share and  $\in$  0.04 per preference share will be proposed for the 2015 financial year at the annual shareholders' meeting. /.

# "We thank all the investors, who believe in the success of Biotest despite of the rebounds in 2015."

# DR MICHAEL RAMROTH, Chief Financial Officer



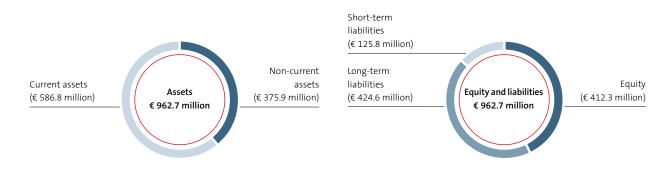
# 2015 AT A GLANCE

BIOTEST GROUP		2015	2014	Change in %
Revenue	in € million	589.6	582.0	1.3
thereof:				
Germany	in € million	123.3	106.0	16.3
Rest of world	in € million	466.3	476.0	-2.0
thereof:				
Therapy	in € million	411.4	409.8	0.4
Plasma & Services	in € million	169.7	157.0	8.1
Other Segments	in € million	8.5	15.2	-44.1
EBITDA	in € million	22.4	85.9	-73.9
Operating profit (EBIT)	in € million	-71.8	53.4	-234.5
EBIT in % of revenue		-12.2	9.2	
Adjusted operating earnings (EBIT)*		91.2	123.2	26.0
Earnings before taxes	in € million		46.9	-258.4
Earnings after taxes	in € million	-82.5	19.2	-529.7
Structure of expenses:				
Personnel expenses	in € million	158.9	138.2	15.0
Research and development costs	in € million	98.8	67.2	47.0
Research and development costs in % of revenue		16.8	11.5	
Capital expenditure in property, plant and equipment and intangible assets	in € million	109.9	47.1	133.3
Financing:				
Cash flow from operating activities	in € million	38.1	-11.4	434.2
Depreciation and amotisation	in € million	94.2	32.5	189.8
Equity (as of 31 December)	in € million	412.3	480.2	-14.1
Equity ratio (as of 31 December)		42.8	46.5	
Balance sheet total (as of 31 December)	in € million	962.7	1,032.6	-6.8
Employees (full-time equivalents as of 31 December)	amount	2,271	2,158	5.2
Earnings per share	€	-2.10	0.48	-537.5

<sup>\*</sup> Derivation page 16 annual report Biotest AG

# FACTS & FIGURES 2015

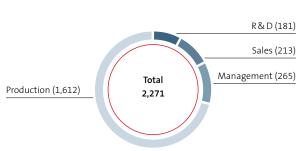
#### BALANCE SHEET STRUCTURE



# Rest of Asia and Pacific (7.2%) Middle East and Africa (20.0%) Central and South America Total Rest of Europe

€ 589.6 million

# ${\sf EMPLOYEES} \ ({\sf full} \ {\sf time} \ {\sf equivalents})$



## DIVIDEND PER SHARE\* in €

REVENUE BY REGION

(2.1%)

USA (21.0%)

	2015**	2014	2013	2012	2011
Ordinary shares	0.02	0.20	0.19	0.17	0.15
Preference shares	0.04	0.22	0.21	0.19	0.17

(28.8%)

<sup>\*</sup> On 15 July 2015, Biotest AG changed its listing following a 1:3 share split. The prior-year figures were adjusted to the new number of shares.

<sup>\*\*</sup> A dividend of € 0.02 per ordinary share and € 0.04 per preference share will be proposed to the annual shareholders' meeting for the financial year 2015.

# CONSOLIDATED STATEMENT OF INCOME

of the Biotest Group for the period from 1 January to 31 December 2015  $\,$ 

in € million	2015	2014
Revenue	589.6	582.0
Cost of sales	-448.3	-357.5
Gross profit	141.3	224.5
Other operating income	2.7	7.0
Distribution costs	-77.8	-74.2
Administrative expenses	-35.6	-31.6
Research and development costs	-98.8	-67.2
Other operating expenses	-3.6	-5.1
Operating profit		53.4
Financial income	38.4	21.4
Financial expenses	-42.9	-27.9
Financial result	-4.5	-6.5
Income from associated companies	2.0	
Earnings before taxes		46.9
Income tax		-27.7
Earnings after taxes		19.2
Attributable to:		
Equity holders of the parent	-82.5	19.2
Non-controlling interests		_
Earnings per share in €	-2.10	0.48*
Additional dividend rights per preference share in €	0.02	0.02
Earnings per preference share in €	-2.08	0.50

 $<sup>^{\</sup>ast}$  Earnings per share was adjusted according to IAS 33.26

# CONSOLIDATED STATEMENT OF FINANCIAL POSITION

of the Biotest Group as of 31 December 2015

in € million	31 December 2015	31 December 2014
ASSETS		
Non-current assets		
Intangible assets	44.7	50.2
Property, plant and equipment	317.2	282.3
Investments in associates	3.5	1.3
Other assets	1.0	0.8
Other financial assets	0.8	5.2
Deferred tax assets	8.7	13.5
Total non-current assets	375.9	353.3
Current assets		
Inventories	218.7	246.0
Trade receivables	173.9	181.6
Current income tax assets	5.8	4.6
Other assets	13.8	12.0
Other financial assets	120.8	55.7
Cash and cash equivalents	53.8	179.4
Total current assets	586.8	679.3
Bilanzsumme	962.7	1,032.6
EQUITY AND LIABILITIES		
Equity	_     _	
Subscribed capital	39.6	33.8
Share premium	219.8	225.6
Retained earnings	235.3	201.5
Share of profit or loss attributable to equity holders of the parent	-82.5	19.2
Equity attributable to equity holders of the parent	412.2	480.1
Non-controlling interests	0.1	0.1
Total equity	412.3	480.2
Non-current liabilities		
Provisions for pensions and similar obligations	72.6	77.5
Other provisions	6.6	6.3
Financial liabilities	335.5	325.8
Other liabilities	2.2	2.5
Deferred tax liabilities	7.7	11.4
Total non-current liabilities	424.6	423.5
Current liabilities		
Other provisions	27.5	23.5
Current income tax liabilities	4.3	8.6
Financial liabilities	9.1	6.1
Trade payables	53.1	55.5
Other liabilities	31.8	32.7
Liabilities from deferred revenue	_	2.5
Total current liabilities	125.8	128.9
Total liabilities	550.4	552.4
TOTAL EQUITY AND LIABILITIES	962.7	1,032.6

# CONSOLIDATED CASH FLOW STATEMENT

of the Biotest Group for the period from 1 January to 31 December 2015  $\,$ 

	2015	2014
in € million	<b>2015</b> -74.3	2014 46.9
Earnings before taxes		46.9
Depreciation, amortisation and impairment of intangible assets and property, plant and equipment	94.2	32.5
Other non-cash income and expense items	6.5	4.9
Income from associated companies	-2.0	_
Losses from the disposal of fixed assets	0.7	0.4
Changes in pension provisions	1.4	-0.1
Financial result	4.5	6.5
Operating cash flow before changes in working capital	31.0	91.1
Changes in other provisions	3.5	-1.0
Changes in inventories, receivables and other assets	45.9	-70.3
Changes in liabilities from deferred revenue	-2.5	-6.9
Changes in trade payables and other liabilities	-18.4	0.9
Cash flow from changes in working capital	28.5	-77.3
Interest paid	-6.1	-5.6
Taxes paid	-15.3	-19.6
Cash flow from operating activities	38.1	-11.4
Cash received on the disposal of fixed assets	0.1	0.8
Payments for investments in fixed assets	-100.7	-44.7
Cash outflows for other financial assets	-60.1	-59.7
Interest received	0.6	1.2
Cash flow from investing activities	-160.1	-102.4
Dividend payments for the previous year		-7.9
Proceeds from the assumption of financial liabilities	10.5	100.5
Payments for the redemption of financial liabilities	-6.8	-5.2
Cash flow from financing activities	-4.6	87.4
Cash changes in cash and cash equivalents		-26.4
Exchange rate-related changes in cash and cash equivalents	1.0	1.4
Cash and cash equivalents on 1 January	179.4	204.4
Cash and cash equivalents on 31 December	53.8	179.4

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# FINANCIAL CALENDAR

# CONTACT

# **ACKNOWLEDGEMENTS**

## 12 MAY 2016

Three-month report for 2016

#### 12 MAY 2016

Annual Shareholders' Meeting

#### 11 AUGUST 2016

Half-year report for 2016

## **10 NOVEMBER 2016**

Nine-month report for 2016

The 2015 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.de</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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# CONCEPT, DESIGN AND PROJECT MANAGEMENT

Scheufele Hesse Eigler Kommunikationsagentur GmbH, Frankfurt am Main, Germany

# **EDITORIAL OFFICE**

cometis AG, Wiesbaden, Germany

# **PHOTOGRAPHY**

Ralf Braum, Frankfurt, Germany (Cover, Page 3, 8, 15, 18, 18, 19, 20)

VFT Film & TV Produktion GmbH & Co. KG, Wiesbaden, Germany (Page 16–17)

Stephan Minx, Fürth, Germany (Page 7, 24, 27)

Thinkstock (Page 11, 25)

Plainpicture (Page 25, on the left)

# PRINTING

Druckhaus Becker GmbH, Ober-Ramstadt, Germany

# KEY FIGURES

		2015	2014	2013	2012*	2011*
Revenue	in € million	589.6	582.0	500.8	440.0	422.0
thereof:						
Germany	in € million	123.3	106.0	93.4	89.4	96.9
Rest of world	in € million	466.3	476.0	407.4	350.6	325.1
thereof:						
Therapy	in € million	411.4	409.8	386.2	330.9	324.7
Plasma & Services	in € million	169.7	157.0	102.5	97	87.9
Other Segments	in € million	8.5	15.2	12.1	12.1	9.4
EBITDA	in € million	22.4	85.9	85.6	76.1	72.4
Operating profit (EBIT)	in € million	-71.8	53.4	53.8	44.7	41.6
EBIT in % of revenue	<u> </u>	-12.2	9.2	10.7	10.2	9.9
Earnings before taxes	in € million		46.9	47.8	36.5	28.6
Earnings after taxes	in € million	-82.5	19.2	32.0	23.1	18.7
Structure of expenses:						
Personnel expenses	in € million	158.9	138.2	126.2	116.1	106.7
Research and development costs	in € million	98.8	67.2	64.6	51.4	49.4
Research and development costs in % of revenue	- <u>%</u> -	16.8	11.5	12.9	11.7	11.7
Capital expenditure in property, plant and equipment and intangible assets	in € million	109.9	47.1	42.9	34.5	26.7
Financing:	-					
Cash flow from operating activities	in € million	38.1			34.7	72.5
Depreciation and amotisation	in € million	94.2	32.5	31.8	31.4	30.8
Equity (as of 31 December)	in € million	412.3	480.2	460.7	369.4	346.7
Equity ratio (as of 31 December)	%	42.8	46.5	52.0	54.1	50.8
Balance sheet total (as of 31 December)	in € million	962.7	1,032.6	886.5	682.3	682.8
Employees (full-time equivalents as of 31 December)	amount	2,271	2,158	1,997	1,727	1,662
Earnings per share	€	-2.10	1.46	2.57	1.94	1.57

<sup>\*</sup> Continuing Operations

BIOTEST AG | Landsteinerstr. 5, 63303 Dreieich, www.biotest.de

