



# Insights

Biotest 2010



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# Clear focus, strong basis

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Biotest is a specialist in immunology and haematology. We develop, produce and distribute drugs used worldwide to prevent and treat serious and often life-threatening illnesses.

In 2010, Biotest invested significantly in the new and further development of immunological and haematological therapy products and in the expansion of its expertise and capacity. We have thus laid the groundwork for strengthening our position as one of the leading providers on the world market.

This forms a solid basis for long-term, high-earnings business performance and an attractive valuation of Biotest stock.

# 2010 at a glance

Biotest Group*		2010	2009	Change %
Revenue	€ million	412.5	390.1	5.7
of which: Germany	€ million	101.8	89.5	13.7
Rest of World	€ million	310.7	300.6	3.4
of which: Plasma Proteins	€ million	412.5	390.1	5.7
EBITDA	€ million	69.8	81.2	-14.0
EBIT	€ million	42.9	57.1	-24.9
EBIT in % of sales	€ million	10.4	14.6	-
Profit before tax	€ million	28.4	45.4	-37.4
Retained earnings attributable to equity holders of Biotest AG	€ million	19.6	29.6	-33.8
Structure of expenses by nature:				
- Cost of materials	€ million	136.7	140.0	-2.4
- Personnel expenditure	€ million	98.7	98.5	0.2
- Research and development expense	€ million	49.0	46.4	5.6
thereof: Biotherapeutics	€ million	21.1	20.7	1.9
- Research and development expense in % of sales		11.9	11.9	-
Capital expenditure in property, plant and equipment and intangible assets	€ million	31.1	37.3	-16.6
Financing:				
- Cash flow**	€ million	41.7	29.0	43.8
- Depreciation and amortisation	€ million	26.9	25.2	6.7
Equity	€ million	307.6	269.9	14.0
- Equity in % of total assets and liabilities		48.6	42.6	-
Total assets and liabilities	€ million	632.3	633.5	-0.2
Number of employees (full-time equivalents) as of year-end		1,611.1	1,548.8	4.0
Earnings per share	€	1.64	2.49	-34.1
Earnings per preference share	€	1.70	2.55	-33.3

\* Continuing Operations (Plasma Proteins segment, Biotherapeutic segment, Corporate). Previous year's cash flow and earnings figures including earnings per share were adjusted accordingly.

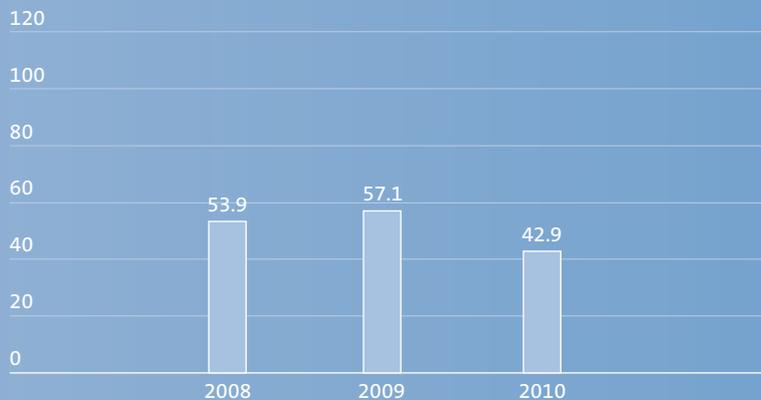
\*\* From operating activities

# Biotest 2008 – 2010

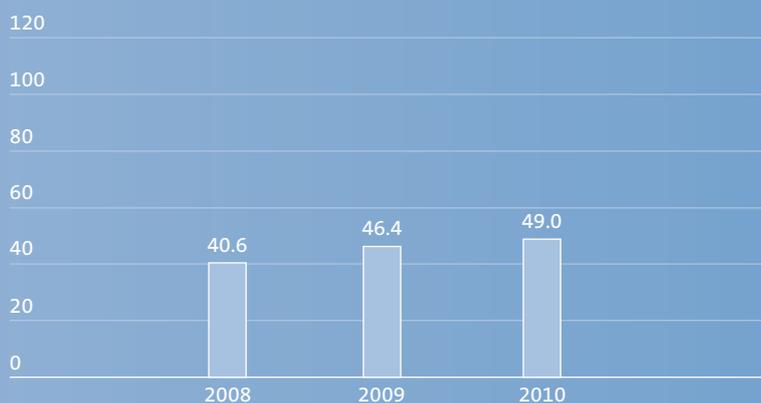
REVENUE OF BIOTEST GROUP\* in € million



EBIT OF BIOTEST GROUP\* in € million



R & D EXPENSES\* in € million



\* Continuing Operations

# 2010 highlights



## JANUARY

Biotest closed the sale of the activities of the transfusion and transplantation diagnostic business to Bio-Rad Laboratories, Inc. The purchase price was €45 million, with profits from the sale before interest and tax and all restructuring expenses totalling €18.4 million, at the end of the year.

Biotest begins marketing the hepatitis B immunoglobulin Zutectra®, authorised for EU-wide distribution in 2009. The preparation will be marketed in the coming months in Germany, Ireland, Italy, Austria and the UK.

## MARCH

Analysis of the final, unblinded data from a phase I/IIa clinical trial demonstrates the efficacy of the monoclonal antibody

BT-061 in the chronic plaque psoriasis indication. Based on these promising data, Biotest is initiating a new phase II clinical trial with multi dose regimen.

## APRIL

A phase III clinical trial of Fovepta™, the hepatitis B hyperimmunoglobulin for neonates, which is under development, is concluded successfully.

## MAY

The Annual Shareholders' Meeting of Biotest AG determines to pay a dividend of €0.34 per ordinary share and €0.40 per preference share for the financial year 2009, a 10% increase over the previous year.

## JUNE

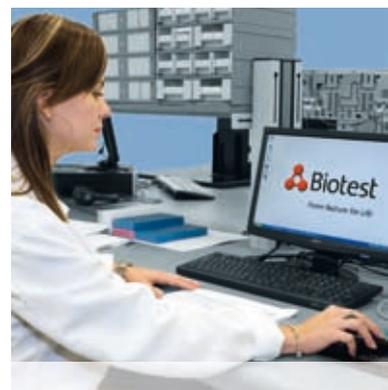
The Supervisory Board extends the contracts of both Board of Management members. The

contract with Prof. Dr. Gregor Schulz will remain in effect until 31 December 2013; Dr. Michael Ramroth's contract was extended until 31 December 2015.

## AUGUST

The final results of a phase IIa clinical trial show competitive efficacy of BT-061 in rheumatoid arthritis, one of the lead indications for this monoclonal antibody. In the same month, a phase IIb trial began for this indications, which will include 175 patients and which will provide the statistical basis for pivotal studies.

Biotest obtains another key patent for BT-061. The monoclonal antibody is thus now protected against imitation in the three largest pharmaceutical markets in the world – the United States, Europe



and Japan. Biotest has also obtained patent protection in Russia, Singapore and four other countries.

Based on encouraging results regarding efficacy and the good tolerability observed from a current phase I clinical trial, Biotest initiates a phase I/IIa clinical trial of BT-062 for the lead indication multiple myeloma.

#### OCTOBER

Pre-clinical studies show BT-061's potential in multiple sclerosis. Thereupon Biotest initiates further analyses to prepare for a possible clinical trial for this indication and joins the "New active agents for neurological diseases" consortium (*Neu<sup>2</sup> Konsortium*), which is supported by the German Federal Ministry of Education and Research.

#### NOVEMBER

Biotest Pharmaceuticals Corporation (BPC) submits the marketing authorisation dossier for Bivigam™ to the FDA, the American regulatory authority. Biotest anticipates marketing authorisation for the polyspecific immunoglobulin at the end of 2011. The product has a potential of annual sales amounting to approximately USD 100 million.

Pre-clinical trials aimed at optimising efficacy are concluded for the hepatitis C hyperimmunoglobulin Civacir™. Together with optimisation of the production process, this lays important foundations for resuming the clinical trial.

#### DECEMBER

Biotest starts discussions about the sale of the Microbiological Monitoring business segment. Due to the company's intention to sell

this segment, it is classified as "Discontinued Operation" in the Annual Report 2010. A corresponding sale agreement was signed with Merck KGaA in March 2011. The transaction is subject to approval by the anti-trust authorities and is expected to be closed in the second half of 2011.

By the end of the year, approximately 7,000 women have been recruited to the current phase III clinical trial of Cytotect® CP for the indication "Avoidance of cytomegalovirus infection transmission and avoidance of impairment of unborn children during pregnancy".

Work starts in Dreieich on expanding the filling and packaging plant for plasma proteins.



**Biotest**  
From Nature for Life

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## Position strengthened, base expanded

In a difficult market environment, Biotest further increased sales but was forced to cope with a decline in profits. Major progress in the expansion of production capacities and development projects lays the groundwork for future earnings increases.

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With growth compared to the previous year of 5.7% to €412.5 million, Biotest was able to increase sales for the sixth straight year. Operating profit (EBIT) from Continuing Operations, however, fell by 24.9% to €42.9 million, compared to 2009.

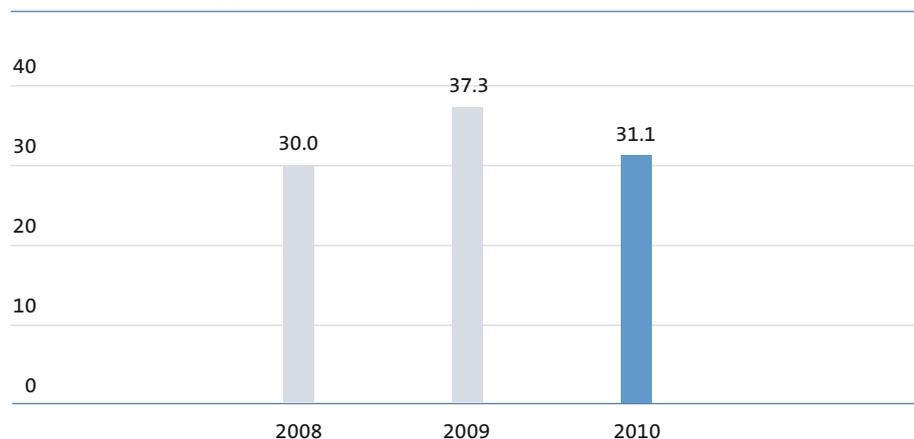
The business and earnings performance of Biotest must be viewed against the backdrop of the market performance. The sharp rise in the supply of plasma and plasma proteins in previous years impacted prices in 2010. Particularly in Europe, obtainable prices were down significantly, especially for polyspecific immunoglobulins and clotting factors. The worsening situation of the public finance systems led to cost-cutting measures in health care, further impacting the market.

Biotest took action in good time to stabilise sales and secure profits, including adjustments in production and a reduction in administrative expenses.

However, no cuts were made in projects aimed at the company's development, choosing instead to intensify our efforts in this area. As in previous years, the focus in 2010 was on expanding our US location as a means of further internationalising our product portfolio. Our projects in the Biotherapeutic segment continued as planned. The research and development costs in 2010 exceeded those of the previous year. The volume of capital expenditures continued to be on a high level in 2010.

We will begin seeing the first positive results of our capital expenditures this year once our expanded plasma protein production facility at BPC goes into regular operation and distribution of the immunoglobulin Bivigam™ in the US begins at the end of the year as expected, allowing us to realise additional sales potential. In addition, new plasma proteins brought to market last year will begin contributing to revenues for a full twelve-month period in 2011.

VOLUME OF CAPITAL EXPENDITURES 2008 – 2010 in € million



Furthermore, we will be able to cover a larger portion of our production of monoclonal antibodies with internal resources. Another one of our goals is to increase efficiency by linking production of plasma proteins in Dreieich with Boca Raton.

We are consistently continuing on our path, begun several years ago, of making Biotest a global specialist for immunology and haematology. For this reason, we decided to cease operating in the area of Diagnostics and intent to sell the Microbiological Monitoring business segment. The generated cash flow will be used to finance our growth in core markets.

This allows us to fully concentrate on the further development of plasma proteins and biotherapeutics while allowing the divisions to be sold to better leverage their strengths under the new ownership structure. So far we have used the proceed from the sale to decrease, in the short term, our liabilities and reduce the use of factoring. In the medium to long term, we will invest them in development and investment projects for our core business.

In 2010, Biotest took the opportunity to further develop its products, resources and structures. We are now equipped to profit from the recovery of the plasma protein market, which we expect to take place in 2011.



Dr. Michael Ramroth, Chief Financial Officer, and Prof. Dr. Gregor Schulz, Chairman of the Board of Management, of Biotest AG.

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## “Foundation for growth in the coming years”

Chairman of the Board of Management, Prof. Dr. Gregor Schulz and CFO Dr. Michael Ramroth discuss Biotest’s performance in 2010 and their expectations for the future.

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**In financial year 2010, Biotest increased its sales over the previous year, but profits were lower. How do you explain these figures?**

**Prof. Dr. Gregor Schulz:** They reflect the situation in the market for plasma proteins in 2010. Consistent growth in demand was faced by an enormous increase in supply, which put heavy pressure on prices in Europe, especially in the first half of the year. We were not able to escape this development, and neither were our competitors.

**Dr. Michael Ramroth:** The numbers also show that Biotest invested significantly in the company’s future in 2010. We laid the foundation for profitable growth in the coming years. First and foremost, we expanded our production capacity for plasma proteins at our US site in Boca Raton. We also continued to invest in research and development in line with our long-term plans.

### Why is the US market so important for Biotest?

**Schulz:** Because it is the largest and most attractive market for immunoglobulins in the world. Prices there are higher and more stable than in other countries. In December 2010, the price per gram of immunoglobulin in the US was approximately €50 converted, while in Europe it was around €30.

**Ramroth:** Our expanded immunoglobulin capacity of 1.5 tons per year gives us a firm foothold in the US. Once Bivigam™ has been approved by the FDA – which we expect to take place in late 2011 – we will be able to distribute a polyspecific immunoglobulin in addition to our hepatitis B preparation, Nabi-HB®. Bivigam™ alone represents an annual sales potential of about USD 100 million.

### In October 2010, some competitors either withdrew their immunoglobulins from the market or their approval has been suspended due to the occurrence of side effects. How did this impact Biotest?

**Schulz:** Our primary goal was to work with other companies to guarantee the continued treatment of chronically ill patients. We were successful in doing that. Thanks to the detailed analyses, we knew that our preparations were not affected by this side effects. Corresponding tests have confirmed this. Our manufacturing process includes steps, which effectively reduce so-called “thrombogenic factors” to an absolutely unobjectionable degree.

**Ramroth:** We also conducted tests on Bivigam™ for possible contamination with clotting factors. That is why we submitted the approval dossier to the FDA several weeks later than planned.

### Progress and timetables for development projects are always a topic of concern among shareholders. What is your response?

**Ramroth:** In developing medications, safety is the highest priority. Problems with a competitor’s product may require additional testing of our own product, as was the case with Bivigam™. Delays are never desirable, but they cannot always be avoided, especially where patient safety is concerned.

**Schulz:** Biotest develops and produces medications that affect complex immunological processes and are administered to seriously ill patients. This makes it impossible to predict the exact timeline for development. Let me

give you an example: patients involved in studies with BT-061 or BT-062 must meet very specific inclusion criteria. It is impossible to say exactly when we will be able to recruit the number of patients called for in the study design. What is important is that the studies are safe and that the data obtained with regard to efficacy and tolerability are good. And that has been the case thus far without exception.

### An important element of Biotest’s biotherapeutics strategy is collaborating with a development partner. When will an agreement be finalised in this regard?

**Schulz:** Our potential partners have been quite impressed by the most recent positive data from analyses of clinical studies in both lead indications. We are currently in advanced negotiations for a global partnership in developing and marketing BT-061 with a global pharmaceutical company.

**Ramroth:** This potential agreement will mark a milestone in the development of Biotest and will have a significant impact on the earnings performance of the Biotherapeutic segment over the next several years. That is why we are working very thoroughly on this issue and not giving in to time pressure.

### In March 2011, you signed an agreement to sell all of the activities of the Microbiological Monitoring segment to Merck KGaA. What was the reason behind that decision?

**Schulz:** With the intended sale, Biotest can focus consistently on developing and marketing innovative pharmaceutical and biotherapeutic drugs in the area of immunology and haematology. For Microbiological Monitoring, the new ownership structure represents an opportunity to better utilise its potential.

### Where do you believe Biotest will stand at the end of 2011?

**Schulz:** In terms of plasma proteins, we will see increased sales and earnings in an improved market environment. And in biotherapeutics, we hope to be able to conclude a licensing agreement this year and, in addition, we will have made progress in further clinical development (phase IIb).

**Ramroth:** And all of it with the continued solid financing that allows us to optimally design and implement our projects.



## A strong investment

The share price of the ordinary and preference shares of Biotest experienced significant gains in 2010.

To strengthen its position as a specialist in immunology and haematology and ensure long-term, high-earnings growth in attractive markets – that is Biotest's goal.

Biotest aims at ensuring business performance based on long-term, sustainable growth. This is reflected in the performance of our stock: in the ten years from the start of 2001 to the end of 2010, the value of our ordinary and preference shares more than tripled. In the same period, the DAX grew by 7.5% and the SDAX by about two-thirds.

BIOTEST SHARE: PERFORMANCE 2010 (Closing price 2009=100)



Source: equinet AG

does well: at the end of 2010, prices for ordinary shares were 25.7% higher than the previous year's closing price; preference share prices rose 34.6% in the same period.

### Intense dialog with the capital markets

Maintaining continuous and open communications with all capital market participants is an important part of our corporate strategy based on sustainable growth. Institutional investors and analysts are informed in individual meetings and roadshows worldwide, while private investors are given an insight into the world of Biotest through informational events. In 2010, we further intensified our communication efforts with the capital markets.

Biotest is working hard to ensure an attractive return on investment for its shareholders, both now and in the future. Increasing the value of the company and maintaining a reliable dividend policy are decisive factors in reaching this goal. In light of our significant investments in research and development and in opening up new markets, we are firmly pursuing our goal of a consistent dividend policy. At the Annual Shareholders' Meeting, the Board of Management and Supervisory Board will recommend a dividend payment of €0.38 per ordinary share and €0.44 per preference share. This reaffirms our commitment to maintaining our dividend policy even in difficult economic times.

Financial analysts from six banks regularly publish studies regarding Biotest. At the end of 2010, all six analysts had a buy recommendation for our shares. Per the analysts' assessment, the average target price for Biotest preference shares on 31 December 2010 was €47.66.

### DATA AND KEY FIGURES FOR THE BIOTEST SHARE

€	2010	2009
Earnings per share	3.12	2.16
Additional dividend rights per preference share	0.06	0.06
Earnings per preference share	3.18	2.22
Dividend per ordinary share <sup>1)</sup>	0.38	0.34
Dividend per preference share <sup>1)</sup>	0.44	0.40
<b>SHARE PRICE FOR ORDINARY SHARES (XETRA data)</b>		
Opening price	39.27	56.00
Highest price <sup>2)</sup>	48.95	56.00
Lowest price <sup>2)</sup>	29.69	26.00
Closing price	48.89	38.90
<b>SHARE PRICE FOR PREFERENCE SHARES (XETRA data)</b>		
Opening price	35.75	45.77
Highest price <sup>2)</sup>	46.60	48.35
Lowest price <sup>2)</sup>	26.90	24.55
Closing price	46.34	34.42
<b>MARKET CAPITALISATION OF BIOTEST AG (as of year's end in € million)</b>		
Total	560.32	433.24
thereof ordinary shares	322.44	256.55
thereof preference shares	237.88	176.69

<sup>1)</sup> 2010 amount to be proposed to the AGM

<sup>2)</sup> Share price relevant figures relate to the price in the XETRA trading (Intraday) on the Frankfurt Stock Exchange.



Strong in  
attractive  
markets

# Complete provider with special competence

Biotest is one of the world's leading producers of plasma protein preparations. We have particular competence in hyperimmunoglobulins, which are used for the treatment of specific diseases. By developing its product range and capacity, Biotest is working on expanding its market position.

Plasma proteins are used in the acute treatment of diseases of the immune system or serious infections, for the prophylaxis of blood clotting disorders and to stabilise the circulation after injury or during surgery. This range of uses demonstrates the great medical importance of these preparations. They can save lives in many cases, or provide a basis for patients affected by serious diseases to lead a largely normal life.

Biotest has been producing plasma proteins for over 60 years and is one of the world's leading suppliers today. Our production is located in ultramodern facilities in Europe and the United States, which meet the strict requirements of European and American authorities. Moreover, together with other producers, Biotest meets additional voluntary quality and safety standards. Furthermore, several virus elimination or inactivation steps are integrated in the production process (see page 17).

## BIOTEST'S PLASMA PROTEINS

Product	Indications
<b>Immunoglobulins</b>	
Intratec® / Intraglobin®	Replacement therapy in antibody deficiency, primary humoral immunodeficiencies or secondary antibody deficiency syndromes as well as autoimmune diseases
<b>Hyperimmunoglobulins</b>	
Cytotec® CP / Biotest Megalotect®	Cytomegalovirus infection (prophylaxis)
Varitect® CP	Zoster virus infection (prophylaxis and treatment)
Hepatect® CP Nabi-HB®	Hepatitis B immunoprophylaxis
Zutectra®	Hepatitis B reinfection prophylaxis after liver transplantation (pre-filled syringe for subcutaneous injection)
Fovepta™*	Hepatitis B prophylaxis for neonates
Bivigam™**	Primary Immunodeficiency (PID)
Civacir™ (development project)	Hepatitis C prophylaxis
<b>Clotting factors</b>	
Haemoctin®	Haemophilia A (acute therapy and prophylaxis)
Haemonine®	Haemophilia B (acute therapy and prophylaxis)
<b>Intensive care and emergency medicine</b>	
Pentaglobin®	Severe bacterial infections
Albiomin Albumin Biseko®	Volume replacement of plasma protein losses, for example, during surgery or as a result of burns

\* Approval expected in 2012

\*\* Approval expected in 2011

## Hepatitis B immunoglobulins Comprehensive product range

Biotest has been producing hyperimmunoglobulins for over 20 years, and this production requires plasma with particular characteristics. For hepatitis B immunoglobulin, for example, the plasma contains a high concentration of a specific antibody, which occurs only in humans who were previously vaccinated against the disease. Building up a bank of such donors is expensive and takes a long time; this is why the prices for hyperimmunoglobulins are usually higher and subject to less fluctuation than is the case with polyspecific immunoglobulins.

The hepatitis B immunoglobulin Hepatect® CP is used to prevent repeat hepatitis B infection following a liver transplantation necessitated by chronic infection with this virus. High doses of hepatitis B immunoglobulin are given during and after the surgery to prevent new infection of the transplanted liver. Hepatect® CP from Biotest is licensed in Europe for this indication and is frequently the physician's first choice. In the United States, we market Nabi-HB® produced by BPC for the same indication and are thus the leading supplier.

Biotest has developed Zutectra® for the long-term prophylaxis with HB immunoglobulin that is required after the intensive phase. The preparation has been designed so that patients can treat themselves weekly by means of a subcutaneous injection (for example, into the abdominal wall). This ensures that the antibody levels in the blood are always optimal. The treatment has become considerably easier for patients, since they achieve greater independence and require fewer doctor visits.

Fovepta™ is another HB immunoglobulin from Biotest, which is currently in development. It is intended for hepatitis B prophylaxis in neonates of hepatitis B-infected mothers, and complements our expertise in this indication.



A look at the sterile filling of plasma proteins at Biotest in Dreieich. We manufacture our products in modern facilities in Europe and the US in accordance with the highest quality and safety standards.

Our particular strength is the development and production of hyperimmunoglobulins, specialised medicinal products characterised by a specific antibody content. These are used for the prevention and treatment of severe infectious diseases. We are the world market leader in a variety of products, and our product range of hepatitis B immunoglobulins is particularly broad (see left box).

A secure supply of human blood plasma is the foundation of our strong market position. The quality of the raw materials is crucial for the final product.

Biotest therefore attaches great importance to covering the entire value chain through its own resources to the greatest possible extent. We operate 21 plasma collection centres of our own in Europe and the United States. For the hyperimmune plasmas we have nearly 100% self-sufficiency. The raw materials for other products we obtain from our own centres and also from suppliers with whom we have long-term collaboration agreements.

### Growing demand

The demand for plasma proteins is growing. For immunoglobulins, the expected annual increase in market volume is between 5% and 8%. Important factors are new indications for administering the preparations and an increase in the number of patients to whom the treatment is provided. Research into new therapeutic indications will further extend the market for immunoglobulins; for example, clinical studies on the treatment of Alzheimer disease are currently in progress. In addition, the preparations are being given in higher dosages based on new medical knowledge, and there is also a considerable and as yet unmet medical need. The supply of immunoglobulins is not yet optimal, particularly in developing and emerging countries, but also in many industrialised states. Furthermore, immune disorders are often not identified as the cause of symptoms or are only identified late. Improved diagnostic methods and a generally greater awareness of immunological diseases might lead to an increase in demand in the future.

The undersupply for clotting disorders is a serious matter: only 10% of the roughly 400,000 people in the world with haemophilia currently have access to appro-



## NANOFILTRATION

HIV	HCV	HBV	HAV	Filter
				
>100 nm	>45 nm	>42 nm	25-30 nm	20 nm

The pores of the filters used for nanofiltration at Biotest have a diameter of 20 nanometres, which is far smaller than many of the smallest known viruses (see illustration). One nanometre is one millionth of a millimetre. In the illustration above, a 20-nanometre pore is shown with a size of two millimetres. If an illustration of a human hair (approx. 0.1 millimetre) were to be magnified by the same factor, it would be 10 metres wide.

HIV – Human Immunodeficiency Virus, HCV – Hepatitis C Virus, HBV – Hepatitis B Virus, HAV – Hepatitis A Virus

appropriate treatment and prophylaxis. There is still a considerable need to catch up, especially in developing and emerging countries.

Biotest invests in expanding its own capacities and increasing production efficiency by greater networking in order optimally to meet the growing demand that results from various market developments and to exploit the associated opportunities for growth.

## Production

### Multiple quality tests for maximum safety

To guarantee the necessary maximum safety of the plasma proteins, safety and quality tests are integrated into the production process at several stages. The purpose is to ensure that the end product is of perfect quality.

#### PLASMA COLLECTION

Biotest uses only plasma from persons whose health status is continuously monitored.

#### STORAGE (QUARANTINE)

All collected plasma is frozen for at least 60 days. If an infection occurs in the donor during this period, the plasma in question is destroyed.

#### VIROLOGICAL TESTING OF EACH INDIVIDUAL PLASMA

Before the individual plasmas are pooled for production, they are tested serologically for viral markers and for the presence of viral nucleic acid. Positive test results lead to exclusion of the plasma.

#### VIRUS INACTIVATION

In plasma fractionation, the individual proteins are separated by means of special technology. The production process already includes several different steps that serve to reduce impurities. Additional steps are integrated in the production

process so that any viruses present are inactivated or eliminated safely and reliably.

#### PURIFICATION

The proteins are further purified by column chromatography (cation exchange principle).

#### NANOFILTRATION

The purified immunoglobulin is passed through filters with a pore size of 20 nanometres under controlled conditions. Even the smallest known viruses can be separated reliably by this nanofiltration technique.

#### FINAL FILLING / QUALITY CONTROL

The products are filled into their final containers using sterile technology and undergo further rigorous quality testing prior to packaging.

Finally, each product lot is tested by the Paul Ehrlich Institute, which releases it for sale.

# Focused on growth





Biotest Pharmaceuticals Corp. has invested heavily in developing one of the world's most modern plasma protein facilities. Here, Biotest can produce 1.5 tons of immunoglobulins each year.

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## Creating the right preconditions

Biotest Pharmaceuticals Corp. is the platform for Biotest's operations in the United States. With the marketing authorisation for the immunoglobulin Bivigam™, which is expected at the end of 2011, we will considerably expand our position in the world's largest and most attractive plasma protein market. Biotest has invested considerably in the expansion and modernisation of production capacity in the United States and Europe to create the foundation for further growth.

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In November 2010, Biotest Pharmaceuticals Corp. (BPC) submitted the marketing authorisation dossier of the polyspecific immunoglobulin Bivigam™ for the treatment of antibody deficiency syndromes to the FDA, the American regulatory authority. Biotest expects to obtain marketing authorisation at the end of 2011. Bivigam™ is a 10% intravenous immunoglobulin that was developed for the American market. A marketing authorisation would mark an important step for the Biotest Group in expanding into the American market for plasma proteins, one of the core points of our growth strategy.

At BPC, Bivigam™ would join the already approved Nabi-HB®. In the financial year 2010, the American subsidiary contributed to the group's sales with the hepatitis B preparation and with the sale of blood plasma. With Bivigam™ alone, we could probably achieve annual sales of USD 100 million after receiving the marketing authorisation expected at the end of 2011.

The American marketing authorisation of the plasma proteins is important for Biotest's long-term development as the American market represents the largest and most attractive immunoglobulin market in the world, with average prices that are significantly higher than in Europe.

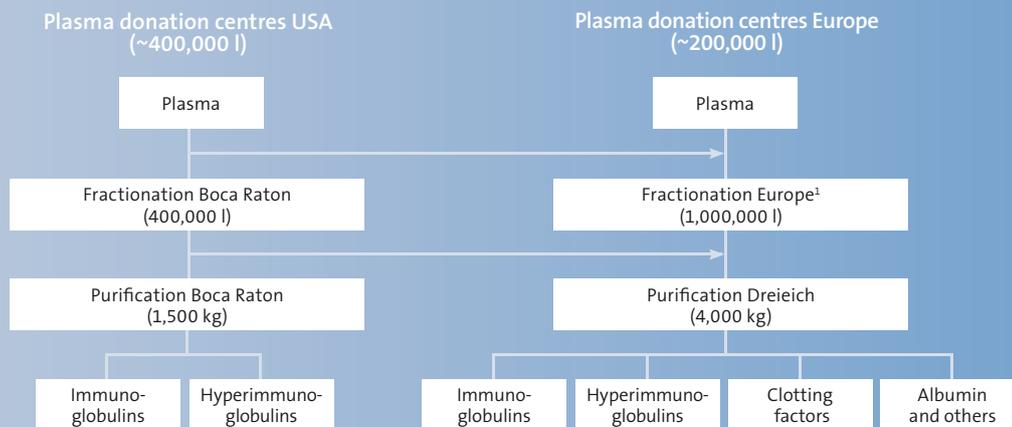


Modernisation and expansion work on the facility was largely completed in 2010. Our production centre in Boca Raton together with our capacity in Europe make up the Biotest production network (see top right graphic).

By expanding its production capacity for plasma proteins, Biotest has created the preconditions to capture a strong position in this market. The production plant in Boca Raton in Florida, acquired in 2007 in a takeover, was broadly modernised and expanded to an annual capacity of up to 1.5 tons of immunoglobulins. It supplements our production in the headquarter Dreieich, which we have expanded in recent years to a capacity of up to 4.0 tons of immunoglobulins annually. Since plasma donated in the United States may also be further processed into drugs in Europe, we can optimally utilise this capacity through the planned transfer of primary and intermediate products from Boca Raton to Dreieich.

Overall, Biotest has invested €115.7 million in the last five years alone to expand and modernise production. This sum also includes investment in our own monoclonal antibody production in the United States. Biotest has rebuild and expanded the BPC plant previously used for vaccine production so that material can be produced there for the clinical trial (see text on page 22f).

## PLASMA PROTEIN PRODUCTION NETWORK



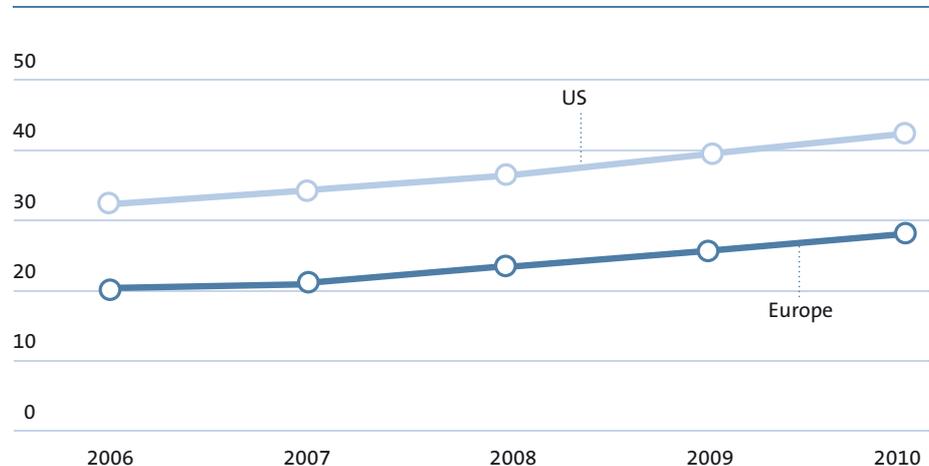
<sup>1</sup> Biotest incl. partners

Thus, in the Biotherapeutic segment as well, we have come closer to our goal of being able to cover all the important parts of the value chain through our own resources.

For the year 2011 Biotest plans to invest about €35 million more in capacity. Construction of a new filling and packaging unit in Dreieich started in December 2010. It will probably be completed in 2013 and the capacity in this area will match the expanded production capacity.

We are thus laying the foundations for optimal utilisation of the growth potential created by the development projects.

## MARKET DEVELOPMENT OF IMMUNOGLOBULINS\* in tons



\* Source: PPTA, MRB and own estimations

# A development with prospects





Biotest is working to develop monoclonal antibodies through its own specialised teams. Our goal is, here as well, to cover all elements of the value chain using our own resources.

## Early intervention

The inflammatory joint disease rheumatoid arthritis is currently incurable. In managing it, physicians are now moving towards early and aggressive treatment of the underlying immune process in order to prevent damage to joint cartilage and bone. Treatment with drugs that intervene specifically in the inflammatory process, so called disease modifying drugs, should keep the negative consequences and undesirable side effects as low as possible. Biotest is developing an active agent that comes one step closer to this goal.

Despite decades of intensive research, the precise causes of rheumatoid arthritis (RA) are still incompletely known. In those affected – about 1% of all adults in industrialised countries – the immune system attacks the body’s own tissues and organs. It is therefore called an autoimmune disease. What exactly causes this malfunction has not yet been clarified. Various malfunctions of the immune system produce the disease condition.

EULAR postulates the principle of

“HIT HARD  
AND EARLY”

start treatment early and bring the disease to a halt promptly or at least arrest it for as long as possible.

The current treatment recommendations of the European League Against Rheumatism (EULAR) envisage using what are known as biological agents at a very early stage in order to halt the inflammation and its consequences effectively. In addition, there continues to be a great need for treatment options with better effectiveness and tolerability.

Today, it is known that there are immune cells in every human body that can attack the body’s own tissues. Normally, these cells are held in check by the regulatory T-cells (T-regs), which play a central role in the immune system. In RA and other autoimmune diseases, this self-regulation of the body’s immune system no longer functions adequately.

The mechanism of action of BT-061 from Biotest is based on this knowledge. The monoclonal antibody activates regulatory T-cells. The immune system is thereby modulated to prevent the harmful over-reaction and thus the disease triggering dysregulation (see graphic on page 25).



## Rheumatoid arthritis New effective therapies also make economic sense

From the high level of suffering endured by patients, it is obvious that the search for new rheumatoid arthritis therapies is an ethical obligation. The economic costs of the disease are also enormous. In 2008, the Rehabilitation and Social Medicine Committee of the German Rheumatology Society came to the conclusion that three-quarters of patients with RA are unfit for work at least once in the first year of the disease. After 10 years of the disease, 40% of patients can no longer be gainfully employed. The indirect costs that arise from this inability to work amount to up to €15.700 per person per year.

The great advantage is that BT-061 strengthens one of the body's natural functions that prevents the excessive immune reactions. While some preparations approved for the treatment of autoimmune diseases can sometimes also suppress the normal immune system, BT-061 works at a central coordinating point in the immune system, acting via a mechanism that restores its original balance (immunomodulation).

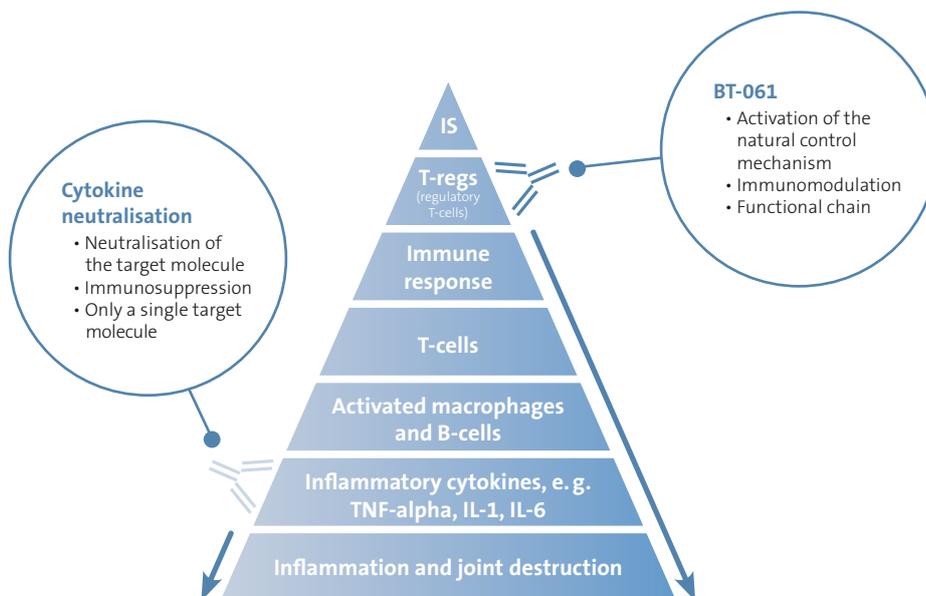
Biotest is developing the monoclonal antibody in the lead indications RA and chronic plaque psoriasis, another autoimmune disease. In 2010 we obtained data from several clinical trials showing that BT-061 is efficient in both lead indications. The monoclonal antibody showed good evidence of efficacy in RA, which is a requirement for possible later marketing authorisation. Since T-reg function is also disturbed in other autoimmune and allergic diseases, there is a possibility that BT-061 might be used in other indications (see right box). The mechanism of action is fully patent-protected.

In the event that marketing authorisation is granted, this antibody alone will represent major growth potential for Biotest. The global market volume in rheumatoid arthritis treatments was estimated at USD 13.5 billion for 2010. Estimates also put the global market volume for biologicals for psoriasis treatment at about USD 3 billion for 2010. There is currently no treatment for either indication that leads to permanent remission or is free from side effects.



Biotest will therefore advance with the clinical development of BT-061. The same applies for BT-062, which is to be used in the treatment of multiple myeloma. For the development of our monoclonal antibodies we will rely on a partnering model in which we intend to collaborate with a large pharmaceutical company from the phase III clinical stage onwards. The interest of potential partners is further evidence of the potential of BT-061, both from the medical aspect and also with a view to Biotest's sales and profits.

#### BT-061'S MECHANISM OF ACTION



The mechanism of action of BT-061: the monoclonal antibody acts at the upper end of the immune system (IS) inflammatory cascade, and can thus have a positive effect on the underlying inflammatory process of RA.

### Biotherapeutics in 2010 Efficacy and tolerability confirmed

In 2010, Biotest further advanced the development of the three monoclonal antibodies in its own pipeline. Clinical data for BT-061 and BT-062 are available from phase I and II clinical trials in the respective lead indications of rheumatoid arthritis and psoriasis (phase II), and multiple myeloma (phase I/II), which confirm efficacy and underscore findings to date regarding their good tolerability.

Furthermore, pre-clinical data generated in 2010 suggest a potential for BT-061 in multiple sclerosis and for BT-062 in the treatment of various solid tumours. Biotest is pursuing these options further and examining whether and in what form clinical development should be initiated.

More about BT-061 and the other development projects at Biotest at: [www.biotest.de/www/de/pub/biotherapeutika.cfm](http://www.biotest.de/www/de/pub/biotherapeutika.cfm)




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## Demonstrating and promoting commitment

Biotest drugs are used in the prophylaxis and therapy of serious diseases. Apart from maximally effective and safe treatment methods, patients also need support in coping with the psychological and social consequences of their disease. This is why Biotest promotes scientific dialogue and the valuable work of patients' organisations.

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A severe chronic illness affects the patient's life in many ways. Apart from the direct physical impairments, the psychological and social consequences often represent a major burden for every patient. To cope with these, it is particularly important that patients and their relatives have a contact person to whom they can turn with their worries and cares and that they can exchange experiences with other patients.

The importance of patients' organisations can therefore not be overestimated. In the areas in which Biotest's drugs are employed, the organisations have been working, sometimes for decades, to increase public awareness of the disease in question and its consequences, and to provide practical help to patients.

In the area of haemophilia, national organisations and the World Federation of Hemophilia campaign for people with blood diseases. They also work towards comprehensive diagnosis and treatment of the disease. Among other things, this includes training medical staff and providing psychological



Impressions from the 2010 Hemophilia World Congress in Buenos Aires, Argentina. Biotest is one of the sponsors of the event, and is itself represented at conferences.

and genetic counselling. Biotest has been providing financial support for the work of haemophilia organisations for over 30 years.

In the area of the immunodeficiencies, Biotest is involved with the International Patient Organisation for Primary Immunodeficiencies (IPOP), the Jeffrey Modell Foundation (JMF) and other organisations. They also campaign in different ways to improve medical care and in particular the psychosocial status of patients.

These initiatives rely on financial and moral support. Biotest regards it as its duty to make a contribution. Naturally, Biotest strictly ensures that the independence of the organisations is maintained and the content of their work is not influenced.

This also applies to Biotest's involvement in specialist medical conferences. Biotest supports a number of such events, for example, the International Symposium on Intensive Care and Emergency Medicine (ISICEM) in Brussels or the World Congress of Hemophilia, which took place in Buenos Aires in 2010.

Biotest AG takes the high ethical importance of its products seriously, also and especially in the day-to-day work, whether in strict quality and safety standards or through compliance requirements. Moreover, Biotest provides regular lectures to keep the staff informed about the therapeutic indications for the drugs and their importance for patients.

## Biotest Health Day

### Working together for prevention

The first Biotest Health Day focused on early risk factor identification and the topic of "Prevention and treatment of back pain". All of the staff at the Dreieich site were able to have various health indicators tested in November 2010 such as blood sugar, blood pressure or lung function, and a wide range of counselling was also available.

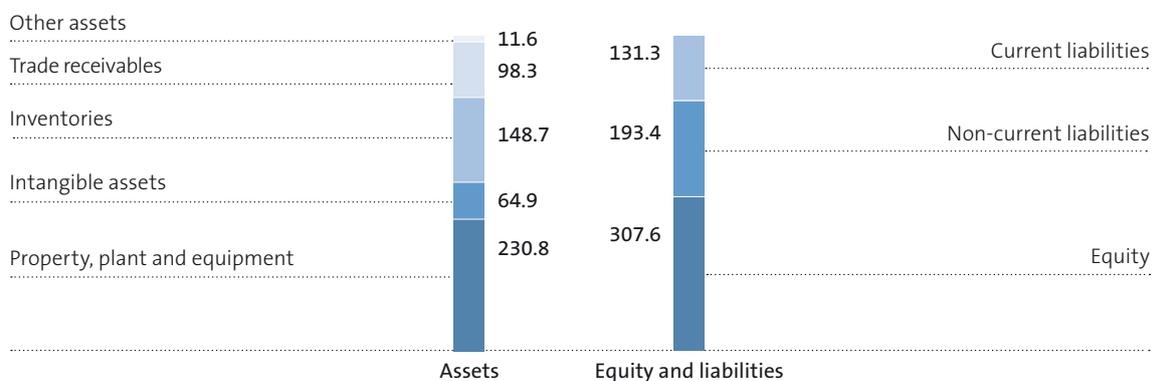
The event arose from an initiative of the works council and took place in collaboration with Biotest's occupational health department and a national health insurance company. Prof. Dr. Gregor Schulz, Chairman of the Biotest Board of Management, served as the host.

Biotest has been promoting health prevention in the company for many years, for example, with smoking cessation measures and tips on a healthy diet.

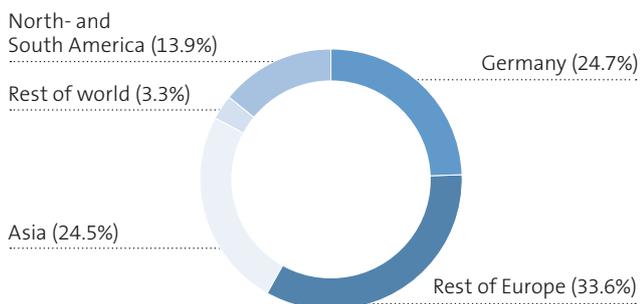


## Facts & figures 2010

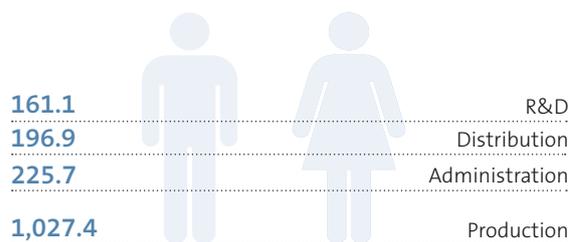
### STRUCTURE OF THE STATEMENT OF FINANCIAL POSITION in € million



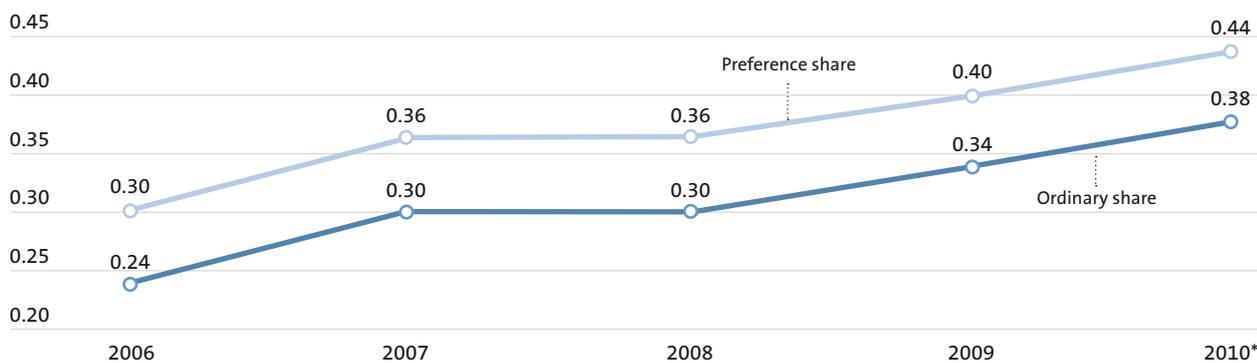
### SALES BY REGION



### EMPLOYEES (FULL-TIME EQUIVALENTS)



### DIVIDEND PER SHARE in €



\*2010: Recommendation

## Statement of income

of the Biotest Group for the period from 1 January to 31 December 2010

€ thousand	Note	2010	2009 *)
Revenue	D1	412,482	390,053
Cost of sales		-247,999	-205,207
<b>Gross profit</b>		<b>164,483</b>	<b>184,846</b>
Other operating income	D5	12,142	8,920
Distribution expenses		-52,456	-52,087
Administrative expenses		-30,729	-32,735
Research and development expenses	D4	-48,968	-46,341
Other operating expenses	D6	-1,578	-5,536
<b>Operating profit</b>		<b>42,894</b>	<b>57,067</b>
Financial income	D7	11,698	6,451
Financial expenses	D8	-26,438	-18,418
<b>Financial result</b>		<b>-14,740</b>	<b>-11,967</b>
Income from associated companies	D9	299	297
<b>Earnings before tax (EBT)</b>		<b>28,453</b>	<b>45,397</b>
Income tax	D10	-8,826	-15,825
<b>Earnings after tax from Continuing Operations</b>		<b>19,627</b>	<b>29,572</b>
Earnings after tax from the Discontinued Operation	D11	19,858	-1,552
<b>Earnings after tax (EAT)</b>		<b>39,485</b>	<b>28,020</b>
Of which:			
<b>Retained earnings attributable to equity holders of the parent company</b>		<b>36,947</b>	<b>25,672</b>
from Continuing Operations		19,615	29,561
from the Discontinued Operation		17,332	-3,889
Minority interest		2,538	2,348
from Continuing Operations		12	11
from the Discontinued Operation		2,526	2,337
<b>Earnings per share in €</b>	<b>E12</b>	<b>3.12</b>	<b>2.16</b>
from Continuing Operations		1.64	2.49
from the Discontinued Operation		1.48	-0.33
<b>Additional dividend rights per preference share in €</b>	<b>E12</b>	<b>0.06</b>	<b>0.06</b>
from Continuing Operations		0.06	0.06
from the Discontinued Operation		-	-
<b>Earnings per preference share in €</b>	<b>E12</b>	<b>3.18</b>	<b>2.22</b>
from Continuing Operations		1.70	2.55
from the Discontinued Operation		1.48	-0.33

\*) Previous year amounts adjusted due to the Discontinued Operation

## Statement of comprehensive income

of the Biotest Group for the period from 1 January to 31 December 2010

€ thousand	2010	2009 *)
<b>Profit for the period</b>	<b>39,485</b>	<b>28,020</b>
Actuarial losses from defined pension benefit plans	-2,766	-4,808
Deferred taxes thereon	801	1,307
Other income / expenses recognised directly in equity	-53	7
Deferred taxes thereon	-	-
Currency translation of foreign subsidiaries	6,170	-2,546
<b>Total deferred taxes on income and expenses recognised in equity</b>	<b>801</b>	<b>1,307</b>
<b>Income and expenses recognised in equity</b>	<b>4,152</b>	<b>-6,040</b>
<b>Comprehensive income</b>	<b>43,637</b>	<b>21,980</b>
<b>Income and expenses recognised directly in equity</b>	<b>4,152</b>	<b>-6,040</b>
from Continuing Operations	4,139	-5,633
from the Discontinued Operation	13	-407
<b>Profit for the period</b>	<b>39,485</b>	<b>28,020</b>
from Continuing Operations	19,627	29,572
from the Discontinued Operation	19,858	-1,552
<b>Comprehensive income</b>	<b>43,637</b>	<b>21,980</b>
from Continuing Operations	23,766	23,939
from the Discontinued Operation	19,871	-1,959
Of which:		
Retained earnings attributable to equity holders of the parent company	41,099	19,663
from Continuing Operations	23,754	23,928
from the Discontinued Operation	17,345	-4,265
Minority interest	2,538	2,317
from Continuing Operations	12	11
from the Discontinued Operation	2,526	2,306
<b>Comprehensive income</b>	<b>43,637</b>	<b>21,980</b>
from Continuing Operations	23,766	23,939
from the Discontinued Operation	19,871	-1,959

\*) Previous year amounts adjusted due to the Discontinued Operation

## Statement of financial position

of the Biotest Group as of 31 December 2010

€ thousand	Note	31 December 2010	31 December 2009
<b>ASSETS</b>			
Intangible assets	E1	64,941	66,680
Property, plant and equipment	E2	230,749	231,955
Investments in affiliates	E3	100	100
Investments in associates	E4	1,050	768
Other financial investments	E5	19,341	215
Other assets	E9	1,735	2,215
Deferred tax assets	E6	5,479	6,260
<b>Total non-current assets</b>		<b>323,395</b>	<b>308,193</b>
Inventories	E7	148,711	170,326
Trade receivables	E8	98,300	95,992
Current income tax assets		2,436	3,686
Other assets	E9	9,814	17,049
Cash and cash equivalents	E10	18,541	6,730
Assets from the Discontinued Operation	E11	31,142	31,478
<b>Total current assets</b>		<b>308,944</b>	<b>325,261</b>
<b>TOTAL ASSETS</b>		<b>632,339</b>	<b>633,454</b>
<b>EQUITY AND LIABILITIES</b>			
Subscribed capital		30,025	30,025
Share premium		153,332	153,332
Reserves		81,260	55,732
Retained earnings attributable to equity holders of the parent company		36,947	25,672
<b>Equity attributable to equity holders of the parent company</b>	<b>E12</b>	<b>301,564</b>	<b>264,761</b>
Minority interests		6,044	5,101
<b>Total equity</b>	<b>E12</b>	<b>307,608</b>	<b>269,862</b>
Provisions for pensions and similar obligations	E13	49,672	48,287
Other provisions	E14	3,111	3,659
Financial liabilities	E15	132,176	153,720
Other liabilities	E16	255	375
Deferred tax liabilities	E6	8,169	8,774
<b>Total non-current liabilities</b>		<b>193,383</b>	<b>214,815</b>
Other provisions	E14	16,454	19,622
Current income tax liabilities		7,047	7,783
Financial liabilities	E15	28,889	50,822
Trades payables		42,779	40,583
Other liabilities	E16	22,431	21,017
Liabilities from the Discontinued Operation	E11	13,748	8,950
<b>Total current liabilities</b>		<b>131,348</b>	<b>148,777</b>
<b>Total liabilities</b>		<b>324,731</b>	<b>363,592</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>632,339</b>	<b>633,454</b>

## Cash flow statement

of the Biotest Group for the period from 1 January to 31 December 2010

€ thousand	Note	2010	2009 *)
Earnings before tax		28,453	45,397
Depreciation and amortisation of intangible assets and property, plant and equipment	E1; E2	26,891	25,186
Income from associated companies		-299	-297
Depreciation and amortisation (appreciation in the previous year) of securities classified as financial assets		17	-471
Gains on disposal of fixed assets		-406	-19
Changes in pension provisions	E13	-2,654	157
Financial result		14,740	11,967
<b>Cash flow from operating activities before changes in working capital</b>		<b>66,742</b>	<b>81,920</b>
Changes in other provisions	E14	-3,550	2,219
Changes in inventories, receivables and other assets		-8,899	-34,411
Changes in accounts payable and other liabilities		774	-2,590
<b>Cash flow from changes in working capital</b>		<b>-11,675</b>	<b>-34,782</b>
Interest paid		-5,753	-9,003
Taxes paid		-7,569	-9,087
<b>Cash flow from operating activities of Continuing Operations</b>		<b>41,745</b>	<b>29,048</b>
Cash flow from operating activities of the Discontinued Operation		36,083	2,634
<b>Total cash flow from operating activities</b>		<b>77,828</b>	<b>31,682</b>
Cash from the disposal of fixed assets		2,526	496
Payments for investment in fixed assets	E1; E2	-29,373	-37,301
Cash from the sale of Medical Diagnostics		45,000	-
Changes in other financial assets		34	22
Interest received		114	35
<b>Cash flow from investing activities in Continuing Operations</b>		<b>18,301</b>	<b>-36,748</b>
Cash flow from investing activities in the Discontinued Operation		-35,144	-3,012
<b>Total cash flow from investing activities</b>		<b>-16,843</b>	<b>-39,760</b>
Dividend payment for the previous year	E12	-4,296	-3,827
Dividend payments to minority interests	E12	-1,595	-1,665
Proceeds from the assumption of financial liabilities	E15	9,398	45,033
Payments for redemption of financial liabilities	E15	-50,783	-31,326
<b>Cash flow from financing activities in Continuing Operations</b>		<b>-47,276</b>	<b>8,215</b>
Cash flow from financing activities in the Discontinued Operation		-1,020	-1,453
<b>Total cash flow from financing activities</b>		<b>-48,296</b>	<b>6,762</b>
Cash changes to cash and cash equivalents		12,689	-1,316
Exchange rate-related changes		-20	-12
Cash and cash equivalents at the beginning of the period	E10	6,744	8,072
<b>Total cash and cash equivalents at the end of the period</b>	<b>E10</b>	<b>19,413</b>	<b>6,744</b>
Less cash and cash equivalents at the end of the period from the Discontinued Operation	E10	872	1,172
<b>Cash and cash equivalents at the end of the period from Continuing Operations</b>	<b>E10</b>	<b>18,541</b>	<b>5,572</b>

\*) Previous year values adjusted due to the Discontinued Operation

## Statement of changes in equity

of the Biotest Group for the period from 1 January 2009 to 31 December 2010

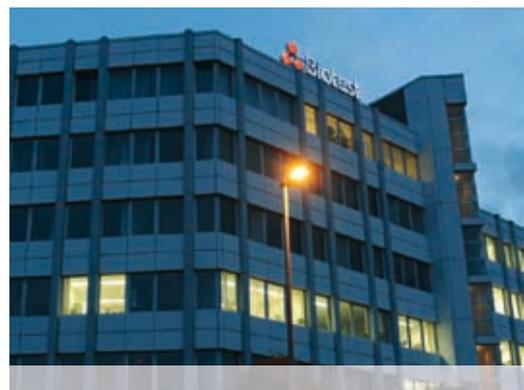
€ thousand	Subscribed capital	Share premium	Accumulated differences from currency translation	Earnings and reserves	Equity excluding minority interests	Minority interests	Total equity
<b>As of 1 January 2009</b>	<b>30,025</b>	<b>153,332</b>	<b>2,097</b>	<b>63,471</b>	<b>248,925</b>	<b>4,449</b>	<b>253,374</b>
Gains/losses recognised directly in equity	–	–	–2,546	–3,463	–6,009	–31	–6,040
Profit for the period	–	–	–	25,672	25,672	2,348	28,020
<b>Comprehensive income</b>	<b>–</b>	<b>–</b>	<b>–2,546</b>	<b>22,209</b>	<b>19,663</b>	<b>2,317</b>	<b>21,980</b>
Dividend payments for 2008	–	–	–	–3,827	–3,827	–1,665	–5,492
<b>As of 31 December 2009</b>	<b>30,025</b>	<b>153,332</b>	<b>–449</b>	<b>81,853</b>	<b>264,761</b>	<b>5,101</b>	<b>269,862</b>
Gains/losses recognised directly in equity	–	–	6,170	–2,018	4,152	–	4,152
Profit for the period	–	–	–	36,947	36,947	2,538	39,485
<b>Comprehensive income</b>	<b>–</b>	<b>–</b>	<b>6,170</b>	<b>34,929</b>	<b>41,099</b>	<b>2,538</b>	<b>43,637</b>
Dividend payments for 2009	–	–	–	–4,296	–4,296	–1,595	–5,891
<b>As of 31 December 2010</b>	<b>30,025</b>	<b>153,332</b>	<b>5,721</b>	<b>112,486</b>	<b>301,564</b>	<b>6,044</b>	<b>307,608</b>

## Segment reporting

€ thousand		Plasma Proteins	Biotherapeutics	Reconciliation	Total Continuing Operations	Discontinued Operation	Total
Revenue with third parties	2010	412,482	–	–	<b>412,482</b>	51,005	463,487
	2009*)	390,053	–	–	<b>390,053</b>	90,908	480,961
Operating profit (EBIT)	2010	73,448	–21,681	–8,873	<b>42,894</b>	24,772	67,666
	2009*)	89,134	–21,062	–11,005	<b>57,067</b>	1,449	58,516
Assets	2010	539,688	5,761	55,748	<b>601,197</b>	31,142	632,339
	2009*)	542,597	5,261	66,036**)	<b>601,976</b>	31,478	633,454
Investments in associates	2010	1,050	–	–	<b>1,050</b>	–	1,050
	2009*)	768	–	–	<b>768</b>	–	768
Capital expenditure	2010	27,524	924	2,612	<b>31,060</b>	2,517	33,577
	2009*)	33,529	1,662	2,110	<b>37,301</b>	3,995	41,296
Liabilities	2010	265,404	10,639	34,940	<b>310,983</b>	13,748	324,731
	2009*)	285,912	14,246	80,948**)	<b>354,642</b>	8,950	363,592
Scheduled depreciation and amortisation	2010	24,489	403	1,999	<b>26,891</b>	1,504	28,395
	2009*)	21,067	549	3,052	<b>24,668</b>	2,421	27,089
Impairment	2010	–	–	–	<b>–</b>	–	–
	2009*)	518	–	–	<b>518</b>	–	518

\*) Previous year values adjusted due to the Discontinued Operation

\*\*\*) Including the former Microbiological Monitoring segment



## Locations of the Biotest Group

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## Would you like to know more?

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For a detailed description of Biotest's performance and outlook, see our 2010 Annual Report, available for download on the Biotest website.

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

If you have any questions, you may also contact us directly:

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## Acknowledgements

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Conception, text and design: ergo Kommunikation, Cologne, Frankfurt/Main, Berlin, Munich

Photography: M. Moog, R. Braum, C. Vogel, stockxchng, World Federation of Hemophilia

Print: ABC-Druck



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