

# 2014 Annual Shareholders' Meeting

## Speech by the Chairman of the Board of Management

*(Translation – original presentation was in German)*

**Prof. Dr. Gregor Schulz**

**7 May 2014**

The spoken word applies.

Ladies and gentlemen,  
On my own behalf as well that of Dr Floß and Dr Ramroth: Welcome. It is my honour to greet all Biotest Group employees, representatives of banks and financial partners, market analysts and the media, and of course above all you, our esteemed shareholders.



“Innovation, quality, responsibility” – this is the guiding theme of our 2013 reporting. Among other things, you will find it in the title of our current Annual Report.

We chose this expression because it nicely summarises what Biotest is and what guides us in the company's continued development. What I would like to do next is explain to you what we understand by this maxim and how we want to live up to it. We are convinced that it is precisely here – that is, where innovation, quality and responsibility come together – that the core factors for Biotest's past and future success can be found.



## Biotest – Our mission

<b>Innovation</b>	<ul style="list-style-type: none"><li>• New drugs, new indications</li><li>• Further development of authorised drugs</li></ul>
<b>Quality</b>	<ul style="list-style-type: none"><li>• Safety</li><li>• Tolerability</li><li>• User friendliness</li></ul>
<b>Responsibility</b>	<ul style="list-style-type: none"><li>• Patient benefit</li><li>• Due diligence</li><li>• Long-term view</li></ul>

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As a pharmaceutical company that develops, produces and markets medications, **innovation** plays a key role for us. Within our three focus areas of haematology, clinical immunology and intensive care medicine, we work continuously to develop new treatments or improve our existing approved drugs. Our current development pipeline is nicely filled. I will tell you about that in more detail in a little while. The second core factor is **quality**. This factor relates to the efficacy of our products, their tolerability and their user friendliness. And it also applies of course to our high safety standards when it comes to collecting and processing the blood plasma that is the central raw material for our plasma proteins. **Responsibility**, lastly, has to do for Biotest above all with the importance of our pharmaceuticals for patients. The people who rely on our drugs suffer from severe and often chronic illnesses; often these drugs are lifesaving for them.

Many of our development projects involve indications for which no treatment options yet exist, or where existing treatments do not do enough or come with severe side effects. So we work in areas with a high medical need and a related high degree of ethical relevance.

Ladies and gentlemen,  
Shepherding a new medication to marketing authorisation can take around 15 years, sometimes even more.

Even when it comes to further developing drugs that already exist in the market, foresight and plenty of patience are needed. The same goes for entering new markets. Strict authorisation requirements that often differ from country to country mean that we cannot simply cross borders from one market to another. This is why, when it comes to the development of our products, but also the company's own growth and development, we think in long timeframes.

There are two consequences to this:

First: we make decisions about investments in new medications, expanding capacities or moving into additional markets based on very thorough weighing of the potential, opportunities and risks as well as the possible costs. This was the case, for example, before our successful entry into the US market, or the decision to expand our albumin production capacities. And it naturally also applies to our "Biotest Next Level" project that lays the foundations for our growth in the coming years.

Second: in implementing these decisions, we stick tenaciously to our chosen path, without letting ourselves be side-tracked by short-term setbacks that may get in the way.

This tenacity and dedication to our goals pay off. They allow our company stable and reliable development, including from a business standpoint. That is how we take account of the rightful interests of our shareholders – your interests, ladies and gentlemen.



The business figures for 2013 and Biotest's development in the preceding years clearly show that our strategy is a successful one and that we have chosen just the right path.

We have also taken actions in the past 12 months to create the conditions for Biotest to continue along this successful route in the coming years. Even more: we have begun a new chapter in the history of the company, that comes with significant additional opportunities.

Before discussing this in detail, I would like to take a look with you at our company's business development over the past 12 months.

## 2013 – one of the best years in Biotest's history



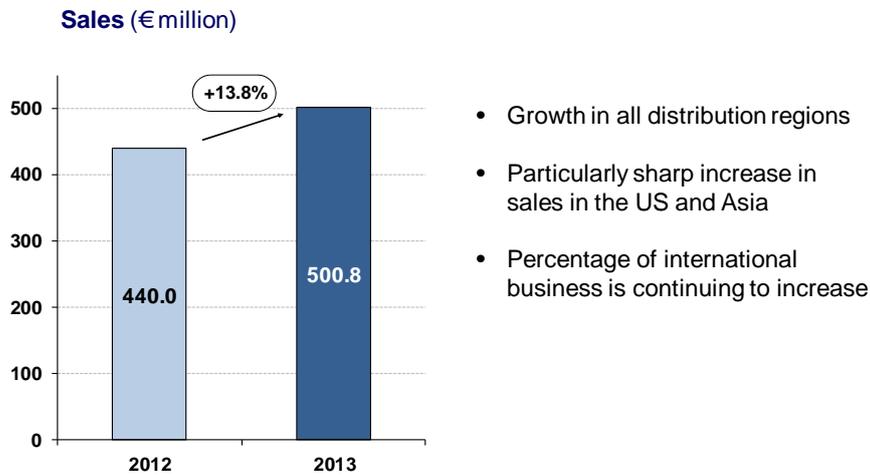
Biotest headquarters in Dreieich

- Record sales, € 500 million threshold exceeded for the first time
- Strong earnings growth
- Position in the US market strengthened, internationalisation driven forward
- Capacity expansion project begun
- Successful on the capital markets

2013 was – I do not think this is an exaggeration – one of the best years in Biotest's history.

- We achieved record sales and exceeded the threshold of a half a billion euros for the first time.
- Profits rose more strongly than our revenue.
- We greatly expanded our position in the US market with the market launch of Bivigam<sup>®</sup>, and our international business also grew strongly elsewhere.
- We launched our capacity expansion programme, and created the necessary financial conditions for further capital expenditure with our capital increase and bond issues in the amount of € 210 million.
- And last but not least: Biotest's stock market value rose by € 500 million or 73% in the past twelve months

## Strong growth in sales



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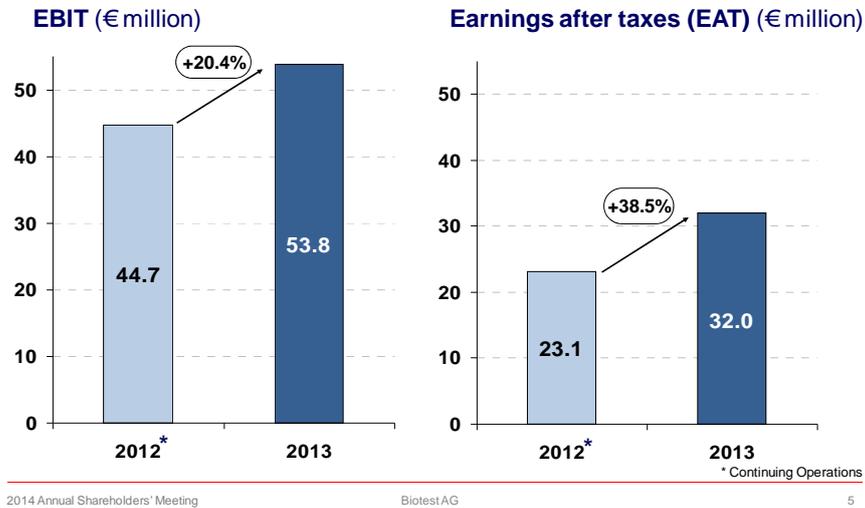
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Our € 500.8 million in sales in 2013 represent nearly 14% growth over the previous year. Rising past the half-billion euro mark is an important milestone for us. Sales rose considerably compared to the previous year in all our sales regions.

At more than 50%, growth in the USA was particularly strong. A key driver here was the Bivigam<sup>®</sup> immunoglobulin from our subsidiary Biotest Pharmaceuticals Corporation (abbr.: BPC). The product was approved by the FDA for the US market at the end of 2012, and we increased Bivigam<sup>®</sup> sales in successive phases over the months that followed. In just a few minutes I will go over our position in the very attractive US market in more detail.

To conclude this review of our sales performance, we can see that we further expanded our business internationally in 2013. The share of sales achieved outside Germany was 81.3% last year. This is due to the excellent development of our US business, as well as continuous growth in Asia and other export markets.

## Above-average increase in EBIT and EAT



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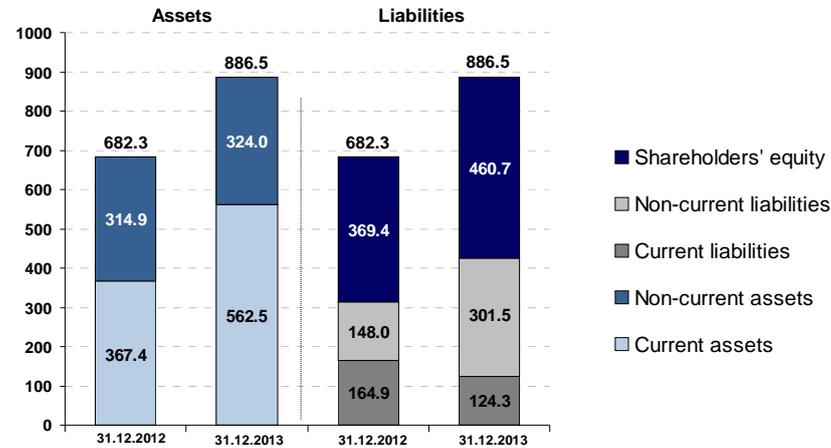
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We were able to increase our operating profit, or EBIT, even more strongly than our sales in 2013, by 20.4% to € 53.8 million. We achieved this growth – as for our sales – in our two major operating segments: Therapy and Plasma & Services. While manufacturing costs rose at about the same rate as sales – so that the cost of production ratio remained essentially constant – the reduction in cost ratio for marketing and sales is a sign of the positive effects of our growth in terms of scale economies.

A financial result up by € 2.2 million and a lower tax rate compared with the previous year mean that our earnings both before (EBT) and after taxes rose even more quickly than the EBIT.

## Financial position shaped by financing measures

Financial position of the Biotest Group (€ million)



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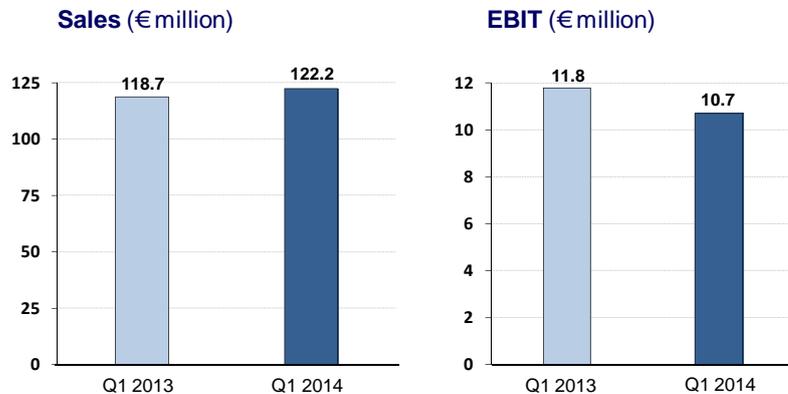
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The statement of financial position is significantly lengthier than last year. Of significance on the asset side due to the company's growth are increased inventories and receivables, as well as a greater liquidity stock. The liabilities side shows the effects of the capital increase carried out in June, and the placement of the loan note for €210 million. Both transactions are for the financing of our planned production expansion in Dreieich. The proceeds from the loan note will also serve to cover general corporate financing.

In addition to all these extremely positive and gratifying developments in 2013, however, we must also report that the investigation pursued by the Frankfurt public prosecutor's office since late 2011 of alleged bribery in our business dealings in Russia continues. Nothing has changed in our response to these accusations as published again in August 2013.

## Sales and earnings in the first quarter



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Ladies and gentlemen,

Let us also take a brief look at the uptick in the current year: in the first three months of the financial year, Biotest Group increased sales compared to the same period last year by close to three percent, to € 122.2 million. We achieved growth in particular in Europe, with a significant 11.5% rise in sales; the increase in Germany was a more moderate 1.8%.

EBIT in the first quarter, at € 10.7 million, remained lower than for the same period last year. This was due to higher research and development expenditure in the course of project progress, and the launch costs for “Biotest Next Level”.

Further burdens on sales and earnings resulted from the recall of lots of Bivigam<sup>®</sup>. I will explain the reasons for this shortly.

We had already accounted the direct costs for the recall in fiscal year 2013, but the recall had a negative impact on sales and earnings in the first quarter. This effect will be felt in the figures for the entire fiscal year.

However, it is likely that sales will significantly increase in the second quarter. This can be forecasted among other things from pending large-volume tender business with Albumin and our Haemoctin<sup>®</sup> clotting medication among others.

Overall, this means that our sales and earnings goal for 2014 has become more challenging, but remains absolutely realistic. Biotest wants to raise both sales and operating profit (EBIT) by around 10% each in the current 2014 fiscal year.

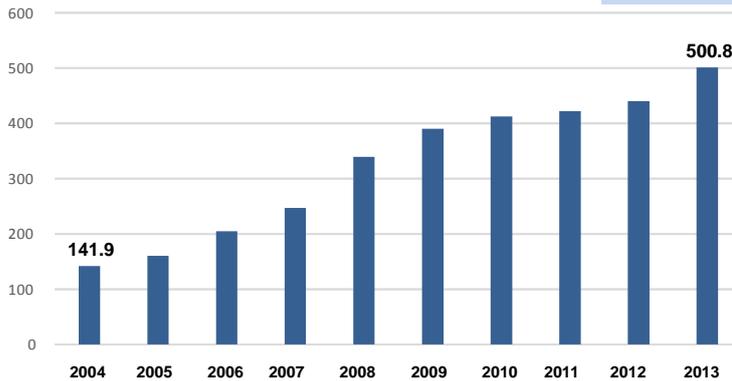
We continue to see Biotest Group's development very positively for 2014 overall.



## Continue and accelerate growth

**Biotest Group: sales 2004–2013 (€million)\***

Sales target for 2020:  
**~ €1 billion**



\* On a comparable basis, only pharmaceutical activities

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Ladies and gentlemen,

This was a brief overview of our business figures. They show that we have added a new chapter to the growth story of the past ten years. Since 2004, Biotest has nearly quadrupled its sales in its core business. Earnings after taxes of €32 million in 2013 have even quintupled compared with the 2004 figure of €5.9 million.

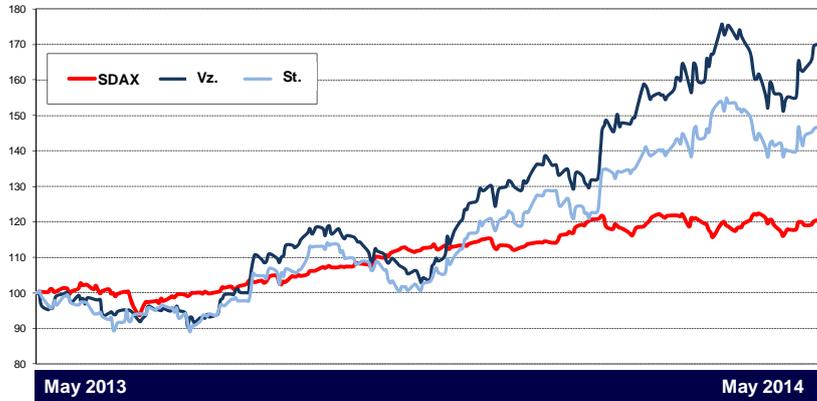
However, we have above all laid the groundwork for further growth, which should lead us to sales in the vicinity of one billion euros by 2020.

Biotest's positive growth over the past ten years can be attributed above all to the performance of its dedicated staff. Here, on behalf of the entire Board of Management, I want to thank them all for their hard work.

I am sure that you our shareholders share this sentiment.

## Biotest stock greatly outperforms the benchmark

**Biotest share price performance** (closing price 8 May 2013 = 100)



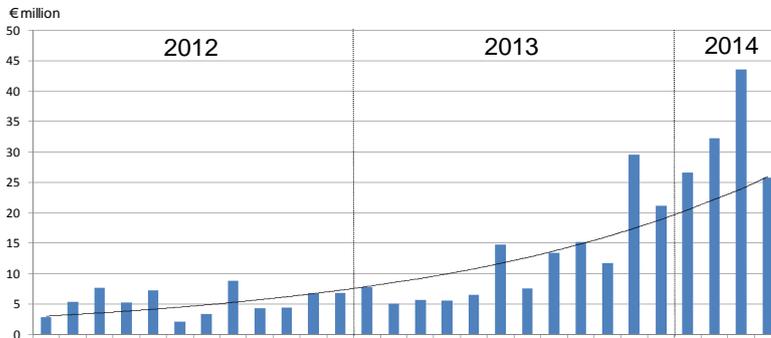
The capital market also recognises Biotest's development and excellent prospects. Both ordinary and preference shares have soared in value in the twelve months since the last annual shareholders' meeting, significantly outperforming the SDAX.

This is even more noteworthy, given that we executed a capital increase during this period. If we compare the stock market value of Biotest AG today with the value from May of last year, we observe, as already stated, a €500 million or 73% increase. The ten-year perspective is also worth looking at here: Since 2004, the stock market value of Biotest AG has increased more than twentyfold.

The proposed dividend for 2013 of €0.57 per ordinary and €0.63 per preference share corresponds to a 28.2% higher payout of €7.9 million. The higher number of shares should also be taken into account here.

## Higher liquidity increases the stock's attractiveness

### Monthly turnover of the Biotest preference share [Xetra in €million]



- Capital increase ensures greater tradability
- Biotest share becomes attractive for international investors

The capital increase in the summer had more positive effects for Biotest than the simple increase in financial resources, which are also beneficial to shareholders. The liquidity of our stock has been significantly improved by this transaction. This is a major requirement for many institutional investors to invest in a stock.

From this perspective, our shareholder basis has greatly expanded in the past twelve months. Big names in Germany and abroad have acquired Biotest shares. They had long been attracted to the substance and potential of our “story” – and now with our improved liquidity they have the opportunity to invest in Biotest. The resulting positive effects on our stock movement can clearly be seen in the share price evolution of the past twelve months.



Ladies and gentlemen,

As I said at the beginning: we take a long-term perspective when it comes to Biotest's corporate development. We began planting the seeds for the strong growth of the past year from 2004 to 2007 by choosing to focus strongly on the pharmaceuticals business, and on internationalising not only our business, but the company itself. We finalised the adoption of this approach in 2010 and 2011 with the disposal of our activities in Medical Diagnostics and Microbiological Monitoring.

Our internationalisation continues.

## Position strengthened in the attractive US market



BPC headquarters in Boca Raton, Florida

- Successful start to the marketing of Bivigam® in 2013
- Sales forecasts for Bivigam®
  - about US\$ 60 million for 2014
  - about US\$ 100 million p.a. from 2015 onwards
- Number of plasma collection centres in the US will increase to 18 by the end of 2014
- Promising development projects

We successfully entered the US market with the acquisition of Nabi's plasma protein business and the founding of BPC in 2007. Our business there has been profitable from the start. With the hepatitis immunoglobulin Nabi HB, as well as Bivigam® since 2013, we now have two products authorised for sale in the world's most important pharmaceutical market.

Bivigam® sales alone will bring in some USD 60 million in 2014, increasing to about USD 100 million the following year.

If you have been following Biotest's development carefully, you will have noticed that we recalled several lots of Bivigam® in February of this year. The reason for this was problems with the glass vials containing the medication, which are sourced from a supplier. The quality of the product itself was irreproachable. These problems have since been eliminated; the costs for the recall and the additional quality testing and new packaging were already fully accounted in the earnings result for 2013. I just presented the impacts on sales and earnings for the quarter and the 2014 fiscal year.

With the acquisition of the Nabi businesses in 2007, we also took over nine plasma collection centres in the USA. By opening new centres we have now raised this number to 15, and we plan to open three more centres by the end of the year.

They are – along with successful products such as Bivigam® and development projects with significant potential such as Civacir®, which I will discuss in a little while – another major reason why our US businesses are so important for Biotest's success.

## Production network offers great advantages



1 Plasma collection in US collection centres, initial processing in Boca Raton

2 Processing into finished products, filling/packaging at Dreieich

3 Global marketing, including in the EU, China or South America

This is because the 15 plasma collection centres and BPC's modern plasma protein production facility are connected to our Dreieich site via a production network.

We can thus take the plasma collected and used to produce intermediates in the USA, and send them to Dreieich to be processed into end products. We do this with albumin, among other things. Here, BPC delivers the raw material – Paste V – harvested from the collected plasma using basic fractionation, to Dreieich for processing to Albiomin<sup>®</sup>, our albumin product. Human albumin is used to stabilise blood circulation under severe conditions such as burns, as well as in chronic liver and kidney disease and other complications involving protein loss.

Only this new production network puts us in a position to supply the rapidly growing market in China, because only human albumin produced from plasma collected in the USA is authorised in that country. Our strong presence in the USA is thus important for Biotest for more than the growth we hope to achieve there. It is the key to serving other attractive markets such as China.

## Entering additional growth markets



- **China:** third largest pharmaceutical market in the world, two-digit growth rates
- Marketing authorisation for Albiomin® 20% expected by Biotest for the fourth quarter 2014



- **Brazil:** fifth largest country (by population) in the world
- Rapidly growing market for plasma proteins
- Marketing authorisation for Albiomin® 20% received in November 2013, further plasma proteins in the marketing authorisation procedure

China is already the third largest pharmaceuticals market in the world today, with annual growth in the double digits.

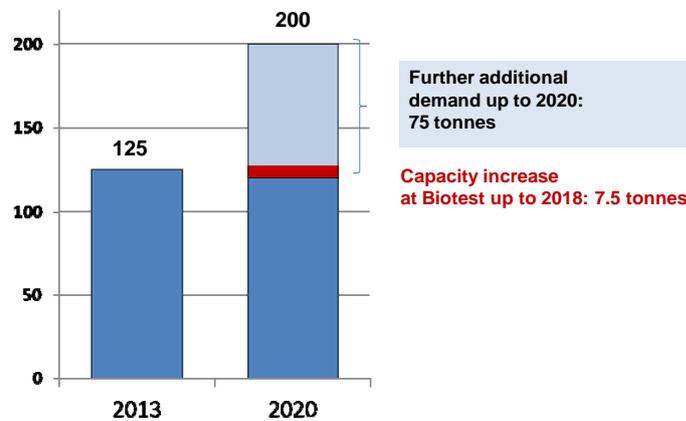
Marketing authorisation is expected for our Albiomin® in the Chinese market in the fourth quarter of this year. We are working on market entry together with Chinese company Wanbang Biopharma, a subsidiary of Fosun Pharma Group, one of the country's largest pharmaceutical companies. This grants us access to our partner's distribution network with offices in 28 provinces and more than 1,200 employees in sales and marketing alone.

Another market for our Albiomin® is Brazil, where it has been authorised since the end of 2013. We serve the Brazilian market via our own company in the country and intend to progressively expand our product portfolio there.

Brazil is the fifth largest country in the world by population (around 200 million), which continues to grow rapidly. The plasma proteins market currently has a volume of USD 400 million, and is growing by some 6% annually. We see significant potential for our hepatitis hyperimmunoglobulins in particular, and will continue to expand our positions in this market. This cannot be done from one day to the next, but we have the necessary staying power to continue securely on this path.

## Global market for immunoglobulins continues to grow

Global market volume for IVIG (tonnes)



Demand for immunoglobulins overall is still growing. Annual growth (CAGR) for the 2008-2013 period was 9%, and this trend will continue. The world market will reach a volume of some 180 tonnes in 2018, and two years later the threshold of 200 tonnes should be reached. This is an increase of 75 tonnes compared with 2013 volumes. If we increase our annual immunoglobulin production capacity by 7.5 tonnes over the next few years, this thus corresponds to only a small portion of the expected market growth. Even if other competitors also carry out significant capacity expansions, we see no risk of oversupply for this key plasma protein industry product in the coming years.

## Biotest Next Level: Investments in growth

Increase in global capacity to:

### Plasma fractionation:

**3.1 million litres per year**

current: 1.5 million litres per year

### Immunoglobulins:

**13 tonnes per year**

current: 5.5 tonnes per year

### Albumin:

**72 tonnes per year**

current: 42 tonnes per year

- Programme for increasing capacity at Dreieich
- Construction of new production facilities at the Dreieich location
- Period: 2013 to 2018
- Investment amount: > € 200 million
- More than 300 additional jobs

Our capacity expansion in Dreieich is a major condition for Biotest to be able to transform this huge potential into growth in the coming years.

We have already invested heavily in expanding our manufacturing capacity – from BPC's plant in the USA, the new Dreieich bottling and packaging facility and additional plasma collection centres in Europe and the USA, to the doubling of our albumin production in Dreieich. With the facility commissioned at end-2013 we can now produce 42 tonnes of albumin annually.

Last year at this time, I presented our "Biotest Next Level" expansion programme to you. With capital expenditure of more than € 200 million by the end of 2018, we will again significantly increase our capacities:

- instead of the current 1.5 million litres, we will be able to process 3.1 million litres of plasma worldwide.
- We will then produce about 13 tons of immunoglobulins per year – we currently produce 5.5 tons.
- In the case of albumin, we can then increase our annual production to 72 tons.

## First projects initiated or already completed



Completed multi-storey car park

### Already completed:

- Expansion of filling and packaging facilities
- First expansion of albumin production
- New multi-storey car park

### Construction started:

- Plasma goods receipt area
- Virological test laboratory

### Next steps:

- Basic engineering completed in Summer 2014
- Ground broken for new production building by the end of 2014

Construction work on the new manufacturing facility is now in full swing. Basic engineering – the detailed planning phase – should be completed in late summer. Construction of a new car park has already been completed. With the completion of the car park building, we can now use the surface area previously dedicated to parking to build the additional production facilities. The ground-breaking for the new production building should take place at the end of the year. Construction of a new plasma product receiving area and a virology test laboratory was already launched a few weeks ago.



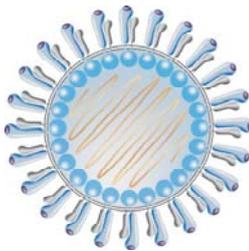
Ladies and gentlemen,

Along with the capacity expansion and internationalisation of sales and marketing, further developing our range of products is the third central element of Biotest's strategy.

Our pipeline is well filled in all three of our therapeutic areas of haematology, clinical immunology and intensive care medicine. I would like to use a few examples to show you the potential it holds and the progress we have achieved here in the past twelve months.



## Clinical Immunology: Civacir®



Model of hepatitis C virus

- Hepatitis C immunoglobulin for reinfection prophylaxis after liver transplantation
- Very high demand:
  - Currently no reliable prophylaxis for the critical period immediately after transplantation
  - New virostatic drugs are not an option
  - In the EU and USA alone, more than 5,000 liver transplants due to hepatitis C each year
  - Phase III study is underway; treatment of the first patients has already been completed

One highly attractive project in immunology is Civacir®. Biotest is developing this hyperimmunoglobulin for prophylaxis of re-infection after liver transplantation necessitated by hepatitis C. It is important to prevent re-infection of the transplanted liver during the most critical phase – the first few weeks after transplantation. Unfortunately, this complication affects more than 60% of patients within four weeks after transplantation despite new virostatic drugs. There is currently no approved treatment option to prevent it.

The only possibility is to administer the right immunoglobulin, such as Civacir®. Treatment with virostatics is not an option during the first months following transplantation, because it would damage the new organ. A phase III clinical trial is currently underway in the USA and Canada involving around 90 patients, the first of whom have already completed treatment.

Civacir<sup>®</sup> offers huge potential: worldwide, around half of all liver transplants are required because of hepatitis C infection, with around 5,000 cases in the EU and the USA alone. This is around ten times the number of liver transplants necessitated by hepatitis B infection.

Because hepatitis C is also much more common in Asia, it is above all in these regions that sizable market potential is expected in the medium term.

In case of marketing authorisation, Civacir<sup>®</sup> would become the only such immunoglobulin. Due to its orphan drug designation, Biotest would receive exclusive marketing rights in Europe for ten years and in the US for seven years.



## Intensive Care Medicine: IgM concentrate and fibrinogen



- IgM concentrate for the treatment of sepsis
- Unique mechanism of action
- Over 100 patients treated to date in phase II study



- Fibrinogen for the treatment of severe acute bleeding due to fibrinogen deficiency
- Ready-to-use product is in development
- First patients treated in phase I/II study

In the area of intensive care medicine, development of IgM concentrate and our Fibrinogen product continues to progress. More than 100 patients are by now involved in the current Phase II study of the IgM concentrate. We are developing the IgM concentrate for the treatment of sepsis, a serious bacterial infection that often leads to patient death.

This product is characterised by a mechanism of action that is very different from drugs previously authorised for this indication and can have a very positive influence on the course of the disease. IgM molecules can not only directly kill bacteria, but also very efficiently neutralise the toxins released by these bacteria. This is important, because these toxins in particular are the cause of life-threatening health issues.

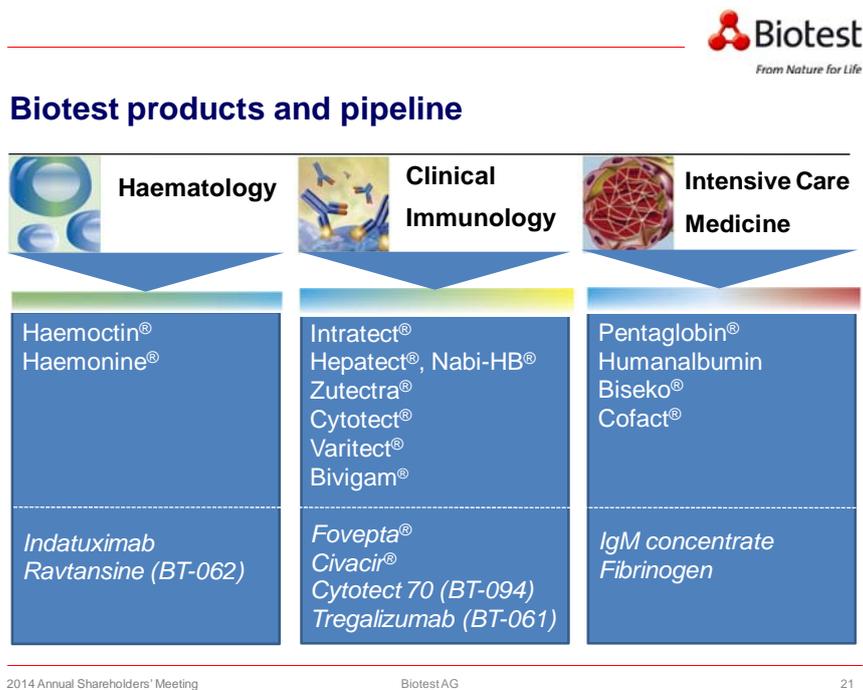
For this project as well, we currently have no direct competition.

In the development of fibrinogen, a Phase I/II clinical study begun in the first half of 2013 is currently underway. Fibrinogen is an important clotting factor.

Severe bleeding is very often related to a fibrinogen deficiency, which can be caused by injuries as well as by surgery. In such emergency situations, speed is of the utmost importance. First the fibrinogen deficiency must be detected, which has now been possible for a few years using a rapid test, and then the deficiency must be corrected using a rapid replacement. Minutes or even seconds can mean life or death.

We are therefore working with a British partner company on a project to develop a ready-to-use solution. This means no time is lost preparing an infusion solution.

As I said, every second counts when it comes to haemorrhage due to fibrinogen deficiency.



An overview of our new and expanded market authorisations shows how we have progressively expanded our product range for plasma proteins within our therapy areas, and opened up new markets for Biotest over the past ten years. In particular for hyperimmunoglobulins used for specific infectious diseases, we have built up a very strong position for ourselves.

This is true especially for prophylaxis of infection and re-infection for hepatitis B.

Here we cover a broad spectrum: from Hepatect® and Nabi HB for intensive care prophylaxis and Zutectra for long-term prophylaxis following liver transplantation necessitated by hepatitis B, to Fovepta for preventive treatment of infants born to

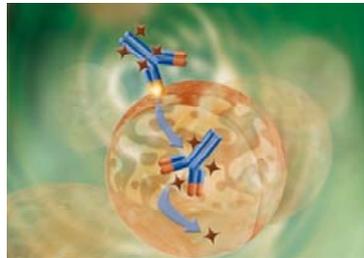
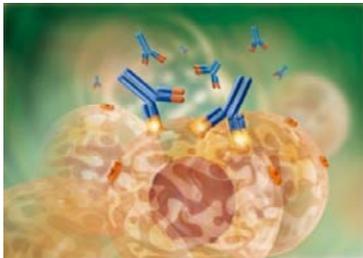
mothers infected with hepatitis B. Cytotect® is also being increasingly accepted for treatment and prophylaxis of cytomegalovirus infection.

The immunoglobulin Intratect® in 10% concentration, designed for faster infusion speed and thus above all for use in ambulatory treatment, is one example of how we further develop approved products to be more user-friendly.

Our other development efforts in this area take this same approach.

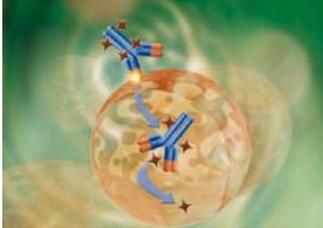


### **Monoclonal antibodies extend the range of products in the Clinical Immunology and Haematology areas**



Our monoclonal antibodies, which are in the clinical development phase, relate to our R&D expertise in haematology and immunology. Here too, I would like to present the current status of development.

## Haematology: Indatuximab Ravtansine (BT-062)



### Targeted mechanism of action:

- Antibody docks on cancer cell and toxin is then released:
  - Targets cancer cells while healthy cells are very largely spared
- Clinical development in the lead indication multiple myeloma is continuing
  - Very convincing data from current phase II study
  - Partial to complete remission of the disease in about 75% of treated patients
  - Presentation of the data at the prestigious ASH conference encountered a great response

In the area of haematology, we are developing an innovative treatment approach for Multiple Myeloma with Indatuximab Ravtansine (this is the new generic international name for BT-062).

This product is what is known as an immunoconjugate. A monoclonal antibody is combined with a highly effective toxin. The antibody targets the antigen CD138, which is overexpressed on the cells of multiple myeloma and other forms of solid cancer, i.e. it is present in large amounts. Once the conjugate binds to the cancer cell, the toxin DM4 is released, which kills the tumour cells.

This specific mechanism of action is very effective at fighting the cancer while sparing healthy cells. Indatuximab Ravtansine thus perfectly meets our aim to combine efficacy with the greatest possible tolerability.

A Phase II clinical study is currently underway, in which Indatuximab Ravtansine is used to treat patients with recurrent and/or therapy-resistant multiple myeloma. It is given in combination with Lenalidomide and Dexamethasone, drugs already authorised to treat this cancer. Treatment continues until the primary disease progresses or until unacceptable side effects appear.

Caution is always required when interpreting data from Phase II clinical studies. This is particularly true in the case of sensitive indications such as cancer, where every new development tends to awaken high expectations in patients, and we must take care not to create false or exaggerated hopes.

However, results achieved so far in the studies for this immunotoxin are really very good. For all treated patients whose data have been analysed so far, an

improvement of symptoms was observed. Partial or full regression of the disease was achieved in more than three-quarters of patients. More than 80% of patients treated with the well tolerated dosage of 100 mg showed an objective response rate.

We should keep in mind here that the patients in this study had exhausted available medical therapies. They had thus already undergone several treatments that did not work or were no longer working.

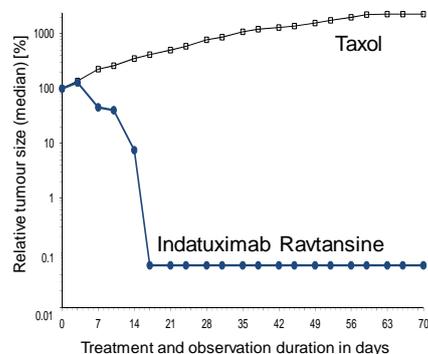
When we presented these results to the Annual Meeting of the American Society of Hematology (ASH), interest among the attendees was very strong and the response without exception positive. These physicians were impressed with the excellent response rate for these very ill patients.

We will thus continue to set a high priority on developing Indatuximab Ravtansine, and are planning to complete the current study by early 2015.



## High efficacy in tumour treatment

### Treatment of human breast cancer implanted in mice



- Very high efficacy with a tolerable dosage in the treatment of solid tumours that do not respond to standard therapy
- Tumours resolved completely within 14 days
- No recurrence (renewed growth) after the end of the treatment, no metastases
- Start of clinical development in breast and bladder cancer

As I said earlier, antigen CD138 targeted by the antibodies is overexpressed on the cells of various solid tumours. We are therefore further developing Indatuximab Ravtansine in this direction as well.

The immunoconjugate proved to be very effective against this type of tumour in preclinical trials. Results of testing on mice in which human tumours – such as breast cancer – had been transplanted, were outstanding. The tumours had completely disappeared in just a few weeks – without metastasis or recurrence, i.e. they did not come back.

We should keep in mind here that these tumours were so-called triple-negative cancers. This means that today's standard treatments for breast cancer are ineffective in these cases.

In the preclinical trial shown by the image on the slide, we can see that the tumour continued to grow when treated with a standard chemotherapy – in this case Taxol – while treatment with Indatuximab Ravnansine caused the tumour to disappear within days.

Based on these excellent data and a comprehensive analysis of the medical need, we have decided that the initial priority will be the indications of triple-negative metastatic breast cancer and invasive metastatic bladder cancer. This is where medical need, market potential and the profile of our monoclonal antibody best come together. The first patient in a corresponding Phase I/II study was treated in March.



## High need and large sales potential

### Indication focus of Indatuximab Ravnansine (BT-062)

	Patients*	Sales potential (peak net sales per year)
 <b>Multiple myeloma (recurrent and treatment-resistant)</b>	~ 80,000	~ €950 million
 <b>Triple-negative metastatic breast cancer</b>	~ 50,000	~ €300 million
 <b>Metastatic bladder cancer</b>	~ 90,000	~ €750 million

\* Anticipated potential patients / Source: Decision Resources 2013 for seven important markets, Biotest estimates

If the so far very reliable and positive data continues to be confirmed and Indatuximab Ravnansine is authorised, this means huge potential from a business perspective: the maximum annual sales potential for the indication of multiple myeloma alone is around one billion euros. If marketing authorisation is granted for both cancer indications, this value would double to two billion euros annually. This corresponds to a quadrupling of our current total sales.

For the further development of this antibody we are taking a similar approach to that used for Tregalizumab, which some of you probably still know under its project name BT-061: we are seeking to cooperate with a large pharmaceutical company to join us in carrying out the very costly studies from Phase III clinical trials on. We will receive a payout from our partner for the research we have already completed, which will

then largely serve to finance our share in the further development costs. It is our aim that Biotest receive exclusive marketing rights in major European markets following marketing authorisation.

As with our partnership for Tregalizumab, we are taking great care in selecting the partner and not allowing ourselves to give into pressure from anyone. The goal is to find the best arrangement for Biotest, and not merely the fastest one.



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## Clinical Immunology: Tregalizumab (BT-061)



- Developed in the lead indications of rheumatoid arthritis (RA) and psoriasis
- Treat 2b: phase IIb trial in RA started in autumn 2013
- Largest clinical trial in Biotest history:
  - Over 300 patients
  - Over 70 trial sites in 14 countries
  - Final results in the first six months of 2015
- Over half of the planned patients have already been entered in the trial

We can see how such patience and care pay off when we look at the development of Tregalizumab. Our collaboration with our partner AbbVie is going very well. The new Phase IIb study of Tregalizumab for the indication of rheumatoid arthritis began in autumn 2013. Its project name is TREAT 2b and it is taking place in more than 70 study sites in several European countries as well as Canada and the USA. With more than 300 participating patients, it will be the largest clinical trial in Biotest's history. Over half of the planned patients have already been entered in the trial.

That completes the overview of our research and development projects. Once they are successfully completed, Biotest will be bringing very interesting new pharmaceuticals to market in all our therapy areas in the coming years. Each candidate holds immense business potential. Our good position in research and development is the best evidence that our investments in new and further developments of pharmaceuticals is money well spent.



Ladies and gentlemen,

Biotest in 2014, in a medium- to long-term perspective, combines excellent prospects with growth and earnings momentum that is already exceptional. The environment for our business is positive and there are no indications that this will change in the foreseeable future.

The company has exciting years ahead, which will bring a leap forward into a new dimension in terms of sales, market coverage and not least strategic direction.

We are moving towards our stated goal of one billion euros in sales by 2020 – with significant additional upside potential from the development of monoclonal antibodies.

We are convinced that it is worth continuing forward along this path with Biotest – whether as an employee, a business partner or a shareholder. I want to thank you for your trust and your support, now and hopefully into the future, for myself and on behalf of Dr. Floß and Dr. Ramroth.

We now look forward to hearing your questions and comments.

Thank you for your attention!