

# **Shareholders Meeting 2016**

# Speech of the CEO Dr. Bernhard Ehmer Mai 12, 2016

The spoken word shall prevail!



Ladies and gentlemen, Shareholders.

On behalf of Dr Ramroth and Dr Floß, I would like to welcome you to the Annual Shareholders' Meeting of Biotest here in Frankfurt.

Biotest founder Dr Dr Hans Schleussner died on 26 November 2015 at the age of 87. We are mourning the loss of an entrepreneur who not only formed and shaped our company and made it a success, but who also promoted culture and science in an exemplary manner. We will honour his memory.

2015 was a difficult year for us. I would like to thank you for standing by us and for being here today. Let's take a look back as I explain the figures for financial year 2015 and the first quarter of 2016. Then I'll discuss the future of Biotest — in particular, the Biotest Next Level project and our strategic realignment. Finally, I'll provide an overview of our latest research results and a look ahead at financial year 2016.



#### **Biotest Group FY 2015**

- Sales FY 2015: € 589.6 million, +1.3%
   EBIT FY 2015: € -71.8 million
- · Re-focusing on core business



- Limitation of R&D investments in monoclonal antibody pipeline after not meeting the primary endpoint in BT-061 study
- Q4 2015 EBIT: € 10.2 million (above guidance\*)
- · Biotest Next Level is on track with respect to timeline and budget
- Positive results for IgM Concentrate, Pentaglobin® and marketing approval for Zutectra® early use
- Start of change process

  \*November 10, 20

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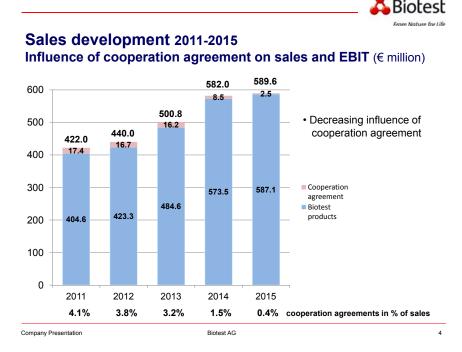
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Financial year 2015: Sales increased last year by 1.3% to € 589.6 million. Compared to the previous year, earnings fell from € 53.4 million to € -71.8 million. This decrease is due in particular to the impairments recognised in the third quarter of 2015.

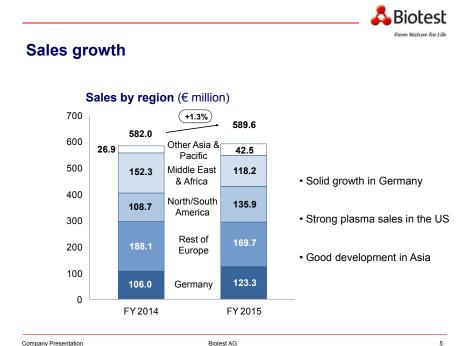
This led us to refocus on our core business – and as a result we sharply limited our research and development investments in monoclonal antibodies.

By the fourth quarter of 2015 we were back on the path to profitable growth. During this period, sales were € 171.7 million, and earnings before interest and taxes (EBIT) amounted to € 10.2 million, exceeding expectations.



Sales have been very good over the past five years. It should be noted that in the beginning, the cooperation agreement with AbbVie has accounted for about 3-4% of sales for each of

these years. When we concluded the agreement in 2011, we received an upfront payment of USD 85 million, which we recognised as sales in the following years. The last portion of this milestone payment, amounting to € 2.5 million, was recognised last year. The impact of the cooperation agreement on sales and EBIT has declined over past few years.



Looking at the regional distribution of sales, we see that sales in Germany were solid. We also see strong growth in North and South America, in particular as a result of plasma sales in the USA. In Asia, we sold more of our products compared to 2015.



# **EBIT and adjusted EBIT**

	2014	2015
EBIT (€ million)	53.4	-71.8
Impairment and one time effects	-	77.2
Biotest Next Level costs*	15.4	23.3
Monoclonal antibodies	38.2	50.1
Idle capacity costs (Boca & Dreieich)	16.2	12.4
EBIT adjusted	123.2	91.2

 $^{\star}$  R&D costs related to the BNL project are included in BNL costs

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The impairments recognised in the third quarter are responsible for the sharp decrease in EBIT last year. The impairments were necessary because of the poorer market prospects for hepatitis C immunoglobulin Civacir® and as a result of the lower sales for the immunoglobulin

product Bivigam<sup>®</sup>. This led to impairments on intangible assets, the US manufacturing facility, and other parts of the building in the USA. In addition to the impairments, there were other factors over the course of the year that impacted earnings. These include impairments related to the suspension of the development of our monoclonal antibody tregalizumab (BT-061) in the indication rheumatoid arthritis because the primary end point of the phase II b study was not reached.

In addition, expenses of € 23 million for Biotest Next Level, our project to expand capacity and develop new products, also had a negative impact on earnings.

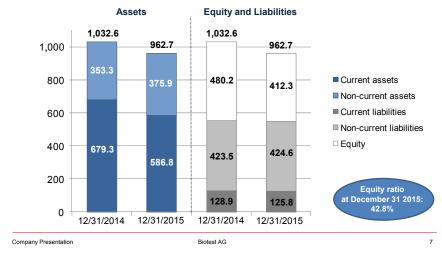
Overall, we had an adjusted EBIT of € 91.2 million. While this is lower than last year, it shows that our core business is profitable.

So we will once again pay you a dividend this year. The proposed appropriation of net profit for 2015 provides for a distribution of  $\in$  1.2 million. Thus, a dividend of  $\in$  0.02 per share will be paid on ordinary shares and a dividend of  $\in$  0.04 per share on preference shares.



#### **Balance sheet**

#### Financial position of the Biotest Group (€ million)



Biotest continues to be fundamentally sound. As a result of past capital measures, the Biotest Next Level expansion programme is fully financed. Biotest has sufficient liquidity to finance growth in its operating business, research and development projects, and all planned capital expenditures.

As a result of impairments in the third quarter, total assets as at 31 December 2015 were € 70 million lower compared to the previous year.

The equity ratio remains stable at 43%.



# Cash flow from operating activities January – December 2015 (in € million)

	2014	2015
Operating CF before changes in working capital	91.1	31.0
Cash flow from changes in working capital	-77.3	28.5
Interest and taxes paid	-25.2	-21.4
Cash flow from operating activities	-11.4	38.1

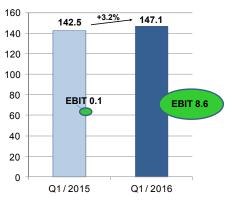
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The impairments last year had no effect on our liquidity: the cash flow from operating activities was  $\in$  38.1 million in financial year 2015. There was an outflow of  $\in$  –11.4 million for the previous year. Cash flow from changes in working capital increased to  $\in$  28.5 million from  $\in$  –77.3 million in the previous year.



#### Sales and EBIT - Q1 2016

### Sales and EBIT (€ million)



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The first quarter of 2016 showed that we are back on the path to profitable growth. During this period, sales rose by 3.2% compared to the same quarter last year, from € 142.5 million to € 147.1 million. Earnings before interest and taxes (EBIT) increased from € 0.1 million to € 8.6 million in the period under review. This solid increase shows that we are on the right path.



# Strategic targets of Biotest

- Re-Focus on plasma business
- Strengthen US profitability
- Expansion project Biotest Next Level
  - Broadening of product portfolio
  - Doubling of production capacity
- Adjustment of R&D programme
  - > Focus on IgG Next Gen, IgM Concentrate, Fibrinogen and Haemophilia
    - Monoclonal antibodies: minimize expenses, continue activities solely up to next milestone to enable partnering
- Continue of "partnering-strategy" in selected areas

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We want to focus on our strengths in the future: the plasma protein business. We have expertise along the entire value chain in this area.

In addition, we want to strengthen profitability in the US business.

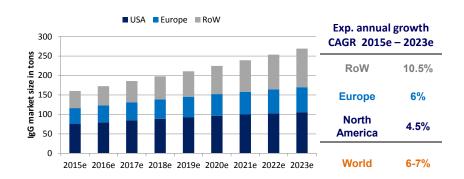
With the investment project Biotest Next Level in Dreieich, we are broadening our product portfolio and doubling our production capacity. I'll go into Biotest Next Level in more detail later on.

We have already adjusted our R&D programme and are focusing on research activities that are part of Biotest Next Level. These projects are IgG Next Generation, IgM Concentrate and fibrinogen. By contrast, we will limit and reduce our spending in the area of monoclonal antibodies. Biotest will finance current activities for each of the three monoclonal antibodies until the next milestone in order to identify suitable partners for future development and marketing during this period. This will allow us to limit risks and costs in the area of monoclonal antibodies in the future. If we do not find a partner by the second quarter of 2017, we will further reduce our capital expenditure.

Partnerships play a key role in our strategy. Our goal is for Biotest to enter into strategic alliances with suitable partners in selected areas. These alliances may involve sales and marketing partnerships or joint production and research activities.



## Global IgG (i.v. + s.c.) market forecast



- The global IgG market is expected to grow to ~270 tons by 2023.
- Expected annual growth is highest in ROW countries.

Sources: Biotest Market Research based on MRB (2013), PPTA (2015), UBS (18 Feb 2015)

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We are focusing on the plasma protein business because the market continues to grow. This slide shows the expected growth of immunoglobulins. In Europe and the USA, there is average growth of about 5% during the forecast period. Growth is even higher in the regions of the world (RoW). Overall, we see average global growth of 6-7%.



- The global FVIII volume is expected to grow by 4% p.a. in the period up to 2020.
- The plasmatic segment will grow by 2% p.a. in volume until 2020. In the recombinant segment, growth will predominantly come from the new long-acting preparations.

 Source: Biotest Market Research
 Note: SA = short-acting, LA = long-acting

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The market for factor VIII is also growing. This growth is moderate but steady. On average, global growth is 4%. Demand for plasmatic factor VIII products will also continue to grow by about 2% annually through 2020.



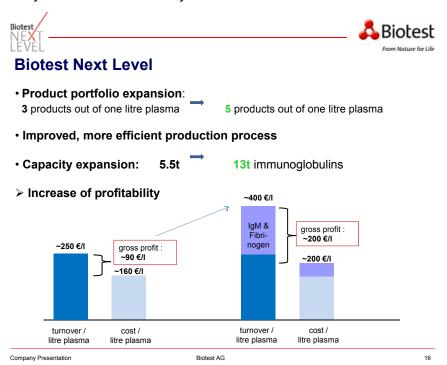
## Strengthen US profitability

Biotest Pharmaceuticals Corporation (BPC) and Kedrion Biopharma Inc., New Jersey signed in January 2016 a cooperation contract on marketing & sales of Bivigam®

- Kedrion will take over exclusively the marketing & selling of Bivigam® in the US
  - > The manufacturing capacity utilization will be significantly increased
  - Increase of profitability, in 2016 by USD 4-5 million

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At the beginning of 2016, we concluded an exclusive cooperation contract with Kedrion Biopharma for the exclusive distribution of Bivigam<sup>®</sup>. Kedrion Biopharma plans to sell 30% more Bivigam<sup>®</sup> units in the first year than Biotest Pharmaceuticals Corporation sold in all of financial year 2015. The agreement guarantees acceptance of minimum volumes and improved utilisation of our US production capacity. This partnership will help us increase profitability in the US business by USD 4-5 million.



This project has three central objectives:

1. We will expand our product portfolio. We will make the pharmaceutical products produced in Dreieich available in all markets around the world. A key step in this process is the

authorisation of our drugs by the US Food and Drug Administration (FDA), which we are currently working on intently. Starting in 2019/20, Biotest will be able to extract five product lines from a litre of blood plasma rather than the previous three. Because plasma as a raw material makes up about 60% of our production costs, this will enable us to improve our competitiveness significantly.

- 2. We will expand our production capacity: Currently, Biotest has a capacity of 5.5 tonnes of immunoglobulins per year. After the expansion, this will increase to 13 tonnes – more than twice as much. We are doing this in response to the increasing demand around the world for immunoglobulin.
- 3. We will increase our profitability: By optimising our production process and making it more efficient, expanding capacity, achieving economies of scale and thus reducing costs, we will become more profitable and increase the value of the company on behalf of our shareholders.



# **Biotest Next Level** Lab building and plasma receiving building



### Lab building

- Virology
- Virus validation

#### Plasma receiving building

- · Sorting area
- · -30°C storage capacity

We commenced the new plasma receiving area and opened the new virological laboratories in December 2015.





# Biotest Next Level As per April 2015



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A lot has happened since we first broke ground on the new production facility in mid-2013. Last autumn, the shell was completed and we celebrated the roofing ceremony. All structural and technical installations should be completed by mid-2017. Next to the production building the new power station is being built at the same time.





# **Biotest Next Level**

On track in terms of timeline and budget (March 2016)

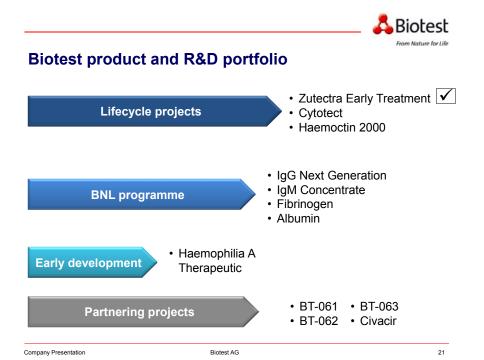


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Biotest Next Level is the key to our future growth. In this context, it is important to note that we have achieved all of the objectives as part of our expansion project over the past year. I want to emphasise that in terms of the timeline and budget we are on track for what is a very large project for Biotest.



Now we come to our research and development activities. On the one hand, we must further develop our current products. We have made good progress with our lifecycle projects. In December 2015, the European Commission gave Biotest approval for the early use of hepatitis B hyperimmunoglobulin Zutectra® following liver transplants.

There is progress elsewhere, as well: According to recent scientific findings, there is a good chance that it will be possible in future to use Cytotect to protect transplanted hearts and lungs. In these cases, the drug protects against cytomegalovirus (CMV) infections. In addition, we have developed a plan to receive marketing authorisation in other countries.

With respect to Haemoctin, our factor VIII product, we mainly need to achieve a higher concentration in order for the application to be more comfortable for patients.

In our Biotest Next Level programme we focus on IgG Next Generation, IgM Concentrate, fibrinogen and albumin.

The future factor VIII product is in the early development phase. I will discuss this in further detail later, along with BT-061, BT-062 and BT-063.



# **IgG Next Generation**

- · Global commercialisation planned
- New efficient production process with high Ig yield established
- "Master product" for the Biotest Next Level production plant

#### Clinical development

- Phase III clinical development (EU/US) planned to start in H2 2016 in two indications
- An additional phase III study in a neurological indication is currently under evaluation - finalization of study design is planned for Q3 2016

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IgG Next Generation is the successor product to Intratect, our polyspecific immunoglobulin, which we sell everywhere in the world except in the USA, and to Bivigam<sup>®</sup>, which is produced for the US market. As a result, we will have just one product in the future. We will market this product around the world. The product is used for primary immune deficiencies (PID) and secondary antibody deficiency syndromes, as well as some autoimmune diseases. We have established a new and very efficient production process that allows us to obtain higher yields of immunoglobulins. The start of two authorisation studies is planned for 2016.



# IgM Concentrate Severe Community Acquired Pneumonia (sCAP)

- Community acquired pneumonia (CAP) is a leading cause of illness and death worldwide<sup>1</sup>
- Mortality rates have not changed significantly over the past several decades despite the availability of improved broad-spectrum antibiotics



Chest radiograph

#### **CIGMA** study

#### **Objectives**

Evaluation of the efficacy and safety of IgM Concentrate in patients with sCAP

### Primary Endpoint / Key Secondary Endpoints

- Increase of ventilator free days (VFD)s
- 28-day all cause mortality

#### Key inclusion criteria

- Pneumonia has been acquired outside the hospital or diagnosed within 72 hours after hospital admission
- Patient receiving adequate antibiotic treatment for pneumonia

1: Wunderink 2014, N Engl J Med 370;6

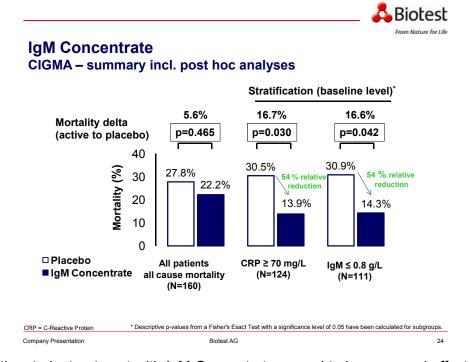
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One of the most important research projects is the development of IgM Concentrate. Immunoglobulin M has a neutralising and anti inflammatory effect and supports the immune system. The product represents a very promising treatment option for various illnesses. We

observed encouraging results in a study involving patients with severe, community-acquired pneumonia who were given IgM Concentrate. The seriously ill patients in this study had to be put on artificial ventilation in intensive care and have a high mortality rate.



In the study, treatment with IgM Concentrate proved to have a good effect and we were able to ascertain a clear trend towards a reduction in mortality. On the basis of these encouraging results, we are now preparing a phase III clinical study. It is expected to start in 2016/17. In addition, Biotest is testing other potential uses for this unique product.



#### Attractive market potential



- Severe Community Acquired Pneumonia
- Market size in sCAP approx. 350,000 patients worldwide\*
  - Sales potential approx. € 500 million p.a.

#### Potential upside indication

- Common Variable Immunodeficiency Disease (CVID)
  - e.g. IgM deficiency



We are confident that IgM Concentrate will save the lives of many seriously ill people. Some 350,000 patients around the world may be eligible for treatment with this drug. Annual sales

could amount to € 500 million. In addition, we are testing other possible uses for IgM Concentrate in other indications.



# Pentaglobin® Encouraging results in lung transplantation

- In lung transplantation donor specific antibodies (DSAs) are risk factors for mortality and acute and chronic graft rejection
- Patients treated with Pentaglobin (a IgM/ IgA enriched immunoglobulin) with early DSAs development after lung transplantation had a significantly higher survival rate than patients treated with therapeutic plasma exchange (standard therapy)
- Published data by the Hannover Medical School\*
  - > > 70% reduction of relative mortality rate after one year
- Mortality risk caused by DSA after lung transplantation was significantly reduced with Pentaglobin® (First generation IgM/ IgA enriched immunoglobulin)

\*: lus.F et al. Transplantation, 2015 Dec 28

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Pentaglobin<sup>®</sup>, a first-generation IgM concentrate, had encouraging results in the treatment of donor-specific antibodies following lung transplants. In the study, which was conducted by the Medizinische Hochschule Hannover (Hanover Medical School), it was shown that patients treated with Pentaglobin<sup>®</sup> had a significantly higher survival rate. The relative reduction in the mortality rate was more than 70%.

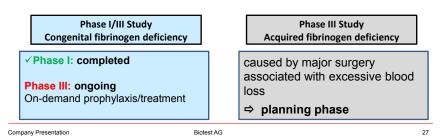


# Fibrinogen

#### Development for congenital and acquired fibrinogen deficiencies

- · Fibrinogen plays an essential role in blood clotting
- In the case of congenital fibrinogen deficiency patients can not produce sufficient or any fibrinogen
- In acquired fibrinogen deficiency, patients lose fibrinogen because of heavy bleeding, for example due to severe injuries and surgery





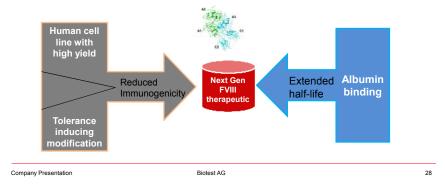
Fibrinogen is a protein that that is important in blood clotting. In the case of congenital fibrinogen deficiency, patients cannot produce sufficient — if any — fibrinogen. However, there are also cases of acquired fibrinogen deficiency, in which patients need additional

clotting factors in the event of heavy bleeding. The phase III clinical trial for congenital fibrinogen deficiency is currently ongoing. A phase III clinical study for acquired fibrinogen deficiency is currently being planned.



# **Next generation Haemophilia A therapeutic**

- Development of a recombinant Factor VIII closely related to the wild type Factor VIII with improved characteristics such as half life extension and lowered immunogenicity
- Preventing inhibitor development
- · Extension of treatment intervals



In the area of haemophilia, we are working on the development of a recombinant factor VIII very similar to our wild type factor VIII. The aim is for the immune system to not recognize it as foreign and for it to have a significantly longer half-life. The goal is to avoid the development of inhibiting antibodies, as well as to extend the treatment intervals.



## **BT-062 Indatuximab Ravtansine Overview**



- Combination of antibody and cytotoxic agent targets cancer cells
- Multiple myeloma: all patients recruited, treatment ongoing; report on study data expected in Q4 2016
- Solid tumours: breast and bladder cancer; phase I completed, recruitment in extension phase ongoing

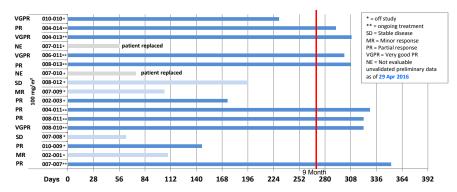
Pomalidomide/Dexamethasone Amendm		t

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Indatuximab raytansine (BT-062) is an antibody drug conjugate and can be used amongst others to treat multiple myeloma, a malignant bone marrow disease. A study is underway to investigate the safety and efficacy of BT-062 in combination with lenalidomide and dexamethasone. The study was expanded last year to include a treatment arm in combination with pomalidomide.



# BT-062 phase I/IIa study no. 983 in Multiple Myeloma Results of BT-062 with Pomalidomide / Dexamethasone



- · A total of 17 patients were enrolled; 2 patients were replaced (not evaluable for efficacy)
- 11/15 = 73% showed a response (≥ PR) to treatment
- · 8 patients without progressive disease for more than 9 months
- 8 patients are on treatment

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The result was that 73% of patients responded well or very well to the treatment, which indicates a reduction in tumour markers of 50% or more. In eight patients who are in treatment, the progress of the disease has been halted for nine months now. The final study assessment is expected to be completed in the fourth quarter.

Biotest is also testing BT-062 in solid tumours. The current monotherapy study involves patients with triple-negative metastatic breast cancer and patients with metastatic bladder cancer who are treated with BT-062.



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#### BT-063 in Systemic Lupus Erythematosus (SLE)

#### Clinical proof of concept study phase Ila study no. 990\*

Patients with moderate to severe SLE on stable medication with joint and cutaneous manifestations

Duration: 3 months treatment + 4 months follow up



#### Study endpoints:

- · Primary: Incidence of adverse events, changes of safety parameter
- Secondary: Improvement of joints, improvement of skin, SLEDAI\*\*

#### Status:

- Last patient recruited in part I of the study
- · First results of interim analysis from part I of the study expected for Q3 2016

\* ClinicalTrials.gov Identifier-No.: NCT02554019; \*\* SLEDAI: SLE Disease Activity Index

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The clinical trial of the monoclonal antibody BT-063 has begun with the treatment of the first patients in the phase II a study. The product is intended to treat the autoimmune disease called Systemic Lupus Erythematosus (SLE).

With this disease, chronic inflammation can occur in different parts of the organism, damaging the tissue. This can lead to serious, and possibly life-threatening, complications in the medium term. It is estimated that some 5 million people around the world suffer from this autoimmune disease. Over the last 50 years, only one new drug has been approved to treat this disease. There is a great medical need for new treatment options. Interest in the progress of our study among scientists is correspondingly high.

The aim of the current Biotest study is to examine the safety and tolerability of the antibody in SLE patients and collect initial data on efficacy. We expect the initial results in the third quarter of 2015.



#### Guidance 2016



#### Outlook 2016

- Increase of profitability (EBIT) >10% in comparison to November 2015
- · Low single digit sales growth expected in 2016
- · Profitable business with attractive R&D pipeline



We expect an increase in sales in 2016 in the low single-digit percentage range. We also anticipate that EBIT will be in the range of € 33-35 million.

With our current products and the products that are currently in the development pipeline, we are very well positioned. In addition, Biotest Next Level represents the basis for future profitable growth. The expansion of the product portfolio in the plasma business will result in a significant increase in future income potential.

I would like to take the opportunity to thank all of the employees of the Biotest Group for their commitment over the past year. I think that you echo these sentiments.

I would also like to thank you on behalf of Dr Ramroth and Dr Floß very much for your past — and also, I hope, your future — trust and support.

We would be happy to take your questions and hear your feedback. Thank you for listening.