

## **Biotest Group: Creating Value. Living Values**



**Analyst Conference – Financial Year 2009**  
**Frankfurt/Main, March 19, 2010**

## Disclaimer

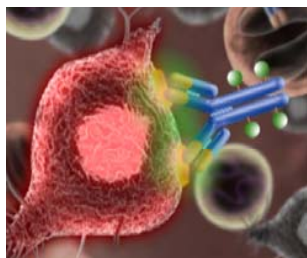
This document contains forward-looking statements on overall economic development as well as on the business, earnings, financial and asset situation of Biotest AG and its subsidiaries. These statements are based on current plans, estimates, forecasts and expectations of the company and thus are subject to risks and elements of uncertainty that could result in deviation of actual developments from expected developments.

The forward-looking statements are only valid at the time of publication. Biotest does not intend to update the forward-looking statements and assumes no obligation to do so.

All figures reported relate to the Continuing Operations of the Biotest Group after the disposal of the transfusion and transplantation diagnostic activities to Bio-Rad Laboratories Inc. The activities are being reported as Discontinued Operations. With the exception of the statement of financial position, the previous year's figures have been adjusted accordingly.

All comparative figures relate to the corresponding last year's period, unless stated otherwise.

## Biotest Group: Highlights 2009 and Q1 2010



- Biotest FY 2009 Group Sales up by 14.1% and EBIT increased by 4.2%
- Sales and EBIT above 2009 Guidance of: Sales +10% and EBIT at € 55 million
- Medical Diagnostics: Closing of purchase agreement with Bio-Rad Laboratories, Inc. on Jan. 6, 2010
- Zutectra<sup>®</sup>: launch started on Feb. 15, 2010 in Germany
- Major milestones achieved in Plasma Proteins and Biotherapeutics
- Completion of first production facility in Boca Raton



**Biotest Group: Creating Value. Living Values.**

## **Financials**

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## **Biotest to sell Medical Diagnostics business to Bio-Rad**

- Contract signed to sell a major part of the Medical Diagnostics segment to Bio-Rad Laboratories Inc. (Hercules, CA/ US)
- Transaction successfully closed on Jan 6, 2010
- Bio-Rad acquired all shares of Biotest Medical Diagnostics GmbH (Dreieich) and Biotest Diagnostics Corporation (Rockaway/ US), as well as the transfusion and transplantation diagnostics business in Biotest Group's international subsidiaries under an asset deal; revenues of activities sold in 2009 : € 40.8 million
- Purchase price of € 45 million being paid by Bio-Rad on Jan 6, 2010

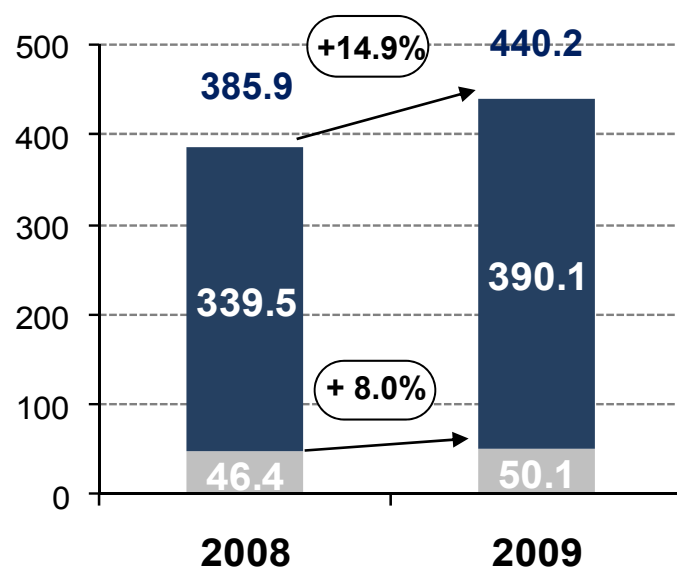
## Gain of transaction Medical Diagnostic Business

	million €
<b><u>Selling Price</u></b>	<b>45,0</b>
Net value of the sold subsidiaries (share deal)	- 8,9
Net value of the sold assets (asset deal)	- 3,2
Transfer of shareholder's loans	- 13,3
Restructuring costs (estimate)	- 4,0
Additional costs of the transaction	- 2,2
<b>Gain of the transaction/ extraordinary income</b>	<b>13,4</b>

- Purchase price of € 45 million was received on Jan. 6<sup>th</sup> 2010

## Strong sales growth

### Sales of Plasma Proteins & Microbiological Monitoring (€ m)

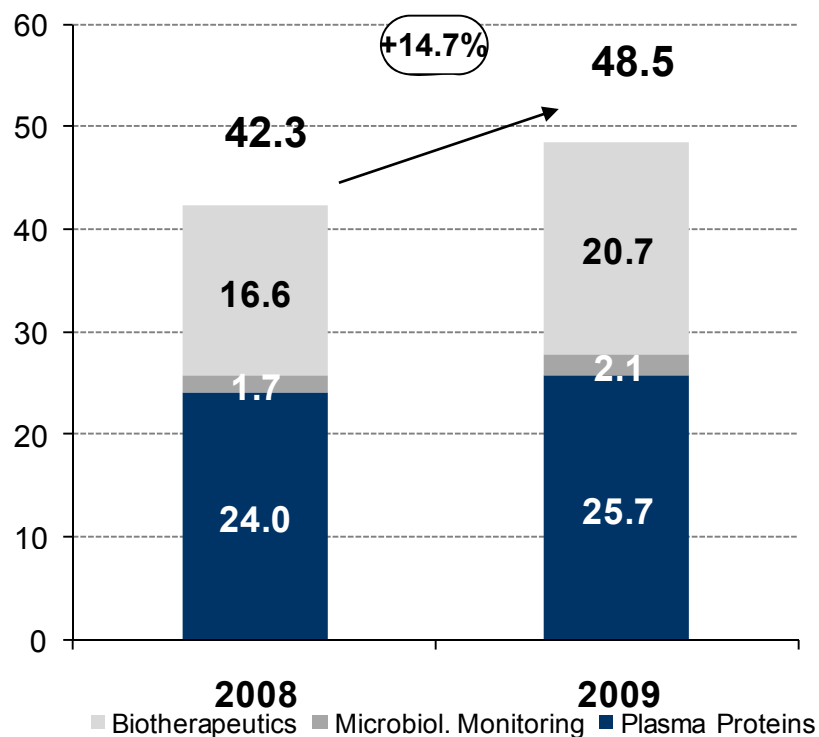


■ Microbiol. Monitoring ■ Plasma Proteins

- Strong sales growth in 2009 in Plasma Proteins and Microbiological Monitoring
- Growth across all Plasma Protein product groups
- Growth of Immunoglobulins due to more indications, higher dosing per patient
- Leading position of Biotest products in several European countries

## R&D Expenses: Continuous increase

### R&D expenses (€ m)



- R&D expenses 2009 stable at 11% of Group sales (2008: 11%)

### Plasma Proteins:

- European approval of Zutectra®
- Additional European approvals for Intratect, Hepatect and Albiomin
- Completion of Phase III of IVIG in the US

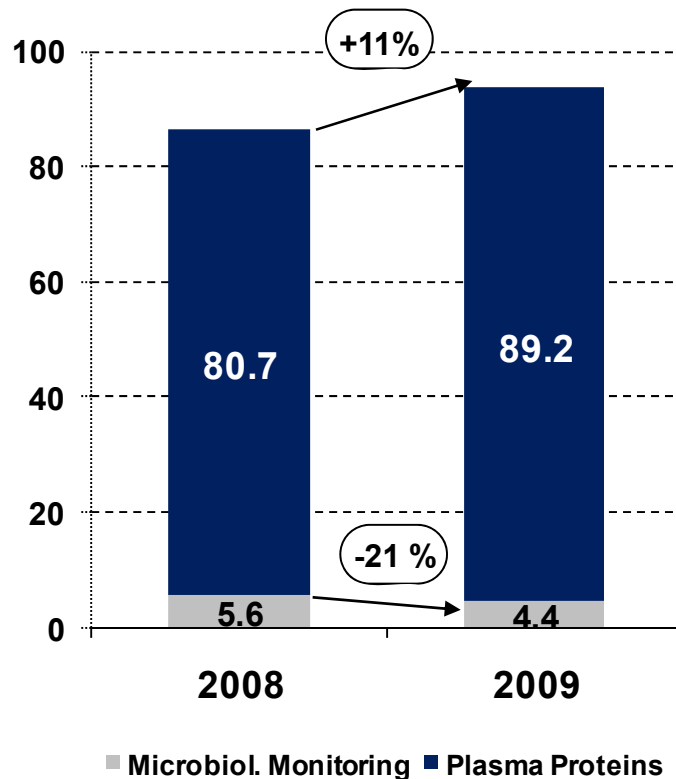
### Biotherapeutics:

- Progress of clinical and preclinical studies
- Establishment of mAb production facility in Boca Raton



## Strong EBIT growth in Plasma Proteins

### EBIT Plasma Proteins and Microbiological Monitoring (€ million)



- Increase in EBIT by 4.2% vs. 2008
- Main reasons for lower EBIT margin:
  - Costs in connection with reconstruction of BPC manufacturing plant
  - Higher raw material costs
  - Depreciation of inventories due to decreasing market prices in

## Plasma Proteins business drives EBIT

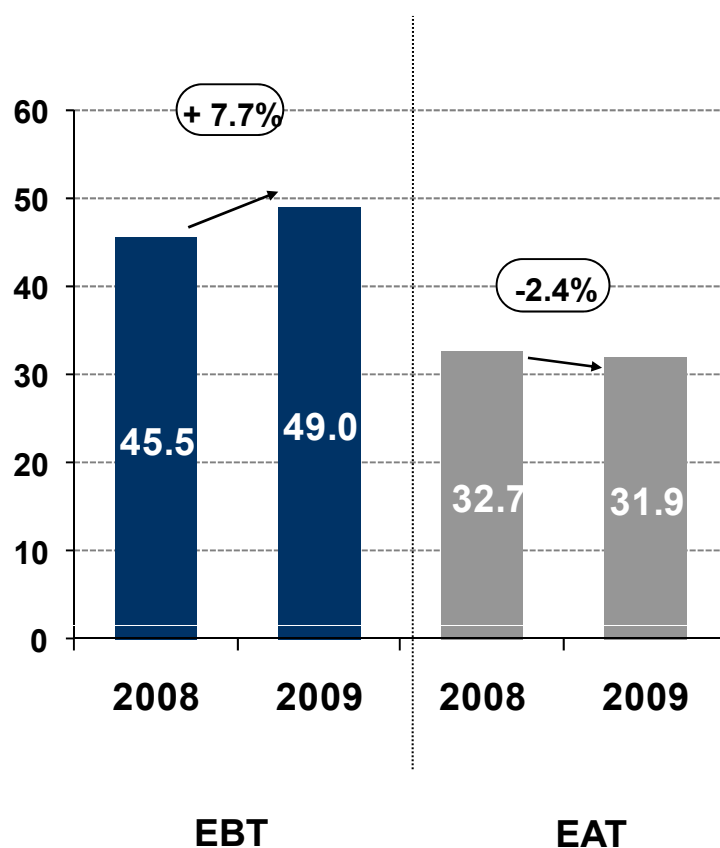
### EBIT by segments (in € million)

	<b>2009</b>	<b>2008</b>
Plasma Proteins	<b>89.2</b>	80.7
Biotherapeutics	<b>-21.1</b>	-16.8
Microbiological Monitoring	<b>4.4</b>	5.6
Corporate/ Reconciliation	<b>-11.0</b>	-10.5
<b>Total Continuing Operations</b>	<b>61.5</b>	<b>59.0</b>

- EBIT of Plasma Proteins segment increased by 10.5 %
- Biotherapeutics EBIT influenced by level of maturity of clinical studies
- EBIT of Microbiological Monitoring planned lower as 2008 due to higher marketing and R&D costs

## Decrease in profit in 2009

EBT and EAT (in € million)



- Rise in earnings before tax (EBT), due to more favourable financial result as a result of lower interest expenses
- Financial result: € -12.8 million (2008: € -13.5 million)
- Earnings after tax (EAT) at € 32.7 million
- Tax impact 2009: € -17.1 m (2008: € -12.8 m) due to higher non tax deductible expenses
- Tax ratio: 34.9% (2008 : 28.1%)

## Key Financial Figures

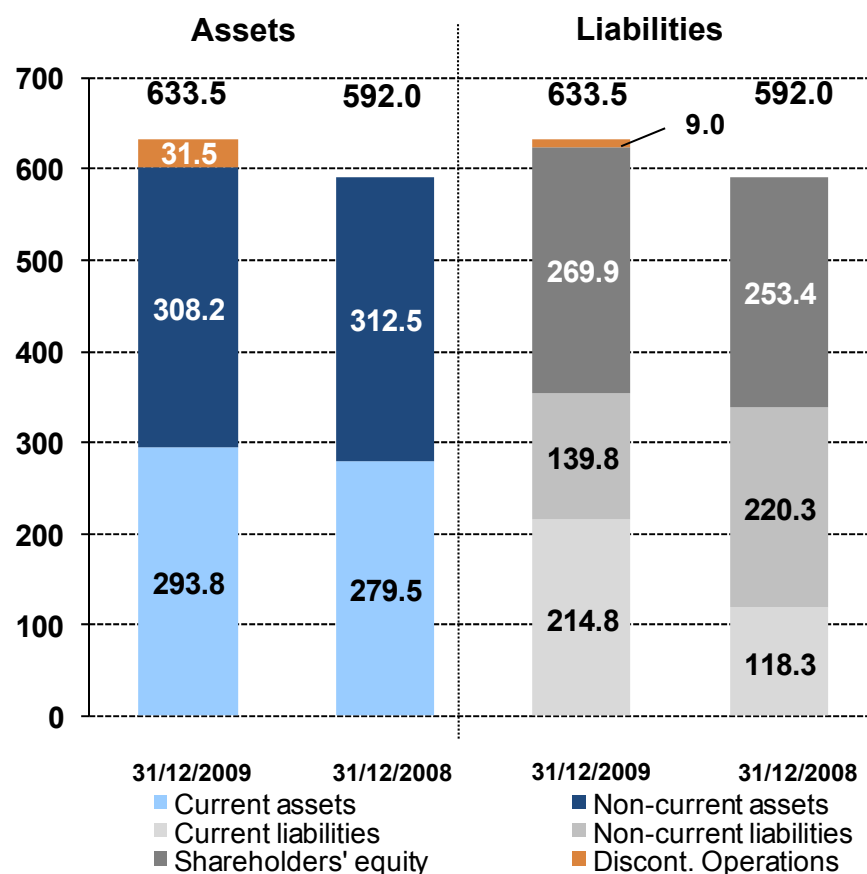
	2009	2008
<b>EAT*</b> before min.	<b>31.9</b>	32.7
<b>EPS*</b> (per ordinary share)	<b>2.49</b>	2.56
<b>EPS*</b> (per preference share)	<b>2.55</b>	2.62
<b>ROCE (%)</b>	<b>11.1</b>	11.7
<b>Dividend**</b> (per ordinary shares)	<b>0.34</b>	<b>0.30</b>
<b>Dividend**</b> (per preference share)	<b>0.40</b>	<b>0.36</b>

- The ROCE was influenced by increase in current assets (working capital)
- Higher dividend to be proposed at the Shareholders' meeting on May 6<sup>th</sup>, 2010

\* Continuing Operations; \*\*The dividend 2009 to be proposed at the Shareholders' meeting on May, 6th, 2010

## Strong balance sheet

### Balance sheet of the Biotest Group (in € million)



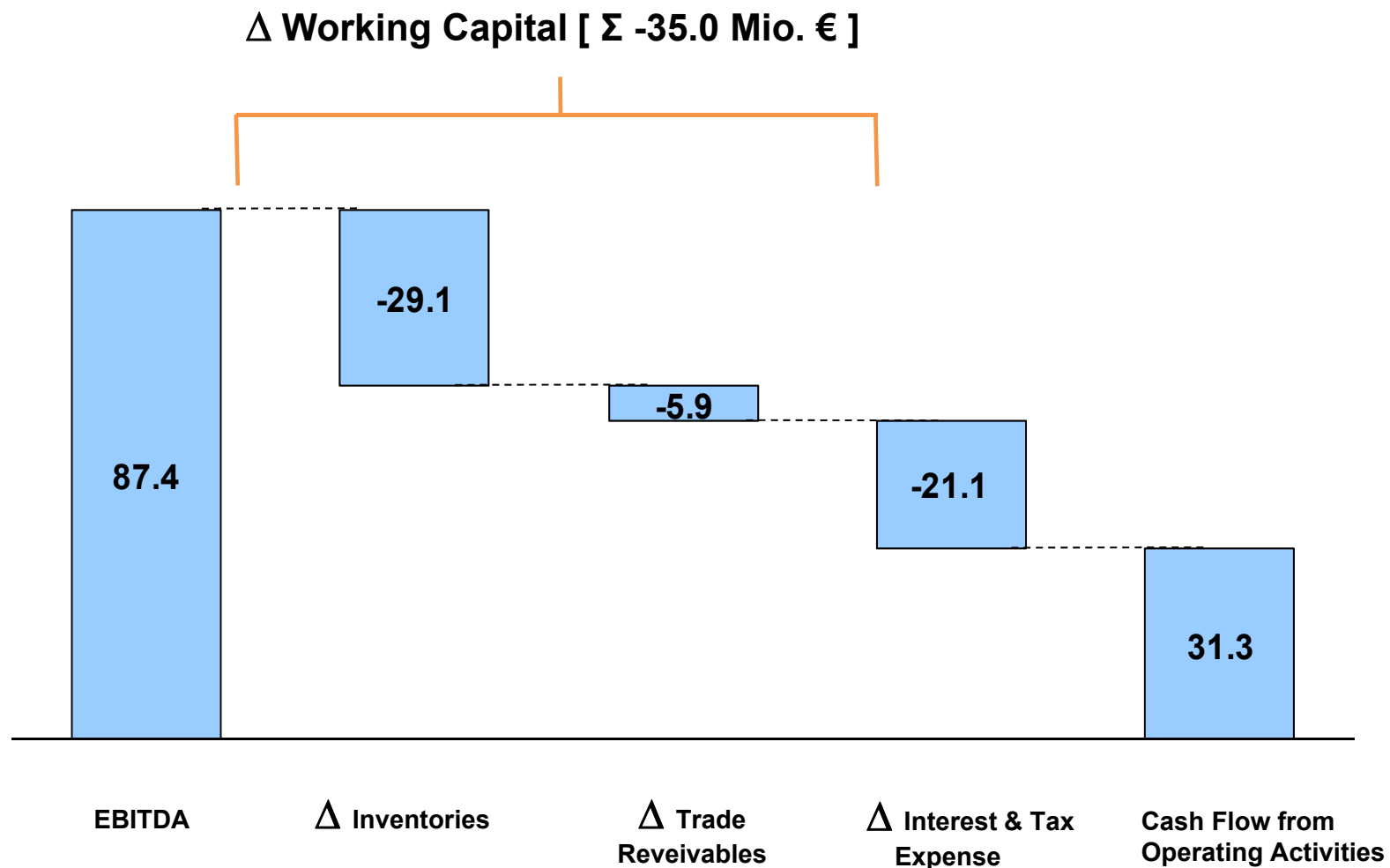
### Assets

- Higher inventories driven by expected growth in 2010
- Higher Trade receivables due to higher sales volumes mainly in the plasma proteins segment

### Liabilities

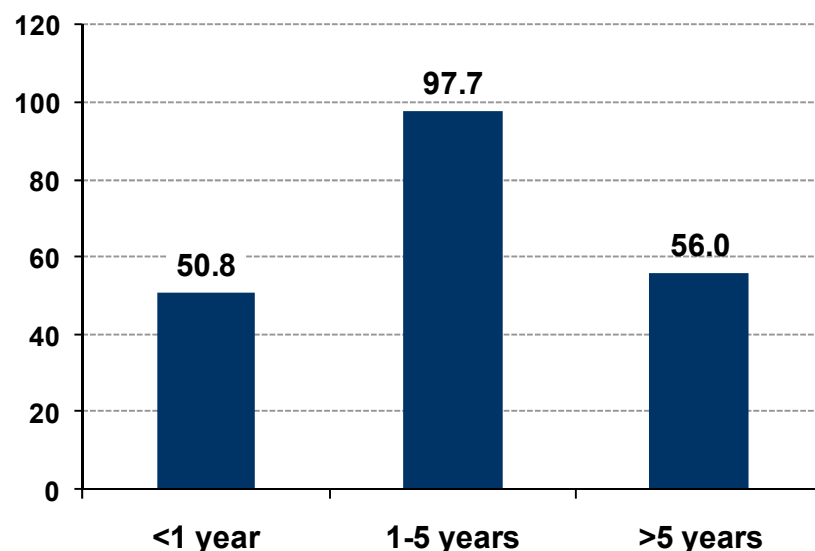
- Increase in current financial liabilities, primarily corresponding to working capital development
- Equity ratio as of 31 Dec. 2009: 42.6% ( 31 Dec. 2008: 42.8%)

## Cash Flow from Operating Activities in € million 2009



## Long term secure debt financing

### Biotest Group: Maturity of financial liabilities (€ million)



- Total financial liabilities as of 31 December 2009: € 204.5 million (2008: € 194.8 million)
- Successful renewal of working capital facility of € 40 million and new working capital line of € 10 million
- Further financing available – but at higher interest rates
- Purchase price of € 45 million was received on Jan. 6<sup>th</sup> 2010

## **Global Economic Crisis: Higher vigilance necessary**

- Most products of the Plasma Proteins segment are life saving in nature
- Plasma Proteins segment with opportunities in both developed and emerging markets
- Geographic diversity due to international business (Eastern Europe, Asia, US)

### **But:**

- Potential challenges in public health care policies and reforms
- Pressure to reduce health care spending might (or will) arise
- Increased risk of loss of receivables (PIGS)



## **Outlook 2010**

### **Start in financial year 2010:**

- Weak start due to high sales end of 2009

### **Our goals for the year 2010:**

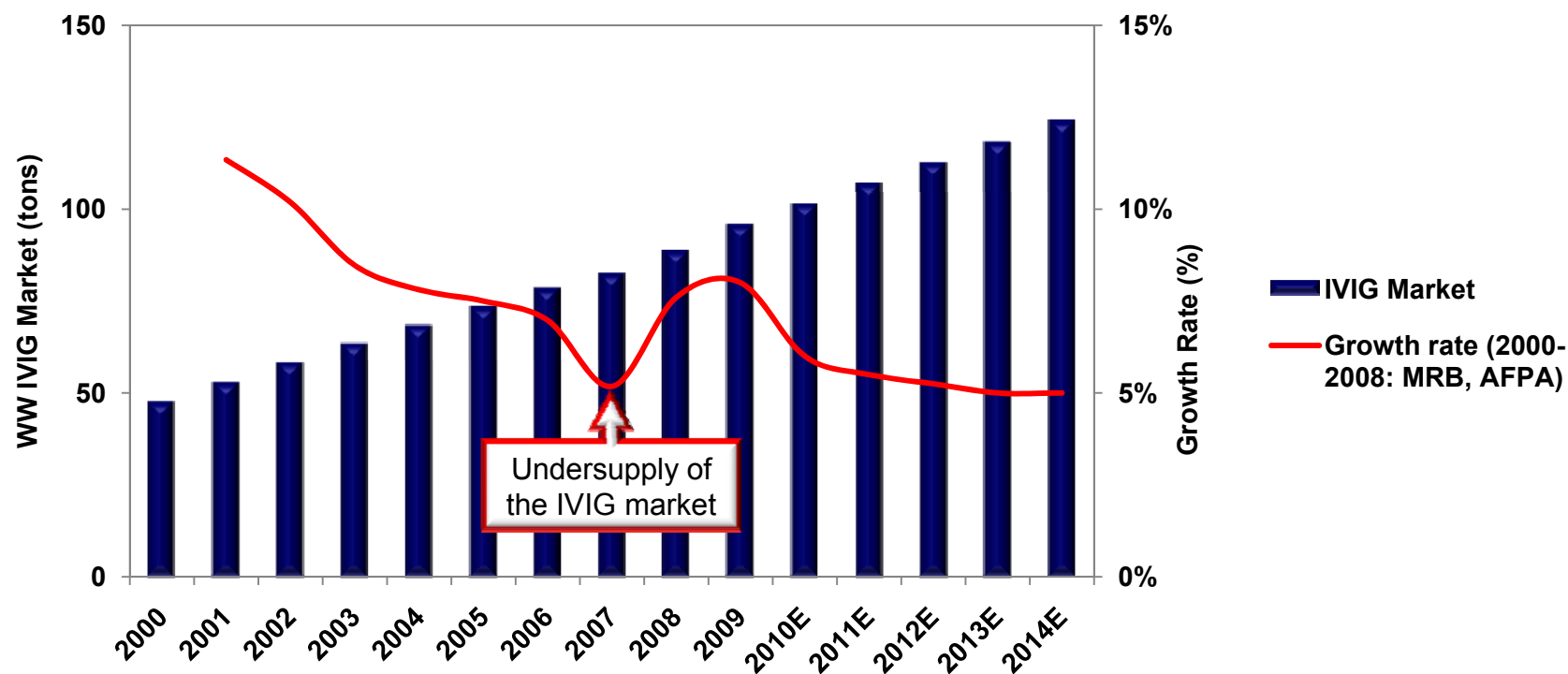
- Increase in a low single digit range - provided tender business on previous year level
- EBIT 2010 on level of 2009, provided that there will be no further price reductions and stable conditions of health care systems



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## **Plasma Proteins**

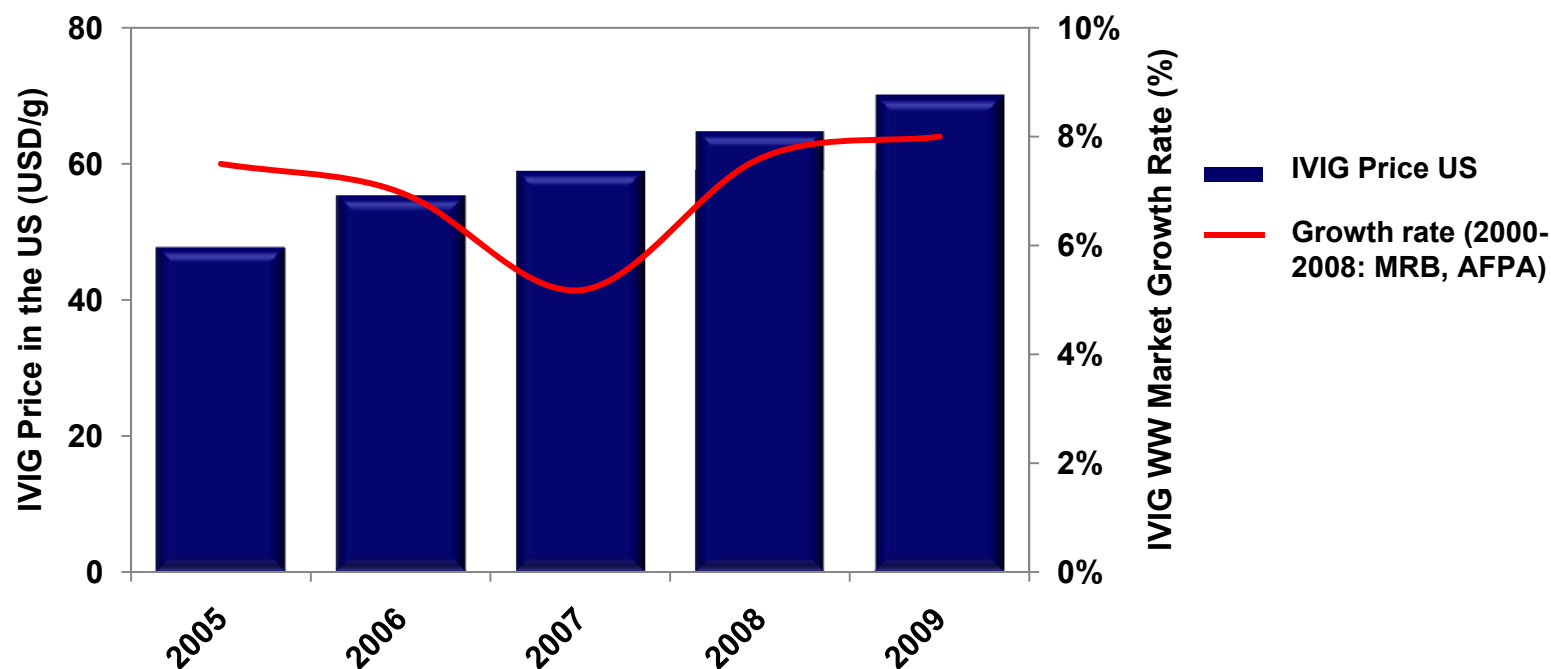
## IVIG Market Development



- For the next 5 years, a stable increase of ~5 % p.a. is expected, with the growth rate in the emerging countries exceeding the one in the developed countries

Source: MRB, APFA, Biotest Market Research

## Development of IVIG Pricing in the US and the WW Market Growth, 2005-2009



- The IVIG pricing in the US market has increased within the last 5 years, regardless of changes in the worldwide market growth rate and overall supply situation
- US as a highly attractive market even if growth rates decline
  - **Biotest's IVIG will enter the US market in 2011**

Source: MRB, APFA, CMS

## **Enlargement of Production Facility in Boca Raton is of high strategic importance**



## Status Projekt IVIG and Boca Raton (USA)

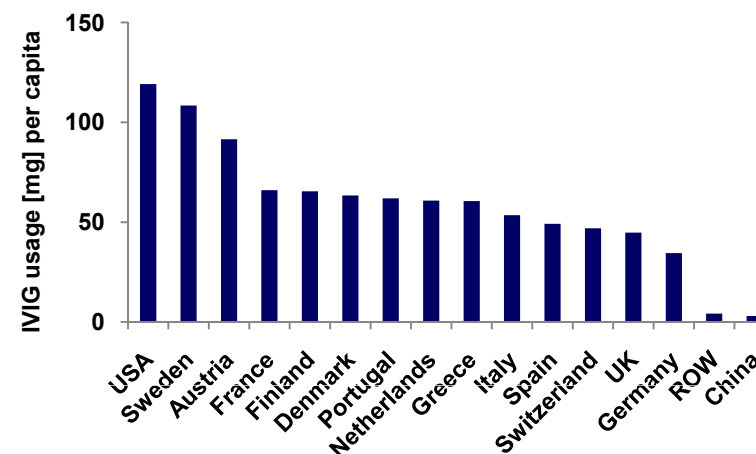
- **IVIG clinical Phase III**
  - Clinical phase III study completed
  - Draft of clinical study report in Dec. 2009
- **Enlargement of production facility**
  - Completion of production facility (part 1) in Q4 2009
  - Final completion of utility systems and warehouse (part 2) in Q2 2010
  - Final capacity: 400.000 l fractionation  
1.5 t immunoglobulin purification
  - Re-Start of Nabi-HB production
  - First IVIG conformance charges produced Dec. 2009
- **Registration of IVIG**
  - Submission of BLA to FDA in Q3 2010
  - Expected approval in Q3 2011



## Further growth of immunoglobulin market expected

### Demand growth driven by

- Favorable demographics: age, weight
- Improved diagnosis, higher dosing level and longer time on therapy
- Continued clinical evidence supporting established and new indications
- Geographical expansion



Source: Global Insight, MRB, PPTA, APFA

### Biotest well positioned by diversified portfolio

- Intratect® – a premium product concerning tolerability \*
- IVIG available in US 2011
- Speciality Hyperimmunoglobulines: Hepatect®, Zutectra®, Varitect®, Cytotect®
- sc application: Zutectra®
- Biotest is world market leader in hepatitis B Hyperimmunoglobulin



\*: Poster: "A European, multicentre, open and prospective study on clinical efficacy, safety, and pharmacological properties of Intratect® (human normal immunoglobulin for iv administration) in patients with primary immunodeficiency (PID)"; E. Bernatowska et al., 2006

## Hepatect® CP and Zutectra®:

The perfect product portfolio for Hepatitis B reinfection prophylaxis after liver transplantation

First 6 months			For life
During transplantation	Week 1 post transplantation	From week 2 onwards, adjustment of consistent anti HBs titres > 100 IU/L	Maintenance therapy, anti HBs titre > 100 IU/L
10,000 IU/200 ml	Daily 2,000 IU/40ml		~ 500 IU/week





## Hepatect<sup>®</sup> CP and Zutectra<sup>®</sup> :

The perfect product portfolio for Hepatitis B reinfection prophylaxis after liver transplantation



- i.v. application for high dosage therapy during and after transplantation
- proven efficacy
- Hepatect CP is worldwide the best documented Hepatitis B Immunglobulin for this indication
- fast, pain free s.c. application for maintenance therapy at any time during the day; well tolerated
- consistent antibody levels achieved by weekly s.c. injections
- self treatment means less visits to physicians and more individual flexibility

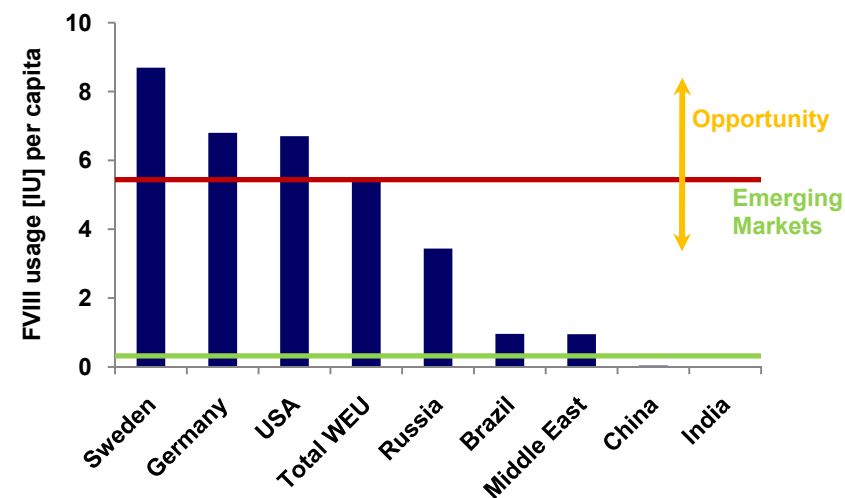
## Opportunities in Haemophilia market

### Increasing global standards of care

- Improving access to care
- Increasing global penetration of hemophilia therapy
- Optimization of compliance, dosing and prophylaxis treatment

### Biotest Products

- Haemonine® (Factor IX) introduced in 2008
- Haemoctin® (Factor VIII) contains high level of von Willebrand factor
- Haemoctin® is stable at RT for 2 years without artificial stabilisers, sugar free
- Haemoctin® has shown to be efficacious in FVIII inhibitor therapy



Source: WFH, PPTA



## Biotest R&D activity in Plasma Proteins

- R&D expenses in 2009 in the Plasma Protein segment: € 25.7 m
- Continuous high investments in R&D in Plasma Proteins will guarantee future growth of the Plasma Proteins business
- Goal:
  - international regulatory registration and approval for all major Biotest products and intermediates



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## Biotest R&D activity in Plasma Proteins

### Cytotect



#### Lead indication:

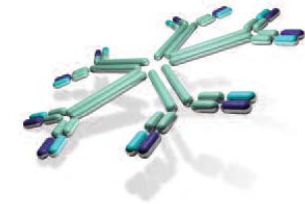
Prevention of congenital CMV infection in newborns of CMV seroconverted women during pregnancy

#### Phase III Trial

- More than 4.000 pregnant women have been screened until end of 2009
- Study centers in Germany, Belgium, Hungary, Austria
- Interim Analysis available end of 2010

## **Biotest R&D activity in Plasma Proteins**

### **IgM Concentrate**



IgM Concentrate is successor product of Pentaglobin, containing approx. 2x amount of IgM; optimal functional properties to neutralise endotoxins and to inactivate bacteria

**Lead indication:** Severe Infections (e.g. severe pneumonia)

**Phase I trial:** Status completed (last patient last visit: Dec 30th, 2009)

- No major safety issues, no occurrence of serious adverse events in both single and repeated dosage
- Pharmacokinetic data confirm expected dose for Phase II

**Phase II trial:**

- Protocol in development
  - Study sites for core-indication are identified
  - Further indication is currently evaluated
-

## **Biotest R&D activity in Plasma Proteins**

### **Hepatitis B immunoglobulin in neonates**



#### **Phase III trial**

- Status: Recruitment ongoing (5 sites have recruited 30 patients)
- End of Study planned for Q3 2010
- Marketing Approval: aiming for marketing approval in Germany first, international marketing authorisations to follow

## Summary Plasma Proteins: Biotest made significant progress in implementation of its corporate strategy

- Biotest will grow the Plasma Proteins segment
- Presence in the U.S. market extended
- Regulatory approval for IVIG expected Q3 2011  
Market potential for this product in USA estimated to be > \$ 100 m
- Strong R&D pipeline: New products and new clinical indications





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## **Biotherapeutics**



# Clinical development BT-061

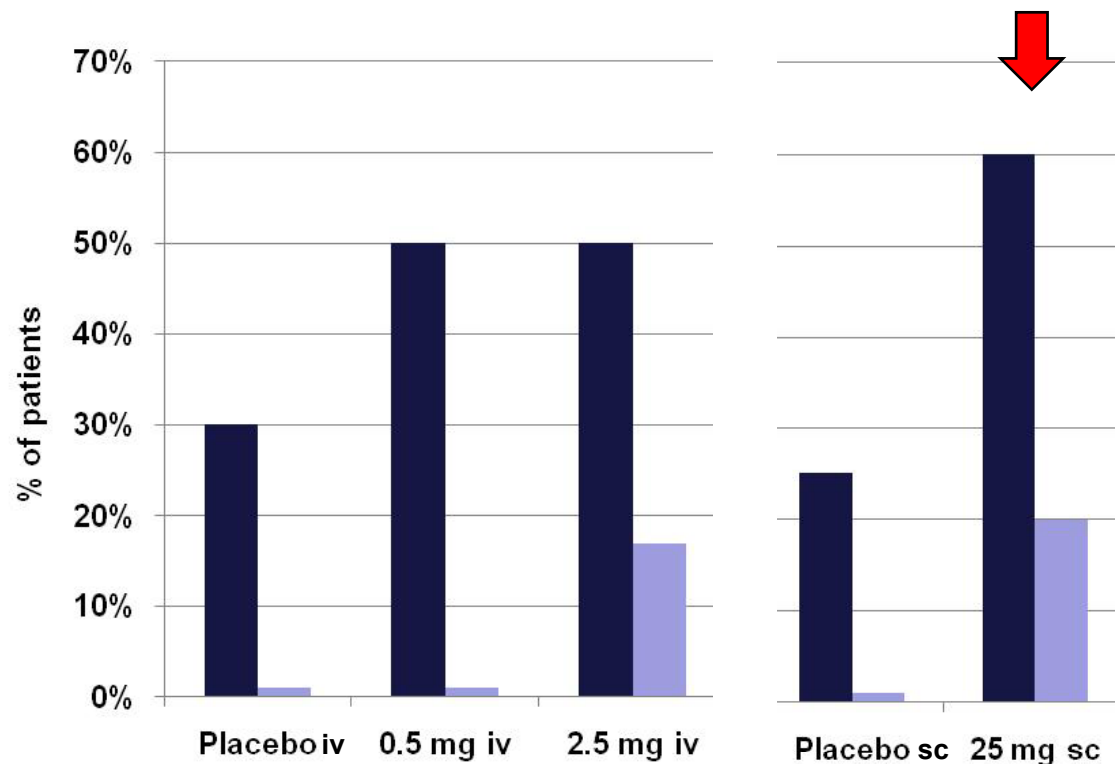
## Overview

<b>Study no.</b>	<b>Indication</b>	<b>Design</b>	<b>Subjects/ Patients Planned</b>	<b>Status</b>
961	Healthy volunteers	single dose iv; and sc up to 180 mg	57	Study completed
967	Phase I/IIa:Psoriasis	single dose, placebo controlled iv and sc	55	Study completed
973	Phase II: Psoriasis	multiple dose, placebo controlled	48	Recruitment Started (Q1- 2010)
962	Phase IIa: Rheumatoid Arthritis	Multiple dose, Placebo controlled	96	Recruitment Ongoing (last study cohort)
971	Phase II: Rheumatoid Arthritis	BT-061 + MTX Multiple dose, Placebo controlled	110	Part I (iv) finalized Part II (sc) ongoing
979	Phase IIb: Rheumatoid Arthritis	BT-061 + MTX Multiple dose, Placebo controlled	~ 300	Submission: Q2-2010

## Psoriasis Phase I/IIa Study (No. 967) Results:

Up to 60% of patients benefit from treatment with BT-061

**PASI 50 and PASI 75 responders at day 75 after single dose  
in most effective dose groups\*\***

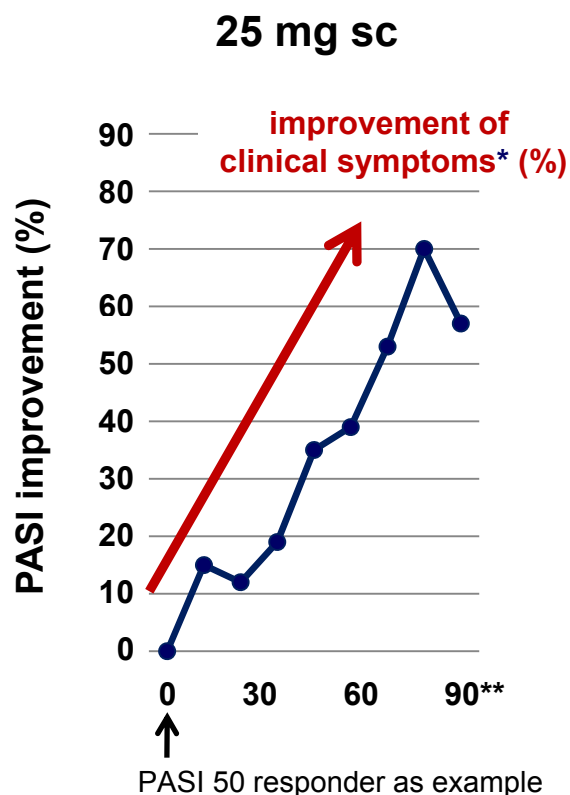


- Up to 60 % of patients (responders) benefit from BT 061 treatment
- Highest response rate in 25 mg sc group

Improvement of clinical symptoms (PASI score)\*:  
 ■ 50% (PASI 50)  
 ■ 75% (PASI 75)

\*PASI (Psoriasis Area and Severity Index) measures the average redness, thickness and scaliness of the lesions, weighted by the area of involvement. \*\* : each with 7 or 8 patients

## Psoriasis Phase I/IIa Study (No. 967) Results: Improvement of clinical symptoms - a characteristic time course



- Highest response rate (improvement of clinical symptoms) in 25 mg sc group
- Duration of clinical benefit up to 90 days after single application of BT- 061
- Good safety and tolerability

\* PASI (Psoriasis Area and Severity Index) measures the average redness, thickness and scaliness of the lesions, weighted by the area of involvement.

\*\* days past treatment

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## **BT-061: Summary clinical results Psoriasis**

### **Psoriasis Phase I/IIa (single dose administration)**

- Highest response rates by subcutaneous administration (25 mg)
- Duration of clinical benefit up to 90 days
- Proof-of-concept achieved in Psoriasis
- Good safety and tolerability

➤ **Improvement of clinical symptoms and Proof-of concept in Phase I/IIa**



### **Psoriasis Phase II (multiple dose administration)**

- Recruitment has started
- Goals:
  - Further improvement of efficacy by repeated dosing (8 weeks)
  - Finalization of dose finding/ frequency of administration
  - Focus on subcutaneous administration

## **BT-061: Summary clinical results Rheumatoid Arthritis**

### **Rheumatoid Arthritis Phase Ia and Phase II:**

Phase Ia: Monotherapy: up to 70% improvement (ACR70) after 6 weeks of treatment (50 mg sc and 2 mg iv)

Phase II: Combination with methotrexate (MTX): up to 70% improvement (ACR70) after 8 weeks of treatment (2 mg iv + MTX)

- Proof-of concept achieved in Rheumatoid Arthritis
- Good safety and tolerability



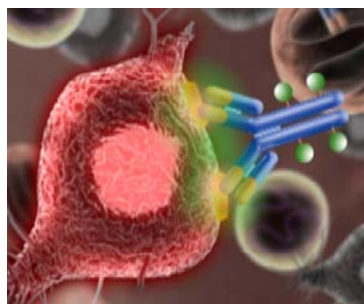
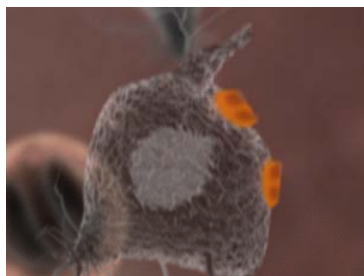
### **Rheumatoid Arthritis Phase IIb (submission Q2/2010):**

- ~ 300 patients
- Combination with MTX
- 12 weeks treatment, once per week and every other week
- Subcutaneous administration
- Goals:
  - Generate statistical basis for phase III
  - Determine final dose schedule

## **Partnering for BT-061: Co-development and co-marketing from Phase III onwards**

- Several globally acting pharmaceutical companies have been approached
- Predominantly positive response
- Development and marketing concept met fundamental approval
- Principle interest in taking part in the project expressed
- Partners require final data of ongoing phase II trials in order to agree to relevant deal structure
- Discussions ongoing

## BT-062 : Clinical efficacy in Multiple Myeloma



- BT-062: specific and highly effective immunotoxin: toxin part mediates high efficacy – antibody part mediates high specificity
- Phase I Study: Repeated single dose, dose escalation study in patients with relapsed or relapsed/refractory Multiple Myeloma
  - Indications of efficacy already with low dosages:
    - **Disease progression halted in some patients for several months**
    - **Clinical benefit for 53% of patients lasting 6 weeks or longer**
    - **Maximum treatment dose defined and cohort extension ongoing**
- Good safety and tolerability

## BT-062: Single-Dose Study 969 in Multiple Myeloma First Efficacy Data

Number of patients	Total	Percentage	Objective response	Clinical benefit (%)
treated with BT-062*	25			
efficacy data available	<b>17</b>	<b>100%</b>		
- disease progression	1	6%		
- no disease progression > 3 weeks	7	41%		
- stable disease $\geq$ 6 weeks	7	41%		<b>53%</b>
- minor response	1	6%	12%	
- partial response	1	6%		

- **BT-062 shows anti-tumor activity already in repeated single dose schedule**
- **Further patients to be enrolled in MTD\*\* cohort up to a total of 15**

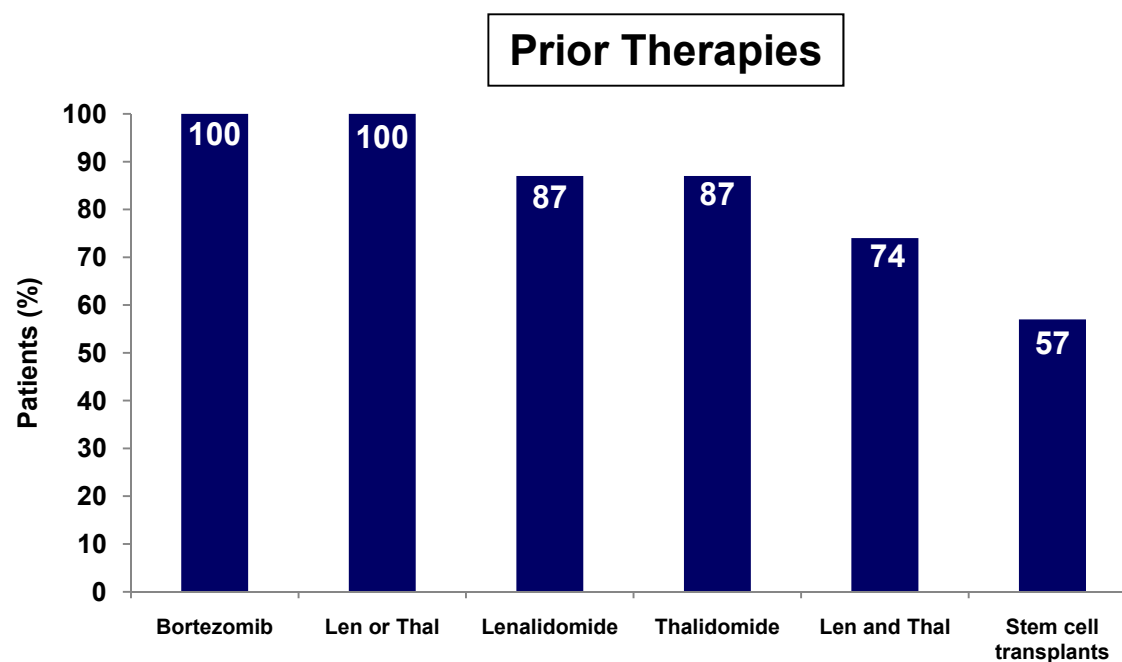
\*Median number of prior chemotherapies: 7 (range: 2-15); 33% of patients had 10 or more prior chemotherapies

\*\*MTD: Maximum tolerated dose; Response criteria as defined by International Myeloma Working Group



## BT-062: Repeated Single Dose Study 969 in Multiple Myeloma - Baseline Characteristics

Patients have been heavily pre-treated; median age of about 65 years and about 6 years median time since initial diagnosis



- All patients have been treated with Bortezomib and at least one Immunomodulator
- About 75% have been pre-treated with both Lenalidomide and Thalidomide
- More than 50% have undergone an autologous stem cell transplantation (ASCT)

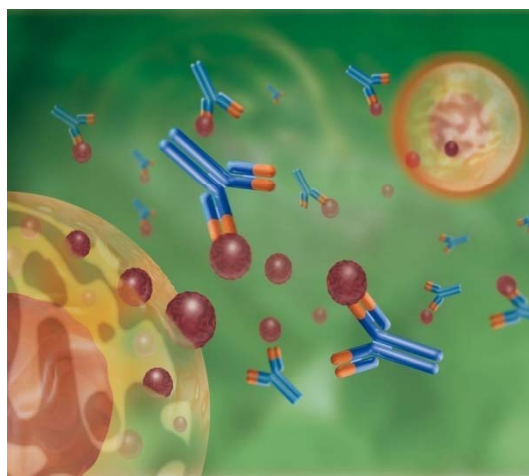
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## **BT-062 : Next steps initiated**

- Based on positive results from Phase I study, study documents for next clinical phase I/IIa have been submitted
- Phase I/IIa Study: Multi dose escalation study in patients with relapsed or relapsed/refractory Multiple Myeloma
  - Study approved by FDA (IND\*-submission)
  - Trial initiation expected in Q2 2010
- Goal: Further definition of dose schedule

\*IND = Investigational New Drug

## BT-063: Phase I study on track



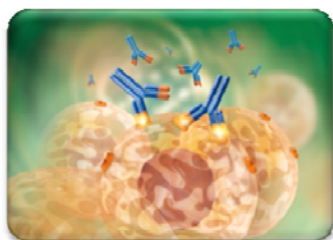
### BT-063 lead indication

- Systemic Lupus Erythematosus (SLE)
- High medical need: SLE incurable today, no new approval since ~ 40 years
- 2.5 million patients are suffering from SLE worldwide today

### Status Phase I

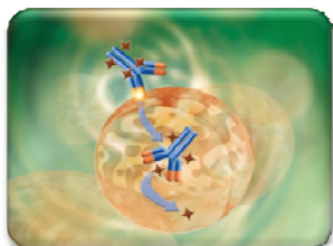
- Dose escalation in healthy volunteers ongoing
- 21 volunteers treated
- So far study medication well tolerated

## Outlook Biotherapeutics: Next Steps in Clinical Development Initiated



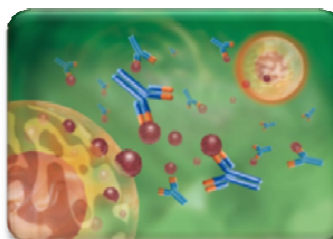
### **BT-061:**

- First encouraging clinical data from both lead indications
- Phase II trial in Psoriasis started
- Phase IIb in RA in preparation
- Discussion with strategic partners ongoing



### **BT-062:**

- First indications of efficacy from dose-escalating study
- Multiple dose phase I/IIa trial approved by FDA
- Study start expected Q2 2010



### **BT-063:**

- Phase I study approved in Sept. 2009
- Treatment at 7th dose level completed (02 2010)

## Summary Biotest Group

### Outlook 2010:

- Increase in a low single digit range - provided tender business on previous year level
- EBIT 2010 on level of 2009, provided that there will be no further price reductions and stable conditions of health care systems; 2010 will be a challenging year
- It is our assumption, that the plasma market environment will stabilise within the next 1-2 years and thereby the pricing situation
- The initiation of operations at the production facility in Boca Raton/ US will have a significant positive effect on Biotest
- Biotherapeutics: well on track



## International Myeloma Working Group Response Criteria

	Major characteristics of response criteria*
<b>Progressive Disease (PD)</b>	Increase of 25% from lowest response value in any one or more of the following: Serum M-component (absolute increase must be $\geq 0.5\text{g}/100\text{ml}$ ) <sup>c</sup> and /or Urine M-component (absolute increase must be $\geq 200\text{ mg}$ per 24 h)
<b>Stable disease (SD)</b>	Not meeting criteria for CR, VGPR, PR or progressive disease
<b>Minor response (MR) in patients with relapsed refractory myeloma</b>	$\geq 25\%$ but $< 49\%$ reduction of serum M protein and reduction in 24 h urine M protein by 50–89%, which still exceeds 200mg per 24 h
<b>Partial response (PR)</b>	$\geq 50\%$ reduction of serum M-Protein and reduction in 24-h urinary M protein by $\geq 90\%$ or to $< 200\text{ mg}$ per 24 h If the serum and urine M-Protein are unmeasurable, a $\geq 50\%$ decrease in the difference between involved and uninvolved FLC levels is required in place of the M-Protein criteria
<b>Maximum Tolerated Dose (MTD)</b>	The highest dose level at which $< 2$ of 6 subjects experience a DLT (Dose Limiting Toxicity) is defined as the MTD.

\* according IMWG, International Myeloma Working Group; Source: Kyle and Rajkumar, 2009;

# Thank you for your attention!



## Contact and Financial Calendar 2010

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### Financial Calendar 2010

**May 06, 2010**      **Annual General Meeting**

**May 11, 2010**      **Q1 Report 2010**

**Aug 12, 2010**      **Q2 Report 2010**

**Nov 08, 2010**      **Analyst's Conference**

**Nov 08, 2010**      **Q3 Report 2010**