

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



**LBBW German Equity Conference - London 28 April 2009**

**Biotest AG**

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## Disclaimer

This document contains forward-looking statements on overall economic developments 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 comparative figures relate to the corresponding last year's period, unless stated otherwise.

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## **Biotest at a glance**

“Biotest is a global specialist for pharmaceutical, biotherapeutic and diagnostic products in the areas of immunology and haematology.”

### **Pharmaceuticals**

#### **Plasma Proteins**

- Immunoglobulins
- Hyper-Immunoglobulins
- Clotting Factors
- Albumin

#### **Biotherapeutics**

- Monoclonal Antibodies

### **Diagnostics**

#### **Medical Diagnostics**

- Transfusion
- Transplantation
- Infectious Disease

#### **Microbiological Monitoring**

- Hygiene Monitoring

## Biotest at a glance

- Headquarters in Dreieich (Frankfurt region)
- Subsidiaries in 10 countries worldwide
- Biotest share listed at the German Stock Exchange since 1987, SDAX member since 2007:
  - 6,595,242 ordinary shares
  - 5,133,333 preference shares



Headquarters, Dreieich

### **Biotest Group: Figures 2008**

Sales	€ 423.0 m
thereof Plasma Proteins	€ 339.5 m (80 %)
thereof outside Germany	€ 310.0 m (73 %)
EBIT	€ 55.6 m
Employees (FTE)	1,952
thereof outside Germany	779



U.S. facilities, Boca Raton

## Biotest Group: Highlights of 2008



- Integration of BPC finalised
- Further internationalisation of business in all segments
- Plasma Proteins: product range broadened
- R&D: important milestones reached
- Biotherapeutics: partnering of BT-061 initiated
- Microbiological Monitoring: innovation leader
- Medical Diagnostics: clear signs of improvement
- Sustained dynamic and profitable growth

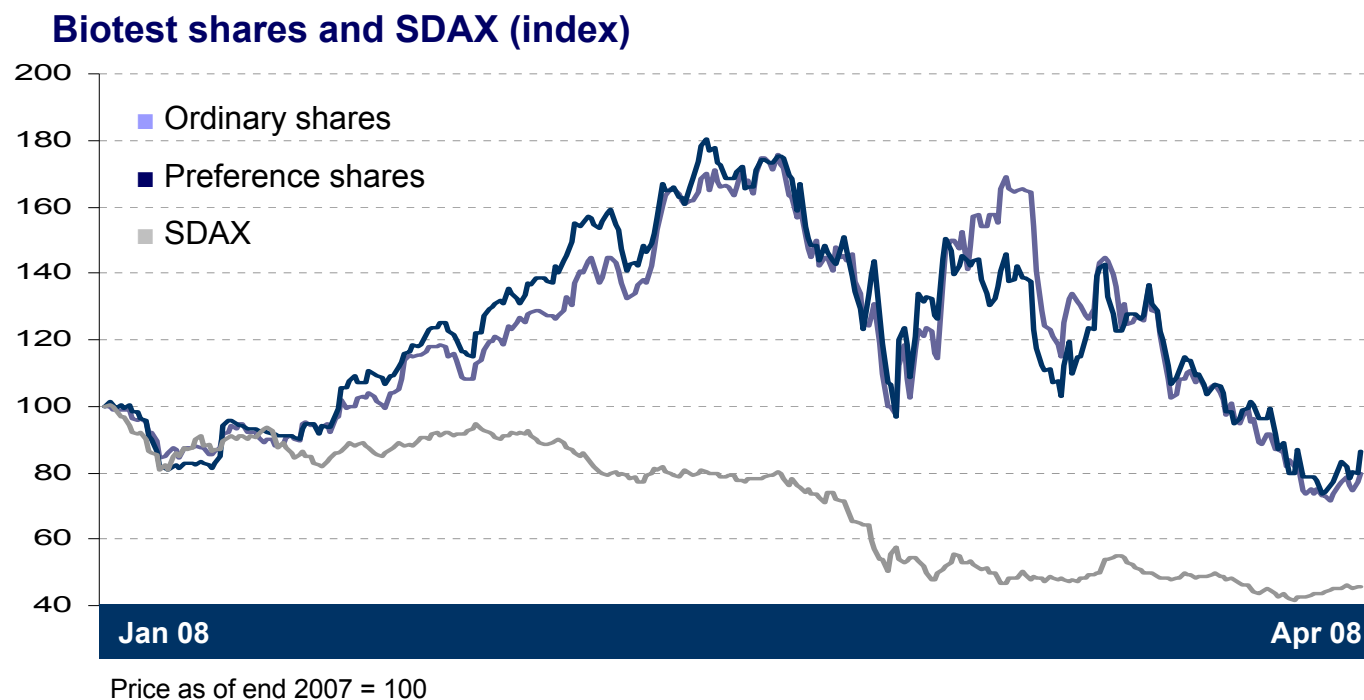


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## **Financials 2008**

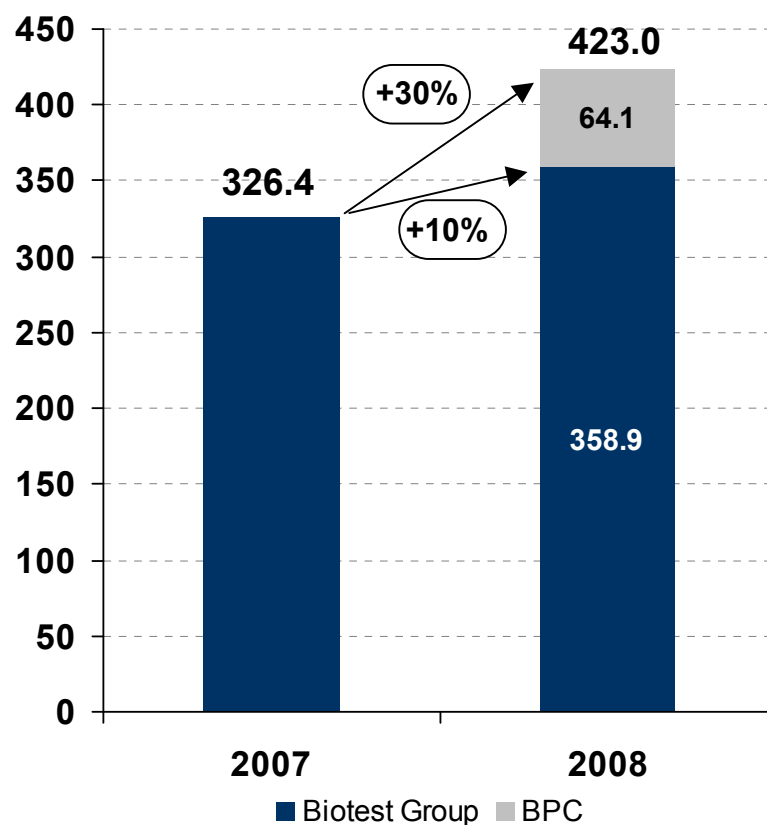
## Biotest shares: turbulent year, but outperformance of SDAX

- Biotest shares reached record level in Aug. 2008: € 67.00 (ord.), € 64.00 (pref.)
- Share price hit by global financial and economic crisis
- Total market cap. € 594.8 m (30. December 2008)



## Strong overall revenue growth

Total sales volume (€ m)

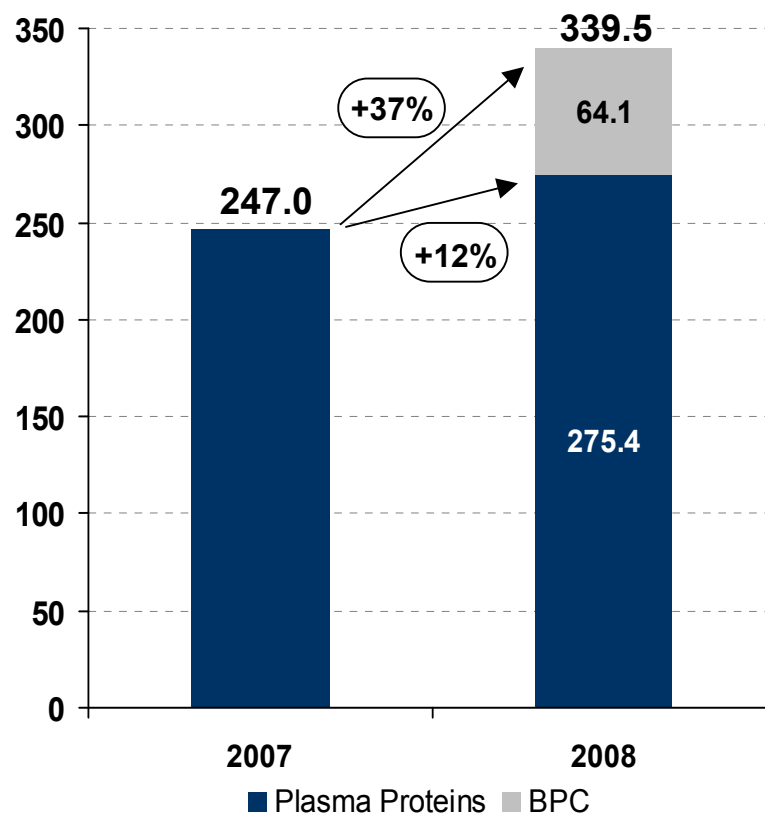


- Strong sales growth in 2008 in 5<sup>th</sup> consecutive year
- Growth across all geographic regions and Plasma Proteins product groups
- 73 % of sales in international markets (2007: 68 %)



## Strong revenue growth in Plasma Proteins business

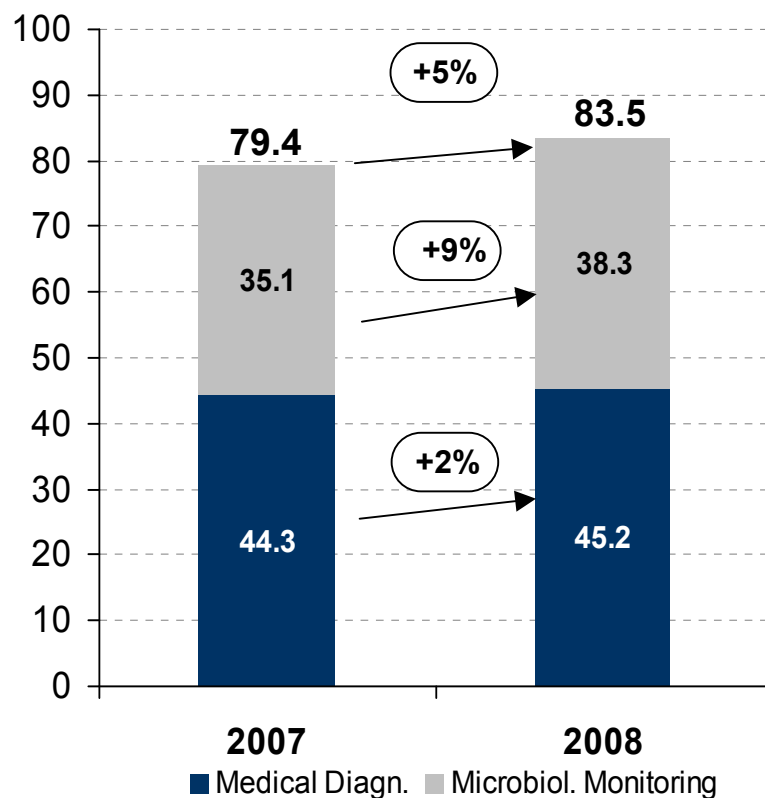
Sales volume Plasma Proteins (€ m)



- Consolidation of BPC leads to jump in sales volume
- Sales BPC € 64.1 m, thereof Plasma: € 44.0 m
- Outstanding: development of Intratect<sup>®</sup> / Intraglobin<sup>®</sup> (+27 %)
- Stable sales with coagulation factors

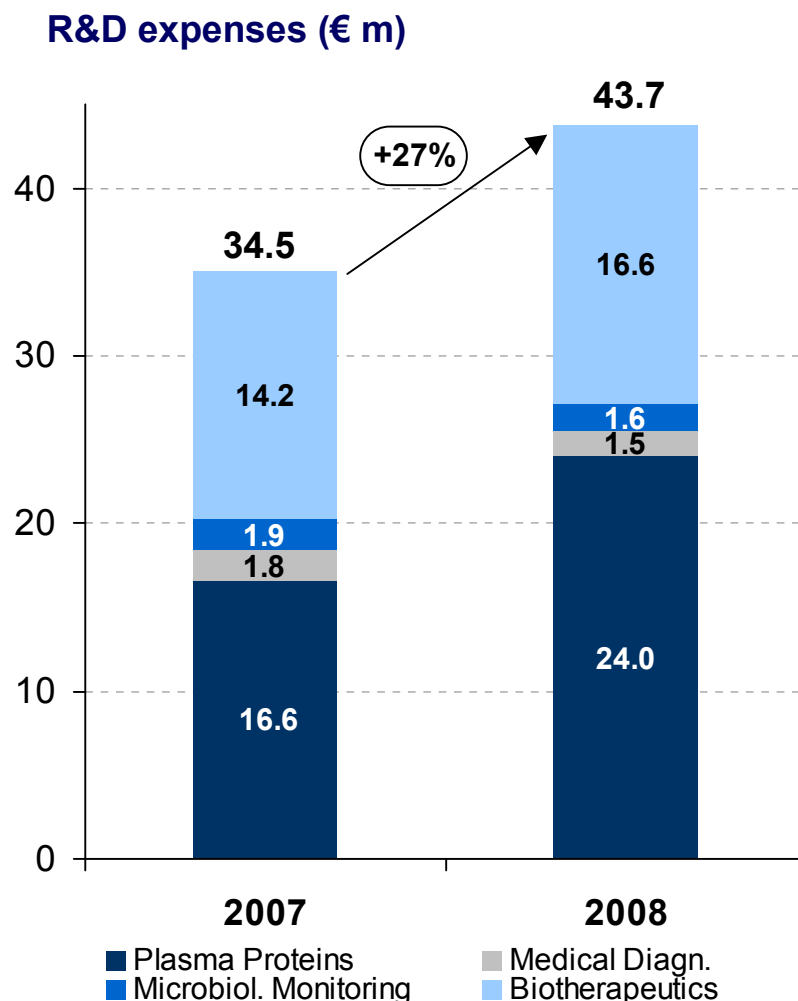
## Strong revenue growth in Microbiological Monitoring, moderate growth in Medical Diagnostics

Sales volume MD and MM (€ m)



- Diagnostics business in two separate segments: Microbiological Monitoring (MM) and Medical Diagnostics (MD)
- **MM:** strong growth in particular with heipha products
- **MD:** sales with transfusion diagnostics (manual reagents and TANGO<sup>®</sup> optimo) up by 10 %, transplantation diagnostics down by 12 %
- U.S.: 50 TANGO<sup>®</sup> optimo systems placed by the end of 2008, more than doubled compared to 2007

## R&D Expenses: continuous increase



- R&D expenses 2008 amount to 10.3 % of Group sales (2007: 10.6 %)

### Plasma Proteins:

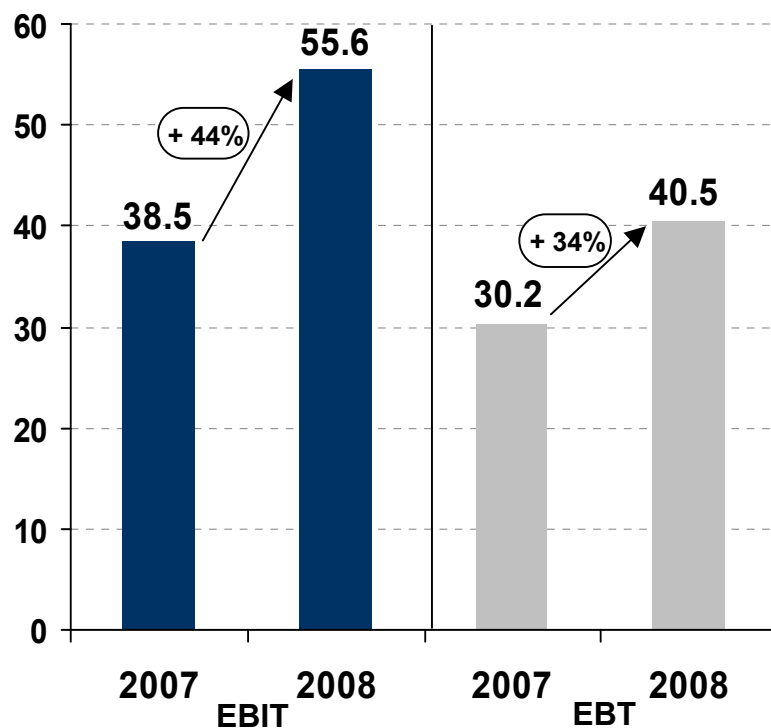
- Application for European approvals (Zutectra®)
- First-time consolidation of BPC
- Preclinical and clinical research in new indications

### Biotherapeutics:

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

## Earnings growth exceeds sales increase

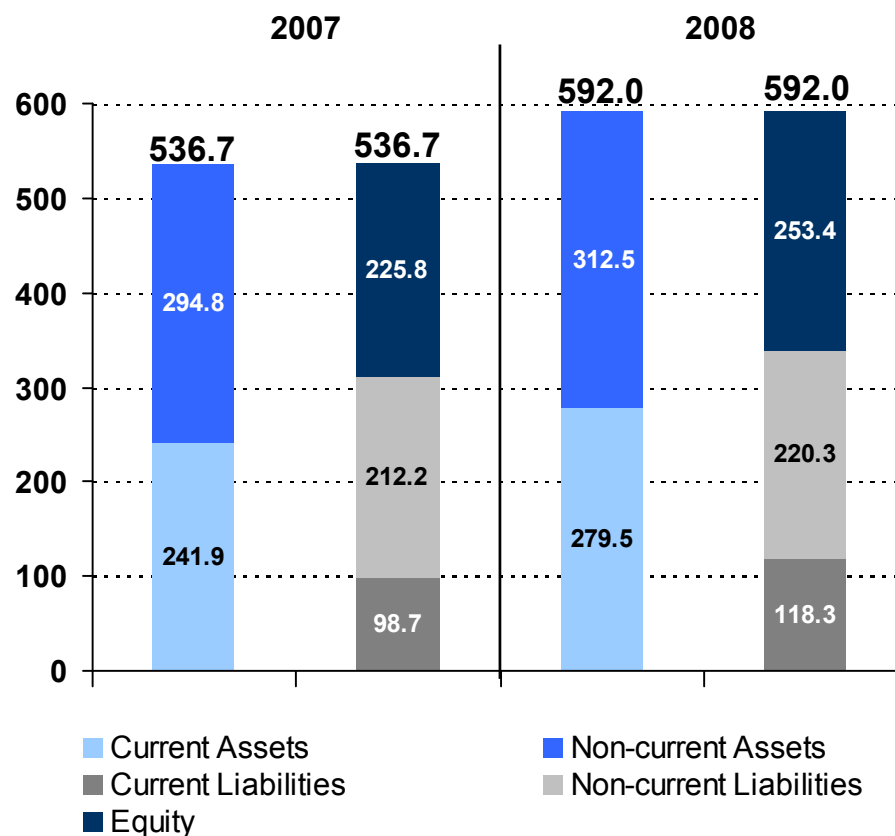
**EBIT and EBT of the Biotest Group (€ m)**



- EBIT increase due to higher sales volume and partially higher prices
- EBIT-growth without BPC: 24 %
- Marketing & Sales expenses grew due to higher sales volume
- Administrative expenses up by € 14 m, thereof € 6.1 m BPC
- Financial result: € -15.1 m (2007: € -8.2 m) – financing BPC
- Net impact of foreign exchange rates on profit 2008: € 0.5 m

## Balance Sheet: solid financial structure

Balance sheet of Biotest Group (€ m)



### Change in Assets:

- Increase in current assets mainly due to higher inventories
- Trade receivables down by 6.5 % due to higher use of factoring
- Rise of non-current assets mainly due to investments in Dreieich

### Change in Liabilities:

- Equity up by profit after tax
- Rise in current liabilities mainly due to higher trade payables
- Equity ratio as of December 31, 2008 at 42.8 % (2007: 42.1 %)



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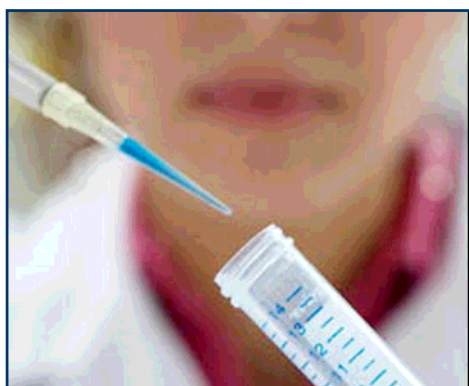
## **Microbiological Monitoring and Medical Diagnostics**

## Microbiological Monitoring: ongoing success



- Continuing success of heipha products in key markets
- Bundling of heipha and HYCON R&D resources
- New products enhance efficacy of monitoring processes
- Focus in R&D on products enabling paperless laboratory

## Medical Diagnostics: significant improvement



- Transfer of activities in Biotest Medical Diagnostics GmbH successfully completed
- Approval of manual transfusion reagents in the U.S. – full-fledged supplier (one of only three)
- Number of TANGO<sup>®</sup> systems placed in the U.S. doubled
- EBIT still negative, but significant upward trend
- Search for strategic partner continued and with high priority



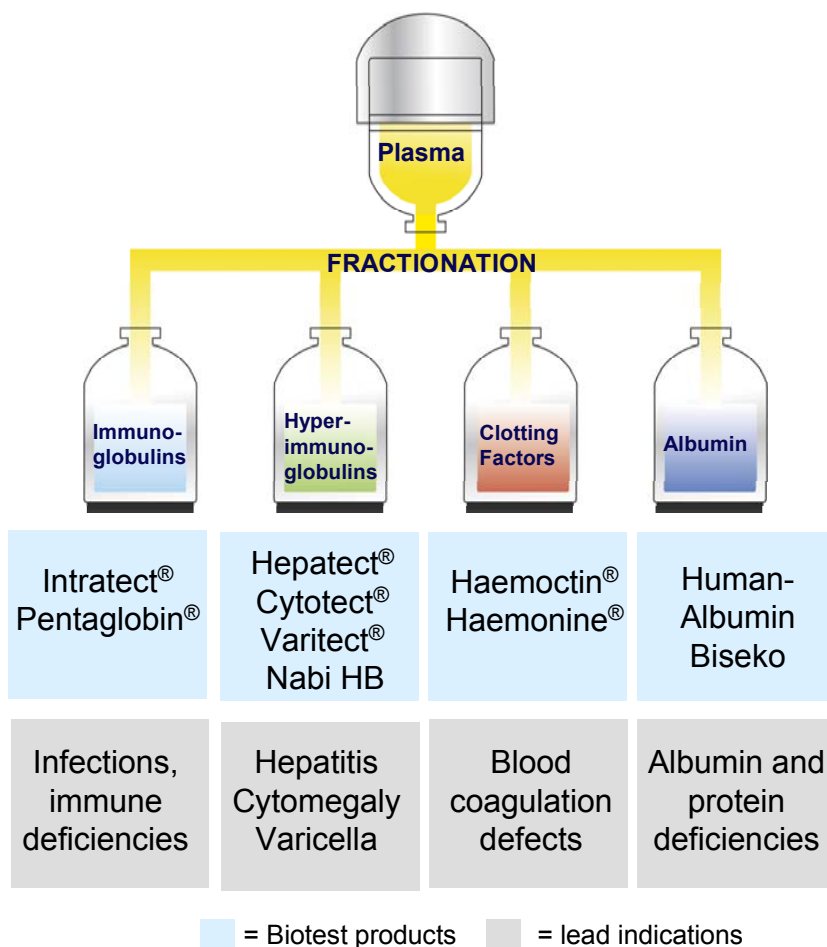


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## **Plasma Proteins**

## Plasma Proteins business at a glance

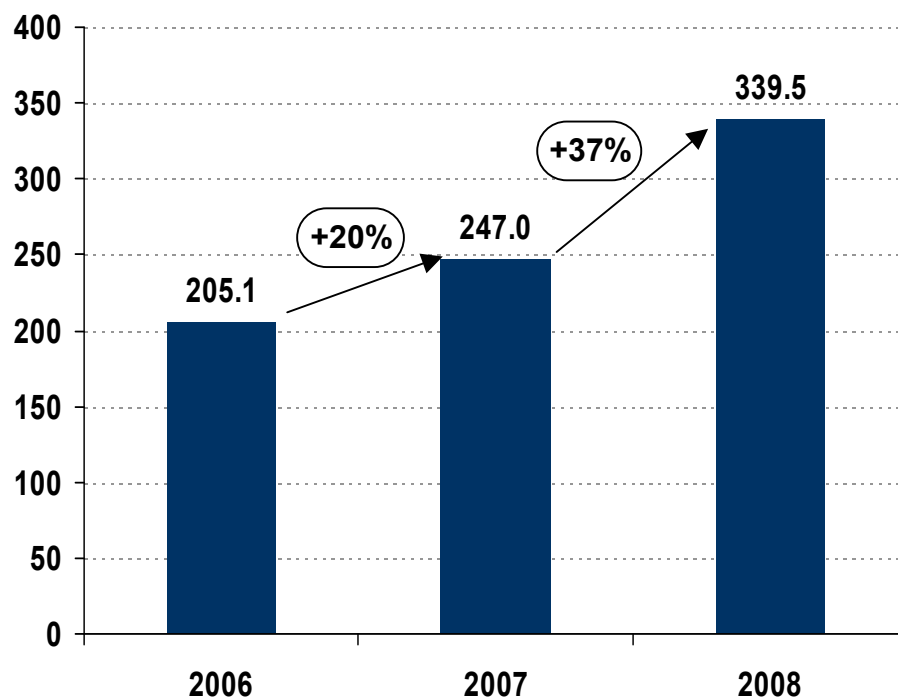
### Biotest Plasma protein products



- Biotest covers full value creation chain: plasma sourcing, production, distribution
- Global market share: 3 %
- Market share in relevant markets (GER, AUT, CH, GRE, UK): 15 %
- Intratect® market share in GER, AUT, CH: > 18 %, in UK: > 8 %
- World market leader with Cytotect® and Varitect®
- Leading position with Hepatect® in Europe and Nabi HB™ in USA

## Plasma Proteins: acquisition of BPC leads Biotest to new dimensions

Plasma Proteins: sales volume (€ m)

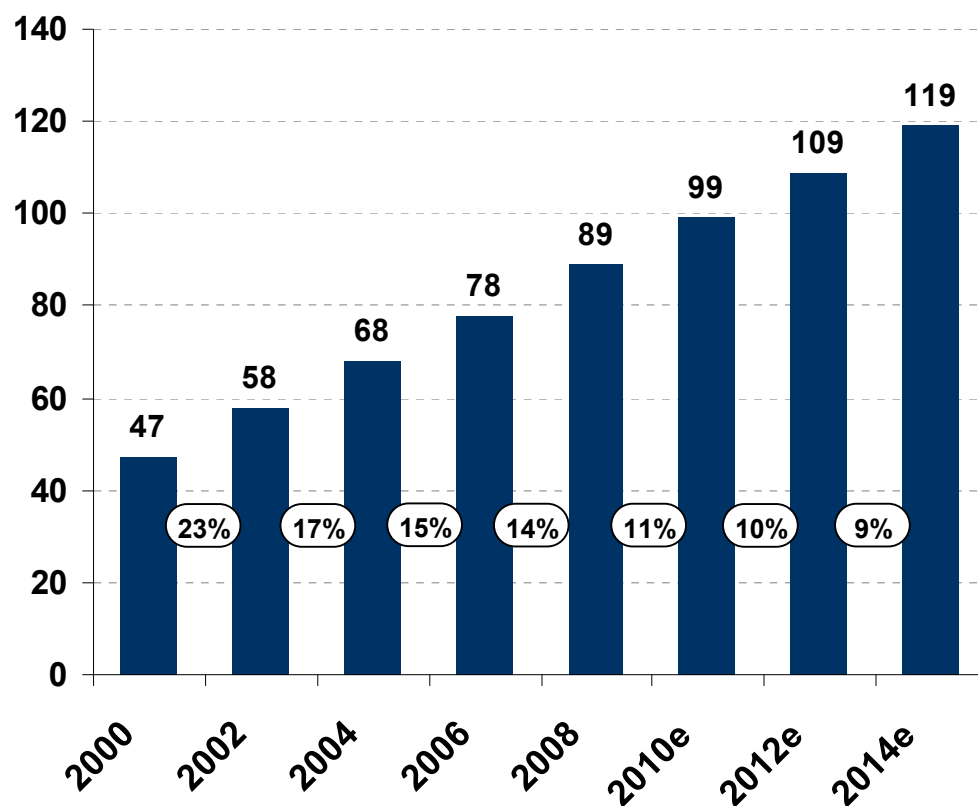


- Sales in Plasma Proteins jumped by 37 %
- Contribution BPC: € 64.1 m
- Biotest sales grew stronger than Plasma Proteins sales of major competitors\*:
  - CSL Behring: +34 %
  - Grifols Bioscience: +23 %
  - Baxter: +22 %
  - Octapharma: 18 %


\*Sales Baxter without rec. Factor VIII / IX regenerative medicine and vaccines  
Sales CSL Behring without rec. Factor VIII  
Based on sales volume in local currencies  
Source: Company Data; Company Announcements

## Plasma Proteins markets: growth rates declining – IVIGs remain driving force

IVIG world market (tons)



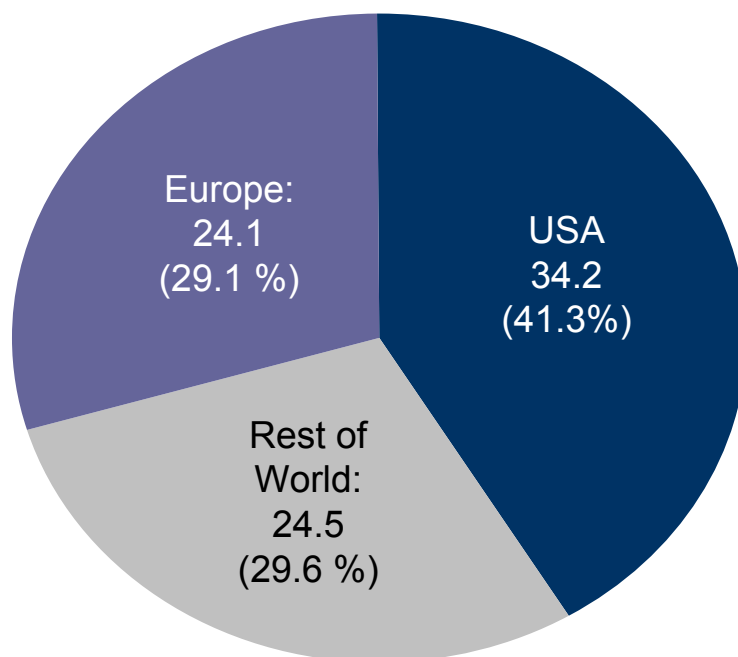
- Market volume for immunoglobulins still rising due to new indications
- Market growth pF VIII almost stable at 3 %
- Positive price trend for all products in key markets has ceased
- Currently, no uniform price trend can be observed

 = growth rate

Source: Review of Australia's Plasma Fractionation Arrangements (Feb 2006); Biotest Market Research

## Immunoglobulins: Approval of US-IVIG bears significant upside potential

### IVIG world market 2007: volume (tons) and regional distribution (%)



Sources: MRB, APFA, UBS, Biotest Market Research

- Total volume IVIG world market as of 2007: 82.8 tons
- USA by far the most important market for IVIG worldwide
- Registration of BPC's US-IVIG (comparable to Intratect®) expected for end of 2010

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## Plasma Proteins: update on progress of clinical studies

**IgM Concentrate:** Phase I protocol submitted as planned on February 16, 2009. Start of clinical phase I development in 2<sup>nd</sup> quarter of 2009. Advisory Board for clinical project has been initiated.

**IVIG (U.S.):** Recruitment of patients for pivotal phase III trial is completed. Registration expected for end of 2010.

**Zutectra<sup>®</sup>:** Hepatitis B immunoglobulin (s.c.), liver transplantation: phase III study completed and submitted for centralised Europ. authorisation procedure. Approval expected for end of 2009.

**Cytotect<sup>®</sup>:**  
(CMV prevention) Clinical study (phase III) is currently in re-evaluation process to optimise recruitment and study procedures.

**Intratect<sup>®</sup>:** Chronic idiopathic pain syndrome: phase III study completed. Excellent clinical response in 30 % of patients. Laboratory parameters are evaluated to identify predictive clusters that are linked to positive outcome.



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## **Biotherapeutics**

## Biotherapeutics: investments with high upside potential

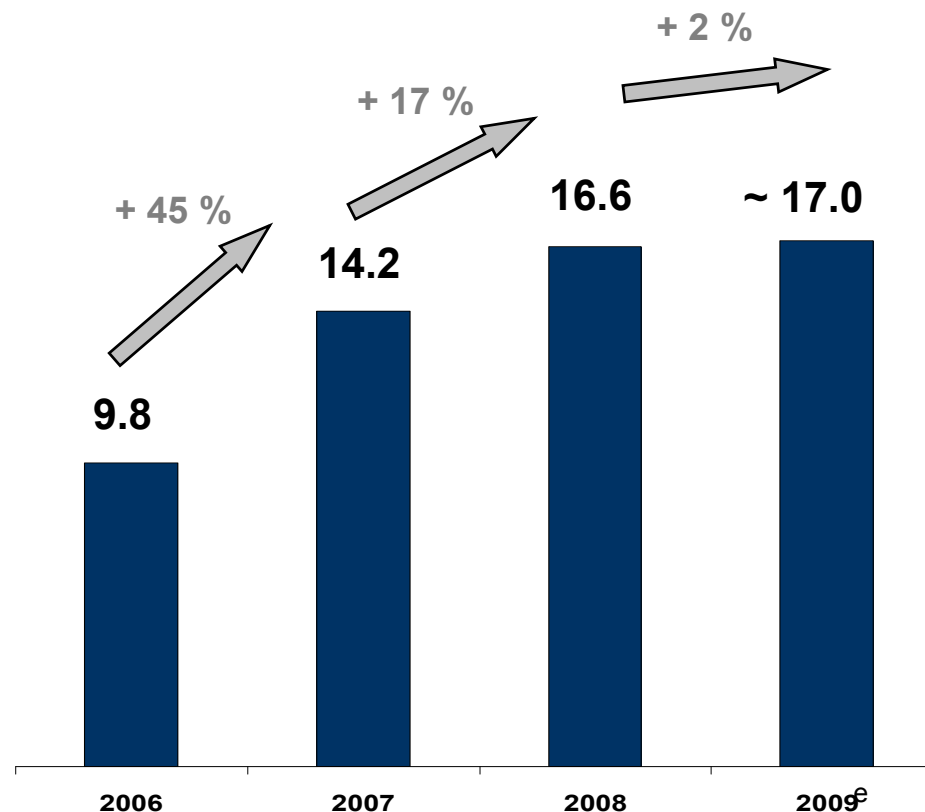
### Common characteristics of Biotest monoclonal antibodies:

- High medical need
- Fast growing markets
- Blockbuster potential

### Biotest mAbs and major indications:

<b>BT-061</b>	Rheumatoid Arthritis, Psoriasis
<b>BT-062</b>	Multiple Myeloma
<b>BT-063</b>	Systemic Lupus Erythematosus and other autoimmune diseases

### R&D expenses Biotherapeutics (€ m)





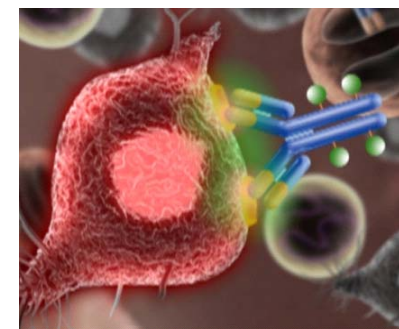
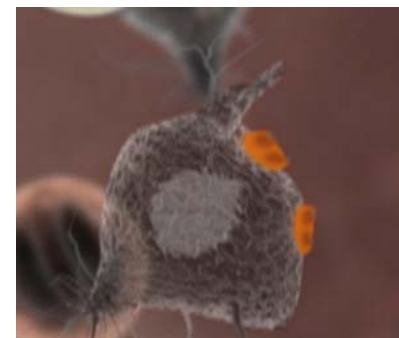
## Monoclonal antibodies – High medical need

### BT-061: Rheumatoid Arthritis (RA), Psoriasis

- Approx. a quarter of all patients do not respond, or not sufficiently, to approved therapies.
- Approx. 6 million patients suffer from Rheumatoid Arthritis.
- Volume of RA drugs in 2008: US\$ 10.4 bn, forecast for 2012: US\$ 17.8 bn

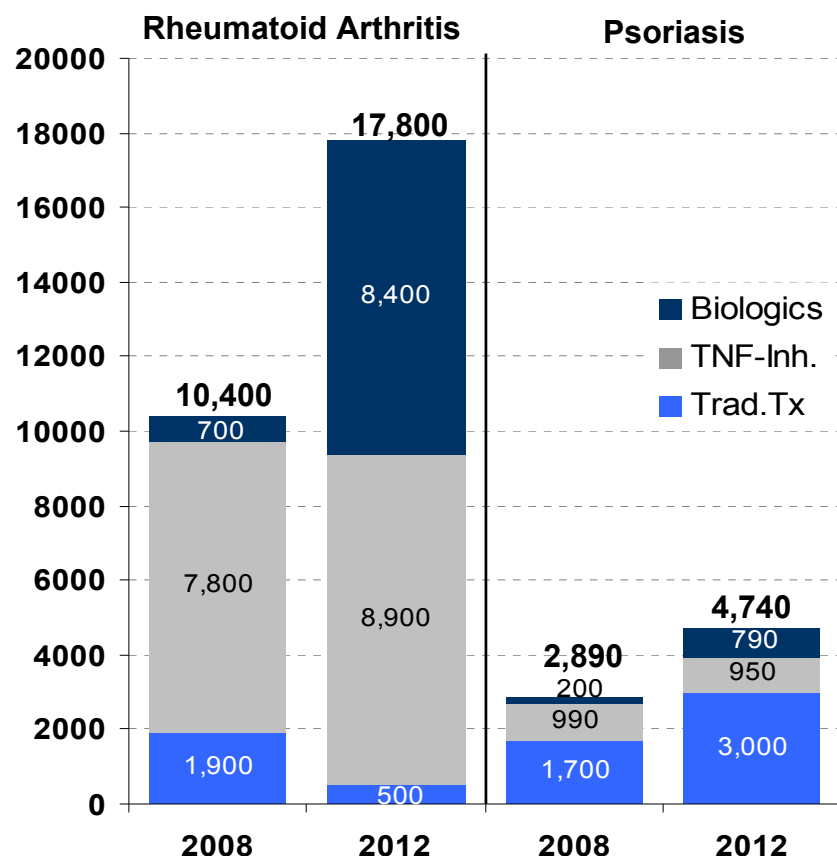
### BT-062: Multiple Myeloma (MM)

- There is no known cure for Multiple Myeloma to date.
- Life expectancy is 10 years from diagnosis in about 5 % of cases.
- Volume of novel targeted MM-therapeutics in 2008: US\$ 2.9 bn, with strong market growth



## Biotherapeutics – A big and fast growing market, Blockbuster potential for Biotest mAbs

### Volume of market for therapy (\$ m)



(Sources: L.E.K. and Biotest analysis 2009)

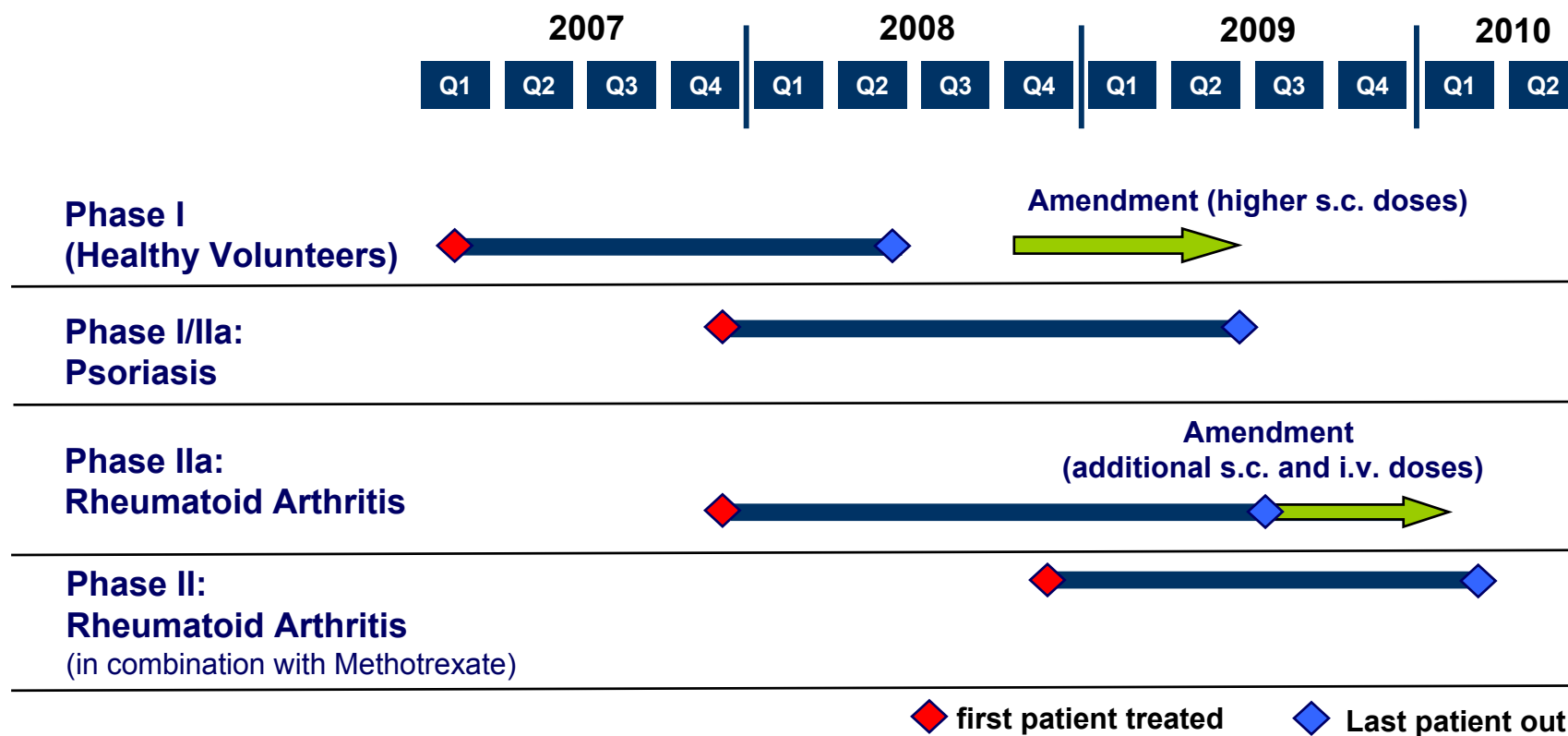
- Strong growth in both indications mainly driven by biologics and new drugs
- After approval of BT-061: significant market potential for both targeted indications
- BT-061 with unique mode of action

## Monoclonal antibody projects are on track, promising data from clinical studies



- BT-061: First successful clinical efficacy data in **Rheumatoid Arthritis** and **Psoriasis**.
- Partnering process for BT-061 started in 2008, should be finalised by end of 2009.
- BT-062 was so far generally well tolerated by critically ill patients (**Multiple Myeloma**).
- Biotest holds a variety of patents (including a US patent) and has submitted further patent applications.
- Establishment of internal manufacturing (BPC, Boca Raton) proceeds according to plan.

## Overview clinical development of BT-061



### Clinical Studies in preparation:

- Phase II Psoriasis: submission postponed until effective s.c. doses identified
- Phase IIb R.A.: planning of study is continued

## Summary of results from ongoing clinical studies

### Rheumatoid Arthritis – Phase IIa

- Multiple dose escalation study
- i.v and s.c. application
- 75 % of patients receive BT-061, 25 % receive placebo

- first effective s.c. dose levels reached; **clinical response** observed in **62.5 % of patients**
- maximum efficacy is expected to be identified by further dose escalation in ongoing study

### Psoriasis – Phase I/IIa

- Single dose escalation study
- i.v and s.c. application
- 75 % of patients receive BT-061, 25 % receive placebo

- in relevant therapeutic dose ranges (i.v.) **clinical response** observed in **75 % of all patients**
- individual patients show improvement of PASI score up to 88 %
- long-lasting effect already at low doses

**Until now, BT-061 has generally been well tolerated.**

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



- Presence in U.S. market increased.
- Plasma Proteins: business grew stronger than market.
- Strong R&D pipeline: products and clinical indications.
- Further growth of Plasma Proteins segment by extension of capacities in plasma sourcing and production.
- Regulatory approval for IVIG expected by end of 2010. Market potential for this product in USA estimated to be US\$ 100 m.
- Biotherapeutics: strong clinical data facilitate search for co-development / co-marketing partner.
- Goals for 2009: to increase sales by more than 10 %, EBIT at € 55 m.

**Thank you for your attention!**



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## Financial Calendar

07 May 2009	Annual General Meeting
15 May 2009	Quarterly Report for Q1 2009
12 August 2009	Quarterly Report for Q2 2009
05 November 2009	Quarterly Report for Q3 2009
05 November 2009	Analysts Conference