

# Biotest Group



Company Presentation

**Biotest AG**

August, 2011

## Disclaimer

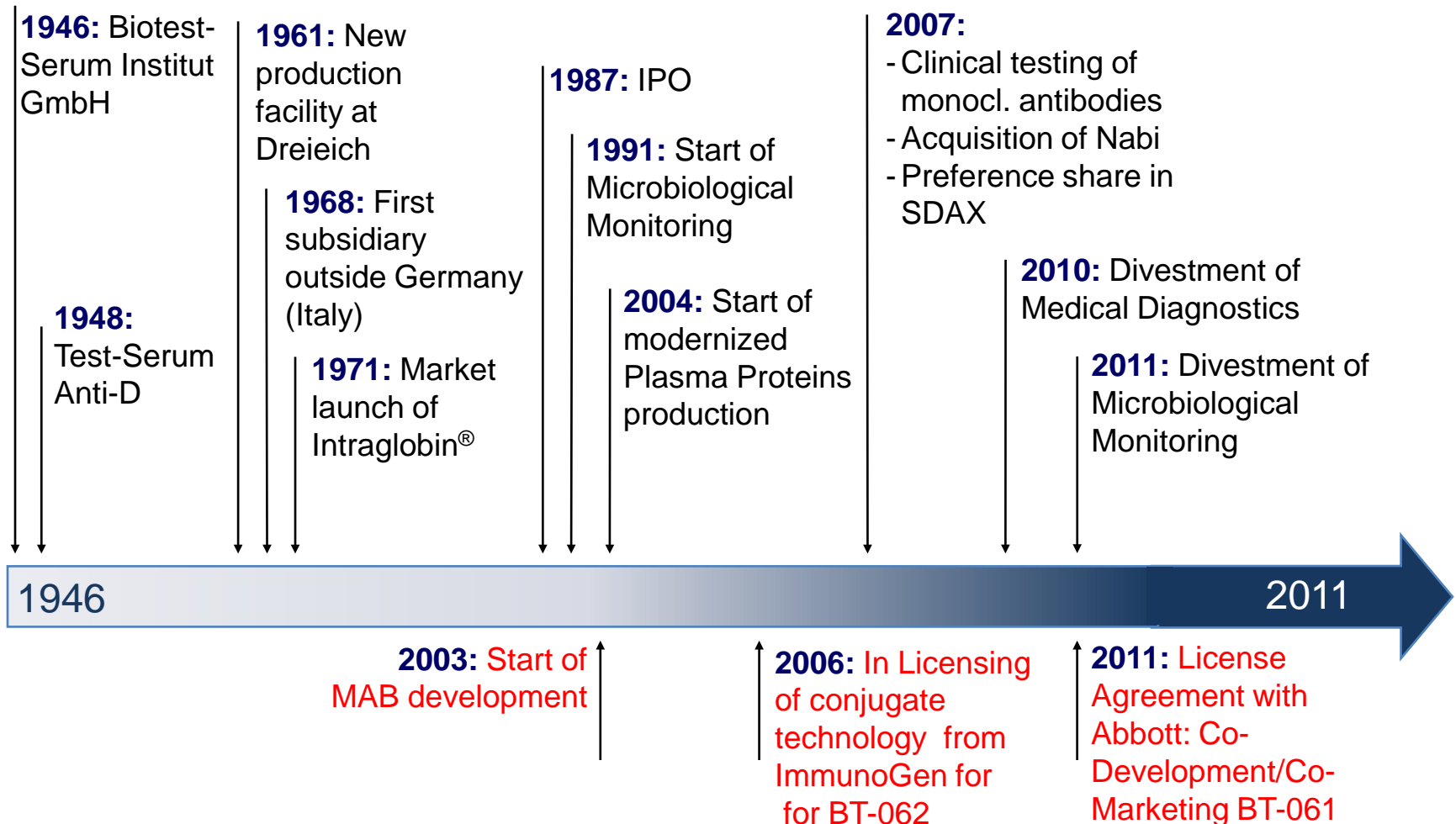
- This document contains forward-looking statements on overall economic development as well as on the business, earnings, financial and asset situation of Biotest AG and its subsidiaries. These statements are based on current plans, estimates, forecasts and expectations of the company and thus are subject 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., and the disposal of the Microbiological Monitoring to Merck KGaA these activities are being reported as Discontinued Operation.
- All comparative figures relate to the corresponding last year s period, unless stated otherwise.

## Biotest Group: Highlights H1 2011



- Biotest H1 2011 Group Sales up by 4.9%; Increase largely attributable to an upfront payment by Abbott on a pro rata basis to the Biotherapeutics segment
- H1 EBIT decreased by 2.9% due to difficult plasma protein market environment and unabsorbed costs in Boca Raton
- Biotest and Abbott signed a Licence, Development and Commercialization Agreement for BT 061 in June 2011
- Microbiological Monitoring: Closing of sale and purchase agreement with Merck KGaA Darmstadt, Germany on 1<sup>st</sup> of Aug.
- Submission of Bivigam™ BLA to FDA on Nov., 2010; first FDA inspections of clinical sites completed
- New plasma protein products developments continue with high priority
- Capacity expansion to meet future demand

# Biotest: History and milestones achieved



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## Big Success for Biotest's Biotherapeutics:



Biotest and Abbott signed a

### **"License, Development and Commercialization Agreement"**

to ensure the further development as well as later on production and worldwide marketing and sales of BT-061

# Biotest and Abbott Global Agreement towards BT-061

- Upfront payment of USD 85 million; Total Potential Milestone Payments USD 395 million;  
**Total Deal Value: USD 480 million**
- Biotest will be eligible to milestone payments pending completion of certain development, regulatory, commercial and sales milestones;
- Biotest will receive royalty payments on net sales achieved outside Europe EU5<sup>1)</sup>
- For Europe EU5 cost/profit split agreed

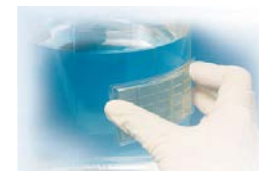
## Partnership Structure

- Joint development by Biotest and Abbott
- Biotest to co-promote BT-061 in Germany, France, United Kingdom, Italy, Spain
- Abbott will have exclusive global rights to commercialize BT-061 outside the EU5
- Biotest Pharmaceuticals Corp. to manufacture product for clinical trials
- Abbott and Biotest will share responsibility for commercial production

1) Germany, France, United Kingdom, Italy, Spain

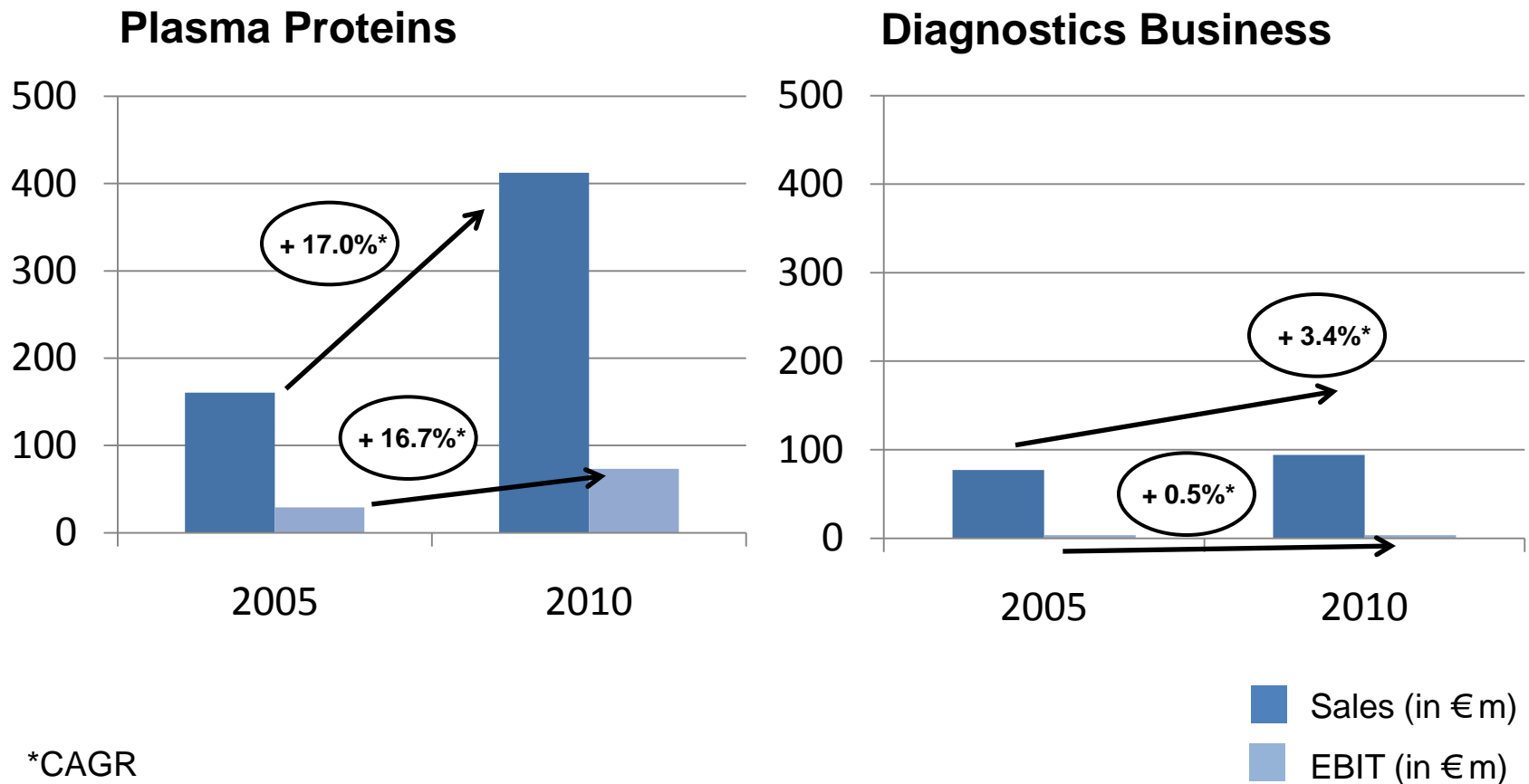
# Biotest sold Microbiological Monitoring business to Merck KGaA

- On 1 August, 2011 the agreement to sell the activities of the Microbiological Monitoring segment to Merck KGaA (Darmstadt/ Germany) went into effect (closing)
- Transfer of activities to Merck KGaA as well as payment of the purchase price
- Biotest received €50.8 million from the transaction. Subject to final cost and tax settlements, Biotest will receive profits from the sale of approximately €30-40 million and the expected cash flow to Biotest will be in the range of €40-50 million



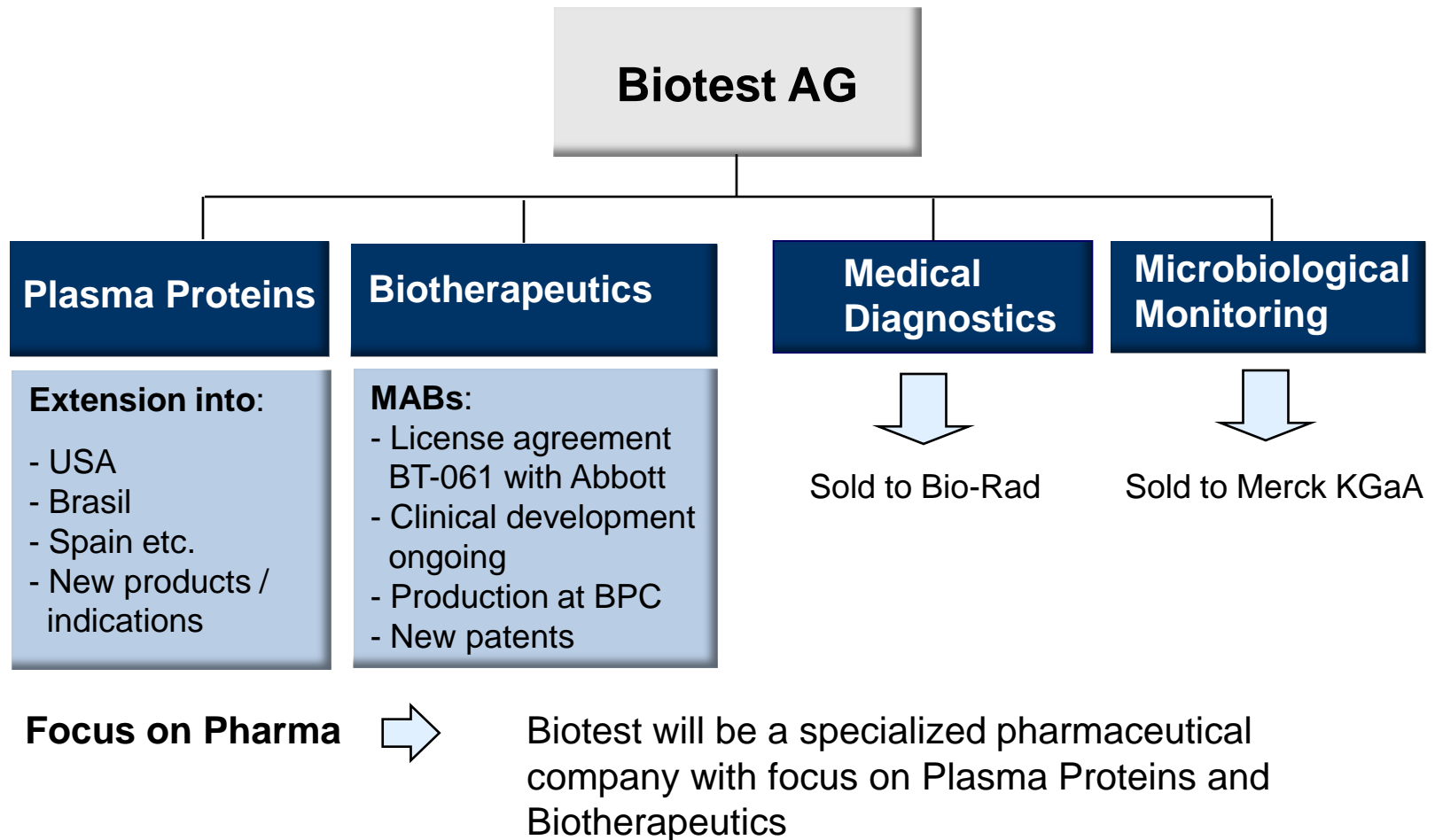
# Strong track record – Plasma Proteins

## Almost stagnation in Diagnostics Business





## Biotest : Future corporate structure



# Biotest Group

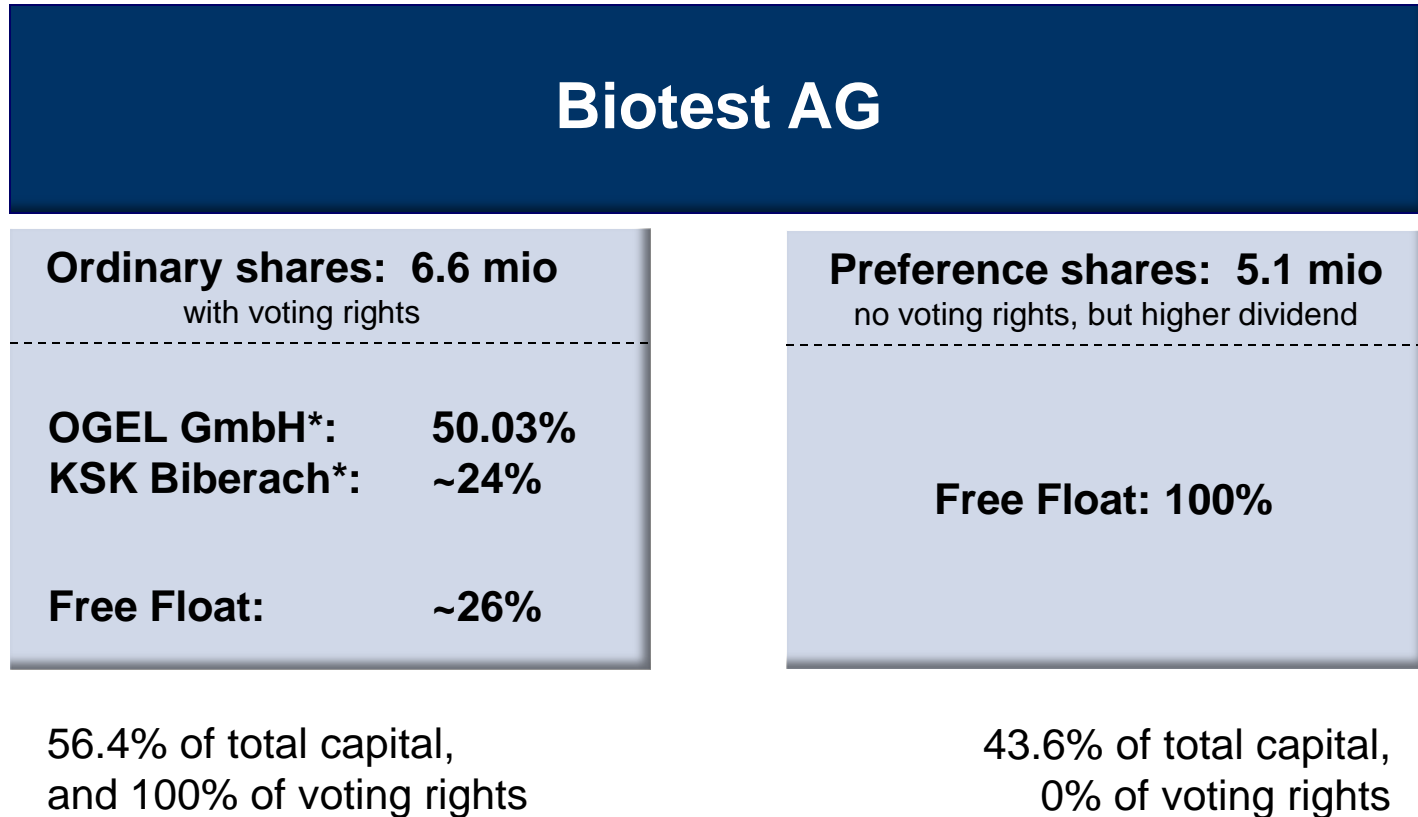
- Headquarters in Dreieich/Germany (Frankfurt area)
- Subsidiaries in 11 countries worldwide
- Employees (FTE)\*: ~1,600\*\*  
    Thereof 45% located outside Germany
- Founded in 1946, IPO in 1987, SDAX in 2007 (preference shares)
- Biotest shares:
  - 6,595,242 ordinary shares
  - 5,133,333 preference shares



Headquarter, Dreieich

\*: as of 30 June, 2011    \*\*: Continuing Operations

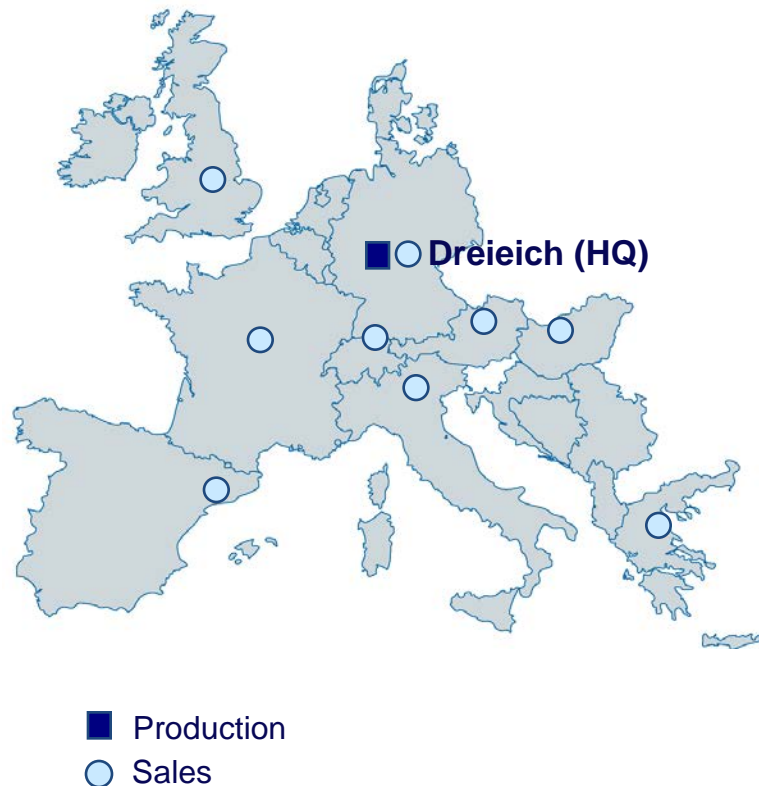
## Shareholder structure



\* as of August 2011

# Biotest Group overview

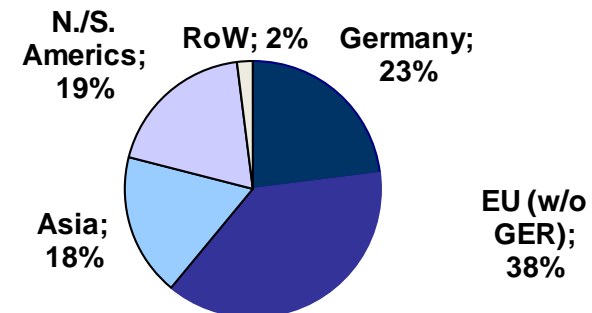
## European production and distribution sites



## Additional sites outside of Europe:

- USA: Florida (■ ○)
- Brasil: Sao Paulo (established) (○)
- Russia: Moscow (established) (■ ○)
- Distribution also via 69 distributors in 60 countries

## Sales by region (H1 2011):



# Biotest: a Specialized Pharmaceutical Company

**Biotest AG**

**Pharmaceuticals**

## Divisions

### Plasma Proteins

Extension into:

- USA
- Spain
- Brazil
- new indications
- new products

Sales*:	€203.8 m
R&D*:	- €11.7 m
EBIT*:	€28.0 m

### Biotherapeutics

- Clinical Development ongoing
- Production at BPC
- New patents
- License Agreement

Sales*:	€9.1 m
R&D*:	- €11.1 m
EBIT*:	- €3.2 m

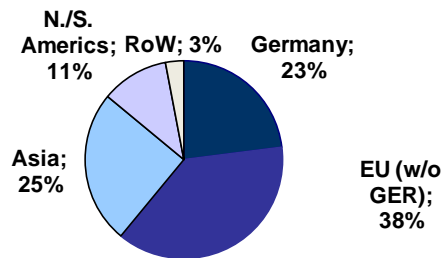
\* H1 2011



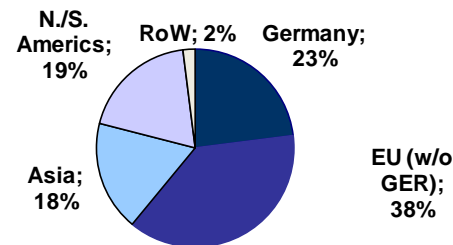
## Plasma Proteins

# Plasma Market situation - a challenging environment

**Sales by region H1 2010**



**Sales by region H1 2011**

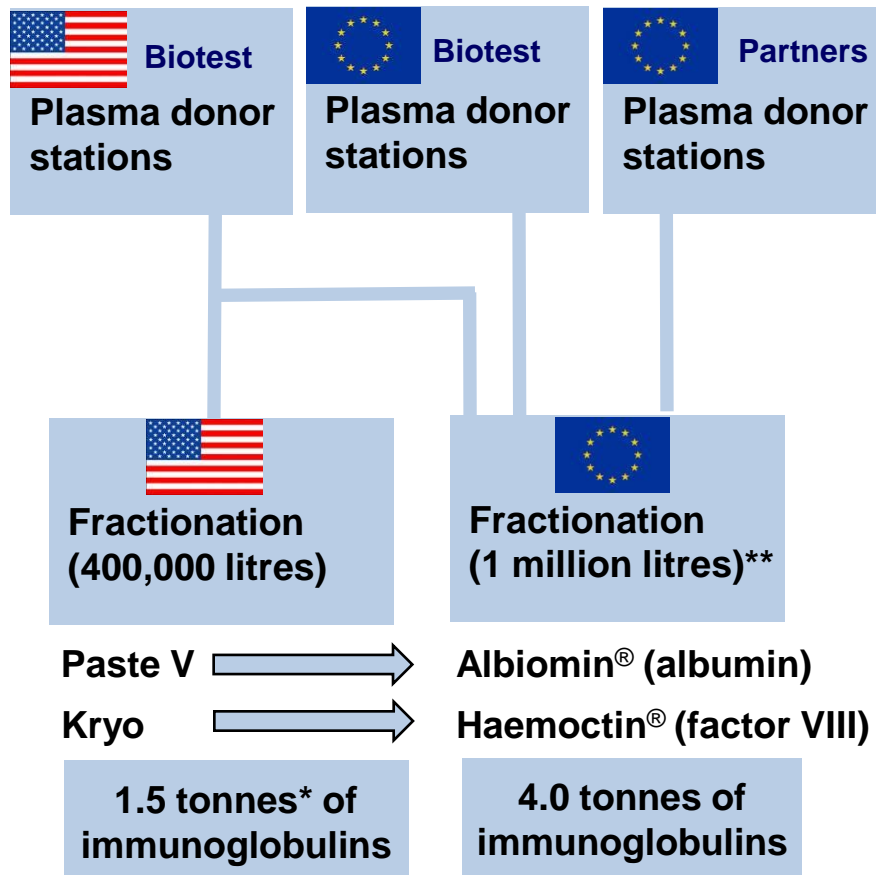


<u>Country</u>	<u>Situation</u>
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Germany	ok
EU	ok
Asia	weak ; tender business in Middle East lost due to price pressure or weak prices
Russia	weak; price pressure

- No albumin available from US plasma to be sold in high price Chinese market
- US sales increase due to sales from Abbott (Biotherapeutics segment)

# Plasma Proteins – Efficient production network



- Acquisition of Nabi Biologics in 2007 (USD 185 million)
- 21 plasma collection centres
- Level of self-sufficiency: 40% for standard plasma
- Exchange of intermediate products from US to Europe planned for 2012
- Network increases EBIT margin
- Capex for investments in production in Dreieich and Boca Raton 2008-2010: ~ USD 110 m

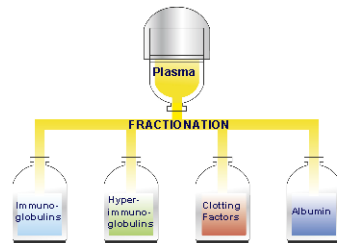
\* Approval will probably be granted Mid of 2012

\*\* Production in Dreieich and capacities at partners



# Plasma Proteins business at a glance

## Biotest Plasma Protein products



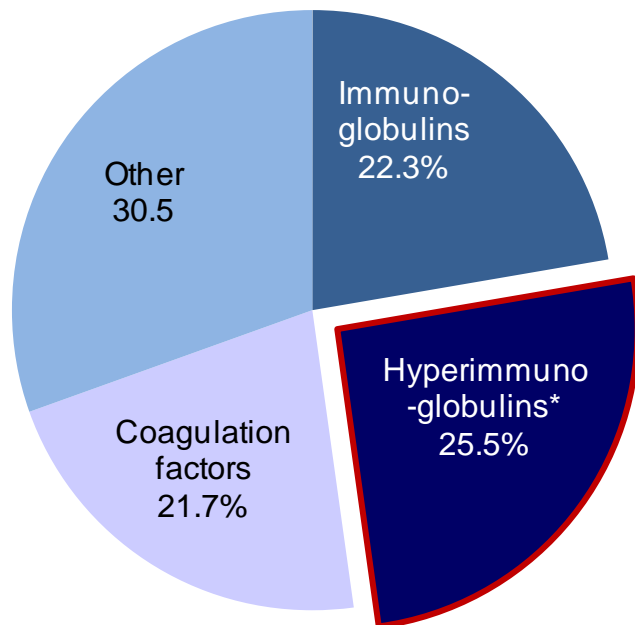
- Global market share IVIG: ~ 3%
  - Intratect<sup>®</sup> market share in GER, AUT: > 17%, in UK, CH, I: > 10%
  - World market leader with Cytotect<sup>®</sup> and Varitect<sup>®</sup>
  - Leading position with Hepatect<sup>®</sup> in Europe and Nabi HB<sup>™</sup> in USA
  - Zutectra<sup>®</sup> launch in Feb. 2010
  - Biotest covers full value creation chain: plasma sourcing, production, distribution
- ➡ vertical integration leads to rationalisation and higher productivity

Intratect <sup>®</sup> Pentaglobin <sup>®</sup>	Hepatect <sup>®</sup> Zutectra <sup>®</sup> Cytotect <sup>®</sup> Varitect <sup>®</sup> Nabi HB	Haemoctin <sup>®</sup> Haemonine <sup>®</sup>	Human-Albumin Biseko
Infections, immune deficiencies	Hepatitis B Cytomegaly Varicella	Blood coagulation defects	Albumin and protein deficiencies

= Biotest products     = lead indications

# Biotest: A market leader in special preparations

**Biotest plasma proteins in 2010:  
sales by product category**



**Hyperimmunoglobulins and special preparations are a very attractive segment:**

- Stable prices
- High market entry barriers
- Biotest is totally self-sufficient in hyperimmune plasma procurement



\* Including special preparations (e.g. Pentaglobin®)

# Bivigam™ (IVIg) FDA filing in US

## Polyspecific immunoglobulin



- Bivigam™ FDA filing on Nov. 3, 2010
- FDA confirmed that BLA dossier is generally accepted; FDA inspections of clinical sites completed
- Restart of production in August after solving severe problems with the automation and control system
- Additional conformance lots to be produced in Q3/4 2011

US Market entrance of strategic importance to Biotest  
**Market potential ~ USD 100 m**

## Major progress in development of Plasma Proteins (I)

### Zutectra®



s.c. Hepatitis Immunoglobulin

Successful market introduction in Germany, Austria, Italy, Ireland; extension to other countries is planned

**Fovepta™**  
(s.c. Hepatitis hyperimmunoglobulin for neonates)

Study report finalised in Feb. 2011

PEI submission in April 2011

### Cytotect® 70







Interim analysis planned for Dec. 2011

Currently 8.500 woman screened in phase III trial

**R & D expenses in H1 2011 in Plasma Protein segment: €11.7 m**

# Major progress in development of Plasma Proteins (II)

<h2>IgM Concentrate</h2> 	<h2>Intratect 10%</h2> 	<h2>Civacir™</h2> 	<h2>Fibrinogen</h2> 
<p>IgM enriched Immunoglobulin</p> <p>High functional activity</p> <p>Phase II study has started</p>	<p>Polyspecific Immunoglobulin 10%</p> <p>Phase III trial</p> <p>Patient recruitment completed</p> <p>End of study Q1 2012</p> <p>Approval expected Q4 2012</p>	<p>Hepatitis C Immunoglobulin</p> <p>New production schedule; formulation improved</p> <p>Restart of clinical development planned for 2012</p>	<p>Indication: acute bleeding disorders</p> <p>Product characteristics have been defined</p> <p>Start of clinical phase I/II in Q1 2012</p>

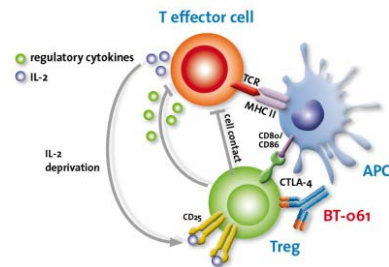


## Biotherapeutics

# Biotest's Biotherapeutics portfolio

## BT-061

Activated Tregs mediate modulation of T effector cells

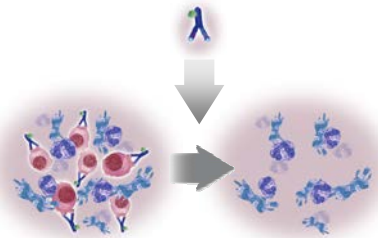


### Potential Indications

- Rheumatoid Arthritis
- Psoriasis
- Other autoimmune diseases

## BT-062

Targeted Antibody Payload (TAP) technology

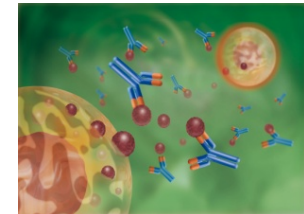


### Potential Indications

- Multiple Myeloma
- Solid tumors

## BT-063

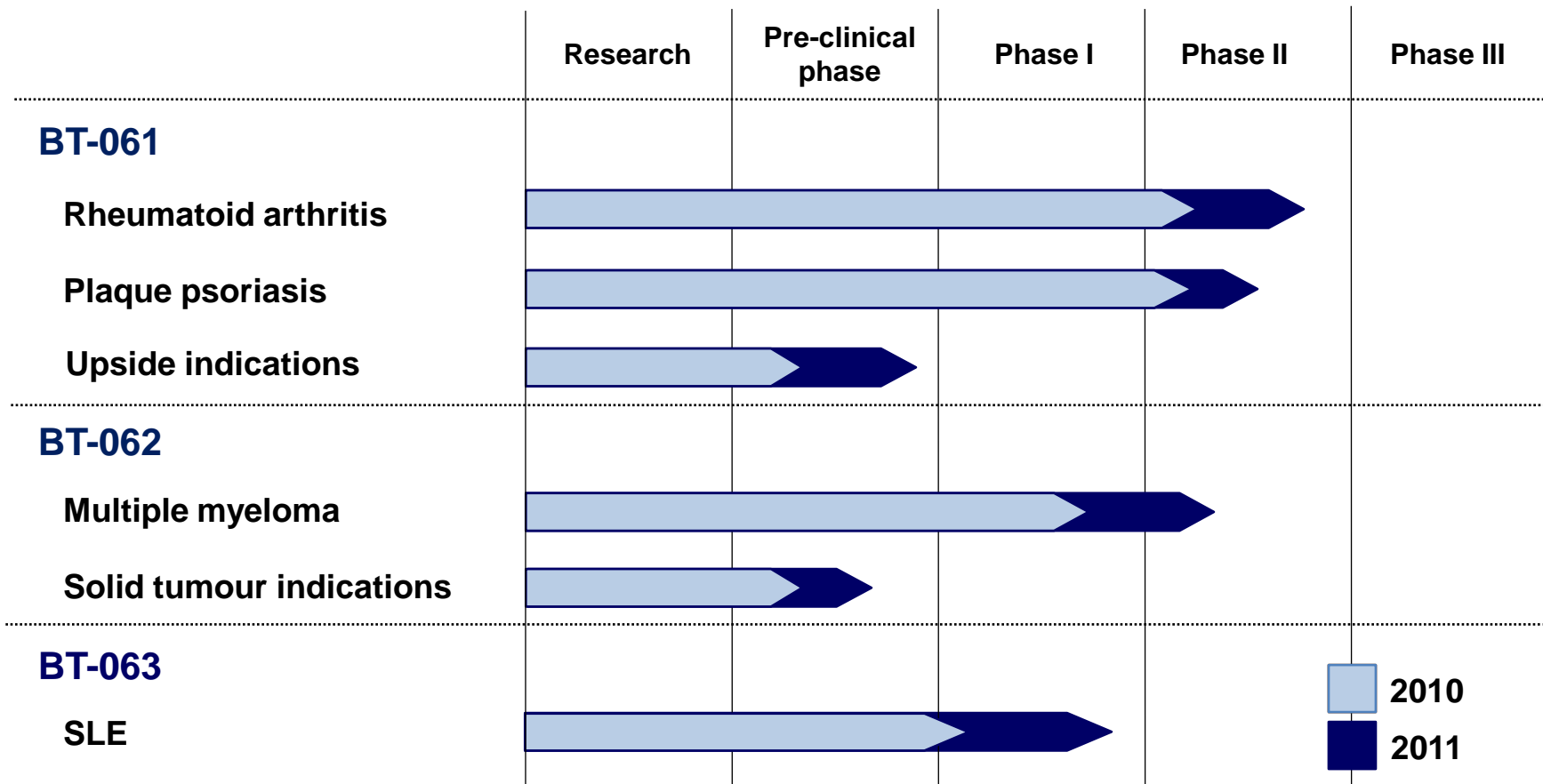
Blockage of immuno-regulatory cytokine with key role in pathogenesis of SLE



### Potential Indications

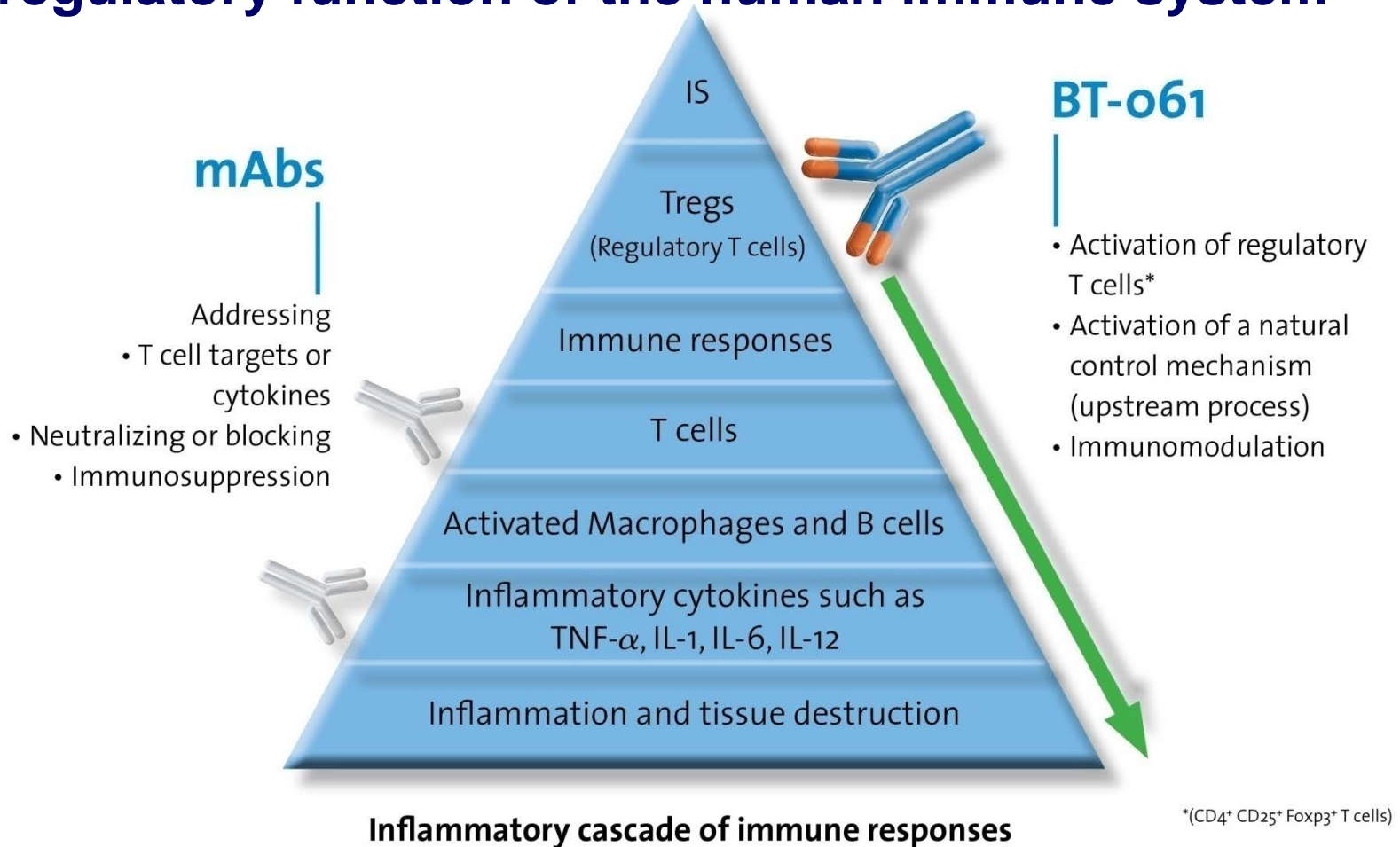
- Systemic Lupus Erythematosus (SLE)
- Oncology

## Biotherapeutics: Significant project progress in 2010 and 2011





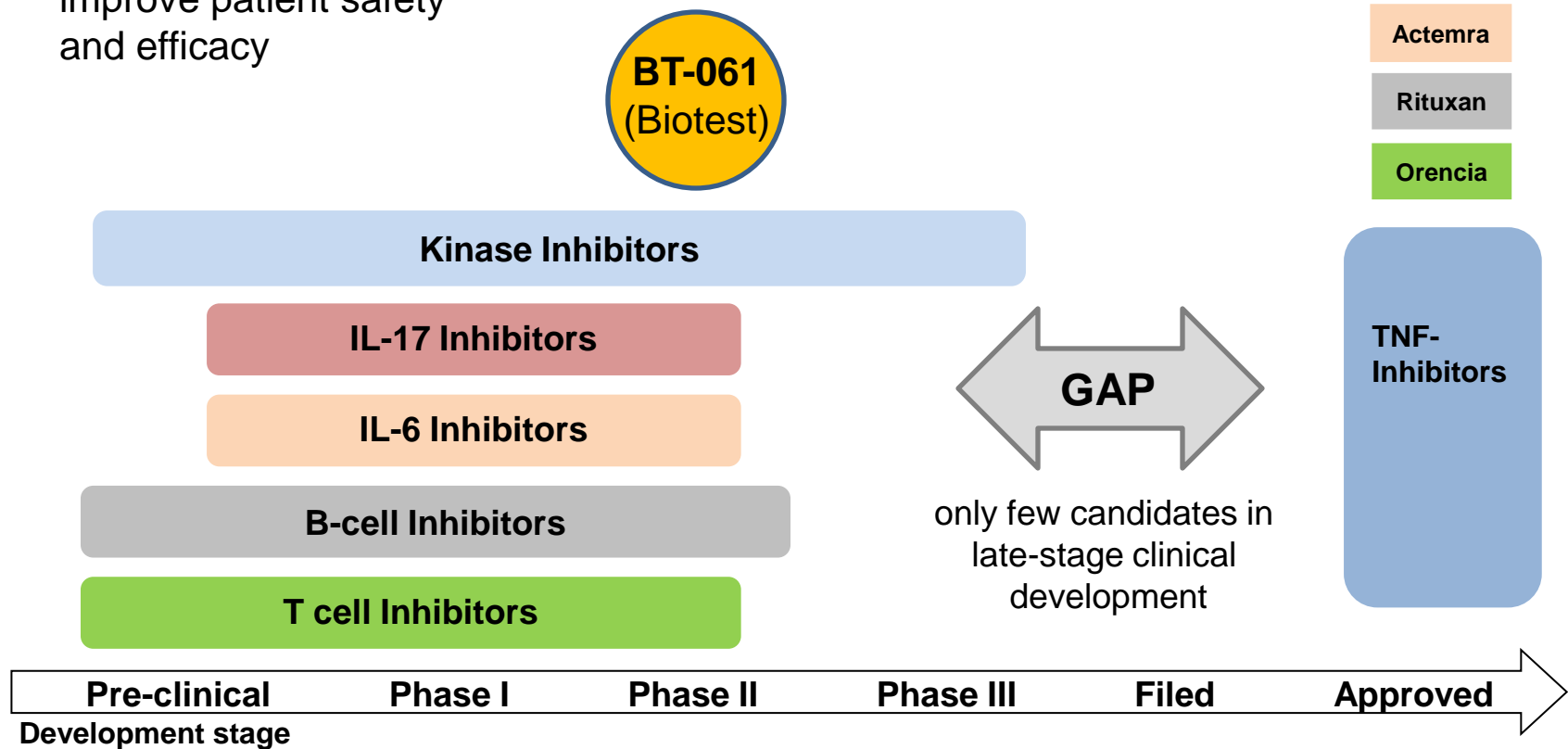
# BT-061 – Specific mode of action addressing key regulatory function of the human immune system



**Mode of action offers significant potential in several upside indications**



# Competitive Environment



- Many candidates stopped within last two years due to lack of clear differentiation
- Pipeline dominated by "me too" candidates
- Only few innovative products in development, but required to further improve patient safety and efficacy



# Clinical development BT-061

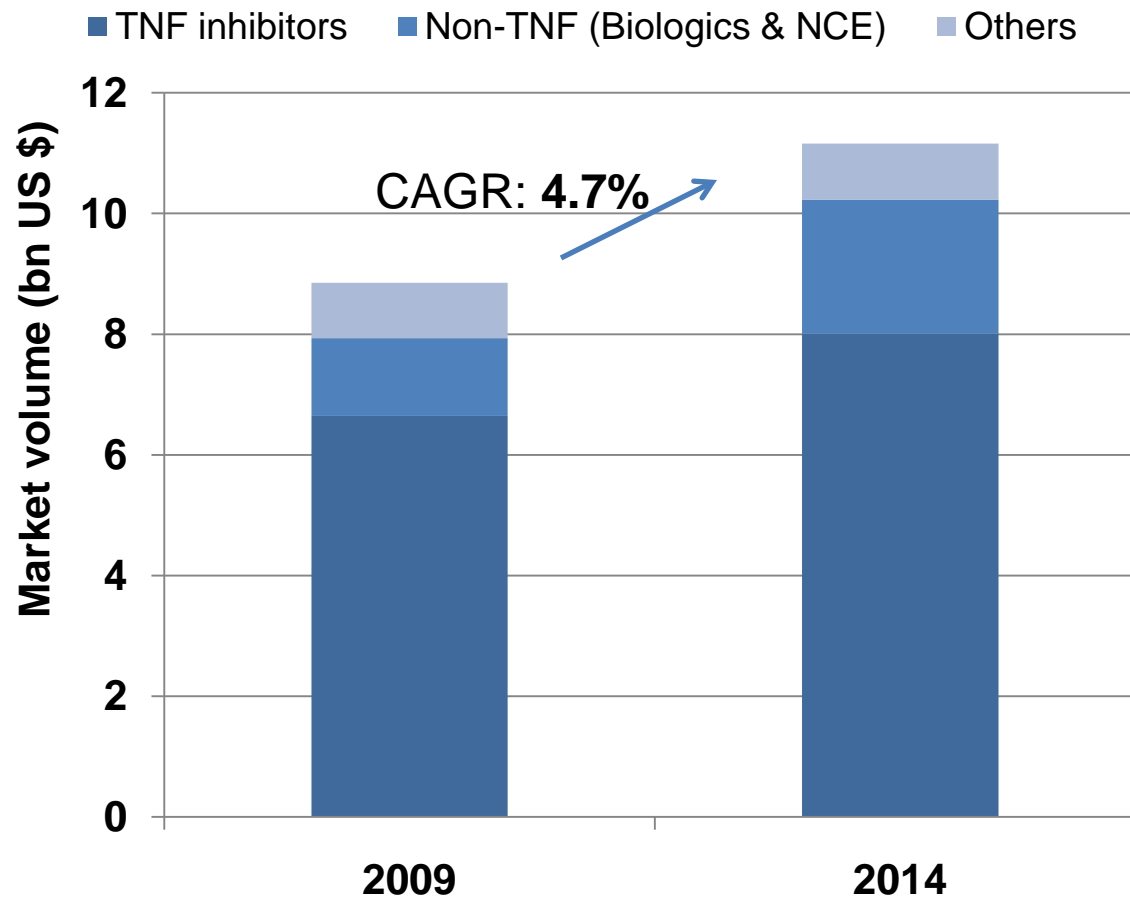
## Overview

Rheumatoid Arthritis	
Trial	Status
<b>Phase IIa, monotherapy</b> (No. 962) 96 patients	<b>Completed</b> 
<b>Phase II, combination with MTX</b> (No. 971) 114 patients	<b>Completed</b> 
<b>Phase IIb, combination with MTX</b> (No. 979) 176 patients	<b>Recruitment ongoing</b>

Psoriasis	
Trial	Status
<b>Phase I/IIa, monotherapy single dose</b> (No. 967) 55 patients	<b>Completed</b> 
<b>Phase II, monotherapy multiple dose</b> (No. 973) 48 patients	<b>Treatment * completed</b>   <b>Final evaluation ongoing</b>

\*: Last patient last visit

# Rheumatoid Arthritis Market:<sup>1</sup> Continuous Growth until 2014 Driven by Biologics

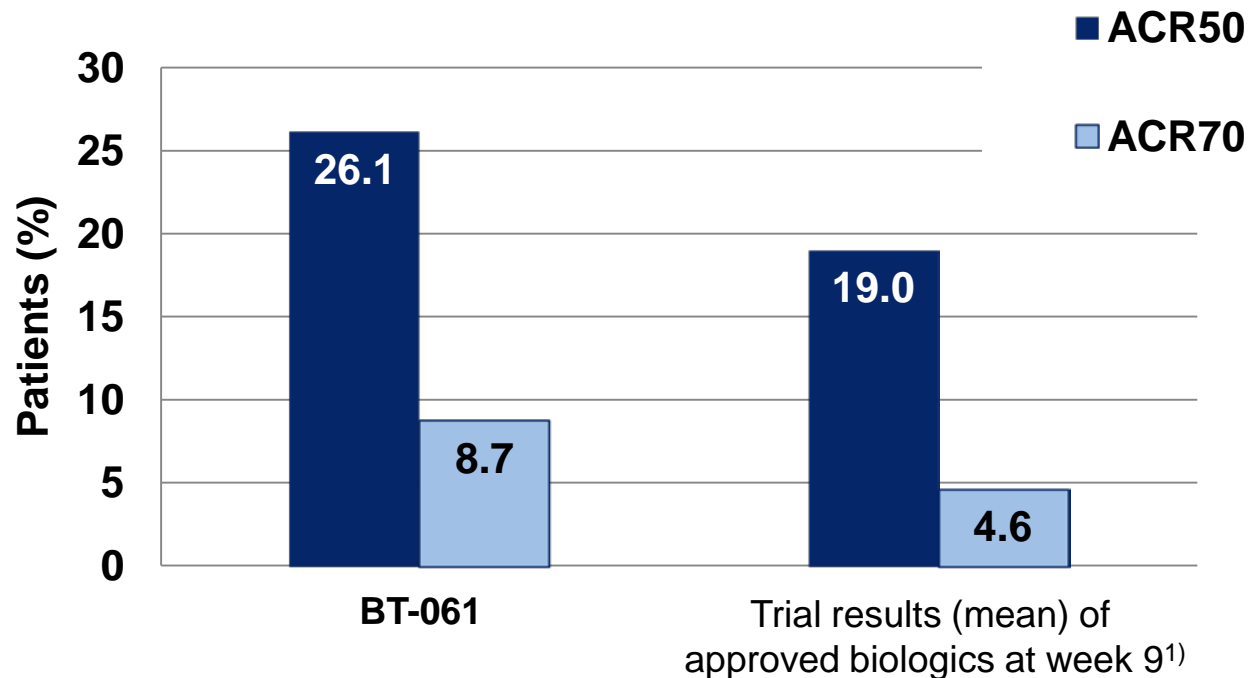


1 = MM7; 7 major markets  
Source: Decision Resources 2011  
NCE: new chemical entities

# Rheumatoid Arthritis Phase II Study (No. 971)

## Preliminary analysis: Favourable Efficacy Results

50 mg BT-061 SC + MTX  
ACR scores [%] at primary endpoint (week 9)



BT-061: only patients that received the complete 8 week treatment cycle were considered for calculation

1) Biotest analysis of trial results of approved biologics

Please note: Trial results (average) from independent trials are shown, which are not directly comparable as patient characteristics, route of administration, dose levels and treatment frequency are different

## **BT-061: Ongoing and planned clinical trials**

Higher patient numbers to confirm product profile seen in early trials

### **Rheumatoid Arthritis, Phase IIb (979)**

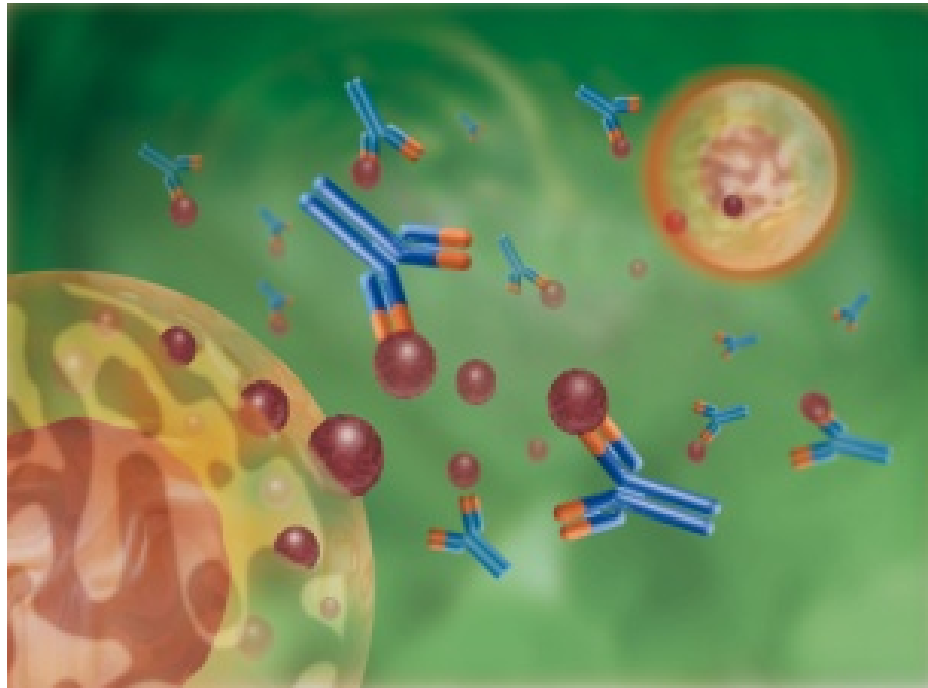
- Confirm/establish superior efficacy and tolerability with larger patient basis
- Establish Proof-of-Differentiation
- **Design:** 175 patients in 3 dose groups, 12 weeks treatment, 12 weeks follow-up

### **Pharmacokinetic/Pharmacodynamic Study – planned**

- Extend current clinical pharmacokinetic and pharmacodynamic data set
- Support dose and schedule finding for phase IIb/III
- **Design:** about 40 subjects in several dose groups

### **Rheumatoid Arthritis, Phase IIb - planned**

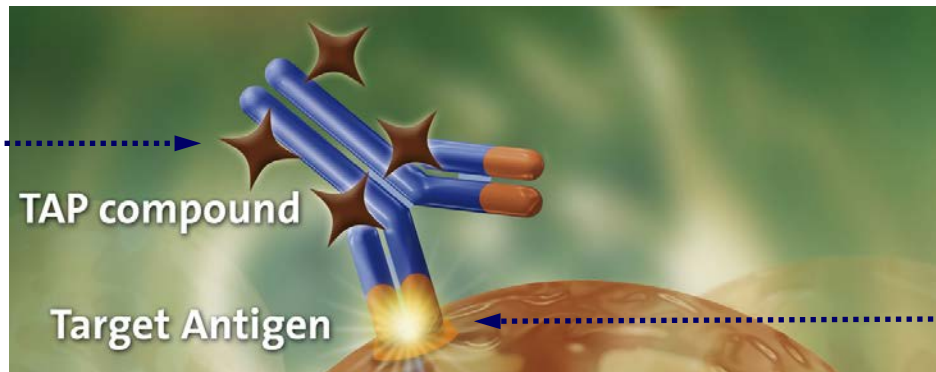
- Confirm favourable compound properties seen in earlier trials
- Establish statistical basis for Phase III
- **Design:** 350 patients in North America and Europe



## **Further monoclonal antibodies in clinical development**

## Competitive edge BT-062

Intrinsic properties provide basis for product positioning



Toxin moiety mediates high efficacy

- **High potency independent of patient's immune system**
- Toxin technology with best track record: Sanofi Aventis, Biogen Idec, Bayer, Roche/Genentech amongst licensees

Antibody moiety mediates high specificity

- Unique targeting to CD138
- CD138 highly overexpressed in MM and other cancer cells
- **CD138 not expressed on bone marrow stroma cells**
- Good tolerability up to 160 mg/m<sup>2</sup>

<sup>1)</sup> TAP: Tumor activated payload

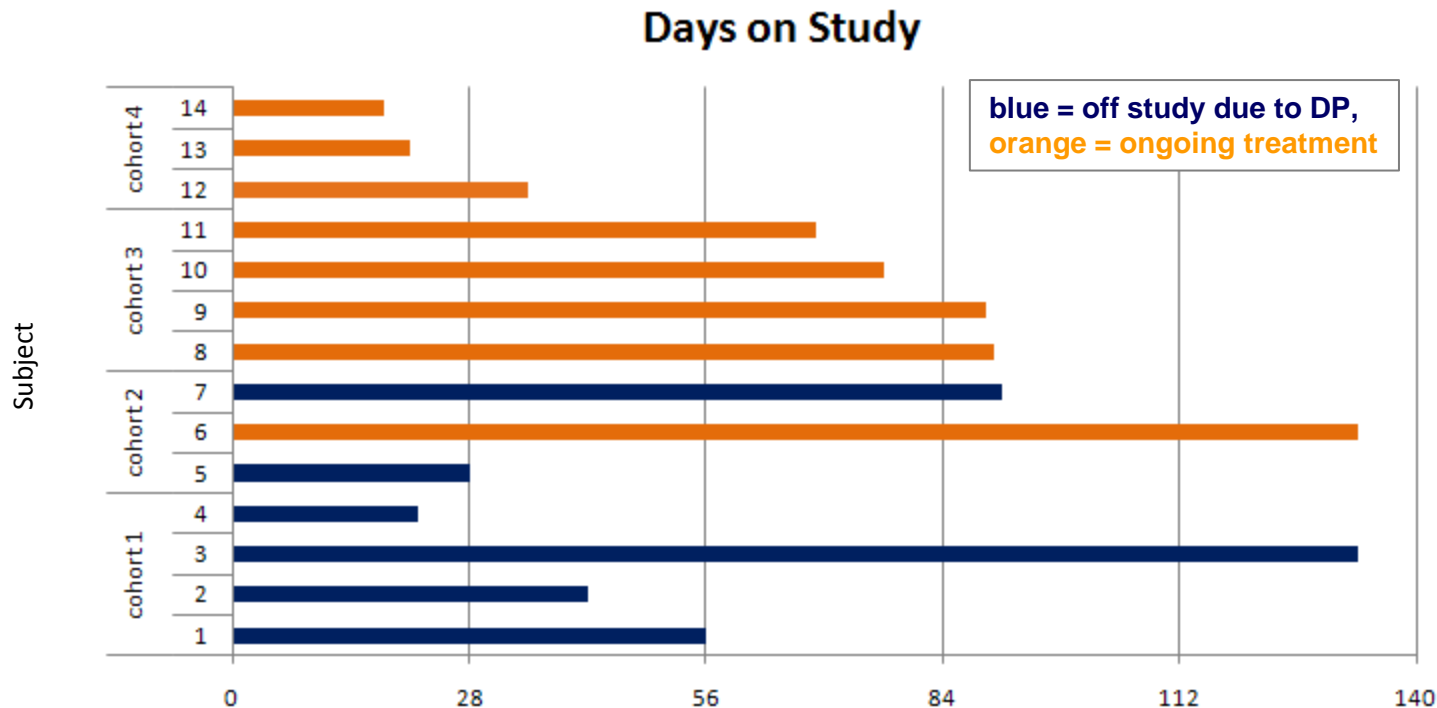


## BT-062: Summary

Study	Dosing Regimen	Results
Monotherapy (No. 969) USA	Repeated single dose	Maximum tolerable dose (MTD) cohort defined Good tolerability Clinical Benefit in >50% of patients, including minor and partial responses
Monotherapy (No. 975) USA	Multiple dose, more intense dosing scheme	Good tolerability in first patients No efficacy results available yet
Combination therapy (No. 983)	Start planned end of 2011	

## BT-062: Repeated Multi Dose Study 975

### Duration of Study Treatment (29 August 2011)



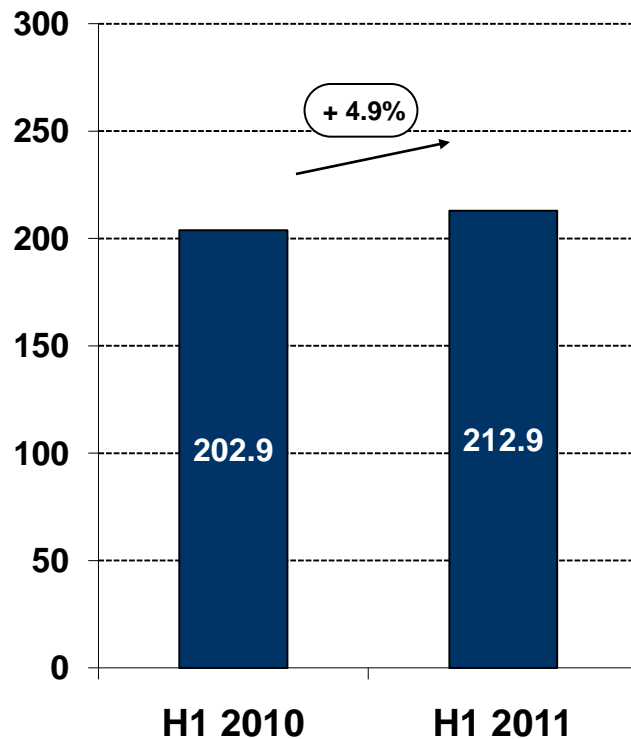
- 14 patients have been treated within one of the first 4 dose levels
- Currently 8 patients receiving ongoing treatment
- 6 patients at low dose levels completed study due to disease progression (DP)
- BT062 up to now well tolerated, no DLT reported



## Financials H1 2011

# Revenue growth in difficult market environment

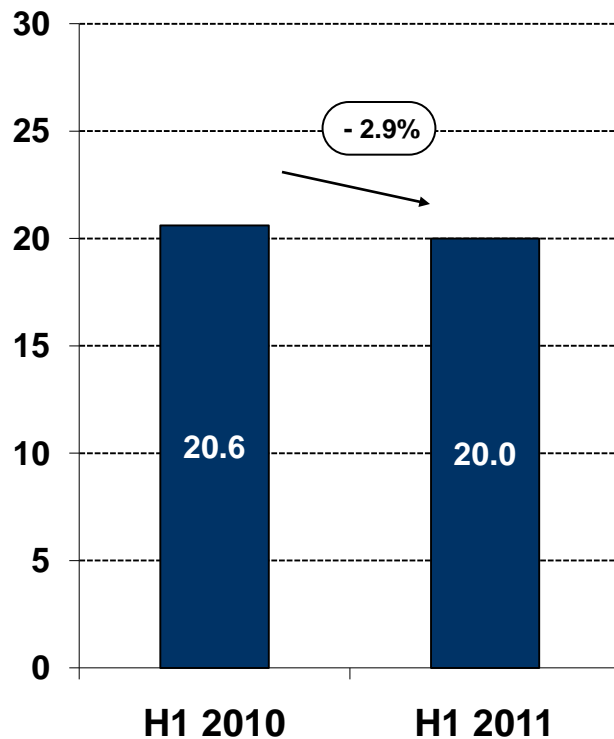
## Revenue (in €m)



- H1 2011 Sales at € 212.9 m, a growth of 4.9% vs € 202.9 m in H1 2010
- Increase largely attributable to an upfront payment by Abbott on a pro rata basis to the Biotherapeutics segment
- Sales in the Plasma Protein segment remained constant
- Prices under pressure, particularly in markets outside the EU and the US

## Despite sales growth, EBIT decreased

### EBIT (in €m)



- Despite 4.9% sales growth, EBIT decreased by 2.9% vs H1 2010
- Continuing price pressure for immunoglobulins and clotting factors, especially in Eastern Europe and Middle East
- Unfavourable cost of sales ratio primarily caused by pressure on prices of plasma proteins, a less favourable product mix and unabsorbed costs in connection with delays in the restart of production at Biotest Pharmaceuticals Corporation (BPC), Boca Raton, USA

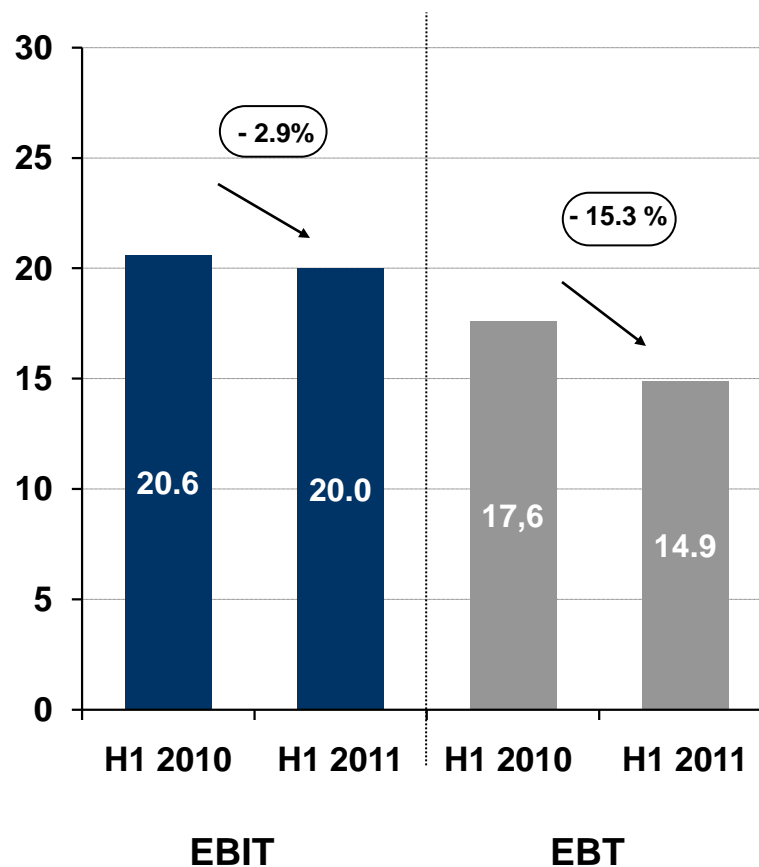
## H1 2011: EBIT Biotest Group (€m)

	H1 2011	H1 2010	Δ
Plasma Proteins	28.0	35.8	- 21.8 %
Biotherapeutics	- 3.2	- 10.4	69.2 %
Corporate	- 4.8	- 4.8	-
<b>Biotest Group*</b>	<b>20.0</b>	<b>20.6</b>	<b>- 2.9 %</b>

\*: Continuing Operations

## Decrease in EBIT and EBT in H1 2011

EBIT and EBT (in € m)

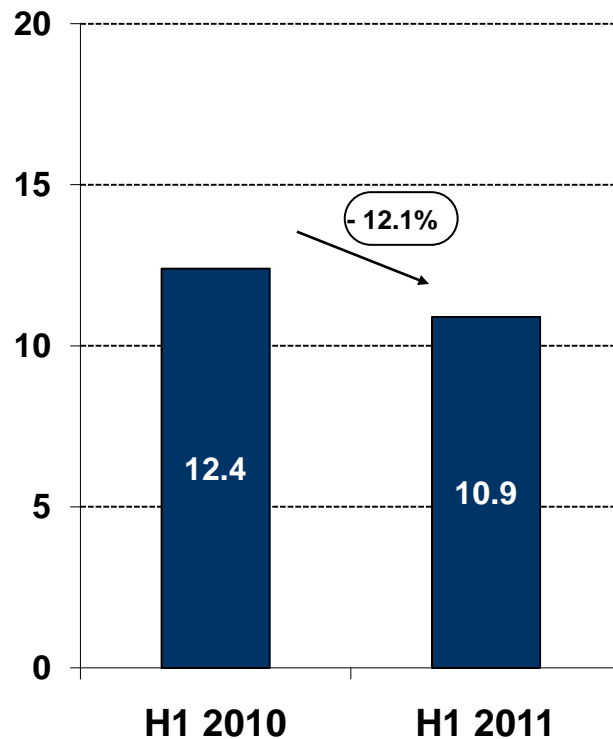


**Financial result H1 2011: - €2.6 m**

- Various re-valuations of Greek zero bonds
- Lower interest expenses

## Low EAT

EAT (in €m)



- Earnings after tax decreased by 12.1%
- Tax rate 26.9% in H1 2011 vs. 29.5% in H1 2010
- Lower tax rate due to losses in countries with high tax rates (BPC/ USA) and some higher profits in countries with low tax rates



# Outlook

## Guidance 2011:

**Sales:** Sales to grow with a low single digit percentage compared to 2010

**EBIT:** EUR 40 million range



The guidance does not take into consideration any extraordinary income from discontinued operations.

## Outlook Biotest Group

- Growing demand for IVIG and albumin
- Stable market for clotting factors and albumin
- Bivigam™ market authorisation expected mid of 2012; annual market potential ~ USD 100 m
- We expect a further reduction of oversupply and improving market conditions in H2 2011
- Promising R & D pipeline for Plasma Proteins and Biotherapeutics

