



## Biotest Group

Press and Analyst Conference  
– Financial Year 2011

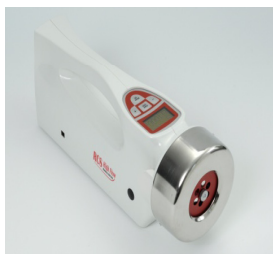
Frankfurt/Main, March 22, 2012

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## 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 sale of the Medical Diagnostic activities to Bio-Rad Laboratories Inc., and the sale of the segment Microbiological Monitoring to Merck KGaA, both activities are being reported as Discontinued Operation.
- All comparative figures relate to the corresponding last year's period, unless stated otherwise.

## Biotest Group: Highlights FY 2011

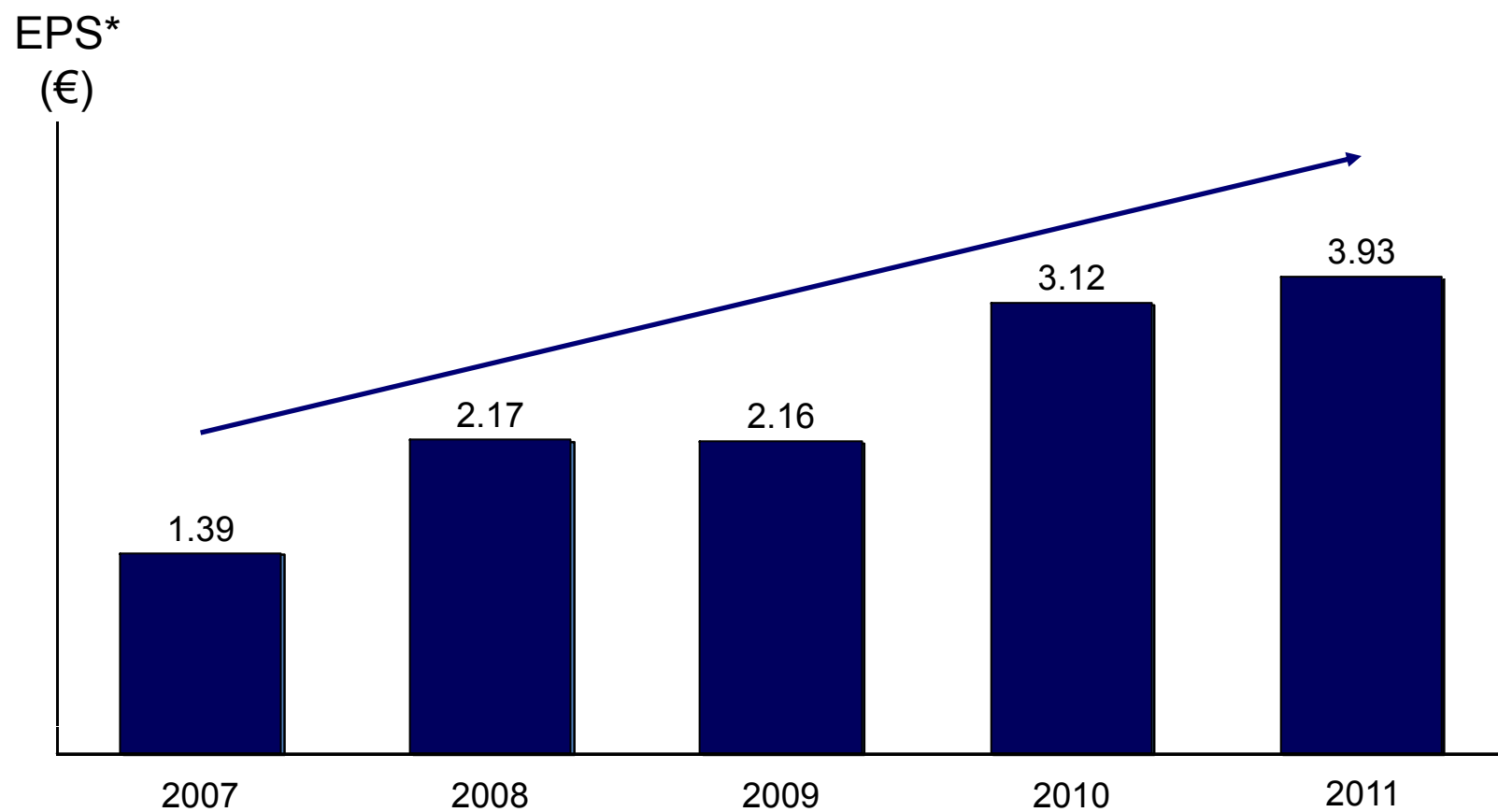


- Highest EAT in Biotest history (Continuing Operations and Discontinued Operation)
- Proposal to increase dividend by 15%
- Reduction of net debt by 61% (€ 86 m)
- Biotest FY 2011 Group Sales up by 2.3%
- In June 2011 Biotest and Abbott signed a Licence, Development and Commercialization Agreement for BT-061 (Tregalizumab)
- Microbiological Monitoring: Closing of a Sale and Purchase Agreement with Merck KGaA Darmstadt, Germany on August 1<sup>st</sup>, 2011. Profit after Tax of € 26.4 m



## Financials FY 2011

## EPS growing



\*Biotest Group: Continuing Operations and Discontinued Operation

## Earnings after tax

<b>EAT</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>
Continuing	29.6	19.6	18.7
Discontinued	-1.6	19.9	29.4
<b>Total*</b>	<b>28.0</b>	<b>39.5</b>	<b>48.1</b>

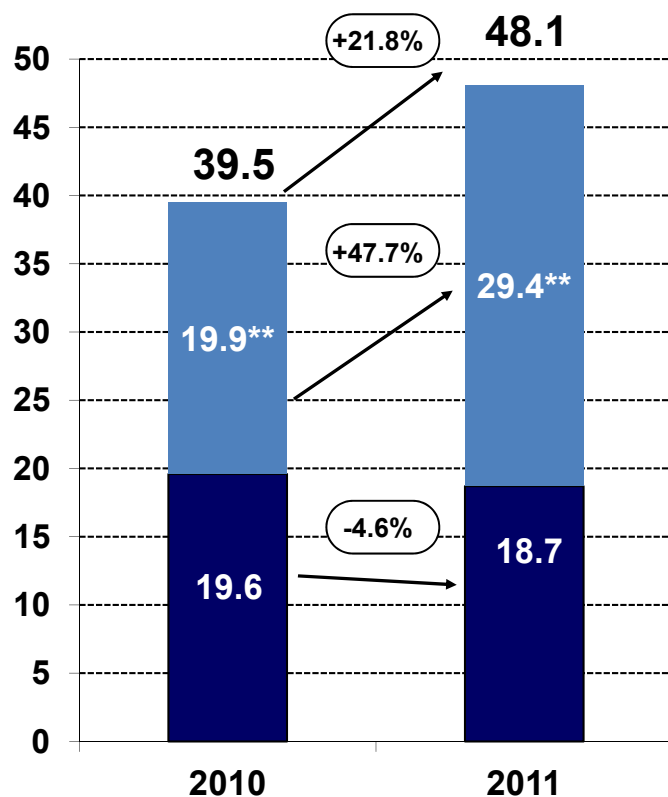
<u>Dividend Proposal to AGM **</u>	<u>2011</u>	<u>2010</u>
Preference share	€ 0.50	€ 0.44
Ordinary share	€ 0.44	€ 0.38

\* Biotest Group: Continuing Operations and Discontinued Operation

\*\* Annual General Meeting takes place on May, 10th 2012 in Frankfurt

## Significant increase in EAT\*

EAT (in € m)



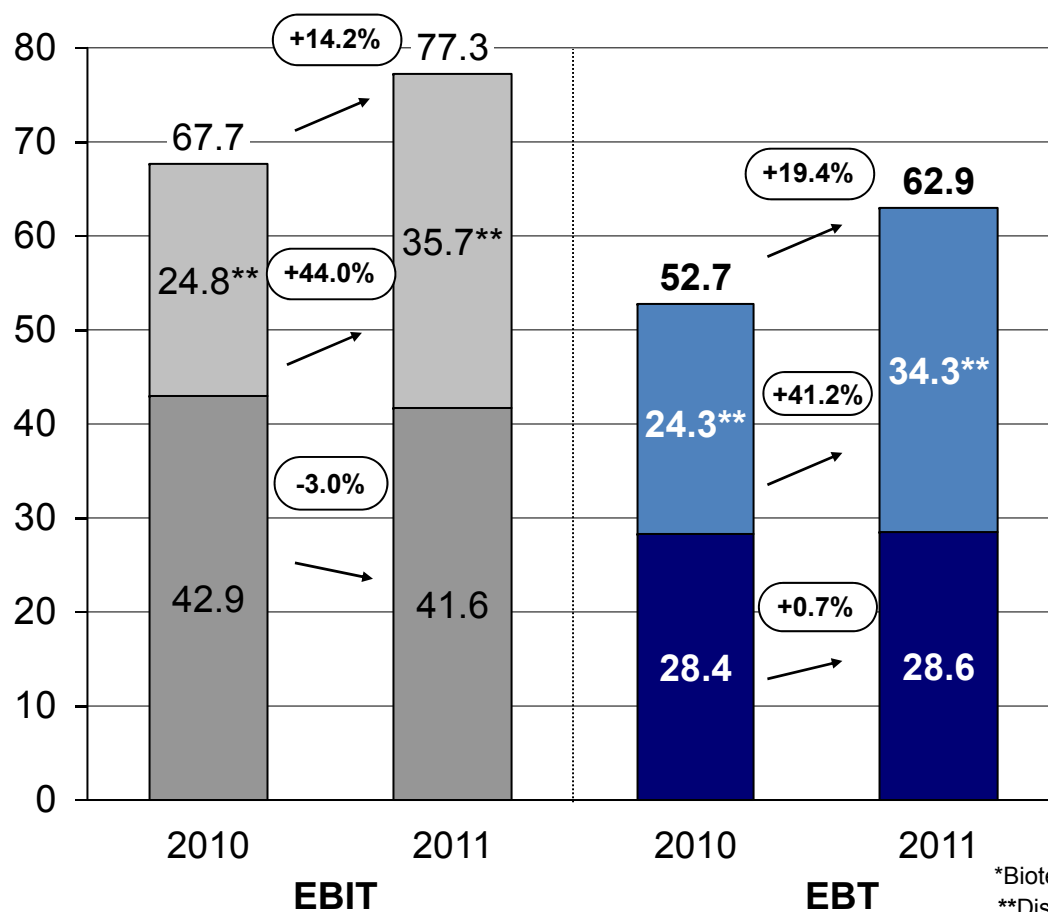
- Earnings after tax (Continuing and Discontinued Operations) up by 21.8%
- Earnings after tax (Continuing Operations) decreased by 4.6%
- Tax rate 34.6% in FY 2011 vs. 31.0% in FY 2010
- Increased tax rate due to higher non tax deductible expenses in 2011 and due to the usage of non capitalized tax assets in 2010

\*Biotest Group: Continuing Operations and Discontinued Operation

\*\*Discontinued Operation

## Increase in EBIT\* – increase in EBT\* in FY 2011

**EBIT\* and EBT\* (in € m)**



### Financial result :

- Financial result FY 2011 at -€13.5 m vs -€14.7 m in 2010
- As of Dec. 31<sup>st</sup>, 2011 the Greek bonds are valued at 28% of the nominal value

\*Biotest Group: Continuing Operations and Discontinued Operation

\*\*Discontinued Operation



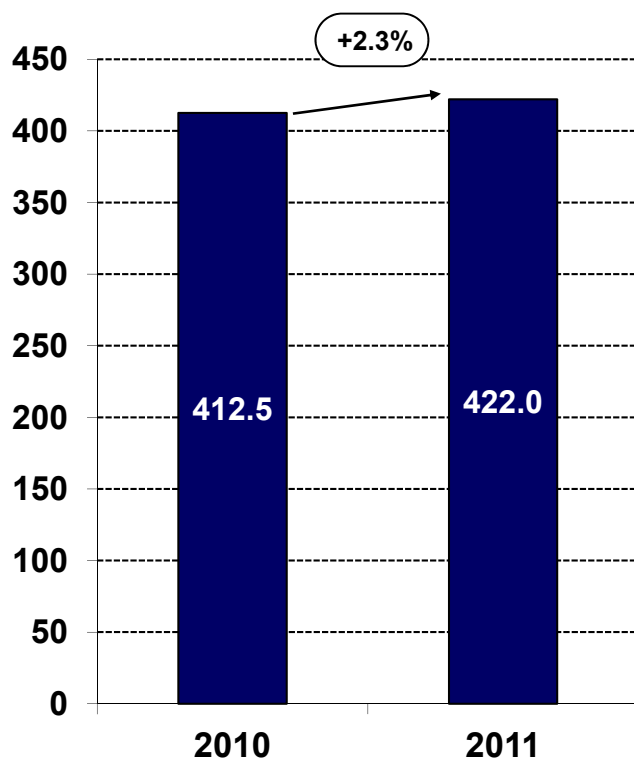
## FY 2011: EBIT Biotest Group (in € m)

	FY 2011	FY 2010	Δ
Plasma Proteins	61.5	73.5	-16.3 %
Biotherapeutics	-7.6	-21.7	65.0 %
Corporate	-12.3	-8.9	-38.2 %
<b>Biotest Group*</b>	<b>41.6</b>	<b>42.9</b>	<b>-3.0 %</b>
Discontinued Operation	35.7	24.8	+44.0 %
<b>Biotest Group Total</b>	<b>77.3</b>	<b>67.7</b>	<b>+14.2 %</b>

\*Continuing Operations

## Revenue growth in difficult market environment

Revenue (in € m)

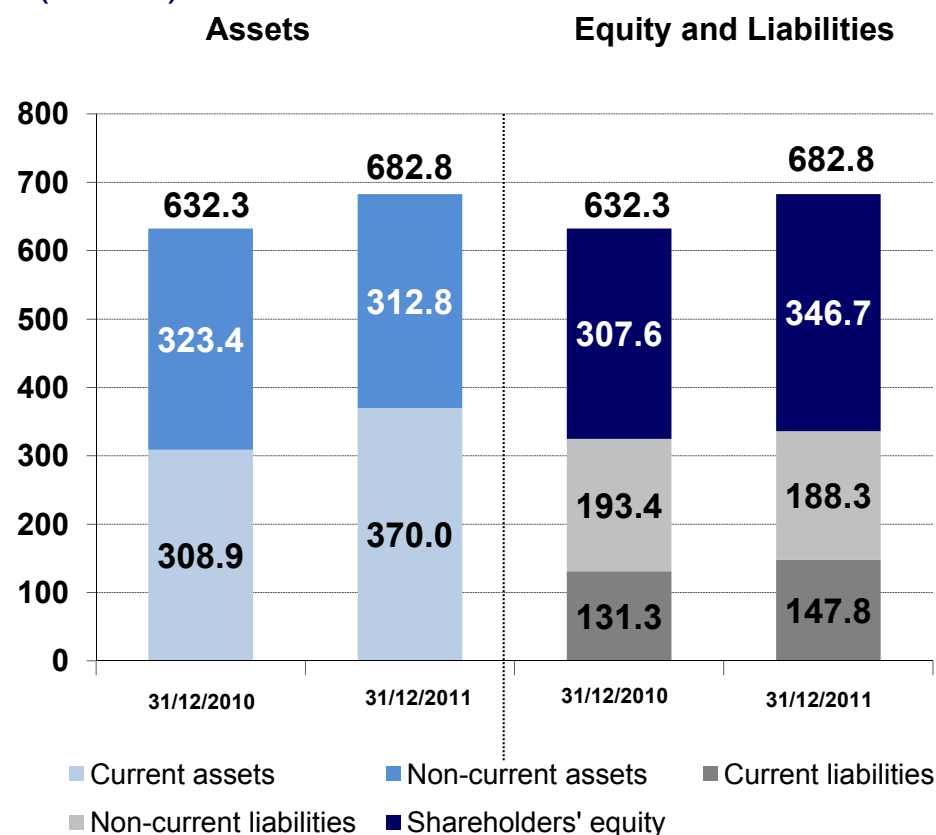


- FY 2011 Sales at € 422.0 m, a growth of 2.3% vs € 412.5 m in FY 2010
- Increase largely attributable to an upfront payment by Abbott on a pro rata basis to the Biotherapeutics segment
- Sales in the Plasma Protein segment decreased by 1.9% due to difficult market environment
- Prices under pressure, particularly in markets outside the EU and the US

## Net debt reduced by more than € 86 m

### Balance sheet of Biotest Group

(in € m)



### Assets

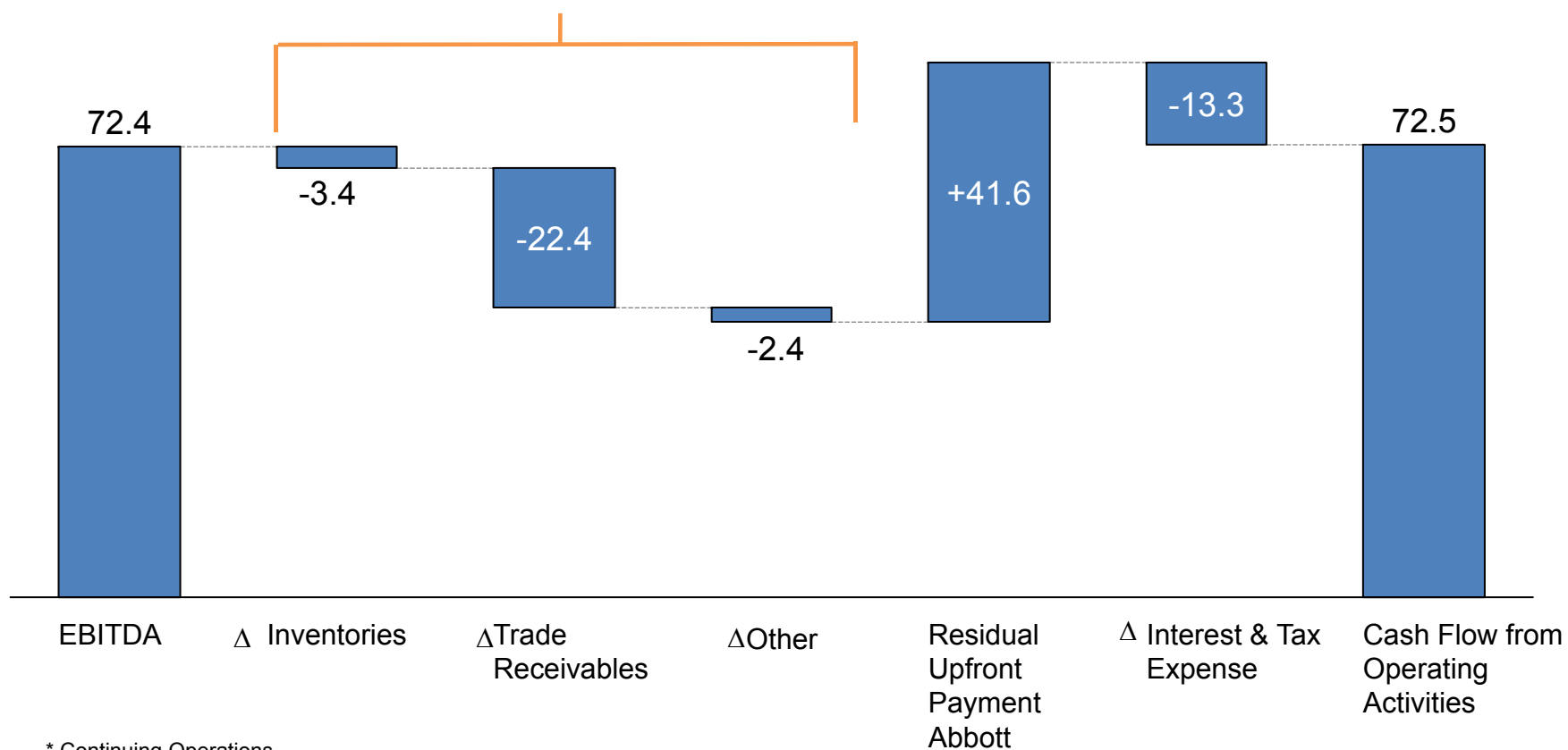
- Strong increase in cash and cash equivalents due to Abbott agreement and the sale of the Microbiology Monitoring segment
- The Greek Zero Bonds have a nominal value of € 15.8 m (31 Dec. 2011). Bonds recognised at a carrying amount of € 4.5 m (28% of the nominal value)

### Equity and Liabilities

- Significant reduction of net debt by 61% to € 55.8 m (vs. € 142.6 m on 31 Dec 2010)
- Equity ratio as of 31 Dec. 2011: 50.8% (31 Dec. 2010: 48.6%)

## Cash Flow from Operating Activities\* January – December 2011 (in € m)

**Δ Working Capital [Σ -€ 28.2 m]**



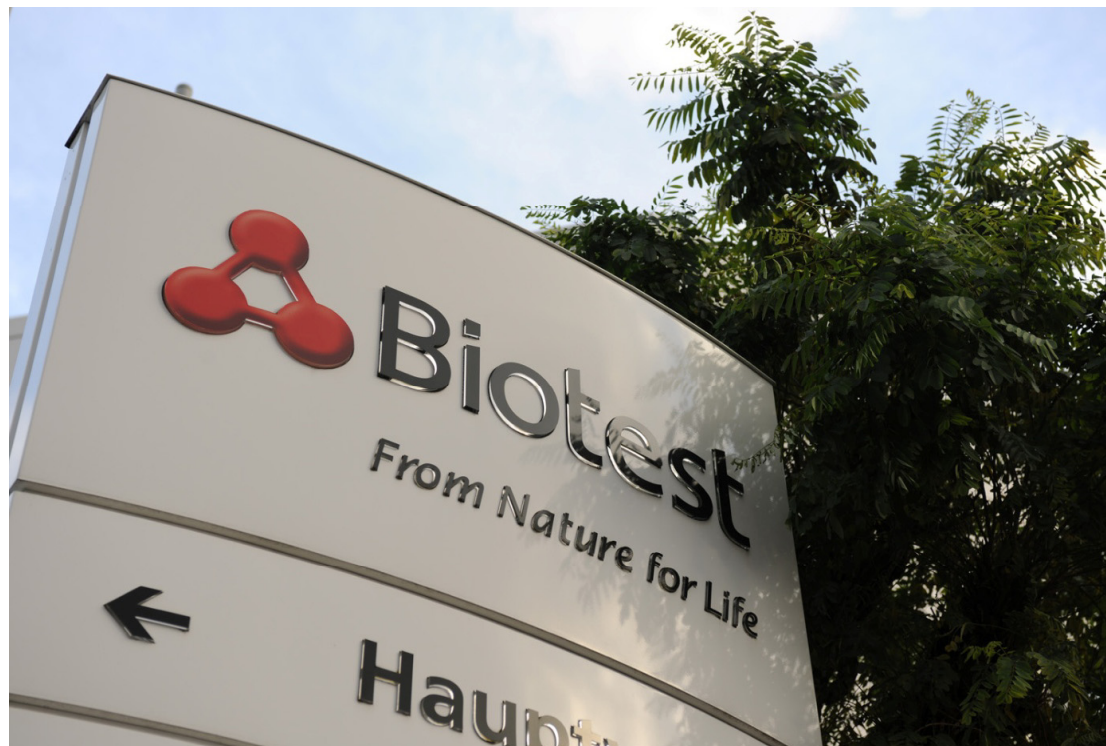
## Guidance 2012

**Sales:** Sales growth of 3-5 percent compared to 2011

**EBIT:** Slight increase vs EBIT of 2011 (€ 41.6 m)  
Still high ramp up costs in US



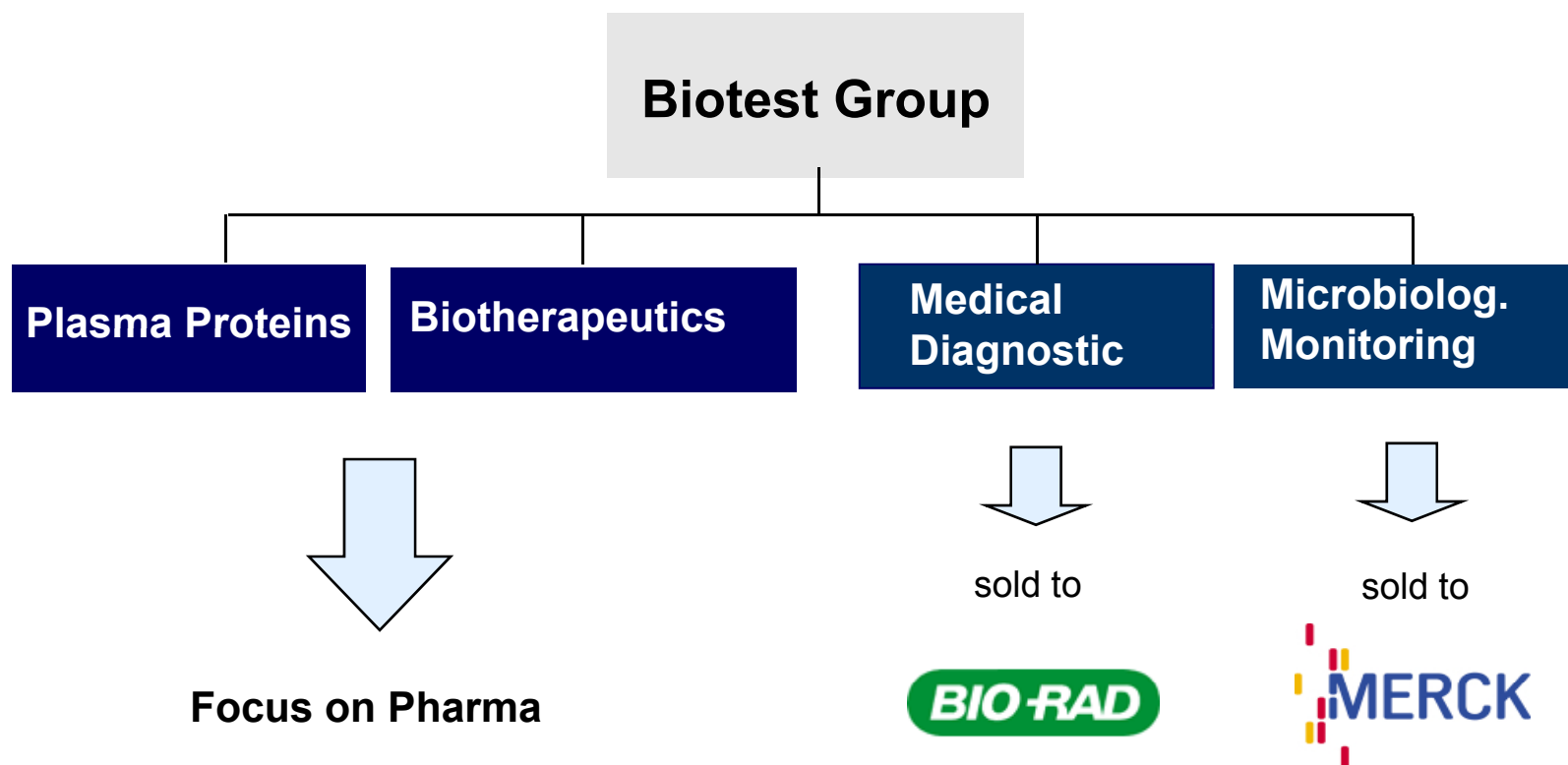
The 2012 guidance assumes that the market environment for our business in countries like Greece, Russia and several countries in the Middle East does not deteriorate due to financial or political reasons. Another precondition is the launch of Bivigam™ in the US in mid of 2012.



## **New Strategy**

## Focus on Pharma

### Divestiture of non-core business segments



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## **Biotest's Future Profile**

Biotest AG is a pharmaceutical company which develops, produces and sells **biological medicinal products**, that are either obtained directly from **human plasma** or manufactured using **biotechnological methods**.

Our products belong to the therapeutic areas

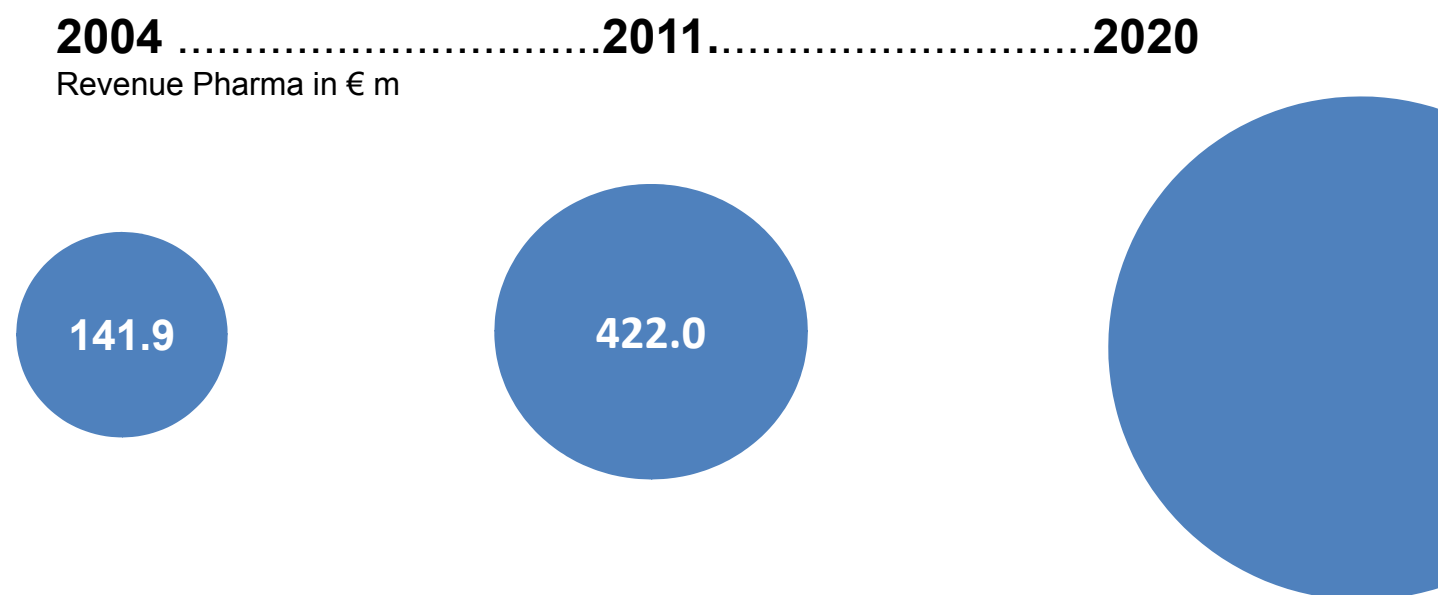
**Haematology**

**Clinical Immunology**

**Intensive Care Medicine.**



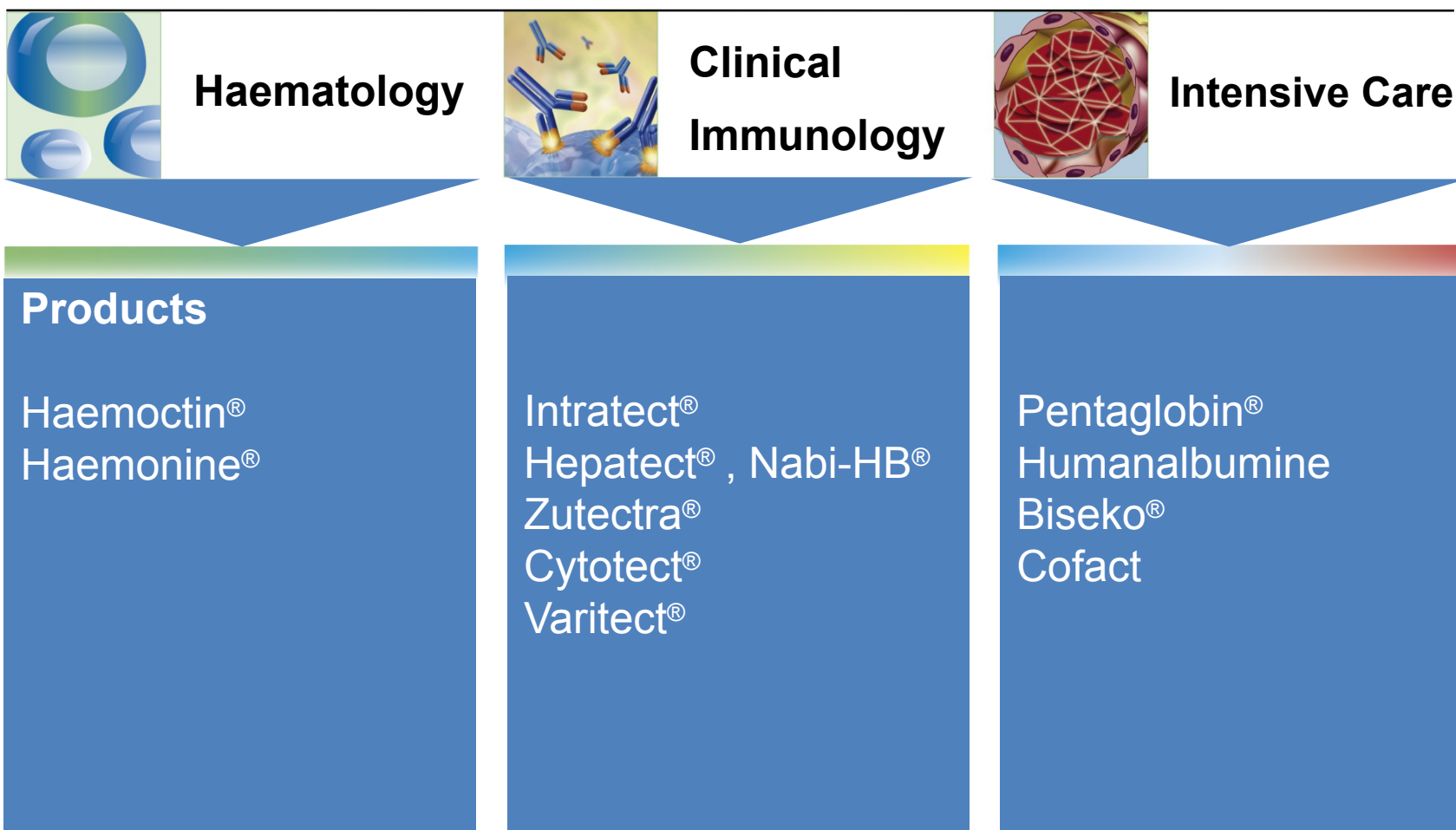
## Continuing strong growth



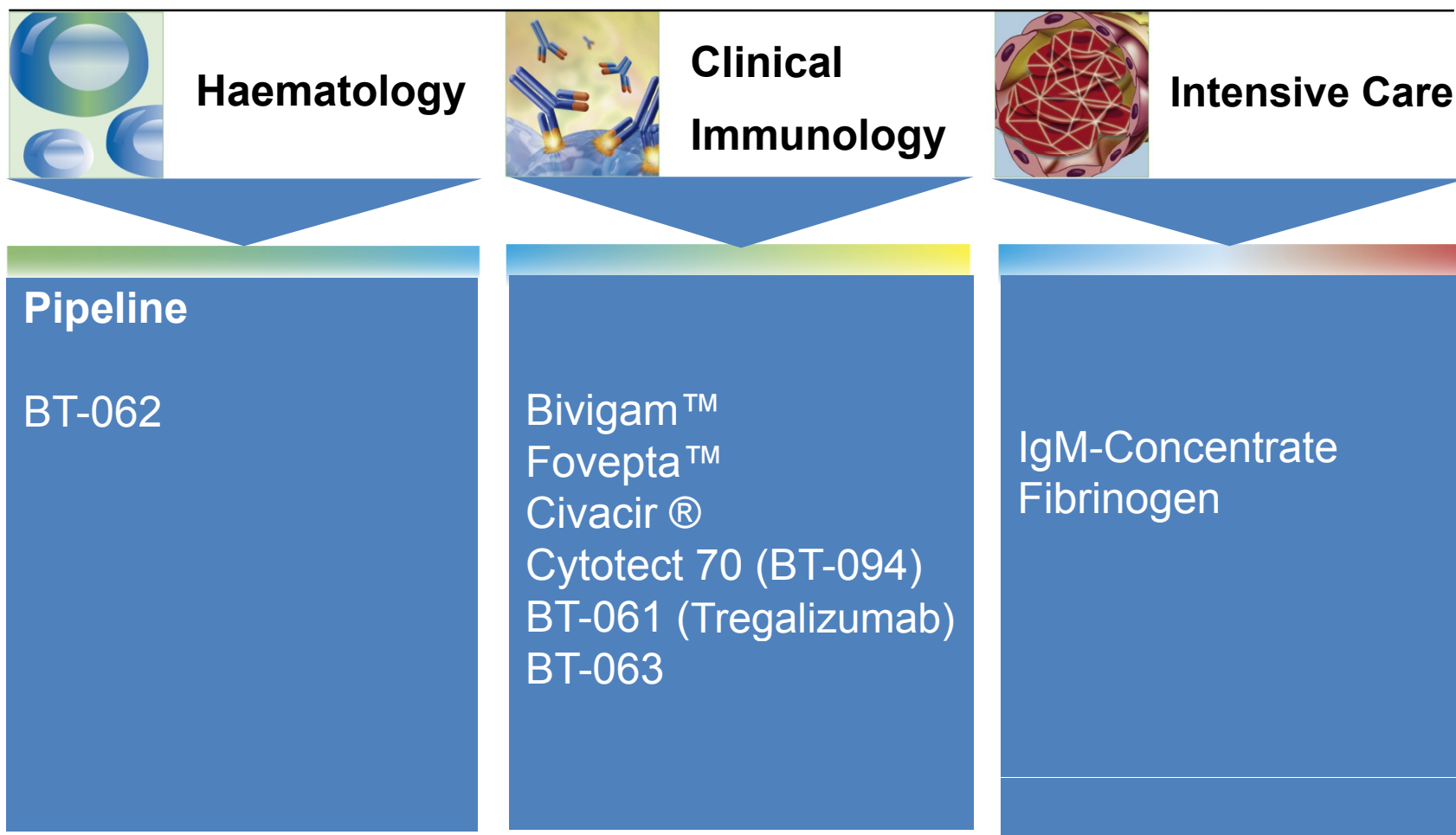
### Growth driven by:

- Further strengthen R&D activities
- In-licensing of close to or marketed products
- Mergers & Acquisitions

## Three strategic areas of therapy: Products



## Three strategic areas of therapy: Pipeline



## Development projects in Haematology

### BT-062: Potential Indication Multiple Myeloma

#### Study 969

- Scope:
  - Tolerability and safety
  - Investigate anti-tumor activity
- Good tolerability and safety up to 160 mg/m<sup>2</sup>
- Clinical benefit in > 50% of patients, including minor and partial responses
- One patient on treatment for 1.8 years (no progression of disease)

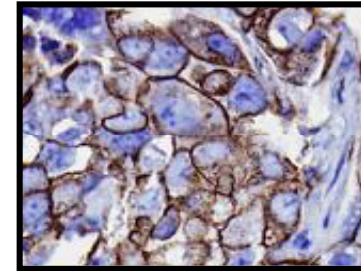
#### Study 975

- Scope:
  - Increase of drug exposure in patients by splitting single monthly dose
  - Investigate anti-tumor activity
- Recruitment of 7<sup>th</sup> cohort in escalation completed, partial response at 80 mg/m<sup>2</sup> confirmed
- Good tolerability
- Clinical benefit in patients up to 220 days

#### Study 983

- Scope:
  - Tolerability and safety in combination with gold standard
- First patient expected mid 2012

## Scientific Rationale for Selection of CD138 Expressing Solid Tumor Indications



IHC: BT-062 reactivity on primary mammary carcinoma

Patients with CD138 positive tumors	Cancer Indication
45%	Breast <sup>1)</sup>
50%	Pancreas <sup>1)</sup>
50%	Prostate <sup>2)</sup>
63%	Bladder <sup>1)</sup>
50%	Lung <sup>1)</sup>
39%	Head and Neck
41%	Ovarian
83%	Cervix



Homogeneous overexpression in primary tumor

- CD138 expression also in **metastatic lesions**
- CD138 expression also in **late disease stage**

=> **Four priority indications chosen for further evaluation**



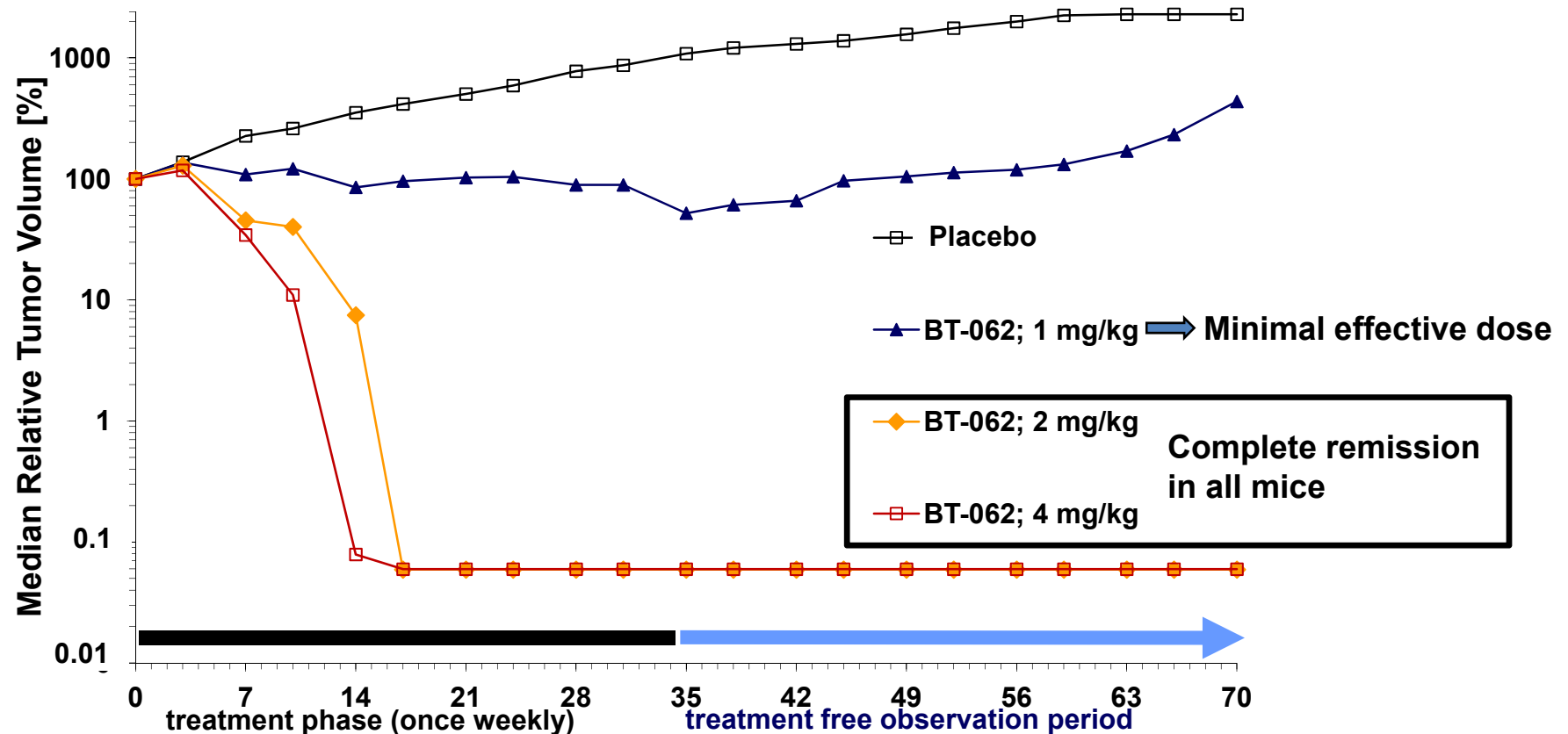
Lower CD138 expression at later disease stages and metastatic lesions

=> **Potential secondary indications**

<sup>1)</sup> xenograft data available

<sup>2)</sup> xenograft models to be evaluated

## Triple negative mammary carcinoma: Full eradication of established human tumors by BT-062 in a nude mouse model



### Complete tumor eradication in all animals:

- with doses of 2 mg/kg or higher
- corresponds to human dose of 80 mg/m<sup>2</sup> : below maximum tolerated dose (MTD) in humans (160mg/m<sup>2</sup>)

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## BT-062 for the treatment of solid tumors

### Summary

- CD138 is over-expressed in many solid tumor indications
- Outstanding efficacy of BT-062 in relevant solid tumor models in a mouse model:
  - **Complete eradication** of transplanted human tumors: complete response (CR) achieved **at 0.6-fold equivalent dose of clinical MTD<sup>1)</sup>**
- Comparison to competitor antibody-drug conjugate (in Phase III clinical development)
  - BT-062 exceeds efficacy of competitor antibody-drug conjugate in mammary carcinoma model (complete tumor eradication)
  - Competitor: higher equivalent doses than clinical MTD<sup>1)</sup> necessary to achieve complete response in animal models
- Selection of most promising indications for clinical development ongoing

<sup>1)</sup> MTD: maximum tolerated dose in patients

## Development projects in Clinical Immunology (I)

**Bivigam™**

**Polyspecific  
Immunoglobulin**

Additional conformance lots were  
produced in Q3 2011

Remaining analytical and stability data  
submitted to FDA

**Expected launch in mid 2012**

Gradual scale up of production in  
H2 2012

**Intratect 10%**



**Polyspecific  
Immunoglobulin 10%**

Phase III clinical trial completed

**Approval expected end 2012**



## Development projects in Clinical Immunology (II)

### Fovepta™



**Hepatitis B  
Immunoglobulin for  
intramuscular and  
subcutaneous injection  
for neonates**

**Approval in Germany in  
March 2012**  
Basis for approval in RoW  
markets

### Civacir®



**Hepatitis C  
Immunoglobulin**

New production process  
established, formulation  
improved, clinical batch  
production in Q2 2012  
Restart of phase I/II clinical  
trial planned end of 2012

**Cytotect 70 (BT-094) Human Cyto-  
megalovirus  
Immunoglobulin**



Currently 10,500 women  
screened in phase III trial  
Positive trend in favour of  
treatment group

## Development projects in Clinical Immunology (III)

### BT-061: Potential Indications Rheumatoid Arthritis/ Psoriasis

#### Study 979

- Scope:
  - Phase IIb RA (BT-061 + MTX\*)
  - Multidose, subcutaneous up to 75 mg, 12 weeks treatment
- Patients: 176
- Patient recruitment in progress

#### Study 985

- Scope:
  - Phase I (Pharmacodynamics, Pharmacokinetics)
  - Single dose, subcutaneous up to 200 mg
- Patients: 36
- Clinical trial protocol submitted for approval

#### Study 986

- Scope:
  - Phase IIb RA (BT-061 + MTX\*), Multidose, subcutaneous six months treatment
- Patients: 350
- First patient expected in H1 2013

\*MTX = Methotrexate

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## Development of projects in Intensive Care

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### **IgM-Concentrate**



**IgM enriched  
Immunoglobulin**

High functional  
activity

Phase II trial ongoing

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### **Fibrinogen**

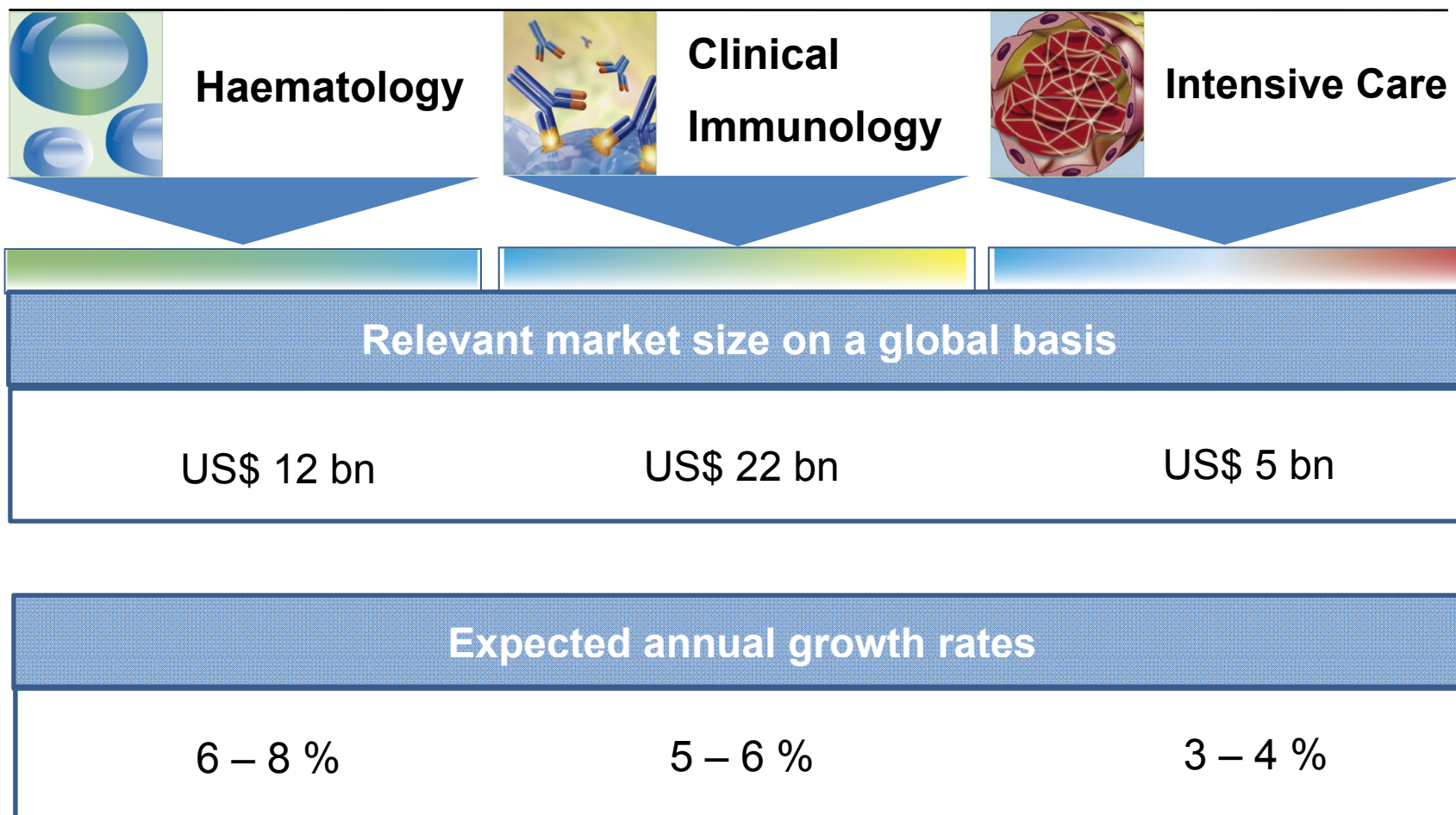
**Essential factor  
for coagulation**

Production process and  
formulation development of  
product completed

Start of clinical  
development in H2 2012

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## Attractive markets with high growth rates



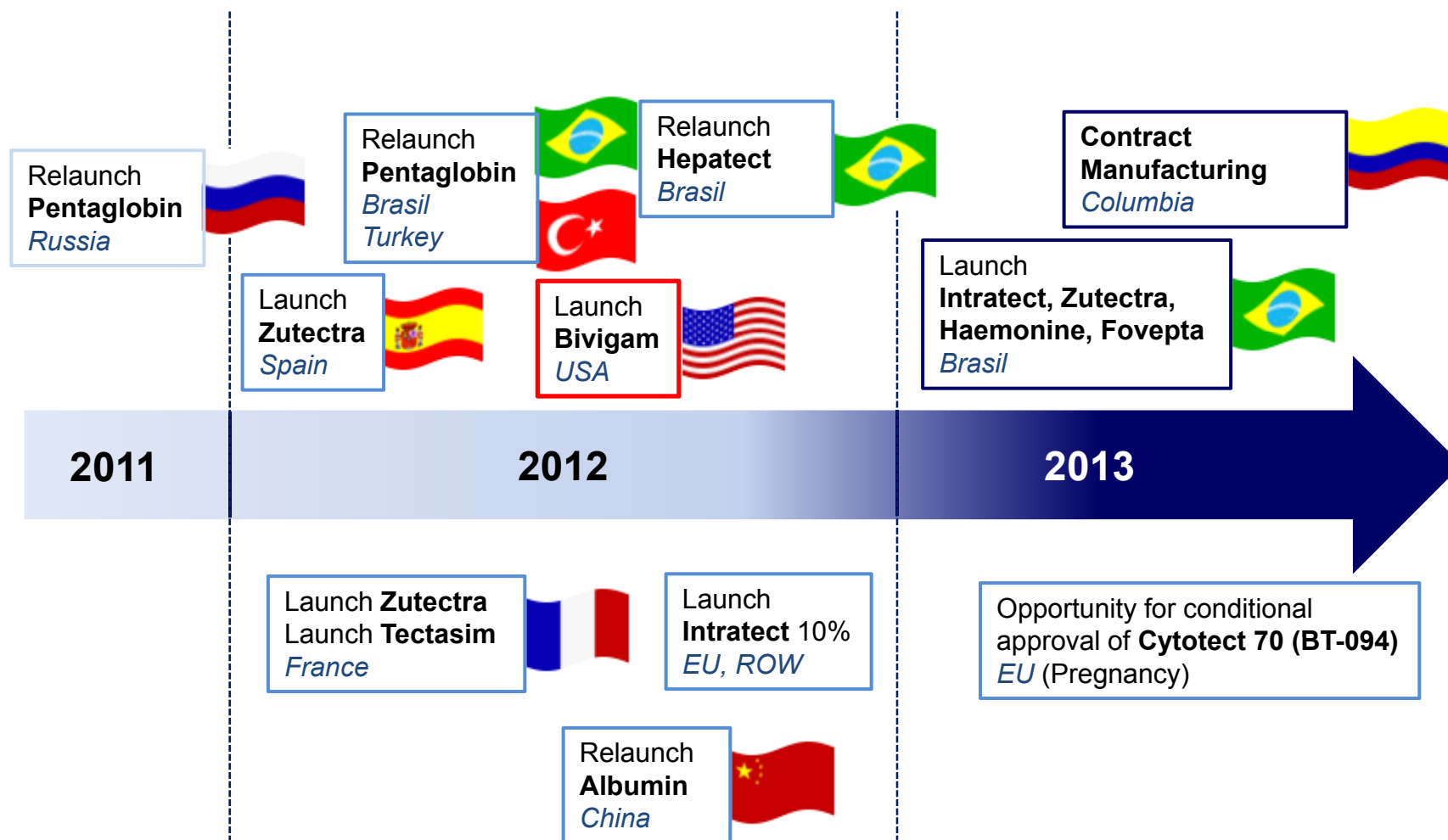
Source: MRB, Decision Resources, Datamonitor, IMS, Biotest estimates

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## **Biotest's Internationalisation Strategy**

- Establish a European wide company
- Access to US market
- RoW countries as future growth factor

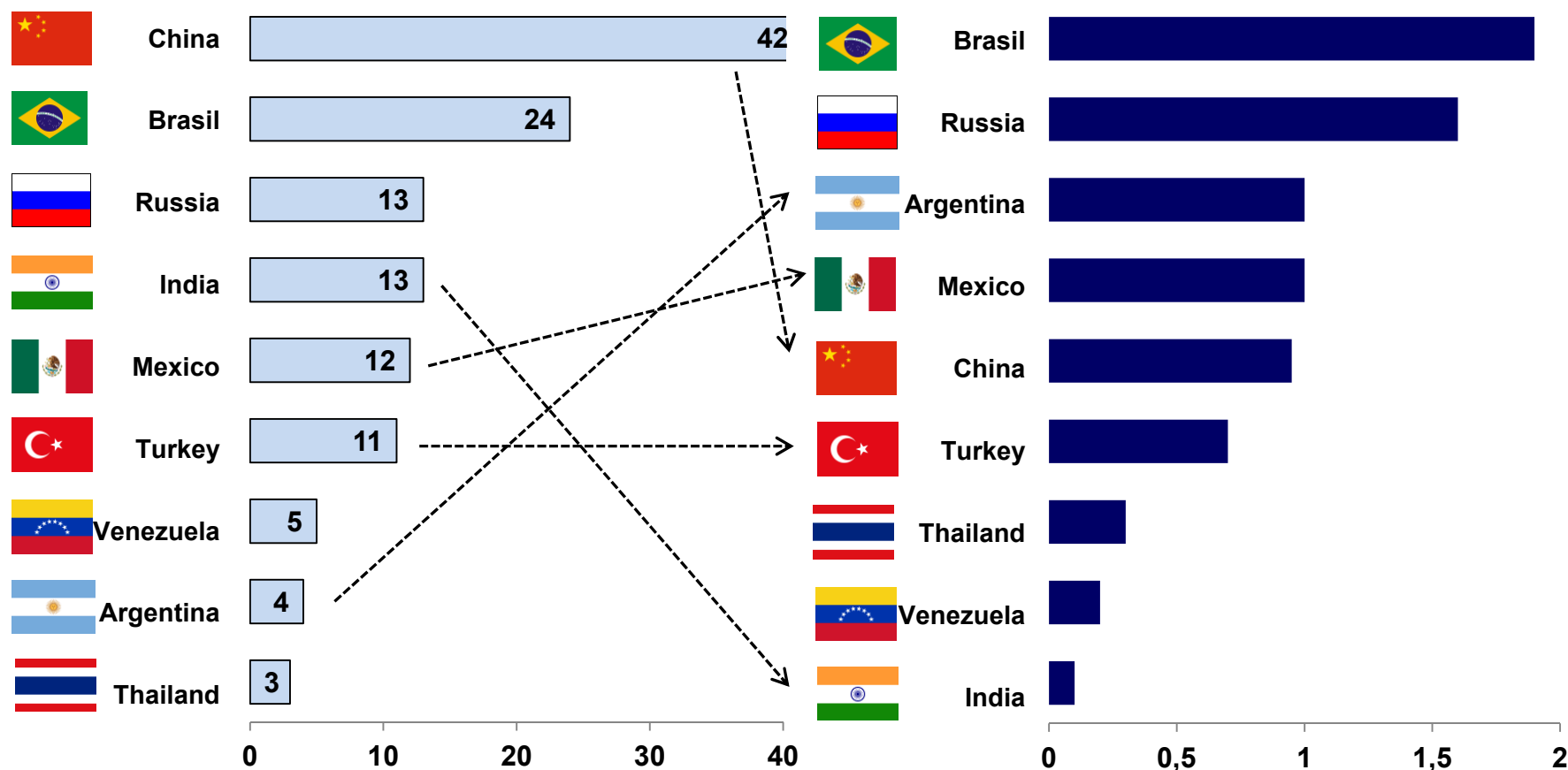
## Short and Mid-term Opportunities for Market Growth



# Opportunities for high cost innovative pharmaceuticals in emerging markets

Total Pharma Market Value (US\$ Bn 2010)

High-Cost Product Potential (US\$ Bn 2010)



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## Biotest 2020 Strategy Implementation

Challenges in the market require a new organisation which

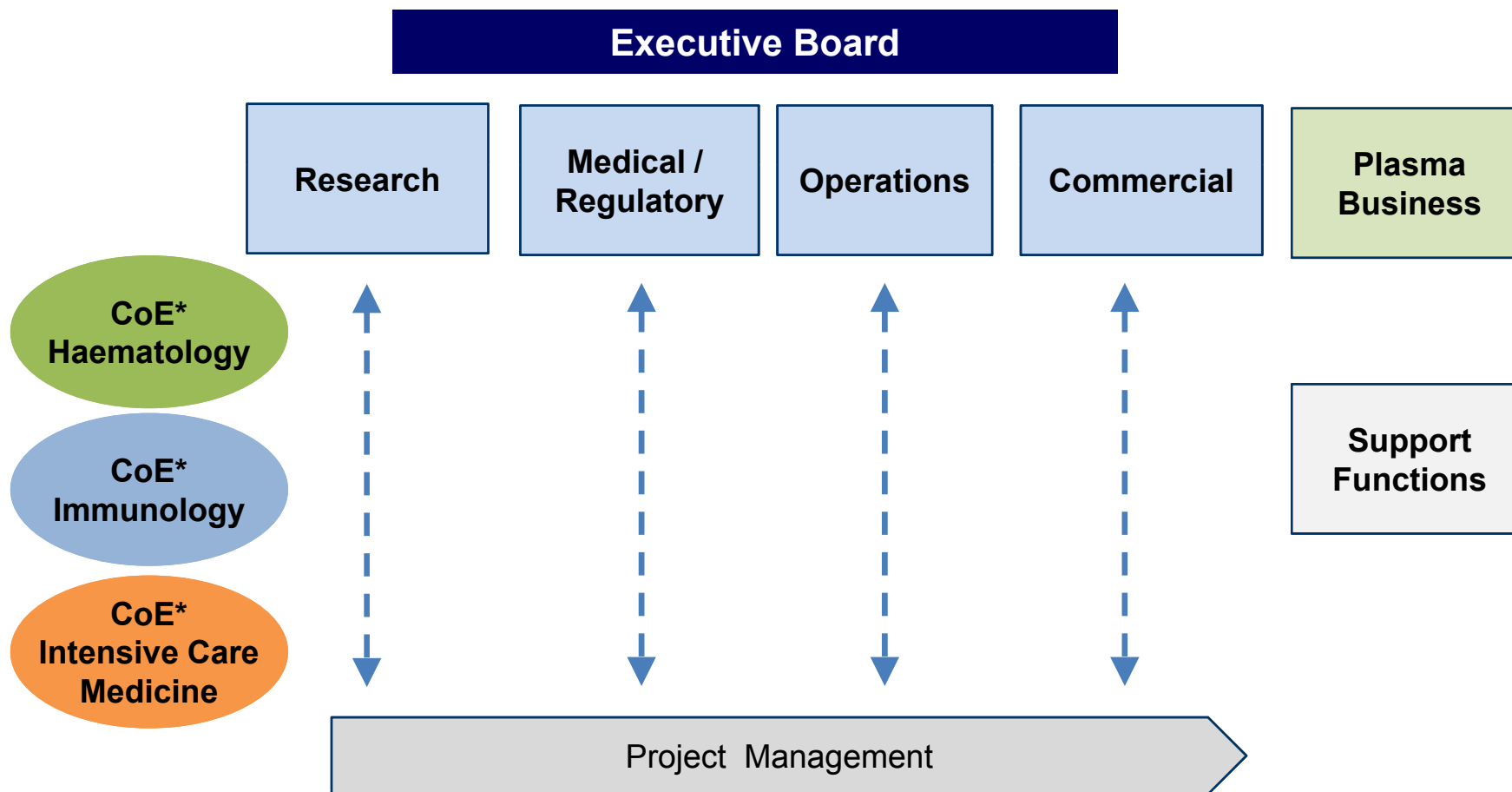
- Is able to focus on patients' and doctors' needs  
→ **Implementation of Therapeutic Areas**
- Provides a platform to search for new business opportunities with strong focus  
→ **Centers of Excellence**
- Maximizes the use of synergies by consolidation of core competences in the same department  
Increases flexibility to react fast and powerful  
→ **New Structure**
- Ensures global acting  
→ **Strengthen functional responsibility**



**New perspectives for shareholders and investors**



## New Functional Structure



\*CoE = Center of Excellence

## Positive Mid-Term Outlook Biotest Group

- Despite the challenges of 2012 the Biotest outlook for the next years is definitely positive
- Growing demand for IVIG and albumin (especially in Asian countries)
- Stable market for clotting factors
- Bivigam™ market authorisation expected mid of 2012
- Launches of plasma protein products in new markets
- Promising R&D pipeline in all therapeutic areas



## Contact and Financial Calendar 2012

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### Financial Calendar 2012

<b>Mar 22, 2012</b>	<b>FY 2011</b> <b>Analyst conference</b>
<b>May 10, 2012</b>	<b>Q1 Report 2012</b>
<b>May 10, 2012</b>	<b>Annual General Meeting</b>
<b>Aug 13, 2012</b>	<b>Q2 Report 2012</b>
<b>Nov 13, 2012</b>	<b>Q3 Report 2012</b> <b>Analyst conference</b>