

## **Biotest – The Specialists**



**Biotest AG First Quarter results 2010**

**11 May 2010**

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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 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.

## Q1 2010 – The Highlights

- Q1 Sales increase + 5.2% to € 115.0 m ; increase of R & D expenses by € 3.5 m (+34%), EBIT € 12.3 m (-18%)
- Earnings after tax (incl. discount. operations) € 22.6 m including the extraordinary income of the sale of Medical Diagnostics
- Plasma protein production in US: stability batches of Bivigam™ (IVIg) completed
- First sales of Zutectra®
- Biotherapeutics: clear indications of clinical efficacy of BT-061 in Psoriasis in a Phase I/IIa trial





## **Financial indicators in Q1 2010**

## Medical Diagnostics sold to Bio-Rad

- Sale of transplantation and transfusion diagnostic activities
- Buyer: Bio-Rad Laboratories, Inc.
- Contract signed: 23 October 2009
- Closing on 6 January 2010
- Sale price: €45 million
- Preliminary sales proceeds: €18.1 million (EBIT)
- Preliminary EAT: € 15.1 million

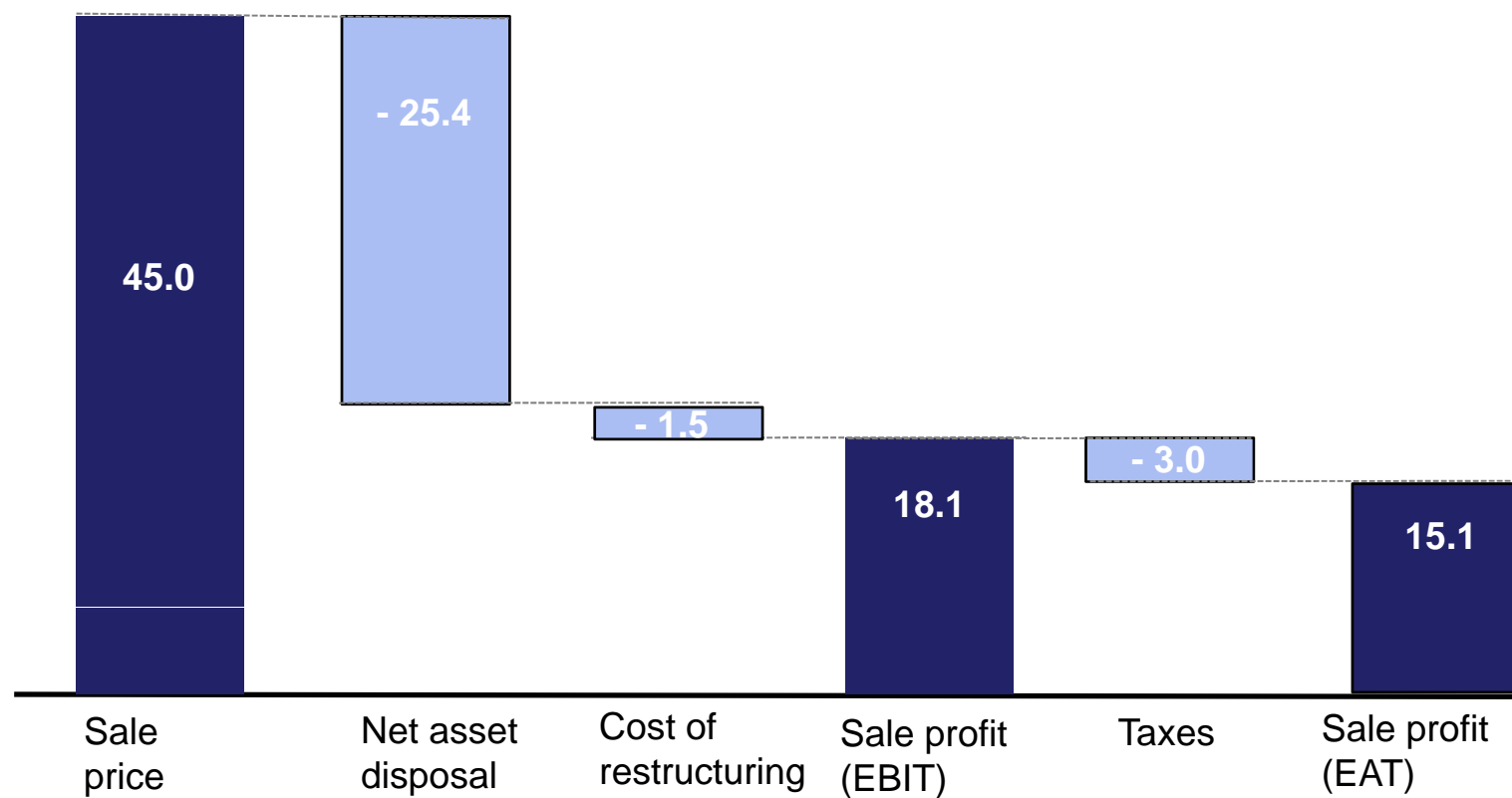


### Transaction comprised:

- Biotest Medical Diagnostics GmbH
- Biotest Diagnostics Corp.
- Activities of international affiliates

## Probable sale profit of €15.1 million after taxes (EAT)

in €million



## Q1 2010: Sales (€million)

	Q1 2009	Q1 2010	Δ
Plasma Proteins	97.4	101.9	+ 4.6 %
Microbiological Monitoring	11.9	13.1	+ 10.1 %
<b>Biotest Group</b>	<b>109.3</b>	<b>115.0</b>	<b>+ 5.2 %</b>

## Sales Plasma Proteins

Sales Plasma Proteins Q1 2009	€ 97.4 m
Volume effect	+ € 12.2 m
Price effect	- € 7.7 m
<b>Sales Plasma Proteins Q1 2010</b>	<b>€ 101.9 m</b>



## EBIT Plasma Proteins Q1 2010 vs Q1 2009

EBIT Plasma Proteins Q1 2009	€	19.8 m
EBIT from increase volume	+ €	5.7 m
EBIT loss from reduced prices	- €	7.7 m
Net changes of other costs/expenses	+ €	0.2 m
<b>EBIT Plasma Proteins Q1 2010</b>	<b>€</b>	<b>18.0 m</b>

## Q1 2010: EBIT Biotest Group (€million)

	Q1 2009	Q1 2010	Δ
Plasma Proteins	19.8	18.0	- 9 %
Biotherapeutics	- 3.7	- 5.1	- 38 %
Microbiological Monitoring	1.3	1.7	+ 31 %
Corporate	-2.4	- 2.3	+ 4 %
<b>Biotest Group</b>	<b>15.0</b>	<b>12.3</b>	<b>- 18 %</b>

## Lower EBIT due to higher R & D Expenses (€million)

	2010	Δ to 2009
<b>EBIT Q1 2010</b> (actual)	<b>12.3</b>	<b>- 18 %</b>
Δ R & D Plasma Proteins	2.1	
Δ R & D Microbiology	0.1	
Δ R & D Biotherapeutics	1.4	
<b>EBIT Q1 2010</b> (adjusted for increased R&D expenses)	<b>15.9</b>	<b>+ 6%</b>

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## Reasons for increased R & D expenses

### **Plasma Proteins:**

- BPC has produced IVIG consistency batches

### **Biotherapeutics:**

- 5 Clinical studies ongoing with BT-061, BT-062 and BT-063

### **Microbiology:**

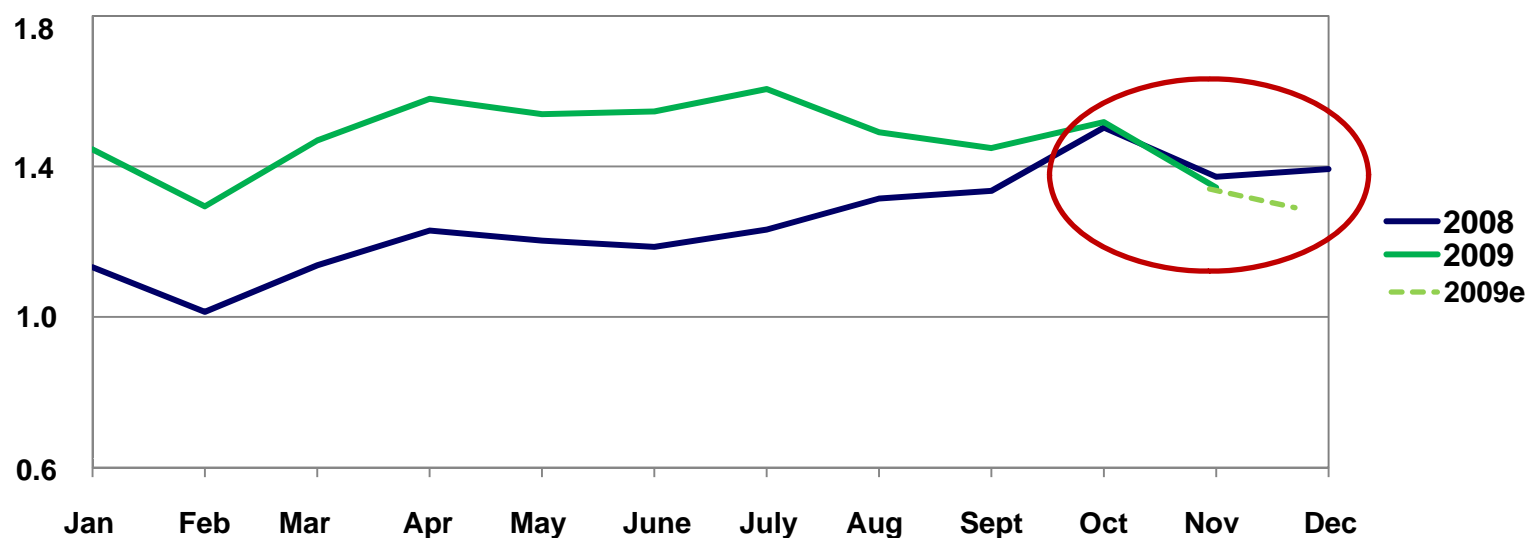
- Development of new pyro detect systems



## Plasma Proteins

## Development of plasma supply in the United States 2008/2009

Volume of US-sourced plasma (in million litres)



- Adjustment of US-sourced plasma volumes to changed market environment end of 2009
- Further decline in plasma volumes expected in 2010; market recovery from 2011
- Biotest recognised trend early and was able to adjust its plasma sourcing strategy accordingly

Source: PPTA

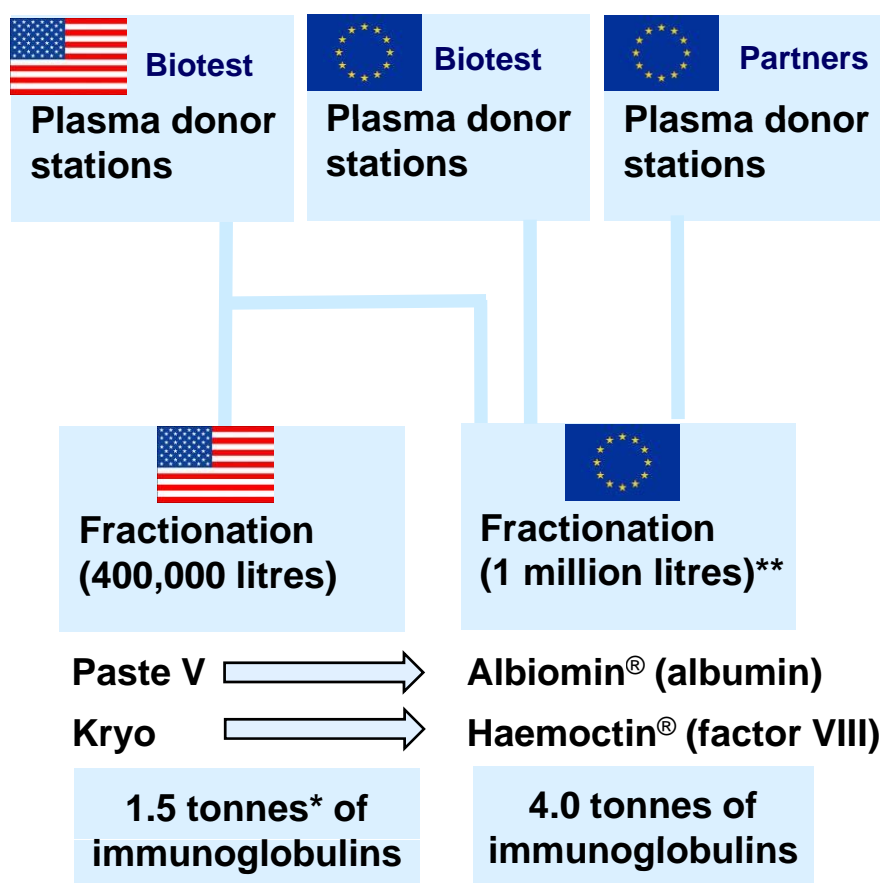
## Bivigam™ (IVIg) development nears successful completion

**Polyspecific immunoglobulin with a wide indication range (incl. antibody deficiency and autoimmune diseases)**



- A polyspecific immunoglobulin comparable to Intratect®
- Clinical development: successful conclusion of phase III
- Production of stability batches completed
- Submission of approval documents in Q3 2010, approval likely in Q3 2011
- Sales potential after approval: around \$100 million per annum

## Plasma Proteins – Efficient production network



- 20 plasma donor stations
- Level of self-sufficiency: 40% for standard plasma
- Exchange of intermediate products between US and Europe from end of 2010
- Network increases EBIT margin

\* Approval will probably be granted in 2011

\*\* Production in Dreieich and capacities at partners



## Civacir™: Attractive project is put on course

**Hepatitis C  
immunoglobulin for  
reinfection prophylaxis  
after liver transplantation  
due to hepatitis C**

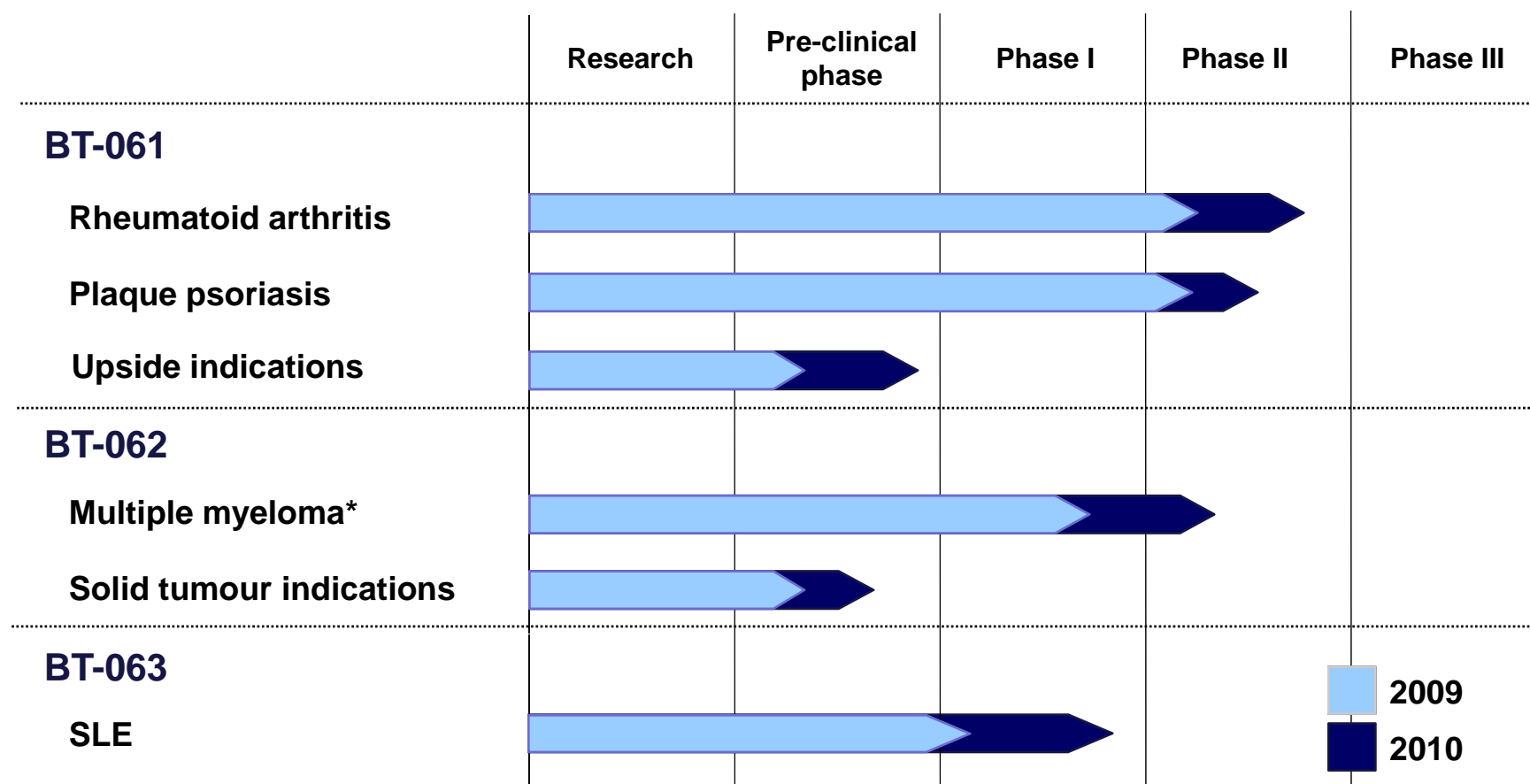


- Hepatitis C: frequent cause for liver transplantation
- prevalence: 5 to 10 times more frequent than hepatitis B
- Civacir™: Project acquired as part of Nabi Biopharmaceuticals takeover
- Optimisation of manufacturing process, e.g. regarding consistency of neutralising antibodies
- Clinical development expected to be continued in 2011



## **Biotherapeutics**

## Biotherapeutics: Significant project progress in financial year 2009



\* Phase I/IIa clinical trial approved by FDA (IND)

## BT-061: Results of clinical trials deliver proof of concept for rheumatoid arthritis



Phase IIa trial:  
BT-061  
vs. placebo

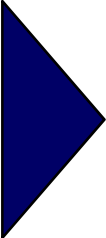
Phase II trial:  
BT-061 + MTX\*  
vs. MTX\* alone

### Initial results\*:

- Clear improvement in symptoms (ACR 20–70)
- Generally good tolerability



### Phase IIb trial (mid-Q2 2010)

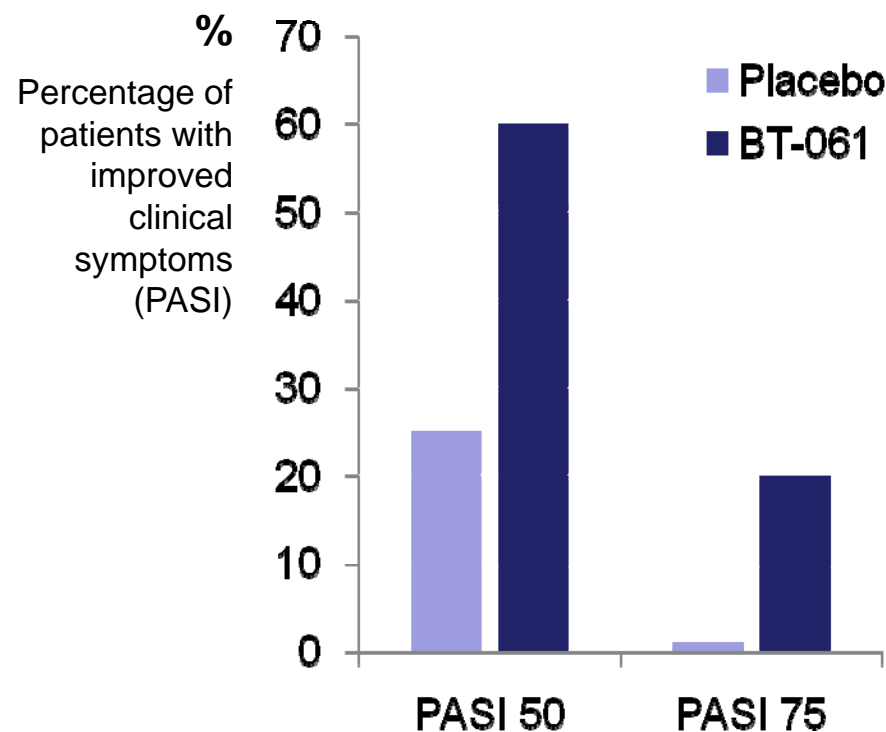
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- BT-061 + MTX\*\* vs. MTX\*\* alone
  - About 200 patients
  - Basis for phase III trial (in 2012 at the earliest)

\* Interim analyses / final results in Q3/Q4 2010

\*\* MTX = methotrexate, a drug used in primary rheumatoid arthritis therapy

## BT-061: Proven efficacy in treating psoriasis\*

PASI\*\* score after single administration  
(25 mg, subcutaneously)



- Substantial improvement in symptoms (PASI\*\* score) after single administration
- Best effect when administered subcutaneously
- Proof of concept

\* Final result of trial 967

\*\* **PASI** = Psoriasis Area and Severity Index, a measurement of the extent and severity of psoriasis condition

## Biotherapeutics: Established own production capacities



### Development structures in the segment:

- GMP production of monoclonal antibodies established in Boca Raton (BPC)
- Manufactured first large-scale batches of BT-061 in own production facility
- Gradual further establishment of teams in drug development



## BT-061 partnership



### **Biotest strategy:**

Cooperation with partner  
from clinical phase III

- Talks with international pharmaceutical companies
- High level of interest
- Desire for confirmation of positive trial results via further phase II clinical trials
- Stand-alone further development of mAb until agreement is reached

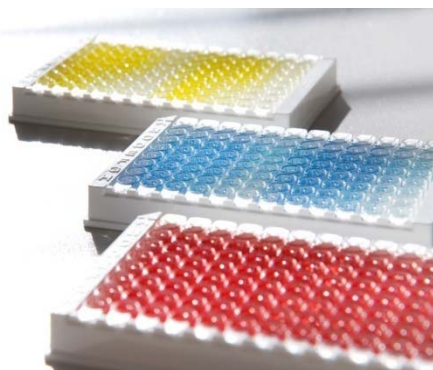


## Microbiological Monitoring



## Segment continues to be successful

- Q1 2010 revenue growth of 10.1%, achieved mainly by heipha, but also Biotest HYCON products contributed to the growth
- Expansion of logistics capacities at heipha in Eppelheim
- Investment in research and development
- Strengthening of sales structures in the United States and Japan





## **Outlook for 2010**

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## Outlook for 2010

### **Biotest's business environment fundamentally attractive and stable:**

- Products often life-saving treatments – long-term demand independent of cyclical effects
- Biotest's business is regionally diversified
- Growth opportunities in industrialised countries and emerging markets

### **But there are grounds for caution:**

- Difficult funding situation of public sector healthcare systems
- Higher credit and default risks in some markets

### **Our targets for 2010:**

- Low single-digit percentage sales growth
  - EBIT at 2009 level
- Prerequisite:
- ➔ – No further price decreases
  - More sales in high-margin markets



**Thank you very much for your attention.**

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## 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**