
Biotest – The Specialists



Biotest AG Annual Shareholders' Meeting 2010

Professor Dr. Gregor Schulz, Chairman of the Board of Management
6 May 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. These 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.

2009 – The Highlights

- Plasma protein production capacity doubled in Dreieich
- Start of production operations in the United States
- Approval of Zutectra®
- Biotherapeutics: clear indications of clinical efficacy
- Sales and earnings clearly up on previous year



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)

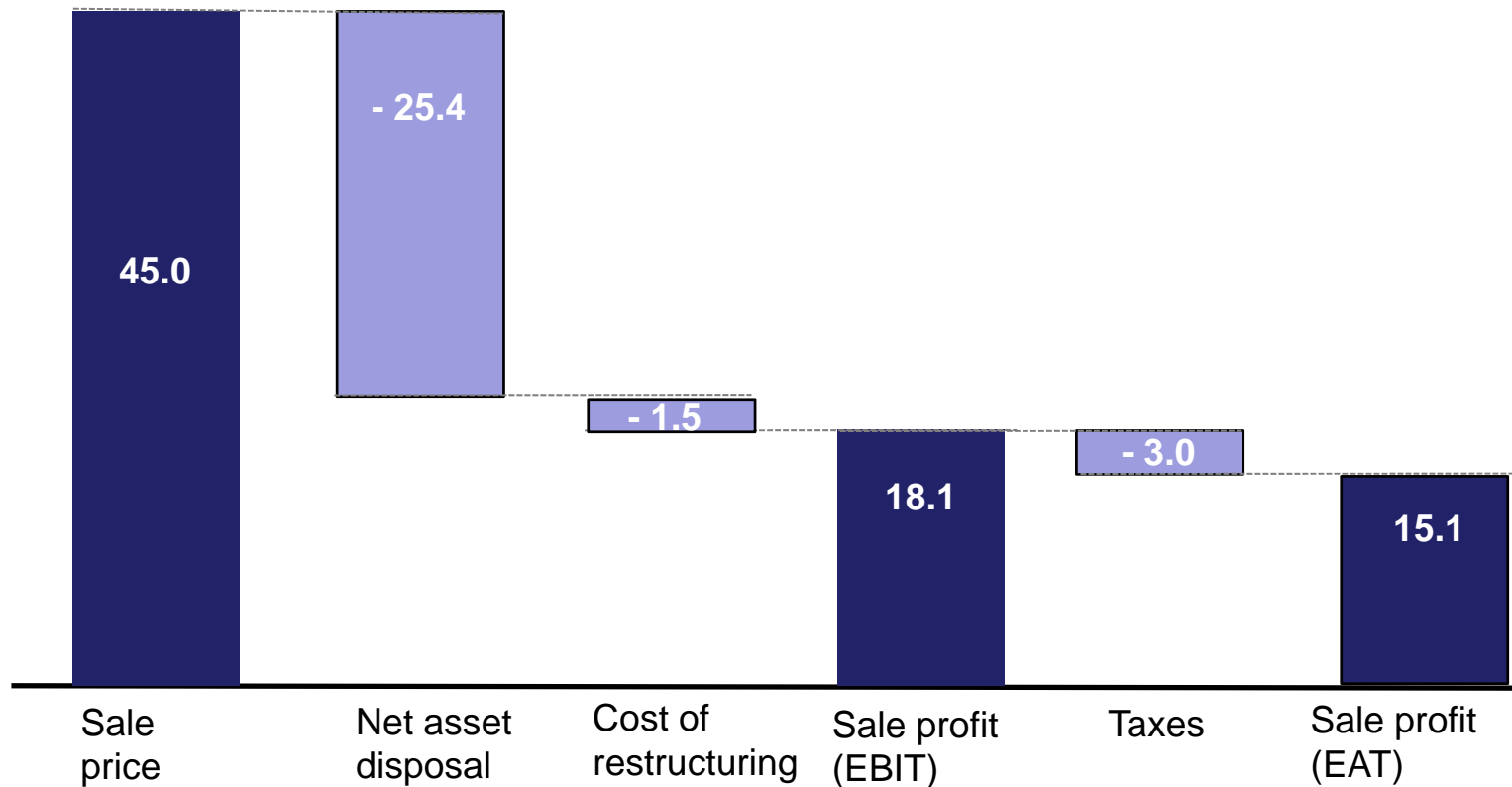


Transaction comprised:

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

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

in €million





Plasma Proteins

Our strategy for Plasma Proteins: Expand position as specialist in innovative immunology and haematology

- Develop new preparations, approvals in further indications
- Open up new international markets
- Demand-based development of capacities



Coagulation factors – Immunoglobulins – Hyperimmunoglobulins – Intensive and emergency medicine

Major progress in development of Plasma Proteins



Zutectra[®] Europe-wide approval
(centralised procedure)



Hepatect[®] Approvals in seven
other European countries
(mutual recognition procedure)



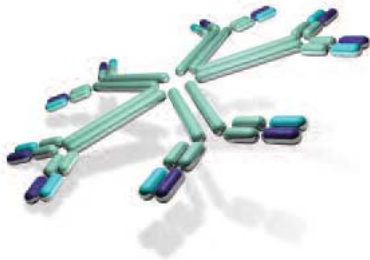
Albiomin[®] Approvals in six
other European countries



Intratect[®] Use in fibromyalgia indication:
trial completed –
scientific publications finalised

IgM concentrate

**IgM-enriched
immunoglobulin for
emergency treatment of
serious bacterial infections
(sepsis)**



- Phase I clinical trial successfully completed
- Phase II clinical trial to start from end of 2010
- Indication spectrum comparable to that of Pentaglobin®
- Very high functional activity
- Good tolerability
- Improved raw material utilisation

Cytotect[®]: Trial is progressing

Prevention of prenatal cytomegalovirus infection of unborn children whose mothers were infected for the first time during the pregnancy



- International phase III clinical trial to confirm positive findings of pilot study
- Extensive immune screening under way (up to 20,000 tests)
- More than 5,000 pregnant women tested so far
- Interim evaluation planned for end of 2010

Zutectra®: Europe-wide approval of first hepatitis B immunoglobulin with subcutaneous administration

Hepatitis B reinfection prophylaxis after a liver transplantation



- Europe-wide approval of new form of administration for hepatitis B immunoglobulin
- Administered subcutaneously (under the skin)
- Fast, pain-free, simple and safe
- Developed for self-treatment

Hepatect® CP and Zutectra® are an ideal combination



**Reinfection prophylaxis
after a liver trans-
plantation due to
hepatitis B infection**



Hepatect® CP:

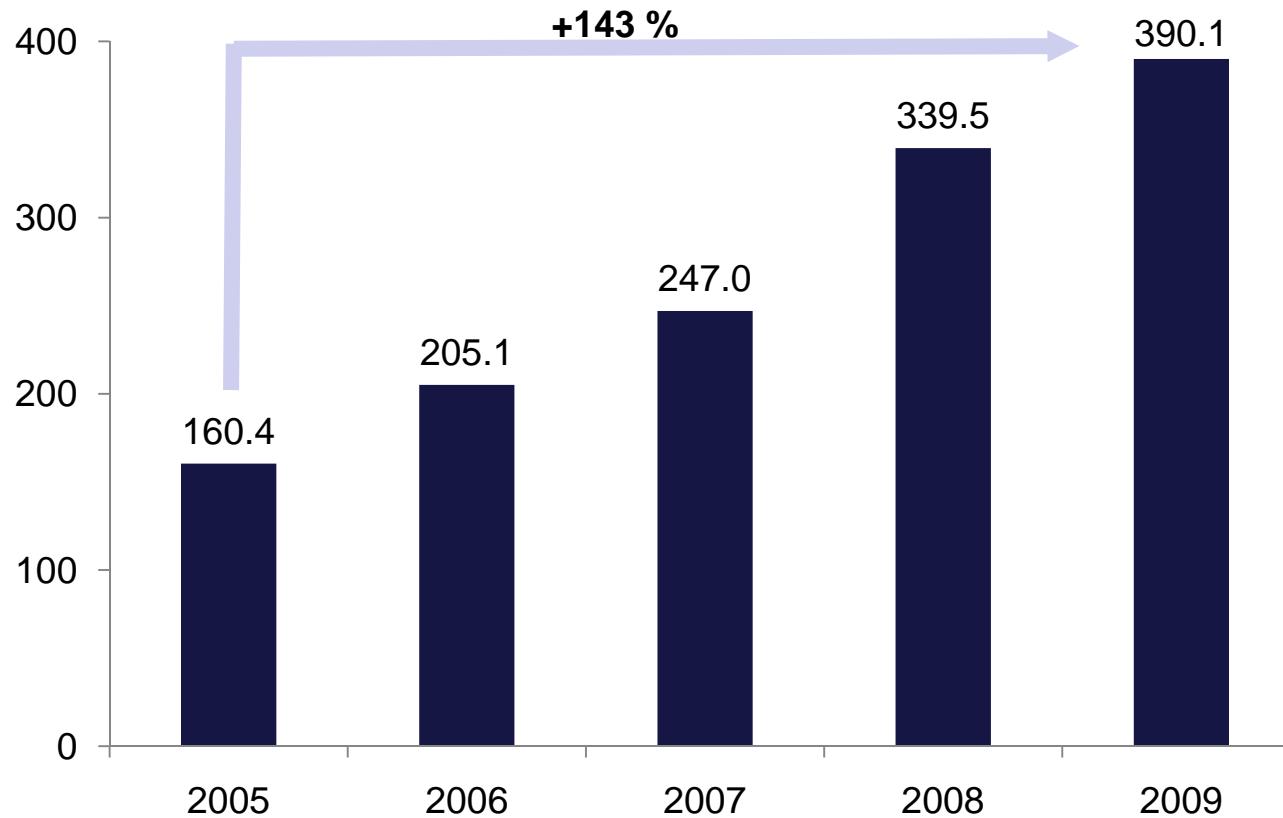
- Administered intravenously
- Optimal for intensive treatment during and immediately after transplantation

Zutectra®:

- Optimal for self-treatment
- Suitable for long-term prophylaxis as administered subcutaneously

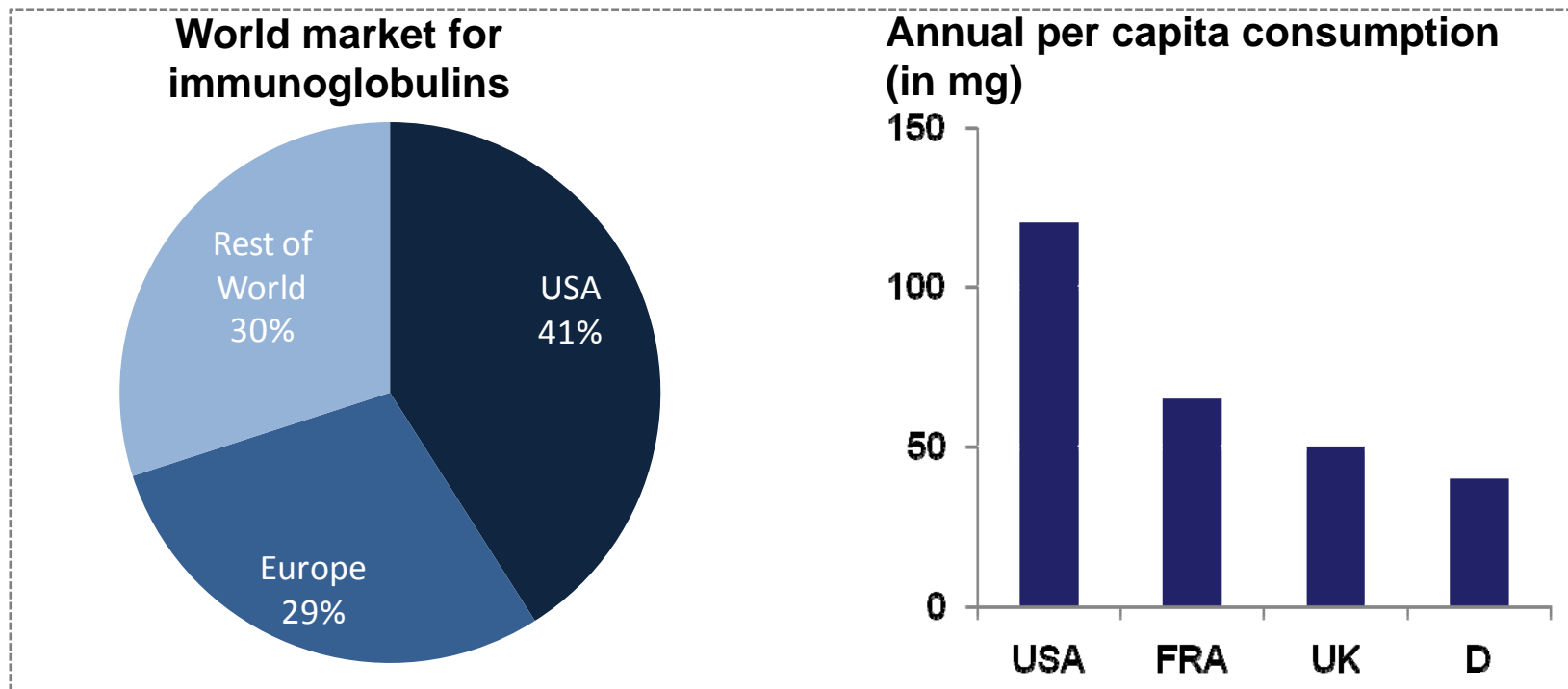
Plasma Proteins: Impressive growth

Plasma Proteins: revenue (in €million)



USA: A highly attractive market for Biotest

- World's largest market
- Highest per capita consumption in the world
- High price levels



US manufacturing plant in operation since end of 2009

- State-of-the-art manufacturing facility at Biotest Pharmaceuticals Corp. (BPC) in Boca Raton, Florida
- Fractionation: 400,000 litres per annum
- Immunoglobulin production: 1.5 tonnes per annum
- Plasma collection at 10 BPC-owned plasma collection centres



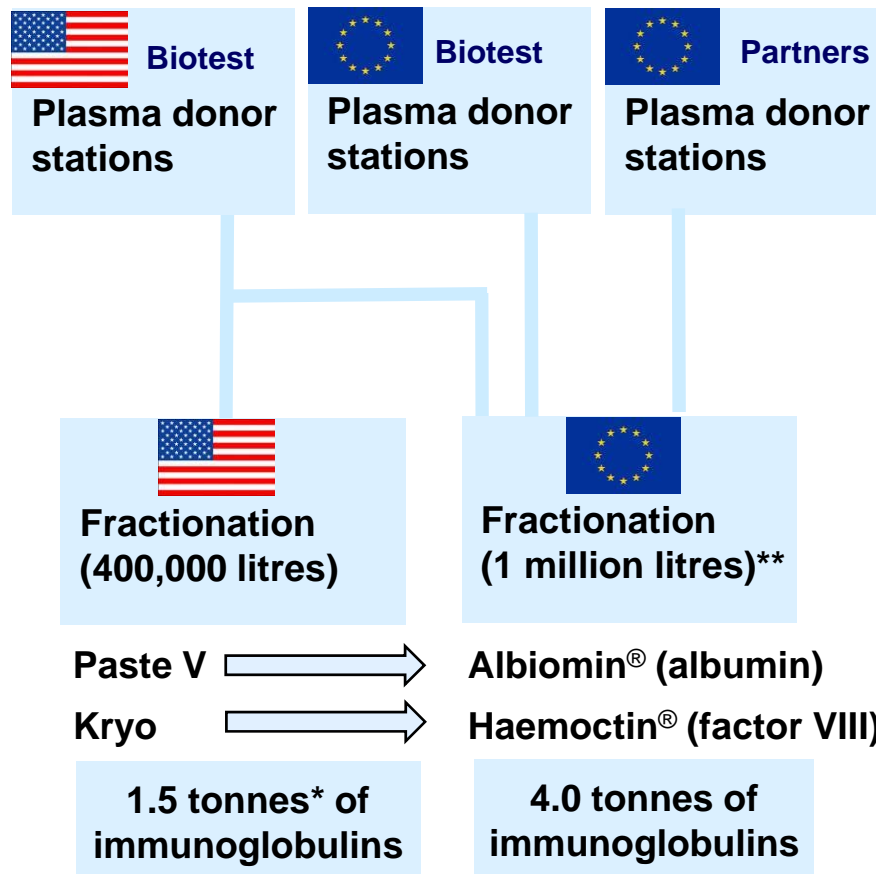
Bivigam™ (IVIg) development nears successful completion

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 collection centres
- Level of self-sufficiency: 40% for standard plasma
- Exchange of intermediate products from US to 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

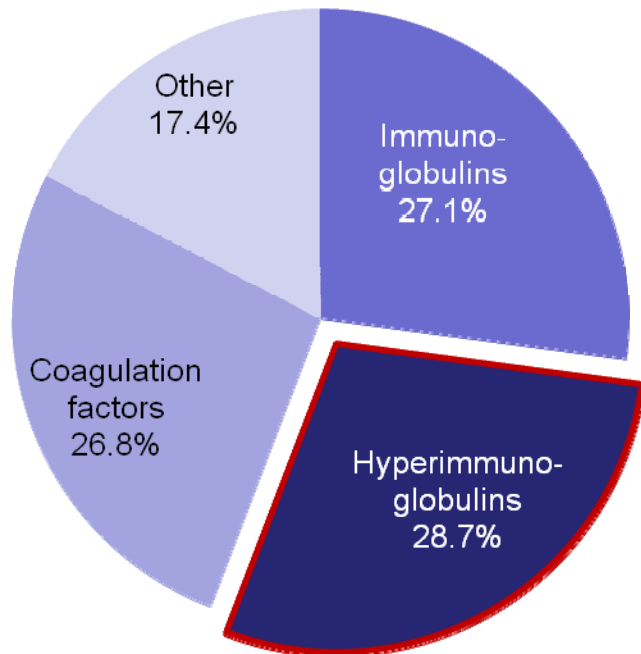
**Hepatitis C
immunoglobulin for
reinfection prophylaxis
after liver transplantation
due to hepatitis C**



- Hepatitis C: frequent cause of liver transplantations
- 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

Biotest: A market leader in special preparations

Biotest plasma proteins in 2009:
sales by product category



Hyperimmunoglobulins and special preparations are a very attractive segment:

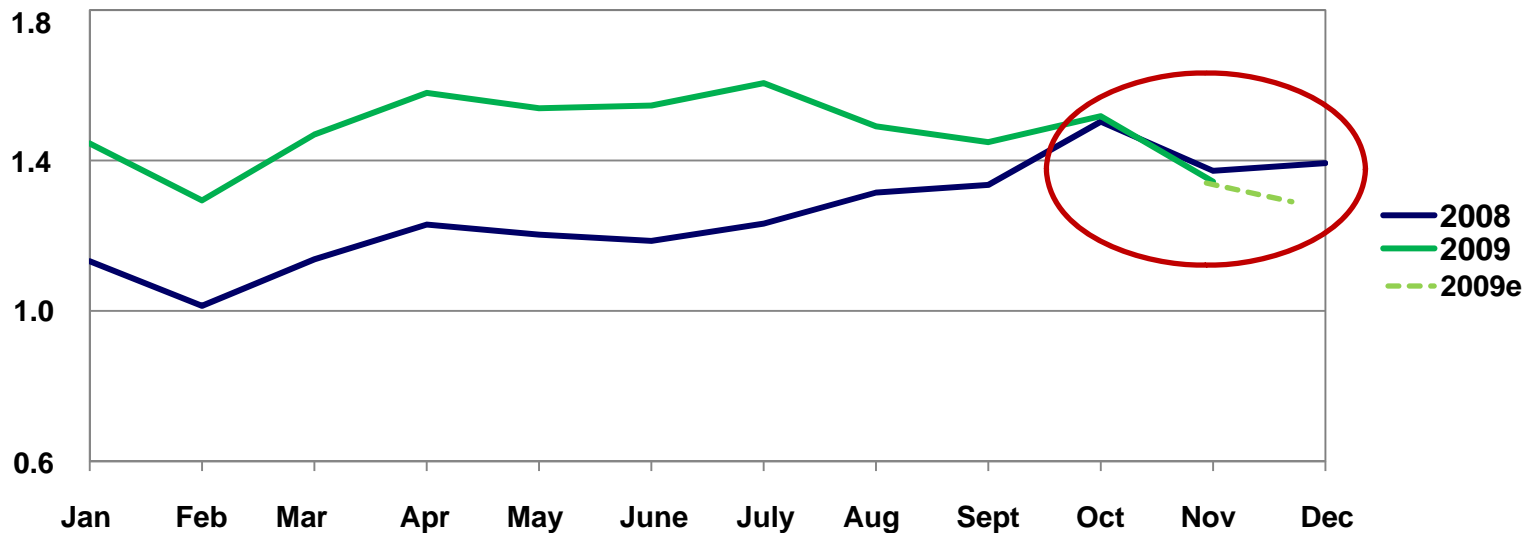
- Stable prices
- High market entry barriers
- Biotest is totally self-sufficient in hyperimmune plasma procurement



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

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

Investment in capacity at Biotest with a long-term horizon

- World demand continues to increase
- Biotest will continue to grow with the plasma segment
- Opening up the attractive US market by means of own production
- Bivigam™ (IVIg) approval expected in Q3 2011

➡ Additional market potential of \$100 million



Interim conclusion: Biotest is well positioned in plasma proteins

- US market entry with Bivigam™ (IVIg) in 2011
- Product range expanded systematically
- Attractive pipeline
- Increased efficiency due to production network

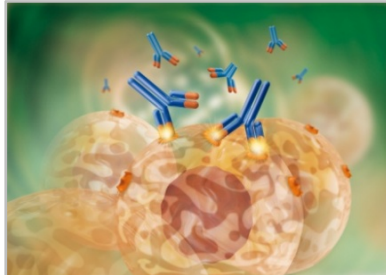


Coagulation factors – Immunoglobulins – Hyperimmunoglobulins – Intensive and emergency medicine

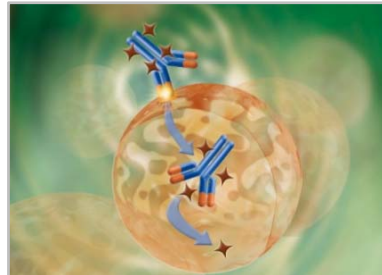


Biotherapeutics

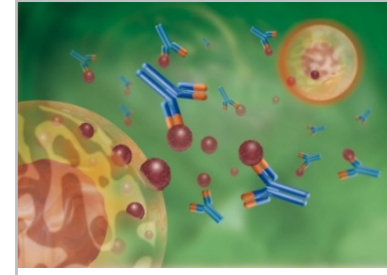
Biotherapeutics: Attractive development projects



BT-061:
Rheumatoid
arthritis,
plaque psoriasis



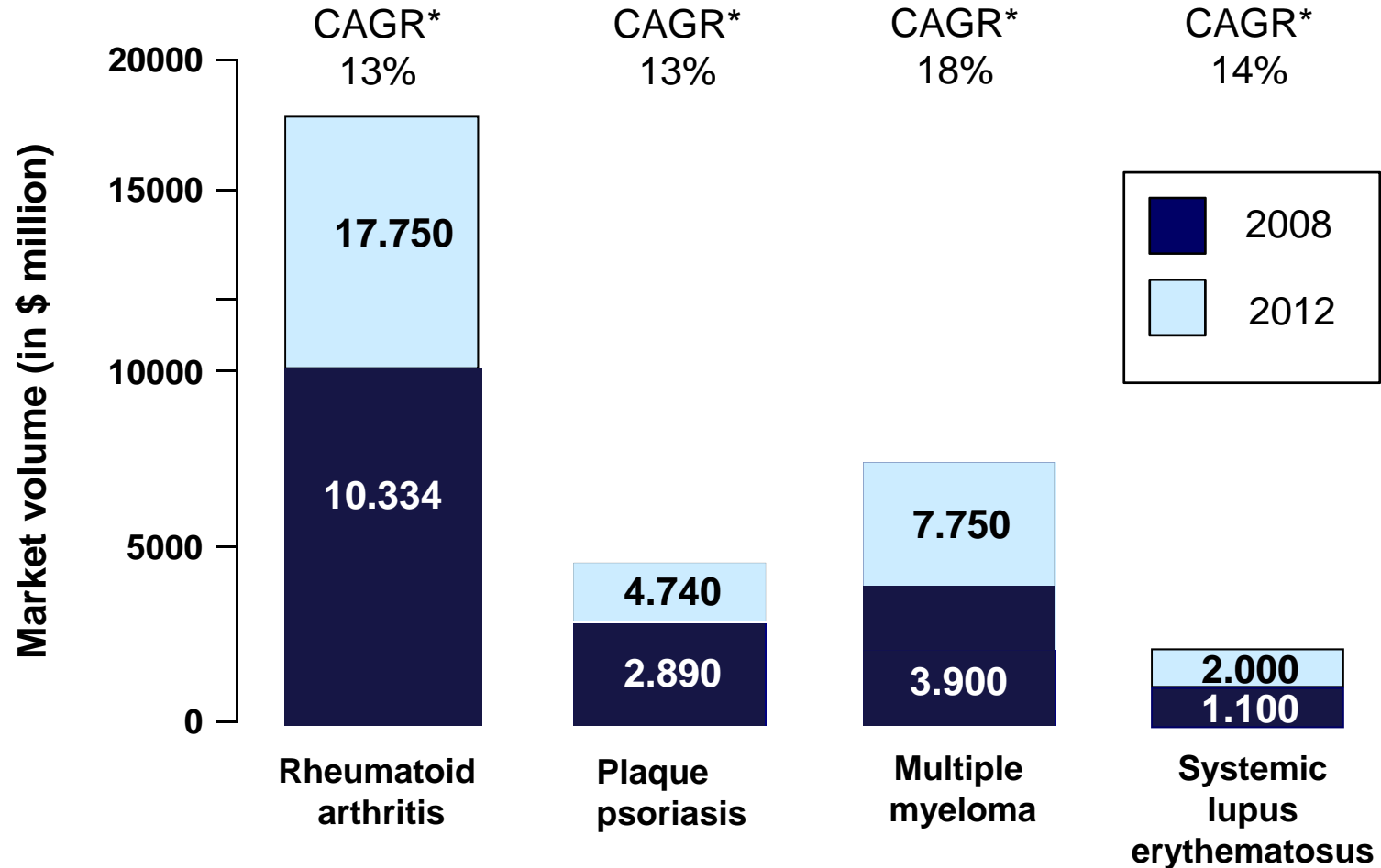
BT-062:
Multiple myeloma



BT-063:
Systemic lupus
erythematosus

- Indications with a high medical need for effective and tolerable treatments
- Antibodies with specific mechanism of action

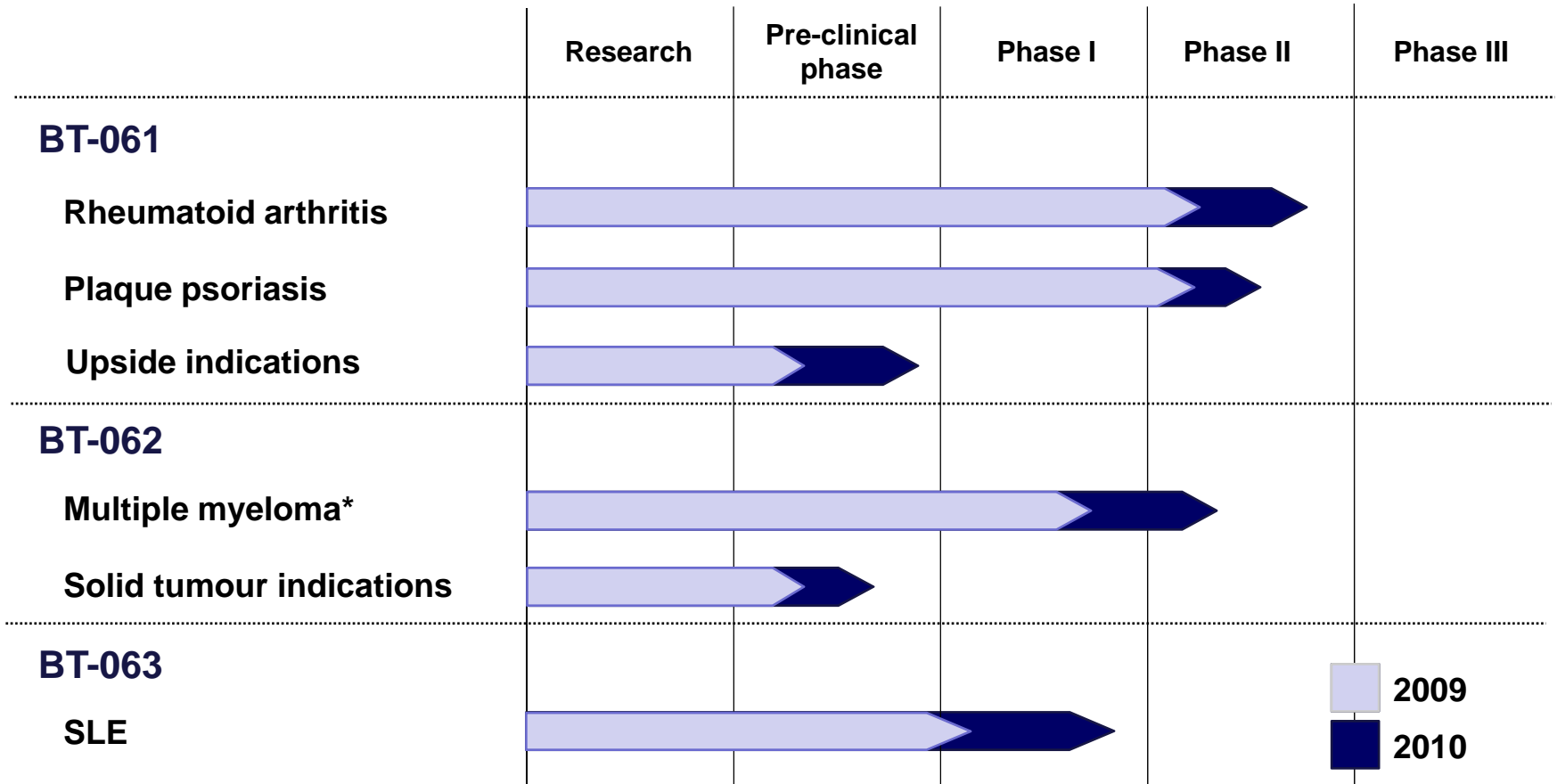
Biotherapeutics: Market potential continues to grow



Source: Datamonitor, Decision Resources, Biotest analyses, annual reports

*CAGR: compound annual growth rate

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

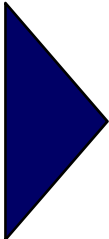
Phase II trial:
BT-061 + MTX*
vs. MTX* alone

Initial results*:

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



Phase IIb trial (mid-Q2 2010)

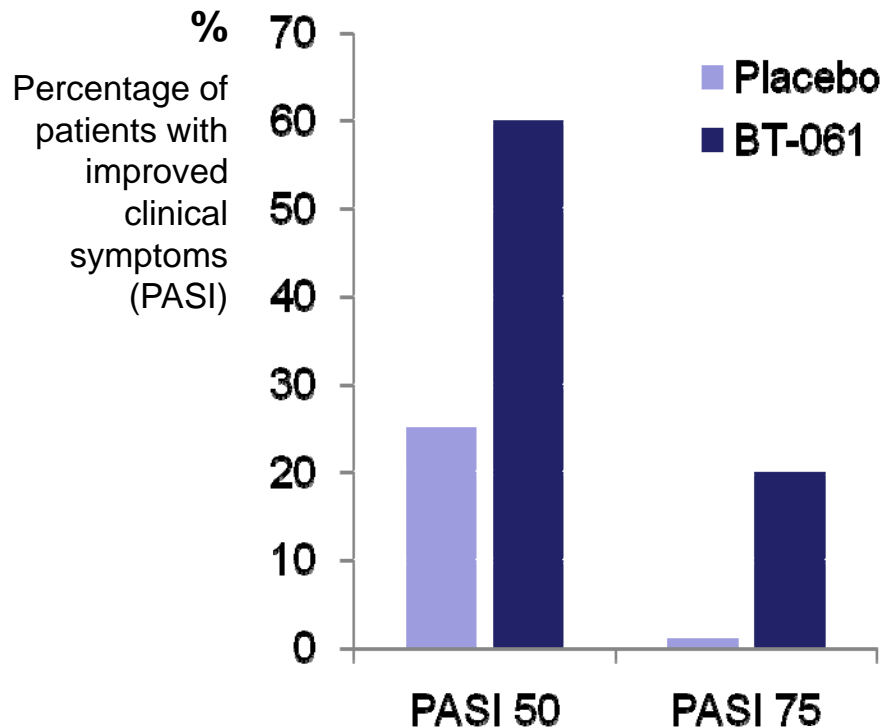
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- BT-061 + MTX** vs. MTX** alone
 - About 200 patients
 - Basis for phase III trial (in 2012 at the earliest)

* 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)

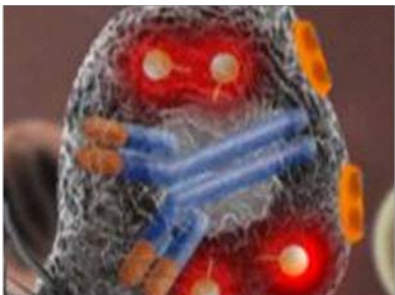
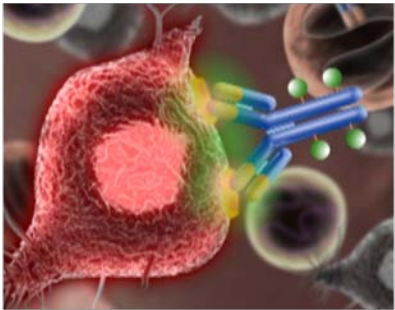
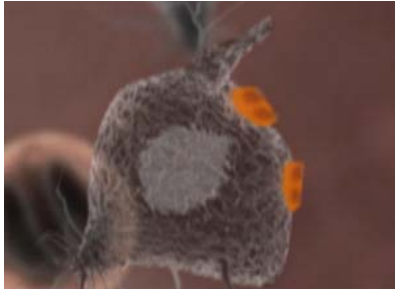


- Substantial improvement in symptoms (PASI** score) after single administration
- Best effect when administered subcutaneously
- Proof of concept

* Final result of trial 967

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

BT-062: Immune conjugate shows signs of efficacy in treating multiple myeloma



- Phase I clinical trial in the United States
- Repeated administration for as long as illness makes no further progress
- Good tolerability
- Indications of efficacy:
 - Progress of disease was halted for over six weeks in 53% of patients
 - In some cases, progress of the disease was halted for several months

Trial participants: Patients with a long history of illness

For ethical reasons tests so far only on seriously ill patients

- Patients whose illness has relapsed / patients on whom other treatments have had no effect

On average, patients have suffered from their illness for six years and have already undergone intensive previous treatment*

- (Up to) 15 rounds of chemotherapy with different cytostatic drugs
- Stem cell transplantations (over 50% of participants)

 **In later stages, patients with shorter illness histories and fewer previous therapies included in trials**

 **Thus increasing likelihood of even better efficacy**

* Median: 8 previous therapies

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

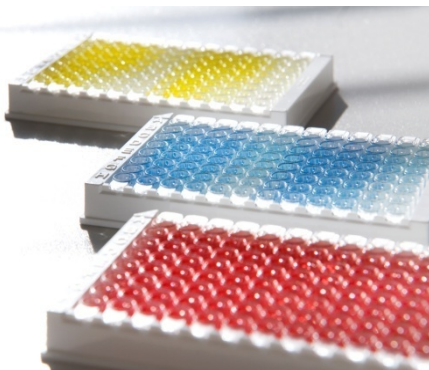
- Talks with international pharmaceutical companies
- High level of interest
- Desire for confirmation of positive trial results via further phase II clinical trials
- Stand-alone further development of mAb until agreement is reached



Microbiological Monitoring

Segment continues to be successful

- 2009 revenue growth of 8%, achieved mainly by heipha and Biotest HYCON
- Expansion of logistics capacities at heipha in Eppelheim
- Investment in research and development
- Strengthening of sales structures in the United States and Japan

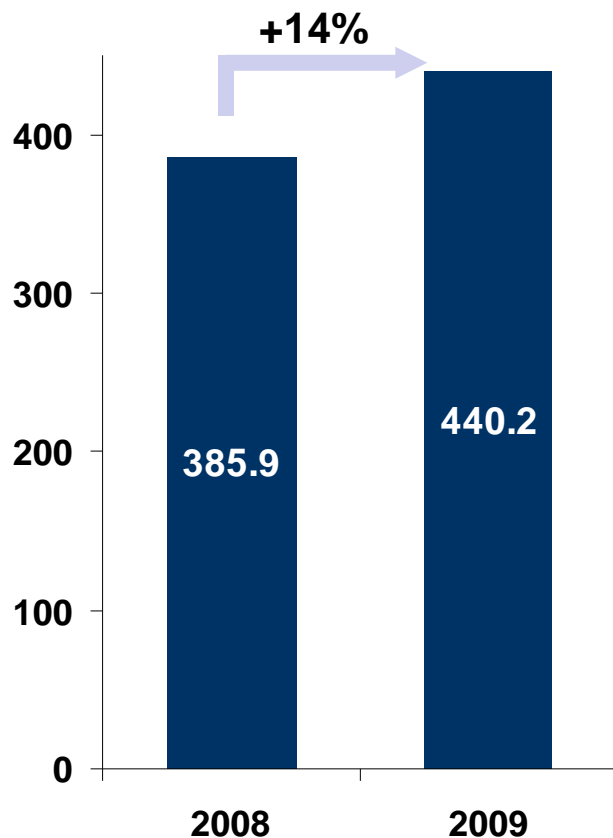




Financial indicators in 2009

Strong sales growth, Plasma Proteins especially dynamic again

Biotest Group* revenue (in €million)

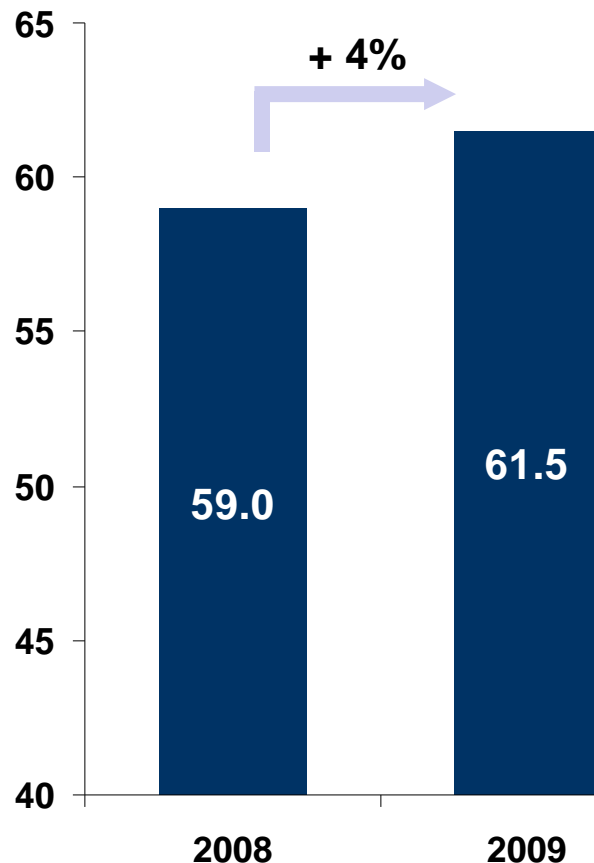


- Plasma Proteins revenue: +15%
- Microbiological Monitoring revenue: +8%
- Highest revenue in Company's history

* Continuing Operations

Operating profit: previous year and expectations

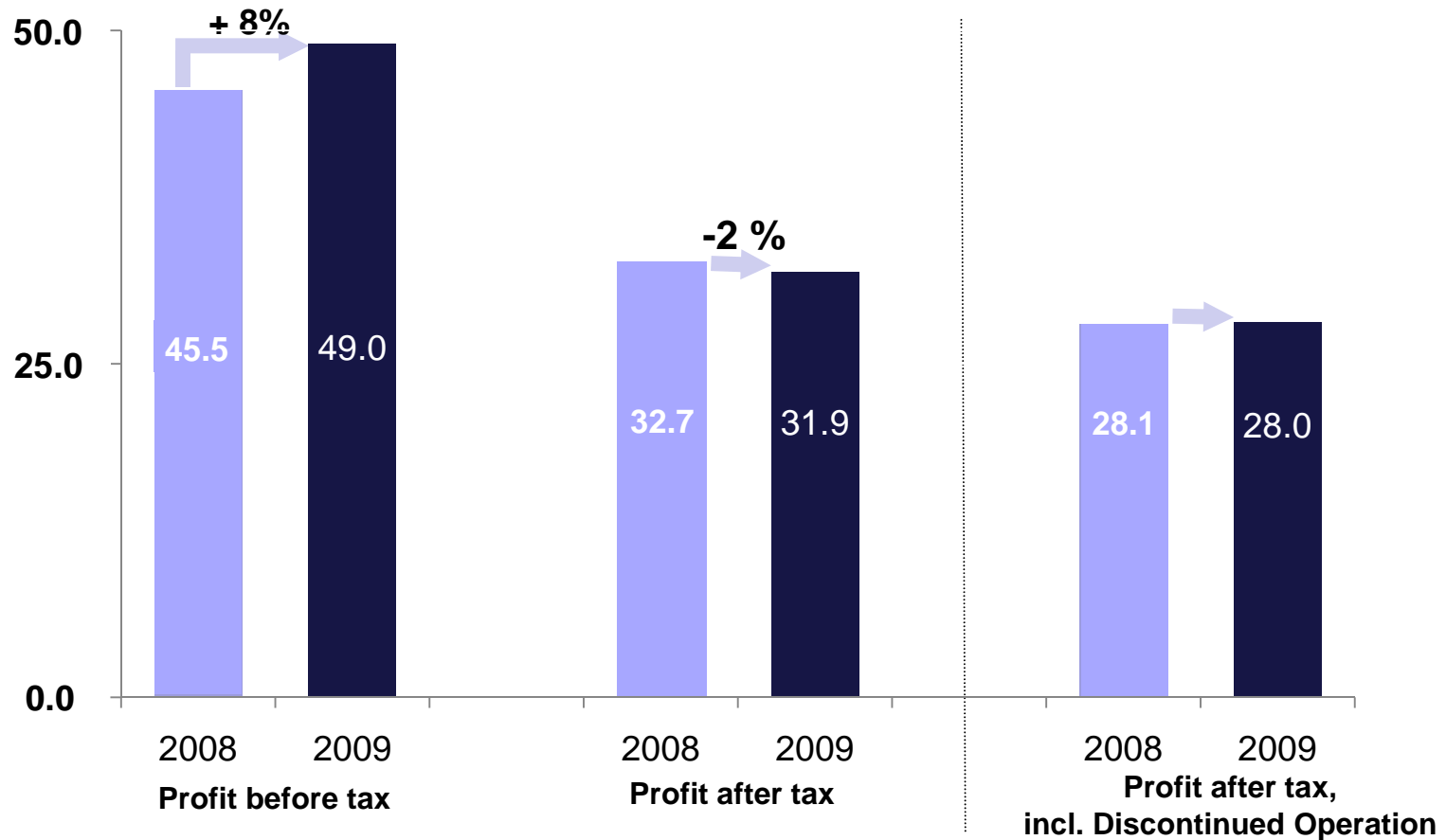
Biotest Group EBIT (in €million)



- EBIT growth: 4%
 - Reconstruction expenses in Boca Raton
 - Raw material costs (mainly in first half-year)
 - Price situation (mainly in second half-year)

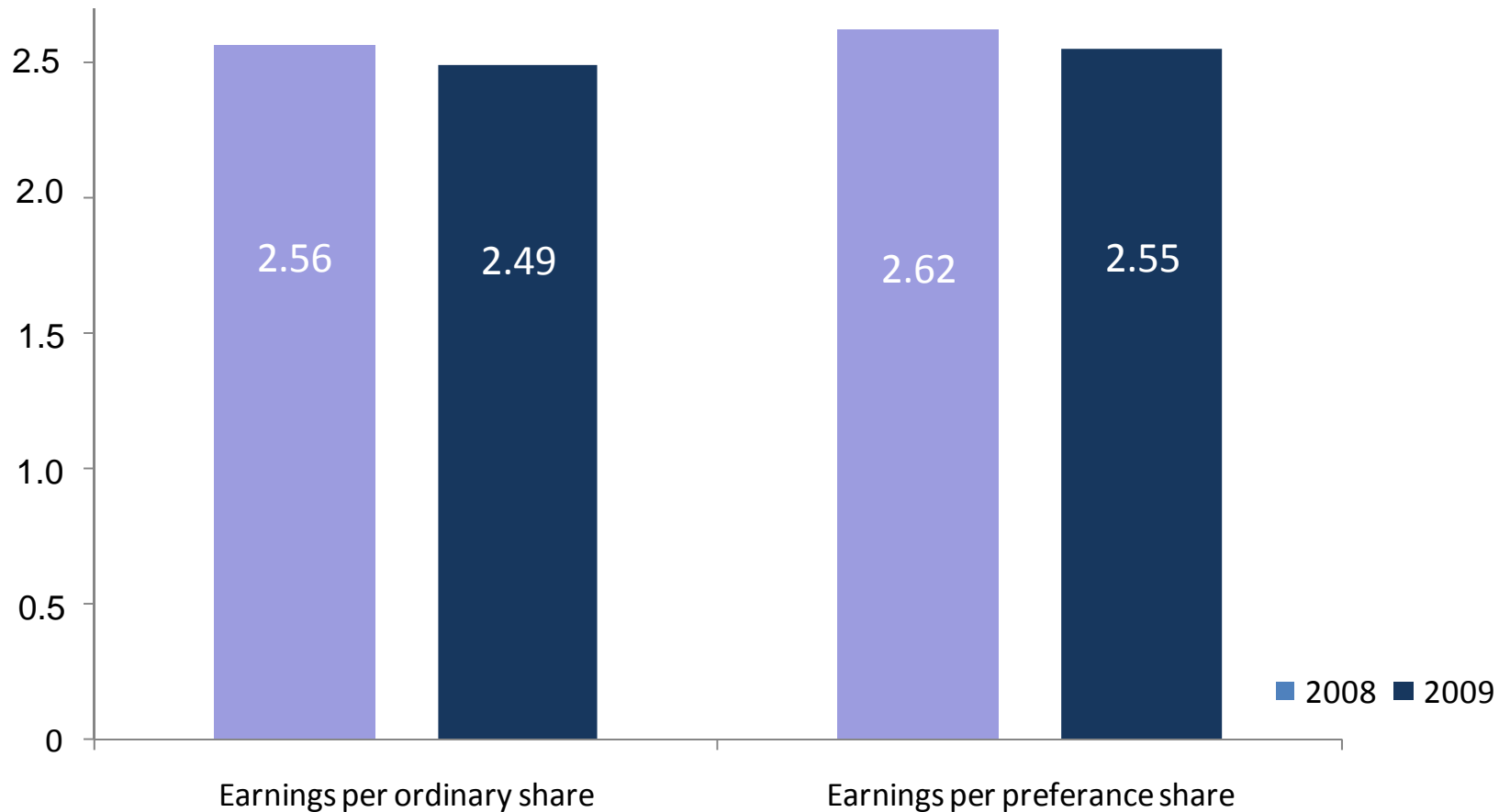
Earnings before taxes up, profit after tax down slightly

Profit before and after tax (in €million)



Slight decline in earnings per share

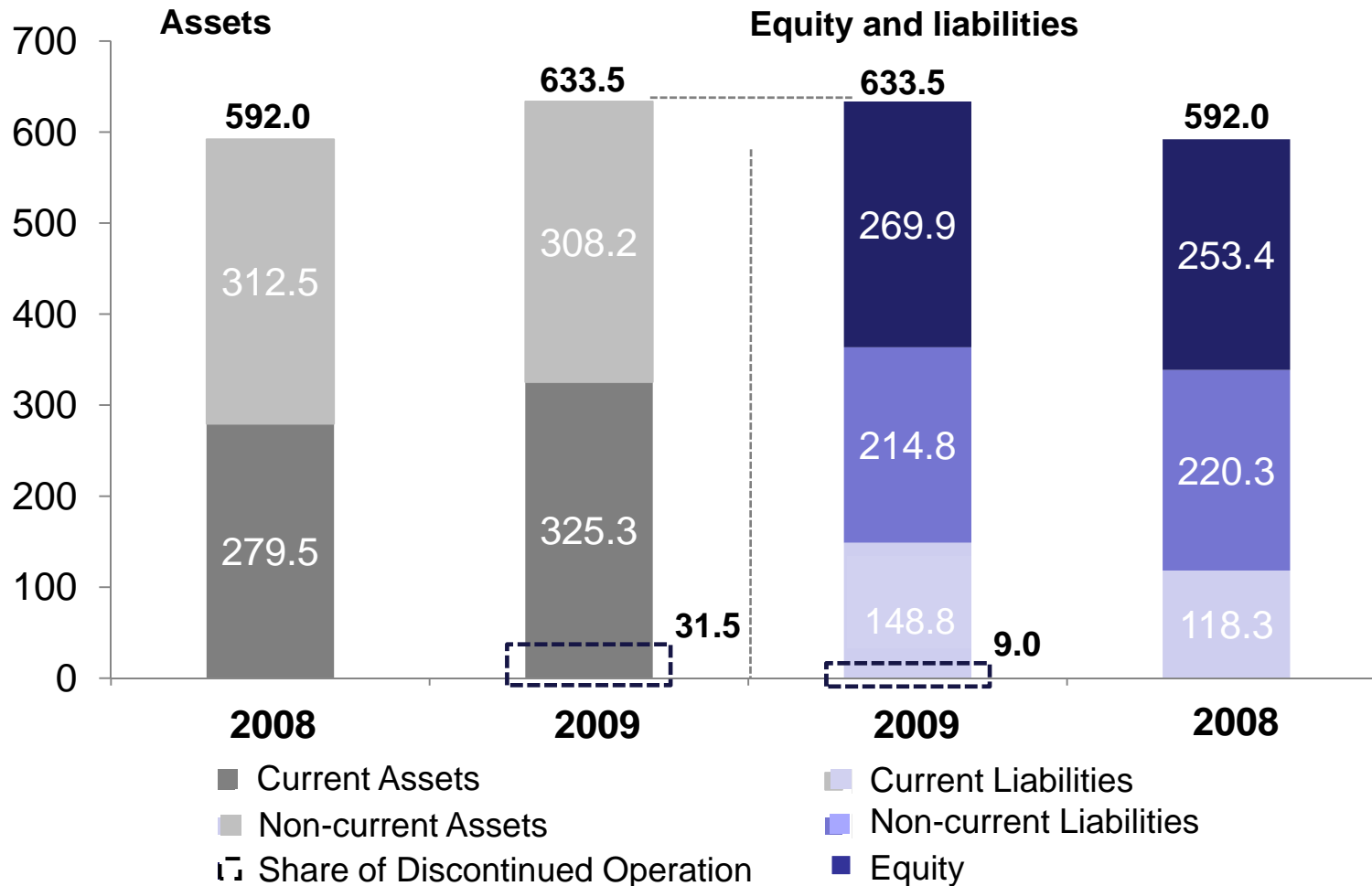
Earnings per share (in €)*



*Continuing Operations

Statement of financial position: Slight increase in current assets

Statement of financial position for Biotest Group (in €million)

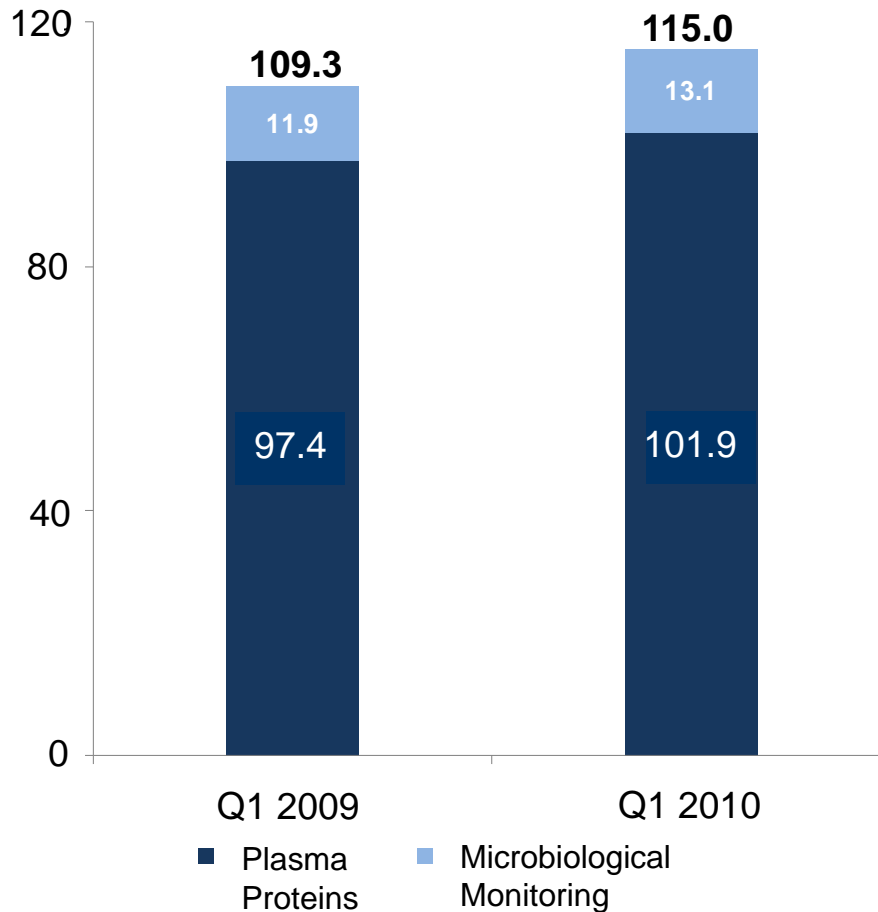




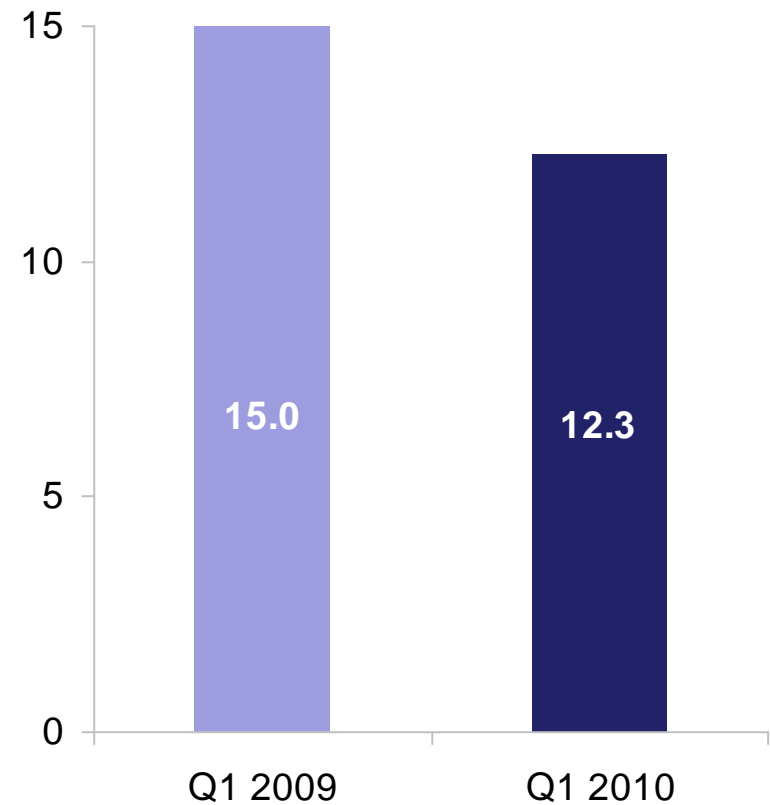
Outlook for 2010

Q1 2010: Sales and earnings in line with expectations

Biotest Group sales (in €million)*



Biotest Group EBIT (in €million)*



* Continuing Operations

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:

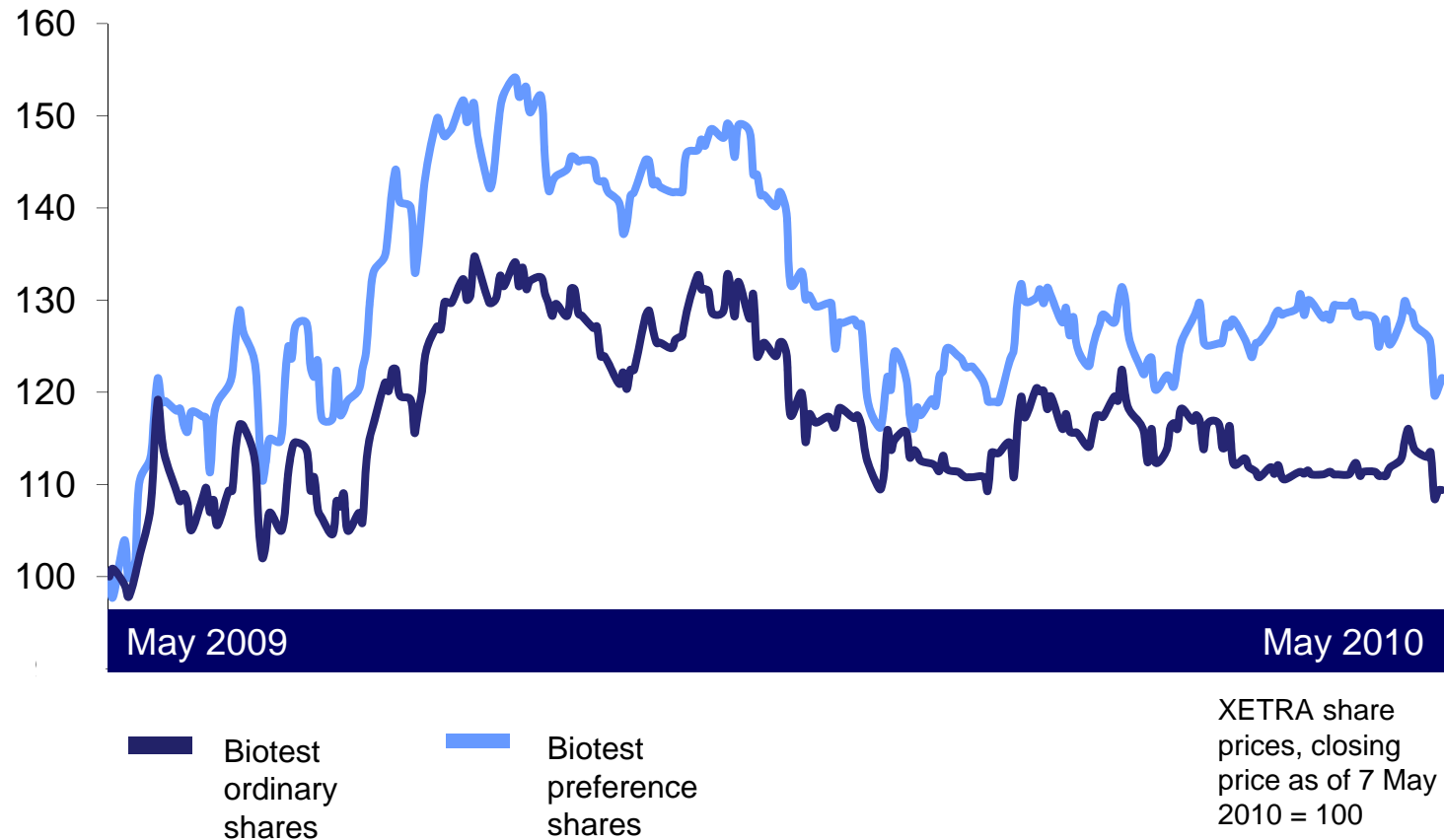
- Difficult funding situation of public sector healthcare systems
- Higher credit and default risks in some markets

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

Performance of Biotest share



Note on agenda item 2 – Appropriation of profits

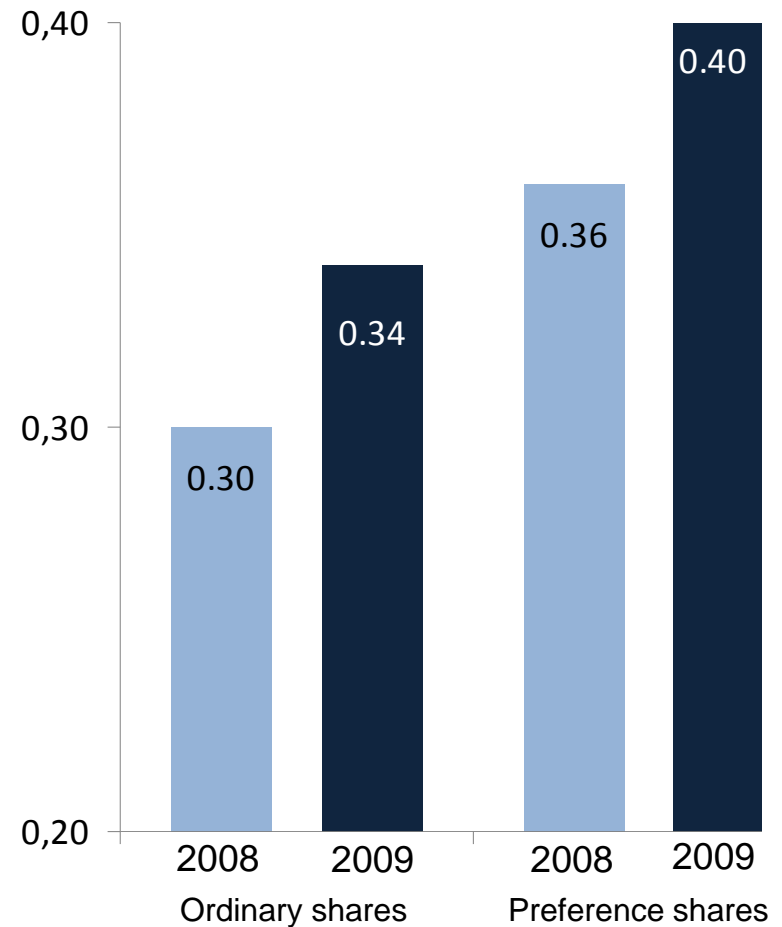
Net profit*:	€17.0 million
- Dividend ordinary shares:	€2.2 million
- Dividend preference shares:	€2.1 million

Balance carried forward: €12.8 million

* Biotest AG's individual financial statements (HGB)

** 2009: proposal

Dividend** per share (in €)



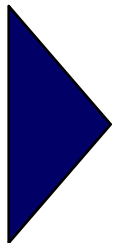
Agenda items 8 and 9

Agenda item 8: Authorised Capital 2010/I

- Capital increase by up to €3.7 million through issuance of new preference shares
- Increase on one or more occasions
- Subscription right for existing shareholders
- Term until 5 May 2015

Agenda item 9: Authorised Capital 2010/II

- Capital increase by up to €3.0 million through issuance of new preference shares
- Increase on one or more occasions
- Subscription right may be excluded
- Term until 5 May 2015



Authorised capital ensures flexibility in future entrepreneurial decisions

No current plans for a capital increase

Conclusion: 2009 – Another successful year for Biotest



- Targets achieved
- Major progress on strategic projects
- Basis established for further good development



Thank you very much for your attention.