Biotest

From Nature for Life

Biotest Group

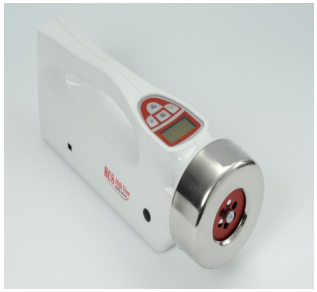
Press and Analyst Conference – Q1 - Q3 2011

Frankfurt/Main, November 10, 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., these diagnostic activities are being reported as Discontinued Operation. Due to the companies intention to sell the segment of Microbiological Monitoring, these activities are also reported under "Discontinued Operation". 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.

Biotest Group: Highlights Q1- Q3 2011



- Biotest Q1- Q3 2011 Group Sales up by 1.9%; Increase largely attributable to an upfront payment by Abbott on a pro rata basis to the Biotherapeutics segment
- Q1- Q3 EBIT decreased by 1.6% 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 a sale and purchase Agreement with Merck KGaA Darmstadt, Germany on 1st of Aug. 2011. Profit after Tax of € 22 million
- Bivigam™: Remaining outstanding data submitted to FDA with additional conformance lots data

Biotest
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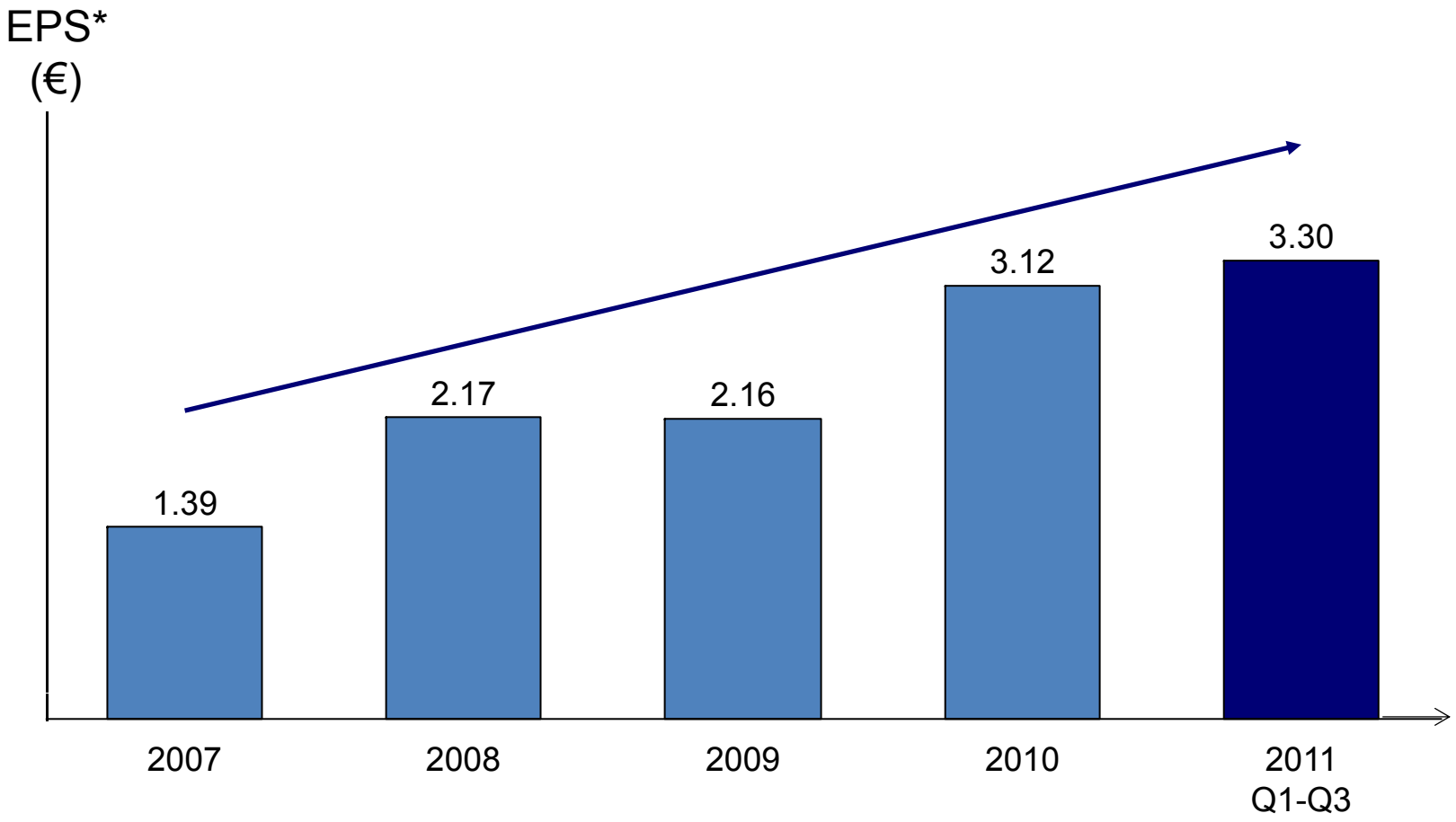
Financials Q1- Q3 2011

EPS growing



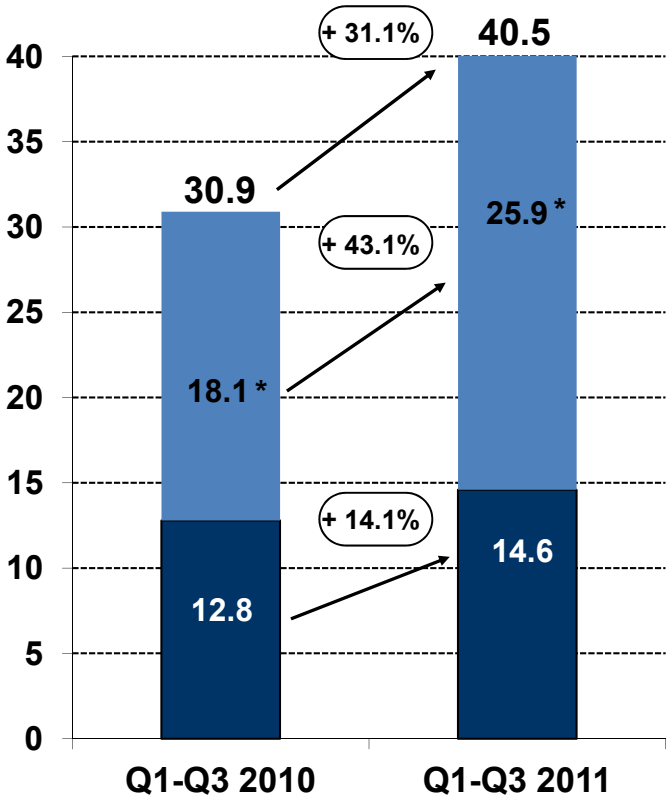
*Biotest Group: Continuing and Discontinued Operations

Earnings after tax

EAT	FY 2009	FY 2010	Q1-Q3 2011
Continuing	29.6	19.6	14.6
Discontinued	-1.6	19.9	25.9
Total	**28.0**	**39.5**	**40.5**

Significant increase in EAT

EAT (in € m)



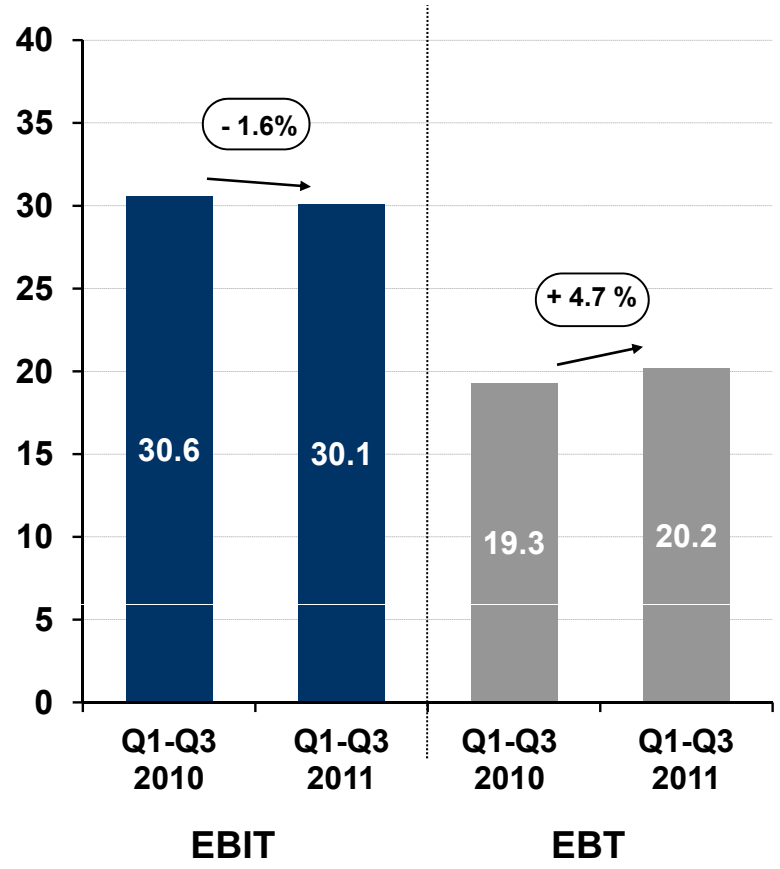
- Earnings after tax (Continuing and Discontinued Operations) up by 31.1%
- Earnings after tax (Continuing Operations) increased by 14.1%
- Tax rate 27.7% in Q1- Q3 2011 vs. 33.7% in Q1- Q3 2010

*Discontinued Operations

Decrease in EBIT – increase in EBT

in Q1-Q3 2011

EBIT and EBT (in € m)



Financial result :

- Financial result Q1- Q3 2011 at -9.9 € million vs -11.3 € million in 2010
- Initial devaluation of Greek receivables/ bonds in the previous year
- Various devaluations of Greek zero bonds in current year
- Today the Greek bonds are valued at 50.5% of the nominal value

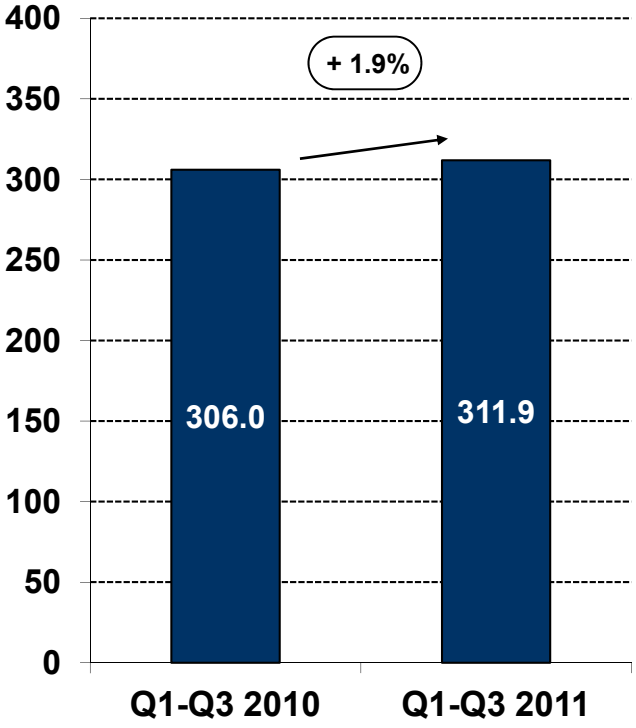
Q1-Q3 2011: EBIT Biotest Group (in € m)

	Q1-Q3 2011	Q1-Q3 2010	Δ
Plasma Proteins	44.1	53.9	- 18.2 %
Biotherapeutics	- 6.4	- 16.3	60.7 %
Corporate	- 7.6	- 7.0	- 8.6 %
Biotest Group*	**30.1**	**30.6**	**- 1.6 %**
Discont. Operations	32.3	22.9	+ 41.0 %
Biotest Group Total	**62.4**	**53.5**	**+ 16.6 %**

*Continuing Operations

Revenue growth in difficult market environment

Revenue (in € m)

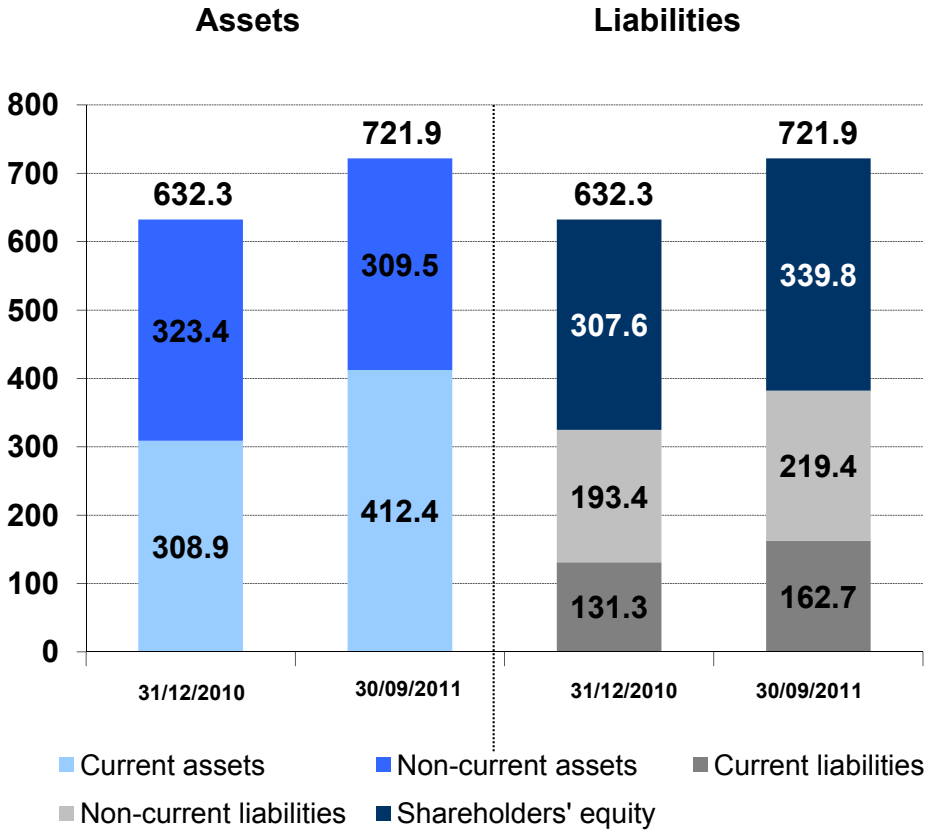


- Q1- Q3 2011 Sales at € 311.9 million, a growth of 1.9% vs € 306.0 million in Q1 - Q3 2010
- Increase largely attributable to an upfront payment by Abbott on a pro rata basis to the Biotherapeutics segment
- Sales in the Plasma Protein segment decreased by 2.4% due to difficult market environment
- Prices under pressure, particularly in markets outside the EU and the US

Strong balance sheet

Balance sheet of Biotest Group

(in € m)



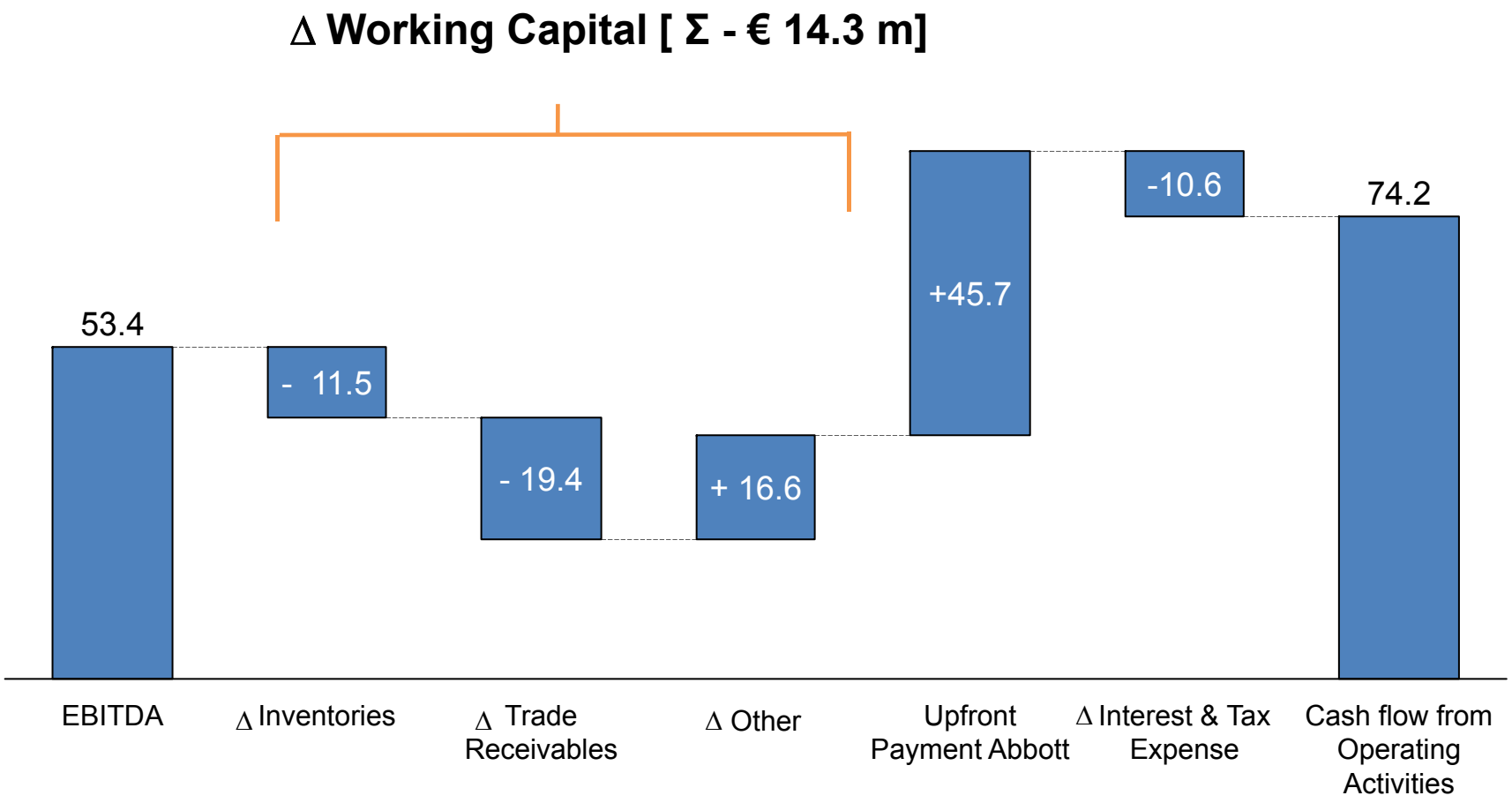
Assets

- Strong increase in cash and cash equivalents due to Abbott agreement and the sale of the microbiology monitoring segment
- The interest-free Greek bonds have a nominal value of € 18.8 million (30 Sep 2011). Bonds recognised at a carrying amount of € 9.5 million (50.5% of the nominal value)

Liabilities

- Significant reduction of net debt to € 41.3 million (vs. € 142.6 million on 31 Dec 2010)
- Equity ratio as of 30 Sep 2011: 47.1% (31 Dec. 2010: 48.6%)

Cash Flow from Operating Activities in € m*
January – September 2011



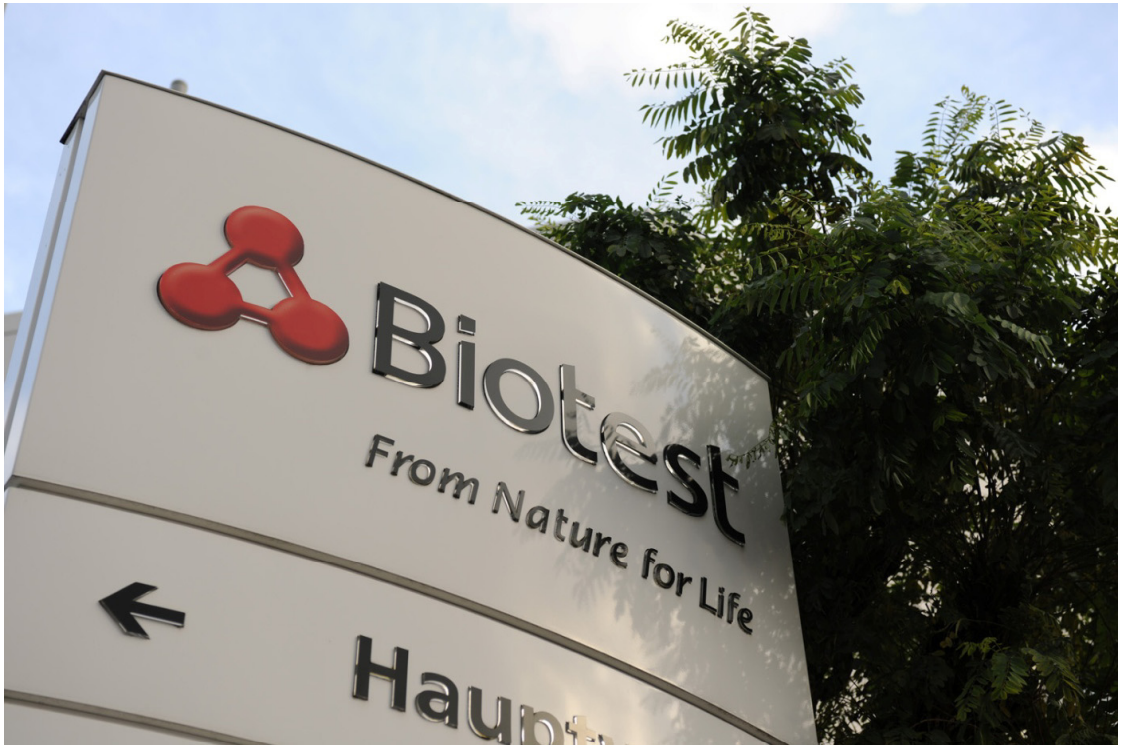
* Continuing Operations

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.



Important strategic milestones

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 for 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
- Joint development by Biotest and Abbott
- Abbott and Biotest will share responsibility for commercial production
- Biotest to co-promote BT-061 in Germany, France, United Kingdom, Italy, Spain

Partnership update

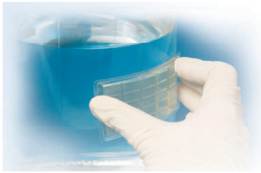
- The joint development has started immediately, implementing respectiv development comitees

Financials

- Sales contribution Biotherapeutics from upfront payment: € 13.2 million
- EBIT contribution: approx. € 12 million

Biotest sold Microbiological Monitoring business to Merck KGaA

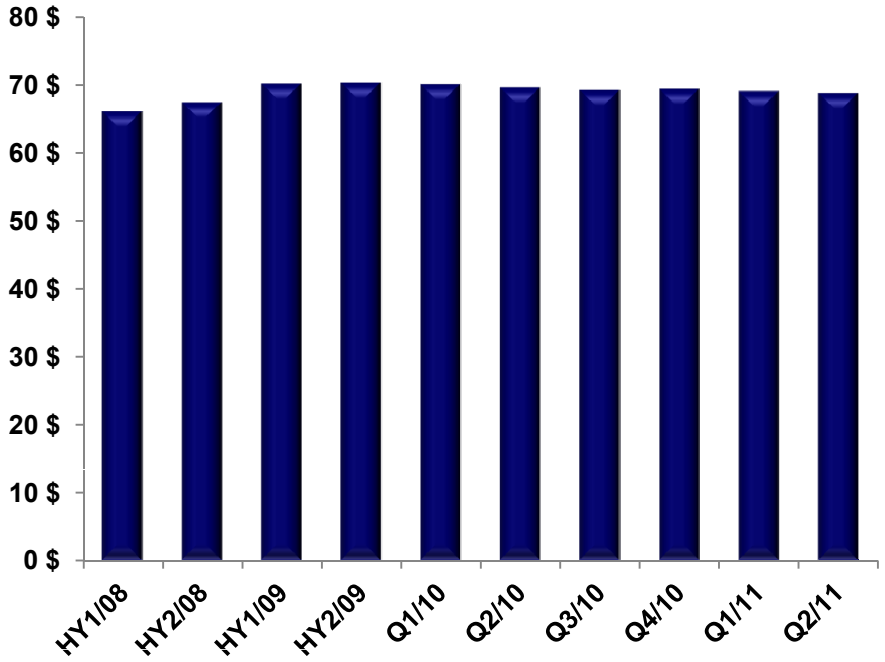
- On 1st August, 2011 the agreement to sell the activities of the Microbiological Monitoring segment to Merck KGaA (Darmstadt/ Germany) went into effect (closing)
- Transfer of activities to Merck KGaA completed
- Profit after tax (Discontinued Operations)
  € 22 million



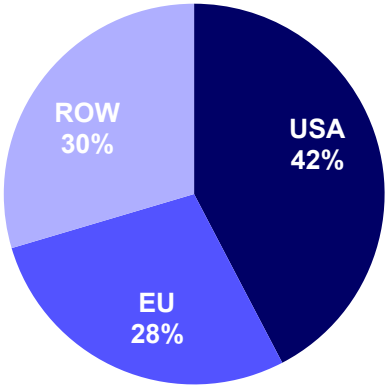
Plasma Proteins

The price of IVIG in the US still stable on a high level

IVIG Price (USD/gram)



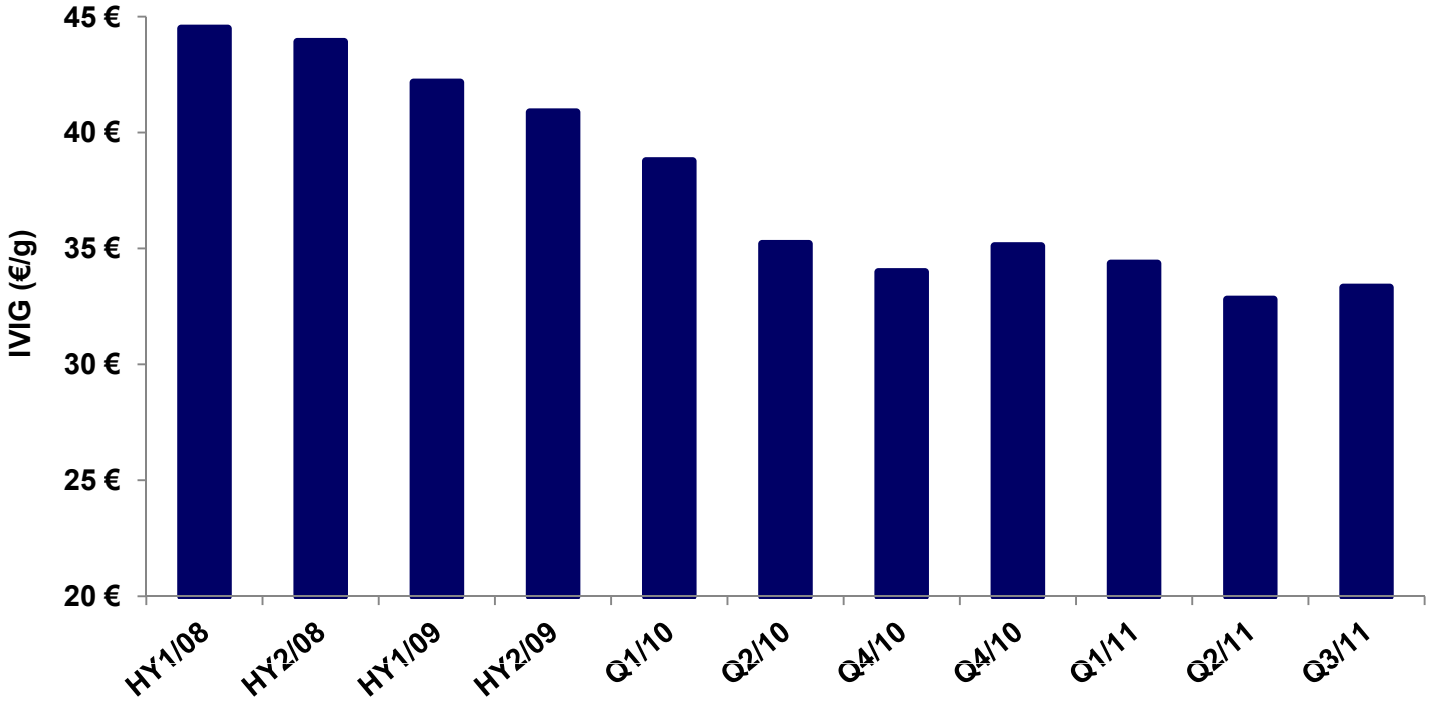
Worldwide IVIG market by regions



- The US is the biggest single immunoglobulin market in the world
- Regardless of the pricing developments in EU and RoW, the price in the US remains stable on a high level

Source: Average Selling Price based on CMS Medicare pricing; IVIG market – MRB and company data

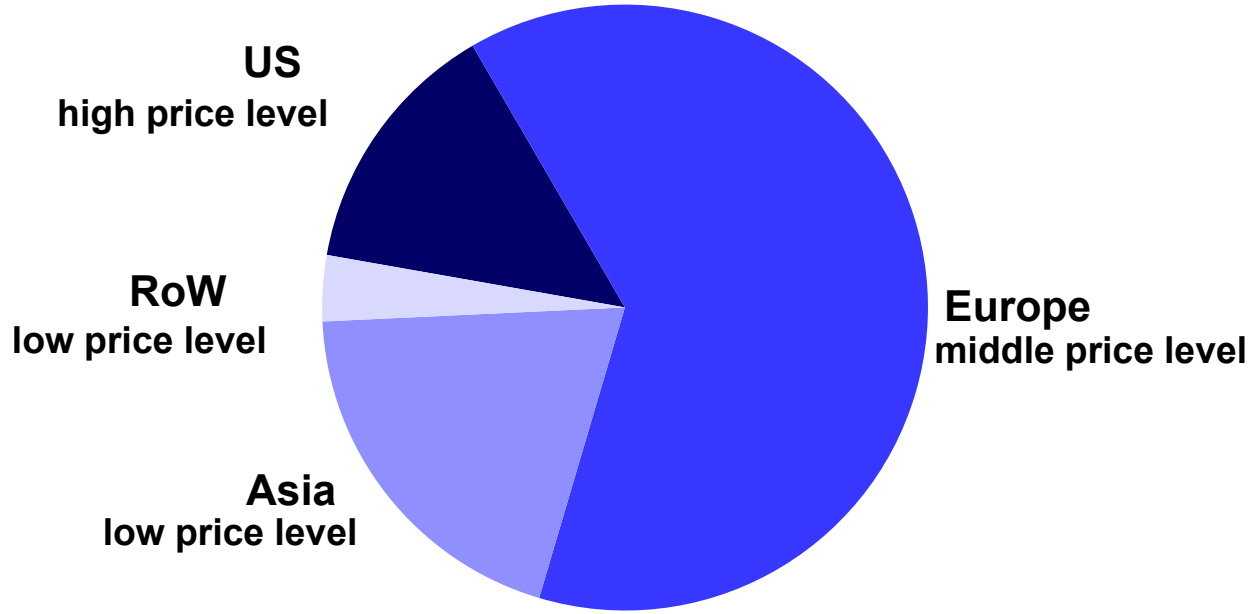
In markets outside of the US, the price of IVIG remains under pressure



- In German hospitals, the price of polyvalent immunoglobulins remains on a low level with several offers significantly below average

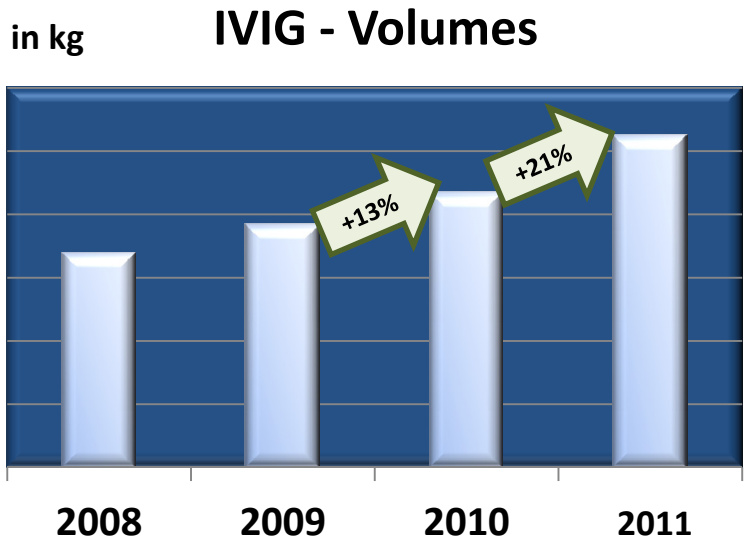
Source: IMS DKM

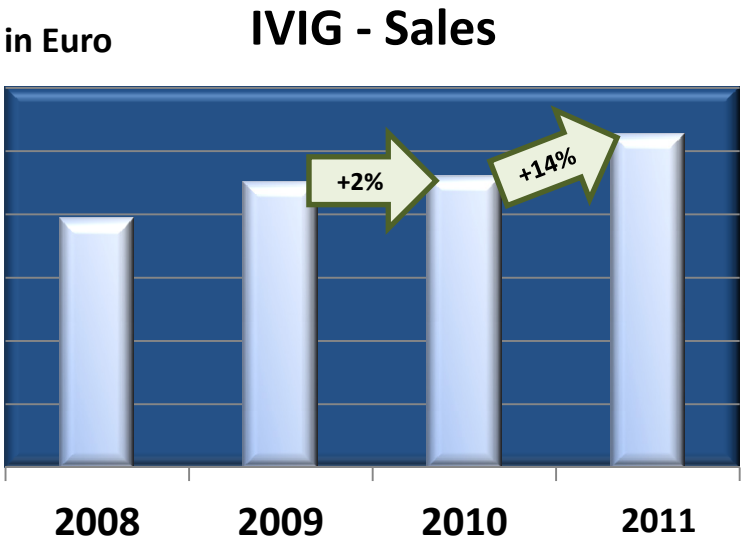
The majority of Biotest's products are currently sold in middle and low price countries



Source: Company data (Q1-3 2011)

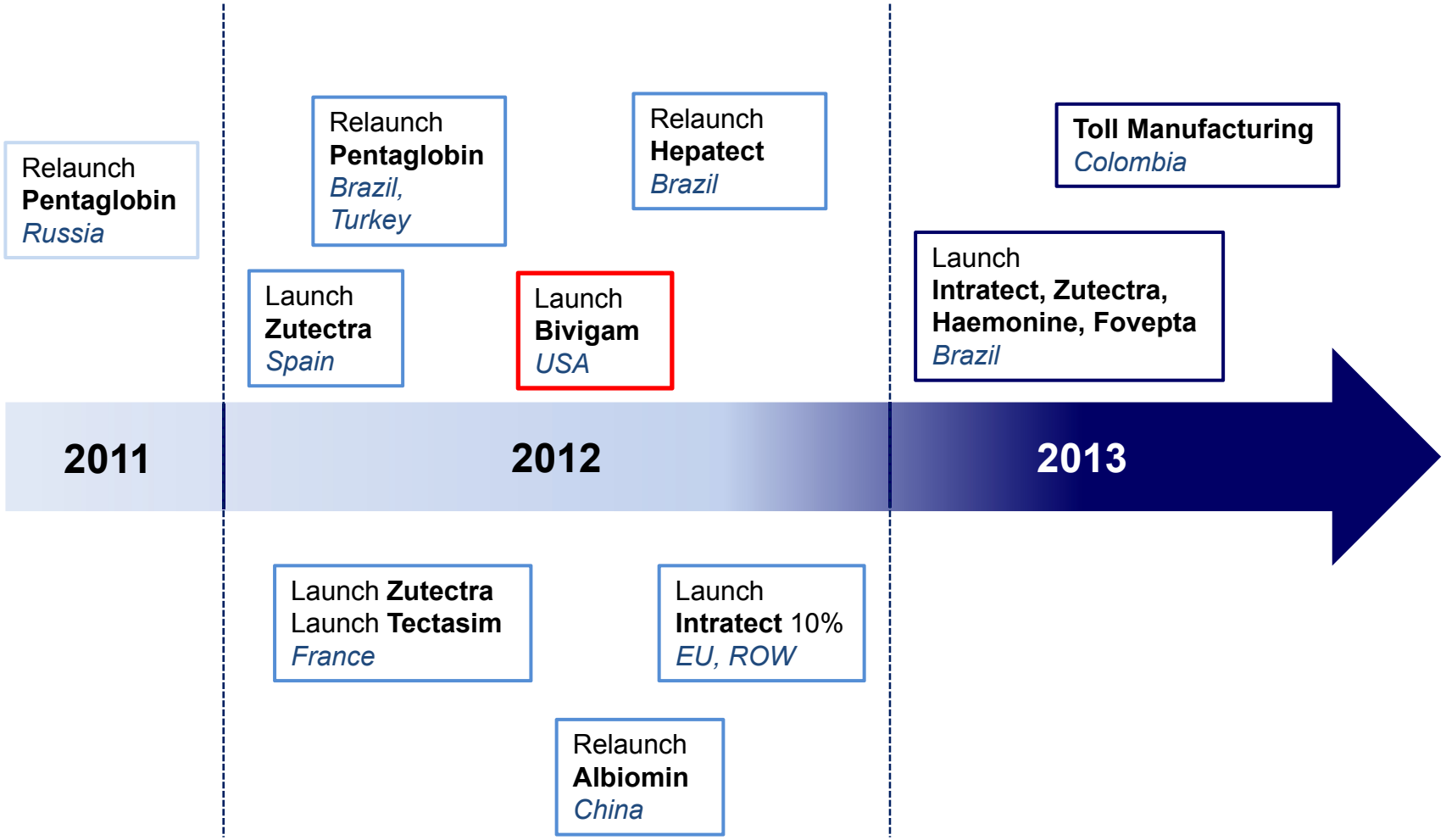
IVIG Biotest





- Strong constant growth in volumes with lower growth rates in terms of sales
  -> result of decreasing prices since 2010

New markets/new products



Bivigam™ (IVIG) FDA filing in US

Polyspecific immunoglobulin

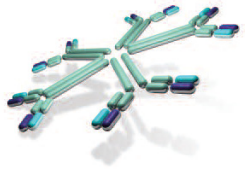
- Restart of production in August after solving severe problems with the automation and control system
- Additional conformance lots were produced in Q3 2011
- Remaining outstanding data with additional conformance lots have been submitted to FDA in Oct. 2011
- Expected launch Mid 2012
- Gradual scale up of production in H2 2012

US Market entrance of strategic importance to Biotest

Major progress in development of Plasma Proteins (I)

 **Zutectra®** 	**Fovepta™**	**Cytotect® 70** 
Hepatitis B Immunoglobulin in a pre-filled syringe for subcutaneous injection Launch completed in: • Germany, UK, Italy, Netherlands, Belgium, Scandinavian countries, Austria and others Launch in H1 2012: • France, Switzerland, Spain	**Hepatitis B Immunoglobulin for intramuscular and subcutaneous injection for neonates** Approval in Germany expected H1 2012 ➔ Basis for approval in RoW markets	**Human Cytomegalovirus Immunoglobulin** Currently 9500 women screened in phase III trial Interim analysis planned for Dec 2011

Major progress in development of Plasma Proteins (II)

IgM Concentrate	Intratect 10%	Civacir®	Fibrinogen
			
IgM enriched Immunoglobulin High functional activity Phase II trial started	**Polyspecific Immunoglobulin 10%** Phase III trial: Recruitment completed, last patient will be treated in Jan 2012 Approval expected End of 2012	**Hepatitis C Immunoglobulin** New production process established, formulation improved Restart of clinical development planned in 2012	**Essential factor for coagulation** Production process and formulation development of product completed Start of clinical development in 2012

Cytotect 70®

Indication

- Prevention of congenital cytomegalovirus (CMV) infection of infants of mothers with primary CMV infection during pregnancy

Market Position

- High medical need
- Unique position in the pharmaceutical market
- Indication with high ethical visibility
- Orphan drug designation in EU and US granted

Status

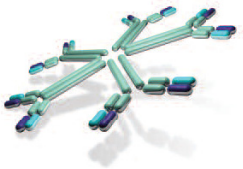
- ~ 9500 pregnant women screened today
- 47 seroconverted (i.e. infected during pregnancy for the first time) women included
- Interim analysis planned for Dec 2011

Competition

- Biotest only supplier of CMV hyperimmunoglobulins in the EU

IgM Concentrate

Rationale



- Data of Pentaglobin® in sepsis show reduction of mortality in sepsis
- IgM concentrate is expected to be superior to Pentaglobin® due to higher content of IgM and higher functional properties

Indication:

- Severe Community-Acquired Pneumonia (sCAP) = Pneumonia acquired from **outside** the hospital
- Ten percent of adult CAP patients require intensive medical care and are transferred to intensive care units. Mortality rate is 35-58%.

Status

- Phase II international, placebo controlled, double blind, randomized study started

Impact of Hepatitis C Infection on the Demand for Liver Transplantation

Estimation:

- ~ 3% (130-170 million people) of the world's population show chronic hepatitis C (HCV) infection
- 3 – 4 million people are infected each year
- 5 - 20% will develop liver cirrhosis*, thereof ~ 5% develop liver failure or liver cancer**
- HCV is the highest risk factor for liver transplantation (~ 40% of all patients receiving a liver transplant) = 4000 liver transplantations due to chronic HCV infection
- No treatment is so far available to protect the new liver from HCV reinfection from the first day on after transplantation

* WHO Fact Sheed No164
** UNOS/Eurotransplant/local transplantation societies

Civacir

Indication:

- Prevention of hepatitis C re-infection of the transplanted liver

  ➔ Protection of the liver transplant from the beginning on with Civacir®

Rational for development

- Protection of the transplant is key
- First 6 month after transplantation are the critical time period for re-infection
- Standard antiviral therapy can not be used up to 6 months after transplantation
- No comparable product is on the market
- Orphan drug designation granted in EU & US

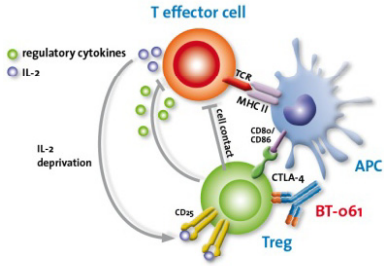
Status

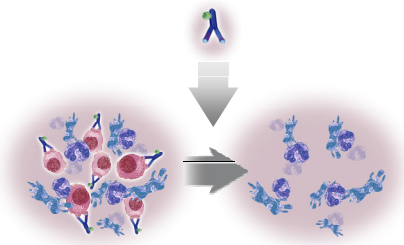
- Phase I clinical trial planned to start in 2012

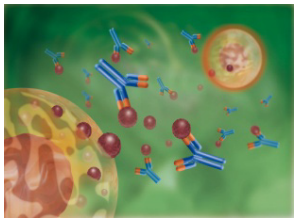
Biotherapeutics

Biotest's Biotherapeutics portfolio

BT-061	BT-062	BT-063
Activated Tregs mediate modulation of T effector cells	Targeted Antibody Payload (TAP) technology	Blockage of immuno-regulatory cytokine with key role in pathogenesis of SLE
Potential Indications • Rheumatoid Arthritis • Psoriasis • Other autoimmune diseases	**Potential Indications** • Multiple Myeloma • Solid tumors	**Potential Indications** • Systemic Lupus Erythematosus (SLE) • Oncology







Cooperation with Abbott successfully established

- Abbott and Biotest benefit from each others strenghts
  - Abbott from deep knowledge of BT-061 provided by Biotest
  - Biotest from experience and operational power of Abbott in the field of Rheumatoid Arthritis
- Joint Development Teams established
- Constructive interaction on working level successfully implemented

New INN[1] name for BT-061

- New INN[1] name for BT-061: **Tregalizumab**[2]

- The World Health Organization (WHO) selected a unique and universally available designated name (INN - International nonproprietary name) of worldwide acceptability for identification of BT-061

- WHO followed Biotest`s suggestion

- "lizumab" indicate that BT-061 is an immunmodulating (li) fully humanized (zu) monoclonal antibody (mab)

1) International nonproprietary name
2) published in WHO Drug Information Vol. 25, No.3, 2011. Recommended INN: List 66

Clinical Development Tregalizumab

Rheumatoid Arthritis	
Trial	**Status**
Phase IIa, monotherapy (No. 962) 96 patients	**Completed** ✓
Phase II, combination with MTX (No. 971) 114 patients	**Completed** ✓
Phase IIb, combination with MTX (No. 979) 176 patients	**Recruitment ongoing**
PK/PD* (No. 985) 36 patients	**Submission end 2011**
Phase IIb, combination with MTX (No. 9xx) approx. 350 patients	**Submission 2012**

Psoriasis	
Trial	**Status**
Phase I/IIa, monotherapy single dose (No. 967) 55 patients	**Completed** ✓
Phase II, monotherapy multiple dose (No. 973) 48 patients	**Completed** ✓

*) Pharmacokinetic and Pharmacodynamic study

Tregalizumab: Preparation of Phase III Program in Rheumatoid Arthritis

Future Clinical Studies	Manufacturing
Study 985 (PK/PD trial) • Intensive PK/PD data set to support dose and schedule finding • Supportive data for mode of action **Phase IIb** • Confirm and improve favourable compound properties by – longer treatment – optimized dosing schedule • Establish statistical basis for Phase III	**Facility modification for mAbs** ☑ **Transfer manufacturing** ☑ **Phase II manufacturing** ☑ **German Authority inspection** ☑ **Phase III manufacturing** ☐

Basis for Phase III trials

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 , Amgen, Novartis, 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**

[1] TAP: Tumor activated payload

BT-062:
Overview Clinical Development (Multiple Myeloma)

Study 969*

- Scope:
  - Tolerability and safety
  - Investigate anti-tumor activity
- Good tolerability and safety up to 160mg/m^2
- Clinical benefit in >50% of patients, including minor and partial responses
- One patient on treatment for 1.4 years (no progression of desease)

Study 975*

- Scope:
  - Increase of drug exposure in patients by splitting single monthly dose
  - Investigate anti-tumor activity
- Recruitment of 5th cohort in escalation completed
- Good tolerability
- Clinical benefit in patients up to 160 days

Study 983

- Scope:
  - Tolerability and safety in combination with gold standard
- Submission end of 2011

*** ASH Meeting 12 Dec. 2011: Abstract and oral presentation on Study 969 and 975**

Summary Biotherapeutics

Next Stage of Biotherapeutics Implementation Plan Reached

BT-061 (Tregalizumab)

- Agreement concluded with partner for Co-Development and Co-Promotion
- Phase II according to plan
- Preparation of Phase III ongoing

BT-062

- Recruitment in multi dose trial in progress
- Combination trial to be submitted end of 2011
- Planning for trial in Europe ongoing

Outlook Biotest Group

- 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 for Plasma Proteins and Biotherapeutics




Contact and Financial Calendar 2011/2012

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Financial Calendar 2011/ 2012

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