



# Biotest Group

Conference Call  
Financial Year 2012  
25 March 2013

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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

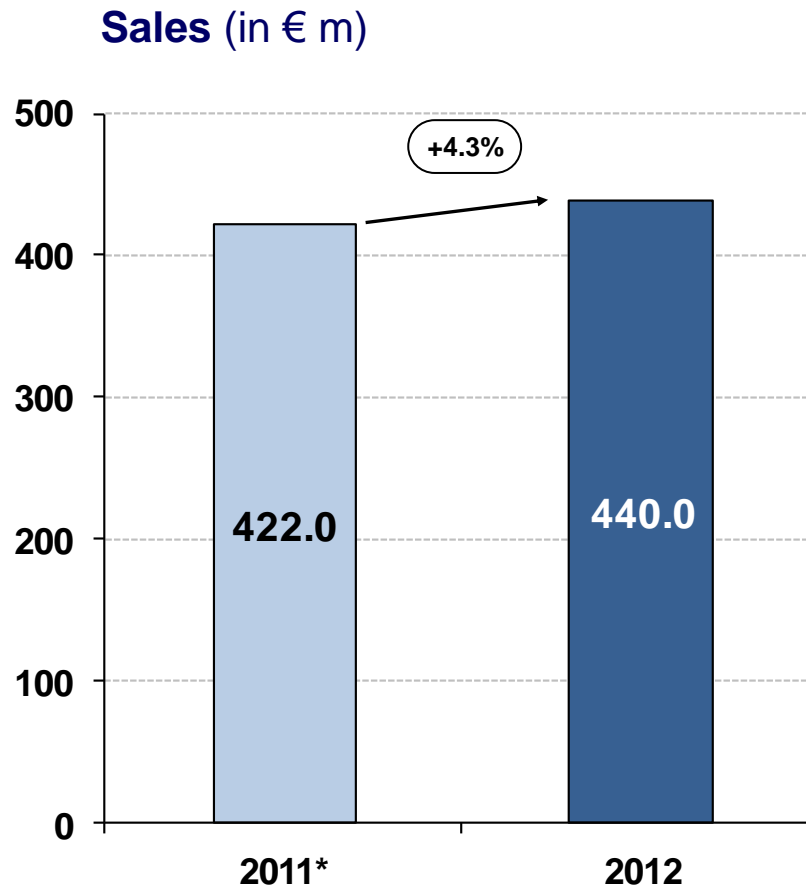


- Biotest 2012 Earnings before tax up by 27.6% to € 36.5 m vs € 28.6 m in 2011; Earnings after tax up by 23.5% to € 23.1 m vs € 18.7 m last year
- 2012 EBIT increase by 7.5% to € 44.7 m
- Sales 2012 reached € 440.0 m, an increase of 4.3%
- Bivigam™: FDA approval on 19 December 2012; first sales in the US in February 2013
- Marketing authorisation of Intratect®100g/l (10%) granted under European Decentralised Procedure; first sales in January 2013 in Germany
- New distributors in China, Russia and Greece



## Financials 2012

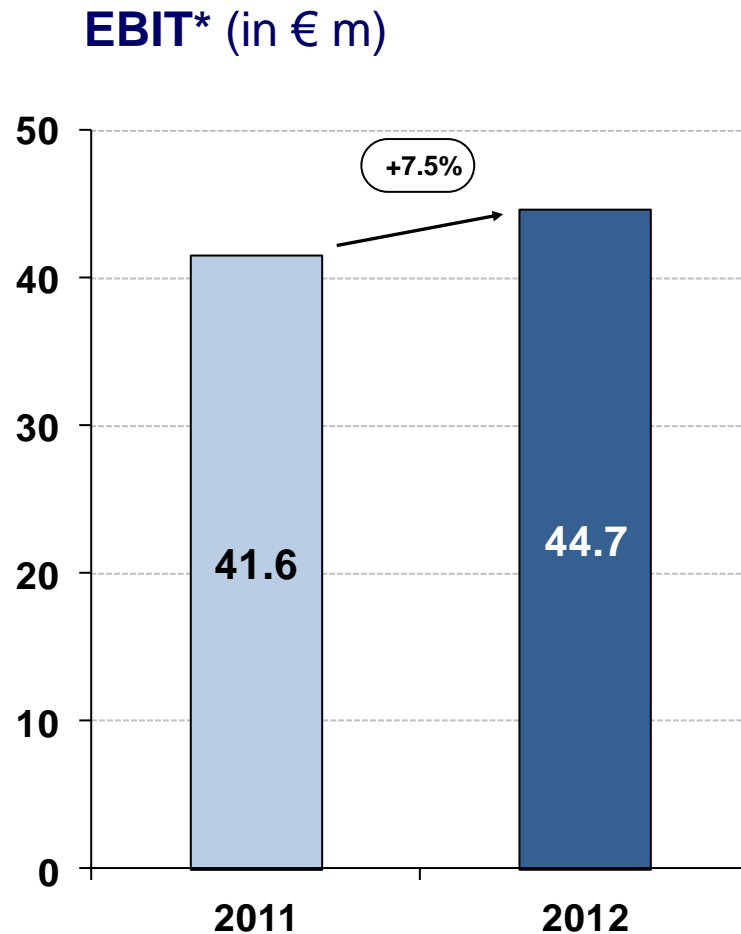
## Biotest with a solid sales growth



- FY 2012 sales at € 440.0 m, a growth of 4.3% vs € 422.0 m in FY 2011
- Increase largely attributable to international markets
- Prices under pressure, particularly in markets outside US and Asia

\* Continuing Operations

## Biotest with a solid EBIT growth



- EBIT increase largely due to international markets, optimisation of production processes with higher yields and therefore a favourable cost of goods sold margin

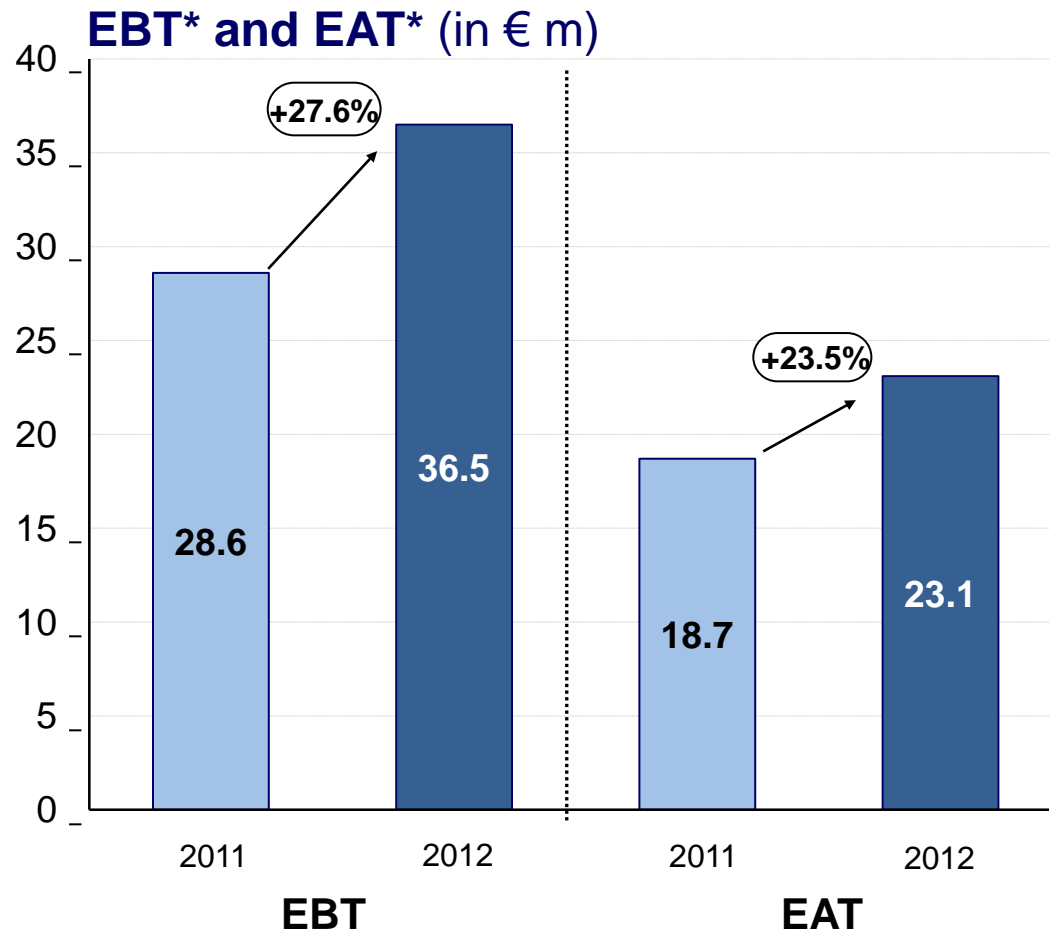
\* Continuing Operations

## FY 2012: EBIT Biotest Group (in € m)

|                       | <b>FY 2012</b> | <b>FY 2011</b> | <b>Δ</b>       |
|-----------------------|----------------|----------------|----------------|
| Therapy               | 26.3           | 24.9           | + 5.6 %        |
| Plasma & Services     | 18.4           | 18.8           | - 2.1 %        |
| Other Segments        | 0.0            | - 2.2          | -              |
| <b>Biotest Group*</b> | <b>44.7</b>    | <b>41.6</b>    | <b>+ 7.5 %</b> |

\* Biotest Group: Continuing Operations

## Strong increase in EBT and in EAT in 2012

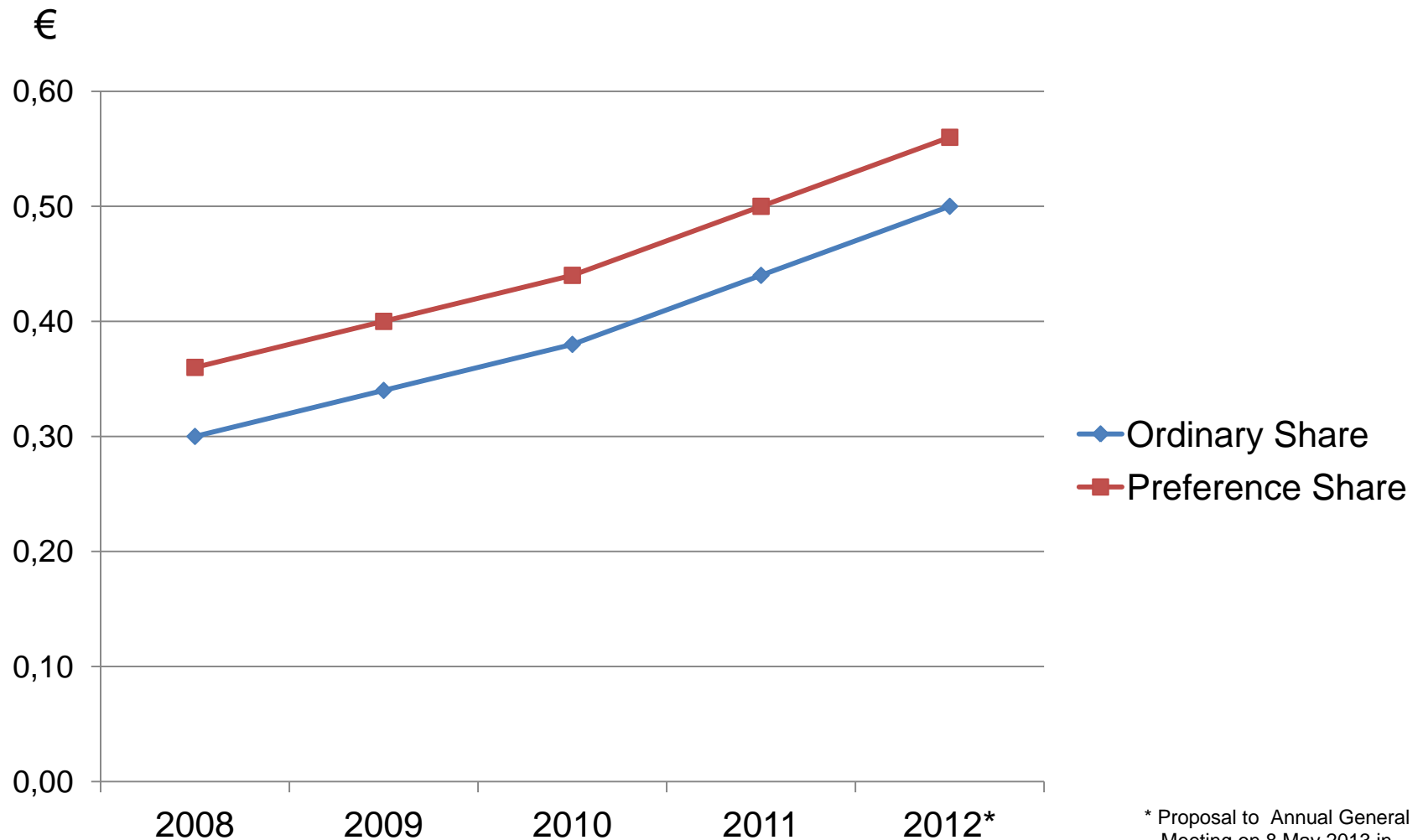


- Tax rate 36.7% in FY 2012 vs. 34.6% in FY 2011
- Increased tax rate due to non-capitalized tax assets in Brazil and Greece
- Financial result FY 2012 at -€ 9.2 m vs -€ 13.5 m in 2011
- In 2011 Greek bonds were devaluated; in Q1/2012 Biotest sold the residual bonds with a loss of -€ 0.7 m

\* Continuing Operations



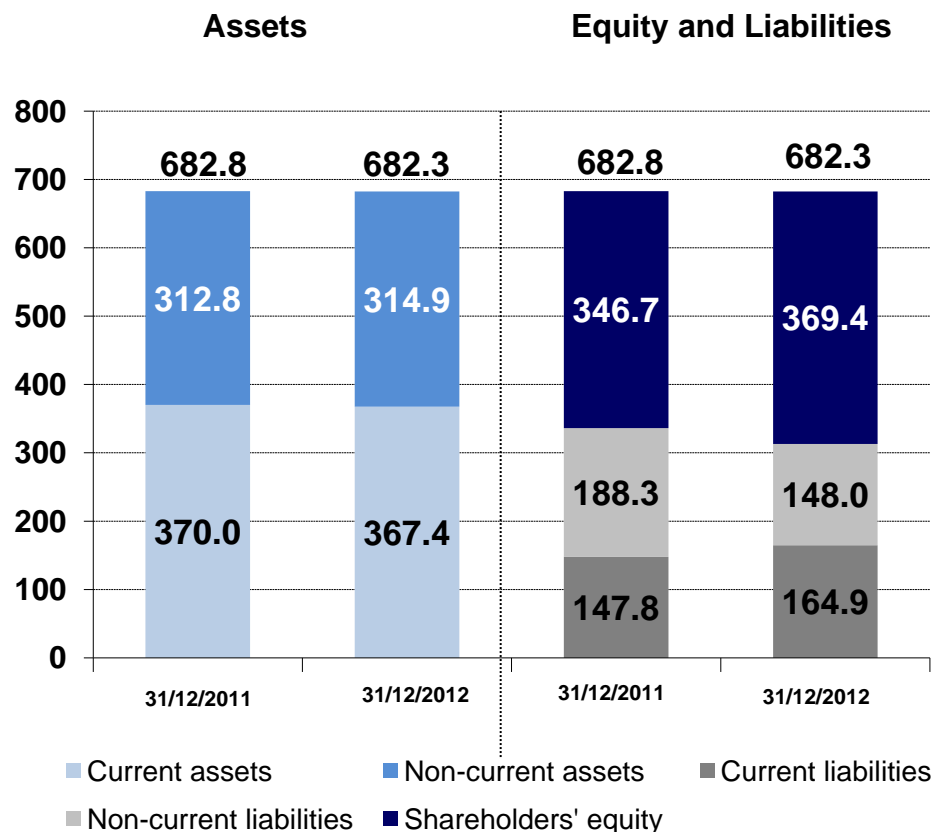
## Development of dividend per share in €



\* Proposal to Annual General Meeting on 8 May 2013 in Frankfurt

# Net debt amounts to € 55 m

## Balance sheet of Biotest Group (in € m)



### Assets

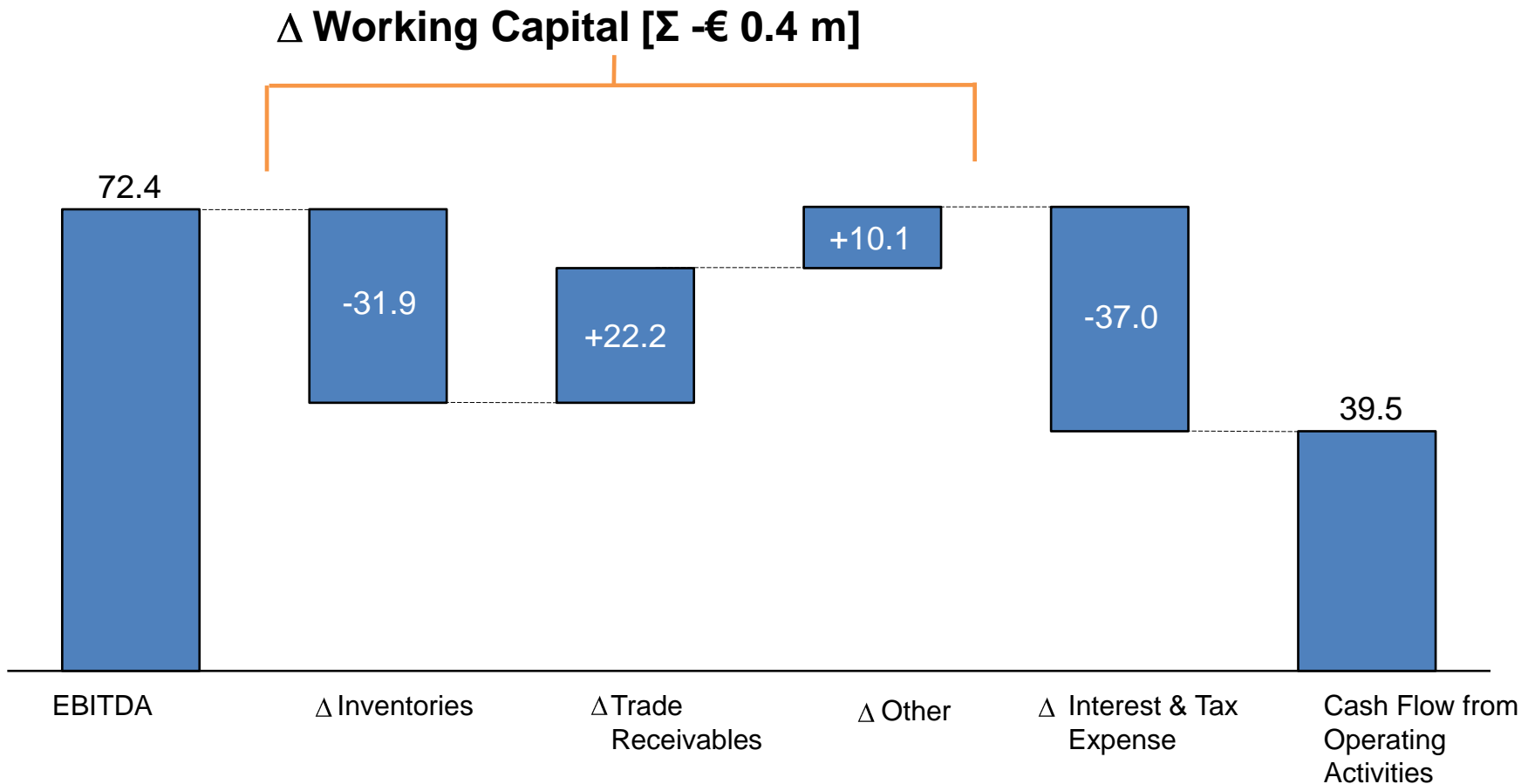
- Current assets include assets from Discontinued Operation (€ 18.4 m claim to the subsequent purchase price payment)
- All remaining Greek Zero Bonds have been sold in Q1 2012

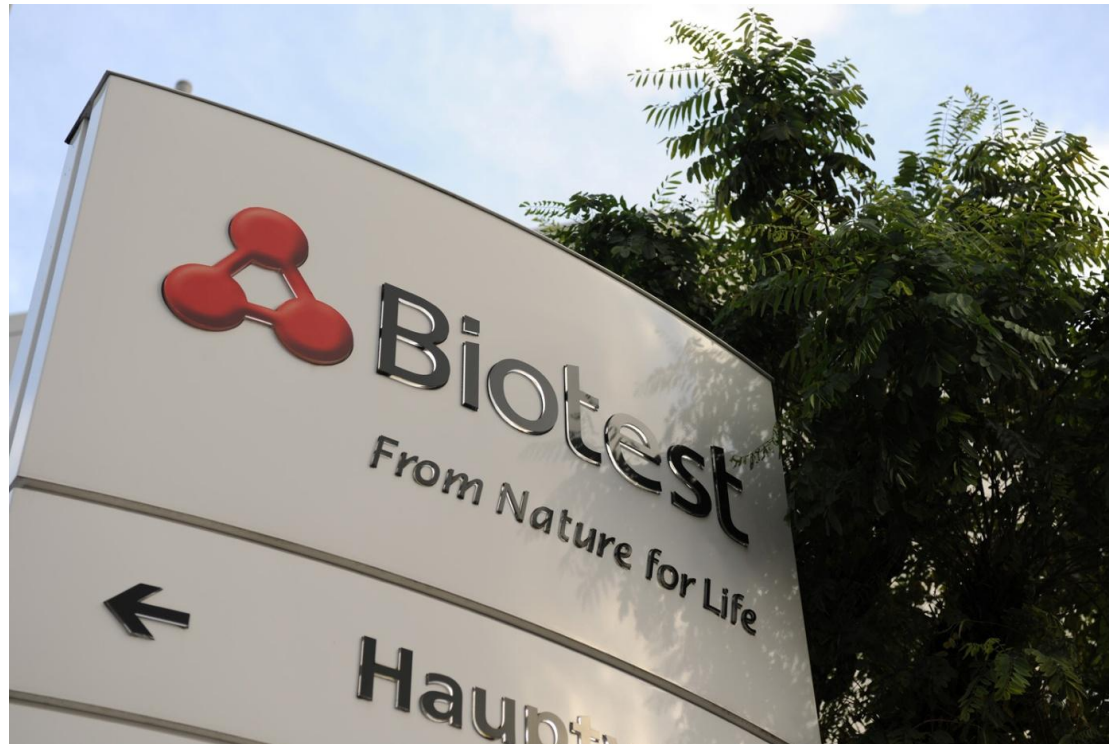
### Equity and Liabilities

- Net debt level remains stable at € 55.3 m (vs. € 55.8 m on 31 Dec 2011), despite € 34.5 m CapEx in 2012
- Equity ratio as of 31 Dec 2012: 54.1% (31 Dec 2011: 50.8%)

# Cash flow from operating activities\*

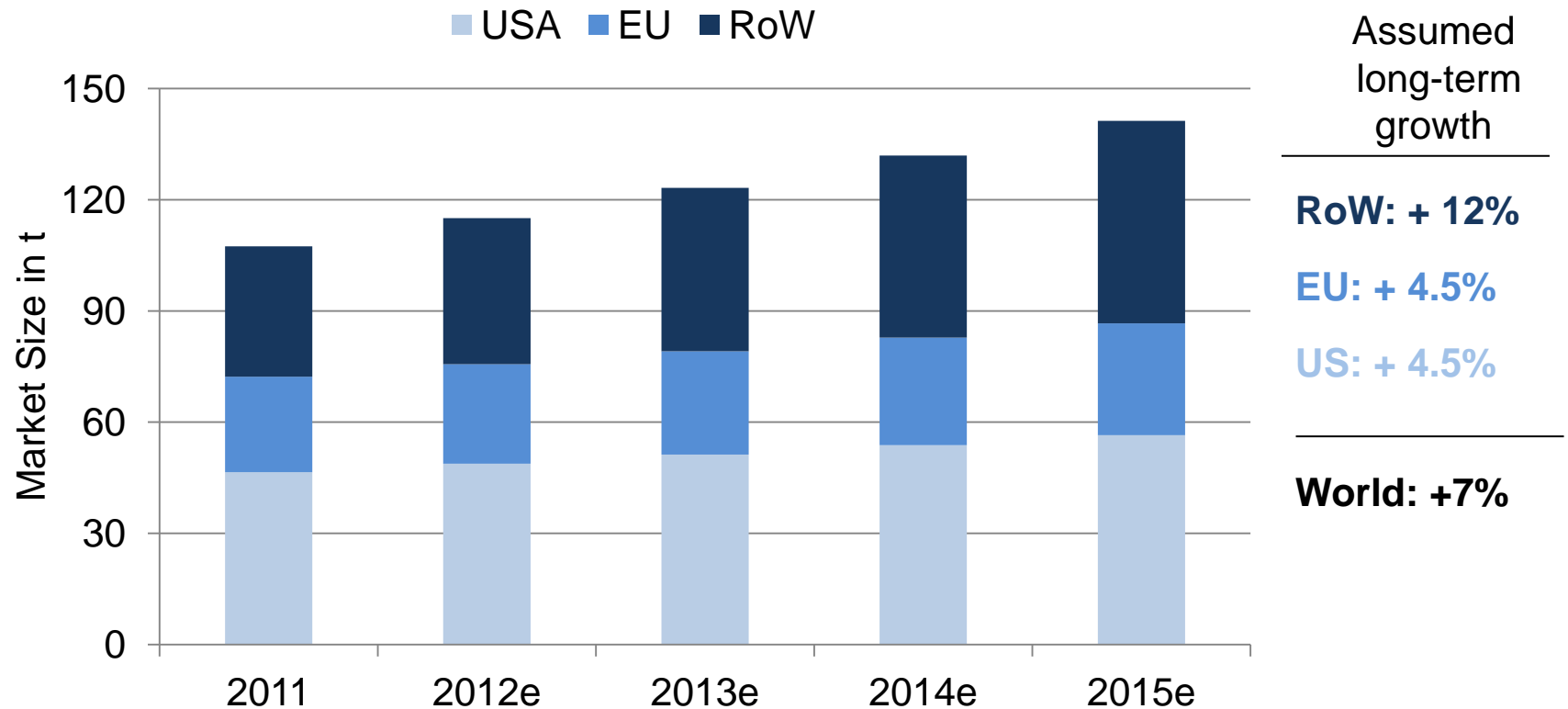
January – December 2012 (in € m)





## **Market environment for immunoglobulins and extension of international business**

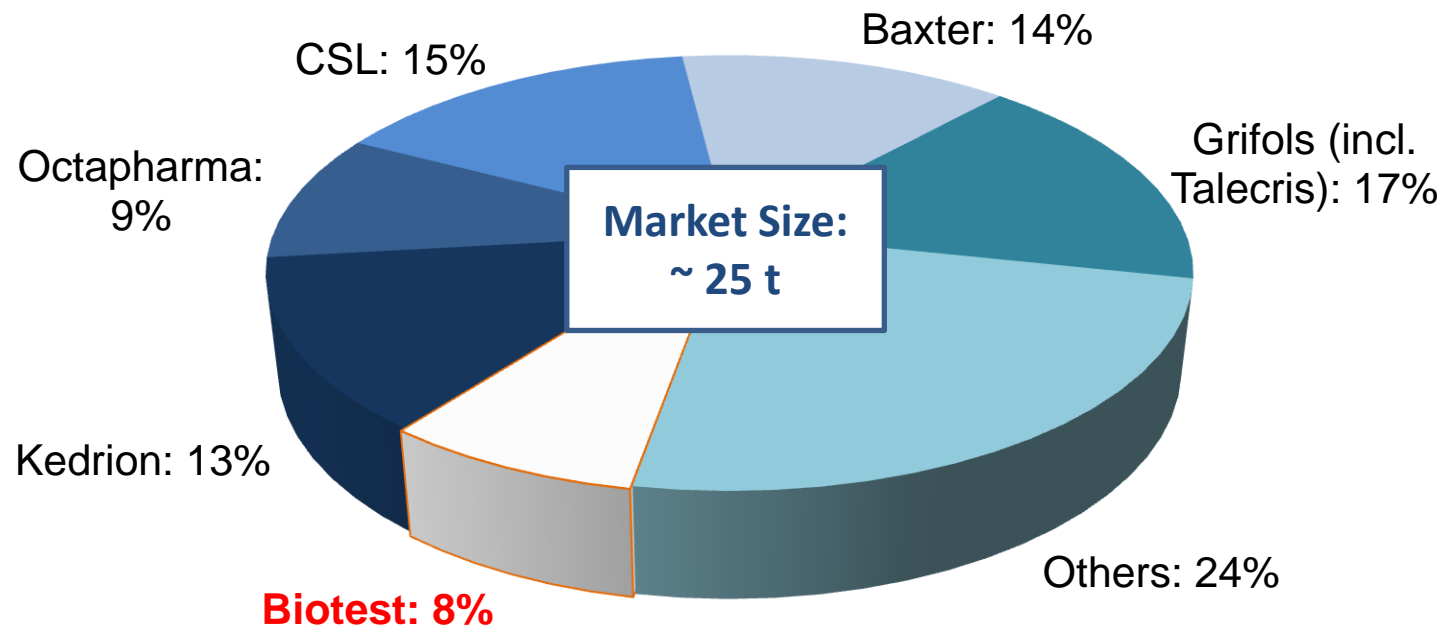
## Future immunoglobulin market trends



- Global growth\* trend will continue
- Global market size 2015: 141 t (SC/IVIG)

\*Growth rates: Expected CAGRs, excluding the Alzheimer upside potential. Sources: MRB (2012)

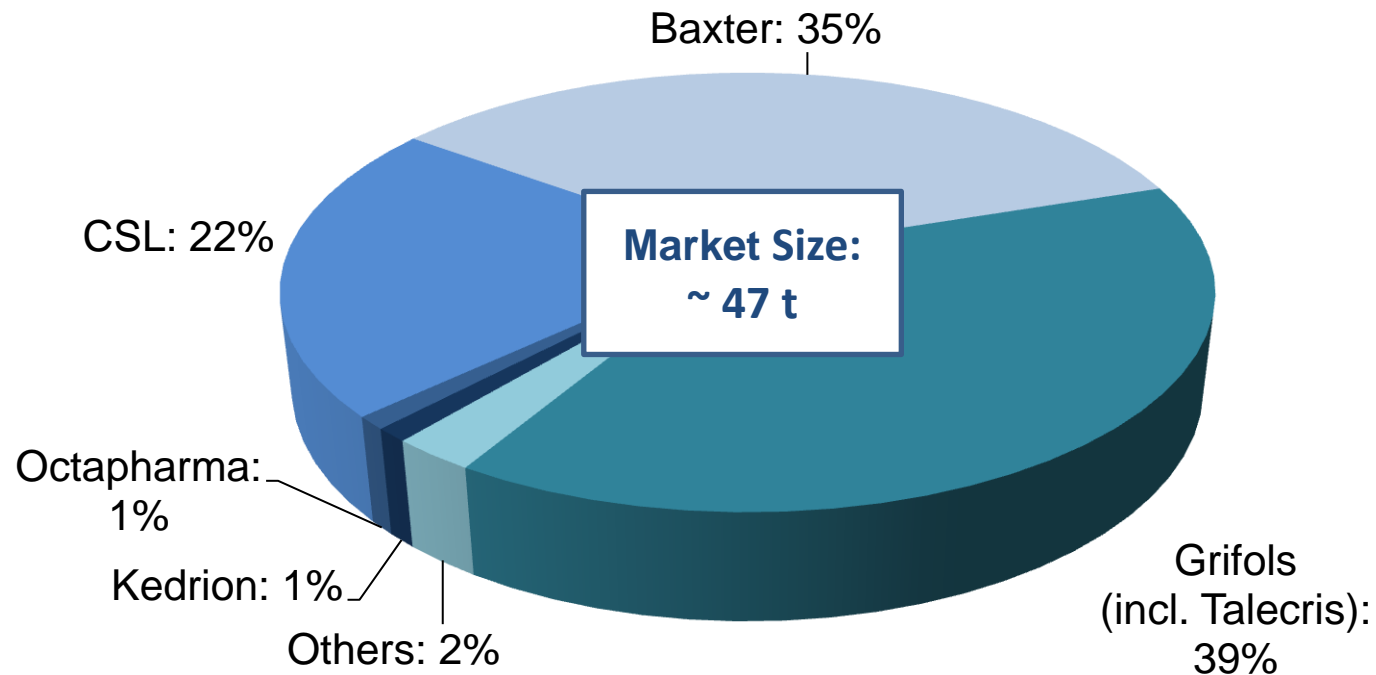
## IVIG market in Europe 2011



Market shares are based on kg IVIG sold.

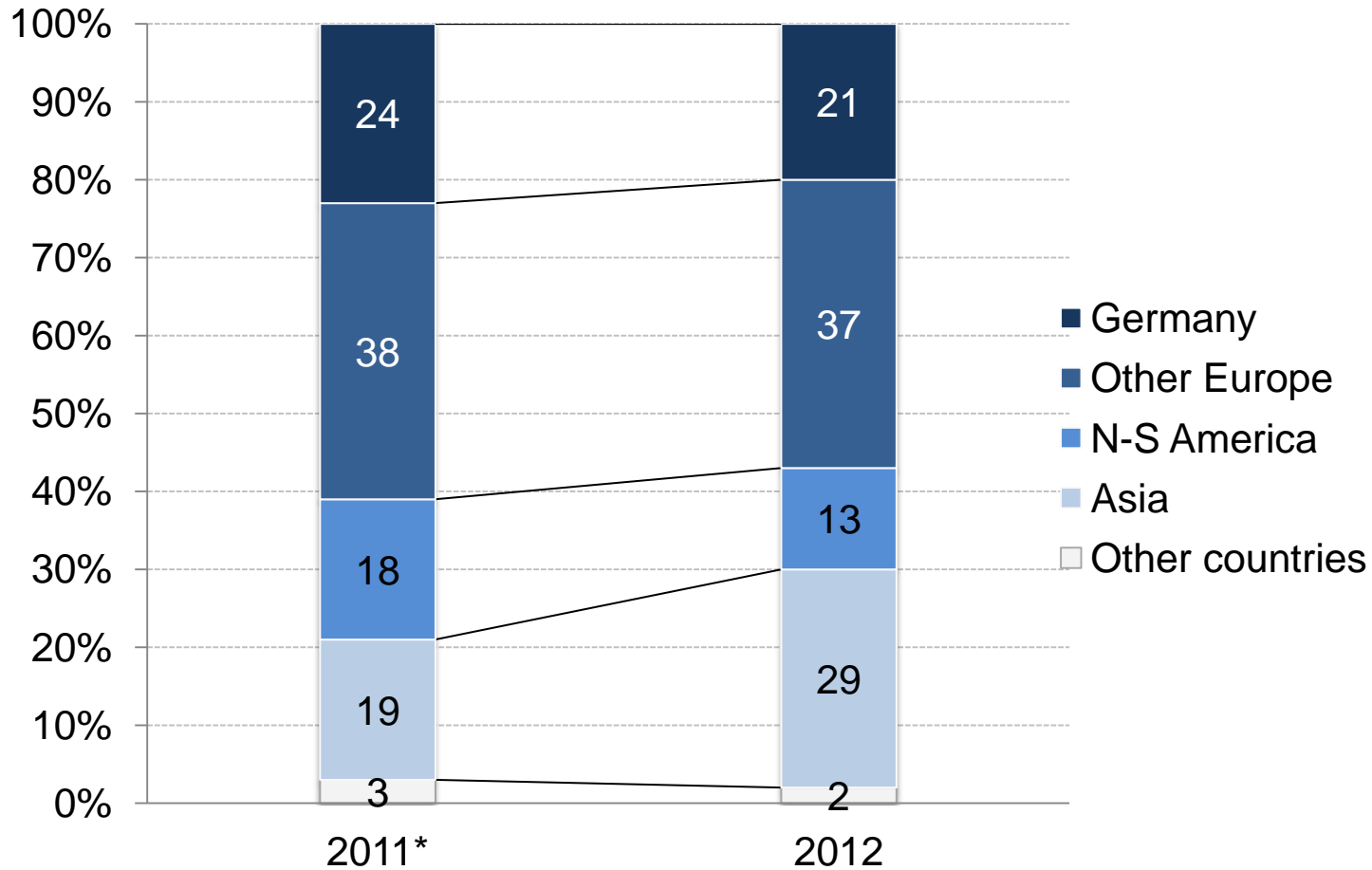
Source: "The Worldwide Plasma Proteins Market 2011", The Marketing Research Bureau; Biotest AG.

## IVIG market in North America 2011



Source: "The Worldwide Plasma Proteins Market 2011", The Marketing Research Bureau; Market shares are based on kg IVIG sold.

## Development of sales by region



\* Continuing Operations



## BPC: US activities

### **BPC (Biotest Pharmaceuticals Corp.):**

- BPC has received marketing authorization of Bivigam™ end of 2012
- Start of first Bivigam™ sales in the US in February 2013
- Target group Home Health Care Companies
- Intermediates for Factor VIII and Albumin shipped to Dreieich



**Successful start in the US with future sales potential of Bivigam™ of USD 100 m**

# Bivigam™: A Three Chapter Story

## The Product



## The Company



## The Channel

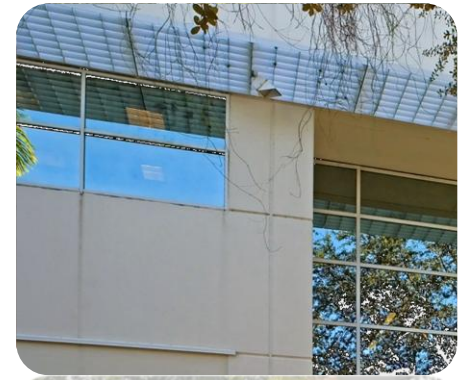
## Chapter I: The Product - Bivigam™

- **Good efficacy and safety profile**
  - Product well tolerated
  - Infusion rate and trough levels realized
  - High patient convenience
- **10% Concentration / Liquid preparation**
- **Non-Sugar (Stabilizer)**
- **State of the Art Production**, nanofiltration (dual viral inactivation); Low-Factor XIa (Reduction of potential thrombogenicity)
- Positive reimbursable level
- U.S. manufactured (“Made in the USA”)



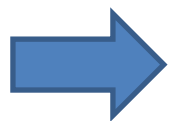
## Chapter II: Biotest Pharmaceuticals Corp. (BPC)

- **BPC - well established US entity**
  - Leading producer of Hepatitis B hyperimmunes
- **Scientifically and technically oriented**
  - Civacir & Zutectra
- **High Quality Production site and Collection Centers (cGMP)**
  - Well engineered global manufacturing facilities
  - New US plant (Significant investment)
  - State of the Art Collection Centers
    - Self-sufficient plasma supply (in United States)
- **Patient oriented**
  - Immune Deficiency Foundation (IDF) and Jeffery Modell Foundation (JMF)
  - Other advocacy (WHF, PPTA, etc.)



## Chapter III: Distribution Channels

- **Supply commitment with selected customers**
  - Close to end user (patients)
  - Customer Service focused
  - Distribution relationships based on long-term supply arrangements
- **Home Health Care Companies:** Infusion services provided at patient's home and/or at local site (Corum, Accredo, Kaiser)
- **Managed Care Organizations (MCOs):** Integrated systems which provide comprehensive care as part of an insurance arrangement
- **Hospital Delivery Networks (IDNs):** Regional network of hospitals and clinics (Hopkins, Baylor)



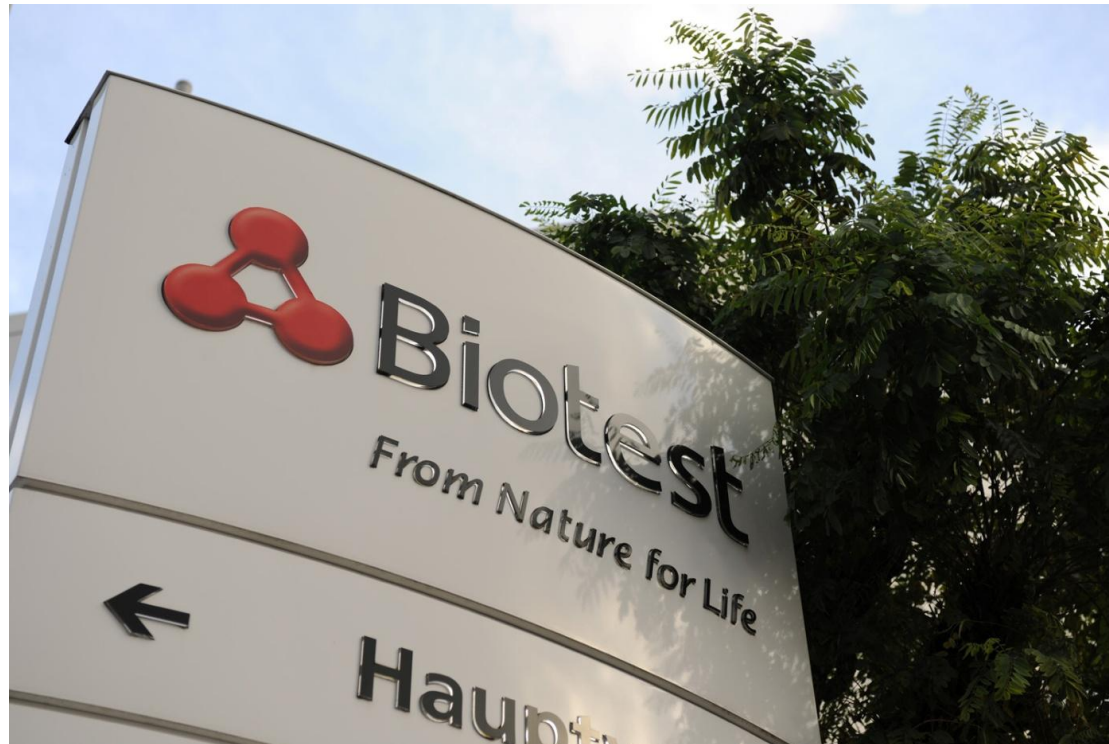
**Priority on channels which serve patients directly, at lower administrative fee and maintain a high percentage of privately insured patients**



## International business

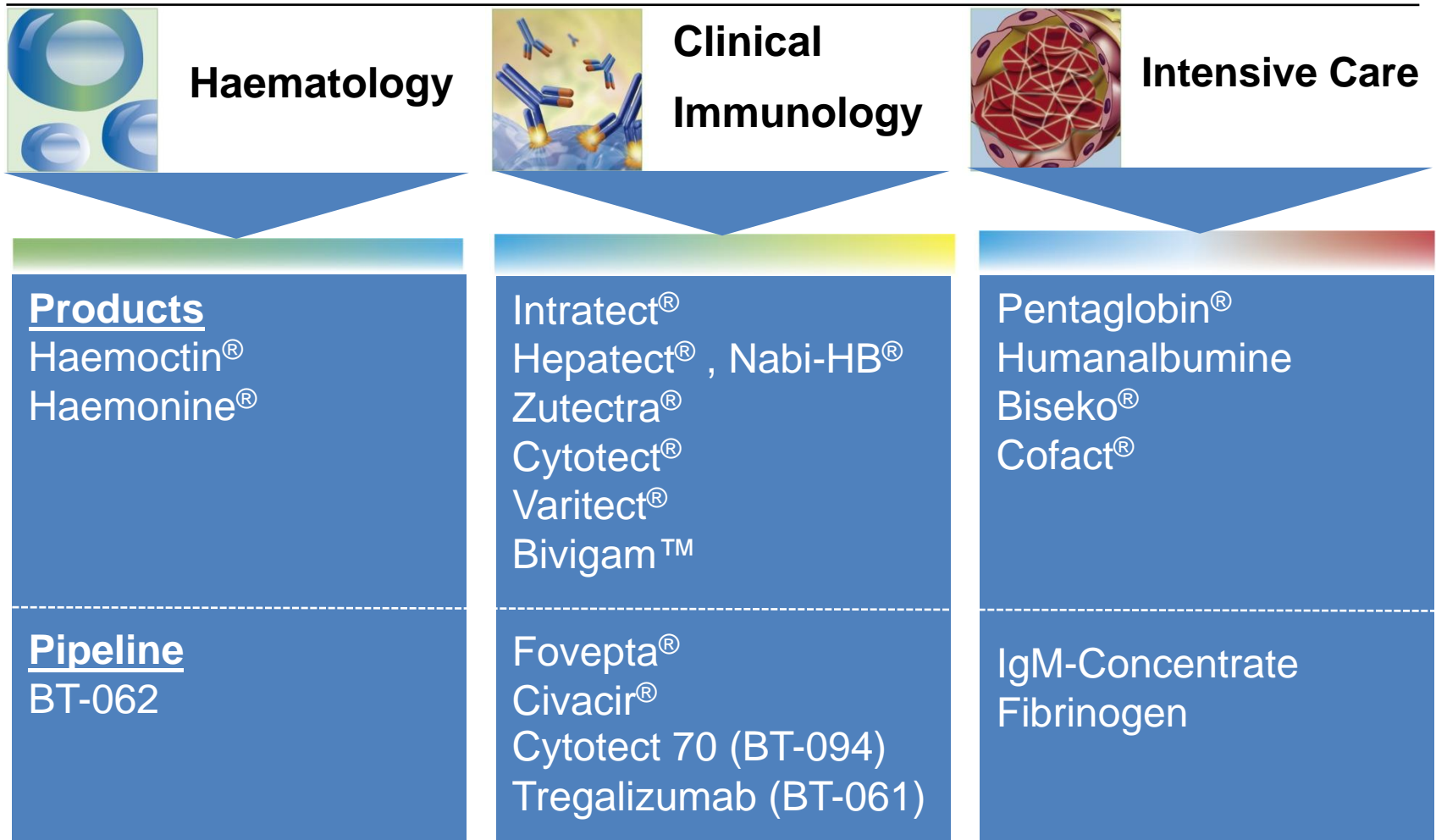


- New opportunities in Asia and South America
  - Registration of Albiomin<sup>®</sup> in China expected end of 2013
  - Introduction of Intratect<sup>®</sup> 10%
  - Zutectra<sup>®</sup> will be introduced for maintenance treatment after liver transplantation in hepatitis B infection
  - Fovepta<sup>®</sup> market introduction for hepatitis B prophylaxis in neonates
- Merz Pharma as new distributor in Russia
- Vianex as new distributor in Greece
  - Deliveries only against first class bank guarantee or payments in advance
  - Distributor took over 6 Biotest Hellas employees
  - Transfer of marketing authorisation of the products to distributor



## Update of Projects

## Three strategic areas of therapy: Products - Pipeline





## **Tregalizumab (BT-061): Additional international Phase IIb study will be started**

### **Interim Analysis of the phase IIb clinical trial (No. 979) of Tregalizumab (BT-061) in Rheumatoid Arthritis**

- Interim Analysis is important to determine the dosage for the new Phase IIb TREAT 2b- trial
- Only few people are unblinded to give dose recommendation
- Clinical investigators and patients are still blinded because study is ongoing



### **Start of a new Phase IIb trial in Rheumatoid Arthritis with 6 months treatment**

- Combination trial TREAT 2b (T cell **RE**gulating **Ar**thritis **T**rial 2b) with Tregalizumab and methotrexate for a treatment period of six months with multiple subcutaneous administrations
- Multiple clinical centers will be involved incl. US, Canada and Europe with up to 350 patients
- IND will be filed in Q2 2013

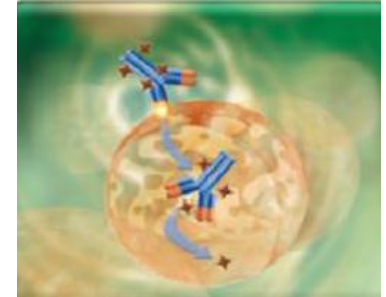
## Intratect<sup>®</sup> 10%

- Specially developed for ambulant treatment and out-patient care of antibody deficiency syndrome
- Approval with the decentralized European procedure (mutual recognition = MR) in October 2012
- Launch has started in Germany in January 2013
- Intratect<sup>®</sup> 5% will be still gold standard for in-patient treatment
- Sales increase by 20% in 2013 expected (Intratect<sup>®</sup> 5% & 10%)



## BT- 062

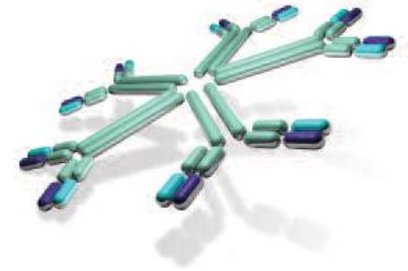
**BT-062:                    Antibody drug conjugate for the treatment  
of multiple myeloma and solid tumors**



- **Combination trial in Multiple Myeloma in the US has started, first patients have been treated (study 983)**
  - **In first dose group 100% partial remissions**
- Monotherapy study 975 finished
- Preclinical evaluation in solid tumors ongoing
- Clinical trial in solid tumors in Europe will start in 2<sup>nd</sup> half of this year

## IgM Concentrate

- Indication: Treatment of severe community acquired pneumonia
- Clinical development: Phase II ongoing
- **Blinded interim analysis after inclusion of 40 patients completed**
- **Recommendation of statistician indicate positive data**



# Fibrinogen

- Developed for congenital and acquired fibrinogen deficiencies
- Fibrinogen is an essential factor to prevent or treat bleeding disorders e.g. in intensive care medicine
- New diagnostic methods are available to diagnose fibrinogen deficiencies in complex bleeding situations
- **Phase I/II clinical trial in congenital fibrinogen deficiency approved in first country; first patient has been treated**
- Development as a ready to use solution ongoing

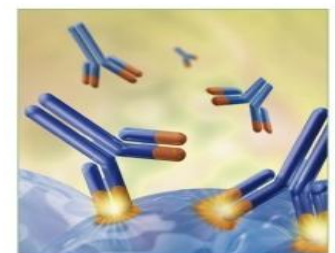
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## **Cooperation agreement with ADMA Biologics, Inc. concerning a RSV hyperimmunoglobulin**

- BPC will produce for ADMA Biologics, Inc., USA, a RSV (**R**espiratory-**S**yncytial-**V**irus) immunoglobulin for the US market
- Biotest AG obtained marketing rights for Europe and other selected countries
- ADMA takes over all development costs for clinical trials and regulatory approval in the USA. Biotest can use these data for regulatory approval in Europe
- RSV infections are especially a problem in immunocompromised patients e.g. after transplantation, with tumor diseases or premature neonates

## Outlook Biotest Group

- Core business expected to remain stable with respect to prices and volume
- International business will have a strong focus in the future
- Development projects successfully on track
- Growing Bivigam™ sales
- Albumin - doubling of capacity
- Intratect® 10% European launch on track



## Guidance 2013

**Sales:** In the financial year 2013 sales will grow 10% to 15%

**EBIT:** We expect an EBIT increase of 10 to 15%



# Contact and Financial Calendar 2013

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## Financial Calendar 2013

|                     |                               |
|---------------------|-------------------------------|
| <b>8 May 2013</b>   | <b>Annual General Meeting</b> |
|                     | <b>Q1 Report 2013</b>         |
| <b>13 Aug. 2013</b> | <b>Q2 Report 2013</b>         |
| <b>12 Nov. 2013</b> | <b>Q3 Report, 2013</b>        |