





#### **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 comparative figures relate to the corresponding last year's period, unless stated otherwise.



# **Biotest Group: Key topics H1 2014**



- Biotest H1 2014 Group Sales up by 8.5% to €264.1m Increase largely attributable to an increase in volume and sales in international markets (Asia)
- H1 2014 EBIT increase by 2.3% to €26.5m
- Slow down of Bivigam<sup>®</sup> sales due to a recall and more competitive market environment in the US
- Revised guidance



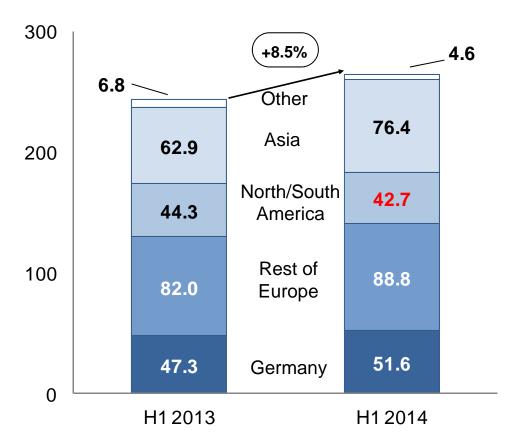


# Financials H1 2014



# Sales grow in line with expectations with exception of US sales

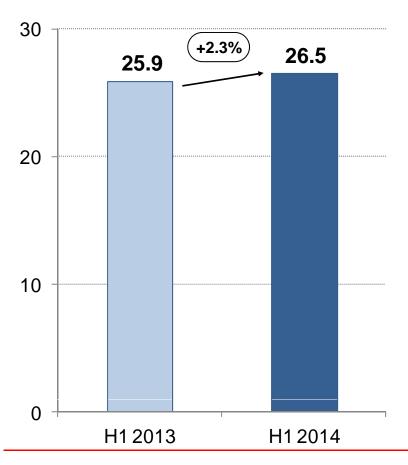
## Sales by region (€ million)





### **Moderate increase in EBIT**

#### **EBIT** (€ million)

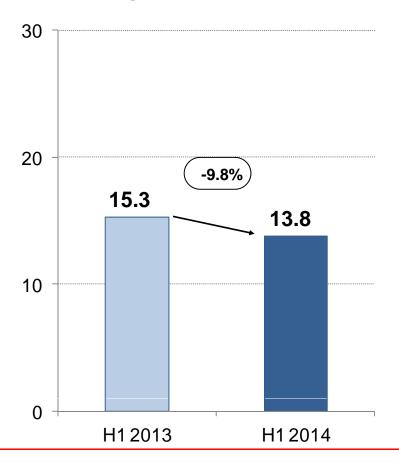


- Higher R&D costs due to positive trend in clinical studies (+ € 4.1m vs. H1 2013)
- Decline of € 6.2m in allocation of upfront payment from AbbVie according to percentage of completion method vs. H1 2013



### **Decrease in EAT**

#### **Earnings after taxes** (€ million)

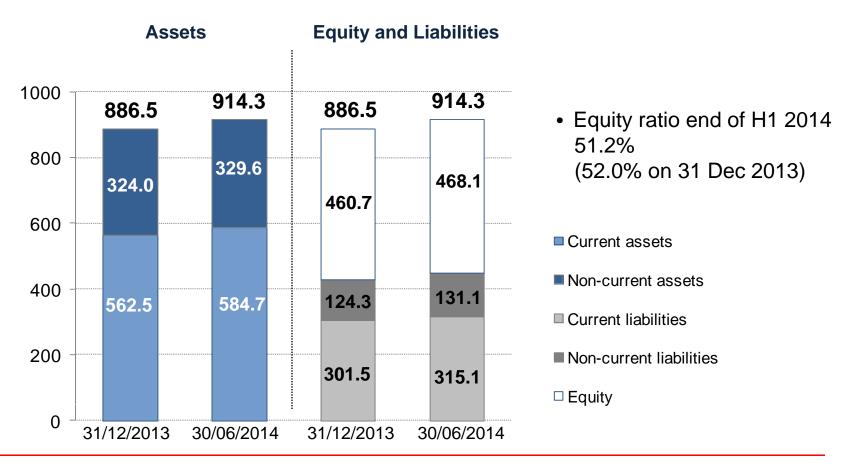


- Financial result at €4.8m
   (vs. €2.5 m in H1 2013) due to
   financing (interest) of the privately
   placed bond (Schuldscheindarlehen)
   of €210 m
- Constant tax rate of 36% vs. 35% in H1 2013 due to not capitalised losses



# Financial position: strong equity base

#### **Financial Position of the Biotest Group** (€ million)





## **Revised Guidance 2014**

## Main components which lead to a revised outlook:

Unplanned negative effects	Planned negative effects
- Reduced revenues of Bivigam	- Increased R+D spendings
<ul> <li>Reduced revenues in crisis regions,</li> <li>e.g. Russia, Iraq, Israel, Libya</li> </ul>	- "Biotest Next Level" (capacity expansion)
<ul> <li>Accelerated production of Civacir and BT-061</li> </ul>	<ul> <li>Reduced allocation of AbbVie upfront payment</li> </ul>
New guidance:	Previous guidance:
Sales: +7%  EBIT: slightly above previous year	Sales: + 10%  EBIT: + 10%



## **Revised Guidance 2014**



**Sales:** In the financial year 2014 sales will grow in the range of 7%

**EBIT:** We expect an EBIT development slightly above previous year





Biotest Strategy for 2020

**Expansion. Future** 



# Bivigam<sup>®</sup> sales below forecast

#### Slower Bivigam<sup>®</sup> sales vs. expectation:

- Negative effects due to recall
- Highly competitive market environment in the US

#### New actions initiated:

- New BPC sales & marketing vice president in US
- Focused marketing & selling strategy
- Intensified marketing activities with new distribution channels
- Positive effects mainly in 2015



Long-term market potential of \$100m delayed



Production site Florida, USA



## **Biotest situation in the US**



BPC headquarters in Boca Raton, Florida

- Number of plasma collection centres in the US will increase to 18 by the end of 2014. Collection volume currently 600.000 l p.a.
- Opening of three new plasma collection centres in 2015
- Plasma sales to third parties increased incl. high margin hyperimmune plasma sales
- US plasma has no geographic restrictions
- Promising development projects e.g. Civacir<sup>®</sup>



# **Entering additional growth markets**



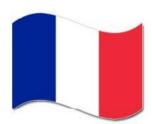
**China**: Third largest pharmaceutical market in the world, two-digit growth rates

 Marketing authorisation for Albiomin<sup>®</sup> 20% expected by Biotest for the fourth quarter 2014; First sales expected end of the year



**Brazil**: Fifth largest country (by population) in the world

- Rapidly growing market for plasma proteins
- Marketing authorisation for Albiomin<sup>®</sup> 20% received in November 2013 with first sales in 2014, further plasma proteins in the marketing authorisation procedure



**France**: First sales with Hepatect® and Zutectra® have started. Tectasim® market authorisation retransfered to Biotest

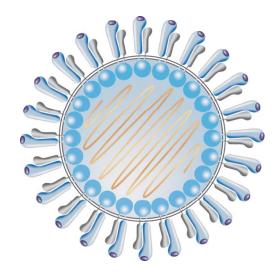


# New products at the horizon

2014 2020 Civacir BT-061 **BT-062 (Accelerated Approval) IgG Next Generation IgM Concentrate Fibrinogen** 



# Clinical Immunology: Civacir®



Model of hepatitis C virus

- Hepatitis C immunoglobulin for reinfection prophylaxis after liver transplantation
- Very high demand:
  - Currently no reliable prophylaxis for the critical period immediately after transplantation
  - New virostatic drugs are not an option in this time period
  - In the EU and USA alone, more than 5,000 liver tranplants due to hepatitis C each year
  - Phase III trial in US ongoing, > 1/3 of patients have been included in study. Part I finalized.<sup>1</sup>
  - First patients have already reached primary endpoint
  - First trend in ongoing study:
    - Re-infection rate in control group: ~40%
       Re-infection rate in highest dose group: 0%

Data will be presented at the American Association of Liver Disease (AASLD) on Nov 9th in Boston

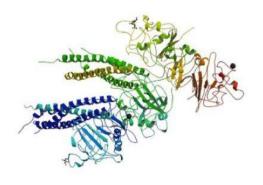


# Intensive Care Medicine: IgM concentrate and Fibrinogen



## **IgM** concentrate

- IgM concentrate for the treatment of severe community acquired pneumonia (sCAP)
- Unique mechanism of action
- Over 130 patients treated to date in phase II study

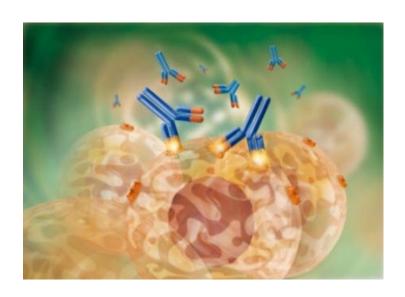


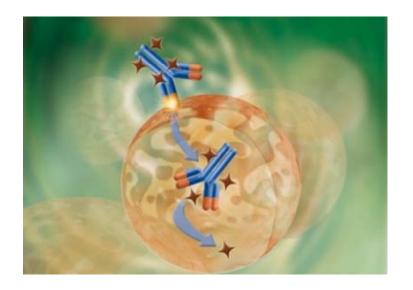
## Fibrinogen

- Fibrinogen for the treatment of severe acute bleeding due to fibrinogen deficiency
- Ready-to-use product is in development
- First patients treated in phase I/II study
- Completion of part I planned in 2<sup>nd</sup> half of 2014



# Monoclonal antibodies extend the range of products in the Clinical Immunology and Haematology areas







# Haematology: Indatuximab Ravtansine (BT-062)



#### **Targeted mechanism of action:**

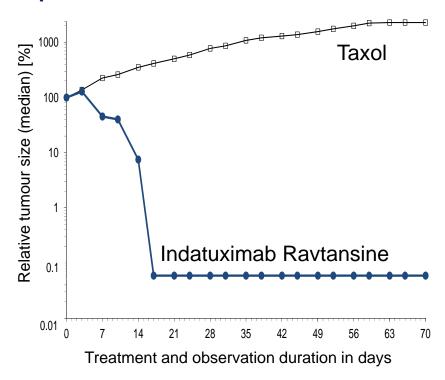
- Antibody docks on cancer cell and toxin is then released:
- Targets cancer cells while healthy cells are very largely spared

- Clinical development in the lead indication multiple myeloma is continuing
- Patient recruitment of study 983 completed
- Very convincing data from this phase II study (combination with Lenalidomide)
- Long-lasting partial to complete remission of the disease in about 75% of treated patients
- Presentation of additional data at the ASH\* conference end of 2014



# Indatuximab Ravtansine (BT-062) High efficacy in tumour treatment

# Treatment of human breast cancer implanted in mice



- Very high efficacy with a tolerable dosage in the treatment of solid tumours that do not respond to standard therapy
- Tumours resolved completely within
   14 days
- No recurrence (renewed growth) after the end of the treatment, no metastases
- Start of development in solid tumours in Q1 2014 in triple negative breast and metastatic bladder cancer; first patients in second dose level included
- Ongoing study confirms high safety

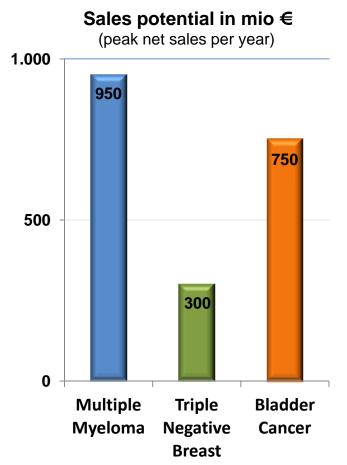


From Nature for Life

# BT-062 - High need and large sales potential

Focus of Indatuximab Ravtansine (BT-062) development on three malignancies

# **Eligible Patient populations\*** Multiple myeloma ~ 80,000 (relapsed and refractory) **Triple-negative** ~ 50,000 metastatic breast cancer Metastatic ~ 90,000 bladder cancer



<sup>\*</sup> potential total number of patients who become eligible for drug treatment at a respective particular setting / Source: Decision Resources 2013 for seven major markets, Biotest estimates



# Tregalizumab (BT-061) Treat 2b study: Patient recruitment almost completed



- Lead indications rheumatoid arthritis (RA) and psoriasis
- Treat 2b: phase IIb trial in RA started in autumn 2013
- Largest clinical trial in Biotest history:
  - Over 300 patients
  - Over 86 trial sites in 14 countries, including USA,
     Canada and Europe
  - Results in H1 2015
- Recruitment of patients will be finalised end of August





# **Investments. Future**



## **New Biotest investments in Dreieich until 2018**





# **Biotest Next Level: Investments in growth**

Increase in global capacity to:

#### Plasma fractionation:

## 3.1 million litres per year

current: 1.5 million litres per year

#### Immunoglobulins:

## 13 tonnes per year

current: 5.5 tonnes per year

#### **Albumin:**

# 72 tonnes per year

current: 42 tonnes per year

- Programme for increasing capacity at Dreieich
- Construction of new production facilities at the Dreieich location
- Period: 2013 to 2018
- Investment amount: > € 200 million
- More than 300 additional jobs



# First projects initiated or already completed





#### Already completed:

- Expansion of filling and packaging facilities
- First expansion of albumin production
- New multi-storey car park

#### **Construction started:**

- Plasma goods receipt area
- Virological test laboratory

#### **Next steps:**

- Basic engineering completed in Summer 2014
- Submission of the building application on July 25<sup>th</sup>, 2014
- Ground broken for new production building by October 2014



#### Global market trends

#### Global IVIG Price trends:

- US: slight increase in prices (54 €/ gram IVIG as industry average)
- ➤ EU: slightly decreasing prices (42 €/ gram IVIG as industry average)

#### Growing IVIG demand:

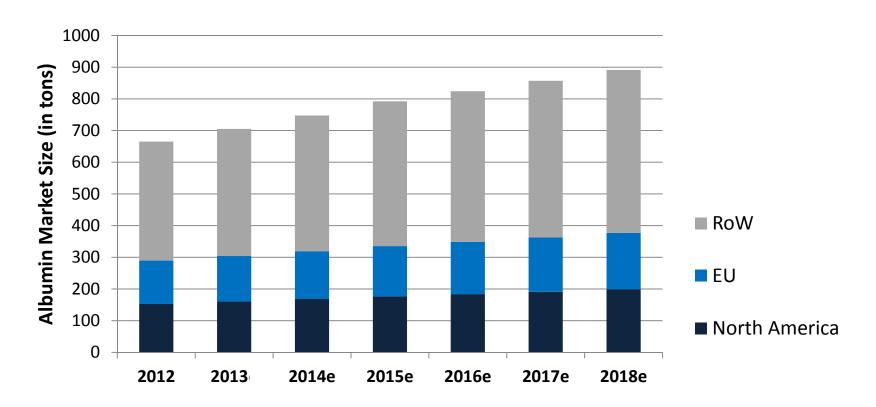
- In the midterm, up to 2015 the following regional growth rates are expected: EU: 4-5%, USA: 4-6%, **RoW: 12-13% CAGR**
- ➤ The global Immunoglobulin market is expected to grow with an average growth rate of ~5-6% p.a. in the period between 2012 and 2025.

#### Global plasma fractionation capacity:

- Global fractionation capacity to grow to 65 m L by 2022
- Biggest single upward step expected in 2015e:
   CAGR 2012-2015e: 7-8%; CAGR 2015e-2022: 3% p.a.
- Strong capacity expansion in US by competitors expected



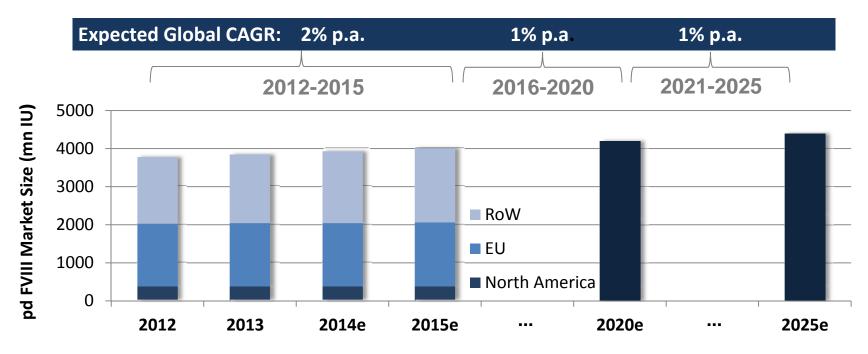
## **Global Albumin Market Forecast**



• The global Albumin market is expected to grow to ~890 tons by 2018.



# Global market trend plasmatic Factor VIII



- In the midterm, up to 2015 the following regional growth rates are expected: EU: 0-1%, USA: 0-1%, RoW: 4% CAGR
- The global pd FVIII market is expected to grow with an average growth rate of ~ 1% p.a. in the period between 2012 and 2025.

Sources: Biotest Market Research based on MRB (2013, 2012)



## Vision – our road to 2020



- Consistent focus on biological drugs for the therapeutic areas of haematology, immunology and intensive care medicine
- Continuous investment in the development of new therapeutic options
- Worldwide operations with a strong base in Europe and the US
- 2020 sales > € 1bn



## **Contact and Financial Calendar 2014**

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**Financial Calendar 2014** 

12 Nov. 2014 9M Report 2014