



# Biotest Group





Press and Analyst Conference call – H1 2012



#### **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 H1 2012**



Biotest H1 2012 Group Sales up by 3.4% to € 220.2 m
 Increase largely attributable to an increase in volume and sales in international markets



• H1 2012 EBIT increase by 14.5% to € 22.9 m



• Start of BT-062 phase I/IIa combination study (study 983)

Confirmation of guidance:
 FY 2012 sales increase of 3-5%
 EBIT at last years level (FY 2011: € 41.6 m), despite effects from Greece and the delay in Bivigam approval



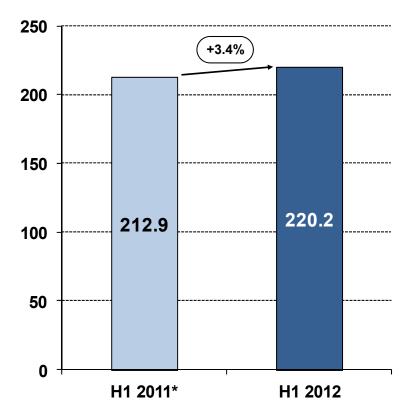


### Financials H1 2012

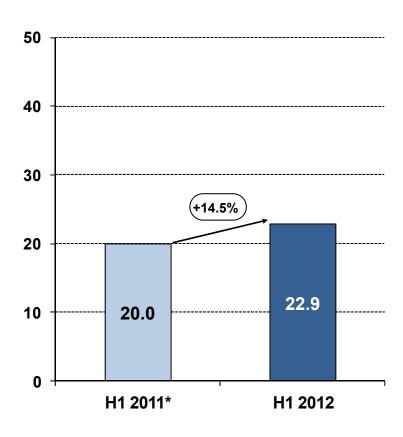


# Biotest with a strong EBIT growth in H1 2012

#### Sales(€ million)



### **EBIT**(€ million)



<sup>\*</sup> Continuing Operations



# **H1 2012: Sales and EBIT by Segments** (in € m)

Sales	H1 2012	H1 2011*	Δ
Therapy	167.5	163.9	2.2 %
Plasma & Services	47.4	43.1	10.0 %
Other Segments	5.3	5.9	-10.2 %
Biotest Group	220.2	212.9	3.4 %

EBIT	H1 2012	H1 2011*	Δ
Therapy	14.4	10.6	35.8 %
Plasma & Services	8.5	9.0	-5.6 %
Other Segments	0.0	0.4	-100.0 %
Biotest Group	22.9	20.0	14.5 %

\*Continuing Operations

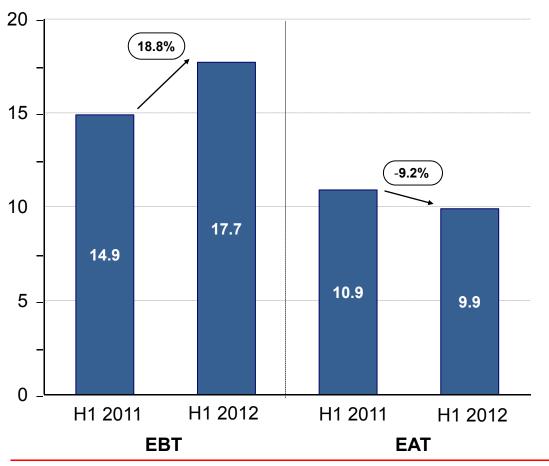
Biotest Analyst Conference August 13, 2012 5



#### Increase in EBT – decrease in EAT

in H1 2012

#### **EBT and EAT** (in € m)



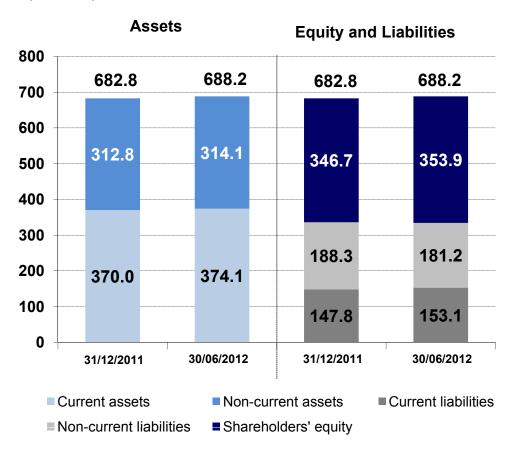
- Financial result H1 2012 at -€ 5.2 m vs -€ 5.1 m in H1 2011
- As of March 31, 2012 all Greek bonds had been sold with a loss of € 1.1 m
- Tax rate 44.1% in H1 2012 vs. 26.8% in H1 2011 due to not capitalised losses in Greece and Brazil



#### **Stable Balance Sheet Structure**

#### **Balance sheet of Biotest Group**

(in € m)



#### **Assets**

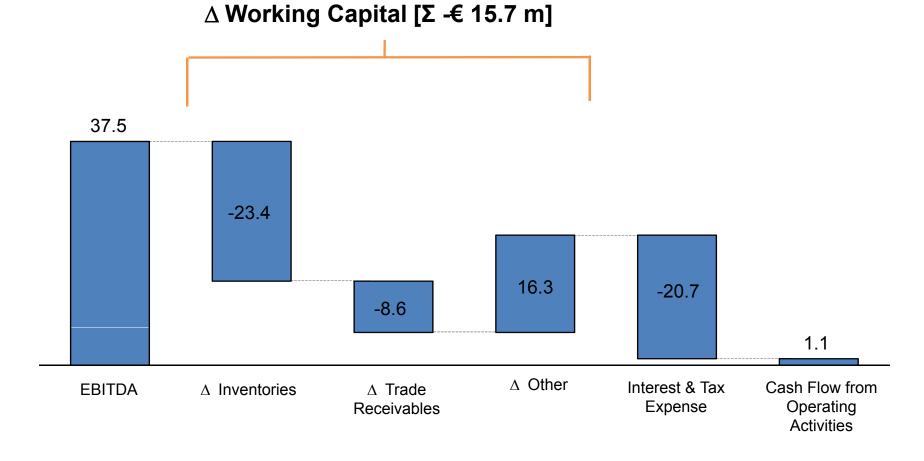
- Capital expenditure in production facility in Dreieich
- All Greek Zero Bonds have been sold with a loss of € 1.1m. Nominal value on Dec. 31 2011 had been € 4.5 m

#### **Equity and Liabilities**

Equity ratio as of 30 Jun. 2012:
 51.4% (Dec. 31 2011: 50.8%)



# Cash Flow from Operating Activities January – June 2012 (in € m)





#### **Guidance 2012**

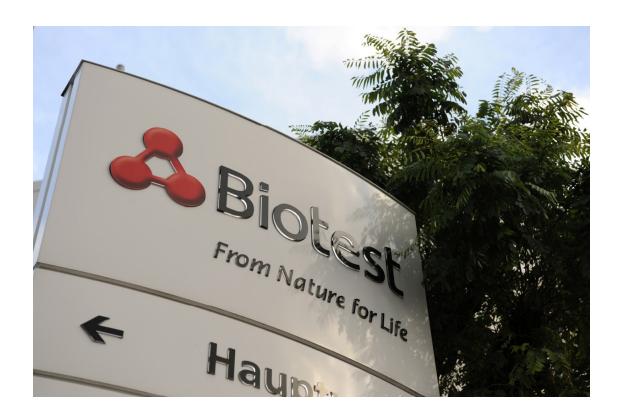
**Sales:** Sales growth of 3-5 percent compared to 2011

**EBIT:** Slight increase vs EBIT of 2011 (€ 41.6 m)



EBIT at last years level (FY 2011: € 41.6 m), despite effects from Greece and the delay in Bivigam<sup>TM</sup> approval. The 2012 guidance assumes that the market environment for our core market is stable.





### **Current projects and new developments**



# Bivigam approval: FDA response

Clinical data on efficacy and safety



High quality of Bivigam<sup>™</sup> accepted



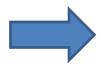




Several systems to detect thrombogenic activity (TGA tests) have been developed, but are not yet validated







Validated TGA test is required for FDA approval



# Consequences of FDA response letter on Biotest business

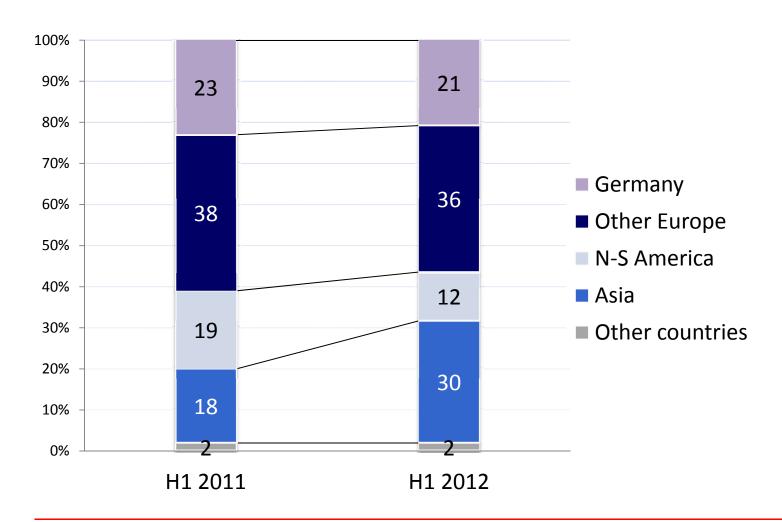
- Delay of Bivigam market entry by several months
- High priority to accelerate TGA\* test validation in close cooperation with FDA
- Missing Bivigam sales and earnings will be compensated by other business
- Confirmation of guidance 2012

\*Thrombogenic activity

Biotest Analyst Conference August 13, 2012 12



# **Development of Sales by Region**





#### Additional international business in China

- Registration of Albumin in China expected in H1 2013
- Contractual negotiations with a new Chinese distributor expected to be finalised in 2012
- Biotest will double production capacity for Albumin until 2013
- China has a huge market for Albumin with very high prices; prices in China are double as high as in Germany
- Consumption of ~ 280 t Albumin in China p.a.





# Clinical immunology development projects (I)

Intratect® 10%: Specially developed for ambulant treatment and outpatient care of antibody deficiency syndrome.

Approval in Germany expected for Q4 2012; EU Q1 2013

Cytotect® 70: Infection prophylaxis of the fetus in the case of

cytomegalovirus infection of the mother during pregnancy

~12.500 pregnant women screened

**Civacir** <sup>™</sup>: Prophylaxis of re-infection following hepatitis C-

induced liver transplantation; clinical material has been

produced in Q2 2012 in Boca Raton; study initiation

planned for Q1 2013



# Clinical immunology development projects (II)

From Nature for Life

Tregalizumab:

Monoclonal antibody for the treatment of rheumatoid

(BT-061) arthritis and psoriasis

A phase IIb trial is ongoing (Study No. 979).

A pharmacokinetic-pharmacodynamic study has been started (Study No. 985). A new phase IIb study with

approx. 350 patients is currently being prepared (No. 986).

# Haematology development project

BT-062:

Antibody drug conjugate for the treatment of multiple myeloma; Combination trial in US has started, first patient treated (study 983)



# Intensive care medicine development projects

**IgM Concentrate:** IgM-enriched immunoglobulin for the treatment of

severe community acquired pneumonia

Phase II ongoing; interim analysis planned for end of

2012

**Fibrinogen:** Developed for congenital and acquired fibrinogen

deficiencies

Phase I/II clinical trial in congenital fibrinogen deficiency approved; study initiation ongoing



# **Outlook Biotest Group**

- Core business expected to remain stable with respect to prices and volume
- International business to be further extended incl. new countries such as China
- Projects successfully on track
- Bivigam approval expected with several months delay but negative effects can be compensated by other business of the Group



#### **Guidance confirmation for 2012**













### **Contact and Financial Calendar 2012**

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**Financial Calendar 2012** 

Nov 13, 2012 Q3 Report 2012/

**Analyst conference** 

Mar 25, 2013 Annual Report 2012/

**Analyst call**