

# **Biotest – The Specialists**



**Biotest AG - Half Year Preliminary Results 2010**July 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.



# H1 2010 – At a glance

- H1 Sales increase + 4.0% to €227.1 million in difficult market environment
- Continued influences on EBIT:
  - further price decrease for plasma protein products
  - continued unabsorbed costs in US (finalisation production facility Boca Raton)
  - increased R&D expenses: €4.1 million (+19%) incl. consistency batches at BPC and regulatory filing for BLA Bivigam<sup>TM</sup>
- H1 EBIT € 23.7 million (-24%)
- Revised EBIT Outlook









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# **Expectations FY 2010**

- Sales growth in lower single digit range
- Further price pressures expected for Intratect and Haemoctin
- Negative impact by German Healthcare Reform
- Continued unabsorbed costs in US (production facility Boca Raton)
- Shifting of products in higher margin markets not successful
  - EBIT level of 2009 will not be reached.



New EBIT guidance: €45 million +/- 10%

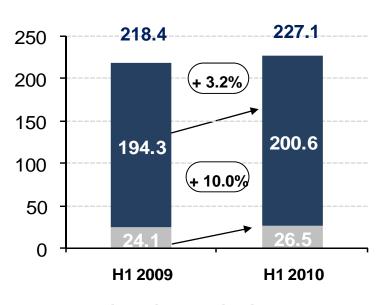
EBIT Guidance incl. Discontinued Operations:

€ 45 million +/- 10% plus € 18 million



# Sales growth despite difficult environment

#### Sales of Plasma Proteins & Microbiological Monitoring (€m)



- Microbiol. Monitoring
- Plasma Proteins

- Sales in the first half year of 2010 were up by 4.0% to 227.1 million vs. H1 2009
- The Microbiological Monitoring segment grew at a rate of 10.0 %, mainly through products manufactured by heipha
- The Group's Plasma Proteins business grew with 3.2%
- Robust performance in challenging business environment



## **Sales Plasma Proteins**

Sales Plasma Proteins H1 2009	€	194.3 m
Volume effect	€	20.9 m
Price effect	€	-14.6 m
Sales Plasma Proteins H1 2010	€	200.6 m



## EBIT Plasma Proteins H1 2010 vs H1 2009

EBIT Plasma Proteins H1 2009	€ 42.7 m
EBIT from increased volume	€ 8.7 m
EBIT loss from reduced prices	€ - 14.6 m
Net changes of other costs/expenses	€ - 1.2 m
EBIT Plasma Proteins H1 2010	€ 35.6 m



# H1 2010: EBIT Biotest Group (€m)

	H1 2009	H1 2010	
Plasma Proteins	42.8	35.6	- 17 %
Biotherapeutics	- 8.8	- 10.4	- 18 %
Microbiology	2.5	3.3	+ 32 %
Corporate	- 5.3	- 4.8	+ 9 %
<b>Biotest Group</b>	31.2	23.7	- 24 %



# Loss in EBIT due to higher R + D Expenses (€m) vs. 2009

EBIT H1 2010 (actual)

∧ R + D Plasma Proteins

∧ R + D Microbiology

 $\wedge$  R + D Biotherapeutics

EBIT H1 2010 (adjusted for increased R+D expenses)

2010	∆ to 2009
23.7	- 24 %
2.1	
0.2	
1.8	
27.8	-11%



# Reasons for increased R & D expenses

#### **Plasma Proteins:**

- ➤ <u>BPC</u> has produced IVIG consistency batches, regulatory expenses for preparartion of BLA submission
- <u>Dreieich</u>: Intensified development of plasma protein projects e.g. IgM, Cytotect and others

#### **Biotheraputics:**

- > 5 Clinical studies ongoing with BT-061,BT-062 and BT-063
- ➤ Production Technology transfer of BT-061 and BT-062 to Boca Raton



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#### **Outlook for 2010**

#### **Reason for revised Guidance:**

- Expected negative impact from anticipated German Healthcare Reform legislation of 5-6 million; driven by increases in mandatory rebates of additional 10% in public sector and out-patient hospital sector
- Transition in Global Plasma Protein market
  - continued price pressure in some markets, slower market growth in some territories

#### **Revised Guidance for 2010:**

- Low single-digit percentage sales growth
- EBIT at € 45 million +/- 10%
- EBIT Guidance incl. Discontinued Operations:
  € 45 million +/- 10% plus € 18 million

#### Outlook statements are subject to:

Material price and volume movements on core plasma products, competitor activity, changes in healthcare regulation and reimbursement policies, pending payments of Greece hospitals and foreign exchange rate movements



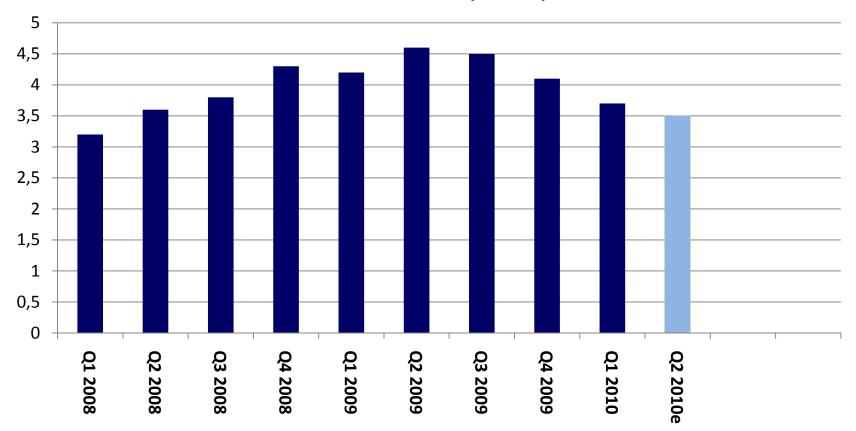
# **Outlook Plasma Protein Industry**

- Volumes of collected plasma decline again; Industry consolidation continues; overcapacities are being reduced
- The demand for final products continues
- Therefore the markets will begin to level out beginning from mid 2011 onwords; prices will stablize and the business will continue to grow



# **Quarterly Volumes of US Source Plasma**

#### Plasma Volume (m liter)



Source: PPTA (July 2010); Q2 2010e: Biotest AG



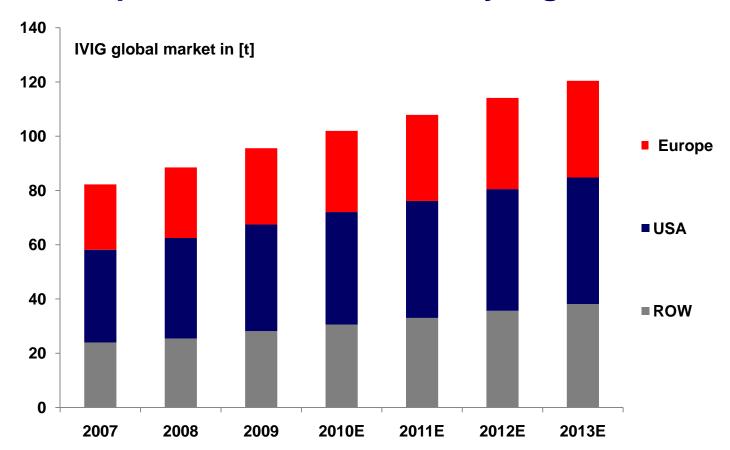
#### **Outlook Plasma Protein Market**

#### **Biotest's business environment fundamentally attractive:**

- Confidence in mid/- long-term growth of plasma proteins products
- Demand driven by:
  - Favorable demographics: age, weight, time on therapy
  - Better diagnosis and awareness driving increased use and higher dosing
  - Continued clinical evidence supporting new and emerging indications
  - Growth opportunities in industrialised countries and emerging markets
- Products often life-saving treatments long-term demand independent of cyclical effects



# **Development of IVIG markets by regions**



 The IVIG market will continue to grow (5% p.a.), particularly by increased demand in emerging markets

Source: MRB, Analyst Reports, Biotest Market Research



# **Further Outlook Biotest Group**

- Despite difficult business environment we continue to invest into R&D of Plasma Protein Projects and Biotherapeutics
- Full pipeline of Plasma Protein products and Biotherapeutics with a potential to reach the market within the next years
- BPC/ USA: access to the single biggest plasma protein market
  - ➤ Q3 2010 BLA submission of Bivigam<sup>TM</sup> on track
  - ▶ Launch of Bivigam<sup>TM</sup> (IVIG) expected to take place in Q3 2011
  - Additional market potential of \$ 100 million