

Biotest Group



Press and Analyst Conference – Financial Year 2010 Frankfurt/Main, March 22, 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 2010 and Q1 2011



- Biotest FY 2010 Group Sales up by 5.7%
- EBIT decreased by 24.9% due to difficult plasma protein market environment



- Microbiological Monitoring: Signing of sale and purchase agreement with Merck KGaA Darmstadt, Germany
- Submission of BivigamTM BLA to FDA on Nov. 3, 2010; first FDA inspections ongoing



- Further milestones achieved in Plasma Proteins and Biotherapeutics
- Transfer of Medical Diagnostics business to Bio-Rad finalized.



Biotest to sell Microbiological Monitoring business to Merck KGaA

- Contract signed to sell worldwide activities of the Microbiological Monitoring segment to Merck KGaA (Darmstadt/ Germany)
- Merck KGaA to acquire 100% of the shares of
 - Biotest Microbiology Corp. (Rockaway/ USA)
 - ➤ Biotest S.a.r.l. (Paris/ France)
 - Biotest K.K. (Yokohama/ Japan)
 - heipha Dr. Müller GmbH (Eppelheim/ Germany; 51% Biotest AG, 49% Dr. Müller)
 - Total Hycon business of Biotest AG
 - as well as the microbiology business of five European subsidiaries of Biotest Group through an asset deal







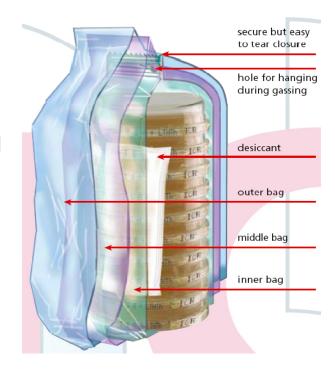






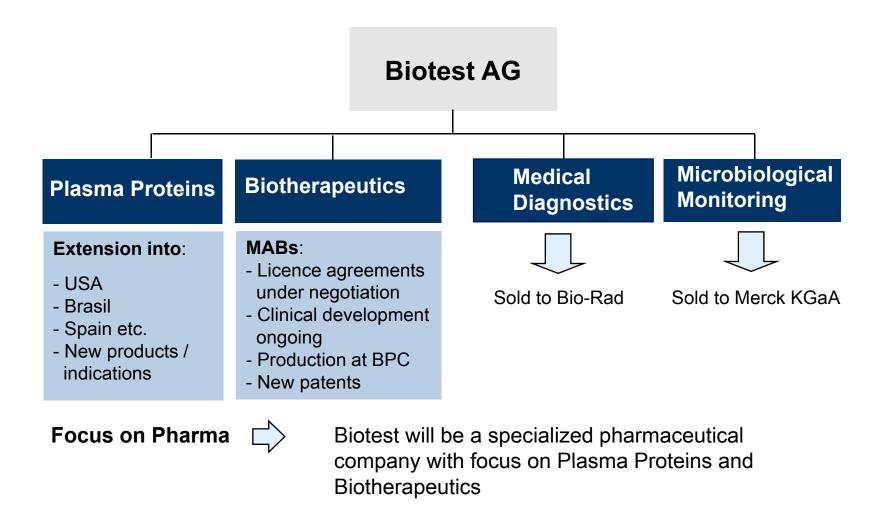
Biotest to sell Microbiological Monitoring business to Merck KGaA

- Revenues of activities in 2010: € 48.7 million
- 290 employees work for the business segment
- The transaction is subject to anti trust clearance and is foreseen to be closed by end of Q3 2011
- Biotest has been advised by @visory partners and FRANZ Rechtsanwälte





Biotest: Future corporate structure



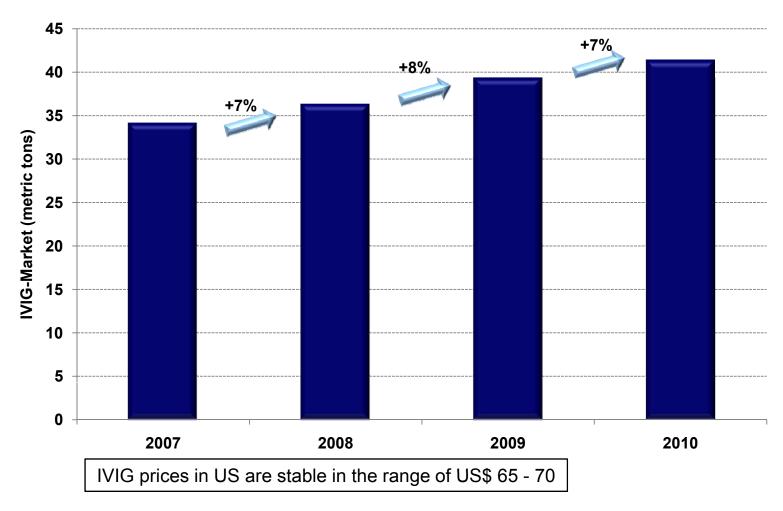




Plasma Proteins



US IVIG market development, 2007 - 2010



Source: PPTA; Estimate volumes October – December 2010 Citigroup, February 28, 2011



Biotest's expectations on IVIG volumes and prices for 2011

- Demand for IVIG will continue to rise due to new indications, higher consumption per patient and new markets
- Without inventory effect in 2011 volumes of IVIG offered to be sold will be 12 – 15 tons lower than in 2010:
 - ➤ Volume of plasma being collected in 2010 in the USA was 2 2.5 m liters lower than in 2009
 - Octapharma has not yet returned to the market in EU and USA



Our previous statements have been confirmed Price stabilisation took place in key countries beginning of 2011 We estimate, that this will lead to price increases in the 2nd half of 2011



Bivigam[™] (IVIG) FDA filing in US

Polyspecific immunoglobulin



- BivigamTM FDA filing on Nov. 3, 2010
- FDA confirmed that BLA dossier is generally accepted; First FDA inspections took place
- Final technical fine tuning ongoing e.g. automation system
- Additional conformance lots to be produced in Q2 2011

Filing of strategic importance to Biotest

Market potential ~ USD 100 m



Major progress in development of Plasma Proteins (I)

Zutectra®



FoveptaTM (s.c. Hepatitis hyperimmunoglobulin for neonates)

Study report finalised in Feb. 2011 PEI submission planned for April 2011

Cytotect® 70



Successful market introduction in Germany, Austria, Italy, Ireland; extension to other countries is planned

Interim analysis (12/2010) indicated clinical efficacy in pregnant women with cytomegaly infections and confirmed positiv data of previous studies

R&D expenses in 2010 in the Plasma Protein segment: € 27.9 m



Major progress in development of Plasma Proteins (II)

IgM Concentrate



Phase II trial protocol submitted to PEI Study start planned Q3 2011

Intratect 10%



Phase III trial started
First patients included
End of study Q4 2011

CivacirTM



New production schedule has been determined, formulation has been improved Validation of screening assays is ongoing

Fibrinogen



Indication: acute bleeding disorders Product characteristics have been defined Start of clinical development end 2011



Facility expansion to ensure further growth of Plasma Proteins





- Expansion of filling and packaging facility in Dreieich has started in Dec. 2010
- Facility expected to be finalised in 2013
- Total capex spending approx. € 25 m



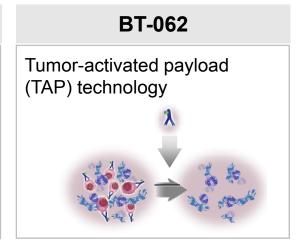


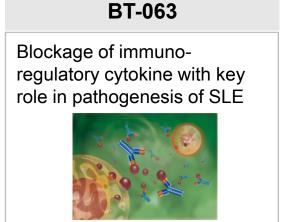
Biotherapeutics



Biotherapeutics portfolio

Activated Tregs mediate modulation of T effector cells Teffector cell regulatory cytokines regulatory cytokines regulatory cytokines regulatory cytokines Teffector cell RI-2 deprivation APC Treg





Potential Indications

- Rheumatoid Arthritis
- Psoriasis
- Other autoimmune diseases

Potential Indications

- Multiple Myeloma
- Solid tumors

Potential Indications

- Systemic Lupus Erythematosus (SLE)
- Oncology

Market volume in 2010¹⁾

RA: USD 13.5 bn

Psoriasis: USD 3 bn

Market volume in 2010¹⁾

MM: USD 4.8 bn

Market volume in 2010¹⁾

SLE: USD 430 m

1) Sources: company reports, Biotests estimates for 2010



Clinical development BT-061 Overview

Rheumatoid arthritis			
Trial	Status		
Phase IIa, monotherapy (No. 962)	Completed 🎺		
Phase II, combination with MTX (No. 971)	Completed 🎺		
Phase IIb, combination with MTX (No. 979)	Recruitment ongoing		

Psoriasis		
Trial	Status	
Phase I/IIa, monotherapy single dose (No. 967)	Completed 🌱	
Phase II, monotherapy multiple dose (No. 973)	Recruitment 🎷 completed	

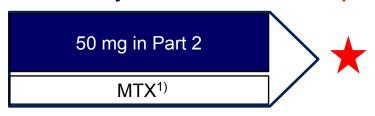


BT-061: Rheumatoid Arthritis Phase II Study (No. 971)

Trial Design and Results

Subcutaneous injection

Study completed



Repeated dose, Placebo controlled

- European multi-center
- Therapeutic arm: BT-061 + MTX
- Control arm: MTX + Placebo
- 8 weeks treatment, once per week
- Total patient number: 41
- Dose-confirmation trial
- Follow-up period 8 weeks

Preliminary Results

- Clear improvement already after only 8 weeks of treatment in relevant SC dose group
- √ Favourable ACR results when compared to approved drugs (week 9²)
- ✓ Further improvement with continued treatment expected, typical plateaus of ACR response for biologics not reached yet³⁾
- ✓ Good tolerability

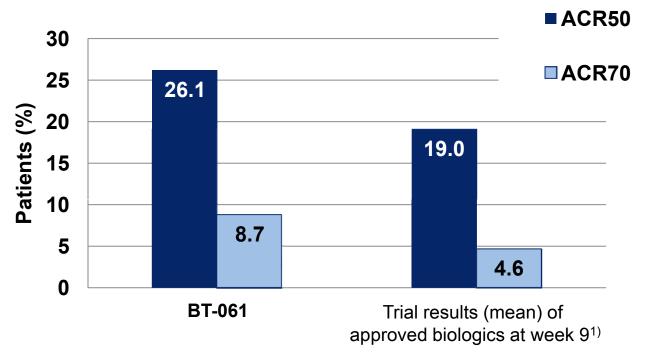
¹⁾ Methotrexate + Placebo 2) ACR50 and ACR70 describe % of patients with improvement of clinical symptoms of at least 50% or 70%, respectively 3) expected plateaus: ACR20 after 3 months; ACR50 after 4 months; ACR70 after 6 months



Rheumatoid Arthritis Phase II Study (No. 971)

Preliminary analysis: Favourable Efficacy Results

50 mg BT-061 SC + MTX ACR scores [%] at primary endpoint (week 9)



BT-061: only patients that received the complete 8 week treatment cycle were considered for calculation 1) Biotest analysis of trial results of approved biologics

Please note: Trial results (average) from independent trials are shown, which are not directly comparable as patient characteristics, route of administration, dose levels and treatment frequency are different



BT-061: Rheumatoid Arthritis Phase IIb Study (No. 979)

Trial Design and Results

Subcutaneous injection

25 mg – 75 mg MTX¹⁾

- Repeated dose, placebo controlled
 - International multi-center study
 - Therapeutic arm: BT-061 + MTX
 - Control arm: MTX + Placebo
 - 12 weeks treatment, once weekly
 - Total patient number: 176
- First RA Study with confirmatory statistics
- Follow-up period 12 weeks

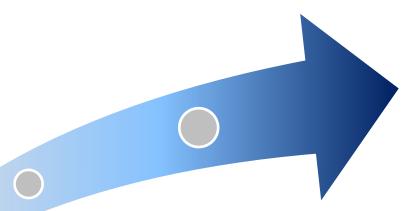
Status

- ✓ Submission in all countries done
- ✓ First patients recruited in 12/2010
- ✓ Recruitment is ongoing

1) MTX + Placebo treated



BT-061 Partnership



Our Goal:
Optimized structure
and transaction
rather than a fast
deal at any price

Favourable efficacy data in phase II trials

Intense negotiations with international pharmaceutical companies Contract negotiations of co-development and co-promotion ongoing



BT-062: Multiple Myeloma Phase I (No. 969)

Trial Design and Results

Recruitment completed

Dose escalation 10 - 200 mg/m²

MTD cohort 160 mg/m2



- Patient population
 Relapsed and relapsed/refractory
 Multiple Myeloma
- Dose-escalation trial
- Therapeutic regiment
 - Repeated Single Dose
 - Dosing every 3 weeks
 - MTD cohort consists of 13 patients

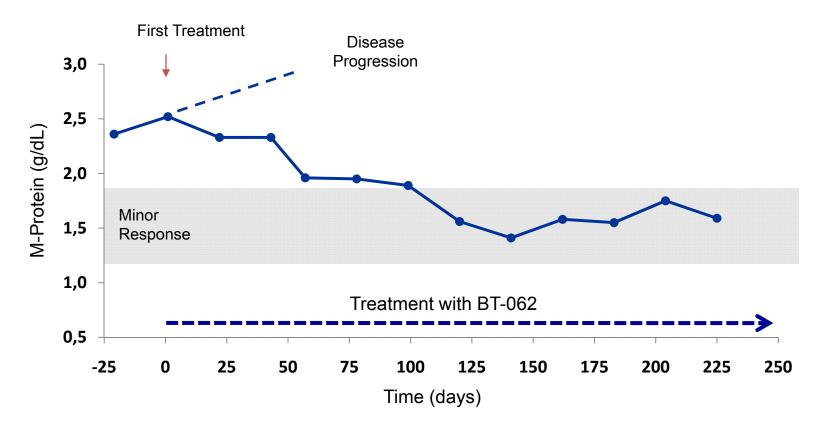
Results

- ✓ Maximal Tolerated Dose (MTD) identified
- ✓ Good tolerability
- ✓ Clinical benefit in more than 50% of heavily pretreated patients
- Stable disease in some patients for several months



BT-062: Repeated Single Dose Study 969

Minor response in patient of MTD cohort



- ➤ Patient progression-free for more than 8 month
- Treatment with BT-062 ongoing



BT-062: Summary

Study	Dosing Regimen	Results
Monotherapy (No. 969) USA	Repeated single dose	Maximum tolerable dose (MTD) cohort defined Good tolerability Clinical Benefit in >50% of patients, including minor and partial responses
Monotherapy (No. 975) USA	Multiple dose, more intense dosing scheme	Good tolerability in first patients No efficacy results available yet
Combination therapy (No. 983) EU	Start planned end of 2011	-



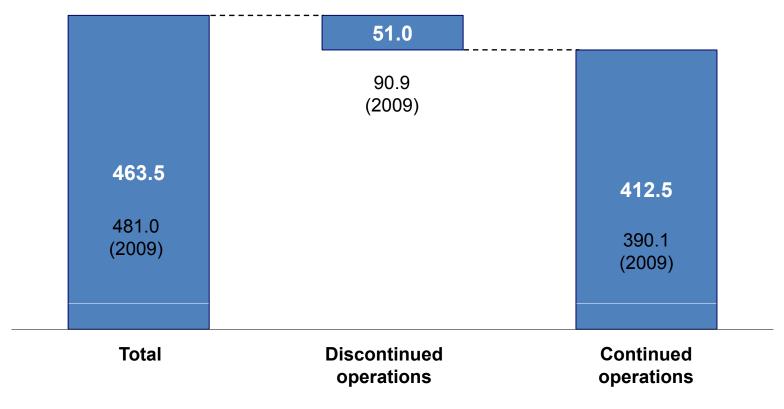


Financials FY 2010



Change in reporting structure 2010

Sales in € m

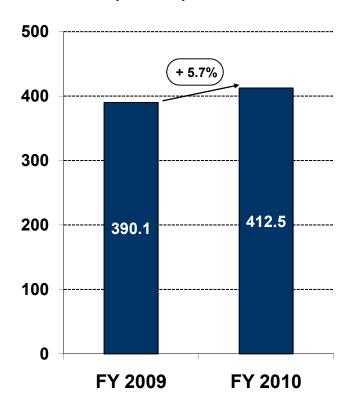


All following figures reflect the ongoing business if not expressly stated otherwise



Solid revenue growth

Revenue (in € m)

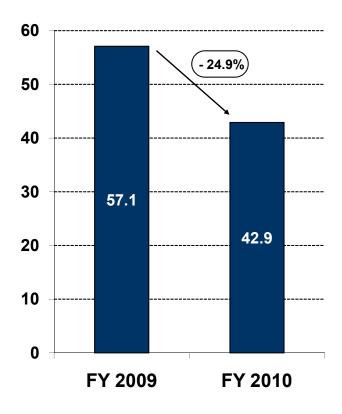


- FY Sales at € 412.5 m, a growth of 5.7% vs € 390.1 m in 2009, despite a difficult market environment
- Sales growth largely attributable to higher sales volumes
- Continuing price pressure for immunoglobulins and clotting factors
- Sales and earnings were reduced by approx.
 € 2 m as result of German healthcare reforms (GKV Änderungsgesetz)



Despite sales growth, EBIT decreased

EBIT (in € m)



- Despite 5.7% sales growth, EBIT decreased by 25% vs 2009
- Continuing price pressure for immunoglobulins and clotting factors
- Increase in volume could not compensate negative price effect
- Unfavorable product mix: more products sold with less attractive margins: plasma, clotting factors
- R&D expenses 5.6% higher than in 2009:

Plasma Proteins: + € 2.2 m Biotherapeutics: + € 0.4 m



FY 2010: EBIT Biotest Group (€ m)

Plasma Proteins
Biotherapeutics
Corporate
Biotest Group

FY 2010	FY 2009	Δ
73.5	89.2	- 17.6 %
- 21.7	- 21.1	- 2.8 %
- 8.9	- 11.0	+ 19.1 %
42.9	57.1	- 24.9 %

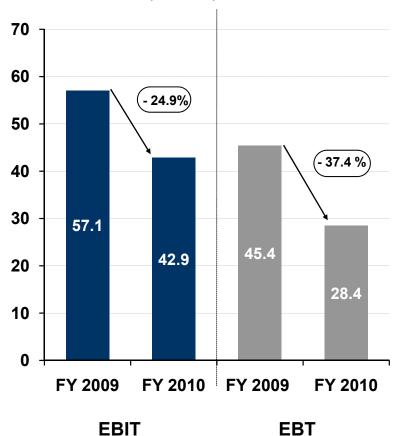


-€ 12.0 m

Sharp decrease in EBIT and EBT

in FY 2010

EBIT and EBT (in € m)



Financial result:

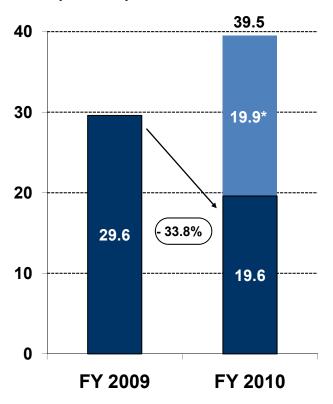
Financial Result FY 2009:

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Discount on Greek zero bonds	- € 5.6 m
Lower interest expenses	+ € 2.7 m
Other	+ € 0.1 m
Financial Result FY 2010:	- € 14.8 m



Low EAT

EAT (in € m)



- Tax rate 31.0% vs. FY 2009 34.8%
- Earnings after tax (Continuing Operations <u>and</u> Discontinued Operation) at € 39.5 m

 Earnings per Share: 	2010	2009
Per preference share	€ 1.70	€ 2.55
Per ordinary share	€ 1.64	€ 2.49

Dividend Proposal to AGM**	2010	2009
Preference share	€ 0.44	€ 0.40
Ordinary share	€ 0.38	€ 0.34

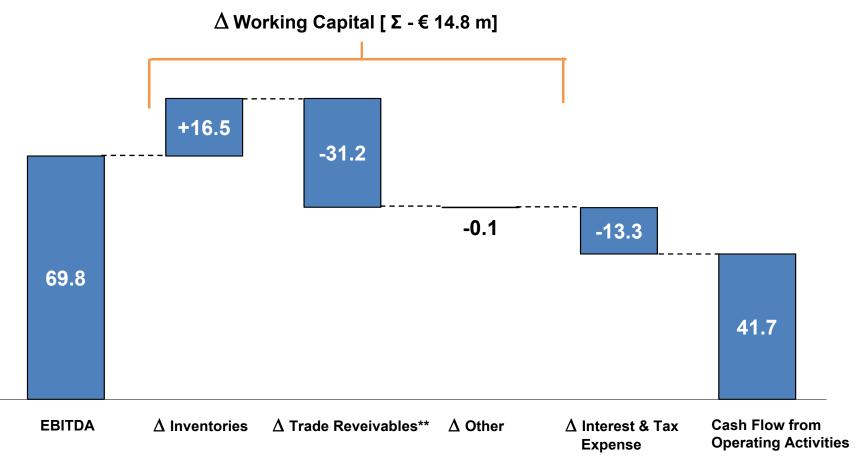
^{*}EAT of discontinued operations

^{**} Annual General Meeting takes place on May, 12th 2011 in Frankfurt



Cash Flow from Operating Activities in € m*

FY 2010 : January – December 2010



*Continued Operations **Reduction of €24.7 m Greek trade receivables without cash impact



Outlook

Guidance 2011:

Sales: Sales to grow with a low single digit percentage

compared to 2010

EBIT: EBIT to grow with a low single digit percentage

The guidance does not take into consideration possible earnings or income from an license agreement or our participation in another project in the Biotherapeutics segment. Also not included is any extraordinary income from discontinued operations.



Outlook Biotest Group

- Growing demand for IVIG with corresponding increasing prices mid of 2011
- Stable market for clotting factors and albumin
- Bivigam[™] market authorisation expected Q4 (2011); annual market potential ~ USD 100 m
- Promising R & D pipeline for Plasma Proteins and Biotherapeutics











Thank you



for your attention!



Contact and Financial Calendar 2011

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Financial Calendar 2011

May 10, 2011 Q1 Report 2011

May 12, 2011 Annual General Meeting

Aug 11, 2011 Q2 Report 2011

Nov 10, 2011 Analyst Conference

Nov 10, 2011 Q3 Report 2011