Biotest

From Nature for Life

Continuing on course

Q3 09

Key figures

Biotest Group		Q1-3 2009	Q1-3 2008	Change %
Revenue	€ million	361.9	323.0	12.0
thereof: Germany	€ million	89.5	85.1	5.2
Rest of World	€ million	272.4	237.9	14.5
thereof: Plasma Proteins	€ million	294.3	261.0	12.8
Medical Diagnostics	€ million	36.3	33.3	9.0
Microbiological Monitoring	€ million	31.3	28.7	9.1
EBITDA	€ million	65.6	62.3	5.3
EBIT	€ million	45.2	43.9	3.0
EBIT in % of revenue	%	*12.5*	*13.6*	
Earnings before tax	€ million	36.0	32.8	9.8
Earnings after tax	€ million	25.1	22.7	10.6
Earnings per share	€	1.97	1.78	10.7
Cash flow*	€ million	8.2	25.5	–67.8
Depreciation and amortisation	€ million	20.4	18.4	10.9
		30 Sept. 2009	**31 Dec. 2008**	
Equity	€ million	269.1	253.4	6.2
Equity ratio	%	*41.8*	*42.8*	
Employees (full-time equivalents)		2,134.7	1,952.3	9.3

* from operating activities

Biotest AG

Q3 2009 | Nine-month Report

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Content

Interim management report as of 30 September 2009

At a glance

The economic environment for manufacturers of plasma proteins, and consequently for the Biotest Group too, became more competitive in the third quarter. Increasing signs of an expanding supply of immunoglobulins accelerated the decline in prices, most notably in the European market. Despite the resulting adverse effects, the Biotest Group once again achieved a significant increase on its previous year's sales in all segments in the third quarter. In the first nine months, the Biotest Group increased sales by 12.0%.

Earnings before interest and tax (EBIT) of €45.2 million were up 3.0% year-on-year. This lower rise in earnings compared with sales is due to a higher cost of sales ratio, increased expenses for the clinical development of plasma proteins and biotherapeutics and the ongoing high level of fixed costs during the expansion phase of production in Boca Raton. In the third quarter, Biotest achieved three important milestones with the positive opinion by the CHMP (Committee for Medicinal Products for Human Use) for EU-wide approval of Zutectra®, a hepatitis B immunoglobulin, publication of further positive efficacy data for the monoclonal antibody BT-061 and the start of clinical development of BT-063.

In light of the successful development in the first nine months, the Board of Management of Biotest AG has confirmed its target of increasing sales by 10% in 2009 as a whole and matching the previous year's EBIT level.

Corporate strategy and implementation

In the current reporting year, the Biotest Group is adhering to its strategy and key corporate targets detailed in the 2008 Annual Report.

In October 2009, Biotest AG reached an agreement with Bio-Rad Laboratories, Inc. (Hercules, California/USA) for the sale of major parts of its Medical Diagnostics segment. Once approved by the anti-trust authorities, the transaction is expected to close in the first quarter of 2010 (see events after the end of the third quarter).

We responded to lower market expectations for plasma proteins, and for polyspecific immunoglobulins in particular, in the third quarter by cautiously adjusting our activities in plasma collection and processing. Through this timely action, we are counteracting the future increase in inventories of preliminary products and the amount of capital employed.

Market environment

Macroeconomic situation

Following the dramatic collapse in the economy in the fourth quarter of 2008 and at the beginning of 2009, there are now increasing signs that the situation will in general bottom out faster than initially feared. Nevertheless, government finances have deteriorated overall as a result of the costs incurred in stabilising the financial markets and stimulating economic activity, plus the reduction in tax revenue. However, to date, this has not had any serious adverse effects on the health budgets.

Developments in the industry

In the third quarter, growth rates in our key sales markets slowed somewhat. Nevertheless, in a nine-month comparison we recorded rising demand across all major product areas. At the same time, pressure on prices increased perceptibly in the third quarter. As a result, the Biotest Group's growth will not be price-driven for the foreseeable future, but will be based on an increase in sales volumes and the launch of products in new markets.

Plasma Proteins

According to the market estimates available to date, global demand for immunoglobulins will rise by 5% to 6% this year. The factors driving growth remain the same: the range of indications for which immunoglobulins are prescribed is increasing and new therapeutic findings are leading to higher dosages being used for each patient treated. In addition, markets in countries that were previously characterised by an undersupply of immunoglobulins are now being increasingly developed. The demand for albumin as well as for factor VIII remains stable.

Producers have responded decisively to the rise in demand, with volume increasing sharply both in plasma raw material and its end products. Forecasts a few months ago were already predicting slight excess supply for the second half of 2009, which could extend into subsequent years unless counteracting measures are adopted. These market expectations have put the price of immunoglobulins under greater pressure in the third quarter. Primarily affected are polyspecific immunoglobulins, including Biotest product Intratect®. In Europe, prices fell by up to 20% compared with the end of 2008, while the US market remained more stable. Coagulation factors and albumin are also currently trending downwards. In contrast, hyperimmunoglobulins, where Biotest has a particularly substantial share of the market, have not been affected by the downward trend in prices.

Medical Diagnostics

The European market for products for transfusion and transplantation diagnostics remained difficult in the third quarter. Fierce competition and the low willingness to buy on the part of customers put a great deal of pressure on prices and margins. A different picture was seen in the USA, where because of the particularly strict approval requirements, there are only two other full service providers of blood group diagnostics in addition to Biotest. Accordingly, prices remained at a satisfactory level.

Microbiological Monitoring

Demand and prices for hygiene monitoring products have risen slightly in the year to date. In this segment, Biotest predominantly operates as a system supplier to the pharmaceutical industry, which uses our products to meet hygiene monitoring and documentation requirements. The trend in sales is proving to be comparatively robust even in times of economic crisis.

Business development

In the third quarter, Biotest more than offset the decline in prices through strong growth in sales volumes. The rise in sales in the first nine months of 2009 totalled 12.0%, with a lower increase of 9.5% for the third quarter as a result of pricing. It should be noted that all producing segments contributed to the Biotest Group's stable growth; the Plasma Proteins segment remains buoyant and 81.3% of the Biotest Group's sales (previous year: 80.8%) were attributable to these products.

Revenue by segment

€ million	Q1-3 2009	Q1-3 2008	Change %
Plasma Proteins	294.3	261.0	12.8
Medical Diagnostics	36.3	33.3	9.0
Microbiological Monitoring	31.3	28.7	9.1
Biotest Group	**361.9**	**323.0**	**12.0**

The export ratio rose from 73.7% in the previous year to 75.3%. The main factor here was the substantial expansion of business volume in Asia, where the comparative figure in 2008 was exceeded by 43.6%.

Plasma Proteins

The increase in revenues in the Plasma Proteins segment of 12.8% to €294.3 million (previous year: €261.0 million) was primarily due to successful sales of immunoglobulins. There has been a substantial increase in manufacturing capacity for these since the second plant for

chromatographic purification was approved in March 2009. For our polyspecific immunoglobulin Intratect®, a negative impact on prices was more than offset by the increase in sales in the rest of Europe. Sales of the hyperimmunoglobulin Hepatect® were also up on the previous year, as was the coagulation factor Haemoctin®. We also supplied the Russian market with Haemoctin® as part of the tender business; a substantial proportion of these transactions are covered against debt defaults.

Growth in business volumes in Asia in all product groups was especially pleasing. Within Europe, besides the German market, business developed positively in Austria and Hungary. In the United Kingdom, we were able to build on the previous year's sales despite the price pressure on Intratect®.

Medical Diagnostics

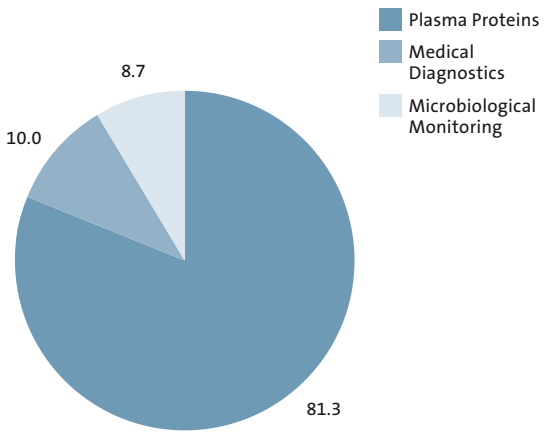
In Medical Diagnostics, which is for sale, revenues in the first nine months of 2009 totalled €36.3 million, an increase of 9.0% on the previous year (€33.3 million). The rise was due almost exclusively to the US market, where sales virtually doubled. Our strategic decision to operate as a full service provider of manual and automated transfusion diagnostics via Biotest Diagnostics Corporation is consequently beginning to bear fruit. However, the critical mass within the Biotest Group is too small to ensure sustained growth. The segment will be able to exploit its potential much better as an integrated part of Bio-Rad.

In September 2009, Biotest Diagnostics Corporation (BDC) agreed on a multi-year sales agreement with Premier Purchasing Partners L.P., a purchasing unit of Premier, Inc. This covers the immunohaematology product group of Biotest Medical Diagnostics GmbH (BMD) and includes traditional blood bank reagents as well as the automated TANGO® optimo blood bank system. The contract between BMD and Premier is a strategic step to guarantee hospitals and laboratories access to cost-effective blood bank systems, thereby enhancing efficiency and productivity in blood-typing.

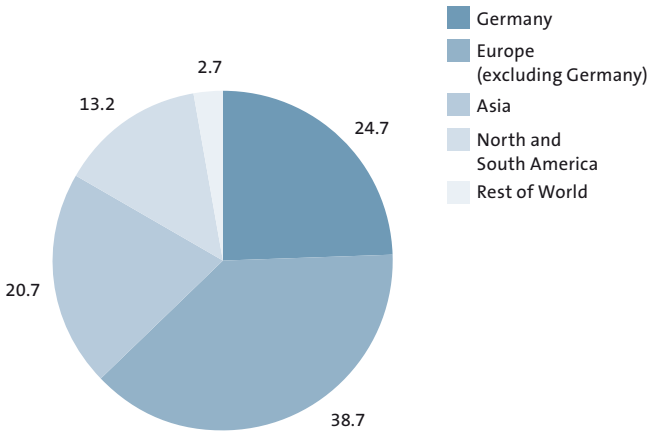
Microbiological Monitoring

In the third quarter, the Microbiological Monitoring segment seamlessly continued the successful development of the first half of 2009. In the period under review, the segment achieved sales of €31.3 million, up 9.1% on the previous year. Our affiliated company heipha Dr. Müller GmbH accounted for a significant portion of these sales. There was continuing strong demand for the data matrix-coded ICRplus plates

Revenue by segment in %



Revenue by region in %

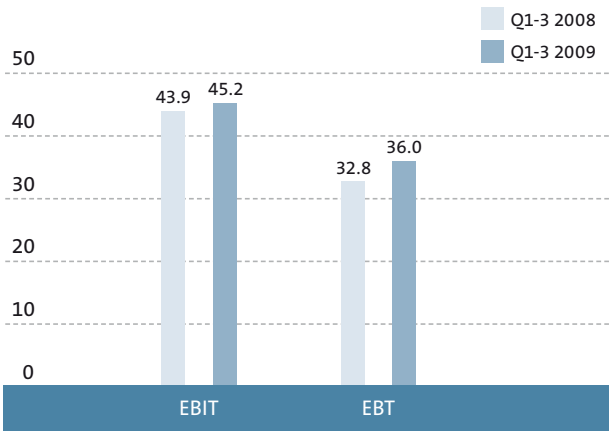


launched in the previous year, with the result that sales were up by around a third year-on-year. These products allow the bacterial load on surfaces to be measured in an easy and safe manner, and to be processed further electronically. heipha Dr. Müller GmbH products now account for around two thirds of the segment's sales.

Earnings position

At €45.2 million, earnings before interest and tax (EBIT) were up 3.0% on the previous year's figure (€43.9 million). The return on sales determined on the basis of EBIT decreased from 13.6% to 12.5%. The annualised return on capital employed (RoCE) decreased to 10.3% (previous year: 11.0%). The change in the relative ratios primarily reflects the price pressure on plasma proteins. The somewhat less favourable sales mix in the Plasma Proteins segment also had an impact. A greater proportion of sales than in the previous year was attributable to the comparatively low margin plasma raw material. We aim to process a greater proportion of this plasma originating from our own donation centres and consequently to generate additional value added. A third reason for the reduction in margins is the renovation and expansion of the production plant in Boca Raton. The plant will probably be out of commission until November 2009, resulting in idle-capacity and contingency costs.

EBIT and EBT in € million



EBITDA increased by 5.3% year-on-year to €65.6 million (previous year: €62.3 million). The slightly higher rise compared with EBIT reflects the increase in the Biotest Group's depreciation and amortisation charges, which rose by 10.9% to €20.4 million (previous year: €18.4 million).

Earnings before tax in the third quarter is on the previous year's level. In the first nine months, it stood at €36.0 million (previous year: €32.8 million). After income tax of €10.9 million, which equates to a tax ratio of 30.3%, a profit for the period of €25.1 million remains (previous year: €22.7 million). This produces earnings per share of €1.97 (previous year: €1.78).

The Biotest Group's EBIT is again primarily attributable to the Plasma Proteins segment, which contributed €63.7 million (previous year: €60.1 million), a rise of 6.0%. In Microbiological Monitoring, at €3.7 million, Biotest almost matched the previous year's figure (€3.9 million), while Medical Diagnostics was able to reduce its negative earnings contribution to €–1.4 million (previous year: €–2.5 million). The Biotherapeutics segment's result of €–13.2 million (previous year: €–10.1 million) illustrates the increasing cost of research and development caused by the increasingly advanced stage of clinical development.

Expenses

The higher cost of sales ratio in a nine month comparison is caused by reduced margins and the somewhat less favourable product mix in Plasma Proteins. While prices of end products decreased, the high plasma input costs remained virtually unchanged.

The rise in distribution expenses was primarily due to commission payments and was consequently attributable to growth. However, the ratio of distribution expenses to sales declined by 1.2 percentage points.

Key cost pools of the Biotest Group*

€ million	Q1-3 2009	% of sales	Q1-3 2008	% of sales
Cost of sales	–188.1	52.0	–158.5	49.1
Distribution expenses	–64.2	17.7	–61.1	18.9
Administration expenses	–27.1	7.5	–27.2	8.4
Research and development expenses	–34.1	9.4	–30.2	9.3
Balance of other operating income and expenses	–3.2	0.9	–2.1	0.7
Financial result	–9.2	2.5	–11.1	3.4

* Expenses are marked with a negative prefix

The Biotest Group invested 9.4% of consolidated sales (previous year: 9.3%) in research and development; 37.3% of the expenses amounting to €34.1 million was attributable to research and development of biotherapeutics and 55.7% to the Plasma Proteins segment.

Financial position and statement of assets

In the current financial year, Biotest adhered to its long-term, balanced financing strategy. Key points of this strategy are maintaining an equity ratio of at least 40%, securing permanent debt financing via long-term credit agreements, financing clinical development projects internally from current operating cash flow and ensuring sufficient liquidity at all times. Current financial liabilities serve primarily as a means of pre-financing and interim financing for sales.

Capital expenditure, depreciation and amortisation

In the period under review, Biotest invested €31.6 million (2008: €22.8 million). Of the additions to the balance sheet, €30.4 million (previous year: €19.6 million) was attributable to investment in property, plant and equipment and €1.2 million to the purchase of intangible assets. The most important investment project is the expansion of the production plant for immunoglobulins in Boca Raton. In the third quarter, we also acquired an additional plot plus buildings in the immediate vicinity in Dreieich on favourable terms, which we will strategically use for our expansion plans.

Investment was countered by depreciation and amortisation of €20.4 million (2008: €18.4 million) with the result that net investment, at €11.2 million, far exceeded the comparative figure in 2008 (€4.4 million).

Cash flow

At €8.2 million, cash flow from operating activities was significantly down on the previous year's figure of €25.5 million, essentially as a result of the sharp rise in working capital.

The majority of the extensive investment programme was financed by debt. The cash flow relating to investing activities of €–30.5 million was countered by a cash flow from financing activities of €19.9 million; this figure includes the dividend payment by Biotest AG of €3.8 million in the second quarter. Overall, the cash and cash equivalents reported in the balance sheet decreased from €8.1 million to €5.7 million. As Biotest has access to unused short-term credit lines at all times, it only holds the cash and cash equivalents needed for its current business operations.

Balance sheet structure

During the year to date, the Biotest Group's balance sheet has been extended by 8.9% or €52.5 million to €644.5 million. On the assets side, non-current assets show only a slight rise of 1.6%. The rise in current assets, which is essentially due to the change in working capital, was the main reason for the extension in the balance sheet. The increase in inventories of 17.1% was attributable to growth as a result of lengthy production times, but also to the fact that the product volumes sold were lower than planned. The 20.0% increase in accounts receivable is primarily the result of higher sales in the Plasma Proteins segment.

The liabilities side shows that the Biotest Group's financing structure remains stable. Equity rose from €253.4 million at the end of 2008 to €269.1 million and the equity ratio stood at 41.8% on the quarterly reporting date (end of 2008: 42.8%). Non-current liabilities totalled €223.3 million (end of 2008: €220.3 million) and consequently accounted for 34.6% of the financing side. As a result, 84.8% of non-current assets were covered by equity as of 30 September 2009.

The increase in current liabilities of 28.6% to €152.1 million on the liabilities side corresponds with the change in working capital; the rise was largely attributable to financial liabilities.

As of 30 September 2009, Biotest had a substantial amount of unused long-term and short-term credit lines at its disposal. In May 2009, we extended our financing options through the agreement of a two-year working capital credit facility of €40 million.

Research and development

Plasma Proteins

Zutectra®, the world's first Hepatitis B immunoglobulin for subcutaneous administration, will be launched throughout the EU shortly. The "Committee for Medicinal Products for Human Use" (CHMP), the scientific committee of the European Medicines Agency (EMEA), adopted a positive opinion for Zutectra® in September 2009. This is based on extensive data, which was submitted to the EMEA and assessed in the course of the centralised approval procedure. On the basis of this positive opinion by the CHMP, we expect to receive final approval to market the drug throughout the EU following a formal review by the European Commission by the end of December. This would be the first EU-wide approval of a Biotest Group pharmaceutical drug under the centralised procedure.

Zutectra® was developed by Biotest specifically for the long-term treatment of patients following liver transplantation; it represents a time-saving and simplified treatment option for the attending physician and the patient. Zutectra® supplements the immunoglobulin Hepatect® CP, which remains essential for high-dose treatment in the first phase of the transplantation. We aim to expand our leading position in the global market for the prophylaxis of hepatitis B reinfection after liver transplantation with this product portfolio.

In the third quarter, we continued the clinical Phase III trial for approval of Cytotect® to treat cytomegalovirus infections during pregnancy. We aim to recruit patients more efficiently, and consequently more rapidly, by focusing on large clinical centres and including other international clinics for this trial.

Having started the clinical Phase I trial for the new IgM concentrate in the second quarter, we were able to include and treat all 24 planned participants in the trial in the last quarter. No serious side effects appeared in the treatment phase. Following treatment, participants move into a 13-week observation phase. This trial focuses on the safety and tolerability of the new IgM concentrate in healthy subjects.

Medical Diagnostics

In the period under review, Biotest Medical Diagnostics GmbH continued to work on optimising serological reagents and finding additional solutions for simplifying and automating transfusion diagnostic processes, with particular attention being paid to the needs of the US market.

In the transplantation diagnostics area, we also continued working on the development of a system for the molecular typing of donors and recipients in organ or bone marrow transplants.

Microbiological Monitoring

In July 2009 we launched newly developed PCR test kits for the detection of bacterial pathogens (e.g. salmonella) in food products. These test kits are used in the food industry for quality assurance purposes in order to ensure

compliance with the statutory regulations and standards in a whole range of different areas, e.g. baby food, dairy products, etc. In September 2009, we launched a quick test (real-time PCR technology) for monitoring cleanroom hygiene in the pharmaceuticals industry. This innovative test, which is used to identify frequently occurring microorganisms quickly and simply, is based on molecular genetic methods and constitutes a good addition to our culture media portfolio for this target group.

Biotherapeutics

We have achieved several milestones in the development of monoclonal antibodies.

Further data is now available on the efficacy of the monoclonal antibody BT-061, which we are developing to treat rheumatoid arthritis and psoriasis.

In an ongoing placebo-controlled Phase II trial in the indication of rheumatoid arthritis, more than half the patients in the relevant dosage groups treated subcutaneously or intravenously over a period of only six weeks showed a considerable improvement in their symptoms based on ACR (American College of Rheumatology) criteria. The maximum improvement in symptoms measured here is usually only achieved after three to six months when using other biotherapeutic treatments.

Following the positive results for the monotherapy in the indication rheumatoid arthritis (RA), data from the first unblinded part of a Phase II combination trial with methotrexate also became available in the third quarter of 2009. These show efficacy of BT-061 also as part of a combination therapy. In this clinical trial, 40 patients with acute, moderate to severe RA, who previously had not responded to one or more disease-modifying antirheumatic drugs (DMARDs), have been assessed so far.

At the same time, the good tolerability and positive safety profile of the antibody in the indication psoriasis were confirmed (see events after the end of third quarter).

We continued the Phase I trial for the development of BT-062 in the indication of multiple myeloma as planned. The immunoconjugate comprising the monoclonal antibody and a highly potent cytotoxic compound is being tested by renowned cancer centres in the USA. In some study participants, the very aggressive course of the disease came to a standstill, at least temporarily even following the administration of relatively low dosages. In some participants, the positive effect lasts for several months.

Clinical development of the antibody BT-063 started in the third quarter of 2009. Following approval of the Phase I trial by the authority in charge and the ethics commission, BT-063 was administered to the first study participants in September. BT-063 is being developed in the lead indication systemic lupus erythematosus (SLE). The monoclonal antibody specifically neutralises a cell growth factor, playing an important role in the onset and development of the disease. 24 healthy volunteers will participate in the monocentric Phase I trial. The aim of this unblinded trial is to test the safety and tolerability of the agent in humans as part of a dosage escalation programme.

This means that all three monoclonal antibodies in the Biotest pipeline are now undergoing clinical trials.

Personnel

In the third quarter, the number of employees (full-time equivalent) rose slightly by 1.7% to 2,135. Compared with the end of 2008, the increase amounted to 9.3%. Of the approximately 180 new full-time equivalent positions created since the beginning of the year, about two thirds were attributable to the Plasma Proteins segment (mainly in the plasma donation centers). The number of jobs in the Biotherapeutic segment has virtually doubled because of ongoing projects. However, given the current market situation, the Group's approach to new recruitment is extremely cautious.

Risk and opportunities report

Risks

During the year to date, there has been no material change in the Biotest Group's risk situation compared to the situation described in the risk report that is included in the 2008 Annual Report 2008 (pages 79–86).

The sales market risks listed there, particularly with regard to the price risks for plasma proteins and increased inventories of preliminary and finished products, have been confirmed in the current year and have, in part, occurred. Biotest counters this risk by adopting a forward-looking and cautious approach to managing its capacity in plasma collection and processing.

Biotest reached a final agreement in the dispute with Nabi Biopharmaceuticals in the third quarter, as described in detail in the 2009 Interim Report. The funds still held in an escrow account will be paid to Nabi as soon as the corresponding documentation relating to the agreement has been issued and signed.

It is the opinion of the Board of Management that Biotest is presently not subject to any risks extending beyond those which are an inevitable part of its business operations. No risks are currently evident which might jeopardise the financial stability of the Biotest Group.

Opportunities

Through the planned sale of the Medical Diagnostics division, Biotest will generate a funds inflow of €45 million in the first quarter of 2010, which we will initially use to reduce current liabilities. In the future, we will be able to utilise this greater financial scope for development and investment projects.

Furthermore, we confirm the presentation of the opportunities for the Biotest Group contained in the 2008 Group management report.

Outlook

With regard to the Biotest Group, the Board of Management is confirming the target set out in the 2008 Annual Report, namely to achieve a 10% year-on-year increase in sales this year. As far as EBIT is concerned, our objective remains to match the very good result achieved in 2008.

This confirmation of our sales and profit targets is given explicitly against the background of the particular challenges resulting from the current market environment.

Biotest will adhere to its Group strategy of long-term value enhancement until the end of 2009 and beyond. This policy also encompasses the financing strategy.

Expected economic environment

We estimate that demand for plasma proteins will continue to grow, although it is likely to lose some momentum. We expect prices of polyvalent immunoglobulins, in particular, to remain under pressure until the end of the year and beyond; following the sharp decline in the European market, it is likely that the negative trend will also affect the US market. However, we continue to see no evidence suggesting that a collapse in prices or volumes is imminent.

In the medium term, we expect that the surplus supply will be reduced in subsequent years, due to a reduction in plasma donation volumes among other factors.

Another negative factor is the difficult state budget situation as a result of the financial market and economic crisis. To safeguard our accounts receivable, we have assigned a proportion to factoring companies and are also using credit insurance.

Expected business development

For the Plasma Proteins segment, we are assuming that sales will continue to grow in the fourth quarter, albeit not at the rate achieved in previous quarters.

Sales growth is likely to continue in Medical Diagnostics, driven by transfusion diagnostics in the USA.

In the Microbiological Monitoring segment, we expect a stable upward trend that is largely independent of economic growth until the end of the year, which will be primarily attributable to the business development of heipha Dr. Müller GmbH.

We will consistently progress the various clinical development projects in the Biotherapeutic segment.

Future financial position

A significant proportion of these projects will continue to be financed by debt. Our expectation is that the liquidity situation up to the end of the year will not differ materially from the situation as of 30 September 2009.

Events after the end of the third quarter

Sale of Medical Diagnostics division

In October 2009, Biotest AG reached an agreement with Bio-Rad Laboratories, Inc. (Hercules, California/USA) to sell a major part of its Medical Diagnostics segment. The transaction is subject to certain closing conditions, including merger approval, and is expected to close in the first quarter of 2010.

The transaction covers all shares in Biotest Medical Diagnostics GmbH (Dreieich) and Biotest Diagnostics Corporation (Rockaway/USA). In addition, Bio-Rad will acquire most of the business operations of the Biotest Group's international subsidiaries attributable to the Medical Diagnostics division under an asset deal. The deal does not include Viro-Immun Labor-Diagnostika GmbH (Oberursel).

With the agreed sale, the Biotest Group is focusing even more closely than before on the development and marketing of innovative, pharmaceutical and biotherapeutic drugs in immunology and haematology.

Bio-Rad is one of the leading global providers of life science research and clinical diagnostics. Integration in the global Bio-Rad Group will open up better growth prospects for Medical Diagnostics.

Clinical development milestones

In October 2009, we published further preliminary data on the efficacy of the monoclonal antibody BT-061 in the indication rheumatoid arthritis. In the unblinded first part of a Phase II combination trial with methotrexate, BT-061 provided positive results. So far, the data of 40 patients with acute, moderate to severe RA, with inadequate response to one or more disease-modifying antirheumatic drugs (DMARDs), have been analysed.

Patients included in the clinical trial were randomly assigned to three different treatment groups. The response rate of patients at week 9 (after 8 weeks of treatment) was evaluated on the basis of the ACR score, the internationally accepted standard rating system developed by the American College of Rheumatology.

In the group receiving 2mg of BT-061, the efficacy at week 9 was higher than in the 0.5mg group and the placebo arm. In 75% of patients of the 2mg group symptoms improved by 20% (ACR 20 response), compared with 50% of patients in the placebo group. A reduction in symptoms of at least 50% was achieved in 41.7% of patients receiving the combination therapy (ACR 50: 41,7%) and 16.7% of patients showed an improvement of symptoms of a minimum of 70% (ACR 70: 16.7%). For treatment with methotrexate alone (placebo group), the relevant values were 25% and 0% respectively. The relatively high response rate of the placebo drug is most probably caused by the simultaneous administration of methotrexate, known to be effective in the treatment of RA.

BT-061 has been administered intravenously to the patients included in this trial so far. In accordance with the study protocol, a further 40 patients will subsequently be included in the second part of this trial and treated subcutaneously. This mode of application is the target of the clinical development as it enables patients to self-medicate at home.

The recruitment of the final patient in the Phase I/II trial in the indication psoriasis was completed at the beginning of November 2009. The antibody trial included a total of 56 patients who were given a single intravenous or subcutaneous injection of the antibody and included in the study. Blinded data show an improvement in 75% of the patients in the therapeutically relevant dosage group. In the best case a reduction in the PASI (Psoriasis Area and Severity Index) score of 88% was achieved. A detailed analysis of the trial is to be presented at international scientific conferences.

Income statement

of the Biotest Group

€ million	Q3 2009	Q3 2008	Q1-3 2009	Q1-3 2008
Revenue	122.7	112.1	361.9	323.0
Cost of sales	−66.8	−56.3	−188.1	−158.5
Gross profit	**55.9**	**55.8**	**173.8**	**164.5**
Other operating income	2.4	1.1	7.1	3.2
Distribution expense	−19.7	−22.7	−64.2	−61.1
Administrative expense	−8.9	−8.7	−27.1	−27.2
Research and development expense	−11.5	−7.9	−34.1	−30.2
Other operating expenses	−2.4	−1.3	−10.3	−5.3
Operating profit	**15.8**	**16.3**	**45.2**	**43.9**
Financial result	−3.2	−3.7	−9.2	−11.1
Earnings before tax	**12.6**	**12.6**	**36.0**	**32.8**
Income tax	−3.5	−4.3	−10.9	−10.1
Earnings after tax	**9.1**	**8.3**	**25.1**	**22.7**
thereof:				
Retained earnings attributable to equity holders of the parent company	**8.4**	**7.7**	**23.1**	**20.9**
Minority interest	0.7	0.6	2.0	1.8
Earnings per shave in €	**0.72**	**0.66**	**1.97**	**1.78**

Consolidated statement of recognised income and expenses

of the Biotest Group

€ million	Q1-3 2009	Q1-3 2008
Differences from currency translation	−3.8	2.0
Income and expenses recognised directly in equity	**−3.8**	**2.0**
Earnings after tax	25.1	22.7
Total recognised income and expenses	**21.3**	**24.7**
Attributable to:		
Equity holders of the Company	19.3	22.9
Minority interest	2.0	1.8
Total recognised income and expenses	**21.3**	**24.7**

Balance sheet

of the Biotest Group

€ million	30 September 2009	31 December 2008
ASSETS		
Intangible assets	67.2	73.8
Property, plant and equipment	222.4	209.8
Financial lease assets	18.5	20.1
Investments in affiliates	0.1	0.1
Other investments	0.2	0.2
Trade receivables	0.5	0.4
Others assets	1.6	2.1
Deferred tax assets	6.9	6.0
Non-current assets	**317.4**	**312.5**
Inventories	183.4	156.6
Trade receivables	112.8	94.0
Current income tax assets	2.5	2.4
Other assets	22.7	18.4
Cash and cash equivalents	5.7	8.1
Current assets	**327.1**	**279.5**
TOTAL ASSETS	**644.5**	**592.0**
EQUITY AND LIABILITIES		
Subscribed capital	30.0	30.0
Share premium	153.3	153.3
Reserves	57.9	39.9
Retained earnings attributable to equity holders of the parent company	23.1	25.7
Shareholders' equity	**264.3**	**248.9**
Minority interest	4.8	4.5
Total Equity	**269.1**	**253.4**
Provisions for pensions and similar obligations	45.5	43.4
Other provisions	4.5	3.7
Financial liabilities	164.8	166.6
Other liabilities	0.3	0.2
Deferred tax liabilities	8.2	6.4
Non-current liabilities	**223.3**	**220.3**
Other provisions	14.7	19.3
Current income tax liabilities	6.5	4.7
Financial liabilities	53.1	28.2
Trade payables	48.2	48.7
Other liabilities	29.6	17.4
Current liabilities	**152.1**	**118.3**
Total liabilities	**375.4**	**338.6**
TOTAL EQUITY AND LIABILITIES	**644.5**	**592.0**

Statement of changes in equity

€ million	2009	2008
Equity as of 1 January	**253.4**	**225.8**
Dividend payments to shareholders	–3.8	–3.8
Earnings after tax	25.1	22.7
Differences from currency translation	–3.8	2.0
Dividend to minority interest	–1.7	–0.1
Equity as of 30 September	**269.2**	**246.6**

Cash flow statement

€ million	2009	2008
Cash flow		
Cash flow from operating activities	8.2	25.5
Cash flow from investing activities	–30.5	–22.0
Cash flow from financing activities	19.9	–1.4
Cash changes in cash and cash equivalents	**–2.4**	**2.1**
Exchange rate-related changes	0.0	0.3
Cash and cash equivalents as of 1 January	8.1	8.9
Cash and cash equivalents as of 30 September	**5.7**	**11.3**

Schedule of assets – net presentation

€ million	Book value as of 1 January 2009	Capital expen-diture	Net disposals	Scheduled depre-ciation	Depre-ciation PPA*	Impair-ment	Currency translation differences	Book value as of 30 September 2009
Intangible assets	73.8	1.2	0.0	–2.2	–3.0	0.0	–2.6	67.2
Tangible assets	229.9	30.4	–1.2	–14.7	–0.3	–0.2	–3.0	240.9
Total	**303.7**	**31.6**	**–1.2**	**–16.9**	**–3.3**	**–0.2**	**–5.6**	**308.1**

* PPA= Purchase Price Allocation

Segment reporting
by business segment

€ million	Q1-3 2009	Q1-3 2008	Change in %
Revenue			
Plasma Proteins	294.3	261.0	12.8
Medical Diagnostics	36.3	33.3	9.0
Microbiological Monitoring	31.3	28.7	9.1
Biotest Group	**361.9**	**323.0**	**12.0**
EBIT			
Plasma Proteins	63.7	60.1	6.0
Medical Diagnostics	−1.4	−2.5	44.0
Microbiological Monitoring	3.7	3.9	−5.1
Corporate/Reconciliation	−7.6	−7.5	−1.3
Biotherapeutics	−13.2	−10.1	−30.7
Biotest Group	**45.2**	**43.9**	**3.0**

Segment reporting
by region

€ million	Q1-3 2009	Q1-3 2008	Change in %
Revenue			
Germany	89.5	85.1	5.2
Europe (excluding Germany)	140.2	131.3	6.8
North and South America	47.6	46.4	2.6
Asia	74.8	52.1	43.6
Rest of World	9.8	8.1	21.0
Biotest Group	**361.9**	**323.0**	**12.0**

Employees
by business segment

	30 September 2009	31 December 2008	Change in %
Employees (full-time equivalents)			
Plasma Proteins	1,481.1	1,356.7	9.2
Medical Diagnostics	290.5	274.1	6.0
Microbiological Monitoring	282.1	269.8	4.6
Corporate / Reconciliation	23.1	13.5	71.1
Biotherapeutics	57.9	38.2	51.6
Biotest Group	**2,134.7**	**1,952.3**	**9.3**

Employees
by operating division

	30 September 2009	31 December 2008	Change in %
Employees (full-time equivalents)			
Distribution	420.8	398.2	5.7
Administration	255.0	246.0	3.7
Production	1,276.9	1,149.8	11.1
Research and development	182.0	158.3	15.0
Biotest Group	**2,134.7**	**1,952.3**	**9.3**

Quarter-to-quarter comparison
by business segment

€ million	Q3 2009	Q2 2009	Q1 2009	Q4 2008	Q3 2008
Revenue					
Plasma Proteins	100.0	96.9	97.4	78.5	91.5
Medical Diagnostics	12.0	12.6	11.7	11.9	10.8
Microbiological Monitoring	10.7	10.3	10.3	9.6	9.8
Biotest Group	**122.7**	**119.8**	**119.4**	**100.0**	**112.1**
EBIT					
Plasma Proteins	21.0	22.9	19.8	21.1	21.5
Medical Diagnostics	−0.1	−1.0	−0.3	−0.8	−0.6
Microbiological Monitoring	1.4	1.1	1.2	1.1	1.1
Corporate/Reconciliation	−2.1	−2.9	−2.6	−3.1	−2.7
Biotherapeutics	−4.4	−5.1	−3.7	−6.6	−3.0
Biotest Group	**15.8**	**15.0**	**14.4**	**11.7**	**16.3**
Earnings before tax	**12.6**	**12.2**	**11.2**	**7.7**	**12.6**

Other information

Accounting principles

The interim report as of 30 September 2009 has been prepared in accordance with the International Financial Reporting Standards of the International Accounting Standards Board (IASB). There have been no changes with regard to the accounting and valuation methods used compared with those used in the consolidated financial statements for 2008. The interim management report and interim financial statements are neither audited nor are they subject to review by an auditor.

No major transactions were concluded with related parties in the period under review.

Dreieich, 5 November 2009
Biotest Aktiengesellschaft

The Management Board

Prof. Dr. Gregor Schulz
Chairman of the
Management Board

Dr. Michael Ramroth
Chief Financial Officer

Financial calendar

19 March 2010	Full-year results Analysts' Conference
6 May 2010	Annual General Meeting
12 May 2010	I. Quarterly Report 2010
11 August 2010	II. Quarterly Report 2010
8 November 2010	III. Quarterly Report 2010 Analysts' Conference

Biotest

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This quarterly report 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 of this quarterly report. Biotest does not intend to update the forward-looking statements and assumes no obligation to do so.