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**MANAGEMENT REPORT.** 2009 was a successful year for the Fresenius Group. We again achieved record levels in sales and earnings across all business segments. Our debt ratios were substantially improved thanks to very good cash flow development.

**OPERATIONS AND BUSINESS ENVIRONMENT**

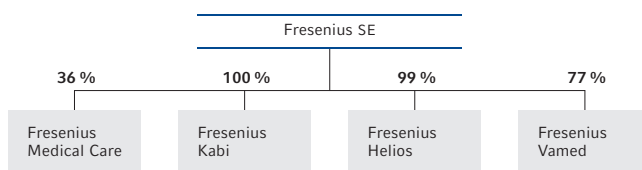
**GROUP STRUCTURE AND BUSINESS**

Fresenius is an international health care group with products and services for dialysis, hospitals, and outpatient medical care. In addition, Fresenius focuses on hospital operations and offers engineering and services for hospitals and other health care facilities. Fresenius is organized in the legal form of a European Company (Societas Europaea or SE). The conversion (from a German stock corporation or AG) became effective with its entry into the Commercial Register on July 13, 2007. The operating business comprises the business segments, all of which are legally independent entities man-

aged by the operating parent company Fresenius SE. This Group structure has been in place since January 1, 2008, and has not changed in the reporting period.

- ▶ Fresenius Medical Care is the world’s leading dialysis company, with products and services for patients with chronic kidney failure. As of December 31, 2009, Fresenius Medical Care treated 195,651 patients at 2,553 dialysis clinics.
- ▶ Fresenius Kabi specializes in infusion therapies, intravenously administered drugs (IV drugs), and clinical nutrition for critically and chronically ill people in hospitals and outpatient care. The company is also a leading supplier of medical devices and products in the area of transfusion technology.
- ▶ Fresenius Helios is one of the largest private hospital operators in Germany. The HELIOS-Kliniken Group operates 61 proprietary clinics, of which 60 are located in Germany and one in Switzerland. HELIOS has a total of more than 18,500 beds.
- ▶ Fresenius Vamed provides engineering and services for hospitals and other health care facilities internationally.

**GROUP STRUCTURE**



- ▶ The segment Corporate/Other comprises the holding activities of Fresenius SE, the IT service provider Fresenius Netcare, and Fresenius Biotech. Fresenius Biotech is active in research and development in the field of antibody therapies. Corporate/Other also includes the consolidation measures conducted among the business segments.

The Fresenius Group operates internationally and all business segments have a regional and decentralized structure. Responsibilities are clearly defined in line with the Company's "entrepreneur in the enterprise" management principle. Additionally, management accountability is reinforced by an earnings-oriented and target-linked compensation system. Fresenius has an international sales network and maintains more than 70 production sites around the globe. Large production sites are located in the United States, China, Japan, Germany, and Sweden. Production plants are also located in other European countries, in Latin America, Asia-Pacific, and South Africa. This international production network allows us to implement our business model while meeting the most exacting logistical and regulatory requirements. The decentralized structure of the production sites also substantially reduces transportation costs and currency exposure.

## MANAGEMENT AND CONTROL

The corporate bodies of the Group are the Management Board, the Supervisory Board, and the General Meeting. Fresenius SE has a **two-tier management and control system** consisting of the Management Board and the Supervisory Board. This is in accordance with Regulation No. 2157/2001 on the Statute for a European Company (SE). The two boards work independently of each other. No one is allowed to be a member of both bodies simultaneously.

The **Management Board** of Fresenius SE conducts the business and represents the Company in dealings with third parties. As of January 1, 2008, the Management Board has seven members. According to the Management Board's rules of procedure, each member is accountable for his own area of responsibility. However, the members have joint responsibility for the management of the Group. The Management Board is required to report to the Supervisory Board regularly, in particular on its corporate policy and strategies, business

profitability, current operations, and any other matters that could be of significance for the Company's profitability and liquidity.

The **Supervisory Board** appoints the members of the Management Board and advises and supervises the Management Board in its management of the Company. It is prohibited from managing the Company directly. However, the Management Board's rules of procedure require it to obtain the Supervisory Board's approval for specific activities.

The Supervisory Board of Fresenius SE comprises six shareholders' representatives and six employees' representatives. All twelve members of the Supervisory Board are appointed by the General Meeting. Six of the twelve members must be appointed on the basis of a proposal put forward by the employees. The General Meeting is bound by the employees' proposal. In accordance with the legal form of an SE, the employee representatives may come from various European countries.

The Supervisory Board must meet at least twice per calendar half-year.

The appointment and dismissal of the members of the Management Board is in accordance with Article 39 of the SE Regulation. The statutes of Fresenius SE also provide that deputy members of the Management Board may be appointed.

The Company's annual corporate governance declaration can be found on pages 12 to 27 of this annual report and on our website [www.fresenius.com](http://www.fresenius.com), see *Who we are/Corporate Governance*. The description of both the compensation structure and individual amounts paid to the Management Board and Supervisory Board are included in the Compensation Report on pages 20 to 27 of this annual report. The Compensation Report is part of the Group's Management Report.

## KEY PRODUCTS, SERVICES, AND BUSINESS PROCESSES

Fresenius Medical Care offers a comprehensive range of products for hemodialysis and peritoneal dialysis and provides dialysis care at its own dialysis clinics in over 35 countries. Dialyzers and dialysis machines are among the most important product lines in the dialysis products business. These products are sold to Group clinics as well as to external dialysis care providers in more than 115 countries. In the United States, the company also performs clinical laboratory tests. Fresenius Kabi is one of the few companies to offer a comprehensive range of enteral and parenteral nutrition therapies.

The company also offers a broad spectrum of products for fluid and blood volume replacement as well as an extensive portfolio of generic IV drugs. Fresenius Kabi's portfolio consists of more than 100 product families. The company sells its products mainly to hospitals in over 150 countries. Fresenius Helios treats approximately 600,000 inpatients and about 1.6 million outpatients each year at its hospitals. Fresenius Vamed provides engineering and services for hospitals and other health care facilities internationally.

### IMPORTANT MARKETS AND COMPETITIVE POSITION

Fresenius operates in about 70 countries through its subsidiaries. **The main markets** are Europe and North America where Fresenius generates 42 % and 43 % of its sales, respectively.

Fresenius Medical Care is the worldwide leader in dialysis. The company holds the leading position in dialysis care, with a market share of 17 % in revenue terms, treats the most dialysis patients, and operates the largest number of dialysis clinics. In dialysis products, Fresenius Medical Care is also the leading supplier, with a market share of 32 %. Fresenius Kabi holds leading market positions in Europe and has strong positions in the growth markets of Asia-Pacific and Latin America. In the United States, Fresenius Kabi is one of the leading suppliers of generic IV drugs. Fresenius Helios is a leading private hospital operator in Germany. Fresenius Vamed is one of the world's leading companies specializing in engineering and services for hospitals and other health care facilities.

### LEGAL AND ECONOMIC FACTORS

The markets of the Fresenius Group are fundamentally stable and relatively independent of economic cycles due to the intrinsic importance of the life-saving and life-sustaining products and treatments that the Group offers. This was demonstrated again in 2009, a year that was marked by difficult macroeconomic conditions. In addition, the markets in which

we offer our products and services are expanding, mainly for three reasons:

- ▶ **demographic trends**
- ▶ **demand for innovative therapies** in the industrialized countries
- ▶ **increasing availability of high-quality health care** in the developing and newly industrializing countries.

Furthermore, the diversification across four business segments provides additional stability for the Group.

The statement of income and the balance sheet can be influenced by currency translation effects as a result of exchange rate fluctuations, especially in the rate of the US dollar to the euro. In 2009, this had a positive impact on the statement of income due to the altered average annual exchange rate between the US dollar and the euro of 1.39 in 2009 as compared to 1.47 in 2008. In the balance sheet, the changed spot rate of 1.44 as of December 31, 2009 – compared to 1.39 as of December 31, 2008 – had a slight impact.

There were no legal aspects that significantly impacted business performance in 2009.

On the whole, the legal and economic factors for the Fresenius Group were largely unchanged, so the Group's operating business was not materially affected.

### CAPITAL, SHAREHOLDERS, STATUTES

The summary below shows the subscribed capital of Fresenius SE. The shares of Fresenius SE are non-par-value bearer shares. Shareholders' rights are regulated by the SE Regulation and the German Stock Corporation Act (AktG – Aktiengesetz). Additionally, the statutes of Fresenius SE contain the following three provisions for the holders of non-voting preference shares:

- ▶ From retained earnings for the year they will receive a € 0.01 higher dividend than for an ordinary share and a minimum dividend of € 0.02 per preference share.

	December 31, 2009			December 31, 2008	
	Number of shares	Subscribed capital €	% of subscribed capital	Number of shares	Subscribed capital €
Ordinary shares/capital	80,657,688	80,657,688.00	50 %	80,571,867	80,571,867.00
Preference shares/capital	80,657,688	80,657,688.00	50 %	80,571,867	80,571,867.00
<b>Total</b>	<b>161,315,376</b>	<b>161,315,376.00</b>	<b>100 %</b>	161,143,734	161,143,734.00

- ▶ The minimum dividend payable on preference shares takes precedence over payment of a dividend on ordinary shares.
- ▶ If the retained earnings of one or more fiscal years is not sufficient to pay a dividend of € 0.02 per preference share, the amounts not distributed will be paid in arrears without interest from the retained earnings in subsequent fiscal years, after distributing the minimum preference dividend for those fiscal years and before payment of a dividend on the ordinary shares. The deferred payment right is a constituent of the share of profits from retained earnings of that fiscal year for which the deferred payment is made.

At the Annual General Meeting on May 8, 2009, resolutions were passed revoking the previous **Approved Capitals I and II**. At the same time, the Management Board was authorized, subject to the consent of the Supervisory Board:

- ▶ to increase the subscribed capital by a total amount of € 12,800,000.00 by May 7, 2014 through a single or multiple issuance of bearer ordinary shares and/or non-voting bearer preference shares against cash contributions (Approved Capital I).
- ▶ to increase the subscribed capital by a total amount of € 6,400,000.00 by May 7, 2014 through a single or multiple issuance of bearer ordinary shares and/or non-voting bearer preference shares against cash contributions and/or contributions in kind (Approved Capital II). Shareholders' pre-emptive rights of subscription can be excluded.

The Approved Capitals I and II were entered in the Commercial Register on July 15, 2009. Against the resolutions of the Annual General Meeting dated May 8, 2009 creating Approved Capitals I and II, two challenging complaints (Anfechtungsklagen) were lodged. The Frankfurt Regional Court has decided in favor of one complaint through judgment dated February 2, 2010, the other complaint was rejected. The judgment of the Frankfurt Regional Court dated February 2, 2010 is not yet final and binding. The clearance procedure pursuant to section 264a of the German Stock Corporation Act (AktG) is pending before the Higher Regional Court in Frankfurt am Main with the view of securing the validity of the approved capital which has already been registered in the commercial register.

In addition, there is the following **conditional capital**:

- ▶ The subscribed capital is conditionally increased by up to € 1,364,934.00 through the issuance of new bearer ordinary shares and non-voting bearer preference shares (Conditional Capital I). The conditional capital increase will only be executed to the extent that subscription rights for ordinary and preference shares are issued under the 1998 Stock Option Plan and the holders of these subscription rights exercise their rights.
- ▶ The subscribed capital is conditionally increased by up to € 4,418,250.00 through the issuance of new bearer ordinary shares and non-voting bearer preference shares (Conditional Capital II). The conditional capital increase will only be executed to the extent that convertible bonds for ordinary and preference shares are issued under the 2003 Stock Option Plan and the holders of these convertible bonds exercise their conversion rights.
- ▶ The subscribed capital is conditionally increased by up to € 6,200,000.00 through the issuance of new bearer ordinary shares and non-voting bearer preference shares (Conditional Capital III). The conditional capital increase will only be executed to the extent that subscription rights for ordinary and preference shares are issued under the 2008 Stock Option Plan and the holders of these subscription rights exercise their rights.

Fresenius SE does not have a **share buyback program**.

**Direct and indirect ownership interests** in Fresenius SE are listed on page 162 of the Notes. The Else Kröner-Fresenius-Stiftung informed Fresenius SE on December 23, 2009, that it holds 46,871,154 ordinary shares of Fresenius SE. This corresponds to a voting interest of 58.11 %.

Changes to the **statutes** are made in accordance with Article 59 of the SE Regulation in accordance with Section 18 (3) of the statutes. Unless mandatory legal provisions require otherwise, amendments of the statutes require a majority of two-thirds of the votes cast or, if at least half of the subscribed capital is represented, the simple majority of the votes cast. If, for the effectiveness of the passing of resolutions, mandatory legal provisions require that, in addition, a majority of the subscribed capital be represented when the

resolution is passed, the simple majority of the subscribed capital represented shall be sufficient, to the extent that this is permitted by law. If the voting results in a tie, a motion is deemed rejected. The Supervisory Board is entitled to make such amendments to the statutes which only concern their wording without a resolution of the General Meeting.

A change of control as the result of a takeover bid under certain circumstances could impact some of our long-term financing agreements embodying change of control agreements. These are customary change of control clauses that grant creditors the right of premature call in the event of a change of control, whereby the right of premature call usually only becomes effective if the change of control is followed by a downgrading of the Company's rating.

### CORPORATE PERFORMANCE CRITERIA, GOALS, AND STRATEGY

The Management Board controls the business segments by setting strategic and operative targets and through various financial ratios. In line with our growth strategy, organic growth is a key performance indicator. Operating income (EBIT – earnings before interest and taxes) is another useful yardstick for measuring the profitability of the business segments.

The Management Board believes that, in addition to operating income, EBITDA (earnings before interest, taxes, depreciation and amortization) is a good indicator of the business segments' ability to achieve positive cash flows and to service their financial commitments. The criteria on which the Management Board measures the performance of the business segments are selected Group-wide in such a way that they include income and expenses within the control of these segments. We also control the operating cash flow contributions of our business segments on the basis of days sales outstanding (DSO) and scope of inventory (SOI).

**Financing** is a central Group function over which the business segments have no control. The financial targets for the business segments therefore exclude both interest payments resulting from financing activities and tax expenses.

Another key performance indicator at the Group level is the **debt ratio**, which is the ratio of net debt to EBITDA. This measure indicates how far a company is in a position to meet its payment obligations. The Group's business segments hold important market positions and operate in growing and

mostly noncyclical markets. They generate stable, predictable, and sustainable cash flows since the majority of our customers are of high credit quality. The Group is therefore able to finance its growth with a high proportion of debt compared to companies in other sectors.

At Group level we use return on operating assets (ROOA) and return on invested capital (ROIC) as benchmarks for evaluating our business segments and their contribution to Group **value added**. Group ROIC rose to 8.2 % (2008: 7.3 %) and Group ROOA to 10.5 % (2008: 9.8 %). The marked improvement in these two ratios versus 2008 was mainly due to the very good earnings growth in all business segments. We expect a continuing improvement in ROIC and ROOA in the future.

The summary shows ROIC and ROOA by business segment:

in %	ROIC		ROOA	
	2009	2008	2009	2008
Fresenius Medical Care	8.5	8.6	12.2	12.3
Fresenius Kabi <sup>1</sup>	7.8	7.0	10.2	8.9
Fresenius Helios	6.7	5.9	7.1	6.3
Fresenius Vamed <sup>2</sup>	–	–	22.8	22.2
Group	8.2	7.3	10.5	9.8

<sup>1</sup> 2008: Pro forma APP Pharmaceuticals and excluding special items from the acquisition.

<sup>2</sup> ROIC: Invested capital is insignificant due to prepayments, cash, and cash equivalents.

Our **investments** are controlled generally using a detailed coordination and evaluation process. As a first step, the Management Board sets the Group's investment targets and the budget based on investment proposals. In a second step, the respective business segments and an internal Acquisition & Investment Council (AIC) determine the individual projects and measures while taking into account the overall strategy, the total budget, and the required and potential return on investment. The investment projects are evaluated on commonly used methods, such as internal rate of return (IRR) and net present value (NPV). The respective investment project is then finally submitted for approval to the executive committees/managements of the business segments, or to the Management Board of Fresenius SE, and to the Supervisory Board if the projects exceed a given size.

## STRATEGY AND GOALS

Our goal is to build Fresenius into a leading global provider of products and therapies for critically and chronically ill people.

We are concentrating our business segments on a few health care areas. Thanks to this clear focus, we have developed unique competencies. We are implementing our long-term strategies consistently and are seizing our opportunities.

Our aim is:

- ▶ to provide best-in-class treatment
- ▶ to grow with new products and services
- ▶ to expand in growth markets
- ▶ to increase our profitability on a sustainable basis

The key elements of Fresenius Group's strategy and goals are:

- ▶ To expand our **market position**: Fresenius' goal is to ensure the long-term future of the Company as a leading international provider of products and services in the health care industry and to grow its market share. Fresenius Medical Care is the largest dialysis company in the world, with a strong market position in the United States. Future opportunities in dialysis will arise from further international expansion in dialysis care and products and in renal pharmaceuticals. Fresenius Kabi is the market leader in infusion therapy and clinical nutrition in Europe and in the key markets in Asia-Pacific and Latin America. In the United States, Fresenius Kabi is one of the leading players in the market for generic IV drugs through APP Pharmaceuticals. To strengthen its position, Fresenius Kabi plans to roll out more products from its portfolio to the growth markets. Market share is also to be expanded through the launch of new products in the field of generic IV drugs and new medical devices for infusion therapy and clinical nutrition. In addition, products from the existing portfolio are to be launched on the US market while, conversely, APP pharmaceuticals products will be marketed outside the United States. Fresenius Helios is in a strong position to take advantage of the further growth opportunities offered by the continuing privatization process in the German hospital market.
- ▶ Investment decisions are based on the continued existence and long-term potential of the clinics to be acquired. Fresenius Vamed will be further strengthening its position as a specialist provider of engineering and services for hospitals and other health care facilities.
- ▶ To extend our **global presence**: in addition to sustained organic growth in markets where Fresenius is already established, our strategy is to diversify into new growth markets worldwide, especially in Asia-Pacific and Latin America. With our brand name, product portfolio, and existing infrastructure, we intend to focus on markets that offer attractive growth potential. And apart from organic growth, Fresenius also plans to make further small to mid-sized selective acquisitions to improve the Company's market position and to diversify its business geographically.
- ▶ To strengthen **innovation** in the development of new products and technologies: Fresenius' strategy is to continue building on its strength in technology, its competence and quality in patient care, and its ability to manufacture cost-effectively. We are convinced that we can leverage our competence in research and development in our operations to develop products and systems that provide a high level of safety and user-friendliness and enable tailoring to individual patient needs. We intend to continue to meet the requirements of best-in-class medical standards by developing and producing more effective products and treatment methods for the critically and chronically ill. Fresenius Helios' goal is to widen brand recognition for its health care services and innovative therapies.
- ▶ To enhance **profitability**: our goal is to continue to improve Group profitability. To contain costs, we are concentrating particularly on making our production plants more efficient, exploiting economies of scale, leveraging the existing marketing and distribution infrastructure more intensively, and practicing strict cost control. By focusing on our operating cash flow and employing efficient working capital management, we will increase our investment flexibility and improve our balance sheet ratios. Another goal is to optimize our weighted average cost of capital (WACC) by deliberately employing a balanced mix of equity and debt funding. Our net debt/EBITDA ratio was 3.0 as of December 31, 2009, after rising to 3.6 at the

end of 2008 as a result of the acquisition of APP Pharmaceuticals. We want to bring down this ratio to a <3.0 again by the end of 2010.

We report on our goals in detail in the Outlook section on pages 97 to 106.

## OVERALL BUSINESS DEVELOPMENT

### ECONOMIC ENVIRONMENT

At the end of 2008 and up to the first half of 2009, the world economy experienced its deepest recession since the end of World War II. After the financial crisis reached its peak in the first quarter of 2009, the world economy steadied towards mid-year 2009 and moved into a recovery phase in the second half.

The recovery is attributable to four main factors:

- ▶ extensive monetary policy
- ▶ government economic programs in numerous countries
- ▶ relative robustness of the emerging market economies
- ▶ the comparatively low oil price in the first half of 2009

Global GDP decreased by 1.1 % compared to 2008. The emerging market and developing economies still showed a slightly positive development, with growth of 1.7 %. Industrial countries proved more vulnerable, with a decline of 3.4 %.

#### GDP SHARE OF LEADING ECONOMIES

in %	2008	2007
United States	20.6	21.3
China	11.4	10.8
Japan	6.3	6.6
India	4.8	4.6
Germany	4.2	4.3
Russia	3.3	3.2

Source: International Monetary Fund (IMF), World Economic Outlook 2009/2008

### Europe

After a sharp decline at the beginning of 2009, the economic situation in the Eurozone steadied towards the middle of the year and picked up slightly in the third quarter. For the full year 2009, GDP in the Eurozone decreased by 3.9 % (2008: +0.6 %). At minus 13.6 %, the decrease in exports was particularly pronounced. Private consumption, on the other hand, declined by only 1.0 %. Almost all countries clearly felt the economic crisis in their labor markets. Growth in unemployment was particularly high in countries that had previously experienced a real estate boom, such as Spain and Ireland.

Due to the still strained situation on the financial markets, the European Central Bank (ECB) within seven months cut its rate from 4.25 % to 1.0 %, its lowest rate ever. Commodity prices also fell sharply. In 2009, the average oil price, for instance, was US\$ 36.76 below the previous year's average of US\$ 97.27 per barrel.

In **Germany**, the weakness of global demand at the beginning of 2009 led to a historically unprecedented decrease in exports. However, fiscal and monetary measures combined with stabilizing labor market programs helped to prevent an even steeper fall. The German government launched two economic programs worth a total of about € 84 billion – equivalent to more than 3 % of 2008 GDP – for 2009 and 2010. The introduction of short-time working and greater flexibility in the collective bargaining settlements especially contributed to the stability of the labor market. Overall, Germany's GDP decreased by 4.9 % in 2009 (2008: +1.4 %).

The financial crisis also had a deep impact on the economies of **Central and Eastern Europe**. They suffered a strong decline in industrial production and exports as the demand from countries in the Eurozone significantly weakened. The countries of Eastern Europe especially, which had accumulated high current account deficits in the previous years, fell into a deep recession as a result of the abrupt worsening of refinancing conditions and reversing capital flows.

### United States

In the United States, the economic downturn slowed significantly in the first half of 2009. A positive rate of GDP growth was again achieved in the second half of the year. For the full year 2009, GDP decreased by 2.4 % (2008: +0.4 %). In the

first half of the year, the economic support came from the external account as imports declined faster than exports. In the second half, however, private consumption was the main driver. In addition, investment activity picked up slightly again, a special contributing factor being the US economic program, the “American Recovery and Reinvestment Act”, under which about US\$ 940 billion – more than 6 % of 2008 GDP – was made available for 2009 and 2010. The easing of the strains on the financial and real estate markets and the brightening external outlook also helped to improve the situation. Although prices stabilized, conditions on the real estate market were still marked by a high surplus supply. The unemployment rate rose to 10.0 % at the end of the year, its highest level in 26 years.

In addition, credit was substantially tightened in the wake of the banking crisis and there was a marked rise in the household saving ratio. Despite the upturn in the second half of the year, consumer spending was down 0.8 % in the full year 2009 and thus decreased more strongly than the year before. The conditions for private consumption, which is particularly important for the US economy, thus remained difficult.

## Asia

The Asian emerging economies managed a notable turnaround after the abrupt collapse of their exports. GDP grew by 5.3 % in Asia (excluding Japan) in 2009. This was due among other things to the positive developments in China. Asia therefore continues to be the fastest growing region in the world. However, this growth is comparatively low versus the average GDP growth of 8 %, and even 13.6 % in China, between 2004 and 2008. A significant aspect of the present situation in Asia is the wide gap between the heavyweights, China and India, on the one hand – in 2009, GDP grew by 8.4 % in China (2008: 9.0 %) and in India by 6.0 % (2008: 7.3 %) – and other countries such as Taiwan, Malaysia, Hong Kong, and Singapore, on the other, which suffered an average decline of 2 %.

Expansionary fiscal and monetary economic support measures, alongside rapidly reviving capital inflows, were the basis for the recovery. **China**, for instance, launched a government economic program worth about US\$ 590 billion, or 13 % of 2008 GDP, for 2009 and the following years. By contrast, the volume of comparable measures in India and Indonesia was much smaller at about 1 % and 1.5 %, respectively. Lending was also stimulated by a relaxation of credit standards.

**India**, where exports account for only about 20 % of GDP, was affected much less by the decrease in world trade. The strong domestic bias therefore proved to be a relative strength.

In **Japan**, the key industrial sectors – automotive industry, engineering, and the electrical & electronics industry – were hit by the effects of the financial crisis. The Japanese economy only returned to a moderate recovery from the second quarter of 2009 onwards as the stimulus from the Asian emerging economies, especially China, made itself felt. However, the sharp decrease was not recouped and Japan’s GDP decreased by 5.6 % in 2009 (2008: -0.7 %).

## Latin America

Most of the countries in Latin America had already overcome the global economic weakness in the second quarter of 2009 and have experienced a relatively rapid recovery since then. Latin America profited not only from a good regional demand, but also from a relatively robust financial sector, which makes it less dependent on foreign capital than Europe, for instance. Commodity and food exports continued to be the main drivers. Overall, the region’s GDP decreased by 2.8 % in 2009 (2008: +4.3 %).

**Mexico** was hit the hardest by the global financial and economic crisis owing to its strong trade ties with the United States. GDP decreased by 6.8 % (2008: +1.8 %).

**Argentina** suffered the next biggest drop in GDP after Mexico, with -3.3 %. The country was hit particularly hard by the global financial crisis and suffered – as other countries with low credit ratings – from the investors’ increased risk averseness. In addition, the political climate in Argentina does not allow the government to push through important economic reforms.

In **Brazil** the economy weakened significantly, but was supported by robust domestic demand and by the broad geographical and sectoral diversification of its exports. Brazil's GDP decreased by 0.3 % in 2009.

**HEALTH CARE INDUSTRY**

The health care sector continued to be one of the most stable industries despite the generally difficult market environment in 2009 and was characterized by its relative insensitivity to economic fluctuations compared to other sectors.

The main **growth factors** for this market are:

- ▶ rising medical needs deriving from aging populations
- ▶ stronger demand for innovative products and therapies
- ▶ advances in medical technology
- ▶ growing health consciousness, which increases the demand for health care services and facilities

In the **emerging countries** additional drivers are:

- ▶ expanding availability and correspondingly greater demand for primary health care
- ▶ increasing national incomes and hence higher spending on health care

At the same time, the **cost of health care** is rising and is claiming an ever-increasing share of national income. Health care spending averaged 8.9 % of GDP in the OECD countries in 2007, with an average of US\$ 2,964 spent per capita. The

United States had the highest per capita spending with US\$ 7,290, followed by Norway, Switzerland, and Luxembourg with over US\$ 4,000. Germany ranked tenth among the OECD countries with per capita spending of US\$ 3,588.

Health care spending in the OECD countries grew at an average annual rate of 3.7 % between 2000 and 2007. In Germany, health care spending increased by 1.4 % per year on average. This is the smallest increase among all OECD countries during this period. The relatively slow growth in health care spending in Germany is partly due to cost-containment measures from past health care reforms.

On average, public sources fund 73.0 % of health care expenditures in the OECD countries, with the exception of the United States and Mexico, where public funding was lowest in 2007, at 45.4 % and 45.2 %, respectively. In Germany, 76.9 % was publicly funded in 2007.

Most of the OECD countries have enjoyed large gains in life expectancy over the past decades thanks to improved living standards, public health interventions, and progress in medical care. In 2006, the average life expectancy in the OECD countries was 79 years. In Germany, life expectancy was nearly a year more than the OECD average of 79.8 years. Japan has the highest life expectancy of all the OECD countries with 82.6 years.

Reforms and cost-containment measures are the main reactions to steadily rising health care expenditures. Outdated health care structures are increasingly being overhauled and market-based elements introduced into the health care system. The aim is to create new incentives for cost and quality-conscious behavior. Quality of treatment plays a crucial role

**HEALTH CARE SPENDING AS % OF GDP**

in %	2007	2000	1990	1980	1970
United States	16.0	13.6	12.2	9.0	7.1
France	11.0	10.1	8.4	7.0	5.4
Switzerland	10.8	10.2	8.2	7.3	5.4
Germany	10.4	10.3	8.3	8.4	6.0

Source: OECD Health Data 2009

in optimizing medical results and reducing overall treatment costs. In addition, ever greater importance is being placed on disease prevention and innovative reimbursement models where quality of treatment is the key parameter.

In the United States, our most important single market in geographical terms, the government has declared the reform of the health care system to be a political priority. The goal is that over 45 million (i. e. one in every eight US citizens) currently uninsured should get access to primary health care. At present, the public health care schemes, Medicaid and Medicare, mainly insure the poor and pensioners.

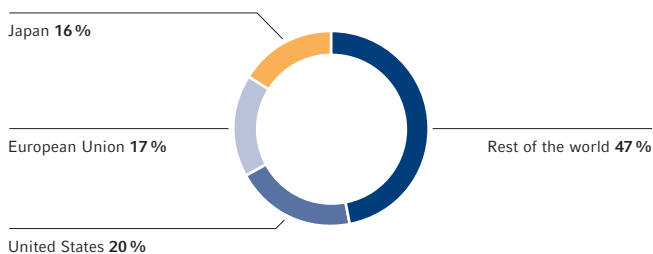
Our most important markets developed as follows:

### The dialysis market

In 2009, the value of the global dialysis market was approximately US\$ 65 billion, with the market for dialysis care (including renal pharmaceuticals) accounting for approximately US\$ 55 billion and the market for dialysis products for about US\$ 10.5 billion.

The number of dialysis patients increased by about 6 % to 1.9 million. The chart shows their regional distribution:

DIALYSIS PATIENTS BY REGION



Prevalence, which is the number of people with terminal kidney failure treated per million population, differs widely from region to region, ranging from well below 100 to over 2,000 patients per million population (p.m.p.). Prevalence is highest in Taiwan with 2,560 p.m.p., followed by Japan with 2,430 p.m.p., and the United States with approximately

1,830 p.m.p. It averages about 1,000 in the 27 countries of the European Union. The far lower global average of approximately 360 p.m.p. is due, on the one hand, to differences in age demographics, distribution of renal risk factors (such as diabetes and hypertension), and genetic pre-disposition and cultural habit (such as diet). On the other hand, access to dialysis treatment is still limited in many countries. A great many individuals with terminal kidney failure do not receive treatment and are therefore not included in the prevalence statistics. A comparison of economic output and national prevalence rates suggests that access to treatment is restricted especially in countries where GDP per capita is less than US\$ 10,000 per person per year. However, the generally rising global prevalence rate suggests that more and more people are receiving dialysis treatment.

### Dialysis care

By the end of 2009, there were approximately 1.9 million patients receiving regular dialysis treatment. More than 89 % of these were treated with hemodialysis, while about 11 % choose peritoneal dialysis. The majority of hemodialysis patients are treated in dialysis clinics. There are about 29,000 dialysis clinics worldwide with an average of 65 hemodialysis patients per clinic.

The organizational structures differ considerably depending on whether a country's health care system is predominantly public or private. In the United States, for instance, most of the approximately 5,000 dialysis clinics are privately run and only about 1 % are publicly operated. By contrast, about 61 % of the approximately 5,000 dialysis clinics in the European Union are publicly owned. In Japan, about 80 % of the dialysis clinics are run by private nephrologists.

**In the United States**, the market for dialysis care is already highly consolidated. Taken together, Fresenius Medical Care and the second largest provider of dialysis care – DaVita – treat about 64 % of all US dialysis patients. In 2009, Fresenius Medical Care maintained its market-leading position of about 33 %.

**Outside the United States**, the markets for dialysis care are much more fragmented. Here, Fresenius Medical Care competes mainly with independent clinics and with clinics that are affiliated with hospitals. Fresenius Medical Care

operates 769 dialysis clinics in 35 countries and treats over 63,000 patients. With that, it has by far the largest and most international network of dialysis clinics.

In 2009, the number of **peritoneal dialysis patients** worldwide rose by more than 6 % to approximately 203,000. Fresenius Medical Care supplies approximately 36,000 patients with peritoneal dialysis products, which is about 17 % of all patients. In the United States, its market share was 31 %.

Dialysis reimbursement systems differ from country to country and often vary even within individual countries.

In the United States, the treatment costs for terminal kidney failure are covered by the public health insurers. The public health care programs, the **Centers for Medicare & Medicaid Services (CMS)**, cover the medical services for more than 80 % of all dialysis patients in the United States. In 2009, CMS reimbursements accounted for about 33 % of Fresenius Medical Care's revenues. Changes in the CMS rates or method of reimbursement therefore have a significant influence on our business in North America. Here, providers mainly compete on quality and availability.

### Dialysis products

In the dialysis products market, the most important products are dialyzers, hemodialysis machines, concentrates and dialysis solutions, and products for peritoneal dialysis. Fresenius Medical Care is the world market leader in dialysis products with a market share of about 32 %. The top three manufacturers have a combined market share of almost 70 %. **Dialyzers** are by far the largest single product group. Approximately 190 million units were sold in 2009, of which about 85 million were produced by Fresenius Medical Care. Of the approximately 65,000 new **hemodialysis machines** that were sold in 2009, about 55 % were produced by Fresenius Medical Care. In the United States, Fresenius Medical Care has a share of over 75 % of the independent market in these two product segments. We define the independent market as all dialysis clinics that do not belong to a major US-wide dialysis care provider such as Fresenius Medical Care or DaVita.

### The market for infusion therapy and clinical nutrition, intravenously administered generic drugs and medical devices

In the market for **infusion therapy and clinical nutrition**, therapies that offer high standards of health care, but at the same time are advantageous from an economic point of view, are increasingly gaining importance in Central and Western Europe due to the general cost pressure. Studies show that, in cases of health or age-induced nutritional deficiencies, the administration of food supplements can reduce hospital costs by an average of € 1,000 per patient – through shorter stays and less nursing care. At the time when they are admitted to hospital, at least 25 % of all patients in Europe are suffering from nutritional deficiencies, or have an elevated risk of developing nutritional deficiencies. Much higher figures of 50 to 60 % are reported for people who require nursing care, especially the elderly. The costs caused by health-induced nutritional deficiencies are about € 170 billion per year Europe-wide.

In Central and Western Europe, the total market for infusion therapy and clinical nutrition is growing at a low single-digit rate. Growth rates are in the high single to double digits in the emerging markets of Asia-Pacific, Latin America, and Eastern Europe.

Based on its own estimates, Fresenius Kabi considers its relevant market for infusion therapy and clinical nutrition (excluding the United States and Japan) to be over € 9 billion.

We also expect the demand for **generics** to continue growing. Generic drugs are more advantageous from health economics aspects than original preparations because of their significantly lower price and they already make a vital contribution to health care today: in Germany alone, generics accounted for over 85 % of prescriptions in 2008.

The **market for intravenously administered drugs** is characterized by moderate volume growth, steady price erosion, and fierce competition. Growth is mainly achieved through new generics that are brought to market when the original preparation goes off-patent. In Europe, the market for intravenously administered drugs is growing at a mid single-digit rate. In the United States, it is growing at a rate of about 5 %. We expect the US market for drugs that go off-patent

from 2009 to 2019 to grow to approximately US\$ 20 billion on a cumulative basis. These figures are based on the sales of the original preparations in 2008 and do not take account of the usual price erosions for generics.

Based on its own survey, Fresenius Kabi expects its relevant market for intravenously administered drugs (without Japan) to be over €9 billion.

The **market for medical devices** for infusion therapy, intravenously administered drugs, and clinical nutrition is growing in Europe at mid single-digit rates. Here, the main growth drivers are technical innovations that focus on application safety and therapy efficiency.

### The German hospital market

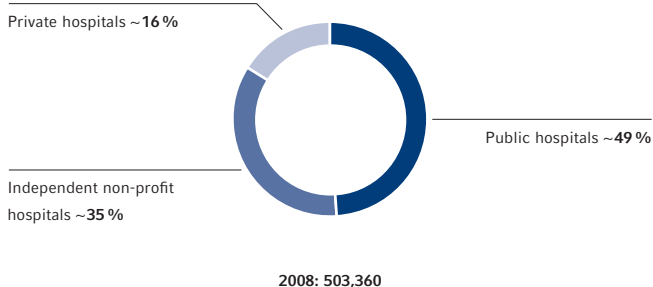
The total volume for hospital treatment (excluding research and teaching) in Germany was about €70 billion in 2008. This was approximately one-fourth of total health care expenditures. Personnel costs account for about 61 % of hospital costs, and material costs for the remainder. Personnel costs rose by 3.4 %, and material costs by 6.3 %.

Over the last five years the number of **hospitals** has fallen at an average annual rate of 1.0 % to 2,083 in 2008, while the number of **beds** has declined at an average annual rate of 1.3 % to 503,360. Nonetheless, with 6.1 beds per 1,000 population in 2008, Germany is still well above the OECD average of 3.8 (2007).

The **average stay** of a patient in an acute care clinic (excluding specialized psychiatric clinics) in Germany fell overall by 0.6 days over the same period and was 8.1 days in 2008.

On the other hand, the number of **inpatient admissions** and the **average costs per admission** have increased. The number of inpatient admissions at acute care clinics in Germany declined at first after the introduction of DRG-based

### HOSPITAL BEDS BY OPERATOR



reimbursement. This was due, on the one hand, to a reduction in unnecessary referrals and growth in the number of outpatient treatments and, on the other, to technical changes in the admission statistics. The number of admissions has risen again slightly since 2006 and was 17.52 million or 213 admissions per 1,000 population in 2008. That was about 341,000 or 2.0 % more than in 2007. Other countries rank well below the German level, e. g. Switzerland, with 174 admissions per 1,000 population. In the last five years leading up to 2008, the number of admissions in Germany has risen at an average annual rate of 1.1 %. The average costs per admission have increased by 2.5 % on average over the last five years.

According to a survey by the German Hospital Institute (DKI), the **financial situation** at hospitals in Germany remains difficult: only 43.7 % of the hospitals expect to earn a surplus in 2009 (2008: 61.6 %), 26.5 % expect to break even (2008: 16.3 %), and 26.4 % expect to make a loss (2008: 19.7 %). However, the hospital sector was able to decouple economically from the poor macroeconomic situation in 2009: only 12 % of the hospitals said they had been affected by the financial and economic crisis.

### KEY FIGURES FOR INPATIENT CARE IN GERMANY

	2008	2007	2006	2005	2004	Change 2008/2007
Hospitals	2,083	2,087	2,104	2,139	2,166	-0.2 %
Beds	503,360	506,954	510,767	523,824	531,333	-0.7 %
Beds per 1,000 population	6.13	6.16	6.20	6.35	6.44	-0.5 %
Length of stay (days)	8.1	8.3	8.5	8.7	8.7	-2.4 %
Number of admissions (millions)	17.52	17.18	16.83	16.54	16.80	2.0 %
Average costs per admission in € <sup>1</sup>	4,146	4,028	3,932	3,813	3,756	2.9 %

<sup>1</sup> Total costs, gross

The difficult financial and economic situation at many hospitals has been caused by rising **investment needs**. This is due in large part to an investment backlog that has accumulated because the federal states have not met their statutory obligation to finance necessary investments and major maintenance measures sufficiently in the past. Moreover, the investment needs are also due to technological advances and higher quality requirements. It is estimated that the current annual investment backlog at German hospitals is about € 5 billion.

Against this backdrop, the **privatization trend** in the German hospital market continued, albeit on a modest scale, with the share of private hospital beds rising to 15.9 % in 2008 (2007: 15.6 %) while the share of public hospital beds fell to 49.0 % (2007: 49.4 %).

According to our research, € 504 million in hospital transaction revenues were acquired in 2009 (2008: € 408 million).

The **Hospital Funding Reform Act** (KHRG) that came into force in March 2009 has had an overall positive effect on the financial situation of hospitals in Germany. Nationwide, hospitals were funded with approximately € 3.55 billion in 2009. That was about 7 % more than in 2008. However, approximately € 1.5 billion of that represented the reversal of past budget cuts. For instance, the contribution hospitals were required to make towards improving the finances of public health insurers (Sanierungsbeitrag) was abolished as of the beginning of 2009: the deduction of 0.5 % on billings to public health insurers and the deduction hitherto of up to 1 % on billings under integrated health care contracts. In addition, the Federal government made funds available for investment grants under government economic programs.

The KHRG also extended the convergence phase for the final introduction of DRG-based reimbursement by one year. The convergence phase now ends as of December 31, 2009. Hospitals will then bill on the basis of standardized base rates valid throughout the particular federal state.

Quality continues to be a key competitive factor for the hospital market. The transparency and comparability of the treatments for the patients and their doctors will play an increasingly decisive role.

In the **post-acute care market** in Germany there was a total of 1,239 clinics in 2008, the same as the year before. The number of beds was 171,060 – 215 more than in 2007. 56.3 % (2007: 57.0 %) of the clinics were private clinics and 26.0 % (2007: 25.3 %) were independent non-profit clinics. 17.8 % (2007: 17.7 %) were public clinics. Independent non-profit clinics and public clinics accounted for 16.2 % (2007: 16.0 %) and 16.9 % (2007: 16.9 %) of the total number of beds, respectively. Private clinics accounted for 66.9 % (2007: 67.2 %). The total number of admissions in Germany rose by 3.4 % to approximately 2.0 million in 2008 (2007: 1.94 million). The average length of stay declined to 25.3 days (2007: 25.5 days).

### The market for engineering and services for hospitals and other health care facilities

The market for engineering and services for hospitals and other health care facilities differs widely from country to country and depends to a large extent on factors such as public health care policies, government regulation, levels of privatization, economic conditions, and demographics.

In established markets, where there is mounting cost pressure, the challenge for hospitals and other health care facilities is to increase their efficiency. Here there is demand especially for optimized hospital processes and technical management services, enabling hospitals to concentrate on their core competency: treating patients. In emerging markets the focus is on building and improving infrastructure.

### THE MANAGEMENT BOARD'S ASSESSMENT OF THE EFFECT OF GENERAL ECONOMIC DEVELOPMENTS AND THOSE IN THE HEALTH CARE SECTOR FOR FRESENIUS

The continued weakening of world economic growth in 2009 has had negligible impact on our industry thus far. On the whole, the health care sector, both in mature and growth markets, developed positively for Fresenius in 2009. While this was responsible for much of the Group's growth, strong demand for its products and services enabled Fresenius to outpace the growth of its respective markets.

## SIGNIFICANT FACTORS AFFECTING OPERATING PERFORMANCE

In 2009, the Fresenius Group's positive development was again driven to a large extent by the very good operating development in all business segments.

The Group's annual financial statements were also affected by a number of **acquisitions**, partly from 2008. This was mainly due to the full-year consolidation of APP Pharmaceuticals in the US as well as Fresenius Kabi Oncology (formerly Dabur Pharma). Both companies were consolidated for the first time as of September 1, 2008. In addition, Fresenius Medical Care acquired a number of dialysis clinics and Fresenius Helios acquired five hospitals.

The annual financial statements for 2009 include the effects of the mark-to-market accounting of the Mandatory Exchangeable Bonds (MEB) and the Contingent Value Rights (CVR) relating to the acquisition of APP Pharmaceuticals. The annual financial statements for 2008 in addition include further special items resulting from the acquisition of APP Pharmaceuticals. These mainly relate to the amortization of acquired in-process R & D activities, which resulted in a non-cash charge of € 272 million. The adjusted earnings figures for 2008 and 2009 represent the Group's business operations in the given reporting period.

## THE MANAGEMENT BOARD'S ASSESSMENT OF BUSINESS RESULTS

The Management Board is of the opinion that the Fresenius Group performed very well in 2009 – with sales and earnings improvements in all business segments. The two business

segments Fresenius Medical Care and Fresenius Kabi profited from the continued strong demand for their products and services and generally outperformed the market. This was reflected in sustained strong organic sales growth of 8 % at both business segments, and significant increases in earnings. Fresenius Helios also achieved excellent organic growth of 7 % and further improved its earnings. Fresenius Vamed was able to report an organic growth of 15 % and a further strong earnings increase in 2009 and achieved in the project business an important all-time high in order intake and order backlog.

## COMPARISON OF THE ACTUAL BUSINESS RESULTS WITH THE FORECASTS

As the summary below shows, Fresenius achieved or exceeded all targets for 2009 that were set when it published its annual financial statements for 2008 in February 2009. We had assumed that strong demand for our products and services would continue despite the difficult macroeconomic environment. This proved to be the case.

The achieved sales growth of 13 % in constant currency was above our forecast of more than 10 %. Growth of 14 % in adjusted net income<sup>1</sup> at constant currency also surpassed our target of about 10 %. All sales and earnings targets for the business segments were also fully achieved or exceeded.

Fresenius invested € 671 million in property, plant and equipment in 2009. That was below the budgeted range of € 700 to 750 million due to the cautious investment policy pursued by the business segments.

### ACHIEVED GROUP TARGETS 2009

	Targets for 2009 announced in February 2009	Achieved in 2009
Sales (growth, in constant currency)	> 10 %	13 %
Net income, adjusted (growth, in constant currency) <sup>1</sup>	~ 10 %	14 %
Capital expenditure	€ 700 – 750 million	€ 671 million

<sup>1</sup> Net income attributable to Fresenius SE; adjusted for the effects of mark-to-market accounting of the Mandatory Exchangeable Bonds (MEB) and the Contingent Value Rights (CVR) relating to the acquisition of APP Pharmaceuticals.

We also clearly exceeded our guidance for operating cash flow with a cash flow rate of 11 %. We had forecast a cash flow rate at the 2008 level of 8.7 %.

## RESULTS OF OPERATIONS, FINANCIAL POSITION, ASSETS AND LIABILITIES

The main acquisition-related effect on operational efficiency was the full-year consolidation of APP Pharmaceuticals, one of the leading manufacturers of IV drugs in North America. APP Pharmaceuticals achieved sales of US\$ 889 million in 2009.

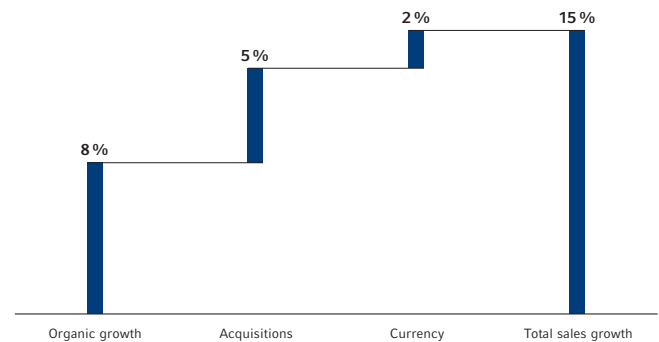
### RESULTS OF OPERATIONS

#### SALES

In 2009, we increased Group sales by 13 % in constant currency and by 15 % at actual rates to € 14,164 million (2008: € 12,336 million).

The chart shows the various influences on Fresenius' Group sales. Strong organic growth reached 8 %, while acquisitions contributed 5 %. Currency translation had a positive effect of 2 %. More information can be found on page 47.

#### SALES GROWTH ANALYSIS



While there were no significant consequences from changes in product mix, price effects in dialysis care contributed positively. In the foreseeable future no significant changes are expected in these two factors.

#### Sales growth by region was as follows:

The largest regions in the Group are Europe and North America, contributing 42 % and 43 % of total sales, followed by Asia-Pacific with 8 %, and Latin America and Africa with 5 % and 2 %, respectively. Germany contributed 22 % to Group sales.

#### SALES BY REGION

in million €	2009	2008	Change	Organic growth	Currency translation effects	Acquisitions/divestitures	% of total sales
Europe	6,045	5,549	9 %	7 %	-2 %	4 %	42 %
North America	6,113	5,029	22 %	8 %	6 %	8 %	43 %
Asia-Pacific	1,088	935	16 %	9 %	3 %	4 %	8 %
Latin America	641	582	10 %	12 %	-4 %	2 %	5 %
Africa	277	241	15 %	13 %	1 %	1 %	2 %
<b>Total</b>	<b>14,164</b>	<b>12,336</b>	<b>15 %</b>	<b>8 %</b>	<b>2 %</b>	<b>5 %</b>	<b>100 %</b>

#### SALES BY BUSINESS SEGMENT

in million €	2009	2008	Change	Organic growth	Currency translation effects	Acquisitions/divestitures	% of total sales
Fresenius Medical Care	8,064	7,213	12 %	8 %	3 %	1 %	57 %
Fresenius Kabi	3,086	2,495	24 %	8 %	-2 %	18 %	22 %
Fresenius Helios	2,416	2,123	14 %	7 %	0 %	7 %	17 %
Fresenius Vamed	618	524	18 %	15 %	0 %	3 %	4 %

In Europe, sales were up 11 % in constant currency, with organic growth of 7 %. In North America, sales rose 16 % in constant currency. This was mainly due to the full-year consolidation of APP Pharmaceuticals. Excellent organic growth was again achieved in Asia-Pacific with 9 % and in Latin America with 12 %.

**Sales growth in the business segments** was as follows:

- ▶ Fresenius Medical Care achieved a sales increase of 12 % to € 8,064 million in 2009 (2008: € 7,213 million) and excellent organic growth of 8 %. Acquisitions had an effect of 1 %. Currency translation had a positive effect of 3 %. Fresenius Medical Care achieved very good increases in constant currency both in dialysis care (10 %) and in dialysis products (6 %). The growth in dialysis care was mainly due to organic growth in treatments and higher average revenues per treatment.
- ▶ Fresenius Kabi increased sales by 24 % to € 3,086 million (2008: € 2,495 million). The company achieved excellent organic growth of 8 %. Net acquisitions had an effect of 18 %. This included the acquisition of APP Pharmaceuticals and Fresenius Kabi Oncology (formerly Dabur Pharma). Currency translation had an effect of -2 % on sales. This was mainly attributable to the weaker currencies in the United Kingdom, Poland, and Mexico against the euro, while the firmer Chinese yuan, had an especially positive effect.
- ▶ Fresenius Helios increased sales by 14 % to € 2,416 million (2008: € 2,123 million) and achieved excellent organic growth of 7 %. This was mainly due to an increase in admissions compared to 2008. Net acquisitions contributed 7 %. This was attributable to the acquisition of a total of five hospitals in Saxony-Anhalt and Lower Saxony.

- ▶ Fresenius Vamed achieved excellent sales growth of 18 % to € 618 million (2008: € 524 million). Organic growth was 15 %. The clinics in the Czech Republic taken over from Fresenius Helios contributed 3 %. Sales in the project business increased by 25 % to € 420 million (2008: € 336 million). Sales in the services business rose by 5 % to € 198 million (2008: € 188 million).

**Order intake and order backlog** in Fresenius Vamed's project business achieved an all-time high: order intake rose by 27 % to € 539 million (2008: € 425 million). Fresenius Vamed increased its order backlog by 19 % to € 679 million (December 31, 2008: € 571 million). This assures a stable level of capacity utilization for our business in the current year. Fresenius Vamed is the only business segment within the Fresenius Group whose business is significantly determined by order intake and order backlog. As the overview for the past five years shows, thanks to the continued strong demand for health care and hospital infrastructure we have been able to sustain the trend in order intake and order backlog despite the difficult macroeconomic development in 2008 and 2009.

## EARNINGS STRUCTURE

We again achieved excellent growth rates in earnings in 2009. **Adjusted Group net income**<sup>1</sup> rose by 14 % to € 514 million. Currency translation in total had no effect, therefore growth in constant currency was 14 % as well. Adjusted earnings per ordinary share rose to € 3.18 and adjusted earnings per preference share to € 3.19 (2008: € 2.85 per ordinary share, € 2.86 per preference share). This represents an increase of 12 % at actual rates and of 11 % in constant currency for both share classes. Including the effects of the mark-to-market accounting, Group net income<sup>2</sup> was € 494 million and earnings

## ORDER INTAKE AND ORDER BACKLOG FRESENIUS VAMED

in million €	2009	2008	2007	2006	2005
Order intake	539	425	395	337	257
Order backlog (December 31)	679	571	510	387	313

<sup>1</sup> Net income attributable to Fresenius SE; adjusted for the effects of the mark-to-market accounting of the Mandatory Exchangeable Bonds (MEB) and the Contingent Value Rights (CVR) relating to the acquisition of APP Pharmaceuticals. These items are not cash relevant.

<sup>2</sup> Net income attributable to Fresenius SE.

per share were € 3.06 per ordinary share and € 3.07 per preference share. Inflation had no significant effect on results of operations in 2009.

**Group EBITDA** rose by 17 % in constant currency and by 19 % at actual rates to € 2,616 million (2008, adjusted: € 2,203 million). **Group EBIT** increased by 17 % in constant currency and by 19 % at actual rates to € 2,054 million (2008, adjusted: € 1,727 million). In 2009, there were no special items affecting Group EBITDA and Group EBIT. The figures for 2008 are shown on an adjusted basis for reasons of comparability. They include a number of special items related to the acquisition of APP Pharmaceuticals that are shown in the reconciliation to adjusted earnings.

The development of EBIT by business segment was as follows:

- ▶ Fresenius Medical Care increased EBIT by 11 % to € 1,259 million (2008: € 1,137 million). Growth in constant currency was 7 %. The EBIT margin was 15.6 % (2008: 15.8 %). The decline was mainly due to higher

personnel expenses, cost increases for pharmaceuticals, and the launch of a generic product for the phosphate binder PhosLo® by a competitor in the United States. These effects were partially offset by an increase in revenue per treatment, the strong development of business in dialysis products, and successful cost control measures.

- ▶ Fresenius Kabi increased EBIT by 37 % to € 607 million (2008: € 443 million). The EBIT margin rose to 19.7 % (2008: 17.8 %). This marked improvement was due to the high-margin business of APP Pharmaceuticals and the good operating results in all regions, cost optimization and efficiency enhancement measures, and changes in product mix.
- ▶ Fresenius Helios achieved an excellent EBIT performance. In 2009, this business segment reported EBIT of € 205 million (2008: € 175 million) thanks to the very good business progress of the established clinics. The newly acquired clinics also performed to Fresenius Helios' full satisfaction. EBIT grew by 17 %. The EBIT margin improved strongly to 8.5 % (2008: 8.2 %).

#### STATEMENT OF INCOME (SUMMARY)

in million €	2009	2008	Change	Change in constant currency
<b>Sales</b>	<b>14,164</b>	12,336	15 %	13 %
Cost of goods sold	-9,528	-8,408	-13 %	-12 %
Gross profit	4,636	3,928	18 %	17 %
Operating expenses	-2,582	-2,451	-5 %	-4 %
<b>EBIT, adjusted<sup>1</sup></b>	<b>2,054</b>	1,727	19 %	17 %
EBIT	2,054	1,477	39 %	37 %
Net interest	-580	-431	-35 %	-35 %
Other financial result	-31	68	-146 %	-144 %
Income taxes <sup>2</sup>	-452	-431	-5 %	-3 %
Noncontrolling interest in profit <sup>2</sup>	-497	-413	-20 %	-16 %
<b>Net income, adjusted<sup>1,3</sup></b>	<b>514</b>	450	14 %	14 %
Net income <sup>4</sup>	494	270	83 %	82 %
Earnings per ordinary share in €, adjusted	3.18	2.85	12 %	11 %
Earnings per ordinary share in €	3.06	1.71	78 %	77 %
Earnings per preference share in €, adjusted	3.19	2.86	12 %	11 %
Earnings per preference share in €	3.07	1.72	78 %	77 %
EBITDA, adjusted <sup>1</sup>	2,616	2,203	19 %	17 %
EBITDA	2,616	2,260	16 %	14 %
Depreciation and amortization	562	783	-28 %	-29 %

<sup>1</sup> The annual financial statements for 2008 include several special items relating to the acquisition of APP Pharmaceuticals.

The adjusted figures reflect the Group's business operations in the reporting period.

<sup>2</sup> Application of the new accounting rules policies of SFAS 160 (US GAAP) resulted in a reclassification of tax expenses related to minority interests in partnerships to noncontrolling interest. The effect is neutral to net income attributable to Fresenius SE.

The prior-year figures have been adjusted.

<sup>3</sup> Net income attributable to Fresenius SE; adjusted for the effects of mark-to-market accounting of the Mandatory Exchangeable Bonds (MEB) and the Contingent Value Rights (CVR) relating to the acquisition of APP Pharmaceuticals.

<sup>4</sup> Net income attributable to Fresenius SE.

## RECONCILIATION

in million €	2009		2008	
	Other financial result	Net income	EBIT	Other financial result Net income
<b>Earnings, adjusted<sup>1</sup></b>		<b>514</b>	<b>1,727</b>	<b>450</b>
Purchase accounting adjustments <sup>2</sup> :				
in-process R & D acquired			-272	-272
inventory step-up (market value)			-35	-22
Foreign exchange gain <sup>2</sup>			57	41
Other financial result <sup>2</sup>				
Mandatory Exchangeable Bonds (MEB) (mark-to-market accounting)	-37	-26		28 20
Contingent Value Rights (CVR) (mark-to-market accounting)	6	6		75 75
One-time financing expenses <sup>3</sup>				-35 -22
<b>Earnings according to US GAAP<sup>4</sup></b>	<b>-31</b>	<b>494</b>	<b>1,477</b>	<b>68</b> <b>270</b>

<sup>1</sup> Earnings attributable to Fresenius SE adjusted for special items resulting from the acquisition of APP Pharmaceuticals.

<sup>2</sup> The special items are included in the column "Corporate/Other" in the segment reporting.

<sup>3</sup> In addition, € 73 million of transaction-related financing expenses have been capitalized and will be depreciated over the lifespan of the respective particular credit facility.

<sup>4</sup> Earnings attributable to Fresenius SE.

- Fresenius Vamed increased EBIT by 20 % to € 36 million (2008: € 30 million). The EBIT margin was 5.8 %, and slightly ahead of the 2008 level (2008: 5.7 %).

## RECONCILIATION TO ADJUSTED EARNINGS

The table above shows the special items relating to the acquisition of APP Pharmaceuticals in the reconciliation from adjusted EBIT and net income to earnings according to US GAAP.

The acquired in-process R & D activities were written off in full at the time of acquisition in 2008 in accordance with US GAAP accounting principles prevailing at the time of acquisition.

The valuation of inventories at market prices led to a valuation step-up in work-in-progress and finished goods. This amount was written off in 2008 over the average sales period of the respective products.

The foreign exchange gain resulted from the firmer US dollar, which increased the value of the US dollar intercompany loan to Fresenius Kabi Pharmaceuticals Holding, Inc. in 2008.

The Mandatory Exchangeable Bonds (MEB) and the Contingent Value Rights (CVR) are recognized as liabilities. The repayment value of the CVR and the derivative elements of the MEB are measured at market prices. The change in value

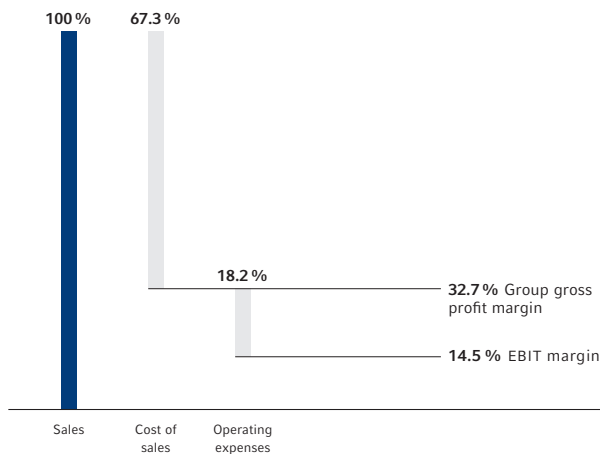
(mark-to-market accounting), which is measured over the entire life of the instruments, results either in a gain or an expense.

The one-time financing expenses included commitment and funding fees for the bridge facility as well as the full write-off of the financing costs of a syndicated credit facility of APP Pharmaceuticals from the year 2007.

## DEVELOPMENT OF OTHER MAJOR ITEMS IN THE STATEMENT OF INCOME

**Group gross profit** increased to € 4,636 million, exceeding the € 3,928 million in 2008 by 18 % (17 % in constant currency). We improved the gross margin to 32.7 % (2008: 31.8 %). The **cost of sales** rose 13 % to € 9,528 million (2008: € 8,408 million; including special items of € 35 million from the inventory step-up due to market price accounting related to the APP acquisition). Cost of sales as a percentage of Group sales sank from 68.2 % in 2008 to 67.3 %. **Selling, general, administrative expenses** consisted primarily of personnel costs, marketing and distribution costs, and depreciation and amortization. These expenses rose by 19 % to € 2,342 million in 2009 (2008: € 1,972 million, including special items of € 57 million from the currency gain on US dollar intercompany loans). Their ratio as a percentage of Group sales was 16.5 % (2008: 16.0 %). **Depreciation and amortization** was € 562 million (2008: € 476 million excluding special items, € 783 million including special items consisting of amortization

## EARNINGS STRUCTURE



of € 272 million on acquired in-process R & D and the valuation step-up in inventories of € 35 million). Their ratio as a percentage of sales was 4.0 % in 2009 (2008: 3.9 % before special items relating to the APP acquisition).

The chart above shows the earnings structure in 2009.

**Group net interest** was € -580 million, an increase of € 149 million versus € -431 million in 2008. Lower average interest rates on liabilities at Fresenius Medical Care were more than offset by incremental debt especially relating to the APP Pharmaceuticals acquisition.

The **other financial result** of € -31 million includes the valuation changes of the fair redemption value of the

Mandatory Exchangeable Bonds (MEB) of € -37 million and the Contingent Value Rights (CVR) of € 6 million. Both are non-cash items.

The adjusted **Group tax rate** (adjusted for the effects of the mark-to-market accounting of the Mandatory Exchangeable Bonds and the Contingent Value Rights) was 31.4 % (2008: 33.4 %, adjusted for special items relating to the APP acquisition). The decline is largely due to the revaluation of a tax claim at Fresenius Medical Care in the second quarter of 2009.

**Noncontrolling interest** rose to € 497 million from € 413 million in 2008 mainly due to the good earnings performance at Fresenius Medical Care. Of this, 93 % was attributable to the noncontrolling interest in Fresenius Medical Care.

The table below shows the profit margin progress:

in %	2009 <sup>1</sup>	2008 <sup>2</sup>
EBITDA margin	18.5	17.9
EBIT margin	14.5	14.0
Return on sales (before taxes and noncontrolling interest), adjusted	10.4	10.5

<sup>1</sup> 2009 return on sales adjusted for the effects of the mark-to-market accounting of the Mandatory Exchangeable Bonds (MEB) and Contingent Value Rights (CVR).

<sup>2</sup> 2008 adjusted for special items relating to the APP acquisition.

## VALUE ADDED

The value added statement shows Fresenius' total output in 2009 less purchased goods and services and less depreciation and amortization. The value added of the Fresenius Group

## VALUE ADDED STATEMENT

in million €

	2009	%	2008	%
<b>Creation</b>				
Company output	14,238	100	12,390	100
Materials and services purchased	6,635	47	5,704	46
Gross value added	7,603	53	6,686	54
Depreciation and amortization	562	4	783	6
<b>Net value added</b>	<b>7,041</b>	<b>49</b>	<b>5,903</b>	<b>48</b>
<b>Distribution</b>				
Employees	4,880	69	4,332	74
Governments	559	8	525	9
Lenders	580	8	431	7
Shareholders	122	2	114	2
Company and noncontrolling interest	900	13	501	8
<b>Net value added</b>	<b>7,041</b>	<b>100</b>	<b>5,903</b>	<b>100</b>

reached €7,041 million in 2009 (2008: €5,903 million). This is an increase of 19% over 2008. The distribution statement shows that, at €4,880 million or 69%, the largest portion of our value added went to our employees. Lenders came next with €580 million (8%) and governments with €559 million (8%). Shareholders received €122 million and noncontrolling interests of €497 million. The Company retained €403 million for reinvestment.

## FINANCIAL POSITION

### FINANCIAL MANAGEMENT POLICIES AND GOALS

Ensuring financial flexibility is key to the financing strategy of the Fresenius Group. We achieve this flexibility through a broad spectrum of financing instruments and a wide diversification of our investors. The maturity profile is characterized by a broad spread of maturities with a large proportion of mid to long-term financing.

Sufficient financial cushion is assured for the Fresenius Group by syndicated and bilateral credit lines that are only partially drawn. Market capacity, investor diversification, flexibility, credit covenants, and the current maturity profile are all taken into consideration when selecting financing instruments. At the same time, we seek to optimize our financing costs.

In line with the Group's structure, financing for Fresenius Medical Care and for the rest of the Fresenius Group is conducted separately. There are no joint financing facilities and no mutual guarantees. The Fresenius Kabi, Fresenius Helios, and Fresenius Vamed business segments are financed primarily through Fresenius SE in order to avoid any structural subordination.

### FINANCING

Fresenius meets its **financing needs** through a combination of operating cash flows generated in the business segments and short, mid, and long-term debt. In addition to bank loans, important financing instruments include the issuance

of Senior Notes, Euro Notes, Trust Preferred Securities, a commercial paper program, a receivables securitization program, and Mandatory Exchangeable Bonds.

In 2009, the Group's **financing activities** mainly involved the refinancing of existing and maturing financing instruments.

In January 2009, Fresenius issued unsecured Senior Notes in two tranches through its subsidiary Fresenius US Finance II, Inc. The proceeds were US\$800 million. The euro tranche was issued in a principal amount of €275 million and was priced at 93.024%. With a coupon of 8.75%, the euro tranche has a yield to maturity of 10.25%. The US dollar tranche was issued in a principal amount of US\$500 million and was priced at 93.076%. With a coupon of 9.00%, its yield to maturity is 10.50%. Both tranches are due in 2015 and are non-callable. Fresenius used the proceeds to refinance the existing US\$650 million bridge facility, which was taken up to finance the APP Pharmaceuticals acquisition, and to repay short-term debt. The financing of the APP Pharmaceuticals acquisition was completed with this transaction.

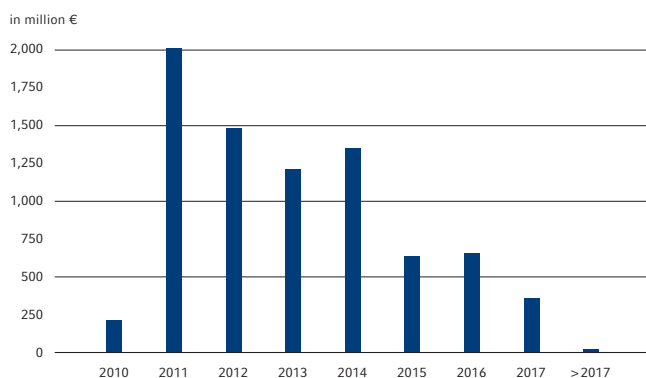
In April 2009, Fresenius Medical Care issued Euro Notes in the principal amount of €200 million in a private placement with European investors. These new Euro Notes, which are senior and unsecured, were issued by Fresenius Medical Care AG & Co. KGaA in four tranches, with maturities of 3.5 and 5.5 years and fixed and floating interest rates. The proceeds were used to redeem Euro Notes that were due in July 2009.

In June 2009, Fresenius placed a tap to its 2006 Senior Notes by Fresenius Finance B.V. This transaction had a principal amount of €150 million and was priced at 92.0%. With a coupon of 5.5%, the yield to maturity is 7.0%. The Notes were also offered in a private placement to institutional investors, which was well oversubscribed. The proceeds were used to repay short-term debt. This has lengthened the maturity profile of our debt.

In January 2010, Fresenius Medical Care issued unsecured Senior Notes due in 2016 in the principal amount of €250 million. The coupon is 5.5%. With an issue price of 98.6636%, the yield to maturity is 5.75%. The proceeds were used to repay short-term debt and for general corporate purposes.

As the chart shows, further larger scale **refinancing** within the Fresenius Group is only due in 2011.

#### MATURITY PROFILE OF THE FRESENIUS GROUP FINANCING FACILITIES<sup>1</sup>



<sup>1</sup> As of December 31, 2009; major financing instruments, excluding the accounts receivables program of Fresenius Medical Care.

Fresenius SE has a **commercial paper program** under which up to € 250 million in short-term notes can be issued. No commercial papers were outstanding as of December 31, 2009 and December 31, 2008.

The Fresenius Group has drawn about € 4.7 billion of bilateral and syndicated credit lines. In addition, the Group had approximately € 1.3 billion in unused credit lines as of December 31, 2009 (including committed credit lines of € 0.8 billion) available. These credit facilities are generally

used for covering working capital needs and are – with the exception of the Fresenius SE 2008 credit agreement and the Fresenius Medical Care 2006 credit agreement – usually unsecured.

As of December 31, 2009, both Fresenius SE and Fresenius Medical Care AG & Co. KGaA, including all subsidiaries, complied with the **covenants** under all the credit agreements.

Detailed information on the Fresenius Group's financing can be found on pages 148 to 157 of the Notes.

#### EFFECT OF OFF-BALANCE-SHEET FINANCING INSTRUMENTS ON OUR FINANCIAL POSITION AND ASSETS AND LIABILITIES

Fresenius is not involved in any off-balance-sheet transactions that could have or will have a significant impact on its financial position, expenses or income, results of operations, liquidity, investments, assets and liabilities, or capitalization.

#### LIQUIDITY ANALYSIS

In 2009, key sources of liquidity were operating cash flows and short, medium, and long-term debt. **Cash flow from operations** is influenced by the profitability of Fresenius' business and by net working capital, especially accounts receivable. Cash flow can be generated from short-term borrowings through the sale of receivables under the Fresenius Medical Care accounts receivable securitization program, by using the commercial paper program, and by drawing on bilateral bank credit agreements. Medium and long-term

#### FINANCIAL POSITION – FIVE-YEAR OVERVIEW

in million €	2009	2008	2007	2006	2005
Operating Cash flow	1,553	1,074	1,296	1,052	780
as % of sales	11.0	8.7	11.4	9.8	9.9
Working Capital <sup>1</sup>	3,088	2,937	2,467	2,322	2,159
in % of sales	21.8	23.8	21.7	21.5	27.4
Investments in property, plant and equipment, net	662	736	662	571	331
Cash flow before acquisitions und dividends	891	338	634	481	449
as % of sales	6.3	2.7	5.6	4.5	5.7

<sup>1</sup> Trade accounts receivable and inventories, less trade accounts payable and payments received on accounts.

funding is provided by the revolving credit facilities of Fresenius Medical Care and Fresenius SE and by bonds, as well as by various other financing instruments. Fresenius believes that its existing credit facilities, as well as the operating cash flows and additional sources of short-term funding, are sufficient to meet the Company's foreseeable liquidity needs.

## DIVIDEND

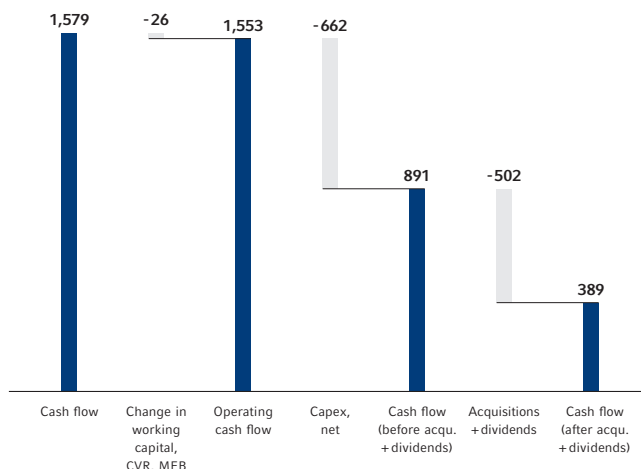
The Management and Supervisory Boards will propose a dividend increase to the Annual General Meeting. For 2009, a dividend of € 0.75 per ordinary share and € 0.76 per preference share is proposed. This is an increase of 7%. The total dividend distribution will increase by 7% to € 121.8 million (2008: € 113.6 million).

## CASH FLOW ANALYSIS

The cash flow statement shows a very positive development. Cash flow increased by 9% to € 1,579 million in 2009 (2008: € 1,454 million). This was mainly due to the Group's excellent earnings performance. The change in working capital in 2009 was € -46 million (2008: € -285 million). This improvement was due to strict working capital management, driven mainly by the decline in trade accounts receivable.

**Operating cash flow** increased by 45% to € 1,553 million in 2009 (2008: € 1,074 million). The cash flow margin rose to 11.0% (2008: 8.7%). Operating cash flow was more than sufficient to meet all the financing needs for investing activities excluding acquisitions, whereby cash used for capital expenditure was € 677 million, and proceeds from the sale of property, plant and equipment were € 15 million (2008: € 759 million and € 23 million, respectively). **Cash flow before acquisitions and dividends** more than doubled to € 891 million (2008: € 338 million). This was sufficient to fully finance the net acquisitions of € 227 million and the Group dividends of € 275 million. Group dividends consisted of dividend payments of € 114 million to the shareholders of Fresenius SE, payments of € 173 million by Fresenius Medical Care to its shareholders, and dividends paid to third parties of € 50 million. Set against this, there was the dividend of € 62 million which Fresenius SE received as a shareholder of Fresenius Medical Care.

## CASH FLOW IN MILLION €



Cash from financing activities (excluding dividend payments) was € -336 million (2008: € 2,869 million, driven by the equity and debt financing for the APP Pharmaceuticals acquisition). In addition to the acquisition expenditure, Group dividend payments led to a cash outflow of € 275 million in 2009

## CASH FLOW STATEMENT (SUMMARY)

in million €	2009	2008
Net income <sup>1</sup>	991	683
Depreciation and amortization	562	783
Change in pension provisions	26	-12
<b>Cash flow</b>	<b>1,579</b>	<b>1,454</b>
Change in working capital	-46	-285
Change in mark-to-market valuation of the MEB and CVR	20	-95
<b>Operating cash flow</b>	<b>1,553</b>	<b>1,074</b>
Property, plant and equipment	-677	-759
Proceeds from the sale of property, plant and equipment	15	23
<b>Cash flow before acquisitions and dividends</b>	<b>891</b>	<b>338</b>
Cash used for acquisitions/proceeds from disposals	-227	-2,957
Dividends	-275	-245
<b>Cash flow after acquisitions and dividends</b>	<b>389</b>	<b>-2,864</b>
Cash provided by/used for financing activities (without dividends paid)	-336	2,869
Effect of exchange rate changes on cash and cash equivalents	-3	4
<b>Change in cash and cash equivalents</b>	<b>50</b>	<b>9</b>

<sup>1</sup> Net income attributable to Fresenius SE and noncontrolling interest.

The detailed cash flow statement is shown in the consolidated financial statements.

(2008: € 245 million). Cash and cash equivalents increased to € 420 million as of December 31, 2009 (December 31, 2008: € 370 million).

### INVESTMENTS AND ACQUISITIONS

The Fresenius Group invested € 931 million in 2009 (2008: € 4,617 million, driven by the acquisition of APP Pharmaceuticals). At € 671 million (2008: € 764 million), **investments in property, plant and equipment** was well above the level of depreciation of € 562 million and serves as the basis for preserving the Company's value over the long term and for expansion. At 4.7 % of sales, investments returned to our targeted long-term level in 2009 after the high capital expenditure in 2007 and 2008, equivalent to 6.2 % of sales in each case. € 260 million was invested in **acquisitions** (2008: € 3,853 million). Of the total capital expenditure in 2009, 72 % was invested in property, plant and equipment; 28 % was spent on acquisitions.

#### INVESTMENTS AND ACQUISITIONS

in million €	2009	2008	Change
Investment in property, plant and equipment	671	764	-12 %
thereof maintenance	50 %	49 %	
thereof expansion	50 %	51 %	
Investment in property, plant and equipment as % of sales	4.7 %	6.2 %	
Acquisitions	260	3,853	-93 %
<b>Total investments and acquisitions</b>	<b>931</b>	<b>4,617</b>	<b>-80 %</b>

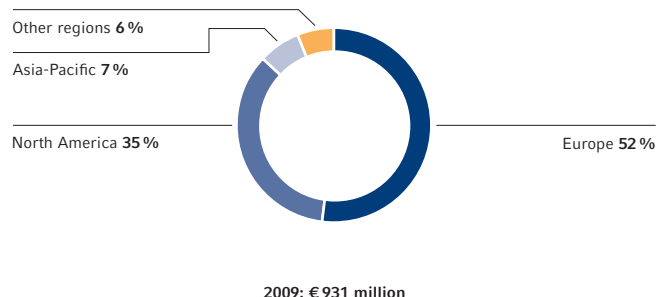
The table shows the distribution of investments by business segment. The pie chart shows the regional breakdown.

The cash outflows for acquisitions related mainly to the acquisition of dialysis clinics at Fresenius Medical Care. At Fresenius Helios, expenditure was for the acquisition of five

#### INVESTMENTS BY BUSINESS SEGMENT

in million €	2009	2008	Thereof property, plant and equipment	Thereof acquisitions	Change	% of total
Fresenius Medical Care	549	687	411	138	-20 %	59 %
Fresenius Kabi	157	3,749	125	32	-96 %	17 %
Fresenius Helios	203	140	124	79	45 %	22 %
Fresenius Vamed	7	39	5	2	-82 %	1 %
Corporate/Other	15	2	6	9	--	1 %
<b>Total</b>	<b>931</b>	<b>4,617</b>	<b>671</b>	<b>260</b>	<b>-80 %</b>	<b>100 %</b>

#### INVESTMENTS BY REGION



acute care hospitals. Fresenius Kabi and Fresenius Vamed made no significant acquisitions in 2009.

The main investments in property, plant and equipment were as follows:

- ▶ start-up of 118 de novo dialysis clinics, of which 85 were in the United States, and expansion and modernization of existing clinics for Fresenius Medical Care
- ▶ expansion and modernization of production facilities for Fresenius Medical Care, including the expansion of production capacities for dialysis products in Germany in response to strong global demand, and for Fresenius Kabi in different regions
- ▶ hospital modernization at Fresenius Helios. The largest single projects were the HELIOS clinics in Berlin-Buch, Krefeld, and Schwerin.

Investments in property, plant and equipment of € 181 million will be made in 2010 to continue with major **ongoing investment projects on the reporting date**. These are chiefly investment obligations for hospitals at Fresenius Helios as well as investments to expand and optimize production facilities for Fresenius Medical Care and Fresenius Kabi. These projects will be financed from operating cash flow.

## ASSETS AND LIABILITIES

### ASSET AND LIABILITY STRUCTURE

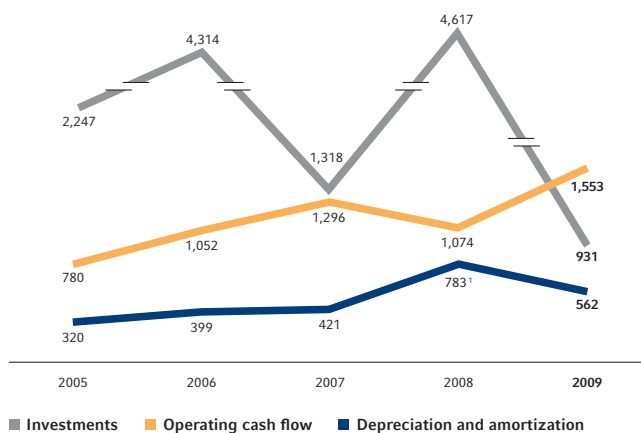
The **total assets** of the Group rose by € 338 million (2 %) to € 20,882 million (December 31, 2008: € 20,544 million). In constant currency, this was an increase of 3 %. The growth of the balance sheet was mainly due to the expansion of existing business activities. Inflation had no significant impact on the assets of Fresenius in 2009.

**Non-current assets** were € 15,519 million (2008: € 15,466 million). The increase was driven by additions to property, plant and equipment.

**Current assets** rose by 6 % to € 5,363 million (2008: € 5,078 million). Within current assets, trade accounts receivable rose by 1 % to € 2,509 million (2008: € 2,477 million); the increase was well below the growth of 15 % in sales. At 65 days, average days sales outstanding was 6 days lower than in 2008; reductions were achieved across all business segments. Inventories rose by 10 % to € 1,235 million (2008: € 1,127 million). The 48 days scope of inventory in 2009 was unchanged compared to 2008. The ratio of inventories to total assets slightly increased to 5.9 % as of December 31, 2009 (December 31, 2008: 5.5 %).

**Shareholders' equity**, including **noncontrolling interest**, rose by 10 %, or € 709 million, to € 7,652 million (2008: € 6,943 million). Group net income (net income attributable to Fresenius SE) increased shareholders' equity by € 494 million. The equity ratio, including noncontrolling interest, rose to 36.6 % as of December 31, 2009 (December 31, 2008: 33.8 %).

### INVESTMENTS, OPERATING CASH FLOW, DEPRECIATION AND AMORTIZATION IN MILLION € – FIVE-YEAR OVERVIEW



<sup>1</sup> Includes special items of € 307 million from the acquisition of APP Pharmaceuticals.

The liabilities and equity side of the balance sheet shows a solid financing structure. Shareholders' equity of the Group, including noncontrolling interest, covers 49 % of non-current assets (2008: 45 %). Shareholders' equity, noncontrolling interest, and long-term liabilities cover all non-current assets and inventories.

**Long-term liabilities** were € 9,702 million as of December 31, 2009, an increase of 3 % (December 31, 2008: € 9,432 million). **Short-term liabilities** declined by 15 % to € 3,528 million (2008: € 4,169 million).

The Group has no significant accruals. The largest single accrual is to cover the settlement of fraudulent conveyance claims and all other legal matters relating to the National

### ASSETS AND LIABILITIES – FIVE-YEAR OVERVIEW

in million €	2009	2008	2007	2006	2005
Total assets	20,882	20,544	15,324	15,024	11,594
Shareholders' equity <sup>1</sup>	7,652	6,943	6,059	5,728	5,130
as % of total assets <sup>1</sup>	37	34	40	38	44
Shareholders' equity <sup>1</sup> /non-current assets, in %	49	45	55	52	64
Debt	8,299	8,787	5,699	5,872	3,502
as % of total assets	40	43	37	39	30
Gearing in %	103	121	88	98	63

<sup>1</sup> Including noncontrolling interest.

Medical Care transaction in 1996 that resulted from the bankruptcy of W.R. Grace. The accrual amounts to US\$ 115 million (€80 million). Please see page 165 of the Notes for details.

Group **debt** was €8,299 million (2008: €8,787 million). Its relative weight in the balance sheet declined to 39.7 % (2008: 42.8 %). Approximately 57 % of the Group's debt is in US dollars. Liabilities due in less than one year were €550 million (2008: €1,262 million), while liabilities with a remaining tenor of one to five years and over five years were €7,749 million (2008: €7,525 million).

The net debt to equity ratio including noncontrolling interest (gearing) has improved and is 103.0 % (2008: 121.2 %). The return on equity after taxes (equity attributable to shareholders of Fresenius SE) rose to 12.0 % (2008: 10.5 %). The return on total assets after taxes and before noncontrolling interest increased to 4.8 % in 2009 (2008: 4.0 %); figures for 2009 adjusted for the effects of the mark-to-market accounting of the MEB and the CVR; figures for 2008 pro forma APP Pharmaceuticals and before special items relating to the acquisition.

The table below shows other key assets and capital ratios:

in million €	Dec 31, 2009	Dec 31, 2008
Debt/EBITDA <sup>1</sup>	3.2	3.8
Net debt/EBITDA <sup>1</sup>	3.0	3.6
EBITDA/interest ratio <sup>1</sup>	4.5	4.0

<sup>1</sup>2008: Pro forma APP Pharmaceuticals and before special items related to the acquisition.

## CURRENCY AND INTEREST RISK MANAGEMENT

The nominal value of all foreign currency hedging contracts was €2,442 million as of December 31, 2009. These contracts had a market value of €19 million. The nominal value of interest rate hedging contracts was €2,698 million. These contracts had a market value of €-134 million. Please see the Risk Report on page 94 and the Notes on pages 170 to 174 for further details.

## NON-FINANCIAL PERFORMANCE INDICATORS AND OTHER SUCCESS FACTORS

### EMPLOYEES

Our employees are the basis on which the Company's success is founded. It is thanks to their achievements, their skills, and their commitment that we command leading positions in our markets. We support our employees through numerous measures and actively promote international and interdisciplinary cooperation.

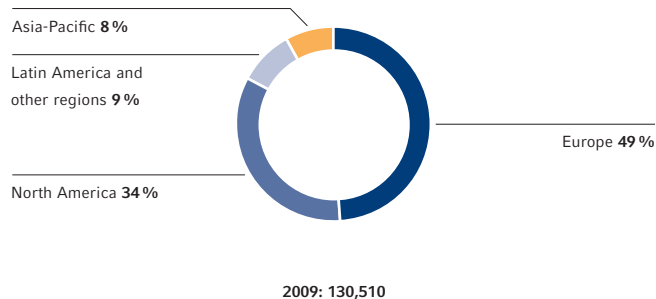
The Fresenius Group had 130,510 employees worldwide at the end of 2009, an increase of 8,293 or 7 % (December 31, 2008: 122,217). Acquisitions accounted for 3 % of the increase.

The **employee numbers** in the business segments were as follows:

Number of employees	Dec 31, 2009	Dec 31, 2008	Change
Fresenius Medical Care	71,617	68,050	5 %
Fresenius Kabi	21,872	20,457	7 %
Fresenius Helios	33,364	30,088	11 %
Fresenius Vamed	2,849	2,802	2 %
Corporate/Other	808	820	-1 %
<b>Total</b>	<b>130,510</b>	<b>122,217</b>	<b>7 %</b>

At the end of 2009, there were 40,416 employees in Germany, an increase of 9 % (2008: 37,078). 90,094 employees (69 %) are employed at our foreign companies. The chart shows the distribution of our employees by region. These percentages roughly correspond to the sales contributions of the respective continents. With an increase of 7 %, the number of employees has grown significantly in Europe. This was mainly due to the hospital acquisitions at HELIOS. The number of employees also rose strongly in Asia-Pacific, with an increase of 14 %. This largely reflects our fast-growing business in this region, where sales growth was 13 % in constant currency.

## EMPLOYEES BY REGION



**Personnel expenses** for the Fresenius Group were € 4,880 million in 2009 (2008: € 4,332 million), equivalent to 34.5 % of sales (2008: 35.1 %). Personnel expenses per employee were € 38.2 thousand (2008: € 36.5 thousand). There were no significant changes to compensation or employment agreements in 2009. The increase was mainly due to collectively bargained pay increases and the higher overall number of employees.

### HUMAN RESOURCES MANAGEMENT

Highly skilled and motivated employees are the foundation for sustained growth. The ever increasing globalization of our markets has changed the parameters for human resources management at Fresenius. This involves factors such as demographics, the transformation toward a service society, and the compatibility of job and family. These issues are set to play an even greater role in the coming years and present new challenges for human resources management.

We are constantly adapting our human resources tools to future needs. In 2010, for instance, we are introducing life work time accounts to supplement our work time models in some business segments and in the Fresenius SE corporate center divisions in Germany. Under this scheme, employees can also credit their own contributions, such as holiday leave or parts of their compensation, into a life work time account in addition to their collectively bargained employment benefits. These accumulated credit balances can then be drawn on later flexibly for sabbaticals for higher education, further training measures, or for phased early retirement.

### TALENT MANAGEMENT

Modern talent management is becoming ever more important given the global market changes that are taking place. This means designing components such as:

- ▶ attractiveness as an employer,
- ▶ personnel development,
- ▶ performance appraisal, and
- ▶ successor planning

in a way that we are able to meet future challenges. Our focus is on the professional development of employees in an international and dynamic environment marked by change and the resulting opportunities. Since the demands of our business segments with respect to personnel development concepts and measures differ – depending on their customer and market structure – they are coordinated, developed, and executed on a segment-specific basis. All measures are oriented to overarching corporate goals on the one hand, and to individual development needs on the other.

We support the development of our employees' **professional and personal skills** through a wide-ranging offering of internal training measures as well as through personal career talks. The strengths of each individual employee are deliberately furthered and tapped. Through the specific transfer of know-how within the framework of our successor planning, we ensure that valuable expertise is not lost.

An outstanding example is our innovative program for the development of dialysis nursing staff. In 2008, the first entrants began their **dialysis nursing training** at the Fresenius Medical Care Institute of Dialysis Nursing (F.I.D.N.), the world's leading education center of its kind. The training program lasts twelve months and includes theoretical courses at the academic level as well as practical experience in a teaching clinic. The institute began regular operations in 2009.

The **Fresenius Advanced Management Program**, which has been conducted for many years in cooperation with the INSEAD business school, is a firmly established component in our development of top management executives. In 2009, the focuses of this program were on imparting leadership skills in a global corporate context and facing challenges constructively – against the backdrop of the current economic situation.

Within the framework of our efforts to attract and further **young talents**, our trainee program offers promising university graduates the opportunity to start a successful career with the Fresenius Group alongside the classic channel of direct job entry. The program combines challenging on-the-job assignments with internal and external training modules.

The HELIOS trainee programs, which were considerably widened in 2008, serve to prepare university graduates for future management positions within the HELIOS-Kliniken Group so as also to meet the demand for management resources created by the Group's ongoing growth. The trainees spend their two-year training at different hospital locations. Working directly with the respective administration and department heads, they learn how to run a clinic or specialist department both strategically and operationally. HELIOS offers these trainee programs in the fields of Hospital Management, Medical Equipment, Controlling & Finance, Purchasing, Pharmaceuticals, Logistics, and IT. Additional programs in the areas of Human Resources, Nursing Care, and Building and Technical Facilities are being introduced in 2010.

Other measures are special development programs for middle-management medical and nursing staff. As in the past, HELIOS offers employees specially tailored programs for the development of management skills. The focus is on preparing them for positions of greater responsibility.

In a global company like Fresenius, the close interaction among employees of different nationalities and with different cultures plays an important role. We therefore further the international mobility of our employees and offer them the opportunity to work abroad. We organize intercultural training programs to develop an awareness and sensitivity for cultural differences for employees who are due to take up assignments at locations abroad. The same applies for employees who come to Germany from our international locations. The program "Living + Working in Germany", for instance, offers language courses and help with handling formalities.

In 2009, we intensified the exchange and interaction between employees from different business segments. Trainees at Fresenius Kabi, for instance, were given the opportunity to get to know the day-to-day routines at the hospitals of the HELIOS-Kliniken Group through first-hand experience. In

addition, HELIOS invited all employees of the Fresenius Group to take advantage of the seminars and workshops offered by the HELIOS Academy, such as the "Medical Seminar for Non-Medics", which attracted strong interest.

## JOB APPLICATION MANAGEMENT

Fresenius' goal is to be the employer of choice for high-potential applicants. We have therefore extended our personnel marketing activities with the addition of a **target university concept**, intensifying our contacts with 16 selected universities by taking part at careers guidance fairs and through presentations by our staff. This is designed to inform potential applicants even more effectively about the opportunities that our Group of companies offers and to encourage them to start a career with Fresenius.

The **online application management system** introduced in 2008 has established itself as a modern recruitment instrument and effectively supports the application process. In its first full year, over 400 job offers were published and over 15,600 applications were received through this system. In addition, we received over 4,600 unsolicited applications. We also used the system for the first time to advertise and fill apprenticeship places for 2010. We have also started to use it as an international internal job vacancies platform in individual business segments. In future, we intend to expand the functions for managing the extensive pool of unsolicited applications and to enter new recruitment channels, especially in the social networking area. For more information: [www.fresenius.com/Career](http://www.fresenius.com/Career). The HELIOS careers portal that was launched in 2008 is also very popular, with over 7,000 applications received in 2009. More information is available on the website at [www.helios-kliniken.de/Karriere](http://www.helios-kliniken.de/Karriere).

## IDEA MANAGEMENT

The aim of our **team@work award** is to further a common identity and to promote teamwork. It also encourages the optimization of work processes and the identification and realization of cost-cutting potential. The award's third round in 2009 again drew an excellent response, with over 100 contestants from all over the world competing with 19 projects – impressive evidence of the energy with which many employees are working together within the Fresenius Group.

We want to further strengthen and foster this team spirit. So the motto for the fourth round is "Working Together, Winning Together". Any form of interdepartmental or interdisciplinary cooperation that results in more sales, less costs, or other measurable improvements is eligible for the award.

### VOCATIONAL TRAINING MANAGEMENT

The transfer of knowledge to the next generation, and thus the professional training of young people, is an important element to secure Fresenius' future over the long term. In this regard we are in a very good position. In Germany at the end of 2009, we employed about 1,500 **apprentices** in 34 different job specifications as well as over 30 students pursuing courses of study at vocational training academies. In 2009, we were therefore again able to increase the number of apprenticeship places offered at all our training locations by over 5 %, after already increasing our intake by over 10 % in 2008.

We regularly offer students interested in the provided job specifications the opportunity to gain first-hand experience in working life through periods of practical work and information days. This enables students to start thinking about their career early on and provides them with valuable guidance in choosing the right profession or course of study. Through intensive marketing in and with schools, we want to attract even more young people to do apprenticeships with Fresenius. We address students as well as teachers. We invite school students to visit us and provide job application guidance and offer teachers various training courses within the *Arbeitskreis SchuleWirtschaft* (School and Industry Working Group).

At the start of the vocational training there is a six-week course during which the apprentices not only learn computer skills; a special focus is also placed on developing their personal skills, with the emphasis on improving communication

skills and teamwork as well as project management. The apprentices at our corporate headquarters also have the opportunity to attend a free English language course.

Our measures are bearing fruit and show that, also in light of the increasing number of high-quality applications we receive, that we are an attractive employer not only for school-leavers, but also for interns and students.

### PROFIT-SHARING SCHEME AND STOCK OPTION PLAN

Our policy is that our employees should share directly in the Company's financial success through a profit-sharing scheme and certain executives through our stock option plan.

Through benefits in the form of shares we provide employees in Germany with a long-term, value-oriented performance incentive. This is based on Group operating profit (EBIT). Employees can receive either the full amount of their profit-sharing bonus in shares or two-thirds of the amount in shares and the rest in cash. The bonus paid in 2009 for fiscal year 2008 was € 1,586 gross for full-time employees. At foreign companies there are also attractive compensation systems aligned with the local schemes in the particular country.

Our executives have already been sharing in Fresenius' growth since 1998 through another value-based compensation component. With our **stock option plan**, we have an internationally recognized compensation instrument linking management's entrepreneurial responsibility to future opportunities and risks. Under the 2008 stock option plan, a total of up to 6,200,000 options on Fresenius SE ordinary and preference shares can be issued to members of the Management Board and certain other executive officers over a period of five years. The stock options can be exercised after a three-year vesting period if Group net income has been increased at an annual

### PROFIT-SHARING BONUS

	2008	2007	2006	2005	2004
Profit-sharing bonus <sup>1</sup> in €	1,586	1,526	1,444	1,000	1,000
Eligible employees	1,630	1,690	1,830	1,780	1,690

<sup>1</sup> The profit-sharing bonus is paid retroactively and is based on Fresenius' Group EBIT in the past year.

rate of at least 8 % during the vesting period. Otherwise, the options granted are forfeited proportionally. In 2009, 1,067,248 stock options were issued under this plan. For further information please see pages 179 to 184 of the Notes.

## RESEARCH AND DEVELOPMENT

Fresenius focuses its R & D efforts on its core competencies:

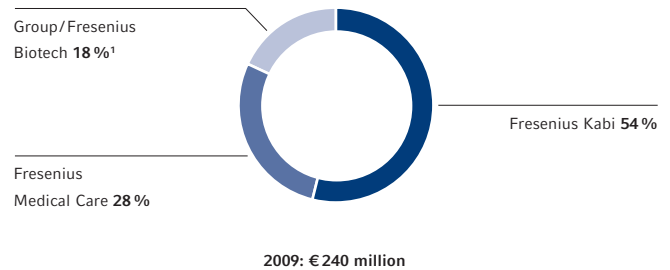
- ▶ Dialysis
- ▶ Infusion and nutrition therapies, generic IV drugs, and medical devices
- ▶ Antibody therapies

Apart from products, we are concentrating on developing optimized or completely new therapies, treatment methods, and services. In 2009 we again successfully continued numerous projects and a number of new products were launched.

**Expenses** on research and development were €240 million in 2009 (2008: €479 million, including €272 million of in-process R & D activities acquired with APP Pharmaceuticals). We therefore invested about 5 % of our product sales in R & D. This matched the previous year's figure excluding the in-process R & D activities acquired. The chart shows R & D expenses by segment. In 2009, Fresenius Medical Care increased its R & D spending by 22 %, and Fresenius Kabi by 18 %. In the segment Corporate/Other, €44 million was spent on R & D at Fresenius Biotech, mostly on the clinical development of trifunctional antibodies. This was slightly

above the €43 million spent in the previous year. Detailed figures are included in the segment reporting on pages 116 to 117.

### R & D EXPENSES BY SEGMENT



As of December 31, 2009, there were 1,421 employees in research and development in the Group (2008: 1,336). Of that number, 494 were employed at Fresenius Medical Care (2008: 427), 829 at Fresenius Kabi (2008: 793), and 98 at Fresenius Biotech (2008: 116).

The table shows a historical comparison of R & D expenses and the number of employees working in R & D.

Our main research sites are in Europe. Production-related R & D activities are also carried out in the United States and in China. Our R & D projects are mainly conducted in-house; external research is commissioned only on a limited scale.

We now inform you about the R & D activities in our business segments:

	2009	2008	2007	2006	2005
R & D expenses in million €	240	207 <sup>1</sup>	184	167	149
as % of product sales	4.7	4.7 <sup>1</sup>	4.9	4.7	4.6
R & D employees	1,421	1,336	999	911	856

<sup>1</sup> Excluding amortization expenses of €272 million on in-process R & D activities acquired with APP Pharmaceuticals.

## FRESENIUS MEDICAL CARE

Fresenius Medical Care focuses its research and development strategy on three essential objectives:

- ▶ to continuously enhance the quality of life of patients with chronic kidney disease using innovative products and treatment concepts
- ▶ to offer our customers high-quality services while keeping our prices as low as possible, and,
- ▶ on this basis, to continue to expand our global leadership in the dialysis market.

In 2009, Fresenius Medical Care expanded its activities in its key areas of strategic development – for example in the field of **online-hemodiafiltration** (Online-HDF) and the 5008 therapy system based on it. In May 2009, we presented another innovation built on this development platform at the industry congress ERA-EDTA (European Renal Association/European Dialysis and Transplant Association): **MIXED HDF**. This treatment method, which is probably the most advanced dialysis treatment available in the world, is a new form of Online-HDF and can be tailored even more precisely to the medical needs of individual patients thanks to a complex new control technology. Fresenius Medical Care was the first company to get MIXED HDF ready for market launch. We are convinced that this innovation will further contribute to establishing Online-HDF as the treatment of choice for dialysis patients, and expect to achieve a clear market edge with this trend-setting technology. Just like the 5008 therapy system, MIXED HDF also saves on resources: the device uses up to 30 % less energy, water and concentrate than traditional hemodialysis methods during treatment. Due to its considerable potential for the medical world, Fresenius Medical Care uses Online-HDF as a long-term innovation platform.

We also continued to develop our portfolio in the area of **home dialysis** in 2009 – another of our strategic development platforms. In 2008, we introduced the Liberty Cyclor, our therapy system for peritoneal dialysis (PD), in the US. It was a resounding success: over 2,500 patients are now being treated with the device. We will have a stronger focus on this product in North America in the future. We have continued to improve the Liberty Cyclor ever since we introduced it – for

instance with an expanded alarm system to help users avoid application errors. With the further development of the device's software, patients' individual treatment settings and results can now be processed even more comprehensively and transmitted to the attending clinic. There, the data is regularly checked to adapt the treatment to individual patients in the best possible way.

As a home dialysis treatment method – i. e., a treatment that is performed in the patient's home environment –, PD requires a high level of individual responsibility from patients as they usually carry it out themselves. It is therefore crucial that these patients receive intensive training on hygiene and safety matters. With its intuitive user interface and easy-to-understand instructions, which guide patients through the device settings step-by-step via a screen, the Liberty Cyclor is one of the simplest and safest devices in this respect. To further increase the user-friendliness of the cyclor, we are currently working on new help software, which uses short instructional videos and text information to demonstrate how the device should be used. It will also allow patients to receive prompt answers to their questions via a help menu, even during treatment. We plan to make this new feature standard for the device in 2011.

Another development focus at Fresenius Medical Care is the **Body Composition Monitor** (BCM) diagnosis machine, which we successfully launched in additional markets in 2009. The BCM can determine the exact make-up of the human body and its fluids (body water, fat, and fat-free body mass). This provides doctors with information on the patients' general health – for instance on the constitution of their blood vessels – and helps them to determine to what extent a patient may be suffering from overhydration. Such information can substantially improve the treatment quality of dialysis, as both heart and vascular diseases and overhydration are common side effects of chronic kidney disease. We are currently working on making the advantages of BCM technology, which to this point have only been documented in the treatment of hemodialysis patients, available to other patient groups. Initial studies have shown, that peritoneal dialysis patients can also benefit from professional fluid management, a regular check of their fluid status with the treatment adjusted accordingly. Another group of patients whose treatment could be improved with the use of BCM technology are people who suffer from acute kidney failure.

Besides the activities in our strategic focal areas, Fresenius Medical Care has also improved and continued to develop our traditional hemodialysis products. The **4008S** classic, for instance, is a new addition to our range of hemodialysis machines. This device offers exceptional treatment quality along with high reliability and safety at an affordable price thanks to its high-quality basic configuration. Thanks to its cost effectiveness and simple operability, it should provide access to high-quality dialysis treatment for even more dialysis patients, especially in areas with a poor infrastructure.

In the United States, we have also tailored our range of products to the needs of our patients and customers. This puts us in an excellent position to cope with the planned introduction of a new quality-oriented lump-sum reimbursement system for dialysis. A good example is the **2008T**, a new product generation of the 2008 hemodialysis series, which gained approval from the FDA (U.S. Food and Drug Administration) in the United States in 2009. In addition to further improving the machine's usability and safety, and thus its treatment performance, the 2008T is the first hemodialysis machine on the US market to use an integrated computer system, which automatically compiles clinical treatment data. The reimbursement reform, which will come into effect in 2011, requires dialysis treatment to fulfill certain quality criteria, among other things. This means that the 2008T, which automatically compiles data, offers a distinct advantage as it can measure the success of the treatment and improve it even more effectively. We presented the new 2008T at the American Society of Nephrology Conference in 2009, and are aiming to launch the device in 2010.

An important partner for Fresenius Medical Care in clinical research is the **Renal Research Institute (RRI)**. The RRI was founded in 1997 as a joint venture between Fresenius Medical Care North America and the Beth Israel Medical Center, a hospital in New York, and is widely recognized as a leading research facility in the field of nephrology. In 2009, the RRI continued research in the field of SORB technology,

among others. This project focuses on so-called sorbents – particular substances that bind toxins in liquids so that they can be removed. These sorbents can be used, for example, to recycle dialysis solution, which absorbs toxins during PD or HD treatment that have been filtered out of the patients' blood. By cleansing and then recycling the dialysate with the help of sorbents, the amount of water typically needed during dialysis treatment can be reduced from 120 to 200 liters to approximately six to ten liters. This innovative sorbent technology is particularly important for our "wearable kidney" project, as a device of this kind must be able to function with a substantially smaller amount of liquid to be light and small enough to be worn on the body. This is an objective we are also working on. Other research projects pursued by the RRI are centered on the lifespan of red blood cells in connection with inflammatory processes in the body, and on citrate anticoagulation, a method which can be used as an alternative to or together with the substance heparin for hemodilution. A more in-depth knowledge of the characteristics of red blood cells can be advantageous for treating dialysis patients more effectively with the erythropoiesis stimulating agent EPO or with iron compounds.

#### **FRESENIUS KABI**

Fresenius Kabi is focused on developing products that significantly support medical advancements in the acute and post-acute treatment of critically and chronically ill patients and on helping to improve their quality of life. At the same time, we want to make high-quality treatments available to patients worldwide.

Our **R & D strategy** is aligned with this focus:

- ▶ develop innovative products in areas where we hold a leading position, such as blood volume replacement and clinical nutrition
- ▶ develop new formulations for drugs no longer protected by patent
- ▶ continue to develop and refine our existing portfolio of pharmaceuticals and medical devices

Our development competency encompasses all the relevant components: the pharmaceutical solution, the primary packaging, the medical device for application, and the production technology. We are also one of the few companies in the world that cover the entire production chain for IV drugs: from the processing of the raw materials and the production of the active pharmaceutical ingredient through to the manufacture of the drug.

A key focus of our R & D work is to expand global distribution of our product portfolio. We continuously apply for authorization to market our products in major sales regions throughout the world – including the United States, where our acquisition of APP Pharmaceuticals will grant us key access to the North American market.

### Infusion therapies

In 2009, we continued our research and development efforts in the area of **blood volume replacement**. More than 130 published studies support the efficacy and safety of our product Voluven®. In the course of our R & D activities we also continued to support randomized, double-blind studies with Voluven® 6 % for sepsis, trauma, and caesarian section. In 2009, we also started a clinical study that examines our product Voluven® 6 % in comparison with crystalloids in the treatment of about 7,000 intensive care patients.

We also intensified our development work on **HESylation® technology**. This technology enables an active pharmaceutical ingredient to be coupled to specific hydroxyethyl starch molecules, decisively modifying a drug's profile. Such coupled products show a longer half-life and a better safety profile than unmodified drugs. In 2009, we entered into partnerships with Bayer Schering Pharma and the Swiss company Octapharma.

### Intravenously administered drugs

In the field of IV drugs we focus on high-quality **generics** for the therapy areas of anesthetics, analgesics, infectious diseases, oncology, and drugs for the treatment of critical diseases.

Our long experience in developing infusion therapies enables us to transfer our extensive expertise in this field, as well as modern pharmaceutical technologies, to the development of generics and achieve specifically targeted improvements in known drugs. The safe application of our products in day-to-day medical care is another important focus for us. Intelligent packaging concepts, like our color code safety concept for instance, enable all products and their different active substance concentrations to be easily distinguished. This guarantees a high degree of safety for the patient and the nursing staff. The clear, safe, and readily transparent system complies with national and international standards.

Our **R & D pipeline** contains an extensive portfolio of active drugs that will be coming to market in the next few years. We currently have about 125 products at different stages of development.

In 2009, we worked intensively on dossiers for the registration of new generics in order to obtain marketing authorization quickly once originator drugs go off-patent. In line with our internationalization strategy for generic IV drugs, we are placing priority on marketing approvals for Europe, North America, Asia-Pacific, and Latin America.

In 2009, our US subsidiary APP Pharmaceuticals obtained marketing authorization for seven generics for the US market. APP currently has 35 ANDAs (Abbreviated New Drug Applications) pending at the FDA.

In the area of generics for critical diseases, we are working intensively on broadening our product portfolio for the European market. In 2009, we filed for four drug applications for this market, and plan to launch nine products in different presentation forms and for various countries in 2010 and 2011.

We also see the launch of new oncology generics as an important driver of future growth. In oncology, we offer an extensive range of drugs in different formulations and dosage forms. In 2009, we filed applications worldwide for the marketing authorization of 15 drugs for products in different formulations and dosage forms. We plan to launch these products in 2010 and 2011.

## Clinical nutrition

In **parenteral nutrition** we concentrate on developing products which have a high therapeutic effect in the care of critically and chronically ill patients. Our **focuses** are:

- ▶ parenteral nutrition products that improve the therapy of patients in hospital
- ▶ innovative containers, e. g. multi-chamber bags that allow maximum application safety and convenience in everyday use

One of our core development areas is the use of lipids in parenteral nutrition therapy. SMOFlipid®, for instance, is a lipid emulsion which has clinical benefits over ordinary lipid emulsions due to its composition and the fact it contains four different lipid components.

The product has become successfully established for severely ill adult patients. Nutrition is also particularly important in pediatric care as only an adequate supply of nutrients suited to the child's age can assure normal growth and proper development. Undeveloped or severe gastrointestinal defects at birth and acute ailments are indications for parenteral nutrition in pediatric patients. In 2009, we obtained approval for SMOFlipid® for use in pediatric care. This product can provide the fat component of a parenteral nutrition therapy supplying all nutrients necessary to prevent malnutrition and support the growth and development of pediatric patients.

In 2009, we introduced a dosage increase of our product Dipeptiven® on the market. Dipeptiven® is a concentrate of alanyl glutamine that, when compatible, can be added to any parenteral nutrition regime. Glutamine is administered to patients in a highly catabolic metabolic condition, which can occur for instance in intensive-care or after major surgery. In such cases glutamine is required in large amounts by the

intestinal and immune cells as an essential source of energy and nitrogen to maintain their functioning. Glutamine deficiencies otherwise can lead to functional disorders.

The high relevance of glutamine in parenteral nutrition for the clinical outcomes of intensive care patients was also confirmed by the European Society for Clinical Nutrition and Metabolism (ESPEN) in its updated guidelines, which recommend that intensive-care patients with an indication for parenteral nutrition receive glutamine.

In our development activities in the area of **enteral nutrition**, we are focusing on sip and tube feed nutrition products for malnourished patients and on therapeutic products for dysphagia, diabetes, oncology, and critical illness. We are thus combining the latest insights in both medical and nutritional science and food and process technology into our product development. This approach enables us to offer innovative nutrition products matched to the specific patient profile. At the same time, we are countering side-effects that arise during long-term therapy, e. g. patients growing tired of the taste, with a broad range of sip feed products featuring different flavors.

In 2009, we continued work on our new product concept in diabetic therapy that can be used especially for diabetes mellitus patients with impaired glucose tolerance and insulin resistance. We plan to launch our new products in 2010.

We also continued to broaden our product offering for dysphagia patients and worked on the development of further Fresubin® products. We plan to launch these new products in the market in 2010. Dysphagia is a term used to refer to difficulties in controlling the swallowing process, which can have a wide range of causes, for instance stroke, cancer diseases, neurological ailments, and Parkinson's disease. In patients with dysphagia the swallowing reflex is delayed or completely inoperative. About 60 % of elderly people in hospitals or living in nursing homes suffer from dysphagia.<sup>1</sup> Nutritional deficiencies and dehydration can be effectively remedied with a product line specially designed for this group of patients.

<sup>1</sup> Clavé P et al. Rev Esp Enferm Dig 2004; 96: 119–131

In the field of medical devices for the application of enteral nutrition, we are constantly working on new technologies that ensure necessary nutrients are supplied safely, efficiently, and conveniently. In 2009, one focus was the development of an innovative connector system for the application of enteral nutrition products. In infusion therapy, connectors are the connecting devices to syringes, canulas, and infusion lines. To avoid the risk of misconnections of enteral nutrition lines in day-to-day medical care, we are working on a novel connector system that excludes accidental connection with intravenous application techniques. A patent application has been filed for the system and we plan to successfully complete development work in the course of 2010.

## FRESENIUS BIOTECH

Fresenius Biotech develops and commercializes innovative therapies with immunotherapeutic products. In 2009, the trifunctional antibody Removab was approved as anti-cancer therapy, thus validating this targeted, immunological approach. For many years, Fresenius Biotech has been successfully marketing ATG-Fresenius S, a polyclonal antibody. This is an immunosuppressive agent used to control immune reactions in transplantation medicine.

### Trifunctional antibodies

After we filed the application for Removab at the end of 2007, the European Commission issued its approval for the intraperitoneal treatment of patients with **malignant ascites** in April 2009. This approval is valid for all 27 member states of the European Union as well as Iceland, Liechtenstein, and Norway. Removab is the first trifunctional antibody in the world to be approved and is also the first drug for malignant ascites. We began marketing Removab in Germany and Austria in May 2009. In 2009, we achieved sales of more than € 1.6 million with the product. The pricing and market introduction procedures were initiated in other European countries.

Parallel to the market introduction, the CASIMAS study, a randomized phase IIIb study, is being carried out in key European countries. This study is examining the tolerability, safety, and effectiveness of treating ascites patients with Removab, applied as a three-hour infusion versus without a corticosteroid pre-medication. So far approval has been issued for an infusion time of six hours. This study is supporting the market entry of Removab and, if the results are positive, can facilitate application.

New data from further evaluations of the pivotal study for malignant ascites supporting the clinical benefits of Removab were presented at a number of international cancer congresses, such as ASCO, WCGIC, and ESMO in 2009. Removab has been significantly shown to improve clinical progress in patients with malignant ascites independently of the underlying tumor or other prognostic factors. In addition, in gastric cancer patients with malignant ascites, treatment with Removab has been observed to prolong survival to a statistically significant extent, while a trend towards prolonged survival was shown for the overall population of all patients treated.

The clinical studies in the different settings of gastric and ovarian cancer were continued and have produced initial results on the use of Removab in earlier stages of treatment, for instance as intra-operative medication in adjuvant treatment situations. An adjuvant therapy following complete removal of tumor tissue aims to destroy any unapparent tumor cells that might still exist. The results of these phase II studies show that Removab is safe to use perioperatively in an adjuvant setting of gastric cancer as well as in first-line therapy and consolidation therapy in advanced ovarian cancer.

Studies on the trifunctional antibody ertumaxomab for the treatment of metastasized breast cancer were, or are being, terminated prematurely. We have shelved these development activities in order to concentrate more intensively on the further development of Removab.

### Immunosuppressive agent ATG–Fresenius S

Sales of ATG-Fresenius S rose by 14 % to € 24 million. The preclinical and clinical development for other applications and distribution in new markets was continued. A clinical study is currently being conducted on the use of ATG-Fresenius S in the prophylaxis of acute Graft-versus-Host disease in stem cell transplantation. The one-year results on its efficacy and safety were very promising. They were published in the medical journal Lancet Oncology 10/2009. The final report on the two-year data is in preparation. Fresenius Biotech filed the marketing authorization application with several European authorities for approval for the prophylaxis of Graft-versus-Host disease.

The study with ATG-Fresenius S in lung transplantation in the United States was continued. The study compares the effects of two different ATG dosage regimes and a placebo (double-blind and placebo-controlled) on organ rejection and mortality rates among patients six months and twelve months after transplantation. One dosage regime arm of the study was closed due to the results of the intermediate analysis.

### PROCUREMENT

An efficient management of the value chain is important for the Fresenius Group profitability. One key element is **global procurement management**, which assures the availability of goods and services as well as the consistent quality of the materials used in production. In an environment characterized by ongoing cost-containment pressure from health insurers as well as price pressure, security of supply and quality play a crucial role. For this reason we are constantly striving to optimize our procurement processes, to tap new procurement sources, and to achieve the best possible pricing structures while remaining flexible and maintaining our strict quality and safety standards.

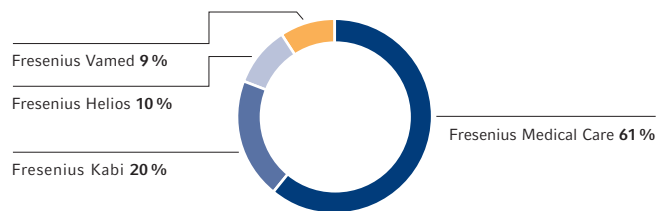
Global **procurement processes** are coordinated centrally within the Fresenius Group, enabling us to bundle similar requirements and negotiate global framework agreements. These central coordinating offices organize purchases for the production sites and arrange comprehensive quality and safety checks of purchased materials and goods. Current market and price developments are analyzed on an ongoing basis.

In 2009, the cost of raw materials and supplies and of purchased components and services was € 4,648 million (2008: € 4,204 million), as the table shows:

in million €	2009	2008
Cost of raw materials and supplies	4,077	3,668
Cost of purchased components and services	571	536
<b>Total</b>	<b>4,648</b>	<b>4,204</b>

The cost of raw materials and supplies increased by 11 % to € 4,077 million (2008: € 3,668 million). Purchased components and services accounted for 12 % of the Group’s total cost of materials (2008: 13 %).

### COST OF MATERIAL BY BUSINESS SEGMENT <sup>1</sup>



<sup>1</sup> Before consolidation

### FRESENIUS MEDICAL CARE

In 2009, Fresenius Medical Care profited from lower energy and raw material prices.

Outside North America, in the **International segment**, we reached agreements with selected suppliers on high supply volumes and secured long-term supply guarantees. In Europe we benefitted from successful pricing contracts. Due to the weak economic environment, risk management was of great importance at our global procurement processes. In Europe, we implemented a new system with the aim to early identify financial risks at our most important suppliers.

Through an efficient **supplier management system**, we carefully select suitable suppliers, with which long-term relationships are established and nurtured. In the International segment, Fresenius Medical Care classifies and evaluates the performance of new and existing suppliers on the basis of **strict quality criteria**. This includes compliance with labor regulations and environmental standards.

Audits are conducted to monitor compliance with these standards. The resulting ratings serve as a key planning and decision-taking basis for our sourcing. In 2009, the quality criteria of our supplier rating system was expanded and further harmonized.

The long-term SCALE project was launched, too. Its aim is to align the supply chain management organizational structure and processes more closely to the demand planning in the production and sales divisions. As a first step, a new, standardized IT system for production planning and inventory management was introduced. This increases the planning precision and transparency for optimized inventory management, especially when new products are launched, older product generations are phased out, or new customer contracts are won.

#### FRESENIUS KABI

In 2009, Fresenius Kabi identified and partially realized attractive cost-cutting potentials. The focus of the procurement activities at Fresenius Kabi was on the **“Global Sourcing Initiative”** project. The project covered all production locations. Several teams were set up at each location to analyze the input materials used, energy consumption, and purchased services. The aim is to identify further potential for optimizing procurement, and for substituting input materials or harmonizing them Group-wide. The project was very successful; the potentials identified will be realized over the long term.

In 2009, the global economic situation strongly affected Fresenius Kabi's **purchase prices**. After the prices of almost all the relevant raw materials reached all-time highs in mid-2008, most of them then fell to their lows for the year. The prices of individual raw materials were still at a very low level at the beginning of 2009. In the later course of the year their prices picked up again. All in all, raw material prices in 2009 were below their corresponding average 2008 levels.

The prices of plastic granulate (for primary packaging and medical devices), foil (for primary and secondary packaging), and cardboard boxes and bag materials (for medical devices) were adjusted at regular intervals to the **development of the underlying commodity prices**. This also applied to glass bottles whose manufacturing processes are very energy-intensive. Their prices fell owing to the lower prices for heating oil and gas. We fixed the prices of products derived from corn by contract in 2009; under our framework agreements these prices will be reduced in 2010 into line with the fallen corn and energy costs. As had been expected, the level of supply on the world market for the processed milk products relevant for Fresenius Kabi was very high until the middle of 2009. We were therefore able to negotiate favorable purchase prices. All in all, the development of raw material prices had a positive effect on our cost of materials in 2009: we reduced our costs compared to 2008.

As expected, the cost of **electricity and natural gas** rose in 2009. As a result, Fresenius Kabi conducted consumption analyses at several production locations aiming to reduce energy consumption or to identify cost-cutting potential.

Fresenius Kabi has made a number of acquisitions in the area of IV drugs over the past years in order to extend its coverage of the supply chain. On this basis, Fresenius Kabi conducted a large number of **make-or-buy projects** in 2009. This analysis of numerous active substances and finished products indicates whether it would be best to manufacture them in-house at one of its own production locations or whether they should continue to be purchased in the market. Fresenius Kabi has already realized initial results and will be continuing these activities in the coming years.

#### FRESENIUS HELIOS

At HELIOS, high medical standards go hand in hand with an efficient, economically sound management of available resources. Its procurement management system combines the expertise of its doctors and nurses with the commercial competence gained in other areas from the various clinics and disciplines. This capability and our standards of medical quality are channeled into all procurement decisions for the benefit of the patient.

Medical devices and drugs have direct relevance for the standard of medical quality. The HELIOS clinics therefore place value on close cooperation with their suppliers and a high level of **standardization** of the products used. The strategic selection of suppliers also serves to **minimize risks** in the sourcing process: only suppliers that have an adequate defects management process, a convincing defects reporting process, and a low risk of business failure can be considered as a business partner for HELIOS.

Today, over 85 % of our **medical supplies** are standardized Group-wide at HELIOS. A system of more than 300 product groups promotes transparency, planning efficiency, and competition. The aim of standardization is to optimize quality. The quality standards are defined from a professional perspective: teams of medical experts from the clinics set binding Group-wide product standards together with the procurement officers. The level of standardization depends on the particular product group. Due to the binding product standards, HELIOS can bundle large volumes and is thus in a very good position to negotiate excellent procurement terms.

In 2009, HELIOS reorganized the pharmacy IT infrastructure at all the clinics. The outcome of this measure is that we have established a **high-quality drug supply** as a guaranteed standard service. 75 % of all the clinics' drug requirements are covered by the in-house pharmacies. HELIOS is supplied with reliable local and central administrative data that enables valuable knowledge to be generated for the benefit of the patients. It is conceivable, for instance, to monitor drugs in order to document their effect on the success of the treatment.

An online ordering system, developed especially for hospitals, was installed at some of the clinics. With this system, staff on the wards can order drugs and medical supplies from the hospital pharmacies via a standard user interface. Their materials management unit and the local purchasing departments use the same system together. This also allows a more efficient controlling of the order processes. The materials management unit can generate monthly ABC analyses for the individual chief medical officer. Clinic or Group-wide analyses, indication group comparisons, trend analyses, and consumption forecasts are also possible. The analyses also incorporate defined benchmarks of the departments and the annual budgeting for drugs. With approximately € 90 million spent

on drugs each year, they represent an important part of the expenditure on medical supplies at the HELIOS clinics.

**Hospitals' energy requirements** are a key cost factor. In 2009, HELIOS spent a total of € 53 million on energy, i. e. for energy, water, and fuels. That does not include the newly acquired clinics. HELIOS has created an energy benchmark database and a web-based sourcing platform, enPortal, which provides transparency on all utilities at all clinic locations. Variances in consumption and costs are promptly detected and directly acted upon. HELIOS monitors the latest price trends on the energy exchanges daily. Because pricing in the energy sector is not determined solely by the actual energy price itself, but also by other components such as third-party access fees, HELIOS does not conclude framework agreements. The enPortal online platform, to which over 200 energy utilities in Germany are linked, is used by other Fresenius business segments besides HELIOS. Thanks to the transparency created and to monitoring current price trends, HELIOS is in a position to buy energy at the best possible times after weighing the opportunities and risks. If HELIOS tags all 61 clinic locations on this platform as buyers of electricity and natural gas, all potential suppliers can quote within a day for each location. While negotiations conducted in the conventional way without the enPortal platform would take about ten to twelve weeks, HELIOS can complete the bidding process and the placement of contracts within three to four days.

## QUALITY MANAGEMENT

The quality of our products and therapies is the basis for best-in-class medical care. All processes are subject to the highest quality and safety standards for the benefit of the patients and to protect our employees. Our **quality management** has the following three objectives:

- ▶ to identify value-enhancing processes oriented to the needs of our customers and to efficiency
- ▶ to monitor and steer these processes on the basis of performance indicators
- ▶ to improve procedures

These objectives overlay the quality of our products as well as all services and therapies that we provide. Our quality management system integrates all product groups – such as drugs, medical devices, and nutrition – as well as our clinics. The quality management system is regularly evaluated through internal audits and external certification bodies. Our products are already closely controlled at the development stage. Our drugs are subject to regulatory approval, so appropriate documentation has to be prepared and submitted in accordance with national and international regulations. Medical devices undergo a **conformity assessment procedure** that documents compliance with the appropriate norms. In enteral nutrition, we already follow the Hazard Analysis Critical Control Point (HACCP) principle during the development process. The HACCP principle is a generally acknowledged method of identifying and examining risk areas in the food production industry. We have established a **quality assurance system** in all our production plants. In addition to the controlled use of materials, validated production procedures, and ambience and in-process controls, each batch produced also undergoes final controls and a formal release procedure. Our quality assurance system also includes measures for protecting employees, for instance when handling hazardous substances. Our production facilities are regularly inspected by regulatory authorities or other independent institutions. Sales and marketing are also an integral part of the quality management system. For example, at any given time we are able to trace where every batch has been supplied.

In recent years, HELIOS has initiated and further developed a **performance indicator system** to evaluate the quality of medical results in hospitals. Within the hospital market this system is acknowledged as a highly innovative procedure. The system is even used as a quality standard in more than 300 German hospitals outside the HELIOS Group. Furthermore, in 2008 the Swiss Federal Office of Public Health (Bundesamt für Gesundheit) started a project based on the HELIOS quality management system to evaluate quality indicators in the hospital market. Those performance indicators are also already in use in Austria.

## FRESENIUS MEDICAL CARE

As the world's leading provider of dialysis care and products, Fresenius Medical Care has a special commitment to maintaining the best possible quality standards for its patients and customers. To meet these demands and the numerous regulatory requirements, Fresenius Medical Care has implemented comprehensive quality management systems in its regions, which reflect both the specific local conditions and the company's global responsibility.

These systems regulate and monitor compliance with **quality and safety standards** for all products and procedures, from development, production, and regulatory approval to clinical application, customer training and handling complaints. The quality management system combines internal regulations and processes with the specification of external standards – such as ISO 9001:2000 for quality management systems and ISO 13485:2003 for medical products. In Europe, for instance, a growing number of dialysis clinics are undergoing the ISO 9001:2000 certification process. In the countries of Latin America and Asia, we are also having our clinics certified to this standard, for instance in Colombia and Ecuador. Most of the production sites in Europe are also certified to ISO 9001:2000 standards. Our North America production sites in Ogden, Utah, and Walnut Creek, California, as well as our Mexican site in Reynosa are certified to ISO Standard 13485:2003 for medical products, as are the production plant in Buzen, Japan and the production facility in Jiangsu, China, which produces bloodlines.

To assess quality in dialysis care, Fresenius Medical Care uses **quality parameters** that are generally recognized throughout the dialysis industry. One example is the so-called Kt/V value, which shows the cleansing performance of the dialysis treatment. This is calculated by analyzing the relationship between the duration of treatment and the amount of specific toxic molecules that were removed from the blood. The number of days patients are hospitalized is also crucial for determining treatment quality, because they are particularly cost-intensive and can significantly reduce the quality of life of dialysis patients. Constantly measuring these and other parameters helps us to further improve our standards in providing dialysis treatment.

The quality management implemented at our sites and at our dialysis clinics is regularly audited. In Europe, this is handled by the TÜV. These conformance and certification experts check our corporate headquarters, the production plants as well as sales organization and clinical organizations as part of their annual audits. In the United States, Fresenius Medical Care's production facilities are regularly audited by the U.S. Food and Drug Administration. We also monitor the effective implementation of our quality management systems through regular internal audits performed by employees who are specially qualified and trained for this purpose. Furthermore, through regular patient and customer surveys, we obtain valuable feedback, for instance, on the acceptance of our customer, delivery, and technical customer service, on our vacation and travel service, as well as on its home visits and on the general quality of the care provided.

#### FRESENIUS KABI

Quality management at Fresenius Kabi is subject to a great many national and international regulations such as Good Clinical Practice (GCP), Current Good Manufacturing Practice (cGMP), Good Distribution Practice (GDP) for drugs and ISO Standard 13485:2003 for medical products. All of these requirements have been integrated into a **quality management system** conforming to ISO Standard 9001:2008 to ensure that the applicable regulations are reliably complied with.

With the exception of the companies acquired in 2008, Fresenius Kabi has included most of the global production plants and the local sales organizations in the external certification process. Quality management at our production sites, in the sales organizations, and at a cross-functional level is reviewed regularly by both national and international regulatory authorities and by customers.

The **matrix certification** to ISO 9001 was continued as planned in 2009. The focus of the new certification was on the Fresenius Kabi compounding centers. The certification process now covers the entire value chain: from the production

of the active substances, the manufacturing of the finished drugs, and the patient-specific compounding through to distribution.

The integration of the quality management systems of Fresenius Kabi Oncology (formerly Dabur Pharma) and APP Pharmaceuticals, started in 2008, was continued in 2009. Fresenius Kabi is concentrating on **"best practice" solutions** perfected to the Group-wide standard in the sense of a continuous improvement of our quality management system. The harmonized standards are being developed at regular meetings of international experts at Fresenius Kabi.

Another special focus is careful and proper handling of hazardous substances. Fresenius Kabi Oncology is a leading supplier of generic drugs and active substances for cancer treatment. Active substances for cancer treatment need to be handled with extreme care, so special attention is paid in our quality management system to the safety of employees who come into contact with this group of products.

#### FRESENIUS HELIOS

The HELIOS **quality management system** is committed to a continuous improvement in patient care. Now, over 1,200 indicators (2008: over 900) cover all the **main diseases and surgical procedures**, so that the number of performed services, partially the use of different surgical methods, and, where possible, indicators for the quality of the outcomes can be recorded. Utilizing over 140 indicators, HELIOS regularly publishes the 30 most important diseases and surgical procedures for the HELIOS Group. The individual clinics provide this information in their hospital guidebooks. Further information can be found on the website at [www.helios-kliniken.de](http://www.helios-kliniken.de) (German only). These publications demonstrate the exemplary transparency of HELIOS' performance externally. **Demanding targets** were defined for 33 indicators. In these areas, the HELIOS clinics aim to be at least as good as the German average. Where benchmark data are available, HELIOS expects the clinics to match best-in-class international standards in surgical medicine. The Group met or significantly exceeded

the targets for 27 of these indicators (2008: 23, including the newly-acquired clinics). An extract is shown by the table below.

#### HELIOS QUALITY PERFORMANCE INDICATORS (EXTRACT)

Indications/standardized mortality ratio (SMR) <sup>1</sup>	2009 SMR	2008 SMR <sup>2</sup>
Acute myocardial infarction (AMI)	<b>0.78</b>	0.75
Heart failure	<b>0.69</b>	0.77
Stroke	<b>0.86</b>	0.86
Ischemic stroke	<b>0.86</b>	0.86
Pneumonia	<b>0.78</b>	0.79
Hip fracture	<b>0.88</b>	0.98

<sup>1</sup> SMR of 1 corresponds to the German average.

SMR < 1 means that the mortality is below the German average.

<sup>2</sup> Adjusted for the newly acquired clinics and adjusted German average.

More information can be found at <http://www.helios-kliniken.de/medizin/qualitaetsmanagement>

In 2009, HELIOS achieved an excellent SMR of 0.69 for heart failure. This indicates that the mortality in the HELIOS clinics was 31 % below the average of all German clinics. Where the targets were not achieved, the deviation from the German average was so small as to be statistically insignificant. The medical teams at HELIOS are also pursuing goals relating to many details of the care in their various specialist areas.

HELIOS launched the **Initiative of Quality Medicine (IQ<sup>M</sup>)** in collaboration with six other hospital operators in 2008. The aim of the initiative is to further improve internal hospital quality management on the basis of performance indicators. Around 1.5 million acute care patients and 4 million ambulatory care patients are treated at the over 100 clinics now covered by this initiative. The members undertake to conduct standardized quality measurements of the treatment results at their clinics, based on administrative data, and to publish the results. This voluntary commitment also includes a form of **peer reviewing**: internal and external experts analyze the treatment results that do not meet the initiative's quality goals and discuss concrete improvements with the clinic involved. The aim of this review is to achieve improvements in the procedures and structures of the treatment process. IQ<sup>M</sup> is the first multi-operator, administrative data-based quality assurance initiative in Germany and furthers HELIOS' interest in improving the transparency of quality data for the German health care market. Further information can be found on the initiative's website at [www.initiative-qualitaetsmedizin.de](http://www.initiative-qualitaetsmedizin.de) (German only).

HELIOS has developed **methods for measuring the long-term results** of medical treatments in collaboration with the National AOK Association and the AOK's research institute. The QSR hospital reports (Qualitätssicherung der stationären Versorgung mit Routinedaten – Securing quality of inpatient treatment with administrative data) published by health insurer AOK are an important extension of the quality indicators based on hospital stays. Indicators for long-term quality results can be derived from the reports. They are currently being used not only in the IQ<sup>M</sup> project, but also by other hospitals and by AOK. The QSR results also show HELIOS clinics to have a quality lead over the German average in many areas. The extensive AOK hospital reports for our clinics can be found on the website at [www.helios-kliniken.de/qsr](http://www.helios-kliniken.de/qsr) under "Quality Reports" (German only). HELIOS believes that these methods might possibly be incorporated in the new overarching quality assurance sector that is due to be created at the federal level in Germany.

However, quality management at HELIOS goes beyond the medical results. Our perception of quality also includes the **standard of nursing care**, the aim being to provide patients with the best medical and nursing care. This is a precondition for successful medical treatment. Our nursing staff – the biggest professional group at the HELIOS clinics – is in continuous communication with the doctors and other professional groups. The aim is to activate the patient's physical, mental, and social abilities, and to restore their natural functioning to the greatest possible extent through preventive, curative, and rehabilitative measures.

#### FRESENIUS VAMED

In the planning and construction of hospitals, Fresenius Vamed sets high quality standards in its flexible design of **parameters across processes and structures**. These parameters include:

- ▶ process optimization (for example surgery, admission and discharge areas, interdisciplinary emergency facilities, and interdisciplinary outpatient clinics)
- ▶ differentiation according to modular care levels (from basic to intensive care)
- ▶ flexible use of buildings and wards in response to shifts in demand – always allowing for particular reimbursement systems and technical developments

VAMED has an internationally experienced team of experts who assure the quality of the structural and process design even when the project is at the concept stage and when services are established.

Internally, the processes are also designed for efficiency and sustainability, using **interdisciplinary quality standards**. These standards are mostly based on ISO 9001:2000 and ISO 13485:2003 standards, as well as the standards of the European Foundation for Quality Management (EFQM). VAMED received the Austrian State Quality Award in the large company category in 2009. In 2008, VAMED had not only qualified for the Austrian State Quality Award, but had also won a jury prize for special achievements. That was the first time ever that a company had received two awards in one year from the Austrian Foundation for Quality Management (AFQM). This prize, which has been in existence since 1996, is awarded to Austrian organizations for their consistent application of excellent, quality-oriented management, for outstanding achievements, and for the generally high standard of the organization and its performance.

Internationally, VAMED has implemented the established JCI certification model (Joint Commission International). The certification was granted to reference projects such as the Neurological Therapy Center Kapfenberg, Austria and the Prince Court Medical Center in Kuala Lumpur, Malaysia.

## RESPONSIBILITY, ENVIRONMENTAL MANAGEMENT, SUSTAINABILITY

We are committed to protecting nature as the basis of life and using its resources responsibly. It is our mission to constantly improve our performance in the areas of environmental protection, occupational health and technical safety, and product responsibility and logistics and to comply with legal requirements. The international ISO Standard 14001:2004 is the most important benchmark for **environmental management** in the corporate sector. Among other things, it stresses the need for continuous assessment of a production site's impact on the environment, for instance with respect to emissions and waste. These international standards are implemented at

our various production plants and most of our dialysis clinics. Key environmental performance indicators are, for instance, not only the volumes of waste and recycling rates, but also energy and water consumption at our locations.

In Europe, our production sites are subject to the **EU regulation REACH** (Registration, Evaluation, and Authorization of Chemicals). The aim of REACH is to protect human health and the environment against hazards and risks from chemical substances. We have implemented this regulation. Fresenius Medical Care is an active member of the REACH Working Group of the German Federal Association of the Medical Device Industry (Bundesverband Medizintechnologie or BVMed). In the few cases where Fresenius Kabi is a manufacturer or importer outside the EU member states, all the relevant substances are pre-registered in compliance with the REACH regulation.

### FRESENIUS MEDICAL CARE

Fresenius Medical Care is committed to promoting environmental awareness and protecting the environment through a wide range of initiatives and projects at its sites. We are continuously improving our operational efficiency, for instance through saving energy or by reducing the amount of raw materials needed in production.

Our environmental management in the regions **Europe, Middle East and Africa** is an integral part of the quality management system and is TÜV-certified. It encompasses eco-controlling at production sites and dialysis clinics and gathers environmental data like emissions, water, and electricity consumption. Our activities include:

- ▶ formulating environmental goals and strategies
- ▶ coordinating internal and external environmental audits
- ▶ providing training and further education to environmental managers within the company
- ▶ raising employees' awareness of environmental issues, and expand our environmental management efforts

Fresenius Medical Care already established an environmental program in these regions. It was launched in 2007, identifying environmental goals to be achieved by 2010.

Our five largest **production sites in Europe** are already certified to ISO 14001 environmental standards. In 2009, we rolled out the environmental management system at another production plant in Germany and at a production plant in Vrsac, Serbia. We expect these two sites to receive ISO 14001 and TÜV certification in 2010. We also continued with the implementation of the EU chemicals directive REACH at our European plants. In 2009, we drew up internal guidelines for compliance with REACH requirements.

In Poland, we carried out a project for developing a set of environmental guidelines for dialysis clinics in 2009. The purpose of these guidelines is to support responsible environmental management officers to further improve the efficiency of the dialysis clinics, for instance with regard to water, electricity, and acid concentrate, and in waste management. In a first step, all the environmental-relevant processes are analyzed. The environmental managers then compile a catalog of environmental targets on the basis of the results.

At the production plant in St. Wendel, Germany, we saved about 400,000 m<sup>3</sup> of natural gas through energy efficiency projects in 2009. That is equivalent to the annual energy consumption of about 170 households. As the production buildings were largely switched over to low-energy lighting, the site was commended as a partner of the European Commission's "Greenlight" program. This project reduced the plant's electricity consumption by over 40 %. In 2009, we also invested in environment-friendly processes and systems for the site. For instance, older steam boilers were replaced with modern, low-emission boilers. This has reduced nitrogen oxide emissions and energy consumption.

At a German plant for dialysis concentrates, we introduced a system for monitoring and controlling the production processes and implemented a new packaging process for our pallets in 2009. These measures will enable us to reduce the consumption of raw materials, water, energy, and packaging materials in future.

In **North America**, we have established a formal, certified program for monitoring environmental and safety standards which reviews all the production processes at our US plants

each year. At our largest production site in North America, Ogden, we have been undertaking process optimizations with the aim of reducing energy consumption, like natural gas or electricity. In the coming years we have set ourselves the target to reduce energy consumption by a further 5 % annually. We also launched a recycling program at the Californian site in Walnut Creek, aimed at reusing parts from our dialysis machines.

#### **FRESENIUS KABI**

In 2009, Fresenius Kabi extended the certification of its environmental management. It was certified by an external organization that the environmental management system at two more **production sites in Europe and Asia** conformed to the requirements of ISO Standard 14001:2004. The certification of further sites is planned.

At our **production sites in Friedberg and Bad Homburg**, Germany, the recycling rate was at the previous year's level of about 95 %. About 5,200 t of waste were recycled (2008: approximately 5,900 t). The volume of waste at the two locations was reduced by about 25 % at the Friedberg plant and by about 17 % at our location in Bad Homburg.

Numerous measures were implemented in 2009 to reduce **energy consumption, CO<sub>2</sub> emissions**, and the **consumption of natural resources** such as water. The building control system at the Friedberg site was extensively overhauled. This enabled Fresenius Kabi to reduce energy consumption at the plant by about 700,000 kWh a year. That represents a reduction of CO<sub>2</sub> emissions by about 180 t.

The useful life of fully demineralized water (FD water) in production was extended. This reduced the use of chemicals and flushing water in the water treatment process. FD water is a preliminary stage of distilled water; both types of water are produced directly at the production site. Fresenius Kabi uses FD water for cleaning processes in production, e. g. for cleaning production lines and equipment. Distilled water is used directly in the production of drugs.

An energy concept was developed for the Friedberg production site in collaboration with an external partner. The aim was to identify potential for further energy savings. First measures are due to be implemented in 2010.

All these measures not only serve the primary purpose of environmental protection, but also helped to reduce energy costs considerably in 2009.

At the **production site in Graz**, Austria, a certified environmental management system has been in place since 2008. This defines various performance indicators, such as the recycling rate. The aim is to guarantee and continuously improve the efficiency of the plant's environmental management over the long term.

In 2009, we were able to increase the **recycling rate** by about 10 % to 70 %. The remaining 30 % serves as a source of energy and is used for this purpose in thermal waste treatment plants. A basic prerequisite for proper recycling is strict, sort-clean waste separation. Other environmental indicators are, for instance, **energy consumption** – by type of energy – and **water consumption**, relative to production output in each case.

The environmental protection measures at the Graz site are continuously optimized through environmental training schemes for employees. Internal audits are carried out to monitor and evaluate their success.

At the **production site in Linz** environmental management had the following focuses in 2009. Firstly, we implemented the environmental management system to ISO 14001:2004 standards and, secondly, an **energy and resource conservation project** was continued. Internal audits were conducted to evaluate the general environmental impact in the individual departments. Here we concentrated above all on waste disposal and the handling of hazardous substances. A number of measures were already successfully implemented in 2009. We achieved reductions in energy and water consumption and in the volume of waste water. In the production of lactulose, for instance, the existing agitator motors in the production vessels were replaced with motors of a higher efficiency rating. This measure reduced the level of energy consumption by about 25 %. The Linz plant is one of the biggest producers of lactulose in the world. Lactulose is produced from lactose through processes of chemical conversion. Due to its detoxifying effect, the product is used in the treatment of diseases of the liver or intestine.

Other long-term measures are planned that will save energy and other resources in future.

At our **plants in Uppsala and Brunna**, Sweden, the total **volume of waste** in 2009 was 3,337 t (2008: 3,412 t). Over the past years we have initiated a number of waste management projects aimed at reducing the volume of waste and, equally, at organizing the disposal of the waste in the most environmentally sound and efficient manner. **Water consumption** increased compared to 2008, due among other reasons to the increase of production output.

In 2009, measures were continued to reduce **energy consumption** at the locations. The operation of ventilation and air-conditioning systems has been much reduced outside production times. A vapor condenser was installed to reduce energy losses in the steam heating system. The condenser recovers the energy from the steam heating system that is released to the atmosphere as vapor after the heating process. In addition, more energy-efficient pumps were installed in the system as well. Furthermore, at the Brunna site the refrigerant HCFC R22 (Hydro chlorofluorocarbons) was replaced by the much more environment-friendly refrigerant HFC R407C (Hydro Fluorocarbons). We are also working on a plan of action to identify potential for further savings.

#### **FRESENIUS HELIOS**

At hospitals, waste disposal, hygiene, and the high energy requirements place exacting demands on environmental management.

In the area of **waste disposal**, the goal is a cost-efficient and environmentally compatible solution. We see waste management as a process that begins already at the purchasing stage and ends with systematic recycling, for example, recycling solvents or the resale of infusion glass bottles. All waste materials are recorded using a standardized system and are classified into corresponding waste categories. We use this data, for instance, as a basis for deciding whether to conclude

contracts with regional waste management companies or to have a Group-wide contract with one company.

More and more **disposable articles** are being used in the medical products at hospitals. However, this is not necessarily at the expense of environmental protection. Disposable covers in the operating theater, for instance, have a better environmental impact than reusable ones. This is because their production and preparation for reuse consumes more energy than that required to produce and dispose of covers that are only used once. Moreover, surfactants and other chemicals are necessary to disinfect those products and harm the environment.

**Hygiene requirements** place limits on the use of regenerative energy sources at hospitals. Solar energy-based water heating systems, for instance, are not a feasible solution for hospitals, in our view. The temperature level of the heat produced, unlike that of conventionally produced heat, provides ideal conditions for the spread of Legionella bacteria. The contamination of drinking water with Legionella can have fatal consequences for patients whose immune system is impaired. For this reason, HELIOS does not use solar energy at its clinics.

A major source of **energy consumption** at hospitals is the need for air-conditioning in the working areas and in patients' rooms. For instance, medical equipment that generates heat, such as a magnetic resonance tomograph, needs to be cooled. The structural condition of a hospital building also has an important influence on energy consumption. HELIOS invests in environmental protection on an ongoing basis through structural measures. All new construction projects and modernizations conform to the latest standards of efficient heat insulation. In 2009, € 82 million was spent on maintenance (2008: € 75 million).

HELIOS sources the energy for all the Group's 61 clinics centrally through an online purchasing platform. This platform not only supplies data on consumption at the clinics, but also benchmarks that enable higher-than-average levels of energy consumption to be detected.

A **pilot environmental and energy-saving project** launched at the HELIOS site Bad Berleburg in 2008 was continued. Under this project HELIOS highlighted numerous ways in which energy could be saved in order to encourage staff

to be environmentally conscious. HELIOS achieved significant savings in the project's first year. Gas consumption was reduced by about 13 %, to which structural measures to improve the insulation of the buildings also contributed. Electricity consumption was reduced by 8 %, thanks mainly to this environmental awareness drive. HELIOS is considering whether to roll out the campaign to other HELIOS clinics.

### FRESENIUS VAMED

In the future, health care systems will also have to pay greater attention to **sustainability**. This factor must especially be taken into account in the hospital sector. As an active contribution toward environmental protection, VAMED already integrates national environmental standards and regulations into the planning and construction of a hospital or other health care facility.

For instance, in its design of a hospital and modern cancer clinic that is being constructed on a turnkey basis in Gabon, VAMED provided for the waste water from the hospital to be cleaned in a proprietary sewage treatment plant. Clinical waste is disposed of in the hospital's own high-temperature incinerator designed to European standards.

For many years, VAMED has been responsible for the technical management of the Vienna General Hospital and University Clinic (AKH), one of the largest hospitals in Austria with over 10,000 employees. Together with the AKH, VAMED has implemented a range of measures designed to conserve energy, especially in the areas of air-conditioning and heat recovery. In 2009, the AKH's **greenhouse gas emissions** were reduced by about 12 % versus 1998, i. e. from approximately 134,000 t to about 118,000 t of CO<sub>2</sub> per year. The international target set by the Kyoto Protocol, to reduce emissions by 5.2 %, has therefore been well exceeded. VAMED measures the hospital's emissions on a **CO<sub>2</sub> equivalent** basis. This is a standard measure that converts greenhouse gas emissions into the equivalent amount of CO<sub>2</sub>, also taking into account other greenhouse gases in order to achieve the Kyoto target, enabling companies to demonstrate the effectiveness of environmental and climate protection measures. The AKH, together with VAMED, has set itself the target of reducing greenhouse gas emissions by 2012 by three times the amount required by the Kyoto Protocol.

## SALES, MARKETING, AND LOGISTICS

Long-term, mutually trusting cooperation with our customers is an essential basis for sustainable growth. We strive to guarantee top quality and outstanding service to our customers, together with reliable logistics and product availability. Thanks to its broad product portfolio and long experience, Fresenius has been able to build and maintain close relationships with its customers worldwide. Close cooperation between sales and research & development divisions enables us to integrate concepts and ideas generated by the sales force with respect to product development. Fresenius has its own sales organizations with trained sales personnel. The sales teams coordinate direct sales promotion measures, including visits to doctors, medical specialists, hospitals, and specialist clinics. The Company also employs distributors in countries where we do not have our own sales team.

Fresenius' products are shipped by the production plants to central warehouses, generally located not far from the production sites. These central warehouses dispatch the products to the regional warehouses, which then distribute them to the clinics and other customers, or directly to a patient's home. The business segments offer after-sales services, training in the local language, technical support, servicing, and maintenance and warranty arrangements in every country in which Fresenius sells its products. Product training is also provided at the Company's production sites. Regional service centers are responsible for day-to-day international service support.

The business segments have the following **customer structure**. Dialysis clinics and hospitals are Fresenius Medical Care's main customers for its products business. In dialysis care, approximately 33 % of Fresenius Medical Care's revenues are derived from the US government's Medicare and Medicaid programs, with about 67 % from hospitals and private and other health care payors.

Fresenius Kabi has a broadly diversified customer base that includes hospitals, wholesalers, purchasing organizations, medical and similar institutions, hospital operators, and home care patients. Fresenius Kabi has no significant dependence on any one source of revenue. In the United States, the products of APP Pharmaceuticals are distributed primarily through

group purchasing organizations (GPOs). In international business, Fresenius Kabi is increasingly bidding in public tenders that are generally issued by government entities.

The customers of Fresenius Helios include social security institutions, health insurers, and private patients.

The clients of Fresenius Vamed are public and private hospitals and other health care facilities.

## OVERALL ASSESSMENT OF THE BUSINESS SITUATION

At the time this Group Management Report was prepared, the Management Board continued to assess the development of the Fresenius Group as positive. Our products and services continue to be in significant demand around the world. Operating performance in the first weeks of 2010 has been in line with our expectations, with further increases in sales and earnings.

## OPPORTUNITIES AND RISK REPORT

Through the complexity and dynamics of our business, the Fresenius Group is exposed to a number of risks. These risks are inevitable consequences of active entrepreneurial activities. However, the willingness to take risks has to be accommodated if opportunities are to be exploited.

As a provider of often life-saving products and services for the severely and chronically ill, we are relatively independent of economic cycles. The diversification through our four business segments, which operate in different segments of the health care market, further minimize the Group's risk profile. Our experience in the development and manufacture of products, as well as in our markets, serves as a solid basis for a reliable assessment of risks.

At the same time, we will continue to take advantage of the wide-ranging opportunities for sustainable growth and expansion that the health care market offers to the Fresenius Group.

## OPPORTUNITIES MANAGEMENT

Managing opportunities is an ongoing, integral part of corporate activity aimed at securing the company's long-term success. In this way, we can explore new prospects and consolidate and improve on what we have already achieved. Opportunities management is closely linked to the Fresenius Group's long-term strategy and medium-term planning. The Group's decentralized and regional organizational and management structure enables the early identification and analysis of trends, requirements, and opportunities in our often fragmented markets; and we can respond to them flexibly and in line with local market needs. Furthermore, we maintain regular contact and dialogue with research groups and institutions and keep a close watch on markets and competitors in order to identify opportunities. Within the Group, opportunities and synergies can be exploited through continuous communication involving the exchange of information and know-how among the various business segments. Anticipated future opportunities for the Fresenius Group are discussed in the Outlook starting on page 97.

## RISK MANAGEMENT

Like opportunities management, risk management is a continuous process. Identifying, controlling, and managing risks are key tools of solid corporate governance. **Fresenius risk management** is closely linked to corporate strategy. Its main part is our **control system**, with which we can identify and counteract at an early stage those developments that might threaten the company's future.

Responsibilities for the processes and for monitoring risks in the individual business segments have been assigned as follows:

- ▶ Using standardized processes, risk situations are evaluated regularly and compared with specified requirements. If negative developments emerge, responses can be initiated at an early stage.
- ▶ The managers responsible are required to report without delay any relevant changes in the risk profile to the Management Board.
- ▶ Markets are kept under constant observation and close contacts maintained with customers, suppliers, and institutions. These policies allow us to swiftly identify and react to changes in our business environment.

Risk management measures are supported both at Group level and in the individual business segments by our risk controlling measures and our management information system. Detailed monthly and quarterly reports are used to identify and analyze deviations of the actual compared to the planned business development. In addition, the risk management comprises a control system that oversees organizational processes and measures, as well as internal controls and audits. Our risk management system is regularly evaluated and, if necessary, adjusted to allow prompt reaction to changes in the markets. This system has proved effective to date.

The functionality and effectiveness of the risk management is reviewed as part of the audit of the annual financial statements, and regularly by the Management Board and the internal auditing department. Conclusions arising from the audits are taken into account in the ongoing refinement of our risk management system. The control management is also reviewed regularly by the Management Board and the internal auditing department.

Fresenius has ensured that the scope and focus of the organizational structure and systems for identifying and evaluating risks, and for developing counter-measures and for the avoidance of risks, are aligned suitably with the company-specific requirements and that they are properly functional. However, there can be no absolute certainty that this will enable all risks to be fully identified and controlled.

## INTERNAL FINANCIAL REPORTING CONTROLS

Correctness and reliability of accounting processes and financial reporting, and thus preparation of annual financial statements, consolidated financial statements and management reports for Fresenius SE and the Group in compliance with applicable rules, is assured by numerous measures and internal controls. Especially our **four-tier reporting process** makes for intensive discussion and controls of the financial results. At each reporting level (local entity, region, business segment, Group), financial data and key figures are discussed and compared regularly on a monthly and quarterly basis with the prior-year figures, the budget, and the latest forecast. In addition, all parameters, assumptions, and estimates that are of relevance for the externally reported Group and segment results are discussed intensively with the department responsible

for preparing the Group's consolidated financial statements. These matters are also reviewed and discussed quarterly in the Supervisory Board's Audit Committee.

Control mechanisms, such as automated and manual reconciliation procedures, and the strict separation of functions are further precautions in place to assure that financial reporting is reliable and that transactions are correctly accounted for. To prevent abuse, we take care to maintain a separation of functions. Management control and evaluations also help to ensure that risks having a direct impact on financial reporting are identified and that controls are in place to minimize them. Moreover, changes in accounting rules are monitored and employees involved in financial reporting are instructed regularly and comprehensively.

Fresenius Medical Care, an important Group company, is additionally subject to the controls of Section 404 of the Sarbanes Oxley Act.

## RISK AREAS

The main risk areas for the operations of the Fresenius Group are as follows:

### GENERAL ECONOMIC RISKS

At present, the development of the global economy exhibits no significant risk to the Fresenius Group. In 2010, overall economic growth should pick up again compared to 2009. Moreover, Fresenius is not affected by general economic fluctuations as much as other sectors. We also expect continued growing demand for our life-saving and life-sustaining products and services.

### RISKS IN THE GENERAL OPERATING FRAMEWORK

The risk situation for each business segment also depends on the development of its markets. Therefore, political, legal, and financial conditions are monitored and evaluated carefully. In addition, the growing internationalization of our markets requires us to keep abreast of country-specific risks.

### RISKS IN THE HEALTH CARE SECTOR

Risks related to **changes in the health care market** are of major importance to the Fresenius Group. The main risks are the development of new products and therapies by competitors, the financing of health care systems, and reimbursement

in the health care sector. In our largely regulated business environment, changes in the law – also with respect to reimbursement – can have decisive consequences for our business progress. This applies especially in the United States, where a large portion of our sales are generated, and where e. g. changes in the reimbursement system could have an impact on our business. Furthermore, a portion of our dialysis service business is currently reimbursed by private insurers or managed care organizations. Any reductions in reimbursement from private insurers and managed care organizations could adversely impact our revenues for products and services. The same applies to the hospital market in Germany, where the DRG system (Diagnosis Related Groups) is intended to increase the efficiency of hospitals while reducing health care spending. The Company constantly monitors further legislative developments of the DRG system. Discussions about ending dual financing in the hospital sector are also being followed. Patients are largely assigned to hospitals by the public health and pension insurers. It is therefore especially important for the Company that the contracts between its hospitals and the insurers and health care institutions are maintained. For this reason, we not only continually monitor legislative changes, but also work together with governmental health care institutions. Generally, our aim is to counter possible regulatory risks through enhanced performance and cost reductions.

In the United States, almost all injectable pharmaceutical products are sold to customers through arrangements with **group purchasing organizations (GPOs)** and distributors. The majority of hospitals contract with the GPO of their choice for their purchasing needs. APP Pharmaceuticals currently derives, and expects to continue to derive, a large percentage of its revenue through a small number of GPOs. Currently, fewer than ten GPOs control a large majority of sales to hospital customers. APP Pharmaceuticals has purchasing agreements with the major GPOs. To maintain these business relationships, APP Pharmaceuticals believes it needs to be a reliable supplier, offer a comprehensive high-quality product line, remain price competitive, and comply with the regulations of the U.S. Food and Drug Administration (FDA). The GPOs also have purchasing agreements with other manufacturers and

the bid process for products is highly competitive. Most of APP Pharmaceuticals' GPO agreements can be terminated at short notice.

In addition, **cooperation with medical doctors and scientists** allows us to identify and support relevant technological innovations and to keep abreast of developments in alternative treatment methods. These enable us to evaluate and adjust our corporate strategy if necessary.

## OPERATING RISKS

### Production, products, and services

We confront potential risks in production and services with the following measures: compliance with **product and manufacturing regulations** is ensured by our quality management systems in accordance with the internationally recognized quality standards ISO 9001 and the corresponding internal standards as defined, for example, in our quality and work procedure manuals. Regular audits are carried out at the Group's production sites and dialysis clinics. These audits test compliance with all regulations in all areas – from management and administration to production and clinical services and patient satisfaction. Our production facilities comply with the international "Good Manufacturing Practice" (GMP) and US "Current Good Manufacturing Practice" (cGMP) guidelines and other internationally and nationally recognized standards. Potential risks, such as those arising from the start-up of a new production site or the introduction of new technologies, are countered through careful planning, regular analysis, and continual progress reviews. We counter the risk of poor-quality purchased raw materials, semi-finished products, and components mainly by requiring that suppliers meet extensive quality standards. Besides certification by external institutes and regular supplier audits, this includes an exhaustive evaluation of advance samples and regular quality controls. We only purchase products of high quality, maximum safety, and proven suitability from qualified suppliers that conform to our specifications and standards.

Performing **medical treatments** on patients in our hospitals, rehabilitation clinics, and dialysis clinics presents inherent risks; in addition, operational risks, for example the need for strict hygiene and sterile conditions, can arise. We counteract these risks with strict operating procedures, continuous personnel training, and patient-oriented working procedures. Furthermore, through our quality management systems we are constantly striving to improve the standard of patient treatment.

Risks can also arise from increasing **pressure on our product prices** and from price increases on the procurement side. For instance, changes in the regulations concerning the reimbursement for erythropoietin (EPO) in the United States, or a change in the dosage, could have a significant impact on the revenues and earnings of Fresenius. EPO is a hormone used in dialysis that stimulates the production of red blood cells. An interruption in supply or worsening procurement conditions for EPO could also reduce revenues and significantly increase Fresenius' costs. Fresenius Medical Care has entered into an agreement with Amgen for the supply of EPO in the United States and Puerto Rico. Amgen is the sole supplier of EPO in the United States. The agreement runs until December 31, 2011. Reimbursement and revenues from the administration of EPO accounted for approximately 7% of total sales of the Fresenius Group in 2009.

Growing **competition** could adversely affect the pricing and sale of our products and services. The introduction of new products and services by competitors could make one or more of our products and services less competitive. On the **procurement** side, we counter risks, which mainly involve possible price increases, by appropriately selecting and working together with our suppliers through long-term framework agreements in certain purchasing segments and by bundling volumes within the Group. Generally, the markets in which we operate are characterized by price pressure, competition, and efforts to **contain health care costs**. These could result in lower sales and adversely affect our business, our financial position, and our results of operations.

We counter the risks associated with the **engineering and hospital services business** through professional project management and control, and with a proven system tailored

to each business activity for identifying, evaluating, and minimizing these risks. This system consists of organizational measures (such as standards for pricing-in risks when preparing quotations, risk assessment before accepting orders, regular project controlling, and continual risk assessment updates), quality assurance measures, and financial measures, such as checking creditworthiness, repayments, letters of credit, and secured credits.

It is of special importance to us that our **compliance programs** and guidelines be adhered to. Through compliance we aim to meet our own expectations and those of our partners and to orient our business activities to generally accepted standards and local laws and regulations. These programs and guidelines set binding rules of conduct for our employees. We believe that we have taken adequate measures to ensure that national and international rules are complied with.

### Research and development

The development of new products and therapies always carries the risk that the ultimate goal might not be achieved. Regulatory approval of new products requires comprehensive, cost-intensive preclinical and clinical studies. The Fresenius Group spreads its risk widely by conducting development activities in various product segments. We also counteract risks from research and development projects by regularly analyzing and assessing development trends and examining the progress of research projects. We also strictly comply with the legal regulations for clinical and chemical-pharmaceutical research and development. With IV drugs, it is also crucial that new products are brought to the market continually and at the right time. The product development process can be controlled on the basis of detailed project roadmaps and a tight focus on the achievement of specific milestones. If the defined targets are not achieved, counter-measures can be initiated.

### Risks from the integration of acquisitions

The **integration** of acquisitions or potential acquisitions carries risks that can adversely affect Fresenius' assets and liabilities, our financial position, and results of operations. Following an acquisition, the infrastructure of the acquired company must be integrated while clarifying legal questions and contractual obligations. Marketing, patient services, and logistics must also be unified. During the integration phase, key managers can leave the company and the course of ongoing business processes as well as relationships with customers can be harmed. In addition, change-of-control clauses may be claimed. The integration process may prove to be more difficult and cost-intensive or last longer than expected. Risks can arise from the operations of the newly acquired company that Fresenius regarded as insignificant or was unaware of. An acquisition may also prove to be less beneficial than initially expected. **Future acquisitions** may be a strain on the finances and management of our business. Moreover, as a consequence of an acquisition Fresenius may become directly or indirectly liable toward third parties or claims against third parties may turn out to be non-assertable.

Acquired by Fresenius in 2008, APP Pharmaceuticals has agreed to indemnify Abraxis BioScience, Inc., which split from it in 2007, from and after the spin-off with respect to all liabilities of the pre-separation company related to APP Pharmaceuticals' business. At the same time, Abraxis BioScience agreed to indemnify APP Pharmaceuticals from and after the spin-off with respect to all liabilities of the pre-separation company not related to APP Pharmaceuticals' business. The extent to which Abraxis BioScience will be able to satisfy these potential claims in future cannot be predicted.

As a result of Fresenius' acquisition of APP Pharmaceuticals, the spin-off from Abraxis BioScience which took place in 2007 could fail to qualify as a tax-free distribution. A fiscal law assessment obtained within the scope of the acquisition confirms that the acquisition of APP Pharmaceuticals should not affect the qualification of the spin-off as a tax-free distribution in 2007. However, this opinion is not binding on the Internal Revenue Service (IRS), nor does it preclude the IRS from asserting a contrary position. If, notwithstanding the opinion, the IRS were to audit the spin-off and successfully

assert that the spin-off failed to qualify for the tax-free status as a result of the acquisition of APP Pharmaceuticals, this would lead to a material tax liability.

We counter risks from acquisitions through detailed integration roadmaps and strict integration and project management so that counter-measures can be initiated in good time if there are deviations from the expected development.

### Personnel risks

The Company uses appropriate recruiting and personnel development measures to counteract a possible shortage of skilled personnel. We are also seeking to keep employees with the Company by introducing life work time accounts in various areas. In addition, we provide our employees with attractive fringe benefits and partly with bonuses. By using targeted personnel marketing measures to recruit a qualified and dedicated workforce, Fresenius counters the general shortage of specialized hospital personnel, thus ensuring our high standards of treatment quality. At the same time, by assisting in the training of young people, we thereby seek to commit them to the Company. For example, HELIOS keeps close contact to young doctors by intensive support already throughout their studies and during their practical year. Risks in personnel marketing are not considered to be significant because of numerous measures designed to minimize them.

### Financial risks

The international operations of the Fresenius Group expose us to a variety of currency risks. In addition, the financing of the business exposes us to certain interest rate risks. We use derivative financial instruments as part of our risk management to avoid possible negative impacts of these risks. However, we limit ourselves to non-exchange traded, marketable instruments, used exclusively to hedge our operations and not for trading or speculative purposes. All transactions are conducted with banks of high rating.

The Fresenius Group's **currency and interest rate risk management** are based on a policy approved by the Management Board that defines the targets, organization, and handling of the risk management processes. In particular, the guidelines assign responsibilities for risk determination, the execution

of hedging transactions, and the regular reporting of risk management. These responsibilities are coordinated with the management structures in the residual business processes of the Group. Hedging transactions using derivatives are carried out solely by the Corporate Treasury Department of the Fresenius Group – apart from a few exceptions in order to adhere to foreign currency regulations – and are subject to stringent internal controls. This policy ensures that the Management Board is fully informed of all significant risks and current hedging activities.

The Fresenius Group is protected to a large extent against currency and **interest rate risks**. As of December 31, 2009, approximately 68 % of the Fresenius Group's debt was protected against increases in interest rates either by fixed-rate financing arrangements or by interest rate hedges. Only 32 %, or €2,656 million, was exposed to an interest rate risk. A sensitivity analysis shows that a rise of 0.5 % in the reference rates relevant for Fresenius would have a less than 1 % impact on Group net income.

As an international company, Fresenius is widely exposed to **translation effects** due to foreign exchange rate fluctuations. The exchange rate of the US dollar to the euro is of particular importance because of our extensive operations in the United States. Translation risks are not hedged. A sensitivity analysis shows that a one cent change in the exchange rate of the US dollar to the euro would have an annualized effect of about €44 million on Group sales and about €1 million on Group net income.

As a globally active company, we have production facilities in all the main currency areas. In our service businesses, the revenue and cost base largely coincide. The exposure to currency risks arising from our business activities (**transaction risks**) does not rise to the same extent as sales. In order to estimate and quantify the transaction risks from foreign currencies, the Fresenius Group considers the cash flows reasonably expected for the following three months as the relevant assessment basis for a sensitivity analysis. For this analysis, the Fresenius Group assumes that all foreign exchange rates in which the Group had unhedged positions as of reporting

date would be negatively impacted by 10 %. By multiplying the calculated unhedged risk positions with this factor, the maximum possible negative impact of the foreign exchange transaction risks on the Group's results of operations would be € 9 million. Information can be found on pages 173 to 175 of the Notes.

Potential financial risks that could arise from acquisitions, investments in property, plant and equipment, and in intangible assets are assessed through careful and in-depth reviews of the projects, sometimes assisted by external consultants. Goodwill and other intangible assets with an indefinite useful life carried in the Group's consolidated balance sheet are tested for **impairment** each year. Further information can be found on page 126 of the Notes.

By carefully assessing the creditworthiness of new customers, we minimize the risk of **late payment and defaults** by customers. We also conduct follow-up assessments and review credit lines on an ongoing basis. Receivables outstanding from existing customers are monitored, and the risk of defaults is assessed.

Fresenius' **debt** has increased significantly as a result of the financing of the APP Pharmaceuticals acquisition in 2008, reaching € 8,299 million as of December 31, 2009. The debt could limit the ability to pay dividends, to arrange refinancing, to be in compliance with its credit covenants, or to implement corporate strategy. Other financing risks could arise for Fresenius against the background of the general financial market crisis. We reduce these risks through a high proportion of medium and long-term funding with a balanced maturity profile. Furthermore, the Group has only limited short-term funding requirements.

### Government reimbursement payments

Fresenius is subject to comprehensive government **regulation** in nearly all countries. This is especially true in the United States and Germany. In addition, Fresenius has to comply with general rules of law, which differ from country to country. There could be far-reaching legal repercussions should Fresenius fail to comply with these laws or regulations. A large part of Group revenue derives from government reimbursement programs, such as the federal dialysis reimbursement

programs in the United States under Medicare and Medicaid. Changes in the law or the reimbursement method could affect the scope of the payments for services as well as of the insurance cover. This could have a significant adverse impact on the assets and liabilities, financial position, and results of operations of the Group.

### Legal risks

Risks that arise from **legal disputes** are continually identified, analyzed, and communicated within the Company. Companies in the health care industry are regularly exposed to actions for breach of their duties of due care, product liability, breach of warranty obligations, treatment errors, and other claims. This can result in claims for damages and costs for legal defense, regardless of whether a claim for damages is actually justified. Legal disputes can also result in inability to insure against risks of this kind at acceptable terms in future. Products from the health care industry can also be subject to recall actions and patent infringement suits.

In 2003, a definitive agreement was signed regarding the settlement of fraudulent conveyance claims and all other legal matters in connection with the National Medical Care transaction in 1996 arising from the bankruptcy of W.R. Grace. Under the settlement agreement, Fresenius Medical Care will pay a total of US\$ 115 million without interest into the W.R. Grace & Co. bankruptcy estate or as otherwise directed by the court upon plan confirmation. The settlement agreement was approved by the competent court. Claims made out of court by certain private US health insurers were also settled by an agreement. Consequently, all legal issues resulting from the NMC transaction have been finally concluded subject to plan confirmation.

FMCH and its subsidiaries, including RCG (before its acquisition by Fresenius Medical Care) received subpoenas from the U.S. Department of Justice in St. Louis (Missouri) in connection with civil and criminal investigations in 2005 (RCG in

August 2005). Documentation must be provided on clinical quality programs, business development activities, compensation of clinic managers, contractual relationships with doctors, joint ventures, and anemia treatment therapies, RCG's suppliers, pharmaceutical and other services which RCG has provided for patients, RCG's relations to companies in the pharmaceutical industry, and RCG's procurement of dialysis machines from FMCH. The Inspector General of the U.S. Department of Health and the Attorney General for the Eastern District of Texas confirmed their involvement in the review of the anemia management program.

In July 2007, the U.S. Attorney General filed a civil action against RCG and FMCH – in its capacity as the present holding company of RCG – before the U.S. District Court for the Eastern District of Missouri. The action claims damages and penalties in respect of the business activities of the RCG Method II supplier company in 2005 – before RCG was acquired by FMCH. Fresenius Medical Care believes that RCG's operation of its Method II supply company was in compliance with applicable law and will defend this litigation.

In June 2009, FMCH received a subpoena from the U.S. Department of Justice, the Attorney General for the District of Massachusetts. Information must be submitted on the results of certain laboratory tests conducted from 2004 to 2009 for patients treated at FMCH dialysis centers.

Further information can be found on pages 165 to 169 of the Notes.

The Fresenius Group is also involved in various legal issues resulting from business operations and, although it is not possible to predict the outcome of these disputes, none is expected to have a significant adverse impact on the assets and liabilities, financial position, and results of operations of the Group.

### Other risks

Other risks, such as **environmental risks and risks involving management and control systems**, or our IT systems, were not considered to be significant. **IT risks** are countered through security measures, controls, and monitoring. In addition, we counter these risks with constant investment in hardware and software as well as by improving our system know-how. Potential risks are covered by a detailed contingency plan which is continuously improved and tested. Redundant systems are maintained for all key systems such as international IT systems or communications infrastructure. A password system is in place to minimize organizational risks such as manipulation and unauthorized access. In addition, there are company guidelines regulating the granting of access authorization, and compliance with these rules is monitored. We also conduct operational and security-related audits.

### ASSESSMENT OF OVERALL RISK

The basis for evaluating overall risk is the risk management that is regularly audited by management. Potential risks for the Group include factors beyond its control, such as the evolution of national and global economies, constantly monitored by Fresenius. Risks also include factors immediately within its control, such as operating risks, which the Company anticipates and reacts to appropriately, as required. There are currently no recognizable risks regarding future performance that appear to present a long-term and material threat to the Group's assets and liabilities, financial position, and results of operations. We have created organizational structures that provide all the conditions needed to rapidly alert us to possible risk situations and to be able to take suitable counteraction.

### CORPORATE RATING

Fresenius' credit quality is assessed and regularly reviewed by the leading rating agencies Moody's, Standard & Poor's, and Fitch. Standard & Poor's rating for Fresenius SE is BB, Moody's rating is Ba1 and Fitch's rating is BB. Following the financing of the APP Pharmaceuticals acquisition, Standard & Poor's and Fitch changed its rating outlook to "negative" in 2008.

Based on its new assessments they raised it again to “stable” in 2009. Moody’s had confirmed its rating, which was raised from Ba2 to Ba1 in May 2008 following the acquisition announcement; its outlook was adjusted from “stable” to “negative”. This was confirmed by Moody’s in 2009.

RATING OF FRESENIUS SE

	Standard & Poor’s	Moody’s	Fitch
Rating	BB	Ba1	BB
Outlook	stable	negative	stable

### SUBSEQUENT EVENTS

There have been no significant changes in the Fresenius Group’s operating environment following the end of the fiscal year 2009. No other events of material importance on the assets and liabilities, financial position, and results of operations of the Group have occurred following the end of the fiscal year.

### OUTLOOK

This Management Report contains forward-looking statements, including statements on future sales, expenses, and investments, as well as potential changes in the health care sector, our competitive environment, and our financial situation. These statements were made on the basis of the expectations and assessments of the Management Board regarding events that could affect the Company in the future. Such forward-looking statements are subject as a matter of course to risks, uncertainties, assumptions, and other factors, so that the actual results, including the financial position and profitability of Fresenius, could therefore differ materially – positively or negatively – from those expressly or implicitly assumed or described in these statements. For further information, please see our Risk Report on pages 91 ff.

### GENERAL AND MID-TERM OUTLOOK

The outlook for the Fresenius Group for the coming years continues to be positive. We are continuously striving to optimize our costs, to adjust our capacities so as to be able to treat patients and supply customers reliably, and to improve our product mix. We expect these efforts to improve our earnings. In addition, good growth opportunities for Fresenius are above all presented by the following factors:

- ▶ The sustained **growth of the markets** in which we operate: Fresenius sees very good opportunities to profit from the considerable health care needs due to aging populations and technical advances, but driven also by the still insufficient access to health care in the developing and emerging countries. There are above-average and sustained growth opportunities for us not only in the markets of Asia and Latin America, but also in Eastern Europe. Appropriate reimbursement structures and efficient health care systems will evolve over time in these countries as economic conditions improve. We will strengthen our local business activities in these regions and successively introduce further products from our portfolio to these markets.
- ▶ The **development of innovative products and therapies**: these will create the potential to further expand our market position in the regions. In addition to innovation, best-in-class quality, reliability, and convenience of our products and therapies are key to being able to exploit opportunities for expansion. Although the research is still in its infancy, the development of portable artificial kidneys is conceivable in the long term at Fresenius Medical Care, for instance
- ▶ The **expansion of our regional presence**: the fast-growing markets in Asia-Pacific and Latin America especially offer further potential for increasing our market shares. China, for instance, which has the world’s biggest population, offers excellent growth opportunities not only in clinical

nutrition and infusion therapies for Fresenius Kabi, which already holds a leading market position in China, but also for Fresenius Medical Care in dialysis.

We also plan to successively roll out products and therapies from our existing portfolio in countries where we do not yet offer a comprehensive range. The acquisition of APP Pharmaceuticals in the Fresenius Kabi business segment, for instance, will enable us to introduce infusion and nutrition therapy products to the US market and also APP Pharmaceutical's products through Fresenius' international marketing and sales network in future.

- ▶ **The broadening of our services business:** Fresenius Helios has concrete opportunities in the German hospital market to profit from the further privatization of public hospitals. Changes in the law could present new opportunities, for instance, for Fresenius Medical Care. Since Japan is one of the world's biggest dialysis markets, changes in the framework conditions for the operation of dialysis clinics for private commercial enterprises there could open up new revenue potential for Fresenius Medical Care.
- ▶ **Selective acquisitions:** besides good organic growth, we will continue to utilize opportunities to grow by making small and mid-sized acquisitions that extend our product portfolio and strengthen our regional presence.

We are also exploiting any **opportunities for tapping potential** within our operations for cost management and efficiency and profitability enhancement measures. These include plans for a further optimized procurement process and cost-efficient production.

Acquisitions, primarily the acquisition of APP Pharmaceuticals, have led to appreciably higher Group debt with a corresponding impact on net interest. Our goal is therefore to further improve the Group's **leverage ratios**. As of December 31, 2009, the net debt/EBITDA ratio was 3.0. We expect to achieve <3.0 by the end of 2010.

This forecast takes account of all events known at the time the annual financial statements were prepared that could influence our operating performance in 2010 and beyond. Significant risks are discussed in the Risk Report. As in the past, we will do our utmost to achieve and – if possible – exceed our targets.

## FUTURE MARKETS

As an international company, we offer our products and services in more than 150 countries. We expect the consolidation process among competitors in our markets in Europe, Asia-Pacific, and Latin America to continue. Consequently, we anticipate that there will be opportunities for Fresenius to penetrate new markets, both by expanding its regional presence and by extending its product portfolio. In the United States, since Fresenius Medical Care and its competitor DaVita already share about two-thirds of the market, acquisitions – also with regard to potential antitrust restrictions – are likely to be small. Other new markets will also open up for Fresenius as we successively roll out our existing product portfolio in other regions. For instance, because of different regional and legal conditions, Fresenius Medical Care only supplies dialysis products in some countries. If conditions change, the company might provide dialysis care in these countries as well.

## ECONOMIC OUTLOOK

The brightening economic outlook in the last months of 2009 – especially in private demand – could help the world economy to recover in 2010. The situation in the financial sector, where challenges and uncertainty still persist, remains critical.

The current recovery of the world economy is driven by the positive momentum in many emerging countries. Industrial countries are also expected to recover in 2010. However, this improvement will probably be modest since some of the positive stimulus currently emanating from the government economic programs should decline. The decisive factor will therefore be whether the emerging economies can step up their role as growth drivers. This appears unlikely at present, however. The world economy is expected to grow by 4.1 % in 2010.

The outlook for inflation in the coming years should continue to stabilize in 2010 and 2011. Experts reckon with global inflation of 3.1 % and 2.9 % in 2010 and 2011, respectively, so there is no acute inflation threat in the mid term despite the monetary expansion. Moreover, because of political pressure, central banks are likely to raise rates only gradually in the coming years.

## EUROPE

A moderate recovery is expected in the Eurozone in 2010. The expansion of government economic programs should continue to provide support in the coming year. Very low short-term interest rates in the Eurozone and reviving export demand will also have an expansionary effect. However, all in all, factors suggesting only modest economic development predominate: firstly, the situation on the labor market is expected to worsen. Secondly, the real estate markets in many countries are still having a dampening effect because real estate prices could stagnate or fall. Thirdly, most countries in Eastern Europe have been hit even harder by the crisis than Western Europe. Fourthly, in Europe the real economy, which is more dependent on bank funding than in other economic regions, is overshadowed by the adjustments still hidden in many financial institutions' balance sheets. Fifthly, at the beginning of the year 2010, the high deficit of some countries in the Eurozone, e. g. Greece, came into the focus of investors and the risk of a potential national bankruptcy increased. The resulting uncertainty can have negative consequences for the economic growth of the entire Eurozone. A continued weakening of the euro could have, however, positive effects, especially for the highly export-linked countries of the Eurozone. GDP growth is expected to be positive at 1.5 % for the Eurozone.

The outlook for **Germany's economy** will mainly depend on two factors: export dynamic and domestic economic effects. The key factors here will be the trend for the labor market and the availability of finance. A recovery is expected for Germany, with GDP growth of 2.1 %.

## UNITED STATES

At the beginning of the year 2010, the economic situation in the United States showed increasing evidence of recovery. Capacity utilization improved and is expected to positively influence the labor market. Improvements in inventories and capital spending are further signs of economic recovery. If the growth prospects continue in the United States, also investor concerns about the sustainability and durability of economic growth should dissipate.

The current economic recovery, however, remains at risk. The fiscal stimulus initiated in the year 2009 will significantly weaken in 2010. Although the real estate market is starting to bottom out, no significant stimulus can be expected as yet from residential construction given the market's continued oversupply. Moreover, households should adjust their spending to the sharp increase in debt over the past years.

In these circumstances, growth of 3.8 % is expected in 2010.

## ASIA

It appears unlikely at present that the emerging economies in Asia can act as key growth drivers for the world economy in the short term. In 2007, the year before the crisis, private consumption in China was just one-eighth the US level. Moreover, a further rise in unemployment is expected in the Asian emerging economies in 2010 and investment activity will remain low as capacity utilization is well below pre-crisis levels in most countries. For Asia (excluding Japan) a GDP growth of 7.7 % is expected in 2010.

In **Japan**, the economic outlook for 2010 will depend very largely on the development of the international environment and foreign demand. GDP growth will probably be 1.7 %. A rigorous consolidation of public finances is necessary given the very high level of government debt.

GDP growth of 9.0 % is forecast for **China** in 2010. Rising inflation, the reduction of industrial overcapacity, and fiscal policy will be the key economic issues. The Chinese government's public investment, which was stepped up strongly in 2009 to stimulate the economy, is likely to become less extensive in the year 2010.

#### LATIN AMERICA

Positive growth of 3.9 % is expected for the region in 2010, driven mainly by **Brazil** and **Chile**. Falling commodity prices are the biggest risk for these two countries. Experts currently predict stable commodity prices in 2010.

The economic outlook for **Mexico** will continue to be influenced largely by growth in the United States. GDP growth of 2.6 % is forecast for Mexico in 2010. For **Brazil**, GDP growth of 5.8 % is expected after a small decrease in 2009. In **Argentina**, GDP growth of 1.5 % is forecast after a sharp decline in 2009.

#### HEALTH CARE SECTOR AND MARKETS

The health care sector will continue to be one of the world's largest industries. The demand for life-saving and life-sustaining products and services will especially remain intact as they are medically needed.

However, experts estimate that a prolonged economic downswing could result in more pricing pressure and slowdown in revenue growth as governments seek to ease their healthcare spending – especially in the United States.

Nonetheless, industry observers believe that, despite all challenges, the sector will also see a comparatively solid financial performance in the foreseeable future. Moreover, favorable demographic trends, such as aging populations, medical advances, and the large number of diseases that are still difficult to cure or are incurable should be growth drivers. In addition, the need to increase the availability of primary health care and the growing demand for high-quality medical treatment in the emerging countries will also continue to generate solid growth rates.

However, in the mid to long term, funds channeled into economic programs to contend with the financial and economic crisis in other sectors may not be available for the health industry.

#### THE DIALYSIS MARKET

We expect the number of dialysis patients worldwide to rise by about 6 % p. a. in the coming years, although significant regional differences will remain. For the United States, Japan, and the countries of Central and Western Europe, where prevalence is already relatively high, we forecast slightly below-average patient growth. In many developing countries, however, where needs are still not met sufficiently, we expect above-average growth in patient numbers of up to 10 %, and in some countries even higher rates. This growth is driven by steadily evolving health care systems that are providing broader patient care. As more than 80 % of the world's population lives in these countries, this opens up strong potential for the entire spectrum of dialysis care and dialysis products.

We expect that the total dialysis market could reach more than US\$ 70 billion in 2011 (unchanged currency relations assumed), almost doubling its volume over a period of just ten years.

We intend to maintain our market leadership at a very high level in the major product groups, such as dialyzers and hemodialysis machines, and to improve it where possible.

In the United States, our biggest market, a new flat-rate reimbursement system for dialysis patients covered by the public health care program (Medicare) is due to be introduced in January 2011. The legislation was passed in July 2008 under the "Medicare Improvements for Patients and Providers Act of 2008". All products and services currently reimbursed according to the so-called composite rate as well as services that have so far been reimbursed separately, such as the administration of certain drugs and the performance of diagnostic laboratory tests, will be reimbursed in future as a single, flat-rate payment. This so-called bundled rate will take individual patient parameters, such as age and weight, into account. Adjustments are also provided for patients who require exceptional medical care, with correspondingly high costs.

Besides being inflation-linked, another special feature of the new reimbursement scheme is its orientation to certain quality parameters. For instance, if dialysis clinics do not meet set quality standards, their reimbursement rates will be reduced. The quality parameters include factors such as patient satisfaction, the control of blood hemoglobin levels (anemia management), and bone mineral metabolism.

The composite rate was already increased in 2009 and is being raised by a further 1 % in 2010.

### THE MARKET FOR INFUSION THERAPIES AND CLINICAL NUTRITION, GENERIC IV DRUGS, AND MEDICAL DEVICES

The market for **infusion therapies and clinical nutrition** in Central and Western Europe will probably grow at a low single-digit rate in the coming years. There continues to be high growth potential in Asia-Pacific – especially China – and in Latin America and Eastern Europe. We expect the market in these regions to continue growing at high single to double-digit rates.

With **intravenously administered generic drugs** the growth dynamic will continue to be driven by original preparations going off-patent. A factor working in the opposite direction is the price erosion for products that are already in the market. We expect the market for IV generics in Central and Western Europe to grow at a mid single-digit rate. In the United States, a key factor will be the direction of the planned health care reform. Given the high cost of the reforms, it can be generally assumed that the US government will encourage the use of low-cost generics, among other things through incentive mechanisms and initiatives to promote cost consciousness. In addition, generics manufacturers should benefit from faster market access. On the other hand, however, it looks as if the pharmaceutical industry will have to grant higher rebates to public payors in future. It has also been proposed that hospital reimbursement rates should be reduced. That could increase pressure on the pharmaceutical industry.

All things considered, we therefore currently expect the US market for IV generics to grow at a mid single-digit rate in 2010, driven by a number of important original preparations going off-patent.

We also expect rising demand for medical devices in the coming years.

### THE GERMAN HOSPITAL MARKET

Although the reimbursement schemes are largely regulated by law, German hospitals will not completely escape the effects of the financial and economic crisis in 2010, after an overall positive year in 2009. Experts see an increasing risk of insolvency for German hospitals in 2010. Due to the further worsening financial situation in the public sector, privatization activities are expected to increase in 2010.

Health insurers' revenues are expected to decrease. Furthermore, negative impact will stem from the health care fund introduced in 2009 and for which a budget deficit of € 4 billion is anticipated. Moreover, the financial situation of local governments has worsened, reducing their ability to cover their hospitals' operating losses and to finance investments. This will further limit the financial scope for supporting loss-making hospitals and investment in public health care facilities.

Another challenge for hospitals is financing investments. Given their high investment needs but declining government support, hospitals are under growing pressure to rigorously tap the potential for rationalization.

Crucial factors for a hospital's success will not only be cost-efficient processes, a well-structured treatment spectrum, and well-trained staff, but also excellent medical standards. HELIOS is convinced that systematic quality management and high-quality medical results should not just serve as marketing instruments, but should be an element of hospital management, and thus part of the reimbursement. In the long run, initiatives are expected that provide for the introduction of quality-based reimbursement (pay for performance) and allow hospitals the option of concluding selective contracts with health insurers. With its strict focus on quality and transparency, HELIOS would be excellently prepared for this future development.

It is generally expected that the privatization process will accelerate further, especially among public hospitals. Private hospital chains and alliances are likely to be able to respond to the pressure to improve efficiency better than public hospitals. They often have more experience in operating commercially and creating efficient structures. Also, they have the potential to secure cost advantages in procurement. Finally, private operators have more experience with the process know-how for acquiring and integrating new facilities and quickly adjusting their cost structures.

There are no signs as yet that the new coalition government will bring decisive changes for clinics in the German acute care and post-acute care market as the political discussion has been confined so far to long-term financing issues. As in the past, a focus on cost-cutting in a future health care reform cannot be ruled out. On the one hand, health insurers' revenues are expected to decline subsequent to the economic crisis. And on the other hand, the health care system is faced with rising costs.

In Germany the new reimbursement system on the basis of the standardized base rates in the individual federal states will enter into force from the beginning of 2010. It remains to be seen how additional services over and above the budgets agreed for 2009 will be negotiated with the health insurers. The different base rates from state to state are to be successively harmonized over a period of five years, starting in 2010, toward a standardized, nationwide base rate corridor.

However, in light of the experience with the DRG system, the above-average increase in the number of admissions, and the convergence steps already completed, HELIOS does not expect any major changes in the reimbursement policy.

Under the Hospital Funding Reform Act (KHRG), the criteria for the introduction of flat-rate investment allowances should be agreed by 2012. Instead of the previous application-based financing of hospital investments, state governments

can decide to fund investments in an entrepreneurial way on the basis of performance-oriented investment allowances. However, important details have still to be resolved, especially the structure of the flat-rate investment allowances.

No consequences from changes in the law are expected in the **post-acute** segment. However, pricing and other controls by health insurers will continue to increase. As a result of growth in acute care cases and continuous improvements in HELIOS' internal referral management, we expect to be able to leverage potentials from the combination of acute care and post-acute care, thereby increasing our number of post-acute care admissions.

### THE MARKET FOR ENGINEERING AND SERVICES FOR HOSPITALS AND OTHER HEALTH CARE FACILITIES

In industrial countries, owing to demographic trends, growing demand for high-quality, efficient medical care – and thus for engineering and services for hospitals and other health care facilities – is expected to continue. The focus is on services, ranging from the maintenance and repair of medical and hospital equipment, facility management, and technical operation, through to total operational management and infrastructure process optimization – especially within the framework of public-private partnership (PPP) models. Additional growth opportunities are presented by the privatization of health care. This trend can be observed especially in Eastern Europe.

In the emerging countries, there is growing demand above all for infrastructure development, but also for efficient, needs-oriented medical care. The provision of primary health care is now very largely in place. In many markets, the focus now is therefore on building up secondary care, developing tertiary health care structures in the form of "centers of excellence", and creating training and research structures. All in all, we expect the market for engineering and services for hospitals and other health care facilities to continue growing in 2010.

## GROUP SALES AND EARNINGS

With its international production and sales platform and its market-oriented products and services, the Fresenius Group is excellently positioned for continued growth in the coming years. Specific opportunities for profitable growth are indicated by the developments described in the section "Health Care Sector and Markets". In 2010, we therefore expect to increase **Group sales** by 7 to 9 % in constant currency.

While our traditional markets in Europe and North America are growing at average low to mid single-digit rates, we see stronger growth potential in the Asia-Pacific region and in Latin America. Here the demand for our life-saving and life-sustaining products continues to be high as access to medical care is still limited. This will also be reflected in sales.

We expect to increase **Group net income** once again in 2010. We aim to achieve this through the growth in sales discussed and by ongoing measures to optimize costs. Despite a market environment which continues to be marked by cost containment and price pressure, we expect to increase net income<sup>1</sup> by 8 to 10 % in constant currency.

### GROUP FINANCIAL TARGETS

	Targets 2010	Fiscal year 2009
Sales, growth (in constant currency)	7–9 %	€ 14,164 million
Net income, growth <sup>1</sup> (in constant currency)	8–10 %	€ 514 million
Capital expenditure	~5 % of sales	€ 671 million
Dividend	Earnings-driven dividend policy	Proposal: +7 % per ordinary and preference share

<sup>1</sup> Net income attributable to Fresenius SE; adjusted for the effects of the mark-to-market accounting of the Mandatory Exchangeable Bonds (MEB) and the Contingent Value Rights (CVR) relating to the acquisition of APP Pharmaceuticals.

## SALES AND EARNINGS BY BUSINESS SEGMENT

We expect further improvements in sales and earnings in 2010 in each of our business segments. The table gives an overview.

### FINANCIAL TARGETS BY BUSINESS SEGMENT

	Targets 2010	Fiscal year 2009
<b>Fresenius Medical Care</b>		
Sales	> US\$ 12 billion	US\$ 11,247 million
Net income <sup>1</sup>	US\$ 950–980 million	US\$ 891 million
<b>Fresenius Kabi</b>		
Sales, growth (organic)	7–9 %	€ 3.086 million <sup>2</sup>
EBIT margin	18–19 %	19.7 %
<b>Fresenius Helios</b>		
Sales, growth (organic)	3–5 %	€ 2.416 million <sup>2</sup>
EBIT	€ 220–230 million	€ 205 million
<b>Fresenius Vamed</b>		
Sales, growth	5–10 %	€ 618 million <sup>2</sup>
EBIT, growth	5–10 %	€ 36 million <sup>3</sup>
<b>Fresenius Biotech</b>		
EBIT	€ -35– -40 million	€ -44 million

<sup>1</sup> Net income attributable to Fresenius Medical Care AG & Co. KGaA.

<sup>2</sup> Sales

<sup>3</sup> EBIT

The number of dialysis patients worldwide should rise by about 6 % in 2010, leading to continued growth in demand for dialysis products and a higher number of treatments. In 2010, Fresenius Medical Care expects to achieve revenue of more than US\$ 12 billion. Net income is expected to be between US\$ 950 million and US\$ 980 million in 2010.

Fresenius Kabi expects its positive operating performance to continue in 2010. The company estimates organic sales growth of 7 to 9 % in constant currency. Good growth potential is expected again in the Asia-Pacific region and in Latin America. Based on the positive sales projection, further cost

optimizations, especially in production, and an improved product mix, Fresenius Kabi again expects to increase earnings in 2010. Fresenius Kabi forecasts an EBIT margin of 18 to 19%. Whilst still at an excellent level, the slightly reduced margin guidance reflects delayed IV drug market launches, lower Heparin product sales and the expectation of further increased price competition in the US IV generics market.

Fresenius Helios expects a continued good performance in the hospital operations business. The company forecasts an organic sales growth of 3% to 5% in 2010. EBIT is expected to increase to € 220 to 230 million.

Given its excellent order backlog of € 679 million and long-term agreements in its service business, Fresenius Vamed expects continued good performance in 2010. In 2010, Fresenius Vamed expects to achieve both sales and EBIT growth between 5% and 10%.

Fresenius Biotech will continue its targeted clinical study program, which will result in significant research and development expenditures. Although positive earnings contributions from the antibody Removab® that was launched on the market in 2009 will offset these expenditures for our biotechnology projects to some extent, we still expect negative EBIT between € -35 and € -40 million in 2010.

## FINANCING

In 2009, we generated an excellent operating cash flow of € 1,553 million. The key drivers were our good earnings performance and tight working capital management. The cash flow margin was 11.0%. In 2010, we expect to achieve a **cash flow margin** at a high single-digit rate of sales.

The **net debt/EBITDA** ratio is a key financial figure for the Fresenius Group. Financing of the APP Pharmaceuticals acquisition caused this ratio to rise to 3.6 as of December 31,

2008. It was improved significantly to 3.0 in 2009. In 2010 our goal is to achieve a ratio of <3.0, primarily through earnings improvements and continued positive cash flows.

Unused credit lines under syndicated or bilateral credit facilities from banks will generally provide us with a sufficient **financial cushion**. Fresenius SE's € 250 million commercial paper program was not utilized. For further details please see page 65.

There will be only limited **refinancing requirements** in 2010. These can be met from cash flow and, if necessary, from existing credit facilities. Of the total refinancing requirements of about € 2 billion in 2011, about € 1.8 billion relates to the Fresenius Medical Care credit facility from 2006, which we intend to refinance through a renewal of the credit agreement and, if necessary, through various capital market transactions.

## INVESTMENTS

We will continue to invest in our future growth. In 2010, we expect to invest about 5% of sales in property, plant and equipment. This will be, relative to sales, in line with the 2009 level.

About 60% of the capital expenditure budgeted will be invested at Fresenius Medical Care, while Fresenius Kabi and Fresenius Helios will each account for about 20%. Investments at Fresenius Medical Care will focus on the construction of dialysis clinics and on expanding production capacities. Fresenius Kabi will invest in expanding and maintaining production facilities and in introducing new manufacturing technologies, enabling further improvements in production efficiency. At Fresenius Helios we will be investing primarily in modernizing hospitals and in hospital equipment.

The regional focus of the Group's investments will be on Europe and North America, which will account for about 50% and 35%, respectively. The remainder will be invested in Asia, Latin America, and Africa. About 30% of the funds will be invested in Germany.

## PROCUREMENT

We will continue optimizing our procurement management in 2010: prices, terms, and especially quality are key factors for securing further earnings growth.

**Fresenius Medical Care** secured long-term supply guarantees and considerable cost reductions in the International segment for the current year. Especially for strategically important raw materials supplies have been secured through framework agreements.

The logistics processes in the International segment are also being further standardized and streamlined. Over the long term, the aim of the SCALE project described on page 80 is to improve flexibility and efficiency of our supply chain management, to harmonize it globally and to enhance profitability.

The high volatility of **commodity prices** makes it difficult to predict the price trends in the coming years for the **Fresenius Kabi business segment**. Producers in the various industrial segments are evidently adjusting their capacities, and thus supply, to the expectation of continued low global demand. This will probably cause raw material prices to rise. It remains to be seen how demand generally will develop in 2010. If it should pick up significantly, this is likely to have an additional price-driving effect given the resulting low supply. We have already fixed the prices for processed corn products for 2010 through purchasing agreements. They are lower than the 2009 prices. For all other products whose prices are linked to those of the underlying commodities, the prices will be fixed at already scheduled dates in 2010. We will continue to pursue projects of the **Global Sourcing Initiative** and implement cost reductions in 2010. The same applies to all **make-or-buy projects**.

At our **HELIOS clinics**, the central materials management currently only covers our own HELIOS hospital pharmacies, and thus 75 % of their total pharmaceutical sourcing. HELIOS intends to integrate the approximately 20 external supply pharmacies into its own IT system. In addition, it is planned to introduce the online ordering system at other clinics and/or pharmacies for their materials management. The project for implementing the master article database, which we discussed in last year's annual report, has taken longer than expected and is now due to be completed in 2010.

We already contracted our electricity supplies for 2010 in the fourth quarter of 2008 and for 2011 in the first quarter of 2009. We were able to reduce our electricity costs by over 7 % for 2010, and by a further 6 % versus 2010 for 2011. The last phase of the liberalization of the natural gas market was completed in 2009. We achieved very good results in our natural gas sourcing thanks to the enPortal online platform and have now covered our natural gas requirements until December 31, 2012. We reduced our natural gas costs for the period 2009/2010 (October 31, 2009 to October 31, 2010) by 13.5 % and for the period 2010/2011 by 10.8 % versus the 2009/2010 period. For the period 2011/2012, we reduced our costs by a further 4.5 %.

## RESEARCH AND DEVELOPMENT

Our R & D activities will continue to play a key role in securing the Group's long-term growth through **innovations and new therapies**. We are concentrating our R & D on further improving our products for the treatment of patients with chronic kidney failure or on broadening their functions. The use of platform technologies, such as our therapy system 5008 and the Online-HDF, will also play an important future role in further developing and improving our products.

Another focus is infusion and nutrition therapies and the development of generic IV drugs.

We are also concentrating on targeted development of antibody therapies in the biotechnology sector. Biotechnology research opens up possibilities for treating diseases which cannot be cured at present and offers Fresenius potential for further growth with innovative cancer therapies. Here we will be focusing on the further clinical development of the antibody catumaxomab. More information can be found on page 78.

We plan to increase the Group's **R & D spending** in 2010. As in 2009, about 5 % of our product sales will therefore be reinvested in research and development. The number of employees in research and development will also be increased.

Market-oriented research and development with strict time-to-market management processes is crucial for the success of new products. We continually review our R & D results using clearly defined milestones. Innovative ideas, product development, and therapies with a high level of quality will continue to be the basis for future market-leading products.

### **CORPORATE STRUCTURE AND ORGANIZATION**

Since January 1, 2008 the Fresenius Group has been divided into four business segments, each of which is a legally independent entity. The business segments are organized on a regional and decentralized basis to provide the greatest flexibility for meeting the demands of their respective markets. The "entrepreneur in the enterprise" principle, with clearly defined responsibilities, has proven itself over many years. We will continue to follow this principle.

### **PLANNED CHANGES IN HUMAN RESOURCES AND THE SOCIAL AREA**

The number of employees in the Group will continue to rise in the future as a result of strong organic expansion. However, we expect the growth in the number of employees will be held below the expected rate of organic sales growth. The regional distribution of our employees will not change significantly – about 50 % will be located in Europe and one-third in North America – with the remainder spread over Asia-Pacific, Latin America, and Africa.

### **DIVIDEND**

Continuity in our dividend policy remains an important priority, clearly demonstrated by dividend increases over the last 16 years. On average, we have passed on about half of the percentage growth in Group net income to our shareholders as a percentage dividend increase. Based on our positive earnings forecasts we want to remain true to our dividend policy in the 2010 fiscal year and expect to offer our shareholders again an earnings-linked dividend.