FRESENIUS MEDICAL CARE CORP
Form 20-F/A
July 13, 2005

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 20-F/A
Amendment No. 1

o **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2004

OR

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission file number 001-14444

FRESENIUS MEDICAL CARE AKTIENGESELLSCHAFT
(Exact name of Registrant as specified in its charter)
FRESENIUS MEDICAL CARE CORPORATION
(Translation of Registrant s name into English)
Germany
(Jurisdiction of incorporation or organization)

Else-Kröner Strasse 1, 61352 Bad Homburg, Germany
(Address of principal executive offices)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
American Depositary Shares representing Preference Shares	New York Stock Exchange
Preference Shares, no par value	New York Stock Exchange(1)
American Depositary Shares representing Ordinary Shares	New York Stock Exchange
Ordinary Shares, no par value	New York Stock Exchange(1)

Securities registered or to be registered pursuant to Section 12(g) of the Act: None
Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: 7 7/8% USD Trust Preferred Securities due 2008, 7 3/8% DM Trust Preferred Securities due 2008, 7 7/8% USD Trust Preferred Securities due 2011, 7 3/8% Euro Trust Preferred Securities due 2011 and related guarantees

(1) Not for trading, but only in connection with the registration of American Depositary Shares representing such shares.

Indicate the number of outstanding shares of each of the issuer s classes of capital or common stock as of the close of the period covered by the annual report:

Preference Shares, no par value 26,296,086

Ordinary Shares, no par value 70,000,000

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days.

Yes þ No o

Indicate by check mark which financial statement item the registrant has elected to follow.

Item 17 o Item 18 þ

This Form 20-F/A amends Item 5 of the Annual Report on Form 20-F for the fiscal year ended December 31, 2004, as filed March 1, 2005, and Note 19 of the Notes to Consolidated Financial Statements included in the Form 20-F as originally filed.

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N/A means: Not applicable

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INTRODUCTION

Forward Looking Statements

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are based upon our current expectations, assumptions, estimates and projections about us and our industry that address, among other things:

- our business development, operating development and financial condition;
- our expectations of growth in the patient population regarding renal dialysis products and services;
- our ability to remain competitive in the markets for our products and services;
- the effects of regulatory developments, legal and tax proceedings and any resolution of government investigations into our business;
- changes in government reimbursement policies and those of private payors;
- changes in pharmaceutical administration patterns or reimbursement policies;
- our ability to develop and maintain additional sources of financing; and
- other statements of our expectations, beliefs, future plans and strategies, anticipated development and other matters that are not historical facts.

When used in this report, the words expects , anticipates , intends , plans , believes , seeks , estimates and expressions are generally intended to identify forward looking statements. Although we believe that the expectations reflected in such forward-looking statements are reasonable, forward-looking statements are inherently subject to risks and uncertainties, many of which cannot be predicted with accuracy and some of which might not even be anticipated. Future events and actual results, financial and otherwise, could differ materially from those set forth in or contemplated by the forward-looking statements contained elsewhere in this report. Important factors that could contribute to such differences are noted in this report under the Risk Factors Section Business Overview in Item 4. Information on the Company , Item 5. Operating and Financial Review and Prospects and Item 8.A.7. Legal Proceedings. These risks and uncertainties include: general economic, currency exchange and other market conditions, litigation and regulatory compliance risks, changes in government reimbursement for our dialysis care and pharmaceuticals, the investigation by the Department of Justice, Eastern District New York, and changes to pharmaceutical utilization patterns.

This report contains patient and other statistical data related to end-stage renal disease and treatment modalities, including estimates regarding the size of the patient population and growth in that population. These data have been included in reports published by organizations such as the Centers for Medicare and Medicaid Services of the U.S. Department of Health and Human Services, the Japanese Society for Dialysis Therapy and the German registry Quasi-Niere. While we believe these surveys and statistical publications to be reliable, we have not independently verified the data or any assumptions on which the estimates they contain are based.

Our business is also subject to other risks and uncertainties that we describe from time to time in our public filings. Developments in any of these areas could cause our results to differ materially from the results that we or others have projected or may project.

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PART I

Item 1. ***Identity of Directors, Senior Management and Advisors***

Not applicable

Item 2. ***Other Statistics and Expected Timetable***

Not applicable

Item 3. ***Key Information***

Selected Financial Data

The following table summarizes the consolidated financial information for our business for each of the years 2000 through 2004. We derived the selected financial information from our consolidated financial statements. We prepared our financial statements in accordance with accounting principles generally accepted in the United States of America and KPMG Deutsche Treuhand-Gesellschaft Aktiengesellschaft Wirtschaftsprüfungsgesellschaft, independent accountants, audited these financial statements. You should read this information together with our consolidated financial statements and the notes to those statements appearing elsewhere in this document and the information under Item 5. Operating and Financial Review and Prospects .

	2004[A]	2003[A]	2002[A]	2001[B]	2000
			(In millions)		
Statement of Operations Data:					
Net revenues	$ 6,228	$ 5,528	$ 5,084	$ 4,859	$ 4,201
Cost of revenues	4,142	3,699	3,428	3,220	2,734
Gross profit	2,086	1,829	1,656	1,639	1,467
Selling, general and administrative	1,183	1,022	914	966	814
Research and development	51	50	47	36	32
Special charge				258	
Operating income	852	757	695	379	621
Interest expense, net	183	211	226	223	216
Income before income taxes	669	546	469	156	405
Net income	$ 402	$ 331	$ 290	$ 63	$ 212
Weighted average of:					
Preference shares outstanding	26,243,059	26,191,011	26,185,178	26,035,330	19,002,118
Ordinary shares outstanding	70,000,000	70,000,000	70,000,000	70,000,000	70,000,000
Basic income per Ordinary share	$ 4.16	$ 3.42	$ 3.00	$ 0.65	$ 2.37
Fully diluted income per Ordinary share	4.14	3.42	3.00	0.64	2.36
Basic income per Preference share	4.23	3.49	3.06	0.70	2.43
Fully diluted income per Preference share	4.21	3.49	3.06	0.69	2.42
	1.39	1.14	1.00	0.22	0.79

Basic and fully diluted net income per Ordinary ADS					
Basic and fully diluted net income per Preference ADS	1.41	1.16	1.02	0.23	0.81
Dividends declared per Ordinary share ([a])	1.12[b]	1.02	0.94	0.85	0.78
Dividends declared per Preference share ([a])	1.18[b]	1.08	1.00	0.91	0.84
Dividends declared per Ordinary share ($)[a]		1.25	1.10	0.78	0.72
Dividends declared per Preference share ($)[a]		1.32	1.17	0.84	0.78

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	2004[A]	2003[A]	2002[A]	2001[B]	2000
			(In millions)		
Balance Sheet Data					
Working capital	$ 508	$ 794	$ 526	$ 402	$ 191
Total assets	7,962	7,503	6,780	6,516	5,979
Total long-term debt[c]	1,824	2,354	2,234	2,165	1,611
Shareholders equity (net assets)	3,635	3,244	2,807	2,617	2,679
Capital Stock Preference shares Nominal Value	70	70	70	70	64
Capital Stock Ordinary shares Nominal Value	229	229	229	229	229

(A) Includes the effect of an accounting change in 2002 relating to the adoption of SFAS No. 142, *Goodwill and Other Intangible Assets*, as of January 1, 2002

(B) Includes the special charge to address 1996 merger related legal matters, estimated liabilities and legal expenses arising in connection with the W.R. Grace Chapter 11 proceedings and the cost of resolving pending litigation and other disputes with certain commercial insurers. You can find a more detailed discussion of this special charge in Notes 6 & 16 of the Notes to our Consolidated Financial Statements.

(a) Amounts shown for each year from 2000 to 2003 represent dividends paid with respect to such year. The actual declaration and payment of the dividend was made in the following year, after approval of the dividend at our Annual General Meeting.

(b) Our Management Board and our Supervisory Board have proposed dividends for 2004 of 1.12 per Ordinary share and 1.18 per Preference share. These dividends are subject to approval by our shareholders at our Annual General Meeting to be held on May 24, 2005.

(c) Total long-term debt represents long-term debt and capital lease obligations, less current portions and (i) at December 31, 2001, the mandatorily redeemable preferred securities of Fresenius Medical Care Capital Trust, Fresenius Medical Care Capital Trust II, Fresenius Medical Care Capital Trust III, Fresenius Medical Care Capital Trust IV, and Fresenius Medical Care Capital Trust V, (ii) at December 31, 2002, 2003 and 2004, the mandatorily redeemable preferred securities of Fresenius Medical Care Capital Trust II, Fresenius Medical Care Capital Trust III, Fresenius Medical Care Capital Trust IV, and Fresenius Medical Care Capital Trust V. On February 14, 2002, we redeemed the entire $360 million aggregate liquidation amount of the trust preferred securities of Fresenius Medical Care Capital Trust.

RISK FACTORS

Risks Relating to Litigation and Regulatory Matters in the U.S.

If we do not comply with the many governmental regulations applicable to our business or with the corporate integrity agreement between us and the U.S. government, we could be excluded from government health care reimbursement programs or our authority to conduct business could be terminated, either of which would result in a material decrease in our revenue

Our operations in both our provider business and our products business are subject to extensive governmental regulation in virtually every country in which we operate. The applicable regulations, which differ from country to country, relate in general to the safety and efficacy of medical products and supplies, the operation of manufacturing

facilities, laboratories and dialysis clinics, the rate of, and accurate reporting and billing for, government and third-party reimbursement, and compensation of medical directors and other financial arrangements with physicians and other referral sources. We are also subject to other laws of general applicability, including antitrust laws.

Fresenius Medical Care Holdings Inc. (FMCH), our North American subsidiary, is party to a corporate integrity agreement with the U.S. government. This agreement requires that FMCH staff and maintain a comprehensive compliance program, including a written code of conduct, training programs, regulatory compliance policies and procedures, annual audits and periodic reporting to the government. The corporate integrity agreement permits the U.S. government to exclude FMCH and its subsidiaries from participation in U.S. federal health care programs if there is a material breach of the agreement that FMCH does not cure within thirty days after FMCH receives written notice of the breach. We derive approximately 38% of our consolidated revenue from U.S. federal health care benefit programs. Consequently, if FMCH commits a material breach of the corporate integrity agreement that results in the exclusion of FMCH or its subsidiaries from continued participation in those programs it would significantly decrease our revenue and have a material adverse effect on our business, financial condition and results of operations.

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While we rely upon our management structure, regulatory and legal resources, and the effective operation of our compliance program to direct, manage and monitor these activities, if employees, deliberately or inadvertently, failed to adhere to these regulations then our authority to conduct business could be terminated or our operations could be significantly curtailed. Any such terminations or reductions could materially reduce our revenues with a resulting adverse impact on our business, financial condition and results of operations.

A reduction in U.S. government reimbursement for dialysis care could materially decrease our revenues and operating profit

For the twelve months ended December 31, 2004 approximately 38% of our consolidated revenues resulted from Medicare and Medicaid reimbursement. Legislative changes may affect the reimbursement rates for the services we provide, as well as the scope of Medicare and Medicaid coverage. A decrease in Medicare or Medicaid reimbursement rates or covered services could have a material adverse effect on our business, financial condition and results of operations. In December 2003, the Medicare Prescription Drug Modernization and Improvement Act was created. See Item 4B, Business Overview Regulatory and Legal Matters Reimbursement.

A change in reimbursement for or utilization of EPO could materially reduce our revenue and operating profit

Reimbursement and revenue from the administration of erythropoetin, or EPO, accounted for approximately 23% of dialysis care revenue in our North America segment for the twelve months ended December 31, 2004. EPO is produced by a single source manufacturer, Amgen Inc. Our current contract with Amgen covers the period from January 1, 2004 to December 31, 2005. A reduction in reimbursement for EPO, a significant change in utilization of EPO, a reduction of the current overfill amount in EPO vials, an interruption of supply or our inability to obtain satisfactory purchase terms for EPO after our current contract expires could reduce our revenues from, or increase our costs in connection with the administration of EPO, which could materially adversely affect our business, financial condition and results of operations. In July 2004, CMS proposed certain changes with respect to its EPO reimbursement and utilization guidelines. See Item 4B, Business Overview Regulatory and Legal Matters Reimbursement.

Creditors of W.R. Grace & Co. Conn. have asserted claims against us

We were formed in 1996 as a result of a series of transactions with W.R. Grace & Co. that we refer to as the merger. At the time of the merger, W.R. Grace & Co.-Conn. had, and continues to have, significant liabilities arising out of product-liability related litigation (including asbestos), pre-merger tax claims and other claims unrelated to its dialysis business. In connection with the merger, W.R. Grace & Co.-Conn. and other Grace entities agreed to indemnify Fresenius Medical Care and its subsidiaries against all liabilities of W.R. Grace & Co., whether relating to events occurring before or after the merger, other than liabilities arising from or relating to National Medical Care s operations. W.R. Grace & Co. and certain of its subsidiaries filed for reorganization under Chapter 11 of the U.S. Bankruptcy Code (the Grace Chapter 11 Proceedings) on April 2, 2001.

Pre-merger tax claims or tax claims that would arise if events were to violate the tax-free nature of the merger, could ultimately be our obligation. In particular, W. R. Grace & Co. has disclosed in its filings with the Securities and Exchange Commission that: its tax returns for the 1993 to 1996 tax years are under audit by the Internal Revenue Service (the Service); W. R. Grace & Co. has received the Service s examination report on tax periods 1993 to 1996; that during those years W.R. Grace & Co. deducted approximately $122 million in interest attributable to corporate owned life insurance (COLI) policy loans; that W.R. Grace & Co. has paid $21 million of tax and interest related to COLI deductions taken in tax years prior to 1993; that a U.S. District Court ruling has denied interest deductions of a taxpayer in a similar situation. In October 2004, W.R. Grace & Co. obtained bankruptcy court approval to settle its COLI claims with the Service. In January 2005, W.R. Grace and Co., FMCH and Sealed Air Corporation executed a settlement agreement with respect to the Service s COLI-related claims and other tax claims. W.R. Grace and Co. has filed a motion with the US District Court seeking approval to satisfy its payment obligations to the Service under the settlement agreement. Subject to certain

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representations made by W.R. Grace & Co., the Company and Fresenius AG, W.R. Grace & Co. and certain of its affiliates agreed to indemnify us against this and other pre-merger and merger-related tax liabilities.

Prior to and after the commencement of the Grace Chapter 11 Proceedings, class action complaints were filed against W.R. Grace & Co. and FMCH by plaintiffs claiming to be creditors of W.R. Grace & Co.-Conn., and by the asbestos creditors committees on behalf of the W.R. Grace & Co. bankruptcy estate in the Grace Chapter 11 Proceedings, alleging among other things that the merger was a fraudulent conveyance, violated the uniform fraudulent transfer act and constituted a conspiracy. All such cases have been stayed and transferred to or are pending before the U.S. District Court as part of the Grace Chapter 11 Proceedings.

In 2003, the Company reached an agreement with the asbestos creditors committees and W.R. Grace & Co. in the Grace Chapter 11 Proceedings to settle these fraudulent conveyance and tax claims. The settlement agreement has been approved by the U.S. District Court. The proposed settlement is subject to confirmation of a final plan of reorganization of W.R. Grace & Co. that meets the requirements of the settlement agreement or is otherwise satisfactory to us. If the proposed settlement with the asbestos creditors committees and W.R. Grace & Co. is not confirmed in such a final plan of reorganization, the claims could be reinstated. If the claims are reinstated and the merger is determined to be a fraudulent transfer and if material damages are proved by the plaintiffs and we are not able to collect, in whole or in part, on the indemnity from any of our indemnitors, a judgment could have a material adverse effect on our business, financial condition and results of operations. We recorded a pre-tax accrual of $172 million at December 31, 2001 to reflect our estimated exposure for liabilities and expenses related to the Grace Chapter 11 Proceedings. See Note 6 to our consolidated financial statements. For additional information concerning the Grace Chapter 11 Proceedings and the settlement agreement see Item 8.A.7 Legal Proceedings.

As health maintenance organizations and other managed care plans grow, amounts paid for our services and products by non-governmental payors could decrease

We obtain a significant portion of our revenues from reimbursement provided by non-governmental third-party payors. Although non-governmental payors generally pay at higher reimbursement rates than governmental payors, managed care plans generally negotiate lower reimbursement rates than indemnity insurance plans. Some managed care plans and indemnity plans also utilize a capitated fee structure or limit reimbursement for ancillary services.

As the managed care industry continues to consolidate, there could be increased pressure to reduce the amounts paid for our services and products. These trends may be accelerated if future changes to the U.S. Medicare ESRD program require private payors to assume a greater percentage of the total cost of care given to dialysis patients over the term of their illness, or if managed care plans otherwise significantly increase their enrollment of renal patients.

If managed care plans reduce reimbursements, our revenues could decrease, and our financial condition and results of operations could be materially adversely affected.

Proposals for health care reform could decrease our revenues and operating profit

Proposals to modify the current health care system in the U.S. to improve access to health care and control its costs are continually being considered by the federal and certain state governments. See Regulatory and Legal Matters Reimbursement U.S. for a discussion of the Medicare Prescription Drug Modernization and Improvement Act of 2003 and proposed changes to CMS s EPO Reimbursement guidelines. We anticipate that the U.S. Congress and state legislatures will continue to review and assess alternative health care reforms, and we cannot predict whether these reform proposals will be adopted, when they may be adopted or what impact they may have on us. Any spending decreases or other significant changes in the Medicare program could reduce our revenues and profitability and have a material adverse effect on our business, financial condition and results of operations.

Other countries, especially those in Western Europe, have also considered health care reform proposals and could materially alter their government-sponsored health care programs by reducing reimbursement payments.

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Any reduction could affect the pricing of our products and the profitability of our services, especially as we expand our international business. This potential development could have a material adverse effect on our business, financial condition and results of operations.

Risks Relating to our Business

Our competitors proposed combination could foreclose certain business opportunities

On December 6, 2004, DaVita agreed to acquire Gambro Healthcare, and to purchase a substantial portion of its dialysis product supply requirements from Gambro Healthcare s parent company during the next ten years. These agreements are subject to regulatory review and/or approval. If the proposed product supply contract is consummated, DaVita s purchases of our products may decrease substantially. Any such reduction in DaVita s purchases will decrease our product revenues and could result in a material adverse affect on our business, financial condition and results of operations.

Our competitors could develop superior technology or impact our product sales

We face numerous competitors in both our dialysis services business and our dialysis products business, some of which may possess substantial financial, marketing or research and development resources. Competition could materially adversely affect the future pricing and sale of our products and services. In particular, technological innovation has historically been a significant competitive factor in the dialysis products business. The introduction of new products by competitors could render one or more of our products obsolete.

We are engaged in both manufacturing dialysis products and providing dialysis services. We compete in the dialysis services business with many customers of our products business. As a result, independent dialysis clinics, those operated by other chains and dialysis centers acquired by other products manufacturers may elect to limit or terminate their purchases of our dialysis products so as to avoid purchasing products manufactured by a competitor. In addition, as consolidation in the dialysis services business continues and other vertically integrated dialysis companies expand, the external market for our dialysis products could be reduced. Possible purchase reductions could decrease our product revenues, with a material adverse effect on our business, financial condition and results of operations.

We also compete with other dialysis products and services companies in seeking selected acquisitions. If we are not able to continue to effect acquisitions in the provider business upon reasonable terms there could be an adverse impact on the growth of our business and our future growth prospects.

We face products liability and other claims which could result in significant liability

Health care companies are subject to claims alleging negligence, products liability, breach of warranty, malpractice and other legal theories that may involve large claims and significant defense costs whether or not liability is ultimately imposed. Health care products may also be subject to recalls. Although product liability claims and recalls have not had a material adverse effect on our businesses in the past, we cannot assure that we will not suffer one or more significant claims or product recalls in the future. Product liability claims or recalls could result in judgments against us or significant compliance costs, which could materially adversely affect our business, financial condition and results of operations.

While we have been able to obtain liability insurance in the past, it is possible that such insurance may not be available in the future either on acceptable terms or at all. A successful claim in excess of the limits of our insurance coverage could have a material adverse effect on our business, results of operations and financial condition. Liability claims, regardless of their merit or eventual outcome, also may have a material adverse effect on our business and reputation, which could in turn reduce our revenues and profitability.

If physicians and other referral sources cease referring patients to our dialysis clinics or cease purchasing our dialysis products, our revenues would decrease

Our dialysis services business is dependent upon patients choosing our clinics as the location for their treatments. Patients may select a clinic based, in whole or in part, on the recommendation of their physician. We

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believe that physicians and other clinicians typically consider a number of factors when recommending a particular dialysis facility to an ESRD patient, including, but not limited to, the quality of care at a clinic, the competency of a clinic s staff, convenient scheduling, and a clinic s location and physical condition. Physicians may change their facility recommendations at any time, which may result in the movement of our existing patients to competing clinics, including clinics established by the physicians themselves. At most of our clinics, a relatively small number of physicians account for the referral of all or a significant portion of the patient base. If a significant number of physicians ceased referring their patients to our clinics, this could reduce our dialysis care revenue and materially adversely affect our overall operations. Our operations are also affected by referrals from hospitals, managed care plans and other sources.

The decision to purchase our dialysis products and other services or competing dialysis products and other services will be made in some instances by medical directors and other referring physicians at our dialysis clinics and by the managing medical personnel and referring physicians at other dialysis clinics, subject to applicable regulatory requirements. A decline in physician recommendations or purchases of our products or ancillary services could reduce our dialysis product and other services revenue, and materially adversely affect our business, financial condition and results of operations.

If we are unable to attract and retain skilled medical, technical and engineering personnel, we may be unable to manage our growth or continue our technological development

Our continued growth in the provider business will depend upon our ability to attract and retain skilled employees, such as highly skilled nurses and other medical personnel. Competition for those employees is intense and the current nursing shortage in North America has increased our personnel and recruiting costs. Moreover, we believe that future success in the provider business will be significantly dependent on our ability to attract and retain qualified physicians to serve as medical directors of our dialysis clinics. Our dialysis products business depends on the development of new products, technologies and treatment concepts. Competition is also intense for skilled engineers and other technical research and development personnel. If we are unable to obtain the services of key personnel, the ability of our officers and key employees to manage our growth would suffer and our operations could suffer in other respects. These factors could preclude us from integrating acquired companies into our operations, which could increase our costs and prevent us from realizing synergies from acquisitions. Lack of skilled research and development personnel could impair our technological development, which would increase our costs and impair our reputation for production of technologically advanced products.

We face additional costs and uncertainties from international operations

We intend to expand our international presence. As a result, we expect that revenues from countries other than the U.S. and Germany will account for an increasing portion of future revenues.

Revenues from international operations are subject to a number of risks, including the following:

Worsening of economic situation in Latin America

Fluctuations in exchange rates could adversely affect profitability;

We could face difficulties in enforcing and collecting accounts receivable under some countries legal systems;

Local regulations could restrict our ability to obtain a direct ownership interest in dialysis clinics or other operations;

Political instability, especially in developing countries, could disrupt our operations;

Some customers and governments could have longer payment cycles, with resulting adverse effects on our cash flow; and

Some countries could impose additional taxes or restrict the import of our products.

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Any one or more of these factors, or any difficulty in integrating businesses we acquire into our operations, could increase our costs, reduce our revenues, or disrupt our operations, with possible material adverse effects on our business, financial condition and results of operations.

Other Risks

Our significant indebtedness may limit our ability to pay dividends or implement certain elements of our business strategy

We have a substantial amount of debt. As of December 31, 2004, our total consolidated liabilities were $4.33 billion, including obligations with respect to all our trust preferred securities of approximately $1.28 billion, our total consolidated assets were $7.96 billion and our stockholders equity was $3.63 billion. Our substantial level of debt presents the risk that we might not generate sufficient cash to service our indebtedness or that our leveraged capital structure could limit our ability to finance acquisitions and develop additional projects, to compete effectively or to operate successfully under adverse economic conditions.

Our senior credit agreement and the indentures relating to our trust preferred securities include covenants that require us to maintain certain financial ratios or meet other financial tests. Under our senior credit agreement, we are obligated to maintain a minimum consolidated net worth and a minimum consolidated interest coverage ratio (ratio of consolidated earnings before interest, taxes, depreciation and amortization (EBITDA) to consolidated net interest expense) and a certain consolidated leverage ratio (ratio of consolidated funded debt to EBITDA).

Our senior credit agreement and our indentures include other covenants which, among other things, restrict or have the effect of restricting our ability to dispose of assets, incur debt, pay dividends, create liens or make capital expenditures, investments or acquisitions. These covenants may otherwise limit our activities. The breach of any of the covenants could result in a default under the credit agreement or the indentures, which could, in turn, create additional defaults under the agreements relating to our other long-term indebtedness.

Because we are not organized under U.S. law, we are subject to certain less detailed disclosure requirements under U.S. federal securities laws

Under pooling agreements that we have entered into for the benefit of minority holders of our Ordinary shares and holders of our Preference shares (including, in each case, holders of American Depositary Receipts representing beneficial ownership of such shares), we have agreed to file quarterly reports with the Securities and Exchange Commission, to prepare annual and quarterly financial statements in accordance with U.S. generally accepted accounting principles, and to file information with the Securities and Exchange Commission with respect to annual and general meetings of our shareholders. However, we are a foreign private issuer, as defined in the Securities and Exchange Commission s regulations, and consequently we are not subject to all of the same disclosure requirements applicable to domestic companies. We are exempt from the Securities and Exchange Commission s proxy rules, and our annual reports contain less detailed disclosure than reports of domestic issuers regarding such matters as management, executive compensation and outstanding options, beneficial ownership of our securities and certain related party transactions. Also, our officers, directors and beneficial owners of more than 10% of our equity securities are exempt from the reporting requirements and short-swing profit recovery provisions of Section 16 of the Securities Exchange Act of 1934. We are also generally exempt from most of the governance rule revisions recently adopted by the New York Stock Exchange, other than the obligation to maintain an audit committee in accordance with Rule 10A-3 under the Securities Exchange Act of 1934, as amended. These limits on available information about our company and exemptions from many governance rules applicable to domestic issuers may adversely affect the market prices for our securities.

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Item 4. *Information on the Company*

A. History and Development of the Company

General

Fresenius Medical Care AG is a stock corporation (Aktiengesellschaft) organized under the laws of Germany. It was incorporated on August 5, 1996. Fresenius Medical Care AG is registered with the commercial register of the local court *(Amtsgericht)* of Hof an der Saale, Germany under HRB 2460. Our registered office *(Sitz)* is Hof an der Saale, Germany. Our business address is Else-Kröner-Strasse 1, 61352 Bad Homburg, Germany, telephone ++49-6172-609-0.

History

Fresenius Medical Care AG was created by the conversion of Sterilpharma GmbH, a limited liability company under German law organized in 1975, into a stock corporation under German law *(Aktiengesellschaft)*. A shareholder s meeting on April 17, 1996 adopted the resolutions for this conversion and the commercial register registered the conversion on August 5, 1996.

On September 30, 1996, we completed a series of transactions to consummate an Agreement and Plan of Reorganization entered into on February 4, 1996 by Fresenius AG and W.R. Grace which we refer to as the Merger elsewhere in this report. Pursuant to that agreement, Fresenius AG contributed Fresenius Worldwide Dialysis, its global dialysis business, including its controlling interest in Fresenius USA, Inc., in exchange for 35,210,000 Fresenius Medical Care AG Ordinary shares. Thereafter, we acquired:

all of the outstanding common stock of W.R. Grace, whose sole business at the time of the transaction consisted of National Medical Care, Inc., its global dialysis business, in exchange for 31,360,000 Ordinary shares; and

the publicly-held minority interest in Fresenius USA, in exchange for 3,430,000 Ordinary shares.

Effective October 1, 1996, we contributed all our shares in Fresenius USA to Fresenius Medical Care Holdings, which conducts business under the trade name Fresenius Medical Care North America, and which is the managing company for all of our operations in the U.S., Canada and Mexico.

Capital Expenditures

We invested, by business segment and geographical areas, the following amounts during the three fiscal years ended December 31, 2004, 2003, and 2002 and have budgeted the following amounts for the year 2005:

	Actual (in millions)			
	2004	2003	2002	Budget 2005
Acquisitions				
North America	$ 65	$ 43	$ 38	
International				
Germany		13		
Rest of World	55	45	50	
Total Acquisitions	$ 120	$ 101	$ 88	$ 200-250
Capital expenditures for property, plant and equipment				
North America	$ 163	$ 177	$ 130	
International				
Germany	37	28	27	
Rest of World	79	86	82	

Total Capital Expenditures	$ 279	$ 291	$ 239	$ 350-400

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During 2004, major areas of spending were for the maintenance of existing clinics and equipment for new clinics. In addition, expenditures were made for maintenance and expansion of production facilities in Germany, North America, France and Italy. We finance our capital expenditures through cash flow from operations or under existing credit facilities.

In December 2004, we acquired dialysis machines that were previously sold in sale-lease back transactions. The machines were acquired for approximately $29 million and are reflected as a capital expenditure in the accompanying consolidated statement of cash flows.

For information regarding recent acquisitions, see Business Overview Acquisitions.

B. Business Overview

Our Business

We are the world s largest kidney dialysis company engaged in both providing dialysis care and manufacturing dialysis products, based on publicly reported revenues and patients treated. We provide dialysis treatment to over 124,400 patients in 1,610 clinics worldwide located in 26 countries. In the U.S. we also perform clinical laboratory testing and provide inpatient dialysis services, therapeutic apheresis, hemoperfusion and other services under contract to hospitals. We also develop and manufacture a complete range of equipment, systems and disposable products, which we sell to customers in over 100 countries. We use the insight we gain when treating patients in developing new and improved products. We believe that our size, our activities in both dialysis care and dialysis products and our concentration in specific geographic areas allow us to operate more cost-effectively than many of our competitors. For the year ended December 31, 2004, we had net revenues of $6.2 billion, an increase of 13% over 2003 revenues. We derived 68% of our revenues in 2004 from our North America operations and 32% from our International operations.

The following table summarizes net revenues for our North America segment and our International segment as well as our major categories of activity for the three years ended December 31, 2004, 2003 and 2002.

	2004	2003	2002
		(in millions)	
North America			
Dialysis Care	$ 3,795	$ 3,429	$ 3,294
Dialysis Products[(1)]	421	426	454
	4,216	3,855	3,748
International			
Dialysis Care	706	550	415
Dialysis Products	1,306	1,123	921
	2,012	1,673	1,336

(1) We evaluate North America product sales based on net available external market. See Item 5.A. Operating Results for explanation and analysis.

Renal Industry Overview

End-Stage Renal Disease

End-stage renal disease (ESRD) is the stage of advanced chronic kidney disease that is characterized by the irreversible loss of kidney function and requires regular dialysis treatment or kidney transplantation to sustain life. A normally functioning human kidney removes waste products and excess water from the blood, which prevents toxin buildup, water overload and the eventual poisoning of the body. A number of conditions diabetes, hypertension, glomerulonephritis and inherited diseases can cause chronic kidney disease. Nearly 60% of all people with ESRD

acquire the disease as a complication of one or more of these primary conditions.

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There are currently only two methods for treating ESRD: dialysis and kidney transplantation. Scarcity of compatible kidneys limits transplants. According to data published by the Centers for Medicare and Medicaid Services (CMS) (formerly the Health Care Financing Administration) of the U.S. Department of Health and Human Services, 14,714 patients of the ESRD patient population, received kidney transplants in the U.S. during 2002, an increase of less than 1% over 2001. According to the United States Renal Data System (USRDS) 2004 Annual Report only 2% of all incident patients received a pre-emptive transplant in 2002. In Germany, the third biggest dialysis market worldwide according to our own internal survey, less than 1% of all incident patients received pre-emptive transplants, as published by the German registry Quasi-Niere, in 2004. Therefore, most patients suffering from ESRD must rely on dialysis, which is the removal of toxic waste products and excess fluids from the body by artificial means. There are two major dialysis methods commonly used today, hemodialysis (HD) and peritoneal dialysis (PD). These are described below under Dialysis Treatment Options for ESRD. Generally, an ESRD patient s physician, in consultation with the patient, chooses the patient treatment method, which is based on the patient s medical conditions and needs.

Based on data published by the CMS, the number of patients in the U.S. who received dialysis for chronic ESRD grew from approximately 66,000 in 1982 to 297,928 at December 31, 2002, a compound annual rate of approximately 8%. We believe that worldwide growth will continue at 6% per year. At the end of 2002, we estimated 1.3 million patients were undergoing dialysis treatment worldwide. According to our own market surveys, Japan is the second largest dialysis market in the world. According to data published by the Japanese Society for Dialysis Therapy, approximately 230,000 dialysis patients were being treated at the end of 2002. In the rest of the world, we estimate that at the end of 2003 there were approximately 310,000 dialysis patients in Europe, approximately 175,000 patients in Asia (excluding Japan) and approximately 160,000 patients in Latin America. We believe that the continuing growth in the number of dialysis patients is principally attributable to:

- increased general life expectancy and the overall aging of the general U.S. and European population;
- shortage of donor organs for kidney transplants;
- improved dialysis technology that makes life-prolonging dialysis available to a larger patient population;
- greater access to treatment in developing countries.
- better treatment and survival of patients with hypertension, diabetes and other illnesses that lead to ESRD.

Dialysis Treatment Options for ESRD

Hemodialysis. Hemodialysis removes toxins and excess fluids from the blood in a process in which the blood flows outside the body through plastic tubes known as bloodlines into a specially designed filter, called a dialyzer. The dialyzer functions as an artificial kidney by separating waste products and excess water from the blood. Dialysis solution flowing through the dialyzer carries away the waste products and excess water, and supplements the blood with solutes that have been depleted due to renal failure. The treated blood is returned to the patient. The hemodialysis machine pumps blood, adds anti-coagulants, regulates the purification process and controls the mixing of dialysis solution and the rate of its flow through the system. This machine can also monitor and record the patient s vital signs.

Hemodialysis patients generally receive treatment three times per week, typically for around three to five hours per treatment. The majority of hemodialysis patients receive treatment at outpatient dialysis clinics, such as ours, where hemodialysis treatments are performed with the assistance of a nurse or dialysis technician under the general supervision of a physician.

According to the most recent data available from the CMS, as of December 31, 2002, there were 4,352 Medicare-certified ESRD treatment clinics in the U.S. Ownership of these clinics is characterized by a relatively small number of players, of which we are one of the largest, owning 70-75% of the clinics and a large number of operators each owning 10 or fewer clinics. We estimate that there were approximately 5,000 dialysis clinics in Europe at the end of 2004, of which almost 60% are government-owned, more than 30% are privately owned, and

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around 10% are operated by health care organizations. In Latin America, privately owned clinics predominate, comprising over 70% of all clinics providing dialysis care.

According to the CMS, as of December 31, 2002, hemodialysis patients represented about 90% of all dialysis patients in the U.S. Japanese Society for Dialysis Therapy data indicate hemodialysis patients comprise approximately 95% of all dialysis patients in Japan, and, according to our most recent studies, hemodialysis patients comprise 89% in the European Union and 85% in the rest of the world.

Peritoneal Dialysis. Peritoneal dialysis removes toxins from the blood using the peritoneum, the membrane lining covering the internal organs located in the abdominal area, as a filter. Peritoneal dialysis patients administer their own treatments in their own homes and workplaces, either by a treatment known as continuous ambulatory peritoneal dialysis or CAPD, or by a treatment we introduced in 1980 known as continuous cycling peritoneal dialysis or CCPD. In both of these treatments, a surgically implanted catheter provides access to the peritoneal cavity. Using this catheter, the patient introduces a sterile dialysis solution from a solution bag through a tube into the peritoneal cavity. The peritoneum operates as the filtering membrane and, after a specified dwell time, the solution is drained and disposed. A typical CAPD peritoneal dialysis program involves the introduction and disposal of dialysis solution four times a day. With CCPD a machine cycles solution to and from the patient s peritoneal cavity while the patient sleeps.

Our Strategy

Our objective is generating revenue growth that exceeds market growth of the dialysis industry, measured by growth in the patient population, while maintaining our leading position in the market and increasing earnings at a faster pace than revenues. Our dialysis care and product revenues have grown faster than the market over the past five years, and we believe that we are well positioned to meet our objectives by focusing on the following strategies:

Continue to Provide High Standards of Patient Care. We believe that our reputation for providing the highest standards of patient care is a competitive advantage.

Differentiated Patient Care Programs from those of Our Competitors. We believe that our UltraCare® Patient Care program offered at our North America dialysis facilities will distinguish and differentiate our patient care programs from those of our competitors. UltraCare® therapy employs single-use high flux polysulfone dialyzers, on-line quality measurement, and Ultra Pure Dialysate, all of which we feel improve mortality and increase the quality of patient care. The change to single-use dialyzers has increased our per treatment dialyzer costs relative to use of multi-use dialyzers. These cost increases have been offset, however, by our ability to achieve economies of scale in the production of these dialyzers, due to our large-scale single-use dialyzer manufacturing capacity. Moreover, we have implemented a staffing model based on single-use that reduces our personnel costs per treatment. Finally, automated controls in our 2008 Series dialysis machine reduces concentrate usage and associated costs.

Expand Presence in Attractive Growth Markets Worldwide. We intend to continue to take advantage of the reputation and market recognition our global product business has created by acquiring and establishing new dialysis clinics within attractive international markets. We believe that we will obtain an increasing percentage of our dialysis care growth from worldwide markets. We believe that increases in per capita income in developing countries will make general health care benefits, which may include payment for dialysis treatment, more widely available and present significant opportunities.

Increase Our Spectrum of Dialysis Services. One of our objectives is to continue to expand our role within the broad spectrum of services for dialysis patients. We implement this strategy by providing expanded and enhanced patient services, including laboratory services, to both our own clinics and those of third parties. We estimate that our Spectra Renal Management division provides laboratory services for approximately 40% of the ESRD patients in the U.S. We have developed disease state management methodologies, which involve the coordination of total patient care for ESRD patients and which we believe are attractive to managed care payors. We have formed Optimal Renal Care, LLC, a joint venture

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with The Permanente Federation. We also formed Renaissance Health Care as a joint venture with participating nephrologists. Renaissance provides ESRD and Chronic Kidney Disease programs to more than 3,000 patients. We also operate a surgical center for the management and care of vascular access for patients, which decreases hospitalization.

Offer Complete Dialysis Product Lines with Recurring Disposable Products Revenue Streams. We offer broad and competitive hemodialysis and peritoneal dialysis product lines. These product lines enjoy broad market acceptance and enable us to serve as our customers single source for all of their dialysis machines, systems and disposable products.

Extend Our Position as an Innovator in Product and Process Technology. We are committed to technological leadership in both hemodialysis and peritoneal dialysis products. We have approximately 350 full time equivalents as members of our research and development team that focuses on developing dialysis systems that are safer, more effective and easier to use and that can be easily customized to meet the differing needs of customers around the world. We believe that our extensive expertise in patient treatment and clinical data will further enhance our ability to develop more effective products and treatment methodologies. Our ability to manufacture dialysis products on a cost-effective and competitive basis results in large part from our process technologies. Over the past several years, we have reduced manufacturing costs per unit through development of proprietary manufacturing technologies that have streamlined and automated our production processes.

Dialysis Care

Dialysis Services

We provide dialysis treatment and related laboratory and diagnostic services at our approximately 1,610 outpatient dialysis clinics, 1,130 of which are in the U.S. and 480 of which are in 25 countries outside of the U.S. Our operations outside the U.S. generated 16% of our 2004 dialysis care revenue. We currently operate or manage dialysis clinics in Argentina, Australia, Brazil, China, Colombia, Chile, Czech Republic, Estonia, France, Germany, Hungary, Hong Kong, Italy, Singapore, Mexico, Portugal, Poland, Slovakia, Slovenia, South Africa, Spain, Taiwan, Turkey, United Kingdom and Venezuela. Our dialysis clinics are generally concentrated in areas of high population density. In 2004, we acquired 29 existing clinics, opened 52 new clinics and consolidated 31 clinics. The number of patients we treat at our clinics increased by about 4%, from approximately 119,250 at December 31, 2003 to approximately 124,400 at December 31, 2004.

With our large patient population, we have developed proprietary patient statistical databases which enable us to improve dialysis treatment outcomes, and improve the quality and effectiveness of dialysis products. We believe that local physicians, hospitals and managed care plans refer their ESRD patients to our clinics for treatment due to:

our reputation for quality patient care and treatment;

our extensive network of dialysis clinics, which enables physicians to refer their patients to conveniently located clinics; and

our reputation for technologically advanced products for dialysis treatment.

We treat approximately 27% of the dialysis patients in the U.S. including those patients treated in clinics we manage. Based on publicly available reports, we believe that currently our next largest competitor treats approximately 17% of U.S. dialysis patients. For the year 2004, dialysis services accounted for 72% of our total revenue.

At our clinics, we provide hemodialysis treatments at individual stations through the use of dialysis machines and disposable products. A nurse attaches the necessary tubing to the patient and the dialysis machine and monitors the dialysis equipment and the patient s vital signs. The capacity of a clinic is a function of the number of stations and such factors as type of treatment, patient requirements, length of time per treatment, and local operating practices and ordinances regulating hours of operation.

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Each of our dialysis clinics is under the general supervision of a Medical Director and, in some cases, one or more associate Medical Directors, all of whom are physicians. See Patients, Physician and Other Relationships. Each dialysis clinic also has an administrator or clinical manager who supervises the day-to-day operations of the facility and the staff. The staff typically consists of registered nurses, licensed practical nurses, patient care technicians, a social worker, a registered dietician, a unit clerk and biomedical technicians.

As part of the dialysis therapy, we provide a variety of services to ESRD patients in the U.S. at our dialysis clinics. These services include administering EPO, a bioengineered protein that stimulates the production of red blood cells. EPO is used to treat anemia, a medical complication that ESRD patients frequently experience, and we administer EPO to most of our patients. Revenues from EPO accounted for approximately 23% of dialysis care revenue in our North America segment for the year ended December 31, 2004. We receive a substantial majority of this revenue as reimbursements through the Medicare and Medicaid programs. Amgen Inc. is the sole manufacturer of EPO in North America, and any interruption of supply could materially adversely affect our business, financial condition and results of operations. Our current contract with Amgen covers the period from January 2004 to December 2005.

Our clinics also offer services for home dialysis patients, the majority of whom receive peritoneal dialysis treatment. For those patients, we provide materials, training and patient support services, including clinical monitoring, follow-up assistance and arranging for delivery of the supplies to the patient s residence. In the U.S. clinic services include supplying EPO. See Regulatory and Legal Matters Reimbursement U.S. for a discussion of billing for these products and services.

We also provide dialysis services under contract to hospitals in the U.S. on an as needed basis for hospitalized ESRD patients and for patients suffering from acute kidney failure. Acute kidney failure can result from trauma or similar causes, and requires dialysis until the patient s kidneys recover their normal function. We service these patients either at their bedside, using portable dialysis equipment, or at the hospital s dialysis site. Contracts with hospitals provide for payment at negotiated rates that are generally higher than the Medicare reimbursement rates for chronic in-clinic outpatient treatments.

We employ a centralized approach with respect to certain administrative functions common to our operations. For example, each dialysis clinic uses our proprietary manuals containing our standardized operating and billing procedures. We believe that centralizing and standardizing these functions enhance our ability to perform services on a cost-effective basis.

The manner in which each clinic conducts its business depends, in large part, upon applicable laws, rules and regulations of the jurisdiction in which the clinic is located, as well as our clinical policies. However, a patient s attending physician, who may be the clinic s Medical Director or an unaffiliated physician with staff privileges at the clinic, has medical discretion to prescribe the particular treatment modality and medications for that patient. Similarly, the attending physician has discretion in prescribing particular medical products, although the clinic typically purchases equipment, regardless of brand, in consultation with the Medical Director.

Fresenius UltraCare® Program

In 2002, we started a new program in the North America dialysis services group called UltraCare®. This program combines our latest product technology with our highly trained and skilled staff to offer our patients a superior level of care. The basis for this form of treatment is the Optiflux polysulfone single-use dialyzer. Optiflux dialyzers are combined with our 2008 Hemodialysis Delivery System series, which has advanced online patient monitoring as well as several systems to allow the tailoring of treatment to meet individual patient needs. Among the other capabilities of this system, staff will be alerted if toxin clearance is less than the target prescribed for the patient, and treatment can be adjusted accordingly. As of year-end 2004, nearly all 1,130 of our North American dialysis clinics have been certified for the UltraCare® program.

Laboratory Services

We provide laboratory testing and marketing services through Spectra Renal Management. Spectra Renal Management is the leading U.S. dialysis clinical laboratory providing blood, urine and other bodily fluid testing

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services to assist physicians in determining whether a dialysis patient s therapy regimen, diet and medicines remain optimal. Spectra Renal Management operates two laboratories, located in New Jersey and Northern California. During the year ended December 31, 2004, Spectra Renal Management performed over 40 million tests for approximately 124,000 dialysis patients in over 1,800 clinics across the U.S., including clinics that we own or operate.

Acquisitions

A significant factor in the growth in our revenue and operating earnings in prior years has been our ability to acquire health care businesses, particularly dialysis clinics, on reasonable terms. Worldwide, physicians own many dialysis clinics that are potential acquisition candidates for us. In the U.S., doctors might determine to sell their clinics to obtain relief from day-to-day administrative responsibilities and changing governmental regulations, to focus on patient care and to realize a return on their investment. Outside of the U.S., doctors might determine to sell to us and/or enter into joint ventures or other relationships with us to achieve the same goals and to gain a partner with extensive expertise in dialysis products and services.

We paid aggregate cash consideration primarily for dialysis clinics of approximately $104 million in 2004 and approximately $92 million in 2003 for acquisitions of dialysis clinics and Fresenius AG s adsorber business.

We continued to enhance our presence in the U.S. and abroad by acquiring individual or small groups of dialysis clinics in selected markets, expanding existing clinics, and opening new clinics.

Quality Assurance in Dialysis Care

Since 2001, our quality management activities have primarily focused on comprehensive development and implementation of an Integrated Quality Management System (IMS). Our goals in this area included not only meeting quality requirements for our dialysis clinics and environmental concerns, but also managing the quality of our dialysis care. This approach resulted in an IMS structure that closely reflects existing corporate processes. We also were able to use the IMS to fulfill many legal and normative regulations covering service lines. In addition, the quality management system standard offers a highly flexible structure that allows us to adapt to future regulations. The most important of these include, among others, ISO 9001 and ISO 14001, which defines environmental management system requirements.

Our dialysis clinics processes and documentation are continuously inspected by internal auditors and external parties. The underlying quality management system is certified and found to be in compliance with relevant regulations, requirements and company policies. Newly developed system evaluation methods, allowing simpler performance comparisons, are used to identify additional improvement possibilities. A focus of our activities in 2004 was the continuing certification of our dialysis clinics under ISO 9001 and ISO 14001, particularly in Slovenia, Czech Republic and Hungary.

The rapid pace of IMS integration will continue in 2005. The integration of a new risk and complaint management system and the further involvement of our subsidiaries in Eastern Europe and Turkey are additional objectives.

At each of our North America dialysis clinics, a quality assurance committee is responsible for reviewing quality of care data, setting goals for quality enhancement and monitoring the progress of quality assurance initiatives. We believe that we enjoy a reputation of providing high quality care to dialysis patients. In 2004, the Company continued to develop and implement programs to assist in achieving our quality goals. Our Access Intervention Management Program (AIM), started in 2001, detects and corrects arteriovenous access failure in hemodialysis treatment, which is the major cause of hospitalization and morbidity.

Sources of U.S. Dialysis Care Net Revenue

The following table provides information for the years ended December 31, 2004, 2003 and 2002 regarding the percentage of our U.S. dialysis treatment services net revenues from (a) the Medicare ESRD program, (b) private/alternative payors, such as commercial insurance and private funds, (c) Medicaid and other government sources and (d) hospitals.

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	Year Ended December 31,		
	2004	2003	2002
Medicare ESRD program	58.3%	61.0%	61.5%
Private/alternative payors	30.0%	29.2%	29.5%
Medicaid and other government sources	4.1%	3.9%	4.5%
Hospitals	7.6%	5.9%	4.5%
Total	100.0%	100.0%	100.0%

Under the Medicare ESRD program, Medicare reimburses dialysis providers for the treatment of certain individuals who are diagnosed as having ESRD, regardless of age or financial circumstances. See Regulatory and Legal Matters Reimbursement.

Patient, Physician and Other Relationships

We believe that our success in establishing and maintaining dialysis clinics, both in the U.S. and in other countries, depends significantly on our ability to obtain the acceptance of and referrals from local physicians, hospitals and managed care plans. A dialysis patient generally seeks treatment at a conveniently located clinic at which the patient s nephrologist has staff privileges.

Medicare ESRD program reimbursement regulations require that a Medical Director generally supervise treatment at a dialysis clinic. Generally, the Medical Director must be board certified or board eligible in internal medicine and have at least twelve months of training or experience in the care of patients at ESRD clinics. Our Medical Directors also maintain their own private practices.

Competition

Dialysis Services. The dialysis services industry is highly competitive. Our major competitors in dialysis services include Gambro AB and DaVita, Inc., which recently announced a proposed transaction whereby DaVita would acquire all of the U.S. dialysis services clinics of Gambro, Baxter International Inc., Renal Care Group and the Kuratorium für Dialyse und Nierentransplantation e.V. Ownership of dialysis clinics in the U.S. is characterized by a relatively small number of players, of which we are one of the largest, owning 70-75% of the clinics and a large number of operators each owning 10 or fewer clinics. Industry consolidation has been ongoing over the last decade as evidenced by the aforementioned proposed Gambro/ DaVita transaction. Many of our dialysis clinics are in urban areas, where there frequently are many competing clinics in proximity to our clinics. We experience direct competition from time to time from former Medical Directors, former employees or referring physicians who establish their own clinics. Furthermore, other health care providers or product manufacturers, some of who have significant operations, may decide to enter the dialysis business in the future.

Because in the U.S. government programs are the primary source of reimbursement for services to the majority of patients, competition for patients in the U.S. is based primarily on quality and accessibility of service and the ability to obtain admissions from physicians with privileges at the facilities. However, the extension of periods during which commercial insurers are primarily responsible for reimbursement and the growth of managed care have placed greater emphasis on service costs for patients insured with private insurance.

In most countries other than the U.S., we compete primarily against individual free-standing clinics and hospital-based clinics. In many of these countries, especially the developed countries, governments directly or indirectly regulate prices and the opening of new clinics. Providers compete in all countries primarily on the basis of quality and availability of service and the development and maintenance of relationships with referring physicians.

Laboratory Services. Spectra Renal Management competes in the U.S. with large nationwide laboratories, dedicated dialysis laboratories and numerous local and regional laboratories, including hospital laboratories. In the laboratory services market, companies compete on the basis of performance, including quality of laboratory testing,

timeliness of reporting test results and cost-effectiveness. We believe that our services are competitive in these areas.

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Other Services. We also provide perfusion, autotransfusion and therapeutic apheresis services in the U.S. Perfusion maintains human heart and lung function during cardiovascular surgery. Autotransfusion is used during surgery to collect, filter and reinfuse a patient s own blood as an alternative to using donor blood. Therapeutic apheresis is the process of separating or removing illness-causing substances from patient s blood or plasma.

Dialysis Products

We are currently the world s largest manufacturer and distributor of equipment and related products for hemodialysis and the second largest manufacturer of peritoneal dialysis products, based on publicly reported revenues, with operations in Germany, the U.S., and in 35 other countries. We sell our dialysis products directly and through distributors in over 100 countries. Most of our customers are dialysis clinics. For the year 2004, dialysis products accounted for 28% of our total revenue.

Overview

The following table shows the breakdown of our dialysis product revenues into sales of hemodialysis products, peritoneal dialysis products and our adsorber business.

	Year Ended December 31,					
	2004		2003		2002	
	Total Product Revenues	% of Total	Total Product Revenues	% of Total	Total Product Revenues	% of Total
	(U.S. dollars in millions)					
Hemodialysis Products	$ 1,453.0	84	$ 1,326.1	85	$ 1,181.0	86
Peritoneal Dialysis Products	242.9	14	211.5	14	194.2	14
Adsorber	30.9	2	11.6	1	0.0	0
Total	$ 1,726.8	100	$ 1,549.2	100	$ 1,375.2	100

Hemodialysis Products

We offer a comprehensive hemodialysis product line and believe that our broad range of technologically sophisticated hemodialysis products makes us a leader in the hemodialysis product field. We continually strive to expand and improve the capabilities of our hemodialysis systems to offer an advanced treatment mode at reasonable cost.

Dialysis Machines. We sell our dialysis machines as Series 2008H and 2008K models in North America and Series 4008 models in the rest of the world. Our dialysis machines offer the following features and advantages:

Volumetric dialysate balancing and ultrafiltration control system. This system, which we introduced in 1977, provides for safe and more efficient use of highly permeable dialyzers, permitting efficient dialysis with controlled rates of fluid removal;

Proven hydraulic systems, providing reliable operation and servicing flexibility;

Compatibility with all manufacturers dialyzers and a wide variety of blood-lines and dialysis solutions, permitting maximum flexibility in both treatment and disposable products usage;

Modular design, which permits us to offer dialysis clinics a broad range of options to meet specific patient or regional treatment requirements. Modular design also allows upgrading through module substitution without replacing the entire machine;

Specialized modules that provide monitoring and response capability for selected bio-physical patient parameters, such as body temperature and relative blood volume. This concept, known as physiological dialysis, permits hemodialysis treatments with lower incidence of a variety of symptoms or side effects, which still occur frequently in standard hemodialysis.

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Sophisticated microprocessor controls, and display and readout panels that are adaptable to meet local language requirements;

Battery backup, which continues operation of the blood circuit and all protective systems up to 20 minutes following a power failure;

Online clearance, measurement of dialyzer clearance for quality assurance with On-Line Clearance Monitoring, providing immediate effective clearance information, real time treatment outcome monitoring, and therapy adjustment during dialysis without requiring invasive procedures or blood samples;

On-line data collection capabilities and computer interfacing with our FINESSE module and FDS08® system. Our systems enable us to:

monitor and assess prescribed therapy;

connect a large number of hemodialysis machines and peripheral devices, such as patient scales, blood chemistry analyzers and blood pressure monitors, to a personal computer network;

enter nursing records automatically at bedside to register and document patient treatment records, facilitate billing, and improve record-keeping and staff efficiency;

adapt to new data processing devices and trends;

perform home hemodialysis with remote monitoring by a staff caregiver; and

record and analyze trends in medical outcome factors in hemodialysis patients.

Dialyzers. We manufacture dialyzers using hollow fiber Fresenius Polysulfone® and Helixone® membranes, a synthetic material. We are the leading worldwide producer of polysulfone dialyzers. We believe that polysulfone offers the following superior performance characteristics compared to other materials used in dialyzers:

higher biological compatibility, resulting in reduced incidence of adverse reactions to the fibers;

greater capacity to clear uremic toxins from patient blood during dialysis, permitting more thorough, more rapid dialysis, resulting in shorter treatment time; and

a complete range of permeability, or membrane pore size, which permits dialysis at prescribed rates high flux and low flux, as well as ultra flux for acute dialysis, and allows tailoring of dialysis therapy to individual patients.

Other Hemodialysis Products

We manufacture and distribute arterial, venous, single needle and pediatric bloodlines. We produce both liquid and dry dialysate concentrates. Liquid dialysate concentrate is mixed with purified water by the hemodialysis machine to produce dialysis solution, which removes the toxins and excess water from the patient s blood during dialysis. Dry concentrate, developed more recently, is less labor-intensive to use, requires less storage space and may be less prone to bacterial growth than liquid solutions. We also produce dialysis solutions in bags, including solutions for priming and rinsing hemodialysis bloodlines, as well as connection systems for central concentrate supplies and devices for mixing dialysis solutions and supplying them to hemodialysis machines. Other products include solutions for disinfecting and decalcifying hemodialysis machines, fistula needles, hemodialysis catheters, and products for acute renal treatment.

Peritoneal Dialysis Therapy

We offer a full line of peritoneal dialysis systems and solutions which include both continuous ambulatory peritoneal dialysis (CAPD) and continuous cycling peritoneal dialysis (CCPD) known also as automated peritoneal

dialysis (APD).

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CAPD Therapy: We manufacture both systems and solutions for CAPD therapy. Our product range offers the following advantages for patients including:

Fewer possibilities for touch contamination. The unique PIN and DISC technology was designed to reduce the number of steps in the fluid exchange process and by doing so has lessened the risk of infection. This is emphasized in the disconnection step where a PIN is inserted into the patient connector to bring about automatic closure without the need for manual intervention. This technology is used in the *stay safe*® product line and is also incorporated in the A.N.D.Y.® l disc system. Both systems make up the vast majority of systems being used worldwide. The North American version of *stay safe* , utilizing polyvinyl chloride (PVC), was introduced in 2004.

Improved biocompatibility. The new *balance* and bica*Vera*® solutions are pH neutral, have very low glucose degradation products (GDPs) and therefore offer the possibility of protecting the peritoneal membrane, thus improving technique survival.

Environmentally friendly material: The *stay safe*® system is made of Biofine®. This is a material, developed by Fresenius, and is composed of polyolefines. Upon combustion Biofine® is reduced to carbon dioxide and water. In addition to this environmental benefit Biofine® does not contain any plasticizers, thus the overall ecological advantages are maximized.

APD Therapy: We have been at the forefront of the development of automated peritoneal dialysis machines since 1980. APD therapy differs from that of CAPD in that fluid is infused into the peritoneal cavity of patients while they sleep. The effectiveness of the therapy is dependant on the dwell times, the composition of the solution used, the volume of solution and the time of the treatment, usually 8-10 hours. APD offers a number of benefits to the patients:

Improved quality of life. The patient is treated at night and therefore is free to lead a normal life during the day.

Improved adequacy of dialysis. By adjusting the parameters of treatment the possibility exists to provide more dialysis to the patient compared to conventional CAPD therapy. This therapy offers important options to physicians such as treating patients with larger body sizes or those who have ultrafiltration failure.

Our automated peritoneal dialysis equipment incorporates microprocessor technology. This offers physicians the opportunity to program specific prescriptions for individual patients. The technology developments are described below together with the benefits to patients:

sleep safe: The *sleep safe* machine has been used since 1999. It has automated connection technology thus further reducing the risk on touch contamination. Another key safety feature is the barcode recognition system for the types of solution bags used. This improves compliance and ensures that the prescribed dosage is administered to the patient. There is also a pediatric option for the treatment of small infants.

North American cycler portfolio: This includes the (a) Freedom® and 90/2® cyclers for pediatric and acute markets, (b) the Freedom® Cycler PD+ with IQ card and (c) the Newton IQ Cycler.

The Freedom® and 90/2® Cyclers offer advantages for acute and pediatric therapy.

The Freedom® Cycler PD+ with IQcard offers the advantage of a credit card-sized IQcard which can provide the physician actual treatment details and results for compliance monitoring.

The Newton IQ Cycler also offers the advantage of the IQ card and allows the ability to upload the patient s prescription into the machine via the card. In addition there is the added convenience of pumping the waste dialysate directly into a receptacle.

Patient Management Software: Specific patient management software tools have developed over recent years to support both CAPD and APD therapies in the different regions of the world. These include:

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PatientOnLine, Pack-PD® and FITTness . These tools can be used by physicians and nurses to design and monitor treatment protocols thus ensuring that therapy is optimized and that patient care is maximized.

Marketing, Distribution and Service

We sell most of our products to clinics, hospitals and specialized treatment clinics. With our comprehensive product line and years of experience in dialysis, we believe that we have been able to establish and maintain very close relationships with our clinic customer base on a global basis. Close interaction between our sales force and research and development personnel enables us to integrate concepts and ideas that originate in the field into product development. We maintain a direct sales force of trained salespersons engaged in the sale of both hemodialysis and peritoneal dialysis products. This sales force engages in direct promotional efforts, including visits to physicians, clinical specialists, hospitals, clinics and dialysis clinics, and represents us at industry trade shows. We also sponsor medical conferences and scientific symposia as a means for disseminating scientific or technical information. Our clinical nurses provide clinical support, training and assistance to customers and assist our sales force. We also use outside distributors to provide sales coverage in countries that our internal sales force does not service.

In our basic distribution system, we ship products from factories to central warehouses which are frequently located near the factories. From this central warehouse, we distribute our dialysis products to regional warehouses. We then distribute peritoneal dialysis products to the patient at home, and ship hemodialysis products directly to dialysis clinics and other customers. Local sales forces, independent distributors, dealers and sales agents sell all our products.

We offer customer service, training and education in the applicable local language, and technical support such as field service, repair shops, maintenance, and warranty regulation for each country in which we sell dialysis products. We provide training sessions on our equipment at our facilities in Schweinfurt, Germany, Chicago, Illinois and Walnut Creek, California and we also maintain regional service centers that are responsible for day-to-day international service support.

Manufacturing Operations

We operate state-of-the-art production facilities worldwide to meet the demand for machines, cyclers, dialyzers, solutions, concentrates, mixes, bloodlines, and disposable tubing assemblies and equipment for water treatment in dialysis clinics. We have invested significantly in developing proprietary processes, technologies and manufacturing equipment which we believe provide a competitive advantage in manufacturing our products. We are using our facilities in St. Wendel, Germany and Ogden, Utah as centers of competence for development and manufacturing.

We produce and assemble hemodialysis machines and CCPD cyclers in our Schweinfurt, Germany and our Walnut Creek, California facilities. We also maintain facilities at our service and local distribution centers in Argentina, Egypt, France, Italy, The Netherlands, China, Brazil and Russia for testing and calibrating dialysis machines manufactured or assembled elsewhere, to meet local end user market needs. We manufacture and assemble dialyzers and polysulfone membranes in our St. Wendel, Germany, L Arbresle, France and Inukai, Japan facilities and at production facilities of our joint ventures in Belarus, Saudi Arabia and Japan. At our Ogden, Utah facilities we manufacture and assemble dialyzers and polysulfone membranes as well as manufacture PD solutions. We have PD production in Mexico and Japan. Our facilities are inspected on a regular basis by national and/or international authorities.

During 2004, we primarily invested in the maintenance and expansion of production facilities in Germany, North America, France and Italy. See History and Development of the Company Capital Expenditures.

Sources of Supply

Our purchasing policy combines worldwide sourcing of high-quality materials with the establishment of long-term relationships with our suppliers. Additionally, we carefully assess the reliability of all materials purchased to ensure that they comply with the rigorous quality and safety standards required for our dialysis

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products. Our International Purchasing Consulting Center (PCC) ensures that we consistently maintain high standards by entering into global agreements. An interactive information system links all our global projects to ensure that they are standardized and constantly monitored.

PCC focuses on further optimizing procurement logistics and reducing purchasing costs. Supplemental raw material contracts for all manufacturers of semi-finished goods will enable us to improve purchasing terms for our complete network. We also plan to intensify, where appropriate, our use of internet-based procurement tools by purchasing raw materials through special on-line auctions. Our sophisticated routing software enables us to distribute our supplies to best accommodate customer requests while maintaining operational efficiency.

New Product Introductions

Research and development focuses strongly on the development of new products, technologies and treatment concepts to optimize treatment quality for dialysis patients, and on process technology for manufacturing our products. Research and development expenditures were $51 million in 2004, $50 million in 2003, and $47 million in 2002.

New or enhanced products introduced in 2004 included the following:

2008K@Home converting the 2008K dialysis machine for the U.S. home hemodialysis market, including task oriented prompts, integrated leakage and pulse sensors and devices for remote monitoring.

POL PatientOnLine improved software covering all aspects of PD, including management of medical data, prescription editor and adequacy tests.

Improved PD Product Line including new connectology and color coding for ease of identification of glucose and calcium concentrations.

sleep.safe BicaVera sleep.safe with a more biocompatible PD solution containing bicarbonate as a buffer.

Patents, Trademarks and Licenses

As the owner of or licensee under patents and trademarks throughout the world, we hold rights under about 1,100 patents and patent applications relating to dialysis technology in major markets. Patented technologies that relate to dialyzers include our polysulfone hollow fiber, an in-line sterilization method, and sterile closures for in-line sterilized medical devices. The more recent generation of DIASAFEplus filters and FX dialyzers are also the subject of patents and pending patent applications.

The Company holds the exclusive license on European patents/patent applications on the Autoprime technology for the automated priming of the extracorporeal hemodialysis blood circuit with dialyzing liquid through the membrane of the dialyzer.

The connector system for our biBag bicarbonate concentrate powder container has been patented in the USA, Norway and Europe while national applications in Japan and Finland are still pending.

Among the Company s more significant protective rights, one patent family protects the Company s polysulfone hollow fiber until 2007 in the United States, and until 2005 in other main markets. The in-line sterilization method is patented until 2010 and the biBag connector is protected until 2013, both in Germany, in the United States, and in other important markets. The dates given represent the maximum life time of the corresponding patents. The Company believes that even after expiration of these patents, our proprietary know-how for the manufacture of these products will continue to constitute a competitive advantage.

For peritoneal dialysis, the Company holds protective rights on our polyolefine film Biofine, suitable for packaging intravenous and peritoneal dialysis fluids and currently used in non-US markets. These patents have been granted in Australia, Germany, and the USA, with patent applications pending in various other countries. A further pending patent family describes a special film for a peelable, non-PVC, multi chamber bag for peritoneal dialysis solutions. A U.S. patent has already been granted.

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We believe that our success will depend, in large part, on our technology. As a standard practice, we obtain legal protections we believe are appropriate for our intellectual property. Intellectual property is, however, subject to infringement or invalidation claims. In addition, technological developments in ESRD therapy could reduce the value of our existing intellectual property. Any such reduction could be rapid and unanticipated. Other than as disclosed in this report, we are not dependent to any material extent upon patents, licenses or contracts.

Competition

The markets in which we sell our dialysis products are highly competitive. Our competitors in the sale of hemodialysis and peritoneal dialysis products include Gambro AB, Baxter International, Inc., Asahi Medical Co., Ltd., Bellco S.p.A., a subsidiary of Sorin Biomedica S.p.A., Bieffe Medital S.p.A., which is an affiliate of Baxter International, Inc., B. Braun Melsungen AG, Nissho Corporation, including Nissho Nipro Corporation Ltd., Nikkiso Co., Ltd., Terumo Medical Corporation and Toray Medical Co., Ltd.

Regulatory and Legal Matters

Regulatory Overview

Our operations are subject to extensive governmental regulation by virtually every country in which we operate including, most notably, in the U.S., at the federal, state and local levels. Although these regulations differ from country to country, in general, non-U.S. regulations are designed to accomplish the same objectives as U.S. regulations regarding the operation of dialysis clinics, laboratories and manufacturing facilities, the provision of quality health care for patients, the maintenance of occupational, health, safety and environmental standards and the provision of accurate reporting and billing for governmental payments and/or reimbursement. In the U.S., some states restrict ownership of health care providers by certain multi-level for-profit corporate groups or establish other regulatory barriers to the establishment of new dialysis clinics. Outside the U.S., each country has its own payment and reimbursement rules and procedures, and some countries prohibit ownership of health care providers or establish other regulatory barriers to direct ownership by foreign companies. In all jurisdictions, we work within the framework of applicable laws to establish alternative contractual arrangements to provide services to those facilities.

Any of the following matters could have a material adverse effect on our business, financial condition and results of operations:

- failure to receive required licenses, certifications or other approvals for new facilities or significant delays in such receipt;
- loss of various federal certifications or termination of licenses under the laws of any state or other governmental authority; and
- changes resulting from health care reform or other government actions that reduce reimbursement or reduce or eliminate coverage for particular services we provide.

We must comply with all U.S., German and other legal and regulatory requirements under which we operate, including the U.S. federal Medicare and Medicaid Fraud and Abuse Amendments of 1977, as amended, generally referred to as the anti-kickback statute , the federal False Claims Act, the federal restrictions on certain physician referrals, commonly known as the Stark Law , U.S. federal rules under the Health Insurance Portability and Accountability Act of 1996 that protect the privacy of patient medical records and prohibit inducements to patients to select a particular health care provider (commonly known as HIPAA) and other fraud and abuse laws and similar state statutes, as well as similar laws in other countries. Moreover, there can be no assurance that applicable laws, or the regulations thereunder, will not be amended, or that enforcement agencies or the courts will not make interpretations inconsistent with our own, any one of which could have a material adverse effect on our business, reputation, financial condition and results. Sanctions for violations of these statutes may include criminal or civil penalties, such as imprisonment, fines or forfeitures, denial of payments, and suspension or exclusion from the Medicare and Medicaid programs. In the U.S., some of these laws have been broadly interpreted by a number of courts, and significant government funds and personnel have been devoted to their enforcement because such enforcement has become a high priority for the federal

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government and some states. Our company, and the health care industry in general, will continue to be subject to extensive federal, state and foreign regulation, the full scope of which cannot be predicted.

Fresenius Medical Care Holdings has entered into a corporate integrity agreement with the U.S. government, which requires that Fresenius Medical Care Holdings staff and maintain a comprehensive compliance program, including a written code of conduct, training programs and compliance policies and procedures. The corporate integrity agreement requires annual audits by an independent review organization and periodic reporting to the government. The corporate integrity agreement permits the U.S. government to exclude Fresenius Medical Care Holdings and its subsidiaries from participation in U.S. federal health care programs and impose fines if there is a material breach of the agreement that is not cured by Fresenius Medical Care Holdings within thirty days after Fresenius Medical Care Holdings receives written notice of the breach.

Product Regulation

U.S.

In the U.S., the Food and Drug Administration (FDA) and comparable state regulatory agencies impose requirements on certain of our subsidiaries as a manufacturer and a seller of medical products and supplies under their jurisdiction. These require that products be manufactured in accordance with Good Manufacturing Practices and that we comply with FDA requirements regarding the design, safety, advertising, labeling, recordkeeping distribution, and reporting of adverse events related to the use of our products. In addition, in order to clinically test, produce and market certain medical products and other disposables (including hemodialysis and peritoneal dialysis equipment and solutions, dialyzers, bloodlines and other disposables) for human use, we must satisfy mandatory procedures and safety and efficacy requirements established by the FDA or comparable state and foreign governmental agencies. Such rules generally require that products be approved by the FDA as safe and effective for their intended use prior to being marketed. Our peritoneal dialysis solutions have been designated as drugs by the FDA and, as such, are subject to additional FDA regulation under the Food, Drug and Cosmetic Act of 1938, as amended.

Germany and Other Non-U.S.

Most countries maintain different regulatory regimes for pharmaceutical products and for medical devices. In each regime, there are regulations governing manufacturers and distributors, as well as regulations governing the final products manufactured and distributed. Treaties or other international law and standards and guidelines under treaties or laws may supplement or supersede individual country regulations.

Some of our products, such as peritoneal dialysis solutions, are considered pharmaceuticals. The European Union has issued a directive on pharmaceuticals, No. 65/65/ EWG (January 26, 1965), as amended. Each member of the European Union is responsible for conforming its law to comply with this directive. In Germany the German Drug Law *(Arzneimittelgesetz)* which implements European Union requirements, is the primary regulation applicable to pharmaceutical products.

The provisions of the German Drug Law are typical of the legal standards in other European countries. The German Drug Law states the requirements for the authorization of a company to manufacture pharmaceuticals. A manufacturer must, among other requirements, appoint pharmacists, chemists, biologists or physicians to be responsible for the quality, safety and efficacy of the pharmaceuticals. At least five responsible persons must be appointed in any pharmaceutical company: a sales manager, a quality control manager, a manufacturing manager, a safety officer, and a drug information officer. Each of these persons may be held personally liable under German criminal laws for violations of the German Drug Law.

International guidelines also govern the manufacture of pharmaceuticals and, in many cases, overlap with national requirements. In particular, the Pharmaceutical Inspection Convention, an international treaty, contains rules which are binding on most countries in which pharmaceuticals are manufactured. Among other things, the Pharmaceutical Inspection Convention establishes requirements for Good Manufacturing Practices which are then adopted at the national level. Another international standard, which is non-binding for pharmaceuticals, is the ISO 9000-9004 system for assuring quality management system requirements. This system has a broader

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platform than Good Manufacturing Practices which are more detailed. Compliance entitles the manufacturer to utilize the CE certification of quality control. In addition to regulating the manufacture of pharmaceuticals, countries directly regulate marketing of the pharmaceuticals produced. A drug needs to be registered and authorized in every country in which it is distributed. European Union rules govern the conditions for a registration, such as pre-clinical and clinical testing.

Historically, medical devices have not been regulated as strictly as pharmaceuticals, but more stringent regulatory schemes have been adopted during the last decade. In 1995, Germany implemented the European Union s Medical Devices Directive when it adopted the Medical Devices Act *(Medizinproduktegesetz)*, which is similar in many ways to the German Drug Law. This Directive applies to both the manufacturer s quality management system and the products technical design. Depending on the risk class of medical devices, a manufacturer may choose alternative regulatory modules to demonstrate compliance with European Union provisions. To assure and demonstrate the high quality standards and performance of our operations, we have subjected our entire European business to the most comprehensive procedural module, which is also the fastest way to launch a new product in the European Union. This module requires the certification of a full quality management system by a notified body charged with supervising the quality management system. A notified body is a group accredited and monitored by governmental agencies that inspects manufacturing facilities and quality control systems at regular intervals and is authorized to carry out unannounced inspections.

When a company receives a European Union certificate for the quality management system of a particular facility, it may assess whether products developed and manufactured in the facility satisfy European Union requirements. European Union requirements for products are laid down in harmonized European Union standards and include conformity to safety requirements, physical and biological properties, construction and environmental properties, and information supplied by the manufacturer. Depending on the risk class, a manufacturer must demonstrate conformity to these requirements by pre-clinical tests, biocompatibility tests, qualification of products and packaging, risk analysis and well-conducted clinical investigations approved by ethics committees.

A manufacturer having a European Union-certified full quality management system has to declare and document conformity of its products to the harmonized European directive. If able to do so, the manufacturer may put a CE mark on the products. The CE mark, which stands for *Conformité Européenne,* demonstrates compliance with the relevant European Union requirements. Products subject to these provisions that do not bear the CE mark cannot be imported, sold or distributed within the European Union.

Our Series 4008, 4008B, 4008E dialysis machines and their therapy modifications, our PD-NIGHT cycler, and our other active medical devices distributed in the European market, as well as our dialysis filters and dialysis tubing systems and accessories, all bear the CE mark. We expect to continue to obtain additional certificates for newly developed products or product groups.

Facilities and Operational Regulation

U.S.

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) subjects virtually all clinical laboratory testing facilities, including ours, to the jurisdiction of the Department of Health and Human Services. CLIA establishes national standards for assuring the quality of laboratories based upon the complexity of testing performed by a laboratory. Certain of our operations are also subject to federal laws governing the repackaging and dispensing of drugs and the maintenance and tracking of certain life sustaining and life-supporting equipment.

Our operations are subject to various U.S. Department of Transportation, Nuclear Regulatory Commission and Environmental Protection Agency requirements and other federal, state and local hazardous and medical waste disposal laws. As currently in effect, laws governing the disposal of hazardous waste do not classify most of the waste produced in connection with the provision of dialysis, or laboratory services as hazardous, although disposal of nonhazardous medical waste is subject to specific state regulation. Our operations are also subject to various air emission and wastewater discharge regulations.

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Federal, state and local regulations require us to meet various standards relating to, among other things, the management of facilities, personnel qualifications and licensing, maintenance of proper records, equipment, quality assurance programs, the operation of pharmacies, and dispensing of controlled substances. All of our operations in the U.S. are subject to periodic inspection by federal and state agencies and other governmental authorities to determine if the operations, premises, equipment, personnel and patient care meet applicable standards. To receive Medicare reimbursement, our dialysis centers, renal diagnostic support business and laboratories must be certified by the Centers for Medicare and Medicaid Services (CMS). All of our dialysis centers, and laboratories that furnish Medicare services have the required certification.

Certain of our facilities and certain of their employees are also subject to state licensing statutes and regulations. These statutes and regulations are in addition to federal and state rules and standards that must be met to qualify for payments under Medicare, Medicaid and other government reimbursement programs. Licenses and approvals to operate these centers and conduct certain professional activities are customarily subject to periodic renewal and to revocation upon failure to comply with the conditions under which they were granted.

Occupational Safety and Health Administration (OSHA) regulations require employers to provide employees who work with blood or other potentially infectious materials with prescribed protections against blood-borne and air-borne pathogens. The regulatory requirements apply to all health care facilities, including dialysis centers and laboratories, and require employers to make a determination as to which employees may be exposed to blood or other potentially infectious materials and to have in effect a written exposure control plan. In addition, employers are required to provide hepatitis B vaccinations, personal protective equipment, blood-borne pathogens training, post-exposure evaluation and follow-up, waste disposal techniques and procedures, engineering and work practice controls and other OSHA-mandated programs for blood-borne and air-borne pathogens.

Some states in which we operate have certificate of need (CON) laws that require any person or entity seeking to establish a new health care service or to expand an existing service to apply for and receive an administrative determination that the service is needed. We currently operate in 13 states, as well as the District of Columbia and Puerto Rico that have CON laws applicable to dialysis centers. These requirements could, as a result of a state s internal determination of its dialysis services needs, prevent entry to new companies seeking to provide services in these states, and could constrain our ability to expand our operations in these states.

Germany and Other Non-U.S.

Countries outside of the U.S. possess a wide variety of operational regulation at disparate levels. Accordingly, our operations are subject to very different regulations in different countries. Most countries regulate dialysis clinic operating conditions and product manufacturing.

We are subject to a broad spectrum of regulation. Our operations must comply with various environmental and transportation regulations in the various countries in which we operate. Our manufacturing facilities and dialysis clinics are also subject to various standards relating to, among other things, facilities, management, personnel qualifications and licensing, maintenance of proper records, equipment, quality assurance programs, the operation of pharmacies, the protection of workers from blood-borne diseases and the dispensing of controlled substances. All of our operations are subject to periodic inspection by various governmental authorities to determine if the operations, premises, equipment, personnel and patient care meet applicable standards. Our dialysis clinic operations and our related activities generally require licenses, which are subject to periodic renewal and may be revoked for violation of applicable regulatory requirements.

In addition, many countries impose various investment restrictions on foreign companies. For instance, government approval may be required to enter into a joint venture with a local partner. Some countries do not permit foreign investors to own a majority interest in local companies or require that companies organized under their laws have at least one local shareholder. Investment restrictions therefore affect the corporate structure, operating procedures and other characteristics of our subsidiaries and joint ventures in these and other countries.

We believe our facilities are currently in compliance in all material respects with the applicable national and local requirements in the jurisdictions in which they operate.

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Reimbursement

U.S.

Dialysis Services. Our dialysis centers provide outpatient hemodialysis treatment and related services for ESRD patients. In addition, some of the Company s centers offer services for the provision of peritoneal dialysis and hemodialysis treatment at home, and dialysis for hospitalized patients.

The Medicare program is the primary source of Dialysis Services revenues from dialysis treatment. For example, in 2004, approximately 58% of Dialysis Services revenues resulted from Medicare s ESRD program. As described below, Dialysis Services is reimbursed by the Medicare program in accordance with the Composite Rate for certain products and services rendered at our dialysis centers. As described hereinafter, other payment methodologies apply to Medicare reimbursement for other products and services provided at our dialysis centers and for products (such as those sold by us) and support services furnished to ESRD patients receiving dialysis treatment at home (such as those of Dialysis Products). Medicare reimbursement rates are fixed in advance and are subject to adjustment from time to time by the U.S. Congress. Although this form of reimbursement limits the allowable charge per treatment, it provides us with predictable per treatment revenues.

Certain items and services that we furnish at our dialysis centers are not included in the Composite Rate and are eligible for separate Medicare reimbursement, typically on the basis of established fee schedule amounts. Such items and services include certain drugs (such as EPO), blood transfusions and certain diagnostic tests.

Medicare payments are subject to change by legislation, regulations and pursuant to deficit reduction measures. The Composite Rate was unchanged from commencement of the ESRD program in 1972 until 1983. From 1983 through December 1990, numerous congressional actions resulted in a net reduction of the average reimbursement rate from $138 per treatment in 1983 to approximately $125 per treatment in 1990. Congress increased the ESRD reimbursement rate, effective January 1, 1991, to an average rate of $126 per treatment. Effective January 1, 2000, the reimbursement rate was increased by 1.2%. In December 2000 an additional increase of 2.4% was approved for the year 2001. Accordingly, there was a 1.2% reimbursement increase on January 1, 2001. A second increase was delayed until April 1, 2001, when rates were increased 1.6% to make up for the delay.

On December 8, 2003, the Medicare Prescription Drug, Modernization and Improvement Act of 2003 was enacted (the Medicare Modernization Act). This law makes several significant changes to U.S. government payment for dialysis services and pharmaceuticals. First, it increased the composite rate for renal dialysis facilities by 1.6% on January 1, 2005. Second, effective January 1, 2005, payments for ten separately billable dialysis-related medications will be based on average acquisition cost (as determined by the OIG and updated by CMS) and payments for the remaining separately billable dialysis-related medications will be based on average sales price (ASP) plus 6% (ASP is defined in the law as a manufacturer s ASP to all purchasers in a calendar quarter per unit of each drug and biological sold in that same calendar quarter, excluding sales exempt from best price and nominal price sales and including all discounts, chargebacks and rebates). Third, the difference between the determined acquisition cost-based reimbursement and what would have been received under the current average wholesale price-based (AWP-based) reimbursement methodology will be added to the composite rate. This add-back amount has been determined to be 8.7% of the composite rate and will be subject to an annual update based on the growth in drug spending. Fourth, effective April 1, 2005, providers will receive higher composite rate payments for certain patients based on their age, body mass index and body surface area. Fifth, beginning in 2006, the Secretary of the Department of Health and Human Services (the Secretary) is authorized to set payment for all separately billed drugs and biologicals at either acquisition cost or average sales price. Lastly, the Secretary is required to establish a three-year demonstration project to test the use of a fully case-mix adjusted payment system for ESRD services, beginning January 1, 2006. Under this project, separately billable drugs and biologicals and related clinical laboratory tests would be bundled into the facility composite rate. Participating facilities would receive an additional 1.6% composite rate increase. For a discussion of the composite rate for reimbursement of dialysis treatments, see Item 4B, Business Overview Regulatory and Legal Matters Reimbursement . We expect that the final regulations could have a non-material negative impact on our revenue from Medicare.

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We are unable to predict what, if any, future changes may occur in the rate of Medicare reimbursement. Any significant decreases in the Medicare reimbursement rates could have a material adverse effect on our provider business and, because the demand for products is affected by Medicare reimbursement, on our products business. Increases in operating costs that are affected by inflation, such as labor and supply costs, without a compensating increase in reimbursement rates, also may adversely affect our business and results of operations.

For Medicare-primary patients, Medicare is responsible for payment of 80% of the Composite Rate set by CMS for dialysis treatments and the patient or third-party insurance payors, including employer-sponsored health insurance plans, commercial insurance carriers and the Medicaid program, are responsible for paying any co-payment amounts for approved services not paid by Medicare (typically the annual deductible and 20% co-insurance), subject to the specific coverage policies of such payors. Each third-party payor, including Medicaid, makes payment under contractual or regulatory reimbursement provisions which may or may not cover the full 20% co-payment or annual deductible. Where the patient has no third-party insurance or the third party insurance does not cover the co-payment or deductible, the patient is responsible for paying the co-payments or the deductible, which we frequently do not fully collect despite reasonable collection efforts. Under an advisory opinion from the Office of the Inspector General, subject to specified conditions, we and other similarly situated providers may make contributions to a non-profit organization that has agreed to make premium payments for supplemental medical insurance and/or medigap insurance on behalf of indigent ESRD patients, including some of our patients.

Laboratory Tests. Spectra Renal Management obtains a substantial portion of its net revenue from Medicare, which pays for clinical laboratory services provided to dialysis patients in two ways.

First, payment for certain routine tests is included in the Composite Rate paid to our dialysis centers. As to such services, the dialysis centers obtain the services from a laboratory and pay the laboratory for such services. In accordance with industry practice, Spectra Renal Management usually provides such testing services under capitation agreements with its customers pursuant to which it bills a fixed amount per patient per month to cover the laboratory tests included in the Composite Rate at the designated frequencies. In addition, in compliance with our Corporate Integrity Agreement, we provide an annual report on the costs associated with the composite rate tests, and have established that our Composite Rate is above those costs.

Second, laboratory tests performed by Spectra Renal Management for Medicare beneficiaries that are not included in the Composite Rate are separately billable directly to Medicare. Such tests are paid at 100% of the Medicare fee schedule amounts, which are limited by national ceilings on payment rates, called National Limitation Amounts (NLAs). Congress has periodically reduced the fee schedule rates and the NLAs, with the most recent reductions in the NLAs occurring in January 1998. (As part of the Balanced Budget Act of 1997, Congress lowered the NLAs from 76% to 74% effective January 1, 1998.) Congress has also approved a five year freeze on the inflation updates based on the Consumer Price Index (CPI) for 2004-2008.

Erythropoetin (EPO). EPO is used for anemia management of patients with renal disease. The administration of EPO is separately billable under the Medicare program, and accounts for a significant portion of our dialysis revenues.

In July 2004, CMS proposed certain changes with respect to its EPO reimbursement and utilization guidelines. Its proposal reflects the agency s conclusion that the appropriate utilization of EPO should be monitored by considering both the patient s hemoglobin/hematocrit level and the dosage. Specifically, it proposed a pre-payment claims review process in which claims for EPO with hemoglobin levels below 13 (or hematocrit of 39) would not be targeted for review, but claims for EPO with hemoglobin levels above 13 would be reviewed based on the hemoglobin value and related EPO doses, and with payment limited to a fixed amount of EPO unless there is medical justification for the hemoglobin levels. The comment period on this policy draft was extended and ended on October 7, 2004. CMS has not yet finalized the new guidelines. If the EPO reimbursement/utilization changes are adopted, this could have an adverse impact on our operating results. In

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addition, any of the following changes could adversely affect our business, and results of operations, possibly materially:

future changes in the EPO reimbursement rate without offsetting changes to the Medicare composite rate;

inclusion of EPO in the Medicare composite rate without offsetting increases to such rate;

changes in the typical dosage per administration;

increases in the cost of EPO after our current supply contract expires; or

reduction by the manufacturer of EPO of the amount of overfill in the EPO vials.

Coordination of Benefits. Medicare entitlement begins for most patients in the fourth month after the initiation of chronic dialysis treatment at a dialysis center. During the first three months, considered to be a waiting period, the patient or patient s insurance, Medicaid or a state renal program are responsible for payment.

Patients who are covered by Medicare and are also covered by an employer group health plan (EGHP) are subject to a 30-month coordination period during which the EGHP is the primary payor and Medicare the secondary payor. During this coordination period the EGHP pays a negotiated rate or in the absence of such a rate, our standard rate or a rate defined by its plan documents. The EGHP payments are generally higher than the Medicare Composite Rate. EGHP insurance, when available, will therefore generally cover as the primary payor a total of 33 months, the 3-month waiting period plus the 30-month coordination period.

Possible Changes in Medicare. Legislation or regulations may be enacted in the future that could substantially modify or reduce the amounts paid for services and products offered by us and our subsidiaries. It is also possible that statutes may be adopted or regulations may be promulgated in the future that impose additional eligibility requirements for participation in the federal and state health care programs. Such new legislation or regulations may adversely affect our businesses and results of operations, possibly materially.

Germany and Other Non-U.S.

As a global company delivering dialysis care and dialysis products in more than 100 countries worldwide, we face the challenge of addressing the needs of dialysis patients in widely varying economic and health care environments.

Health care systems and reimbursement structures for ESRD treatment vary by country. In general, the government pays for health care and finances its payments through taxes and other sources of government income, from social contributions, or a combination of those sources. However, not all health care systems provide for dialysis treatment. In many developing countries, only limited subsidies from government or charitable institutions are available, and dialysis patients must finance all or substantially all of the cost of their treatment. In some countries patients in need of dialysis do not receive treatment on a regular basis but rather when the financial resources allow it.

In the major European and British Commonwealth countries, health care systems are generally based on one of two models. The German model is based on mandatory employer and employee contributions dedicated to health care financing. The British model provides a national health care system funded by taxes. Within these systems, provision for the treatment of dialysis has been made either through allocation of a national budget or a billing system reimbursing on a fee-for-service basis. The health care systems of countries such as Japan, France, Belgium, Austria and the Netherlands are based on the German model. Countries like Canada, Denmark, Sweden and Italy established their national health services using the British model.

Ownership of health care providers and, more specifically dialysis care providers, varies within the different systems and from country-to-country. In Europe almost 60% of the clinics providing dialysis care and services are publicly owned, more than 30% are privately owned and approximately 10% belong to a health care organization. It should be noted that health care organizations treating a significant patient population operate only in Germany and France. Publicly operated clinics care for almost 100% of the dialysis populations in Canada and more than 85% in Australia. Within Europe, nearly 100% of the dialysis population is treated in

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public clinics in the Netherlands, Finland and Belgium and to more than 80% in the United Kingdom while the majority of dialysis clinics are privately owned in Spain, Hungary and Portugal.

In Latin America privately owned clinics predominate, constituting more than 70% of all clinics providing dialysis care while in Asia, with the exception of Japan, publicly owned clinics are predominant. In the U.S., less than 5% of all dialysis clinics are publicly operated and in Japan only approximately 15%. Unlike the U.S., however, Japan has a premium-based, mandatory social insurance system, and the structure of its health care system is more closely comparable to the German system.

Financing policies for ESRD treatment also differ from country-to-country. In countries with a health care system that includes provisions for ESRD patient care, treatment is generally financed through a government budget allocation or on a fee-for-service basis. Germany has introduced a payment system utilizing a weekly fixed payment independent of treatment modality.

Treatment components included in the cost of dialysis may vary from country-to-country or even within countries, depending on the structure and cost allocation principles. Where treatment is reimbursed on a fee-for-service basis, reimbursement rates are sometimes allocated in accordance with the type of treatment performed. We believe that it is not appropriate to calculate a global reimbursement amount, because the services and costs for which reimbursement is provided in any such global amount would be likely to bear little relation to the actual reimbursement system in any one country. Generally, in countries with established dialysis programs, reimbursements range from $100 to more than $300 per treatment. However, a comparison from country to country would not be meaningful if made in the absence of a detailed analysis of the cost components reimbursed, services rendered and the structure of the dialysis clinic in each country being compared.

Health care expenditures are consuming an ever-increasing portion of gross domestic product worldwide. In the developed economies of Europe, Asia and Latin America, health care spending is in the range of 5%-14% of gross domestic product. In many countries, dialysis costs consume a disproportionately high amount of health care spending and these costs may be considered a target for implementation of cost containment measures. Today, there is increasing awareness of the correlation between the quality of care delivered in the dialysis unit and the total health care expenses incurred by the dialysis patient. Accordingly, developments in reimbursement policies might include higher reimbursement rates for practices which are believed to improve the overall state of health of the ESRD patient and reduce the need for additional medical treatment.

Anti-kickback Statutes, False Claims Act, Health Care Fraud, Stark Law and Fraud and Abuse Laws in North America

Some of our operations are subject to federal and state statutes and regulations governing financial relationships between health care providers and potential referral sources and reimbursement for services and items provided to Medicare and Medicaid patients. Such laws include the anti-kickback statute, health care fraud statutes, the False Claims Act, the Stark Law, other federal fraud and abuse laws and similar state laws. These laws apply because our Medical Directors and other physicians with whom we have financial relationships refer patients to, and order diagnostic and therapeutic services from, our dialysis centers and other operations. As is generally true in the dialysis industry, at each dialysis facility a small number of physicians account for all or a significant portion of the patient referral base. An ESRD patient generally seeks treatment at a center that is convenient to the patient and at which the patient s nephrologist has staff privileges.

Anti-kickback Statutes

The federal anti-kickback statute establishes criminal prohibitions against and civil penalties for the knowing and willful solicitation, receipt, offer or payment of any remuneration, whether direct or indirect, in return for or to induce the referral of patients or the ordering or purchasing of items or services payable in whole or in part under Medicare, Medicaid or other federal health care programs. Sanctions for violations of the anti-kickback statute include criminal and civil penalties, such as imprisonment or criminal fines of up to $25,000 per violation, and civil penalties of up to $50,000 per violation, and exclusion from the Medicare or Medicaid programs and other federal programs. In addition, certain provisions of federal criminal law that may be applicable provide that

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if a corporation is found guilty of a criminal offense it may be fined no more than twice any pecuniary gain to the corporation, or, in the alternative, no more than $500,000 per offense.

Some states also have enacted statutes similar to the anti-kickback statute, which may include criminal penalties, applicable to referrals of patients regardless of payor source, and may contain exceptions different from state to state and from those contained in the federal anti-kickback statute.

False Claims Act and Related Criminal Provisions

The federal False Claims Act (the False Claims Act) imposes civil penalties for knowingly making or causing to be made false claims with respect to governmental programs, such as Medicare and Medicaid, for services billed but not rendered, or for misrepresenting actual services rendered, in order to obtain higher reimbursement. Moreover, private individuals may bring qui tam or whistle blower suits against providers under the False Claims Act, which authorizes the payment of a portion of any recovery to the individual bringing suit. Such actions are initially required to be filed under seal pending their review by the Department of Justice. A few federal district courts have interpreted the False Claims Act as applying to claims for reimbursement that violate the anti-kickback statute or federal physician self-referral law under certain circumstances. The False Claims Act generally provides for the imposition of civil penalties of $5,500 to $11,000 per claim and for treble damages, resulting in the possibility of substantial financial penalties for small billing errors that are replicated in a large number of claims, as each individual claim could be deemed to be a separate violation of the False Claims Act. Criminal provisions that are similar to the False Claims Act provide that if a corporation is convicted of presenting a claim or making a statement that it knows to be false, fictitious or fraudulent to any federal agency it may be fined not more than twice any pecuniary gain to the corporation, or, in the alternative, no more than $500,000 per offense. Some states also have enacted statutes similar to the False Claims Act which may include criminal penalties, substantial fines, and treble damages.

The Health Insurance Portability and Accountability Act of 1996

HIPAA was enacted in August 1996 and expanded federal fraud and abuse laws by increasing their reach to all federal health care programs, establishing new bases for exclusions and mandating minimum exclusion terms, creating an additional exception to the anti-kickback penalties for risk-sharing arrangements, requiring the Secretary of Health and Human Services to issue advisory opinions, increasing civil money penalties to $10,000 (formerly $2,000) per item or service and assessments to three times (formerly twice) the amount claimed, creating a specific health care fraud offense and related health fraud crimes, and expanding investigative authority and sanctions applicable to health care fraud. It also prohibits a provider from offering anything of value which the provider knows or should know would be likely to induce the patient to select the provider.

The law expands criminal sanctions for health care fraud involving any governmental or private health benefit program, including freezing of assets and forfeiture of property traceable to commission of a health care offense.

HIPAA included a health care fraud provision which prohibits knowingly and willfully executing a scheme or artifice to defraud any health care benefit program, which includes any public or private plan or contract affecting commerce under which any medical benefit, item, or service is provided to any individual, and includes any individual or entity who is providing a medical benefit, item, or service for which payment may be made under the plan or contract.

HIPAA regulations establish national standards for certain electronic health care transactions, the use and disclosure of certain individually identifiable patient health information, and the security of the electronic systems maintaining this information. These are commonly known as the HIPAA transaction and code set standards, privacy standards, and security standards. Health insurance payers and healthcare providers like us must comply with the new HIPAA standards. Violations of these HIPAA standards may include civil money penalties and potential criminal sanctions.

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Balanced Budget Act of 1997

The Balanced Budget Act of 1997 (the BBA) contained material adjustments to both the Medicare and Medicaid programs, as well as further expansion of the federal fraud and abuse laws. Specifically, the BBA created a civil monetary penalty for violations of the federal anti-kickback statute whereby violations will result in damages equal to three times the amount involved as well as a penalty of $50,000 per violation. In addition, the new provisions expanded the exclusion requirements so that any person or entity convicted of three health care offenses is automatically excluded from federally funded health care programs for life. Individuals or entities convicted of two offenses are subject to mandatory exclusion of 10 years, while any provider or supplier convicted of any felony may be denied entry into the Medicare program by the Secretary of HHS if deemed to be detrimental to the best interests of the Medicare program or its beneficiaries.

The BBA also provides that any person or entity that arranges or contracts with an individual or entity that has been excluded from a federally funded health care program will be subject to civil monetary penalties if the individual or entity knows or should have known of the sanction.

Stark Law

The original Stark Law, known as Stark I and enacted as part of the Omnibus Budget Reconciliation Act (OBRA) of 1989, prohibits a physician from referring Medicare patients for clinical laboratory services to entities with which the physician (or an immediate family member) has a financial relationship, unless an exception applies. Sanctions for violations of the Stark Law may include denial of payment, refund obligations, civil monetary penalties and exclusion of the provider from the Medicare and Medicaid programs. The Stark Law prohibits the entity receiving the referral from filing a claim or billing for services arising out of the prohibited referral.

Provisions of OBRA 93, known as Stark II, amended Stark I to revise and expand upon various statutory exceptions, to expand the services regulated by the statute to a list of Designated Health Services, and expanded the reach of the statute to the Medicaid program. The provisions of Stark II generally became effective on January 1, 1995, with the first phase of Stark II regulations finalized on January 4, 2001. Most portions of the first phase regulations became effective in 2002. The additional Designated Health Services include: physical therapy, occupational therapy and speech language pathology services; radiology and certain other imaging services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services. The first phase of the final regulations implementing the Stark Law contains an exception for EPO and certain other dialysis-related outpatient prescription drugs furnished in or by an ESRD facility under many circumstances. In addition, the regulations made clear that services reimbursed by Medicare to a dialysis facility under the ESRD composite rate do not implicate the Stark Law. Further, the final Phase I regulations also adopted a definition of durable medical equipment which effectively excludes ESRD equipment and supplies from the category of Designated Health Services. Phase II of the final regulations to the Stark Law was released on March 26, 2004, and became effective on July 26, 2004. This phase of the regulations finalized all of the compensation exceptions to the Stark Law, including those for personal services arrangements and indirect compensation arrangements. In addition, Phase II revised the exception for EPO and certain other dialysis-related outpatient prescription drugs furnished in or by an ESRD facility to include certain additional drugs.

Several states in which we operate have enacted self-referral statutes similar to the Stark Law. Such state self-referral laws may apply to referrals of patients regardless of payor source and may contain exceptions different from each other and from those contained in the Stark Law.

Other Fraud and Abuse Laws

Our operations are also subject to a variety of other federal and state fraud and abuse laws, principally designed to ensure that claims for payment to be made with public funds are complete, accurate and fully comply with all applicable program rules.

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The civil monetary penalty provisions are triggered by violations of numerous rules under the Medicare statute, including the filing of a false or fraudulent claim and billing in excess of the amount permitted to be charged for a particular item or service. Violations may also result in suspension of payments, exclusion from the Medicare and Medicaid programs, as well as other federal health care benefit programs, or forfeiture of assets.

In addition to the statutes described above, other criminal statutes may be applicable to conduct that is found to violate any of the statutes described above.

Health Care Reform

Health care reform is considered by many countries to be a national priority. In the U.S., members of Congress from both parties and officials from the executive branch continue to consider many health care proposals, some of which are comprehensive and far-reaching in nature. Several states are also currently considering health care proposals. We cannot predict what additional action, if any, the federal government or any state may ultimately take with respect to health care reform or when any such action will be taken. Health care reform may bring radical changes in the financing and regulation of the health care industry, which could have a material adverse effect on our business and the results of our operations.

C. Organizational Structure

The following chart shows our organizational structure and our significant subsidiaries. Fresenius Medical Care Holdings, Inc. conducts its business as Fresenius Medical Care North America.

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D. Property, plant and equipment

Property

The table below describes our principal facilities. We do not own the land and buildings comprising our principal facilities in Germany. Rather, we lease those facilities on a long-term basis from Fresenius AG or one of its affiliates. This lease is described under Item 7.B. Related Party Transactions Real Property Lease.

Location	Floor Area (Approximate Square Meters)	Currently Owned or Leased by Fresenius Medical Care	Lease Expiration	Use
Bad Homburg, Germany	11,524	leased	December 2006	Corporate headquarters and administration
St. Wendel, Germany	49,732	leased	December 2006	Manufacture of polysulfone membranes, dialyzers and peritoneal dialysis solutions; research and development
Schweinfurt, Germany	19,605	leased	December 2006	Manufacture of hemodialysis machines and peritoneal dialysis cyclers; research and development
Palazzo Pignano, Italy	70,212	owned		Manufacture of bloodlines and tubing
L Arbresle, France	13,524	owned		Manufacture of polysulfone dialyzers, special filters and dry hemodialysis concentrates
Nottinghamshire, UK	5,110	owned		Manufacture of hemodialysis concentrate solutions
Barcelona, Spain	2,000	owned		Manufacture of hemodialysis concentrate solutions
Antalya, Turkey	8,676	leased	December 2022	Manufacture of bloodlines
Ankara, Turkey	1,000	leased	February 2009	Manufacture of hemodialysis concentrate solutions
Casablanca, Morocco	2,823	owned		Manufacture of hemodialysis concentrate solutions
Guadalajara, México	26,984	owned		Manufacture of peritoneal dialysis bags
Buenos Aires, Argentina	10,100	owned		Manufacture of hemodialysis concentrate solutions, dry hemodialysis concentrates, bloodlines and desinfectants
São Paulo, Brazil	5,734	owned		Manufacture of hemodialysis concentrate solutions
Bogotá, Colombia	5,700	owned		Manufacture of hemodialysis concentrate solutions, peritoneal

				dialysis bags, intravenous solutions
Hong Kong	1,013	Leased	February 2006	Corporate headquarters and administration Asia-Pacific
Hong Kong	3,515	Leased	November 2005 November 2006	various leases of Warehouse facility
Taiwan	1,315	leased	November December 2006	Sales & Technical & Administration office-FMC & Nephrocare
Milson Point, Australia	557	leased	November 2007	Administration
Smithfield, Australia	5,350	owned		Manufacture of hemodialysis
Altona VIC, Australia	2,400	leased	June 2006	Warehouse
Petaling Jaya, Malaysia	1,173	leased	November 2007	Administration & Warehouse
Seoul, South Korea	2,425	leased	March 2005 and August 2005	Administration
South Korea	1,067	leased	March 2005 March 2006	Branch offices
South Korea	3,306	leased	March 2005 and December 2005	Warehouses
Bangkok, Thailand	800	leased	December 2006	Warehouse

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Location	Floor Area (Approximate Square Meters)	Currently Owned or Leased by Fresenius Medical Care	Lease Expiration	Use
Tokyo, Japan	1,153	leased	December 2006 with 3-year renewal option	Headquarter and administration
Inukai, Japan	3,598	owned		Manufacture of filters
Buzen, Japan	8,369	owned		Manufacture of solutions
Fukuoka, Japan	4,541	leased	November 2005 with 1-year renewal option (terminated already at the end of February 2005)	Warehouse
Saga, Japan	4,970	leased	March 2010 with 5-Year renewal option	Warehouse
Lexington, Massachusetts	20,258	leased	October 2007 with 5-year renewal option	Corporate headquarters and administration North America
Newport Beach	143	leased	February 2007 with 2-year renewal option	General office use and administration North America
Walnut Creek, California	9,522	leased	June 2012 with 5-year renewal option	Manufacture of Hemodialysis machines and peritoneal dialysis cyclers; research and development; warehouse space
Ogden, Utah	41,807	owned		Manufacture polysulfone membranes and dialyzers and peritoneal dialysis solutions; research and development
Oregon, Ohio	13,934	leased	April 2019	Manufacture of liquid hemodialysis concentrate solutions
Perrysburg, Ohio	3,252	leased	August 2008	Manufacture of dry hemodialysis concentrates
Livingston, California	2,973	leased	October 2011 with a 5-year renewal option	Manufacture of liquid hemodialysis concentrates
Freemont, California	6,645	leased	August 2007 with 2-year renewal option	Clinical laboratory testing 3 Buildings
Rockleigh, New Jersey	7,897	leased	June 2007 with two 5-year renewal options	Clinical laboratory testing
Irving, Texas	6,506	leased	December 2010	Manufacture of liquid hemodialysis solution
Reynosa, Mexico	13,936	leased	June 2013	Manufacture of bloodlines

Reynosa, Mexico	4,645	owned		Warehouse
Pharr, Texas	511	leased	Month to Month	Warehouse
Redmond, Washington	1,904	leased	December 2008	Manufacture of Prosorba Columns

We lease most of our dialysis clinics, manufacturing, laboratory, warehousing and distribution and administrative and sales facilities in the U.S. and foreign countries on terms which we believe are customary in the industry. We own those dialysis clinics and manufacturing facilities that we do not lease.

For information regarding plans to expand our facilities and related capital expenditures, see Item 4.A. History and Development of the Company Capital Expenditures.

Item 5. ***Operating and Financial Review and Prospects***

You should read the following discussion and analysis of the results of operations of Fresenius Medical Care AG and its subsidiaries in conjunction with our historical consolidated financial statements and related notes contained elsewhere in this report. Some of the statements contained below, including those concerning future revenue, costs and capital expenditures and possible changes in our industry and competitive and financial conditions include forward-looking statements. We made these forward-looking statements based on our management s expectations and beliefs concerning future events which may affect us, but we cannot assure that such events will occur or that the results will be as anticipated. Because such statements involve risks and

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uncertainties, actual results may differ materially from the results which the forward looking statements express or imply. Such statements include the matters that we described in the discussion in this report entitled Forward-Looking Statements.

Our business is also subject to other risks and uncertainties that we describe from time to time in our public filings. Developments in any of these areas could cause our results to differ materially from the results that we or others have projected or may project.

Critical Accounting Policies

The Company s reported financial condition and results of operations are sensitive to accounting methods, assumptions and estimates that are the basis for our financial statements. The critical accounting policies, the judgments made in the creation and application of these policies, and the sensitivities of reported results to changes in accounting policies, assumptions and estimates are factors to be considered along with the Company s financial statements, and the discussion in Results of Operations .

Recoverability of Goodwill and Intangible Assets

The growth of our business through acquisitions has created a significant amount of intangible assets, including goodwill, trade names and management contracts. At December 31, 2004, the carrying amount of goodwill amounted to $3,445 million and non-amortizable intangible assets amounted to $441 million representing in total approximately 50% of our total assets.

In accordance with Statement of Financial Accounting Standards (SFAS) No. 142 *Goodwill and Other Intangible Assets*, we perform an annual impairment test of goodwill and non-amortizable intangible assets at least once a year for each reporting unit, or if events occur or circumstances change that would indicate the carrying value might be impaired (See also Note 1g) in our consolidated financial statements).

To comply with the provisions of SFAS No. 142, the fair value of the reporting unit is compared to the reporting unit s carrying amount. We estimate the fair value of each reporting unit using estimated future cash flows for the unit discounted by a weighted average cost of capital specific to that unit. Estimated cash flows are based on our budgets for the next three years, and projections for the following years based on an expected growth rate. The growth rate is based on industry and internal projections. The discount rates reflect any inflation in local cash flows and risks inherent to each reporting unit.

If the fair value of the reporting unit is less than its carrying value, a second step is performed which compares the fair value of the reporting unit s goodwill to the carrying value of its goodwill. If the fair value of the goodwill is less than its carrying value, the difference is recorded as an impairment.

A prolonged downturn in the healthcare industry with lower than expected increases in reimbursement rates and/or higher than expected costs for providing healthcare services and for procuring and selling products could adversely affect our estimated future cashflows. Future adverse changes in a reporting unit s economic environment could affect the discount rate. A decrease in our estimated future cash flows and/or a decline in the reporting units economic environment could result in impairment charges to goodwill and other intangible assets which could materially and adversely affect our future financial position and operating results.

Legal Contingencies

We are party to litigation relating to a number of matters as described in Note 16 Legal Proceedings in our Consolidated Financial Statements. The outcome of these matters may have a material effect on our financial position, results of operations or cash flows.

We regularly analyze current information including, as applicable, our defenses and provide accruals for probable contingent losses including the estimated legal expenses to resolve the matters. We use the resources of our internal legal department as well as external lawyers for the assessment. In making the decision regarding the need for loss accrual, we consider the degree of probability of an unfavorable outcome and our ability to make a reasonable estimate of the amount of loss.

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The filing of a suit or formal assertion of a claim or assessment, or the disclosure of any such suit or assertion, does not automatically indicate that accrual of a loss may be appropriate.

Accounts Receivable and Allowance for Doubtful Accounts

Trade accounts receivable are a significant asset of ours and the allowance for doubtful accounts is a significant estimate made by management. Trade accounts receivable were $1,463 million and $1,230 million at December 31, 2004 and 2003, respectively, net of allowances. The allowance for doubtful accounts was $180 million and $166 million at December 31, 2004 and 2003, respectively. The majority of our receivables relates to our dialysis service business in North America.

Dialysis care revenues are recognized and billed at amounts estimated to be receivable under reimbursement arrangements with third party payors. Medicare and Medicaid programs are billed at pre-determined net realizable rates per treatment that are established by statute or regulation. Revenues for non-governmental payors where we have contracts or letters of agreement in place are recognized at the prevailing contracted rates. The remaining non-governmental payors are billed at our standard rates for services and, in our North America segment, a contractual adjustment is recorded to recognize revenues based on historic reimbursement experience with those payors for which contracted rates are not predetermined. The contractual adjustment and the allowance for doubtful accounts are reviewed quarterly for their adequacy. No material changes in estimates were recorded for the contractual allowance in the periods presented.

The allowance for doubtful accounts is a significant management estimate and is based on the local payment and collection experience. FMS has over 500 subsidiaries and operates in over 53 different countries. Most payors are government institutions or government-sponsored programs with significant variations between the countries and even between payors within one country in local payment and collection practices. Specifically, public health institutions in a number of countries outside the U.S. require a significant amount of time until payment is made. Payment differences are mainly due to the timing of funding by local, state or federal government to the agency that is sponsoring the program that purchases our services or products. The collection of accounts receivable from product sales to third party distributors or dialysis clinics is affected by the same underlying causes, since these buyers of the products are reimbursed as well by government institutions or government programs.

In our US operations, the collection process is usually initiated 30 days after service is provided or upon the expiration of the time provided by contract. For Medicare and Medicaid, once the services are approved for payment, the collection process begins upon the expiration of a period of time based upon experience with Medicare and Medicaid. In all cases where co-payment is required the collection process usually begins within 30 days after service has been provided. In those cases where claims are approved for amounts less than anticipated or if claims are denied, the collection process usually begins upon notice of approval of the lessor amounts or upon denial of the claim. The collection process can be confined to internal efforts, including the accounting and sales staffs and, where appropriate, local management staff. If appropriate, external collection agencies may be engaged.

For our international operations, a significant number of payors are government entities whose payments are often determined by local laws and regulations. Depending on local facts and circumstances, the period of time to collect can be quite lengthy. In those instances where there are non-public payors, the same type of collection process is initiated as in the US.

Due to the number of subsidiaries and different countries that FMS operates in, our policy of determining when a valuation allowance is required considers the appropriate local facts and circumstances that apply to an account. While payment and collection practices vary significantly between countries and even agencies within one country, the government payors usually represent low credit risks. Accordingly, the length of time to collect does not indicate an increased credit risk and it is our policy to determine when receivables should be classified as bad debt on a local basis taking into account local practices. In all instances, local review of accounts receivable is performed on a regular basis, generally monthly. When all efforts to collect a receivable, including the use of outside sources where required and allowed, have been exhausted, and after appropriate management review, a receivable deemed to be uncollectible is considered a bad debt and written off.

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Estimates for the allowances for doubtful accounts receivable from the dialysis service business are mainly based on past collection history. Specifically, the allowances for the North American operations are based on an analysis of collection experience, recognizing the differences between payors and aging of accounts receivable. From time to time, accounts receivable are reviewed for changes from the historic collection experience to ensure the appropriateness of the allowances. The allowances in the international segment and the products business are also based on estimates and consider various factors, including aging, creditor and past collection history. Write-offs are taken on a claim by claim basis when the collection efforts are exhausted. A significant change in our collection experience, a deterioration in the aging of receivables and collection difficulties could require that we increase our estimate of the allowance for doubtful accounts. Any such additional bad debt charges could materially and adversely affect our future operating results.

If, in addition to our existing allowances, 1% of the gross amount of our trade accounts receivable as of December 31, 2004 was uncollectible through either a change in our estimated contractual adjustment or as bad debt, our operating income for 2004 would have been reduced by approximately 2%.

The following table shows the portion of major debtors or debtor groups of trade accounts receivable as at December 31, 2004. No single debtor other than U.S. Medicaid and Medicare accounted for more than 5% of total trade accounts receivable. Trade accounts receivable in the International segment are mainly due from government or government-sponsored organizations that are established in the various countries within which we operate.

Composition of trade accounts receivable as at December 31, 2004

U.S. Medicare and Medicaid Programs	22%
U.S. Commercial Payors	21%
U.S. Hospitals	7%
Self-Pay of U.S. patients	1%
Others	1%
International product customers and dialysis payors	48%
Total	100%

Self-Insurance Programs

FMCH, our largest subsidiary, is partially self-insured for professional, product and general liability, auto liability and worker s compensation claims under which we assume responsibility for incurred claims up to predetermined amounts above which third party insurance applies. Reported balances for the year include estimates of the anticipated expense for claims incurred (both reported and incurred but not reported) based on historical experience and existing claim activity. This experience includes both the rate of claims incidence (number) and claim severity (cost) and is combined with individual claim expectations to estimate the reported amounts.

Financial Condition and Results of Operations

Overview

We are engaged primarily in providing dialysis services and manufacturing and distributing products and equipment for the treatment of end-stage renal disease. In the U.S., we also perform clinical laboratory testing and provide perfusion, autotransfusion and therapeutic apheresis services. Perfusion maintains human heart and lung function during cardiovascular surgery. Autotransfusion is used during surgery to collect, filter and reinfuse a patient s own blood as an alternative to using donor blood. Therapeutic apheresis is the process of separating or removing illness causing substances from patient s blood or blood plasma. Dialysis is a lifesaving treatment for irreversible, lifelong end stage renal disease, and necessitates multiple treatments per week for the remainder of a patient s life. We estimate that providing dialysis services and distributing dialysis products and equipment represents an over $40 billion worldwide market with expected annual patient growth of 6%. Patient growth results from factors such as the aging population; increasing incidence of diabetes and hypertension, which

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frequently precedes the onset of ESRD; improvements in treatment quality, which prolong patient life; and improving standards of living in developing countries, which make life saving dialysis treatment available. Key to continued growth in revenue is our ability to attract new patients in order to increase the number of treatments performed each year. For that reason, we believe the number of treatments performed each year is a strong indicator of continued revenue growth and success. In addition, the reimbursement and ancillary services utilization environment significantly influences our business. In the past we experienced and also expect in the future generally stable reimbursements for dialysis services. This includes the balancing of unfavorable reimbursement changes in certain countries with favorable changes in other countries. The majority of treatments are paid for by governmental institutions such as Medicare in the United States. As a consequence of the pressure to decrease health care costs, reimbursement rate increases have been limited. Our ability to influence the pricing of our services is limited. Profitability depends on our ability to manage rising labor, drug and supply costs.

On December 8, 2003, the Medicare Prescription Drug, Modernization and Improvement Act of 2003 was enacted (the Medicare Modernization Act). This law makes several significant changes to U.S. government payment for dialysis services and pharmaceuticals. First, it increased the composite rate for renal dialysis facilities by 1.6% on January 1, 2005. Second, effective January 1, 2005, payments for ten separately billable dialysis-related medications will be based on average acquisition cost (as determined by the Office of the Inspector General (OIG) and updated by the Centers for Medicare and Medicaid Services of the U.S. Department of Health and Human Services, (CMS) and payments for the remaining separately billable dialysis-related medications will be based on average sales price (ASP) plus 6% (ASP is defined in the law as a manufacturer s ASP to all purchasers in a calendar quarter per unit of each drug and biological sold in that same calendar quarter, excluding sales exempt from best price and nominal price sales and including all discounts, chargebacks and rebates). Third, the difference between the determined acquisition cost-based reimbursement and what would have been received under the current average wholesale price-based (AWP-based) reimbursement methodology will be added to the composite rate. This add-back amount has been determined to be 8.7% of the composite rate and will be subject to an annual update based on the growth in drug spending. Fourth, effective April 1, 2005, providers will receive higher composite rate payments for certain patients based on their age, body mass index and body surface area. Fifth, beginning in 2006, the Secretary of the Department of Health and Human Services (the Secretary) is authorized to set payment for all separately billed drugs and biologicals at either acquisition cost or average sales price. Lastly, the Secretary is required to establish a three-year demonstration project to test the use of a fully case-mix adjusted payment system for ESRD services, beginning January 1, 2006. Under this project, separately billable drugs and biologicals and related clinical laboratory tests would be bundled into the facility composite rate. Participating facilities would receive an additional 1.6% composite rate increase. For a discussion of the composite rate for reimbursement of dialysis treatments, see Item 4B, Business Overview Regulatory and Legal Matters Reimbursement . We expect that the final regulations could have a non-material negative impact on our revenue from Medicare.

In July 2004, CMS proposed certain changes with respect to its EPO reimbursement and utilization guidelines. Its proposal reflects the agency s conclusion that the appropriate utilization of EPO should be monitored by considering both the patient s hemoglobin/hematocrit level and the dosage. Specifically, it proposed a pre-payment claims review process in which claims for EPO with hemoglobin levels below 13 (or hematocrit of 39) would not be targeted for review, but claims for EPO with hemoglobin levels above 13 would be reviewed based on the hemoglobin value and related EPO doses, and with payment limited to a fixed amount of EPO unless there is medical justification for the hemoglobin levels. The comment period on this policy draft was extended and ended on October 7, 2004. CMS has not yet finalized the new guidelines. If the EPO reimbursement/ utilization changes are adopted, this could have an adverse impact on our operating results.

Our operations are geographically organized and accordingly we have identified three operating segments, North America, International, and Asia Pacific. For reporting purposes, we have aggregated the International and Asia Pacific segments as International. We aggregated these segments due to their similar economic characteristics. These characteristics include same services provided and same products sold, same type patient population, similar methods of distribution of products and services and similar economic environments. Our Management Board member responsible for the profitability and cash flow of each segment s various businesses supervises the management of each

operating segment. The accounting policies of the operating segments are the

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same as those we apply in preparing our consolidated financial statements under accounting principles generally accepted in the United States (U.S. GAAP). Our management evaluates each segment using a measure that reflects all of the segment s controllable revenues and expenses.

With respect to the performance of our business operations, our management believes the most appropriate measure in this regard is operating income which measures our source of earnings. Financing is a corporate function which segments do not control. Therefore, we do not include interest expense relating to financing as a segment measurement. We also regard income taxes to be outside the segments control.

A. Results of Operations

The following tables summarize our financial performance and certain operating results by principal business segment for the periods indicated. Inter-segment sales primarily reflect sales of medical equipment and supplies from the International segment to the North America segment. We prepared the information using a management approach, consistent with the basis and manner in which our management internally disaggregates financial information to assist in making internal operating decisions and evaluating management performance.

	For the years ended December 31,		
	2004	2003	2002
		(in millions)	
Total revenue			
North America	$ 4,218	$ 3,857	$ 3,750
International	2,051	1,709	1,363
Totals	6,269	5,566	5,113
Inter-segment revenue			
North America	2	2	2
International	39	36	27
Totals	41	38	29
Total net revenue			
North America	4,216	3,855	3,748
International	2,012	1,673	1,336
Totals	6,228	5,528	5,084
Amortization and depreciation			
North America	126	120	139
International	105	95	70
Corporate	2	2	2
Totals	233	217	211
Operating Income			
North America	590	532	491
International	298	254	222
Corporate	(36)	(29)	(18)

Totals	852	757	695
Interest income	14	19	18
Interest expense	(197)	(230)	(244)
Income tax expense	(266)	(213)	(175)
Minority interest	(1)	(2)	(4)
Net income	$ 402	$ 331	$ 290

Year ended December 31, 2004 compared to year ended December 31, 2003

Highlights

Like 2003, the earnings increase in 2004 is characterized by improving margins in the North American segment partially offset by a decline of margins in Asia Pacific. Cash flow provided from operations reached

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$828 million and exceeded the prior year s cash flow from operations by $74 million. This favorable development is a result of our increased net income and focus on working capital management partially offset by a lower impact of liquidity provided by hedging of intercompany financings.

Consolidated Financials

Key Indicators for Consolidated Financials

			Change in %	
	2004	2003	as reported	at constant exchange rates
Number of treatments	18,794,109	17,821,185	5%	
Same store treatment growth in %	3.6%	4.9%		
Revenue in $ million	6,228	5,528	13%	10%
Gross profit in % of revenue	33.5%	33.1%		
Selling, general and administrative costs in % of revenue	19.0%	18.5%		
Net income in $ million	402	331	21%	

Net revenue increased for the year ended December 31, 2004 over the comparable period in 2003 due to growth in revenue in both dialysis care and dialysis products.

Dialysis care revenue grew by 13% to $4,501 million (12% at constant exchange rates) mainly due to higher treatment rates, acquisitions, as a result of an accounting change (implementation of Financial Accounting Standards Board Interpretation 46R (FIN 46R) issued December 2003 and effective March 31, 2004), and the effect of two additional treatment days in 2004. Same store treatment growth in 2004 declined from 2003 as a result of the loss of tenders in the International segment and the general market growth slow down in the North American segment. Dialysis product revenue increased by 11% to $1,727 million (5% at constant exchange rates) in the same period.

Gross profit margin improved in 2004 to 33.5% from 33.1% for 2003. The increase is primarily a result of higher treatment rates, higher margins for ancillary services in North America, higher number of treatments as a result of two additional treatment days in North America, operating improvements in Latin America and growth in regions which have higher gross margins offset by higher personnel and recruiting costs due to the nursing shortage in North America, a one time discount provided to a distributor in Japan, and reimbursement related price pressure in Japan. Depreciation and amortization expense for the period was $233 million compared to $217 million for the same period in the prior year.

Approximately 38% of the Company s 2004 worldwide revenues, as compared to 40% in 2003, are paid by and subject to regulations under governmental health care programs, primarily Medicare and Medicaid, administered by the United States government.

Selling, general and administrative costs increased from $1,022 million in 2003 to $1,182 million in 2004. Selling, general and administrative costs as a percentage of sales increased from 18.5% in 2003 to 19.0% in 2004. The increase is mainly due to increased personnel expenses in North America and growth in regions which have higher selling, general and administrative costs partially offset by receipt of a one time indemnification payment related to a clinic in the Asia Pacific region and reduced expenses due to cost efficiency control in Latin America. Net income for the period was $402 million compared to $331 million in 2003.

In 2004, 18.79 million treatments were provided. This represents an increase of 5.4% over 2003. Same store treatment growth was 3.6% with additional growth of 1.8% from acquisitions.

At December 31, 2004 we owned, operated or managed 1,610 clinics compared to 1,560 clinics at the end of 2003. During 2004, we acquired 29 clinics, opened 52 clinics and consolidated 31 clinics. The number of patients treated in clinics that we own, operate or manage increased to 124,400 at December 31, 2004 from approximately 119,250 at

December 31, 2003. Average revenue per treatment for worldwide dialysis services increased to $240 from $223 mainly due to worldwide improved reimbursement rates and favorable currency developments.

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The following discussions pertain to our business segments and the measures we use to manage these segments.

North America Segment

Key Indicators for North America Segment

	2004	2003	Change in %
Number of treatments	12,908,788	12,366,028	4%
Same store treatment growth in %	3.1%	3.8%	
Revenue in $ million	4,216	3,855	9%
Depreciation and amortization in $ million	126	120	6%
Operating income in $ million	590	532	11%
Operating income margin in %	14.0%	13.8%	

Revenue

Net revenue for the North America segment for 2004 increased because dialysis care revenue increased by 11% from $3,429 million to $3,795 million. This was partially offset by a 1% decrease in product sales.

The 11% increase in dialysis care revenue in 2004, was driven by organic revenue growth of 7%, 1% increase attributable to two extra dialysis days in 2004, 2% resulting from implementation of FIN 46R and 1% resulting from acquisitions. Organic revenue growth is a result of 3% growth in number of treatments and a 4% revenue per treatment growth. Same store treatment growth in 2004 declined from 2003 as a result of the general market growth slow down in the North America. For 2004, the administration of EPO represented approximately 23% of total North America revenue.

At the end of 2004, approximately 85,500 patients were being treated in the 1,130 clinics that we own, operate or manage in the North America segment, compared to approximately 82,400 patients treated in 1,110 clinics at the end of 2003. The average revenue per treatment, excluding laboratory testing revenue, increased from $267 in 2003 to $278 in 2004. Including laboratory testing, the average revenue per treatment increased from $278 in 2003 to $289 during 2004.

Dialysis product sales in both 2004 and 2003 include the sales of machines to third-party leasing companies which are leased back by our dialysis services division and sales to other vertically integrated dialysis companies. The volume of both these type transactions has been reduced in 2004 compared to 2003. In addition, the Company decided to focus sales efforts more on its internally produced products while decreasing emphasis on relatively low margin ancillary products manufactured by third-parties. These two factors resulted in a 1% decrease in dialysis product revenue from $426 million in 2003 to $421 million in 2004. Our dialysis products division measures its external sales performance based on its sales to the net available external market .

The Net available external market sales excludes machine sales to third parties, i.e., leasing companies, for machines utilized in our services division as well as sales to other vertically integrated dialysis companies and sales related to our adsorber business. Net available external market sales were flat in 2004 over the comparable period for 2003. The detail is as follows:

	Year ended December 31, 2004	Year ended December 31, 2003
	(in millions)	
Dialysis product sales	$ 421	$ 426
less sales to other vertically integrated dialysis companies and to leasing company of dialysis machines leased back	(28)	(34)

less sales related to adsorber business		(5)		(3)
Net available external market sales	$	388	$	389

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Operating income

Operating income margin increased 20 basis points from 13.8% in 2003 to 14.0% in 2004. The primary drivers of this margin improvement during 2004 are increases in commercial payor rates, improved ancillary margins, and incremental profits provided by two additional dialysis days in 2004 partially offset by the effect of the implementation of FIN 46R (0.2%). Cost per treatment increased from $242 in 2003 to $251 in 2004, primarily due to increased personnel and benefit costs, higher ancillary costs, and other miscellaneous costs partially offset by improvements in medical supply costs and reduced depreciation and amortization expense, as a percentage of revenue, mainly as a result of completing the depreciation and amortization of patient relationships acquired in 1997.

International Segment

Key Indicators for International Segment

			Change in %	
	2004	2003	as reported	at constant exchange rates
Number of treatments	5,885,321	5,455,157	8%	
Same store treatment growth in %	4.6%	7.7%		
Revenue in $ million	2,012	1,673	20%	11%
Depreciation and amortization in $ million	105	95	10%	
Operating income in $ million	298	254	17%	
Operating income margin in %	14.8%	15.2%		

Revenue

The increase in net revenues for the International segment resulted from increases in both dialysis care and dialysis product revenues. Acquisitions contributed approximately 3% while consolidations resulting from initial consolidation of entities as a result of an accounting change (implementation of FIN 46R) contributed approximately 1%. Organic growth during the period was 7% at constant exchange rates. Same store treatment growth in 2004 declined from 2003 as a result of the loss of tenders. The revenue increase was also attributable to a 9% exchange rate effect due to the continued strengthening of various local currencies against the dollar in 2004 and 2003.

Total dialysis care revenue increased during 2004 by 28% (19% at constant exchange rates) to $706 million in 2004 from $550 million for 2003. This increase is a result of organic growth of 6%, a 7% increase in contributions from acquisitions, a 6% contribution from consolidations resulting from implementation of FIN 46R and approximately 9% due to exchange rate fluctuations.

As of December 31, 2004, approximately 38,900 patients were being treated at 480 clinics that we own, operate or manage in the International segment compared to 36,850 patients treated at 450 clinics at December 31, 2003. In 2004, the average revenue per treatment increased from $101 to $120 ($111 at constant exchange rates) due to the strengthening of the local currencies against the U.S. dollar and increased reimbursement rates partially offset by higher growth in countries with reimbursement rates below the average.

Total dialysis product revenue for 2004 increased by 16% (7% at constant exchange rates) to $1,306 million mainly driven by organic growth.

Including the effects of the acquisitions, European region revenue increased 22% (11% at constant exchange rates), Latin America region revenue increased 30% (27% at constant exchange rates), and Asia Pacific region revenue increased 6% (1% at constant exchange rates).

Operating income

Our operating income margin decreased from 15.2% during 2003 to 14.8% in 2004. The main cause for the margin decrease was price pressure in Japan as a result of biannual reimbursement rate reductions, a one-time

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discount provided to a distributor in Japan, unfavorable foreign currency transaction effects related to the purchase of products from our European production sites coupled with the appreciation of the euro against local currencies and the effect of the implementation of FIN 46R (0.2%) partially offset by receipt of a one-time indemnification payment related to a clinic in the Asia Pacific region, operating improvements in Latin America such as a reimbursement rate increase in Venezuela and cost control improvements throughout Latin America.

Latin America

Our subsidiaries in Latin America contributed approximately 4% of our worldwide revenue and approximately 3% of our operating income in 2004. Our operations in Latin America were affected by the financial crisis and currency devaluations in some currencies in Latin America. Because of these issues, we continue to experience lower than anticipated reimbursement rates, margin pressure and foreign currency exchange losses.

In 2004, sales in Latin America increased 30% (27% at constant exchange rates) and operating income increased 175% (161% at constant exchange rates) compared to 2003. The consolidation of dialysis clinics in accordance with FIN46R contributed 13% of the revenue growth and had no significant impact on operating income. A worsening of the economic situation in Latin America, a further devaluation of the Latin American currencies against the U.S. dollar or other unfavorable economic developments in Latin America, could result in an impairment of long-lived assets and goodwill.

Corporate

We do not allocate corporate costs to our segments in calculating segment operating income as we believe that these costs are not within the control of the individual segments. These corporate costs primarily relate to certain headquarters overhead charges including accounting and finance, professional services, etc.

Total corporate operating loss was $36 million in 2004 compared to $29 million in the same period of 2003.

The following discussions pertain to our total Company costs.

Interest

Interest expense for 2004 decreased 15% compared to the same period in 2003 due to a lower debt level resulting from the use of positive cash flows, lower interest rates, and the conversion of a portion of debt from fixed into variable interest rates.

Income Taxes

The effective tax rate for 2004 was 39.7% compared to 39.0% in 2003.

Year ended December 31, 2003 compared to year ended December 31, 2002

Highlights

The earnings increase in 2003 is characterized by a stabilization of the operating margins. This was a result of two developments:

- improving operating margin in North America. After significant investments into our UltraCare program, which included the conversion to single-use dialyzers, the program now provides returns which contributed to an improvement of the operating margin in North America from 13.1% in 2002 to 13.8% in 2003.

- price pressure in Germany, impact from the politically unstable situation in the Middle East and changes in the distribution system in Asia Pacific which led to a reduction of the operating margins in the International segment from 16.6% in 2002 to 15.2% in 2003.

During 2003, we reached settlements on all litigation relating to activities involving W.R. Grace before the 1996 Merger. We believe that the 2001 special charge for legal matters is sufficient to cover all related costs.

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Cash flow provided from operations reached $754 million and exceeded the prior year s cash flow from operations by $204 million. This favorable development is a result of our focus on receivable collections and $132 million of temporary liquidity provided by hedging of certain inter-company financing transactions.

Consolidated Financials

Key Indicators for Consolidated Financials

			Change in %	
	2003	**2002**	**as reported**	**at constant exchange rates**
Number of treatments	17,821,185	16,383,615	9%	
Same store treatment growth in %	4.9%	4.8%		
Revenue in $ million	5,528	5,084	9%	5%
Gross profit in % of revenue	33.1%	32.6%		
Selling, general and administrative costs in % of revenue	18.5%	18.0%		
Net income in $ million	331	290	14%	

Net revenue increased for the year ended December 31, 2003 over the comparable period in 2002 due to growth in revenue in both dialysis care and dialysis products.

Dialysis care revenue grew by 7% to $3,978 million (6% at constant exchange rates) in 2003 mainly due to the growth in same store treatments, combined with acquisitions and the transition of billing for Medicare peritoneal dialysis patients from Method II billing to Method I billing. In 2002, peritoneal dialysis patients in the United States were billed by our products division (Method II) for their treatments. Beginning on January 1, 2003, they were billed by our services division (Method I). Dialysis product revenue increased by 13% to $1,549 million (3% at constant exchange rates) in the same period.

Gross profit margin improved to 33.1% in the year ended December 31, 2003 from 32.6% for 2002. The increase is primarily a result of reduced dialysis care operating costs and dialysis product margin improvements in North America partially offset by the lower margin in the International segment. Depreciation and amortization expense for 2003 was $217 million compared to $211 million in 2002.

Approximately 40% of the Company s worldwide revenues are paid by and subject to regulations under governmental health care programs, primarily Medicare and Medicaid, administered by the United States government in both 2003 and 2002, respectively.

Selling, general and administrative costs increased from $914 million in 2002 to $1,022 million in 2003. Selling, general and administrative costs as a percentage of sales increased from 18.0% in 2002 compared to 18.5% in 2003. This was in part due to the one time pension curtailment gain of $12.6 million in 2002 which reduced our selling, general and administrative costs for that year. The remaining increase is mainly due to growth in international regions which have higher selling, general and administrative expenses partially offset by $19 million of amortization expense for certain patient relationships and other intangible assets acquired in the 1996 Merger which were fully amortized in the fourth quarter of 2002. Net income for the period was $331 million compared to $290 million in 2002. Net income in 2002 was impacted by the $12 million loss attributable to the early redemption of trust preferred securities.

In 2003, 17.8 million treatments were provided. This represents an increase of 9% over the same period in 2002. Same store treatment growth was 5% with additional growth of 3% from acquisitions. The remaining 1% increase in dialysis treatments was due to the transition of peritoneal dialysis patients from Method II (dialysis products) to Method I (dialysis service) billing in North America.

At December 31, 2003 we owned, operated or managed 1,560 clinics compared to 1,480 clinics at the end of 2002. During 2003, we acquired 42 clinics, opened 76 clinics and combined 38 clinics. The number of patients treated in

clinics that we own, operate or manage increased from approximately 112,200 at December 31, 2002 to 119,250 at December 31, 2003. Average revenue per treatment for world-wide dialysis services decreased from

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$226 to $223 mainly due to the transition of peritoneal patients from Method II billing (dialysis products) to Method I (dialysis services).

The following discussions pertain to our business segments and the measures we use to manage these segments.

North America Segment

Key Indicators for North America Segment

	2003	2002	Change in %
Number of treatments	12,366,028	11,638,740	6%
Same store treatment growth in %	3.8%	3.6%	
Revenue in $ million	3,855	3,748	3%
Depreciation and amortization in $ million	120	139	-14%
Operating income in $ million	532	491	8%
Operating income margin in %	13.8%	13.1%	

Revenue

Net revenue for the North America segment for the year ended December 31, 2003 grew in 2003 because dialysis care revenue increased by 4% from $3,293 to $3,429 million. This was partially offset by a decrease in product sales.

The increase in dialysis care revenue was driven by a 6% increase in treatments. Same store treatment growth was 4% and 1% resulted from acquisitions. A further 2% increase in dialysis treatments was due to a transition of peritoneal dialysis patients from Method II (billed by dialysis products) to Method I (billed by dialysis services). This was offset by a 1% decrease in treatments lost from clinics that were sold or closed and one less treatment day in 2003 compared to 2002. For this year the administration of EPO represented approximately 23% of total revenue.

At the end of 2003, approximately 82,400 patients were being treated in the 1,110 clinics that we own, operate or manage in the North America segment, compared to approximately 79,600 patients treated in 1,080 clinics at the end of 2002. The average revenue per treatment excluding laboratory testing revenue decreased from $274 in 2002 to $267 in 2003. Including laboratory testing the average revenue per treatment decreased from $285 in 2002 to $278 during 2003. This was mainly due to the transfer of our Method II patients to Method I.

Dialysis product sales in both 2003 and 2002 include the sales of machines to a third-party leasing company which are leased back by our dialysis services division. Dialysis product sales in 2002 also includes Method II peritoneal dialysis revenues for our dialysis services patients. Method II patients were transferred to Method I effective January 1, 2003. Therefore there were no similar Method II revenues recorded in 2003. This reclassification of patients was the main cause of a 6% decrease in dialysis product revenue from $454 million in 2002 to $426 million in 2003. This was offset by an increase of product sales due to the acquisition of the adsorber business of Fresenius AG in 2003. Our dialysis products division measures its external sales performance based on its sales to the net available external market. The net available external market sales excludes machine sales to third parties for machines utilized in the services division and Method II revenues involving our dialysis services division as well as sales to other vertically integrated dialysis companies and sales

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related to the adsorber business. Net available external market sales increased by 4% in 2003 over the comparable period 2002. The detail is as follows:

	Year ended December 31, 2003	Year ended December 31, 2002
	(in millions)	
Dialysis product sales	$ 426	$ 454
less sales to other vertically integrated dialysis companies and to leasing company of dialysis machines leased back	(34)	(42)
less method II and other		(37)
less sales related to adsorber business	(3)	
Product sales to available external market	$ 389	$ 375

Operating income

The increase in our operating margin was caused by lower depreciation and amortization as a result of the completion of amortization relating to patient relationships and other intangible assets acquired in the 1996 merger with an estimated useful life ending in the fourth quarter of 2002 and by completion of the single-use dialyzer conversion which resulted in a reduction of dialysis care operating costs and an increase in product margin. Previous periods had been adversely affected by implementation costs of the single-use dialyzer program. This was partially offset by the pension curtailment gain of $12.6 million in 2002.

International Segment

Key Indicators for International Segment

			Change in %	
	2003	2002	as reported	at constant exchange rates
Number of treatments	5,455,157	4,744,875	15%	
Same store treatment growth in %	7.7%	8.1%		
Revenue in $ million	1,673	1,336	25%	11%
Depreciation and amortization in $ million	95	70	37%	
Operating income in $ million	254	222	14%	
Operating income margin in %	15.2%	16.6%		

Revenue

The increase in net revenues for the International segment resulted from increases in both dialysis care and dialysis product revenues. Acquisitions contributed approximately $53 million (4%). Organic growth during the period was 7% ($90 million) at constant exchange rates. Revenues also benefited from a $193 million (14%) exchange rate effect due to the continued strengthening of the euro against the dollar in 2003.

Total dialysis care revenue increased during 2003 by 32% (18% at constant exchange rates) to $550 million in 2003 from $416 million the same period of 2002. This increase is a result of base business growth of $40 million combined with $36 million in growth from acquisitions, improved by approximately $58 million due to exchange rate fluctuations.

As of December 31, 2003, approximately 36,850 patients were being treated at 450 clinics that we own, operate or manage in the International segment compared to 32,600 patients treated at 400 clinics at December 31, 2002. The average revenue per treatment increased from $88 to $101 ($90 at constant exchange rates) due to the strengthening of the local currencies against the U.S. dollar and increased reimbursement rates partially offset by growth in countries with reimbursement rates below the average.

Total dialysis product revenue for 2003 increased by 22% (7% at constant exchange rates) to $1,123 million. Including the effects of the acquisitions, the European region revenue increased $272 million, a 30% increase

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(10% increase at constant exchange rates), the Latin America region revenue increased $36 million or 24% (30% at constant exchange rates), while the Asia Pacific region revenue increased $28 million or 10% (4% at constant exchange rates).

Operating income

Our operating income margin decreased from 16.6% to 15.2%. The main causes of this decrease were price pressure in Europe, especially related to reimbursement changes in Germany which came into effect in the middle of 2003, increased cost of revenue due to the strengthening of the euro, lost revenues due to political instability in the Middle East, changes in the distribution system in Asia Pacific and higher depreciation and amortization mainly as a result of the expansion of production facilities in Europe and Asia Pacific. These negative factors were partially offset by retroactive reimbursement rate increases in Italy, Portugal and Venezuela.

Latin America

Our subsidiaries in Latin America contributed approximately 3% of our worldwide revenue and approximately 1% of our operating income in 2003. Our operations in Latin America were affected by the financial crisis and currency devaluations in nearly all currencies in Latin America whereas the Argentine Peso has recovered slightly. Because of these issues, we are experiencing lower than anticipated reimbursement rates, margin pressure and foreign currency exchange losses. In addition, the start-up of production and the entry into the peritoneal dialysis market in Mexico had an adverse effect on our margin in 2003.

In 2003, sales in Latin America increased 24% (30% at constant exchange rates) and operating income increased 21% (17% at constant exchange rates) compared to 2002. A worsening of the crisis in Latin America, a further devaluation of the Latin American currencies against the U.S. dollar or other unfavorable economic developments in Latin America, could result in an impairment of long lived assets and goodwill.

Corporate

We do not allocate corporate costs to our segments in calculating segment operating income as we believe that these costs are not within the control of the individual segments. These corporate costs primarily relate to certain headquarters overhead charges including accounting and finance, professional services, etc.

Total corporate operating loss was $(29) million in the year ended December 31, 2003 compared to $(18) million in the same period of 2002 to a large extent due to currency effects.

The following discussions pertain to our total Company costs.

Interest

Interest expense for 2003 decreased 6% compared to the same period in 2002 due to the charge recorded in the first quarter of 2002 for the redemption of trust preferred securities. See Note 9 Mandatorily Redeemable Trust Preferred Securities in our Consolidated Financial Statements.

Income Taxes

The effective tax rate for the year ended December 31, 2003 was 39.0% compared to 37.4% during the same period in 2002. This increase was caused by an increase of additional tax provisions and an increase in German tax rates in 2003.

B. Liquidity and Capital Resources

Liquidity

Our primary sources of liquidity have historically been cash from operations, cash from short-term borrowings as well as from long-term debt from third parties and from related parties and cash from issuance of Preference shares and trust preferred securities. Cash from operations is impacted by the profitability of our business and the development of our working capital, principally receivables. The profitability of our business

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depends significantly on reimbursement rates. Approximately 72% of our revenues are generated by providing dialysis treatment, a major portion of which is reimbursed by either public health care organizations or private insurers. For the year ended December 31, 2004, approximately 38% of our consolidated revenues resulted from U.S. federal health care benefit programs, such as Medicare and Medicaid reimbursement. Legislative changes could affect all Medicare reimbursement rates for the services we provide, as well as the scope of Medicare coverage. A decrease in reimbursement rates could have a material adverse effect on our business, financial condition and results of operations and thus on our capacity to generate cash flow. See Overview , above, for a discussion of recent Medicare reimbursement rate changes. Furthermore cash from operations depends on the collection of accounts receivable. We could face difficulties in enforcing and collecting accounts receivable under some countries legal systems. Some customers and governments may have longer payment cycles. This could have a material adverse effect on our capacity to generate cash flow.

The accounts receivable balance at December 31, 2004 and 2003, net of valuation allowances, represented approximately 84 and 89 days of net revenue, respectively. This favorable development is mainly a result of our management effort to improve collection of receivables. The development of days sales outstanding by operating segment is shown in the table below.

Development of Days Sales Outstanding

	As at Dec. 31, 2004	As at Dec. 31, 2003
North America	67	72
International	119	127
Total	84	89

Cash from short-term borrowings can be generated by selling interests in accounts receivable (accounts receivable facility) and by borrowing from our parent Fresenius AG. Long-term financing is provided by the revolving portion and the term loan under our 2003 Senior Credit Agreement and has been provided through the issuance of our euro notes and trust preferred securities. We believe that our existing credit facilities, cash generated from operations and other current sources of financing are sufficient to meet our foreseeable needs.

At December 31, 2004 and 2003, we had approximately $635 million and $463 million, respectively, of unused borrowing capacity available under the revolving portion of our 2003 Senior Credit Agreement.

Our amended 2003 Senior Credit Agreement and the indentures relating to our trust preferred securities include covenants that require us to maintain certain financial ratios or meet other financial tests. Under our 2003 Senior Credit Agreement, we are obligated to maintain a minimum consolidated net worth, a minimum consolidated interest coverage ratio (ratio of consolidated EBITDA to consolidated net interest expense as defined in the 2003 Senior Credit Agreement) and a certain consolidated leverage ratio (ratio of consolidated funded debt to consolidated EBITDA as defined in the 2003 Senior Credit Agreement).

Our amended 2003 Senior Credit Agreement and our indentures include other covenants which, among other things, restrict or have the effect of restricting our ability to dispose of assets, incur debt, pay dividends (limited to $180 million in 2005, dividends paid in 2004 were $122 million) and other restricted payments, create liens or make capital expenditures, investments or acquisitions. The breach of any of the covenants could result in a default under the 2003 Senior Credit Agreement or the notes underlying our trust preferred securities, which could, in turn, create additional defaults under the agreements relating to our other long-term indebtedness. In default, the outstanding balance under the amended 2003 Senior Credit Agreement becomes due at the option of the Lenders. As of December 31, 2004, we are in compliance with all financial covenants under the 2003 Senior Credit Agreement.

The Company has an accounts receivable facility whereby certain receivables are sold to NMC Funding, a special purpose entity and a wholly-owned subsidiary. NMC Funding then sells and assigns undivided ownership interests in the accounts receivable to certain bank investors. Effective January 1, 2004 the accounts receivable facility was amended whereby NMC Funding now retains the right to repurchase all transferred interests in the

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accounts receivable sold to the banks under the facility. As we now have the right at any time to repurchase the then outstanding interests, the receivables remain on our Consolidated Balance Sheet and the proceeds from the sale of undivided interests are recorded as short-term borrowings. The repurchase of all transferred interests in the accounts receivable would result in the termination of the accounts receivable facility under the terms of the facility agreement. On October 21, 2004 the Company amended the accounts receivable facility to extend the maturity date to October 20, 2005.

Our capacity to generate cash from the accounts receivable facility depends on the availability of sufficient accounts receivable that meet certain criteria defined in the agreement with the third party funding corporation. A lack of availability of such accounts receivable could have a material impact on our capacity to utilize the facility for our financial needs.

The settlement agreement with the asbestos creditors committees on behalf of the W.R. Grace & Co. bankruptcy estate (see Item 8.A.7, Legal Proceedings) provides for payment by the Company of $115 million upon approval of the settlement agreement by the U.S. District Court, which has occurred, and confirmation of a W.R. Grace & Co. bankruptcy reorganization plan that includes the settlement. The $115 million obligation is included in the special charge we recorded in 2001 to address 1996 merger-related legal matters.

We are subject to ongoing tax audits in the U.S., Germany and other jurisdictions. We have received notices of unfavorable adjustments and disallowances in connection with certain of the audits. We are contesting, including appealing certain of these unfavorable determinations. We may be subject to additional unfavorable adjustments and disallowances in connection with ongoing audits. If our objections and any final audit appeals are unsuccessful, we could be required to make additional tax payments. With respect to adjustments and disallowances currently on appeal, we do not anticipate that an unfavorable ruling would have a material impact on our results of operations. We are not currently able to determine the timing of these potential additional tax payments. If all potential additional tax payments and the Grace Chapter 11 Proceedings settlement payment were to occur contemporaneously, there could be a material adverse impact on our operating cash flow in the relevant reporting period. Nonetheless, we anticipate that cash from operations and, if required, our available liquidity will be sufficient to satisfy all such obligations if and when they come due.

Dividends

Consistent with prior years, we will continue to follow an earnings-driven dividend policy. The Management Board and the Supervisory Board will propose to the shareholders at the Annual General Meeting a dividend, with respect to 2004 and payable in 2005, of 1.12 per ordinary share (2003: 1.02) and 1.18 per preference share (2003: 1.08) for shareholder approval at the annual general meeting on May 24, 2005. The total expected dividend payment is approximately 109 million and we paid approximately $122 million in 2004 for dividends with respect to 2003. Our 2003 Senior Credit Agreement limits disbursement for dividends and certain other transactions relating to our own equity type instruments during 2005 to $180 million in total.

Analysis of Cash Flow

Year ended December 31, 2004 compared to year ended December 31, 2003

Operations

We generated cash from operating activities of $828 million in the year ended December 31, 2004 and $754 million in the comparable period in 2003, an increase of about 10% over the prior year. Cash flows were primarily generated by increase in net income and working capital improvements.

Investing

Cash used in investing activities decreased from $369 million to $365 million mainly because of decreased capital expenditures but this decrease was offset by increased cash acquisition payments. In 2004, we paid approximately $104 million ($65 million for the North American segment and $39 million for the International segment) cash for acquisitions consisting primarily of dialysis clinics. In the same period in 2003, we paid approximately $92 million ($40 million for the North American segment and $52 million for the International

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segment) cash for acquisitions consisting primarily of dialysis clinics and the adsorber business acquired from Fresenius AG.

In addition, capital expenditures for property, plant and equipment net of disposals were $261 million in 2004 and $276 million in 2003. In 2004, capital expenditures were $157 million in the North America segment and $104 million for the International segment. In 2003, capital expenditures were $170 million in the North America segment and $106 million for the International segment. The majority of our capital expenditures was used for the maintenance of existing clinics, equipping new clinics, distribution activities in our products business and the expansion of production facilities in Germany, France, Italy and North America. Capital expenditures were approximately 4% of total revenue.

Financing

Net cash used in financing was $452 million in 2004 compared to cash used in financing of $416 million in 2003. Although we increased our Accounts Receivable Facility, our total external financing needs decreased due to higher cash from operating activities partially offset by higher dividend payments. Cash on hand was $59 million at December 31, 2004 compared to $48 million at December 31, 2003.

On February 21, 2003, we entered into an amended and restated bank agreement, (the 2003 Senior Credit Facility), with Bank of America N.A., Credit Suisse First Boston, Dresdner Bank AG New York, JPMorgan Chase Bank, The Bank of Nova Scotia and certain other lenders (collectively, the Lenders), pursuant to which the Lenders made available to the Company and certain subsidiaries and affiliates an aggregate amount of up to $1.5 billion through three credit facilities.

Through a series of amendments in 2003 and 2004, we voluntarily reduced the aggregate amount available to $1.2 billion while increasing the available amounts under the revolving credit portion and reducing the amounts available under the term loan portion. In addition, the amendments reduced the term loan interest rates by 25 basis points in 2003 and an additional 75 basis points in 2004 and the revolving credit interest rates by 62.5 basis points in 2004. The termination date was extended until February 28, 2010. Under the 2004 amendments, we can increase the amount of revolving credit by up to $200 million during the life of the 2003 Senior Credit Agreement.

The Company has approximately $6 million in financing outstanding at December 31, 2004, from Fresenius AG including $3 million in loans and approximately $3 million due May 2005 representing the balance due on the Company s purchase of the adsorber business from Fresenius AG in 2003. At December 31, 2003, the balance outstanding was $30 million from Fresenius AG.

On March 28, 2003, FMCH redeemed all of its outstanding shares of Class D Special Dividend Preferred Stock (Class D Shares) at a total cash outflow of approximately $9 million.

EBITDA

EBITDA (earnings before interest, taxes, depreciation and amortization) was approximately $1,085 million, 17.4% of sales, for 2004 and $974 million, 17.6% of sales, for 2003. EBITDA is the basis for determining compliance with certain covenants contained in our 2003 Senior Credit Agreement, our Euro Notes and the indentures relating to our outstanding trust preferred securities. You should not consider EBITDA to be an alternative to net earnings determined in accordance with U.S. GAAP or to cash flow from operations, investing activities or financing activities. In additions, not all funds depicted by EBITDA are available for management s discretionary use. For example, a substantial portion of such funds are subject to contractual restrictions and functional requirements for debt service, to fund necessary capital expenditures and to meet other commitments from time to time as described in more detail elsewhere in this annual report on Form 20-F. EBITDA, as

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calculated, may not be comparable to similarly titled measures reported by other companies. A reconciliation of cash flow provided by operating activities to EBITDA is calculated as follows:

Reconciliations of measures to consolidated totals.

	2004	2003	2002
Total EBITDA of reporting segments	$ 1,084,931	$ 973,813	$ 905,522
Interest expense, net	(183,746)	(211,759)	(226,517)
Income tax expense, net	(265,415)	(212,714)	(175,074)
Deferred income taxes	34,281	91,312	58,449
Changes in operating assets and liabilities	141,979	(17,910)	(47,011)
Cash inflow from Hedging	14,514	131,654	24,542
Other items, net	1,299	(377)	10,007
Net cash provided by operating activities	$ 827,843	$ 754,019	$ 549,918

Year ended December 31, 2003 compared to year ended December 31, 2002

Operations

We generated cash from operating activities of $754 million in 2003 and $550 million in the comparable period in 2002, an increase of approximately 37% over the prior year. Cash flows benefited from $132 million of temporary liquidity provided by hedging of certain intercompany financing transactions, improved accounts receivable collections and lower prepaid expenses and other current assets. We classify the cash outflows from our accounts receivable securitization program in the amount of $287 million as a financing activity.

Investing

Cash used in investing activities increased from $281 million to $369 million mainly because of increased purchases of property, plant and equipment. Capital expenditures for property, plant and equipment net of disposals were $276 million for the year ended December 31, 2003 and $201 million for the comparable period in 2002. In 2003, capital expenditures were $170 million in the North America segment and $106 million for the International segment. In 2002, capital expenditures were $98 million in the North America segment and $103 million for the International segment. The majority of our capital expenditures were used for equipment in new clinics, the buyout of an equipment lease for our Ogden, Utah, facility, improvements to existing clinics, and expansion of production facilities. Net capital expenditures were approximately 5% of total revenue.

In 2003, we paid approximately $92 million ($40 million for the North American segment and $52 million for the International segment) cash for acquisitions consisting primarily of the adsorber business acquired from Fresenius AG and dialysis clinics. In accordance with the requirements of the pooling agreements relating to outstanding Ordinary shares and Preference shares, the acquisition of the Fresenius AG adsorber business was approved by our independent directors. See Item 10, Additional Information Description of the Pooling Agreements. In the same period in 2002, we paid approximately $80 million ($38 million for the North American segment and $42 million for the International segment) cash for acquisitions consisting primarily of dialysis clinics.

Financing

Net cash used in financing was $416 million in 2003 compared to $265 million in 2002. Our financing needs decreased due to higher operating cash flow partially offset by higher payments for investing activities, higher dividend payments and payments for the redemption of the FMCH Class D Preferred Stock. Cash on hand was $48 million at December 31, 2003 compared to $65 million at December 31, 2002.

On February 21, 2003, we entered into an amended and restated bank agreement with Bank of America N.A., Credit Suisse First Boston, Dresdner Bank AG New York, JPMorgan Chase Bank, The Bank of Nova Scotia and certain other lenders (collectively, the Lenders), pursuant to which the Lenders have made

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available to the Company and certain subsidiaries and affiliates an aggregate amount of up to $1.5 billion through three credit facilities. On August 22, 2003, the 2003 Senior Credit Agreement was amended so that, in effect, the aggregate amount of $1.5 billion was voluntarily reduced to $1.4 billion and the interest rate on a new term loan facility (Loan C) was 25 basis points lower than the interest rate on Loan B which was repaid. Funds available under this agreement were used to refinance the previous credit agreement s outstanding balances and to pay down $287 million of our accounts receivable facility.

On March 28, 2003, FMCH redeemed all of its outstanding shares of Class D Special Dividend Preferred Stock (Class D Shares) at a total cash outflow of approximately $9 million.

On February 14, 2002, we redeemed the entire $360 million amount outstanding of our 9% Trust Preferred Securities due 2006, utilizing funds borrowed under our 1996 senior credit agreement. A loss of $12 million after tax was incurred as a result of the early redemption of debt, consisting of $16 million of redemption premiums plus a $4 million write-off of associated debt issuance costs, less a $8 million tax benefit.

Further financing was provided by Fresenius AG at different levels throughout the year. As of December 31, 2003 the balance outstanding was $30 million.

Obligations

The following table summarizes, as of December 31, 2004, our obligations and commitments to make future payments under our long-term debt, trust preferred securities and other long-term obligations, and our commitments and obligations under lines of credit and letters of credit.

		Payments due by period of		
Contractual Cash Obligations	**Total**	**1 Year**	**2-5 Years**	**Over 5 Years**
Trust Preferred Securities	$ 1,279	$	$ 650	$ 629
Long Term Debt	769	227	466	76
Capital Lease Obligations	7	3	3	1
Operating Leases	1,048	239	542	267
Unconditional Purchase Obligations	151	87	64	
Other Long-term Obligations	2	2		
Letters of Credit	80	80		
	$ 3,336	$ 638	$ 1,725	$ 973

		Expiration per period of		
Available Sources of Liquidity	**Total**	**1 Year**	**2-5 Years**	**Over 5 Years**
Unused Senior Credit Lines	$ 635	$	$	$ 635
Other Unused Lines of Credit	128	128		
	$ 763	$ 128	$	$ 635

The amount of guarantees and other commercial commitments at December 31, 2004 is not significant.

Borrowings

Short-term borrowings of $83 million and $89 million at December 31, 2004, and 2003, respectively, represent amounts borrowed by certain of our subsidiaries under lines of credit with commercial banks. The average interest rates on these borrowings at December 31, 2004, and 2003 was 4.69% and 3.38%, respectively. For information regarding short-term borrowings from affiliates see Note 2b) in our Consolidated Financial Statements.

Excluding amounts available under the 2003 Senior Credit Agreement (as described under Financing above), at December 31, 2004, we had $128 million available under such commercial bank agreements. Some of these lines of credit are secured by the individual borrowers accounts receivable and contain various covenants

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including, but not limited to, requirements for maintaining defined levels of working capital, net worth, capital expenditures and certain financial ratios.

In January 2004, we amended our accounts receivable securitization program which provides borrowings up to a maximum of $460 million on an ongoing basis. Under the terms of the amendment, we now retain the rights to repurchase all transferred interests in the accounts receivable sold to the banks under the facility. As a result, the receivables remain on the Consolidated Balance Sheet with the proceeds from the sale of the undivided interests recorded as short-term borrowings. Prior to the amendment, the receivables sold were removed from the Consolidated Balance Sheet. At December 31, 2004, we had outstanding borrowings under the facility of $336 million with effective interest rates ranging from 1.00%-2.23% during the year. At December 31, 2003, $158 million had been received and were reflected as reductions to accounts receivables. On October 21, 2004, we amended the facility to extend the maturity date to October 21, 2005.

On February 21, 2003, we entered into an amended and restated senior credit agreement with Bank of America N.A, Credit Suisse First Boston, Dresdner Bank AG New York, JPMorgan Chase Bank, The Bank of Nova Scotia, and certain other financial institutions. Pursuant to the agreement, the Lenders made available to the Company and certain subsidiaries and affiliates a credit facility comprising revolving and term loan facilities, currently a revolving facility of $750 million and a term loan facility of $450 million (Loan A-1). (See Financing above.)

In 2001, we issued four tranches of senior notes (Euro Notes) totaling 129 million. The first tranche was for 80 million with a fixed interest rate of 6.16% and the second and third tranches for 29 million and 15 million, respectively, with variable interest rates which averaged 3.51% in 2004 and 3.84% in 2003. The final tranche was for 5 million at a fixed rate of 5.33%. All four tranches have a maturity date of July 13, 2005. Both floating rates are tied to the EURIBOR rate.

Recently Issued Accounting Standards

In November, 2004, the Financial Accounting Standards Board issued SFAS No. 151, *Inventory Costs an amendment of ARB No. 43, Chapter 4* (FAS 151), which is the result of its efforts to converge U.S. accounting standards for inventories with International Financial Reporting Standards. This statement requires abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage) to be recognized as current-period charges. It also requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. FAS 151 will be effective for inventory costs incurred during fiscal years beginning after June 15, 2005. We are in the process of determining the impact on our consolidated financial statements.

In December, 2004, the Financial Accounting Standards Board issued its final standard on accounting for share-based payments (SBP), SFAS No. 123R (revised 2004), *Share-Based Payment* (FAS 123R), that requires companies to expense the cost of employee stock options and similar awards. SFAS 123R requires determining the cost that will be measured at fair value on the date of the SBP awards based upon an estimate of the number of awards expected to vest. There will be no right of reversal of cost if the awards expire without being exercised. Fair value of the SBP awards will be estimated using an option-pricing model that appropriately reflects the specific circumstances and economics of the awards. Compensation cost for the SBP awards will be recognized as they vest. Such cost is not deductible under German law. We will have three alternative transition methods, each having a different reporting implication. The effective date is for interim and annual periods beginning after June 15, 2005. We are in the process of determining the transition method we are going to adopt and the potential impact on our consolidated financial statements.

C. Research and development

Our research and development activities aim to improve the quality of dialysis treatment by matching it more closely with the individual needs of the patient, while reducing the overall cost for treatment. With our vertical integration, our research and development department can apply our experience as the world s largest provider of dialysis treatments to product development. To maintain and further enhance a continuous stream of product innovations, we have approximately 350 full time equivalents working in research and development worldwide at

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December 31, 2004. Approximately two-thirds of our research and development activities are based in Germany and one third in North America.

Research and development focuses strongly on the development of new products, technologies and treatment concepts to optimize treatment quality for dialysis patients, and on process technology for manufacturing our products. Research and development expenditures were $47 million in 2002, $50 million in 2003, and $51 million in 2004. For information regarding recent product introductions, see Item 4.B. Business Overview New Product Introductions.

We intend to continue to maintain our central research and development operations for disposable products at our St. Wendel, Germany facility and for durable products at our Schweinfurt and Bad Homburg, Germany facilities. Local activities will continue to focus on cooperative efforts with those facilities to develop new products and product modifications for local markets.

In North America, we have concentrated our business development activities on expanding our products business in three main areas:

- pharmaceutical products utilized in treating our renal patient base
- innovative products to improve vascular access outcomes for our renal patients
- products and technologies which leverage our core competencies to provide extracorporeal therapies to treat other diseases

D. Trend information

For information regarding significant trends in our business see Item 5.A. Operating Financial Review and Prospects.

Item 6. ***Directors, Senior Management and Employees***

A. Directors and senior management

General

In accordance with the German Stock Corporation Act, we have a Supervisory Board and a Management Board. The two boards are separate and no individual may simultaneously be a member of both boards.

Our Supervisory Board

Our Supervisory Board consists of six members who are elected by the holders of Ordinary shares at our Annual General Meeting. Pursuant to pooling agreements for the benefit of the public holders of our ordinary shares and the holders of our preference shares, at least one-third (but no fewer than two) of the members of the Supervisory Board elected by the shareholders are required to be independent directors as defined in the pooling agreements, i.e., persons with no substantial business or professional relationship with us, Fresenius AG or any affiliate of either.

If and when either:

- Fresenius Medical Care AG itself has more than 500 employees; or
- we enter into a domination agreement with a German subsidiary having more than 500 employees, or if that subsidiary is integrated into Fresenius Medical Care AG;

the German employees of Fresenius Medical Care AG and our German subsidiaries will elect one-third of the members of the Supervisory Board. If and when the aggregate number of employees of Fresenius Medical Care AG and our German subsidiaries exceeds 2,000, consideration must be given to increase the Supervisory Board to 12 persons and, if increased, the holders of Ordinary shares will elect six members and the German employees of Fresenius Medical Care and our German subsidiaries will elect six members. In that case, the Chairman of the

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Supervisory Board will be selected from the members elected by the shareholders and will have the tie-breaking vote.

The term of a member of the Supervisory Board will expire at the end of the general meeting of shareholders after the fourth fiscal year following the year in which the member was elected, but not counting the fiscal year in which such member s term begins. Members of the Supervisory Board elected by our shareholders may be removed by a resolution of our general meeting. This resolution requires a three-fourths majority of the votes cast at that meeting. The Supervisory Board ordinarily acts by simple majority vote and the Chairman has a tie-breaking vote in case of any deadlock.

The principal function of the Supervisory Board is to appoint and to supervise the Management Board and to approve mid-term planning, dividend payments and matters which are not in the ordinary course of business and are of fundamental importance to us.

The table below provides the names of the members of our Supervisory Board and their ages as of December 31, 2004.

Name	Age as of December 31, 2004
Dr. Gerd Krick, Chairman[1]	66
Dr. Dieter Schenk, Deputy Chairman	52
Dr. Ulf M. Schneider	39
Prof. Dr. Bernd Fahrholz	57
Walter L. Weisman[1][3]	69
John Gerhard Kringel[1][2][3]	65
Stephen M. Peck[3][4]	

(1) Members of Audit Committee

(2) Registered by Court on Oct. 20, 2004 and to be submitted for shareholder approval at AGM, May 24, 2005

(3) Independent Director for purposes of our pooling agreement

(4) Deceased March 30, 2004

DR. GERD KRICK has been Chairman of our Supervisory Board since January 1, 1998. He was Chairman of the Fresenius AG Management Board from 1992 to May 2003 at which time he became chairman of the Supervisory Board. Prior to 1992, he was a Director of the Medical Systems Division of Fresenius AG and Deputy Chairman of the Fresenius AG Management Board. From September 1996 until December 1997, Dr. Krick was Chairman of the Management Board of Fresenius Medical Care. Dr. Krick is a member of the Board of Directors of Adelphi Capital Europe Fund, of the Administrative Board of Dresdner Bank Luxembourg S.A., of the Supervisory Board of Vereinte Krankenversicherung AG, of the Advisory Board of HDI Haftpflichtverband der deutschen Industrie V.a.G. and of the Board of Trustees of the Donau Universität Krems. He is also the Chairman of the Supervisory Board of Vamed AG.

Dr. ULF M. SCHNEIDER has been a member of our Supervisory Board since May 2004. He was our Chief Financial Officer from November 2001 until March 2003. On March 7, 2003, Dr. Schneider announced his resignation from our Management Board to become Chairman of the Management Board of Fresenius AG, effective May 28, 2003. Previously he was Group Finance Director for Gehe UK plc., a pharmaceutical wholesale and retail distributor, in Coventry, United Kingdom. He has held several senior executive and financial positions since 1989 with Gehe s majority shareholder, Franz Haniel & Cie. GmbH, Duisburg, a diversified German multinational company.

PROF. DR. BERND FAHRHOLZ has been a member of our Supervisory Board since 1998. He is an attorney and is a partner in the law firm of Nörr Stiefenhofer Lutz since 2004. He was a member of the Management Board of Dresdner Bank AG since 1998 and was Chairman from April 2000 until he resigned in March of 2003. He also served as the deputy chairman of the Management Board of Allianz AG and chairman of

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the Supervisory Board of Advance Holding AG until March 25, 2003. He served on the Supervisory Boards of BMW AG until May 13, 2004 and Heidelberg Cement AG until May 6, 2004.

JOHN GERHARD KRINGEL has been a member of the Supervisory Board since October 20, 2004 when his appointment to fill a vacancy was approved by the local court. His election to the Supervisory Board is to be submitted for shareholder approval at the Annual General Meeting scheduled for May 24, 2005. He is a director of E-Surg, Inc. and Medical Research Labs, Inc. Mr. Kringel spent 18 years with Abbott Laboratories prior to his retirement as Senior Vice President, Hospital Products, in 1998. Prior to Abbot Laboratories, he spent three years as Executive Vice President of American Optical Corporation, a subsidiary of Warner Lambert Co. and ten years in the U.S. Medical Division of Corning Glassworks.

DR. DIETER SCHENK has been Vice Chairman of our Supervisory Board since 1996. He is an attorney and tax advisor and has been a partner in the law firm of Nörr Stiefenhofer Lutz since 1986. Dr. Schenk is also a member of the Supervisory Board of Fresenius AG. He also serves as a member and chairman of the Supervisory Board of Gabor Shoes AG, a member and vice-chairman of the Supervisory Boards of Greiffenberger AG and TOPTICA Photonics AG.

WALTER L. WEISMAN has been a member of our Supervisory Board since 1996. He is a private investor and a former Chairman and Chief Executive Officer of American Medical International, Inc. Mr. Weisman is on the board of Community Care Health Network, Inc., Maguire Properties, Inc., and Occidental Petroleum Corporation. He is Vice-Chairman of the Board of Trustees for the California Institute of Technology, Chairman of the Board of Trustees of the Los Angeles County Museum of Art, Chairman of the Board of Trustees of the Sundance Institute, and a trustee of the Samuel H. Kress Foundation and the Public Broadcasting Service, Inc.

STEPHEN M. PECK was a member of our Supervisory Board from 1999 until his death March 30, 2004.

Management Board

Each member of our Management Board is appointed by the Supervisory Board for a maximum term of five years and is eligible for reappointment thereafter. Their terms expire at our Annual General Meeting in the years listed below.

The table below provides names, positions and terms of office of the members of our Management Board and their ages as of December 31, 2004.

Name	Age as of Dec. 31, 2004	Position	Year Term Expires
Dr. Ben J. Lipps	64	Chairman of the management board, Chief Executive Officer of our Company	2008
Roberto Fusté	53	Chief Executive Officer for Asia Pacific	2006
Dr. Emanuele Gatti	49	Chief Executive Officer for Europe, Middle East, Africa and Latin America	2005
Lawrence A. Rosen	47	Chief Financial Officer	2006
Dr. Rainer Runte	45	General Counsel and Chief Compliance Officer	2010
Rice Powell	49	Co-Chief Executive Officer, Fresenius Medical Care North America and President Products & Hospital Group	2006
Mats Wahlstrom	50	Co-Chief Executive Officer, Fresenius Medical Care North America and President Fresenius Medical Services North America	2006

DR. BEN J. LIPPS has been Chairman of the Management Board and Chief Executive Officer of Fresenius Medical Care AG since May 1, 1999 and was Vice Chairman of the Management Board from September 1998

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until May 1999. He was Chief Executive Officer of Fresenius Medical Care North America until February 2004. He was President, Chief Executive Officer, Chief Operating Officer and a director of Fresenius USA from October 1989 through February 2004, and served in various capacities with Fresenius USA s predecessor from 1985 through 1989. He has been active in the field of dialysis for more than 35 years. After earning his master s and doctoral degrees at the Massachusetts Institute of Technology in chemical engineering, Dr. Lipps led the research team that developed the first commercial Hollow Fiber Artificial Kidney at the end of the 1960s. With that, the triumphal procession of the artificial kidney the dialyzer commenced. Before joining the Fresenius Group in 1985, Dr. Lipps held several research management positions, among them with DOW Chemical.

DR. EMANUELE GATTI has been a member of our Management Board since May 1997 and is Chief Executive Officer for Europe, Latin America, Middle East and Africa. After completing his studies in bioengineering, Dr. Gatti lectured at several biomedical institutions. He continues to be involved in comprehensive research and development activities focusing on dialysis and blood purification, biomedical signal analysis, medical device safety and health care economics. Dr. Gatti has been with the company since 1989. Before being appointed to the Management Board in 1997, he was responsible for the dialysis business in Southern Europe.

ROBERTO FUSTÉ has been a member of our Management Board since January 1, 1999 and is Chief Executive Officer for Asia-Pacific. After finishing his studies in economic sciences at the University of Valencia, he founded the company Nephrocontrol S.A. in 1983. In 1991, Nephrocontrol was acquired by the Fresenius Group, where Mr. Fusté has worked since. Before being appointed to the Management Board of Fresenius Medical Care AG in 1999, Mr. Fusté held several senior positions within the company in Europe and the Asia-Pacific region.

DR. RAINER RUNTE has been a Member of the Management Board for Law & Compliance of Fresenius Medical Care AG since January 1, 2004, and has worked for the Fresenius group for 14 years. Previously he served as scientific assistant to the law department of the Johann Wolfgang Goethe University in Frankfurt and as an attorney in a law firm specialized in economic law. Dr. Runte took the position as Senior Vice President for Law of Fresenius Medical Care in 1997 and was appointed as deputy member of the Management Board in 2002.

LAWRENCE A. ROSEN has been a member of our Management Board since November 1, 2003 and is Chief Financial Officer. Prior to that, he worked for Aventis S.A., Strasbourg, France, and its predecessor companies, including Hoechst AG, beginning in 1984. His last position was Group Senior Vice President for Corporate Finance and Treasury. He holds a Masters of Business Administration (MBA) from the University of Michigan and a Bachelor of Science in Economics from the State University of New York at Brockport.

RICE POWELL has been a member of our Management Board since February 2004 and is Co-Chief Executive Officer of Fresenius Medical Care North America. He is also is member of the Management Board for the Products & Hospital Group of Fresenius Medical Care in North America. Since 1997 he has been the President of Renal Products division of Fresenius Medical Care in North America including the Extracorporal Therapy and Laboratory Services. He has more than 25 years of experience in the healthcare industry. From 1978 to 1996 he held various positions within Baxter International Inc. (USA), Biogen Inc. (USA) and Ergo Sciences Inc. (USA).

MATS WAHLSTROM has been a member of our Management Board since February 2004 and is Co-Chief Executive Officer of Fresenius Medical Care North America. He has nearly 20 years of experience in the renal field. From 1983 to 1999, Mats Wahlstrom held various positions at Gambro AB (Sweden), including President and CEO of Gambro in North America as well as CFO of the Gambro Group. In November 2002 he joined Fresenius Medical Care as President of Fresenius Medical Care s services division in North America.

The business address of all members of our Management Board and Supervisory Board is Else-Kröner-Strasse 1, 61352 Bad Homburg, Germany.

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B. Compensation

Compensation of Our Management Board and our Supervisory Board

For the year ended December 31, 2004, we paid aggregate compensation to all members of the Management Board of approximately $9.2 million, $4.1 million in fixed compensation and $5.1 million in variable compensation. The aggregate compensation fees to all members of the Supervisory Board was $0.41 million including compensation to Dr. Krick for his duties as Chairman of the Supervisory Board. We pay an annual retainer fee to each member of the Supervisory Board, with the Chairman paid twice that amount and the Deputy Chairman paid 150% of that amount. We reimburse Supervisory Board members for their reasonable travel and accommodation expenses incurred with respect to their duties as Supervisory Board members. The aggregate compensation reported above does not include amounts paid as fees for services rendered by certain business or professional entities with which some of the Supervisory Board members are associated.

During 2004 we awarded 235,800 options with or without stock price targets to members of the Management Board to purchase our preference shares under the FMC International 2001 Plan. At December 31, 2004 Management Board members held options to acquire 91,600 Preference shares, all of which were exercisable at a weighted average exercise price of 36.85 under FMC 98 Plan 2 and 479,397 options, of which 110,108 are exercisable at a weighted average exercise price of 50.65 under the FMC 2001 stock incentive plan. A Board member exercised 8,000 options at an exercise price of 32.41 under FMC 98 Plan 2 during 2004.

During 1999, the Company granted to a member of the Management Board a five-year loan of $2 million with interest at 6.0% per annum. This loan was repaid in 2003.

C. Board Practices

For information relating to the terms of office of our Management Board and our Supervisory Board and the periods in which the members of those bodies have served in office, see Item 6.A. above. We do not have a remuneration committee. Our Supervisory Board carries out the functions usually performed by the remuneration committee, and our Supervisory Board reviews the compensation of the members of our Management Board. Our current audit committee members are Dr. Gerd Krick, Walter Weisman and John Gerhard Kringel. The primary function of the audit committee is to assist the Board in fulfilling its oversight responsibilities, primarily through:

- overseeing management s conduct or our financial reporting process and the internal accounting and financial control systems and auditing of our financial statements;
- monitoring our internal controls risk program;
- monitoring the independence and performance of our outside auditors;
- providing an avenue of communication among the outside auditors, management and the Supervisory Board;
- retaining the services of our independent auditors (subject to the approval by our shareholders at our Annual General Meeting) and approval of their fees; and
- pre-approval of all audit and non-audit services performed by KPMG Deutsche Treuhand-Gesellschaft AG Wirtschaftsprüfungsgesellschaft, the accounting firm which audits our consolidated financial statements.

Governance Matters

American Depositary Shares representing our Ordinary shares and our Preference shares are listed on the New York Stock Exchange (NYSE). However, because we are a foreign private issuer, as defined in the rules of the Securities and Exchange Commission, we are exempt from the governance rules set forth in Section 303A of the NYSE s Listed Companies Manual, except for the obligation to maintain an audit committee in accordance with Rule 10A-3 under the Securities Exchange Act of 1934, as amended, and the obligation to notify the NYSE if any of our executive officers becomes aware of any material non-compliance with any applicable provisions of Section 303A. Instead, the NYSE requires that we disclose the significant ways in which

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our corporate practices differ from those applicable to U.S. domestic companies under NYSE listing standards. You can review a summary of the most significant differences by going to Corporate Governance on the Investor Relations page of our web site, www.fmc-ag.com.

D. Employees

At December 31, 2004, we had 44,526 employees, as compared to 41,097 at December 31, 2003 and 39,264 at December 31, 2002. They are employed in our principal segments as follows: North America 28,154 employees and International 16,372. The following table shows the average number of employees by segment and our major category of activities for the last three fiscal years.

	2004	2003	2002
North America			
Dialysis Care	23,258	21,986	21,628
Dialysis Products	4,896	4,967	4,861
	28,154	26,953	26,489
International			
Dialysis Care	9,739	7,788	6,924
Dialysis Products	6,633	6,356	5,851
	16,372	14,144	12,775

We are members of the Chemical Industry Employers Association for most sites in Germany and we are bound by union agreements negotiated with the respective union representatives in those sites. We generally apply the principles of the Association and the related union agreements for those sites where we are not members. We are also party to additional shop agreements negotiated with works councils at individual facilities that relate to those facilities. In addition, approximately 2% of our U.S. employees are covered by collective bargaining agreements. During the last three fiscal years, we have not suffered any labor-related work disruptions.

E. Share ownership

As of December 31, 2004, no member of the Supervisory Board or the Management Board beneficially owned 1% or more of our outstanding Ordinary shares or our outstanding Preference shares. At December 31, 2004 Management Board members held options to acquire 570,997 Preference shares of which options to purchase 201,708 Preference shares were exercisable at a weighted average exercise price of 44.29. Those options expire at various dates between 2008 and 2014.

Options to Purchase Our Securities

Stock Option Plans

At December 31, 2004, we had awards outstanding under the terms of various stock-based compensation plans, including the 2001 plan, which is the only plan with stock option awards currently available for grant. Under the 2001 plan, convertible bonds with a principal of up to 10,240 may be issued to the members of the Management Board and other employees of the Company representing grants for up to 4 million non-voting Preference shares. The convertible bonds have a par value of 2.56 and bear interest at a rate of 5.5%. Except for the members of the Management Board, eligible employees may purchase the bonds by issuing a non-recourse note with terms corresponding to the terms of and secured by the bond. The Company has the right to offset its obligation on a bond against the employee s obligation on the related note; therefore, the convertible bond obligations and employee note receivables represent stock options issued by the Company and are not reflected in the consolidated financial statements. The options expire in ten years and one third of each grant can be exercised beginning after two, three or four years from the date of the grant. Bonds issued to Board members who did not issue a note to the Company are recognized as a liability on the Company s balance sheet.

Upon issuance of the option, the employees have the right to choose options with or without a stock price target. The conversion price of options subject to a stock price target becomes the stock exchange quoted price of

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the Preference shares upon the first time the stock exchange quoted price exceeds the Initial Value by at least 25%. The Initial Value is the average price of the Preference shares during the last 30 trading days prior to the date of grant. In the case of options not subject to a stock price target, the number of convertible bonds awarded to the eligible employee would be 15% less than if the employee elected options subject to the stock price target. The conversion price of the options without a stock price target is the Initial Value. Each option entitles the holder thereof, upon payment the respective conversion price, to acquire one Preference share. Up to 20% of the total amount available for the issuance of awards under the 2001 plan may be issued each year through May 22, 2006. At December 31, 2004, options for up to 1,094,612 Preference shares are available for grant in future periods under the 2001 Plan.

During 1998, the Company adopted two stock incentive plans (FMC98 Plan 1 and FMC98 Plan 2) for FMS s key management and executive employees. These stock incentive plans were replaced by the 2001 plan and no options have been granted since 2001. Under these plans eligible employees had the right to acquire Preference shares of the Company. Options granted under these plans have a ten-year term, and one third of them vest on each of the second, third and fourth anniversaries of the award date. Each Option can be exercised for one Preference share.

At December 31, 2004 under all plans, there were 4,661,437 options outstanding with a weighted average remaining contractual life of 6,82 years with 2,392,544 exercisable at a weighted average exercise price of 46.63.

Item 7. ***Major Shareholders and Related Party Transactions***

A. Major Shareholders

Security Ownership of Certain Beneficial Owners of Fresenius Medical Care

Our outstanding share capital consists of Ordinary shares and non-voting Preference shares that are issued only in bearer form. Accordingly, unless we receive information regarding acquisitions of our shares through a filing with the Securities and Exchange Commission or through the German statutory requirements referred to below, we have no way of determining who our shareholders are or how many shares any particular shareholder owns except as described below with respect to our shares held in American Depository Receipt (ADR) form. Because we are a foreign private issuer under the rules of the Securities and Exchange Commission, our directors and officers are not required to report their ownership of our equity securities or their transactions in our equity securities pursuant to Section 16 of the Exchange Act. Under the German Securities Exchange Law *(Wertpapierhandelsgesetz)*, holders of voting securities of a German company listed on the official market *(amtlicher Handel)* of a German stock exchange or a corresponding trading segment of a stock exchange within the European Union are obligated to notify the company of the level of their holding whenever such holding reaches, exceeds or falls below certain thresholds, which have been set at 5%, 10%, 25%, 50% and 75% of a company s outstanding voting rights.

We have been informed that as of December 31, 2004, Fresenius AG owned the majority, 50.8%, of our Ordinary shares. At December 31, 2004 Fresenius AG s Ordinary shares represented approximately 37% of our total share capital. JPMorgan Chase Bank, our ADR depositary, informed us, that as of December 31, 2004, 1,887,079 Ordinary ADSs, each representing one-third of an Ordinary share, were held of record by 7,592 U.S. holders and 21,183 Preference ADSs, each representing one-third of a Preference share, were held of record by 4 U.S. holders. Ordinary shares and Preference shares held directly by U.S. holders accounted for approximately 1% of our Ordinary shares outstanding and less than 1% of our Preference shares outstanding as of December 31, 2004. For more information regarding ADRs and ADSs see Item 10.B. Memorandum and Articles of Association Description of American Depositary Receipts.

Security Ownership of Certain Beneficial Owners of Fresenius AG

Fresenius AG s share capital consists of Ordinary shares and non-voting Preference shares. Both classes of shares are issued only in bearer form. Accordingly, Fresenius AG has no way of determining who its shareholders are or how many shares any particular shareholder owns. However, under the German Securities Exchange Law,

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holders of voting securities of a German company listed on the official market *(amtlicher Handel)* of a German stock exchange or a corresponding trading segment of a stock exchange within the European Union are obligated to notify the company of certain levels of holdings, as described above.

Based on the most recent information available, Vermögensverwaltungsgesellschaft Nachlass Else Kröner mbH owns 67.4% of the Fresenius AG Ordinary shares. In addition, Allianz Lebensversicherungs-AG informed Fresenius AG that it owns 9.7% of the Fresenius AG Ordinary shares.

B. Related party transactions

In connection with the formation of Fresenius Medical Care, and the combination of the dialysis businesses of Fresenius AG and W.R. Grace, Fresenius AG and its affiliates and Fresenius Medical Care and its affiliates entered into several agreements for the purpose of giving effect to the merger and defining our ongoing relationship. Fresenius AG and W.R. Grace negotiated these agreements. The information below summarizes the material aspects of certain agreements, arrangements and transactions between Fresenius Medical Care and Fresenius AG and their affiliates. Some of these agreements have been previously filed with the Securities and Exchange Commission. The following descriptions are not complete and are qualified in their entirety by reference to the agreements, copies of which have been filed with the Securities and Exchange Commission and the New York Stock Exchange. We believe that the leases, the supply agreements and the service agreements are no less favorable to us and no more favorable to Fresenius AG than would have been obtained in arm s-length bargaining between independent parties. The trademark and other intellectual property agreements summarized below were negotiated by Fresenius AG and W.R. Grace, and, taken independently, are not necessarily indicative of market terms.

Dr. Gerd Krick, the Chairman of our Supervisory Board and Dr. Dieter Schenk, its Vice-Chairman, are also Chairman and a member, respectively, of the Supervisory Board of Fresenius AG, and Dr. Ulf M. Schneider, a member of our Supervisory Board, is Chairman of the management Board and CEO of Fresenius AG.

In the discussion below regarding our contractual and other relationships with Fresenius AG:

the term we (or us) and our affiliates refers *only* to Fresenius Medical Care AG and its subsidiaries; and

the term Fresenius AG and its affiliates refers *only* to Fresenius AG and affiliates of Fresenius AG *other than* Fresenius Medical Care AG and its subsidiaries.

Real Property Lease

We did not acquire the land and buildings in Germany that Fresenius Worldwide Dialysis used when we were formed. Fresenius AG or its affiliates have leased part of the real property to us, directly, and transferred the remainder of that real property to two limited partnerships. Fresenius AG is the sole limited partner of each partnership, and the sole shareholder of the general partner of each partnership. These limited partnerships, as landlords, have leased the properties to us and to Fresenius AG, as applicable, for use in our respective businesses. The aggregate annual rent payable by us under these leases is approximately 11.8 million, which was approximately $14.8 million as of December 31, 2004, exclusive of maintenance and other costs, and is subject to escalation, based upon the German cost of living index for a four-person employee household. The leases for manufacturing facilities have a ten-year term, followed by two successive optional renewal terms of ten years each at our election. The leases for the other facilities have a term of ten years. Based upon an appraisal, we believe that the rents under the leases represent fair market value for such properties. For information with respect to our principal properties in Germany, see Item 4.D. Property, plants and equipment.

Covenants Not to Compete

Each of Fresenius AG and W.R. Grace has agreed that, for a period of ten years after our formation, it will not compete with us in any aspect of the business of supplying renal care-related goods and services, including laboratories. However, Fresenius AG may continue its home care business.

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Trademarks

Fresenius AG continues to own the name and mark Fresenius and its F logo. Fresenius AG and Fresenius Medical Care Deutschland GmbH, our principal German subsidiary, have entered into agreements containing the following provisions. Fresenius AG has granted to our German subsidiary, for our benefit and that of our affiliates, an exclusive, worldwide, royalty-free, perpetual license to use Fresenius Medical Care in our corporate names, and to use the Fresenius marks, including some combination marks containing the Fresenius name that were used by Fresenius AG s dialysis business, and the Fresenius Medical Care name as a trade name, in all aspects of the renal business. Our German subsidiary, for our benefit and that of our affiliates, has also been granted a worldwide, royalty-free, perpetual license:

- to use the Fresenius Medical Care mark in the then current National Medical Care non-renal business if it is used as part of Fresenius Medical Care together with one or more descriptive words, such as Fresenius Medical Care Home Care or Fresenius Medical Care Diagnostics ;
- to use the F logo mark in the National Medical Care non-renal business, with the consent of Fresenius AG. That consent will not be unreasonably withheld if the mark using the logo includes one or more additional descriptive words or symbols; and
- to use Fresenius Medical Care as a trade name in both the renal business and the National Medical Care non-renal business.

We and our affiliates have the right to use Fresenius Medical Care as a trade name in other medical businesses only with the consent of Fresenius AG. Fresenius AG may not unreasonably withhold its consent. In the U.S. and Canada, Fresenius AG will not use Fresenius or the F logo as a trademark or service mark, except that it is permitted to use Fresenius in combination with one or more additional words such as Pharma Home Care as a service mark in connection with its home care business and may use the F logo as a service mark with the consent of our principal German subsidiary. Our subsidiary will not unreasonably withhold its consent if the service mark includes one or more additional descriptive words or symbols. Similarly, in the U.S. and Canada, Fresenius AG has the right to use Fresenius as a trade name, but not as a mark, only in connection with its home care and other medical businesses other than the renal business and only in combination with one or more other descriptive words, provided that the name used by Fresenius AG is not confusingly similar to our marks and trade names. After the expiration of Fresenius AG s ten-year covenant not to compete with us, Fresenius AG may use Fresenius in its corporate names if it is used in combination with one or more additional descriptive word or words, provided that the name used by Fresenius AG is not confusingly similar to the Fresenius Medical Care marks or corporate or trade names.

Other Intellectual Property

Some of the patents, patent applications, inventions, know-how and trade secrets that Fresenius Worldwide Dialysis used prior to our formation were also used by other divisions of Fresenius AG. For Biofine, the polyvinyl chloride-free packaging material, Fresenius AG has granted to our principal German subsidiary, for our benefit and for the benefit of our affiliates, an exclusive license for the renal business and a non-exclusive license for all other fields except other non-renal medical businesses. Our German subsidiary and Fresenius AG will share equally any royalties from licenses of the Biofine intellectual property by either our German subsidiary or by Fresenius AG to third parties outside the renal business and the other non-renal medical businesses. In addition, Fresenius AG has transferred to our German subsidiary the other patents, patent applications, inventions, know-how and trade secrets that were used predominantly in Fresenius AG s dialysis business. In certain cases Fresenius Worldwide Dialysis and the other Fresenius AG divisions as a whole each paid a significant part of the development costs for patents, patent applications, inventions, know-how and trade secrets that were used by both prior to the merger. Where our German subsidiary acquired those jointly funded patents, patent applications, inventions, know-how and trade secrets, our subsidiary licensed them back to Fresenius AG exclusively in the other non-renal medical businesses and non-exclusively in all other fields. Where Fresenius AG retained the jointly funded patents, patent applications, inventions, know-how and trade secrets, Fresenius AG licensed them to our German subsidiary exclusively in the

renal business and non-exclusively in all other fields.

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Supply Agreements

We produce most of our products in our own facilities. However, Fresenius AG manufactures some of our products for us, principally dialysis concentrates, at facilities that Fresenius AG retained. These facilities are located in Brazil and France. Conversely, a facility in Italy that Fresenius AG transferred to us produces products for Fresenius Kabi AG, a subsidiary of Fresenius AG.

Our local subsidiaries and those of Fresenius AG have entered into supply agreements for the purchase and sale of products from the above facilities. Prices under the supply agreements include a unit cost component for each product and an annual fixed cost charge for each facility. The unit cost component, which is subject to annual review by the parties, is intended to compensate the supplier for variable costs such as costs of materials, variable labor and utilities. The fixed cost component generally will be based on an allocation of the 1995 fixed costs of each facility, such as rent, depreciation, production scheduling and quality control. The fixed cost component will be subject to adjustment by good-faith negotiation every twenty-four months. If the parties cannot agree upon an appropriate adjustment, the adjustment will be made based on an appropriate consumer price index in the country in which the facility is located. During 2004, we recognized sales of $35.1 million to Fresenius AG and its affiliates and we made purchases of $36.1 million from Fresenius AG and its affiliates.

Each supply agreement has a term that is approximately equal to the estimated average life of the relevant production assets, typically having terms of four and one-half to five years. Each supply agreement may be terminated by the purchasing party after specified notice period, subject to a compensation payment reflecting a portion of the relevant fixed costs.

The parties may modify existing or enter into additional supply agreements, arrangements and transactions. Any future modifications, agreements, arrangements and transactions will be negotiated between the parties and will be subject to the approval provisions of the pooling agreements and the regulatory provisions of German law regarding dominating enterprises.

Services Agreement

We obtain administrative and other services from Fresenius AG headquarters and from other divisions and subsidiaries of Fresenius AG. These services relate to, among other things, data processing, financial and management accounting and audit, human resources, risk management, quality control, production management, research and development, marketing and logistics. For 2004, Fresenius AG charged us approximately $25.6 million for these services. Conversely, we have provided certain services to other divisions and subsidiaries of Fresenius AG relating to research and development, plant administration, patent administration and warehousing. For 2004, we charged approximately $10.8 million to Fresenius AG s other divisions and subsidiaries for services we rendered to them.

We and Fresenius AG may modify existing or enter into additional services agreements, arrangements and transactions. Any such future modifications, agreements, arrangements and transactions will be negotiated between the parties and will be subject to the approval provisions of the pooling agreements and the regulations of German law regarding dominating enterprises.

Financing

At December 31, 2004, aggregate loans outstanding from Fresenius AG amounted to $3 million which bore interest at market rates at year-end. The borrowed funds were used to reduce bank debt. Interest paid during 2004 was $0.03 million. In addition, the final payment, due in May 2005, relating to the acquisition of Fresenius AG s adsorber business for approximately $3 million was outstanding.

Other Interests

Dr. Gerd Krick, chairman of our Supervisory Board, is a member of the administration board of Dresdner Bank, Luxembourg, S.A., a subsidiary of Dresdner Bank AG. See Security Ownership of Certain Beneficial Owners of Fresenius AG. Dresdner Bank AG, through its New York and Cayman branches, is a documentation agent and one of the joint lead arrangers and book managers under 2003 Senior Credit Agreement. It was also

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one of four co-arrangers of our prior principal credit agreement and one of the managing agents under that facility. Dresdner Bank AG also acts as custodian under the deposit agreement for the ADSs evidencing our Ordinary shares and under the deposit agreement for the ADSs evidencing our Preference shares, and an affiliate of Dresdner Kleinwort Wasserstein Securities LLC (a wholly-owned subsidiary of Dresdner Bank AG) is the New York Stock Exchange specialist for the ADSs evidencing our Ordinary shares.

Dr. Dieter Schenk, Deputy Chairman of our Supervisory Board and a member of the Supervisory Board of Fresenius AG, and Prof. D. Bernd Fahrholz, a member of our Supervisory Board, are partners in the law firm of Nörr Stiefenhofer Lutz, which has provided legal services to Fresenius AG and Fresenius Medical Care. During 2004, Nörr Stiefenhofer Lutz was paid approximately $1,383 for these services. See Security Ownership of Certain Beneficial Owners of Fresenius AG. Dr. Schenk is one of the executors of the estate of the late Mrs. Else Kröner. Vermögensverwaltungsgesellschaft Nachlass Else Kröner mbH, a 100 per cent subsidiary of Else Kröner Fresenius Stiftung, a charitable foundation established under the will of the late Mrs. Kröner, owns the majority of the voting shares of Fresenius AG.

Products

During 2004, we recognized $35.1 million of sales to Fresenius AG and its affiliates. We made purchases from Fresenius AG in the amount of $36.1 million during 2003.

Item 8. ***Financial information***

The information called for by parts 8.A.1 through 8.A.6 of this item is in the section beginning on Page F-1.

8.A.7. Legal Proceedings

This section describes material legal actions and proceedings relating to us and our business.

Commercial Litigation

We were formed as a result of a series of transactions pursuant to the Agreement and Plan of Reorganization (the Merger) dated as of February 4, 1996 by and between W.R. Grace & Co. and Fresenius AG. At the time of the Merger, a W.R. Grace & Co. subsidiary known as W.R. Grace & Co.-Conn. had, and continues to have, significant potential liabilities arising out of product-liability related litigation, pre-Merger tax claims and other claims unrelated to NMC, which was W.R. Grace & Co. s dialysis business prior to the Merger. In connection with the Merger, W.R. Grace & Co.-Conn. agreed to indemnify us, FMCH, and NMC against all liabilities of W.R. Grace & Co., whether relating to events occurring before or after the Merger, other than liabilities arising from or relating to NMC s operations. W.R. Grace & Co. and certain of its subsidiaries filed for reorganization under Chapter 11 of the U.S. Bankruptcy Code (the Grace Chapter 11 Proceedings) on April 2, 2001.

Pre-Merger tax claims or tax claims that would arise if events were to violate the tax-free nature of the Merger, could ultimately be our obligation. In particular, W.R. Grace & Co. has disclosed in its filings with the Securities and Exchange Commission that: its tax returns for the 1993 to 1996 tax years are under audit by the Internal Revenue Service (the Service); W.R. Grace & Co. has received the Service s examination report on tax periods 1993 to 1996; that during those years W.R. Grace & Co. deducted approximately $122 million in interest attributable to corporate owned life insurance (COLI) policy loans; that W.R. Grace & Co. has paid $21 million of tax and interest related to COLI deductions taken in tax years prior to 1993; that a U.S. District Court ruling has denied interest deductions of a taxpayer in a similar situation. In October 2004, W.R. Grace & Co. obtained bankruptcy court approval to settle its COLI claims with the Service. In January 2005, W.R. Grace and Co., FMCH and Sealed Air Corporation executed a settlement agreement with respect to the Service s COLI-related claims and other tax claims. W.R. Grace and Co. has filed a motion with the US District Court seeking approval to satisfy its payment obligations to the Service under the settlement agreement. Subject to certain representations made by W.R. Grace & Co., the Company and Fresenius AG, W.R. Grace & Co. and certain of its affiliates agreed to indemnify us against this and other pre-Merger and Merger-related tax liabilities.

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Prior to and after the commencement of the Grace Chapter 11 Proceedings, class action complaints were filed against W.R. Grace & Co. and FMCH by plaintiffs claiming to be creditors of W.R. Grace & Co.-Conn., and by the asbestos creditors committees on behalf of the W.R. Grace & Co. bankruptcy estate in the Grace Chapter 11 Proceedings, alleging among other things that the Merger was a fraudulent conveyance, violated the uniform fraudulent transfer act and constituted a conspiracy. All such cases have been stayed and transferred to or are pending before the U.S. District Court as part of the Grace Chapter 11 Proceedings.

In 2003, we reached agreement with the asbestos creditors committees on behalf of the W.R. Grace & Co. bankruptcy estate and W.R. Grace & Co. in the matters pending in the Grace Chapter 11 Proceedings for the settlement of all fraudulent conveyance and tax claims against it and other claims related to us that arise out of the bankruptcy of W.R. Grace & Co. Under the terms of the settlement agreement as amended (the Settlement Agreement), fraudulent conveyance and other claims raised on behalf of asbestos claimants will be dismissed with prejudice and we will receive protection against existing and potential future W.R. Grace & Co. related claims, including fraudulent conveyance and asbestos claims, and indemnification against income tax claims related to the non-NMC members of the W.R. Grace & Co. consolidated tax group upon confirmation of a W.R. Grace & Co. bankruptcy reorganization plan that contains such provisions. Under the Settlement Agreement, we will pay a total of $115 million to the W.R. Grace & Co. bankruptcy estate, or as otherwise directed by the Court, upon plan confirmation. No admission of liability has been or will be made. The Settlement Agreement has been approved by the U.S. District Court. Subsequent to the Merger, W.R. Grace & Co. was involved in a multi-step transaction involving Sealed Air Corporation (Sealed Air , formerly known as Grace Holding, Inc.). We are engaged in litigation with Sealed Air to confirm our entitlement to indemnification from Sealed Air for all losses and expenses incurred by the Company relating to pre-Merger tax liabilities and Merger-related claims. Under the Settlement Agreement, upon confirmation of a plan that satisfies the conditions of our payment obligation, this litigation will be dismissed with prejudice.

On April 4, 2003, FMCH filed a suit in the United States District Court for the Northern District of California, *Fresenius USA, Inc., et al., v. Baxter International Inc., et al.*, Case No. C 03-1431, seeking a declaratory judgment that it does not infringe on patents held by Baxter International Inc. and its subsidiaries and affiliates (Baxter), that the patents are invalid, and that Baxter is without right or authority to threaten or maintain suit against it for alleged infringement of Baxter s patents. In general, the alleged patents concern touch screens, conductivity alarms, power failure data storage, and balance chambers for hemodialysis machines. Baxter has filed counterclaims against FMCH seeking monetary damages and injunctive relief, and alleging that it willfully infringed on Baxter s patents. FMCH believes its claims are meritorious, although the ultimate outcome of any such proceedings cannot be predicted at this time and an adverse result could have a material adverse effect on our business, financial condition, and results of operations.

Other Litigation and Potential Exposures

In October 2004, FMCH and its Spectra Renal Management subsidiary received subpoenas from the U.S. Department of Justice, Eastern District of New York in connection with a civil and criminal investigation, which requires production of a broad range of documents relating to our operations, with specific attention to documents relating to laboratory testing for parathyroid hormone (PTH) levels and vitamin D therapies. We are cooperating with the government s requests for information. While we believe that we have complied with applicable laws relating to PTH testing and use of vitamin D therapies, an adverse determination in this investigation could have a material adverse effect on our business, financial condition, and results of operations.

From time to time, we are a party to or may be threatened with other litigation, claims or assessments arising in the ordinary course of our business. Management regularly analyzes current information including, as applicable, our defenses and insurance coverage and, as necessary, provides accruals for probable liabilities for the eventual disposition of these matters.

We, like other health care providers, conduct our operations under intense government regulation and scrutiny. We must comply with regulations which relate to or govern the safety and efficacy of medical products and supplies, the operation of manufacturing facilities, laboratories and dialysis clinics, and environmental and occupational health and safety. We must also comply with the Anti-Kickback Statute, the False Claims Act, the

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Stark Statute, and other federal and state fraud and abuse laws. Applicable laws or regulations may be amended, or enforcement agencies or courts may make interpretations that differ from our interpretations or the manner in which it conducts its business. Enforcement has become a high priority for the federal government and some states. In addition, the provisions of the False Claims Act authorizing payment of a portion of any recovery to the party bringing the suit encourage private plaintiffs to commence whistle blower actions. By virtue of this regulatory environment, as well as our corporate integrity agreement with the government, our business activities and practices are subject to extensive review by regulatory authorities and private parties, and continuing audits, investigative demands, subpoenas, other inquiries, claims and litigation relating to our compliance with applicable laws and regulations. We may not always be aware that an inquiry or action has begun, particularly in the case of whistle blower actions, which are initially filed under court seal.

We operate many facilities throughout the U.S. In such a decentralized system, it is often difficult to maintain the desired level of oversight and control over the thousands of individuals employed by many affiliated companies. We rely upon our management structure, regulatory and legal resources, and the effective operation of our compliance program to direct, manage and monitor the activities of these employees. On occasion, we may identify instances where employees, deliberately or inadvertently, have submitted inadequate or false billings. The actions of such persons may subject us and our subsidiaries to liability under the Anti-Kickback Statute, the Stark Statute and the False Claims Act, among other laws.

Physicians, hospitals and other participants in the health care industry are also subject to a large number of lawsuits alleging professional negligence, malpractice, product liability, worker s compensation or related claims, many of which involve large claims and significant defense costs. We have been and are currently subject to these suits due to the nature of our business and expect that those types of lawsuits may continue. Although we maintain insurance at a level which we believe to be prudent, we cannot assure that the coverage limits will be adequate or that insurance will cover all asserted claims. A successful claim against us or any of our subsidiaries in excess of insurance coverage could have a material adverse effect upon it and the results of our operations. Any claims, regardless of their merit or eventual outcome, could have a material adverse effect on our reputation and business.

We have also had claims asserted against us and have had lawsuits filed against us relating to businesses that we have acquired or divested. These claims and suits relate both to operation of the businesses and to the acquisition and divestiture transactions. When appropriate, we have asserted our own claims, and claims for indemnification. A successful claim against us or any of our subsidiaries could have a material adverse effect upon us and the results of our operations. Any claims, regardless of their merit or eventual outcome, could have a material adverse effect on our reputation and business.

Accrued Special Charge for Legal Matters

At December 31, 2001, we recorded a pre-tax special charge of $258 million to reflect anticipated expenses associated with the defense and resolution of pre-Merger tax claims, Merger-related claims, and commercial insurer claims (see Note 6 and Note 16 to the consolidated financial statements in this report). The costs associated with the Settlement Agreement and settlements with insurers have been charged against this accrual. While we believe that our remaining accruals reasonably estimate our currently anticipated costs related to the continued defense and resolution of the remaining matters, no assurances can be given that our actual costs incurred will not exceed the amount of this accrual.

8.A.8. Dividend Policy

We generally pay annual dividends on both our Preference shares and our Ordinary shares in amounts that we determine on the basis of the prior year unconsolidated earnings of Fresenius Medical Care AG as shown in the statutory financial statements that we prepare under German law, subject to authorization by a resolution to be passed at our general meeting of shareholders. Under our articles of association, the minimum dividend payable on the Preference shares is 0.12 per share and, if we declare dividends, holders of our Preference shares must receive 0.06 per share more than the dividend on an Ordinary share. Under German law, we must, in all cases,

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pay the annual dividend declared on our Preference shares before we pay dividends declared on our Ordinary shares.

Our Management Board and our Supervisory Board propose dividends and the shareholders approve dividends for payment in respect of a fiscal year at the Annual General Meeting in the following year. Since all of our shares are in bearer form, we either remit dividends to the depositary bank (*Depotbank*) on behalf of the shareholders or, in the case of shareholders holding physical certificates, we pay dividends through the paying agents that we appoint against presentation of the relevant dividend coupon. Details of the paying agents are published in the German Federal Gazette (*Bundesanzeiger*).

Our senior credit agreement and outstanding euro notes, as well as the senior subordinated indentures relating to our trust preferred securities, restrict our ability to pay dividends. Item 5.B. Operating and Financial Review and Prospects Liquidity and Capital Resources and the notes to our consolidated financial statements appearing elsewhere in this report discuss this restriction.

The table below provides information regarding the annual dividend per share that we paid on our Preference shares and Ordinary shares. The dividends shown for each year were paid with respect to our operations in the preceding year.

Per Share Amount	2004	2003	2002
Preference share	1.08	1.00	0.91
Ordinary share	1.02	0.94	0.85

We have announced that our Management Board and our Supervisory Board have proposed dividends for 2004 payable in 2005 of 1.18 per Preference share and 1.12 per Ordinary share. These dividends are subject to approval by our shareholders at our Annual General Meeting to be held on May 24, 2005.

Except as described herein, holders of ADSs will be entitled to receive dividends on the Ordinary shares and the Preference shares represented by the respective ADSs. We will pay any cash dividends payable to such holders to the depositary in euros and, subject to certain exceptions, the depositary will convert the dividends into U.S. dollars. Fluctuations in the exchange rate between the U.S. dollar and the euro will affect the amount of dividends that ADS holders receive. Dividends paid on the Preference shares and dividends paid to holders and beneficial holders of the ADSs will be subject to deduction of German withholding tax. You can find a discussion of German withholding tax below in Item 10.E. Taxation .

B. Significant Changes

There have been no significant changes since December 31, 2004.

Item 9. ***The Offer and Listing Details***

A.4. and C. Information regarding the trading markets for price history of our stock

Trading Markets

The principal trading market for the Ordinary shares and the Preference shares is the Frankfurt Stock Exchange. All Ordinary shares and Preference shares have been issued in bearer form. Accordingly, we have no way of determining who our holders of Ordinary and Preference shares are or how many shares any particular shareholder owns, with the exception of the number of shares held in ADR form in the United States. For more information regarding ADRs see Item 10.B. Memorandum and articles of association Description of American Depositary Receipts. However, under the German Stock Corporation and Securities Law, holders of voting securities of a German company listed on a stock exchange within the EU are obligated to notify the company of certain levels of holdings as described in Item 7.A. Major Shareholders . The Ordinary shares have been listed on the Frankfurt Stock Exchange since October 2, 1996. The Preference shares have been listed on the Frankfurt Stock Exchange since November 25, 1996.

Since October 1, 1996, ADSs each representing one-third of an Ordinary share (the Ordinary ADSs), have been listed and traded on the New York Stock Exchange (NYSE) under the symbol FMS. Since

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November 25, 1996, ADSs, each representing one-third of a Preference share (the Preference ADSs), have been listed and traded on the NYSE under the symbol FMS-p. The Depositary for both the Ordinary ADSs and the Preference ADSs is JPMorgan Chase Bank, N.A. (the Depositary).

Trading on the Frankfurt Stock Exchange

Deutsche Börse AG operates the Frankfurt Stock Exchange, which is the most significant of the eight German stock exchanges. As of December 31, 2004, the most recent figures available, the shares of 6,209 companies traded on the official market, regulated market and the regulated unofficial market of the Frankfurt Stock Exchange. Of these 816 were German companies and 5,393 were foreign companies.

Trading on the floor of the Frankfurt Stock Exchange begins every business day at 9:00 a.m. and ends at 8:00 p.m., Central European Time (CET). Securities listed on the Frankfurt Stock Exchange generally trade in the auction market, but also change hands in interbank dealer markets. Prices are noted by publicly commissioned stock brokers who are members of the Frankfurt Stock Exchange, but who do not as a rule deal with the public. These prices are determined by out-cry. The prices of actively traded securities, including the shares of large corporations, are continuously quoted during trading hours.

FMS s shares are traded on Xetra (Exchange Electronic Trading) in addition to being traded on the auction market. Starting on November 3, 2003, the Deutsche Börse AG shortened the trading hours for Xetra to between 9:00 a.m. and 5:30 p.m. CET instead of between 9:00 a.m. and 8:00 p.m. Only brokers and banks that have been admitted to Xetra by the Frankfurt Stock Exchange may trade on the system. Private investors can trade on Xetra through their banks and brokers.

Deutsche Börse AG publishes information for all traded securities on the Internet, webpage http://www.exchange.de.

Transactions on the Frankfurt Stock Exchange (including transactions through the Xetra system) settle on the second business day following the trade. Transactions off the Frankfurt Stock Exchange (such as, for example, large trades or transactions in which one of the parties is foreign) generally also settle on the second business day following the trade, although a different period may be agreed to by the parties. Under standard terms and conditions for securities transactions employed by German banks, customers orders for listed securities must be executed on a stock exchange unless the customer gives specific instructions to the contrary.

The Frankfurt Stock Exchange can suspend a quotation if orderly trading is temporarily endangered or if a suspension is deemed to be necessary to protect the public.

The Hessian Stock Exchange Supervisory Authority and the Trading Monitoring Unit of the Frankfurt Stock Exchange, which is under the control of the Stock Exchange Supervisory Authority, both monitor trading on the Frankfurt Stock Exchange.

The Federal Supervisory Authority for Securities Trading (*Bundesaufsichtsamt für den Wertpapierhandel*), an independent federal authority, is responsible for the general supervision of securities trading pursuant to provisions of the German Securities Trading Act (*Wertpapierhandelsgesetz*).

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The table below sets forth for the periods indicated, the high and low closing sales prices in euro for the Ordinary shares on the Frankfurt Stock Exchange, as reported by the Frankfurt Stock Exchange Xetra system. Since January 4, 1999, all shares on German stock exchanges trade in euro.

		Price per ordinary share ( )	
		High	**Low**
2005	February	67.66	61.23
	January	62.17	57.37
2004	December	59.45	55.72
	November	62.90	58.48
	October	63.63	59.50
	September	62.47	59.62
2004	Fourth Quarter	63.63	55.72
	Third Quarter	62.60	58.55
	Second Quarter	63.33	53.55
	First Quarter	57.42	49.46
2003	Fourth Quarter	57.00	48.25
	Third Quarter	53.77	42.00
	Second Quarter	50.90	39.32
	First Quarter	48.79	38.00
2004	Annual	63.63	49.46
2003	Annual	57.00	38.00
2002	Annual	73.00	19.98
2001	Annual	92.90	66.77
2000	Annual	103.60	72.40

The average daily trading volume of the Ordinary shares traded on the Frankfurt Stock Exchange during 2004 was 255,747 shares. The foregoing numbers are based on total yearly turnover statistics supplied by the Frankfurt Stock Exchange. On February 28, 2005, the closing sales price per Ordinary share on the Frankfurt Stock Exchange was 67.66, equivalent to $89.70 per Ordinary share.

The table below sets forth for the periods indicated, the high and low closing sales prices in euro for the Preference shares on the Frankfurt Stock Exchange, as reported by the Frankfurt Stock Exchange. As all shares on German stock exchanges trade in euro since January 4, 1999 (see the discussion under Item 11. Quantitative and Qualitative Disclosures about Market Risk with respect to the rates of exchange between euro and deutsche mark).

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		Price per preference share ( )	
		High	Low
2005	February	47.90	44.17
	January	44.60	41.60
2004	December	42.65	39.35
	November	44.60	41.18
	October	44.92	42.05
	September	44.00	42.20
2004	Fourth Quarter	44.92	39.35
	Third Quarter	44.81	41.98
	Second Quarter	45.45	36.64
	First Quarter	40.95	33.73
2003	Fourth Quarter	41.00	35.01
	Third Quarter	40.50	30.09
	Second Quarter	36.00	28.50
	First Quarter	35.60	27.36
2004	Annual	45.45	33.73
2003	Annual	41.00	28.50
2002	Annual	53.90	15.17
2001	Annual	65.25	46.01
2000	Annual	58.00	38.00

The average daily trading volume of the Preference shares traded on the Frankfurt Stock Exchange during 2004 was 46,504 shares. The foregoing numbers are based on total yearly turnover statistics supplied by the Frankfurt Stock Exchange. On February 28, 2005, the closing sales price per Preference share on the Frankfurt Stock Exchange was 47.90, equivalent to $63.50 per Preference share.

Trading on the New York Stock Exchange

The table below sets forth, for the periods indicated, the high and low closing sales prices for the Ordinary ADSs on the NYSE:

		Price per ordinary ADS ($)	
		High	Low
2005	February	29.88	26.59
	January	26.97	25.09
2004	December	26.94	24.74
	November	27.23	25.80
	October	26.83	25.45
	September	25.71	24.13
2004	Fourth Quarter	27.23	24.74
	Third Quarter	25.75	24.13
	Second Quarter	25.79	21.82
	First Quarter	24.59	20.41

2003	Fourth Quarter	23.54	18.80
	Third Quarter	20.20	16.00
	Second Quarter	18.00	15.33
	First Quarter	17.49	13.20
2004	Annual	27.23	20.41
2003	Annual	23.54	13.20
2002	Annual	21.60	6.70
2001	Annual	28.30	19.80
2000	Annual	30.19	22.56

On February 28, 2005, the closing sales price per Ordinary ADS on the NYSE was $29.82.

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The table below sets forth, for the periods indicated, the high and low closing sales prices for the Preference ADSs on the NYSE:

		Price per preference ADS ($)	
		High	**Low**
2005	February	20.90	19.26
	January	19.20	18.16
2004	December	19.15	17.50
	November	18.90	18.20
	October	18.50	17.80
	September	17.70	17.09
2004	Fourth Quarter	19.15	17.50
	Third Quarter	18.24	17.09
	Second Quarter	18.40	14.91
	First Quarter	17.10	13.86
2003	Fourth Quarter	16.68	13.74
	Third Quarter	15.00	11.50
	Second Quarter	12.60	10.90
	First Quarter	12.35	9.85
2004	Annual	19.15	13.86
2003	Annual	16.68	9.85
2002	Annual	15.70	4.90
2001	Annual	19.64	14.00
2000	Annual	16.91	13.25

On February 28, 2005, the closing sales price per Preference ADS on the NYSE was $20.90.

Item 10. ***Additional information***

B. Articles of Association

Fresenius Medical Care AG is a stock corporation (Aktiengesellschaft) organized under the laws of Germany. Fresenius Medical Care AG is registered with the commercial register of the local court *(Amtsgericht)* of Hof an der Saale, Germany under HRB 2460. Our registered office *(Sitz)* is Hof an der Saale, Germany. Our business address is Else-Kröner-Strasse 1, 61352 Bad Homburg, Germany, telephone +49-6172-609-0.

Corporate Purposes

Under our articles of association, our corporate purposes are:

developing, producing, distributing and selling, health care products, systems and procedures, primarily dialysis products and systems;

planning, establishing, acquiring and operating health care businesses, including, but not limited to, dialysis clinics, directly or through third parties and through participation in joint ventures and other entities;

developing, producing and distributing other pharmaceutical products and the provision of health care services;

providing advice in the medical and pharmaceutical areas and disseminating scientific information and documentation; and

providing laboratory services for dialysis and non-dialysis patients and home health services. We conduct our business directly and through subsidiaries within and outside Germany.

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Voting Rights

Each Ordinary share entitles the holder thereof to one vote at general meetings of our shareholders. Resolutions are passed at a general or special meeting of our shareholders by a majority of the votes cast, unless a higher vote is required by law or our articles of association.

Our Preference shares do not have any voting rights, except as described in this paragraph. If we do not pay the minimum annual dividend payable on the Preference shares for any year in the following year, and we do not pay both the dividend arrearage and the dividend payable on the Preference shares for the following year in full in the next following year, then the Preference shares shall have the same voting rights as the Ordinary shares (one vote for each share held or for each three ADSs held) until all Preference share dividend arrearages are fully paid up. In addition, holders of Preference shares are entitled to vote on any matters affecting their preferential rights, such as changes in the rate of the preferential dividend. Any such vote requires the affirmative vote of 75% of the votes cast in a meeting of holders of Preference shares.

Dividend Rights

Our Management Board and Supervisory Board will propose any dividends for approval at the Annual General Meeting of shareholders, which must be held within the first eight months following the end of a fiscal year. Usually the shareholders vote on a recommendation made by our Management Board and our Supervisory Board as to the amount of dividend to be paid. Any dividends are paid once a year.

Under German law, dividends are payable from the prior year unconsolidated retained earnings of Fresenius Medical Care AG, determined in accordance with German accounting principles (*Bilanzgewinn*).

Dividends are paid on presentation of the relevant dividend coupon to us or to our paying agent or agents appointed by us from time to time. If the Ordinary shares and the Preference shares which are entitled to dividend payments are held in a clearing system, the dividends will be paid in accordance with the rules of the individual clearing system. We will publish notice of the dividends paid and the appointment of the paying agent or agents for this purpose in the German Federal Gazette (*Bundesanzeiger*).

In the case of holders of ADRs, the depositary will receive all dividends and distributions on all deposited securities and will, as promptly as practicable, distribute the dividends and distributions to the holders of ADRs entitled to the dividend. See Description of American Depositary Receipts Share Dividends and Other Distributions.

For each fiscal year, our Management Board and the Supervisory Board propose the treatment of all unappropriated profits, including the amount of our net profits which will be distributed by way of dividends, subject to shareholder approval. The Management Board and the Supervisory Board may allocate up to 50% of unappropriated profits to our free reserve (that is, they may determine not to distribute such profits) without shareholder approval, in which case the shareholders approve the treatment of the balance of such profits. Under German law, we must pay the annual dividend on the Preference shares, in all cases, before we pay any dividend on the Ordinary shares.

Liquidation Rights

In accordance with the German Stock Corporation Act (*Aktiengesetz*), upon a liquidation, any liquidation proceeds remaining after paying all of our liabilities will be distributed among the holders of Preference shares and the holders of Ordinary shares in proportion to the total number of the shares held by each holder. The Preference shares are not entitled to a preference in liquidation.

Preemptive Rights

Under the German Stock Corporation Act, an existing stockholder in a stock corporation, including a holder of Preference shares, has a preferential right to subscribe for any issue by that corporation of shares, debt instruments convertible into shares and participating debt instruments in proportion to the number of shares held by that stockholder in the existing capital of the corporation. The German Stock Corporation Act provides that

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this preferential right can only be excluded by a resolution of the general meeting passed at the same time as the resolution authorizing the capital increase. A supermajority of at least three quarters of the share capital represented at the general meeting is required for the exclusion. The waiver of the preemptive rights of the holders of Preference shares requires a vote of these holders of 75% of the capital represented by Preference shares at the meeting at which the vote is taken. In addition, a special justification by the corporation stating that the goal pursued by the corporation with the issuance of the new security could not reasonably be achieved without and outweighs the elimination of preemptive rights, is generally required for the exclusion. A special justification is not required for any increase in the share capital for contributions in cash if the increase does not exceed 10% of the existing capital and the issue price is not materially less than the price for the shares quoted on a stock exchange.

General Meeting

Our Annual General Meeting must be held within the first eight months of each fiscal year at the location of Fresenius Medical Care AG s registered office, or in a German city where a stock exchange is situated or at the location of a registered office of a domestic affiliated company. Each of our shareholders is entitled to participate in a general meeting regardless of whether they possess voting rights. To attend the meeting, shareholders must deposit their shares no later than on the fifth day before the shareholders meeting with the company, a Notary in Germany, or a Wertpapiersammelbank (a bank for the central depository of securities) or with any other body designated in the notice of meeting. The deposit must remain in effect until the end of the shareholders meeting. If credit institutions are closed on the last day for deposit, the deposit must be made by the end of the preceding working day of the credit institutions. Shares shall be deemed to have been properly deposited if they are blocked until the end of the shareholders meeting at a credit institution in the name of and with the consent of a depository.

Description of American Depositary Receipts

JPMorgan Chase Bank, N.A., a New York banking corporation, is the depositary for our Ordinary shares and our Preference shares. Each ADS represents an ownership interest in one-third of one Ordinary share or one Preference share. We deposit the underlying shares with the custodian, as agent of the depositary, under the deposit agreements among ourselves, the depositary and all of the ADS holders of the applicable class. Each ADS also represents any securities, cash or other property deposited with the depositary but not distributed by it directly to ADS holders. The ADSs are evidenced by securities called American depositary receipts or ADRs. An ADR may be issued in either book-entry or certificated form by the depositary. If an ADR is issued in book-entry form, owners will receive periodic statements from the depositary showing their ownership interest in ADSs.

The depositary s office is located at 4 New York Plaza, New York, NY 10004, USA.

An investor may hold ADSs either directly or indirectly through a broker or other financial institution. Investors who hold ADSs directly, by having an ADS registered in their names on the books of the depositary, are ADR holders. This description assumes an investor holds ADSs directly. Investors who hold ADSs through their brokers or financial institution nominees must rely on the procedures of their brokers or financial institutions to assert the rights of an ADR holder described in this section. Investors should consult with their brokers or financial institutions to find out what those procedures are.

Because the depositary s nominee will actually be the registered owner of the shares, investors must rely on it to exercise the rights of a shareholder on their behalf. The obligations of the depositary and its agents are set out in the deposit agreement. The deposit agreement and the ADSs are governed by New York law.

The following is a summary of the material terms of the deposit agreements. Because it is a summary, it does not contain all the information that may be important to investors. Except as specifically noted, the description covers both Ordinary ADSs and Preference ADSs. For more complete information, investors should read the entire applicable deposit agreement and the form of ADR of the relevant class which contains the terms of the ADSs. Investors may obtain a copy of the deposit agreements at the SEC s Public Reference Room which is located at 450 Fifth Street, N.W., Washington, D.C. 20549.

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Share Dividends and Other Distributions

We may make various types of distributions with respect to our Ordinary shares and our Preference shares. The depositary has agreed to pay to investors the cash dividends or other distributions it or the custodian receives on the shares or other deposited securities, after deducting its expenses. Investors will receive these distributions in proportion to the number of underlying shares of the applicable class their ADSs represent.

Except as stated below, to the extent the depositary is legally permitted it will deliver distributions to ADR holders in proportion to their interests in the following manner:

Cash. The depositary shall convert cash distributions from foreign currency to U.S. dollars if this is permissible and can be done on a reasonable basis. The depositary will endeavor to distribute cash in a practicable manner, and may deduct any taxes or other governmental charges required to be withheld, any expenses of converting foreign currency and transferring funds to the United States, and certain other expenses and adjustments. In addition, before making a distribution the depositary will deduct any taxes withheld. If exchange rates fluctuate during a time when the depositary cannot convert a foreign currency, investors may lose some or all of the value of the distribution.

Shares. If we make a distribution in shares, the depositary will issue additional ADRs to evidence the number of ADSs representing the distributed shares. Only whole ADSs will be issued. Any shares which would result in fractional ADSs will be sold and the net proceeds will be distributed to the ADR holders otherwise entitled to receive fractional ADSs.

Rights to receive additional shares. In the case of a distribution of rights to subscribe for Ordinary shares, Preference shares or other rights, if we provide satisfactory evidence that the depositary may lawfully distribute the rights, the depositary may arrange for ADR holders to instruct the depositary as to the exercise of the rights. However, if we do not furnish the required evidence or if the depositary determines it is not practical to distribute the rights, the depositary may

sell the rights if practicable and distribute the net proceeds as cash, or

allow the rights to lapse, in which case ADR holders will receive nothing.

We have no obligation to file a registration statement under the Securities Act in order to make any rights available to ADR holders.

Other Distributions. If we make a distribution of securities or property other than those described above, the depositary may either:

distribute the securities or property in any manner it deems fair and equitable;

after consultation with us if practicable, sell the securities or property and distribute any net proceeds in the same way it distributes cash; or

hold the distributed property in which case the ADSs will also represent the distributed property.

Any dollars will be distributed by checks drawn on a bank in the United States for whole dollars and cents (fractional cents will be withheld without liability for interest and added to future cash distributions).

The depositary may choose any practical method of distribution for any specific ADR holder, including the distribution of foreign currency, securities or property, or it may retain the items, without paying interest on or investing them, on behalf of the ADR holder as deposited securities.

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADR holders.

There can be no assurance that the depositary will be able to convert any currency at a specified exchange rate or sell any property, rights, shares or other securities at a specified price, or that any of these transactions can be completed within a specified time period.

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Deposit, Withdrawal and Cancellation

The depositary will issue ADSs if an investor or his broker deposits Ordinary shares or Preference shares or evidence of rights to receive Ordinary shares or Preference shares with the custodian. Shares deposited with the custodian must be accompanied by certain documents, including instruments showing that such shares have been properly transferred or endorsed to the person on whose behalf the deposit is being made.

The custodian will hold all deposited shares for the account of the depositary. ADR holders thus have no direct ownership interest in the shares and only have the rights that are contained in the deposit agreement. The custodian will also hold any additional securities, property and cash received on or in substitution for the deposited shares. The deposited shares and any additional items are referred to as deposited securities.

Upon each deposit of shares, receipt of related delivery documentation and compliance with the other provisions of the deposit agreement, including the payment of the fees and charges of the depositary and any taxes or other fees or charges owing, the depositary will issue an ADR or ADRs of the applicable class in the name of the person entitled to them. The ADR or ADRs will evidence the number of ADSs to which the person making the deposit is entitled. Certificated ADRs will be delivered at the depositary s principal New York office or any other location that it may designate as its transfer office.

All ADSs issued will, unless specifically requested to the contrary, be part of the depositary s book-entry direct registration system, and a registered holder will receive periodic statements from the depositary which will show the number of ADSs registered in the holder s name. An ADR holder can request that the ADSs not be held through the depositary s direct registration system and that a certificated ADR be issued. If ADRs are in book-entry form, a statement setting forth the holder s ownership interest will be mailed to holders by the depositary.

When an investor surrenders ADSs at the depositary s office, the depositary will, upon payment of certain applicable fees, charges and taxes, and upon receipt of proper instructions, deliver the whole number of shares of the applicable class represented by the ADSs turned in to the account the investor directs within Clearstream Banking AG, the central German clearing firm.

The depositary may only restrict the withdrawal of deposited securities in connection with:

- temporary delays caused by closing our transfer books or those of the depositary, or the deposit of shares in connection with voting at a shareholders meeting, or the payment of dividends,
- the payment of fees, taxes and similar charges, or
- compliance with any U.S. or foreign laws or governmental regulations relating to the ADRs.

This right of withdrawal may not be limited by any other provision of the applicable deposit agreement.

Voting Rights

Only the depositary s nominee is able to exercise voting rights with respect to deposited shares. Upon receipt of a request from the depositary for voting instructions, a holder of ADSs may instruct the depositary how to exercise the voting rights for the shares which underlie their ADSs. After receiving voting materials from us, the depositary will notify the ADR holders of any shareholder meeting or solicitation of consents or proxies. This notice will describe how holders may instruct the depositary to exercise voting rights for the shares which underlie their ADSs. For instructions to be valid, the depositary must receive them on or before the date specified in the depositary s request for instructions. The depositary will try, as far as is practical, subject to the provisions of and governing the underlying shares or other deposited securities, to vote or to have its agents vote the shares or other deposited securities as instructed. The depositary will only vote or attempt to vote as holders instruct. The depositary will not itself exercise any voting discretion. Neither the depositary nor its agents are responsible for any failure to carry out any voting instructions, for the manner in which any vote is cast or for the effect of any vote.

Our Preference shares are non-voting, except in a limited number of circumstances. In those circumstances in which Preference shares are entitled to vote, the procedures and limitations described above will apply in

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connection with the depositary s request for voting instructions from holders of ADSs representing Preference shares.

There is no guarantee that holders will receive voting materials in time to instruct the depositary to vote and it is possible that holders, or persons who hold their ADSs through brokers, dealers or other third parties, will not have the opportunity to exercise a right to vote.

Description of the Pooling Agreements

The information under the heading DESCRIPTION OF THE POOLING AGREEMENTS set forth in the prospectus of Fresenius Medical Care AG dated July 20, 2000 is incorporated herein by reference.

C. Material contracts

For information regarding certain of our material contracts, see Item 7.B. Major Shareholders and Related Party Transactions Related Party Transactions. For a description of our stock option plans, see Item 6.E. Directors, Senior Management and Employees Share Ownership Options to Purchase our Securities. For a description of our 2003 Senior Credit Agreement, see Item 5B. Operating and Financial Review and Prospects Liquidity and Capital Resources. Our material agreements also include the agreements that FMCH and certain of its subsidiaries entered into with the U.S. government when we settled a U.S. government investigation. Our Report on Form 6-K filed with the SEC on January 27, 2000 contains a description of the agreements comprising the settlement, including the plea agreements and a corporate integrity agreement in Part II, Item 5 Other Events OIG Investigation, which is incorporated herein by reference.

Our material agreements include the settlement agreement that we, FMCH and NMC entered into with the Official Committee of Asbestos Injury Claimants, and the Official Committee of Asbestos Property Damage Claimants of W.R. Grace & Co. A description of the terms of the settlement agreement appears in Item 8.A.7 Legal Proceedings.

D. Exchange controls

Exchange Controls and Other Limitations Affecting Security Holders.

At the present time, Germany does not restrict the export or import of capital, except for investments in areas like Iraq, Serbia, Montenegro or Sierra Leone. However, for statistical purposes only, every resident individual or corporation residing in Germany must report to the German Federal Bank (*Deutsche Bundesbank*), subject only to certain immaterial exceptions, any payment received from or made to an individual or a corporation resident outside of Germany if such payment exceeds 12,500. In addition, residents must report any claims against, or any liabilities payable to, non-residents individuals or corporations, if such claims or liabilities, in the aggregate 5 million at the end of any month.

There are no limitations imposed by German law or our articles of association (*Satzung*) on the right of a non-resident to hold the Preference shares or Ordinary shares or the ADSs evidencing Preference shares or Ordinary shares.

E. Taxation

The following is a discussion of the material United States federal income and German tax consequences to Qualified Holders holding Fresenius Medical Care Ordinary shares, preference shares or ADSs with respect to such shares (collectively the shares). This discussion is based upon existing United States federal income and German tax law, including legislation, regulations, administrative rulings and court decisions, as in effect on the date of this Annual Report, all of which are subject to change, possibly with retroactive effect. For purposes of this discussion, in general, a Qualified Holder means a beneficial owner of Fresenius Medical Care shares that (1) is a resident of the United States for purposes of the United States-Germany income tax treaty (the Income Tax Treaty), which generally includes an individual United States resident, a corporation created or organized under the laws of the United States, any state thereof or the District of Columbia and a partnership, estate or trust, to the extent its income is subject to taxation in the United States as the income of a United States resident, either

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in its hands or in the hands of its partners or beneficiaries, (2) does not hold Fresenius Medical Care shares as part of the business property of a permanent establishment located in Germany or as part of a fixed base of an individual located in Germany and used for the performance of independent personal services and (3) if not an individual, is not subject to the limitation on benefits restrictions in the Income Tax Treaty. This discussion assumes that the Qualified Holder holds Fresenius Medical Care shares as a capital asset. This discussion does not address all aspects of United States federal income and German taxation that may be relevant to all Qualified Holders in light of their particular circumstances, including for example Qualified Holders whose stock was acquired pursuant to the exercise of an employee stock option or otherwise as compensation or Qualified Holders who are subject to special treatment under United States federal income tax laws (for example, financial institutions, insurance companies, tax-exempt organizations and broker-dealers). This discussion also does not address any aspects of state, local or non-United States (other than certain German) tax law.

EACH QUALIFIED HOLDER IS STRONGLY URGED TO CONSULT HIS OR HER TAX ADVISOR AS TO THE UNITED STATES FEDERAL INCOME AND GERMAN TAX CONSEQUENCES OF HOLDING FRESENIUS MEDICAL CARE SHARES, INCLUDING THE PARTICULAR FACTS AND CIRCUMSTANCES THAT MAY BE UNIQUE TO SUCH QUALIFIED HOLDER, AND AS TO ANY OTHER TAX CONSEQUENCES OF HOLDING OUR SHARES.

Taxation of Dividends

For dividends distributed in 2005 out of profits earned in or before 2004, German corporations are required to withhold German tax on dividends in an amount equal to 20% of the gross amount paid to resident and non-resident stockholders. A partial refund of this 20% withholding tax can be obtained by Qualified Holders under the Income Tax Treaty (subject to certain limitations). Qualified Holders are generally subject to United States federal income tax on dividends paid by German corporations. Subject to applicable limitations of United States federal income tax law, Qualified Holders may be able to claim a foreign tax credit for certain German income taxes paid. The amount of the refund of German withholding tax and the determination of the foreign tax credit allowable against United States federal income tax generally depend on whether or not the Qualified Holder is a United States corporation owning at least 10% of the voting stock of Fresenius Medical Care AG (a 10% Holder).

In the case of any Qualified Holder other than a 10% Holder, the German withholding tax on the dividends paid in 2005 is partially refunded under the Income Tax Treaty, effectively reducing the withholding tax to 15% of the gross amount of the dividend. Thus, for each $100 of gross dividend paid by Fresenius Medical Care AG in 2005 to a Qualified Holder (other than a 10% Holder), the dividend after partial refund of the 20% withholding tax under the Income Tax Treaty will be subject to a German withholding tax of $15.

In the case of a 10% Holder, the 20% German withholding tax on dividends paid in 2005 is reduced under the Income Tax Treaty to 5% of the gross amount of the dividend. Such 10% Holders may, therefore, apply for a refund of German withholding tax on the dividend paid in 2005 in the amount of 15% of the gross amount of the dividend. Subject to applicable limitations of United States federal income tax laws, a 10% Holder may be entitled to a foreign tax credit for the 5% German withholding tax on dividends and for the portion of the total income taxes (trade income tax and corporation income tax, including any surtax) paid by Fresenius Medical Care AG attributable to distributed profits.

Dividends paid in euros to a Qualified Holder of Fresenius Medical Care shares will be included in income in a dollar amount calculated by reference to the exchange rate in effect on the date the dividends (including any deemed refund of German corporate tax) are received or treated as received by such holder. If dividends paid in euros are converted into dollars on the date received or treated as received, Qualified Holders generally should not be required to recognize foreign currency gain or loss in respect of each dividend.

A surtax on the German withholding tax is currently levied on dividend distributions paid by a German resident company. The rate of this surtax is 5.5%, which is a 1.1% surcharge (5.5% on 20% withholding tax) of the gross dividend amount. Under the Income Tax Treaty, Qualified Holders are entitled to a full refund of this surtax.

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Refund Procedures

To claim the refund reflecting the current reduction of the German withholding tax from 20% to 15%, the additional 5% treaty refund and the refund of the effective 1.1% German surtax, when applicable, a Qualified Holder must submit (either directly or, as described below, through the U.S. transfer agent for Fresenius Medical Care shares or the Depository Trust Company) a claim for refund to the German tax authorities, with the original bank voucher (or certified copy thereof) issued by the paying entity documenting the tax withheld within four years from the end of the calendar year in which the dividend is received. Claims for refunds are made on a special German claim for refund form, which must be filed with the German tax authorities: Bundesamt für Finanzen, 53221 Bonn-Beuel, Germany. The German claim for refund forms may be obtained from the German tax authorities at the same address where the applications are filed or from the Embassy of the Federal Republic of Germany, 4645 Reservoir Road, N.W., Washington, D.C. 20007-1998; alternatively, you can download the form from the following website: http://www.bff-online.de/ Steuer Vordrucke/ KSt KapSt/ AntragErstattungKapE USA.pdf.

Qualified Holders must also submit to the German tax authorities certification (IRS Form 6166) of their last filed United States federal income tax return. Such certification is obtained from the office of the Director of the Internal Revenue Service Center by filing a request for the certification with the Internal Revenue Service Philadelphia Service Center, Foreign Certification Request, P.O. Box 16347, Philadelphia, PA 19114-0447. Additional information, including IRS Publication 686, can be obtained from the Internal Revenue Service website at http://www.irs.gov/pub/irs-pdf/p686.pdf Requests for certification are to be made in writing and must include the Qualified Holder s name, social security number or employer identification number, tax return form number and tax p