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

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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

Exhibit 13.1

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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 | | | | |