

D. Risk Factors

Before you invest in our securities, you should be aware that the occurrence of any of the events described in the following risk factors, elsewhere in or incorporated by reference into this report, and other events that we have not predicted or assessed could have a material adverse effect on our results of operations, financial condition and business. If the events described below or other unpredicted events occur, then the trading price of our securities could decline and you may lose all or part of your investment.

Risks Relating to Litigation and Regulatory Matters.

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

For the twelve months ended December 31, 2009, approximately 33% of our consolidated revenues resulted from Medicare and Medicaid reimbursement. Legislative changes or changes in government reimbursement practice 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. For a discussion of the rules proposed by the Centers for Medicare and Medicaid Services to implement recent Medicare reimbursement rate changes including provisions for implementation of a “bundled rate” by January 1, 2011, see Item 5, “Operating and Financial Review and Prospects – Overview.”

A reduction in reimbursement for or a change in the utilization of EPO could materially reduce our revenue and operating profit. An interruption of supply or our inability to obtain satisfactory terms for EPO could reduce our revenues.

Revenue from the administration of erythropoietin, or EPO, accounted for approximately 21% of total dialysis care revenue in our North America segment for the year ended December 31, 2009. Synthetic EPO is produced in the U.S. by a single source manufacturer, Amgen Inc., under the brand names Epogen® (epoetin alfa) and Aranesp® (darbepoetin alfa). Our supply contract with Amgen USA, Inc., a subsidiary of Amgen, Inc. covers the period from October 1, 2006 to December 31, 2011. Pricing is based on Amgen’s list price and is subject to change within certain parameters. Any of the following developments could materially adversely affect our business, financial condition and results of operations: (i) an increase in Amgen’s price for EPO without a corresponding and timely increase in reimbursement for EPO by the Centers for Medicare and Medicaid Services (“CMS”), (ii) a reduction of the current overfill amount in EPO vials which we currently use (liquid medications, such as EPO, typically include a small overfill amount to ensure that the fill volume can be extracted from the vial as administered to the patient), (iii) an interruption of supply of EPO, or (iv) decreased utilization of EPO. Under the new expanded bundled reimbursement system to be implemented by January 1, 2011, material increases in the utilization of or acquisition costs for EPO or reduction in EPO overfill could materially and adversely affect our business, financial condition and results of operations.

If we do not comply with the many governmental regulations applicable to our business, 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. We are also subject to other laws of general applicability, including antitrust laws. The applicable regulations, which differ from country to country, cover areas that include:

- the quality, safety and efficacy of medical and pharmaceutical products and supplies;
- the operation of manufacturing facilities, laboratories and dialysis clinics;
- 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.

Failure to comply with one or more of these laws or regulations, may give rise to a number of legal consequences. These include, in particular, monetary and administrative penalties, increased costs for compliance with government orders, complete or partial exclusion from government reimbursement programs or complete or partial curtailment of our authority to conduct business. Any of these consequences could have a material adverse impact on our business, financial condition and results of operations.

The Company's pharmaceutical products are subject to detailed, rigorous and continually changing regulation by the U.S. Food and Drug Administration ("FDA"), and numerous other national, supranational, federal and state authorities. These include, among other things, regulations regarding manufacturing practices, product labeling, quality control, quality assurance, advertising and post-marketing reporting, including adverse event reports and field alerts due to manufacturing quality concerns. We cannot assure that all necessary regulation approvals for new products or product improvements will be granted on a timely basis or at all. In addition, the Company's facilities and procedures and those of its suppliers are subject to periodic inspection by the FDA and other regulatory authorities. The FDA and comparable regulatory authorities outside the U.S. may suspend, revoke, or adversely amend the authority necessary for manufacture, marketing, or sale of our products and those of our suppliers. The Company and its suppliers must incur expense and spend time and effort to ensure compliance with these complex regulations, and if such compliance is not maintained, could be subject to significant adverse regulatory actions in the future. These possible regulatory actions could include warning letters, fines, damages, injunctions, civil penalties, recalls, seizures of the Company's products and criminal prosecution. These actions could result in, among other things, substantial modifications to the Company's business practices and operations; refunds; a total or partial shutdown of production while the alleged violation is remedied; and withdrawals or suspensions of current products from the market. Any of these events, in combination or alone, could disrupt the Company's business and have a material adverse effect on the Company's business, financial condition and results of operations.

We rely upon the Company's management structure, regulatory and legal resources and the effective operation of our compliance programs to direct, manage and monitor our operations to comply with government regulations. If employees were to deliberately or inadvertently fail to adhere to these regulations, then our authority to conduct business could be terminated and our operations could be significantly curtailed. Such actions could also lead to claims for repayment or other sanctions. Any such terminations or reductions could materially reduce our sales, with a resulting material adverse effect on our business, financial condition and results of operations.

FMCH and its subsidiaries, including Renal Care Group ("RCG") (prior to the RCG Acquisition), received subpoenas in 2005 from the U.S. Department of Justice for the Eastern District of Missouri, in connection with a joint civil and criminal investigation. The subpoenas require production of a broad range of documents relating to FMCH's and RCG's operations, with specific attention to documents related to clinical quality programs, business development activities, medical director compensation and physician relationships, joint ventures, and anemia management programs, RCG's Method II home dialysis supply company, pharmaceutical and other services that RCG provides to patients, RCG's relationships to pharmaceutical companies, and RCG's purchase of dialysis equipment from FMCH. The Office of the Inspector General of the U.S. Department of Health and Human Services and the U.S. Attorney's office for the District of Texas participated in the Eastern District of Missouri's investigation of FMCH's and RCG's utilization of Epogen begun in 2005. On July 16, 2007, the U.S. Attorney's office filed a civil complaint against RCG and FMCH in its capacity as RCG's current corporate parent in United States District Court, Eastern District of Missouri. The complaint seeks monetary damages and penalties with respect to issues arising out of the operation of RCG's Method II supply company through 2005, prior to the date of FMCH's acquisition of RCG. On August 11, 2009, the Court granted RCG's motion to transfer venue to the Middle District of Tennessee (Nashville), where the case is proceeding toward trial. The Company believes that RCG's operation of its Method II supply company complied with applicable law and will defend this litigation vigorously. We will continue to cooperate in the ongoing investigation. An adverse determination in this investigation or litigation or any settlement arising out of this investigation or litigation could result in significant financial penalties and possible exclusion from participation in federal and state health care programs, and any adverse determination in any litigation arising out of the investigation could have a material adverse effect on the Company's business, financial condition and results of operations.

If our joint ventures violate the law, our business could be adversely affected.

A number of the dialysis centers we operate are owned by joint ventures in which we hold a controlling interest and one or more hospitals, physicians or physician practice groups hold a minority interest. The physician owners may also provide medical director services to those centers or other centers we own and operate. The majority of these joint ventures were acquired in the RCG Acquisition. While we have structured our joint ventures to comply with many of the criteria for safe harbor protection under the Federal Anti-Kickback Statute, our investments in these joint venture arrangements do not satisfy all elements of such safe harbor. While we have established comprehensive compliance policies, procedures and programs to ensure ethical and compliant joint venture business operations, if one or more of our joint ventures were found to be in violation of the Anti-Kickback Statute or the Stark Law, we could be required to restructure or terminate them. We also could be required to repay to Medicare amounts received by the joint ventures pursuant to any prohibited referrals, and we could be subject to monetary penalties and exclusion from Medicare, Medicaid and other federal and state health care programs.

Imposition of any of these penalties could have a material adverse effect on our business, financial condition and results of operations.

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

Many of the countries in which we operate have been considering proposals to modify their current health care systems to improve access to health care and control costs. We cannot predict whether and when these reform proposals will be adopted in countries in which we operate or what impact they might have on us. In the U.S., Congress has debated bills that, if adopted, would make significant changes to the health care system. It is difficult to determine at this time whether a health care reform bill will be passed and if passed, what the provisions of such a bill would be. Any significant changes in health care reform which radically change the financing and regulation of the health care industry in countries in which we operate, particularly significant changes in the U.S. Medicare and Medicaid programs, could reduce our sales and profitability and have a material adverse effect on our business, financial condition and results of operations.

Risks Relating to our Business

A significant portion of our North American profits are dependent on the services we provide to a minority of our patients who are covered by private insurance.

In recent reviews of dialysis reimbursement, the Medicare Payment Advisory Commission, also known as MedPAC, has noted that Medicare payments for dialysis services are less than the average costs that providers incur to provide the services. Since Medicaid rates are comparable to those of Medicare and because Medicare only pays us 80% of the Medicare allowable amount (the patient, Medicaid or secondary insurance being responsible for the remaining 20%), the amount we receive from Medicare and Medicaid is less than our average cost per treatment. As a result, the payments we receive from private payors both subsidize the losses we incur on services for Medicare and Medicaid patients and generate a substantial portion of the profits we report. We estimate that Medicare and Medicaid are the primary payors for approximately 80% of the patients to whom we provide care in North America but that only 54% of our North America Dialysis Care net revenues in 2009 were derived from Medicare and Medicaid. Therefore, if the private payors who pay for the care of the other 20% of our patients reduce their payments for our services, or if we experience a shift in our revenue mix toward Medicare or Medicaid reimbursement, then our revenue, cash flow and earnings would decrease, and our cash flow and profits would be disproportionately impacted.

Over the last few years, we have generally been able to implement modest annual price increases for private insurers and managed care organizations, but government reimbursement has remained flat or has been increased at rates below typical consumer price index ("CPI") increases. There can be no assurance of similar future price increases to private insurers and managed care organizations. Any reductions in reimbursement from private insurers and managed care organizations could adversely impact our operating results. Any reduction in our ability to attract private pay patients to utilize our dialysis services relative to historical levels could adversely impact our operating results. Any of the following events could have a material adverse effect on our operating results:

- a portion of our business that is currently reimbursed by private insurers or hospitals may become reimbursed by managed care organizations, which generally have lower rates for our services; or
- a portion of our business that is currently reimbursed by private insurers at rates based on our billed charges may become reimbursed under a contract at lower rates.

We are exposed to product liability, patent infringement and other claims which could result in significant costs and liability which we may not be able to insure on acceptable terms in the future.

Health care companies are typically subject to claims alleging negligence, product 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 and patent infringement claims. We cannot assure you that such claims will not be asserted against us, that significant adverse verdicts will not be reached against us for patent infringements or that large scale recalls of our products will not become necessary. In addition, the laws of some of the countries in which we operate provide legal rights to users of pharmaceutical products that could increase the risk of product liability claims. Product liability and patent infringement claims, other actions for negligence or breach of contract and product recalls or related sanctions could result in significant costs. These costs could have a material adverse effect on our business, financial condition and results of operations. See Note 18 of the Notes to Consolidated Financial Statements, "Legal Proceedings."

While we have been able to obtain liability insurance in the past to partially cover our business risks, we cannot assure that such insurance will be available in the future either on acceptable terms or at all. In addition, FMCH, our largest subsidiary, is partially self-insured for professional, product and general liability, auto liability and worker's compensation claims, up to pre-determined levels above which our third-party insurance applies. 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 sales and profitability.

The Company is vigorously defending certain patent infringement lawsuits described in Note 18 of the Notes to Consolidated Financial Statements, "Legal Proceedings – Commercial Litigation". While we believe we have valid defenses to these claims, an adverse determination in any of these matters could have a material adverse effect on the Company's business, financial condition and results of operations.

Our growth depends, in part, on our ability to continue to make acquisitions.

The health care industry has experienced significant consolidation in recent years, particularly in the dialysis services sector. Our ability to make future acquisitions depends, in part, on our available financial resources and could be limited by restrictions imposed in the United States of America or other countries competition laws or under our credit agreements. If we make future acquisitions, we may need to incur additional debt, assume significant liabilities or create additional expenses relating to intangible assets, any of which might reduce our reported earnings and our earnings per share and cause our stock price to decline. In addition, any financing that we might need for future acquisitions might be available to us only on terms that restrict our business. We may also issue ordinary shares for non-cash consideration without first offering the shares to our existing shareholders, which could dilute the holdings of these shareholders. Acquisitions that we complete are also subject to risks relating to, among other matters, integration of the acquired businesses (including combining the acquired company's infrastructure and management information systems with ours, harmonization of its marketing, patient service and logistical procedures with ours and, potentially, reconciling divergent corporate and management cultures), possible non-realization of anticipated synergies from the combination, potential loss of key personnel or customers of the acquired companies, and the risk of assuming unknown liabilities not disclosed by the seller or not identified during due diligence. If we are not able to effect acquisitions on reasonable terms, there could be an adverse effect on our business, financial condition and results of operations.

We also compete with other dialysis products and services companies in seeking suitable acquisition targets and the continuing consolidation of dialysis providers and combinations of dialysis providers with dialysis product manufacturers could affect future growth of our product sales. If we are not able to continue to effect acquisitions on reasonable terms, especially in the international area, this could have an adverse effect on our business, financial condition and results of operations.

We face specific risks from international operations.

We operate dialysis clinics in more than 35 countries and sell a range of equipment, products and services to customers in over 115 countries. Our international operations are subject to a number of risks, including but not limited to the following:

- the economic situation in developing countries could deteriorate;
- 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 and economic instability, especially in developing and newly industrializing countries, could disrupt our operations;
- some customers and governments could have longer payment cycles, with resulting adverse effects on our cash flow;
- some countries could impose additional taxes or restrict the import of our products; and
- failure to receive or the loss of required licenses, certifications or other regulatory approvals for operation of dialysis clinics or sale of equipment, products, or services.

Any one or more of these or other factors 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.

If physicians and other referral sources cease referring patients to our dialysis clinics or cease purchasing or prescribing 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 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 transfer 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 often account for the referral of all or a significant portion of the patient base. Our dialysis care business also depends on recommendations by hospitals, managed care plans and other health care institutions. If a significant number of physicians, hospitals or other health care institutions cease referring their patients to our clinics, this would reduce our dialysis care revenue and would materially adversely affect our overall operations.

The decision to purchase or prescribe 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 recommendations from other sources for purchases of our products or ancillary services would reduce our dialysis product and other services revenue, and could materially adversely affect our business, financial condition and results of operations.

Our pharmaceutical product business could lose sales to generic drug manufacturers or new branded drugs.

Our branded pharmaceutical product business is subject to significant risk as a result of competition from manufacturers of generic drugs and other new competing medicines or therapies. For information regarding the impact of the launch of a generic version of our phosphate binder PhosLo®, see Item 5, "Operating and Financial Review and Prospects." We are obligated to make certain minimum annual royalty payments under certain of our pharmaceutical product license agreements, irrespective of our annual sales of the licensed products. Either the expiration or loss of patent protection for one of our products, or the "at-risk" launch by a generic manufacturer of a generic version of one of our branded pharmaceutical products or the launch of new branded drugs that compete with one or more of our products, could result in the loss of a major portion of sales of that branded pharmaceutical product in a very short time period with no concomitant reduction in our license royalty payment obligations, which could materially and adversely affect our business, financial condition and results of operations.

Our competitors could develop superior technology or otherwise impact our 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 and especially new competitive developments 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 or services less competitive or even obsolete.

Global economic conditions may have an adverse effect on our businesses.

There was a material deterioration of the global economy and tightening of the financial markets in 2008 and 2009, and the outlook for the global economy in 2010 is uncertain. We depend on the financial markets for access to capital, as do our renal product customers and commercial healthcare insurers. Limited or expensive access to capital could make it more difficult for these customers to do business with us, or to do business generally, which could adversely affect our businesses. The continuation, or worsening, of domestic and global economic conditions could continue to adversely affect our businesses 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 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. If we are unable to achieve that goal or if doing so requires us to bear increased costs this could adversely impact our growth and results of operations.

Our dialysis products business depends on the development of new products, technologies and treatment concepts to be competitive. Competition is also intense for skilled engineers and other technical research and development personnel. If we are unable to obtain and retain 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.

Diverging views of fiscal authorities could require us to make additional tax payments.

We are in dispute with the German tax authorities and the U.S. Internal Revenue Service (IRS) on certain tax deductions disallowed in past tax audits. We are also 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 these audits and we may be subject to additional unfavorable adjustments and disallowances. We are contesting, and in some cases appealing or litigating certain of the unfavorable determinations. If our objections, audit appeals or court claims are unsuccessful, we could be required to make additional tax payments, which could have a material adverse impact on our results of operations and operating cash flow in the relevant reporting period. (See Item 5, "Operating and Financial Review and Prospects – B. Liquidity and Capital Resources – Liquidity" as well as Note 18 of the Notes to Consolidated Financial Statements, "Legal Proceedings.")

Risks Relating to our Securities

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

At December 31, 2009, we had consolidated debt of \$5,568 million, including \$656 million of our trust preferred securities, and consolidated total shareholders' equity of \$7,030 million. Our debt could have significant consequences to our operations and our financial condition. For example, it could require us to dedicate a substantial portion of our cash flow from operations, as well as the proceeds of certain financings and asset dispositions, to payments on our indebtedness, thereby reducing the availability of our cash flow and such proceeds to fund working capital, capital expenditures and for other general corporate purposes.

Our 2006 Senior Credit Agreement, Senior Notes, European Investment Bank Agreements, Euro Notes 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 fixed charge ratio (ratio of EBITDAR – consolidated earnings before interest, taxes, depreciation and amortization (EBITDA) plus rent – to consolidated fixed charges) and subject to a maximum consolidated leverage ratio (ratio of consolidated funded debt to EBITDA).

Our 2006 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 and other restricted payments, create liens or make investments or acquisitions. These covenants may otherwise limit our activities. The breach of any of the covenants could result in a default and acceleration of the indebtedness under the credit agreement or the indentures, which could, in turn, create additional defaults and acceleration of the indebtedness under the agreements relating to our other long-term indebtedness which would have an adverse effect on our business, financial condition and results of operations

Fresenius SE owns 100% of the shares in the general partner of our Company and is able to exercise management control of FMC-AG & Co. KGaA.

Fresenius SE owns approximately 36.0% of our voting ordinary shares and 100% of the outstanding shares of the general partner of the Company. As the sole shareholder of Fresenius Medical Care Management AG, the general partner of the Company, Fresenius SE has the sole right to elect the supervisory board of the general partner which, in turn, appoints the management board of the general partner. The management board of the general partner is responsible for the management of the Company. Through its ownership of the general partner, Fresenius SE is able to exercise de facto management control of FMC-AG & Co. KGaA even though it owns less than a majority of our outstanding voting shares. Such de facto control limits public shareholder influence on management of the