

We conduct our business on a global basis in various currencies with major operations located in the U.S. and Germany. We prepare our consolidated financial statements, from which we derived the selected financial data above, utilizing the euro as our reporting currency. We have converted the balance sheets of our non-euro denominated operations into euro at the exchange rates prevailing at the balance sheet date. Revenues and expenses are translated at the average exchange rates for the respective period, as shown.

A summary of the spot and average exchange rates for the euro to U.S. dollars for the last three years is set forth below. The European Central Bank ("ECB") determines such rates ("Reference Rates") based on the regular daily averaging of rates between central banks within and outside the European banking system. The ECB normally publishes the Reference Rates daily around 4p.m. (CET).

Exchange rates					
	December 31, 2018 spot exchange rate in €	December 31, 2017 spot exchange rate in €	2018 average exchange rate in €	2017 average exchange rate in €	2016 average exchange rate in €
1 U.S. dollar	0.87336	0.83382	0.84678	0.88519	0.90342

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 or elsewhere in this report, and other events that we have not predicted or assessed could have a material adverse impact on our business, financial condition and results of operations. 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 regulatory matters.

We operate in a highly regulated industry such that the potential for legislative reform provides uncertainty and potential threats to our operating models and results.

The delivery of healthcare services and products is highly regulated in most of the countries in which we operate. Proposals for legislative reform in these countries are often introduced to improve access to care, address quality of care issues and manage costs of the healthcare system. In the U.S., the Trump Administration and the 115th Congress have publicly announced their desire to pursue, and may enact, significant changes to existing health care programs. Certain health insurance provisions of the Patient Protection and Affordable Care Act of 2010 (Pub.L. 111-148), as amended by the Health Care and Education Reconciliation Act (Pub.L. 111-152) (collectively, "ACA") are targets for change. Changes of such nature could have significant effects on our businesses, both positive and negative, but the outcomes are impossible to predict.

While the Trump Administration announced in late 2017 its intention to cease cost-sharing reduction ("CSR") payments under the insurance exchanges created under the ACA, the Administration eventually did fund CSRs in 2018 and has requested funding for CSRs in 2019. If CSR funding ceases at any point, commercial insurers have indicated that premium rates would need to increase and that they may withdraw from the insurance exchanges created under the ACA. So far average premiums for 2019 appear to be only moderately higher compared to 2018, though there is large variation between states with some states having significant increases. In addition, there is ongoing litigation over the Federal Government's obligation to pay the CSRs and over the constitutionality of provisions of the ACA. We cannot predict whether the Trump Administration will agree to pay the CSRs in 2019, continue to dismantle the insurance exchanges through other means, or how the ongoing litigation might be determined. As a result, a reduction in the availability of insurance through such exchanges could reduce the number of our commercially insured patients and shift such patients to Medicare and Medicaid. Because Medicare and Medicaid reimbursement rates are generally lower than the reimbursement rates paid by commercial insurers, a shift of commercially insured patient to Medicare and Medicaid could have a material adverse impact on our business, financial condition and results of operations. See "- Changes in reimbursement and/or governmental regulations for health care could materially decrease our revenues and operating profit."

Changes in reimbursement and/or governmental regulations for health care could materially decrease our revenues and operating profit.

We receive reimbursement for our healthcare services from both public, government-sponsored payors and private, commercial payors. A large portion of our businesses is reimbursed by government payors, in particular the Medicare and Medicaid program in the U.S. For the years ended December 31, 2018 and 2017, approximately 33% and 34%, respectively, of our consolidated revenues resulted from Medicare and Medicaid reimbursement. The Medicare and Medicaid programs change their payment methodologies and funding from time to time in ways that are driven by changes in statute, economic conditions, and policy. For example, the Budget Control Act of 2011 ("BCA") effected a 2% reduction to Medicare payments and subsequent activity in Congress, a \$1.2 trillion sequester (across-the-board spending cuts) in discretionary programs, took effect on April 1, 2013, which continues in force. In addition, options to restructure the Medicare program in the direction of a defined-contribution, "premium support" model and to shift Medicaid funding to a block grant or per capita arrangement, with greater flexibility for the states, are also likely to be considered. Changes in payment methodologies and funding or payment requirements of (without limitation) the End-Stage Renal Disease Prospective Payment System, the Physician Fee Schedule, the Clinical Laboratory Fee Schedule, and the Ambulatory Surgical Center Payment System may have material effects on our operating results. We have very little opportunity to influence or predict the magnitude of those changes. For further information regarding Medicare and Medicaid reimbursement, see Item 4B, "Information on the Company - Business Overview - Regulatory and Legal Matters - Reimbursement" and Item 5, "Operating and Financial Review and Prospects - Overview."

Government reimbursement programs generally pay less than private insurance. In addition, we may experience higher write-offs of Medicare deductibles and other amounts due to uninsured and underinsured patients, resulting in an increase in uncollectible accounts. As a result, the payments we receive from private payors generate a substantial portion of the profits we report. Please see the table "U.S. patient service revenue" detailing the percentage generated from government reimbursement and private payors in the U.S. in Item 4B, "Information on the Company - Business overview - U.S. patient service revenue."

Any of the following events, among others, could have a material adverse impact on our business, financial condition and results of operations:

- we may be subject to reductions in reimbursement from private payors, including, for example, through their use of lower contract rates rather than rates based on our billed charges;
- we may experience a reduction in our ability to obtain commercially insured patients to utilize our health care services relative to historical levels;
- efforts by private payors to continue to control the cost of and/or the eligibility for access to health care services, including relative to products on and off the health care exchanges established by the ACA;
- a portion of our business that is currently reimbursed by private insurers or hospitals may become reimbursed by integrated care organizations, which may use payment methodologies that reduce reimbursement for our services. There can be no assurance that we can achieve future price increases from private insurers and integrated care organizations offering private insurance coverage to our patients; or
- if efforts to restrict or eliminate the charitable funding of patient insurance premiums are successful, a portion of our patients who are currently covered by private insurers may elect to transition to government funded reimbursement programs that reimburse us at lower rates for our services. See Item 4B, "Information on the Company - Business Overview - Regulatory and Legal Matters - Reimbursement - Potential changes impacting our private payors" for further information.

In addition to the foregoing factors, the health care insurance industry is experiencing continuing consolidation among insurers and pharmacy benefit managers. Such consolidation could increase the bargaining power of such private payors vis-à-vis the Company and adversely affect our ability to negotiate favorable coverage terms and reimbursement rates.

If we do not comply with the numerous governmental regulations applicable to our business, we could suffer adverse legal consequences, including exclusion from government healthcare reimbursement programs or termination of our authority to conduct business, any of which would result in a material decrease in our revenue; this regulatory environment also exposes us to claims and litigation, including "whistle-blower" suits.

Our operations in both our health care services 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:

- regulatory approvals for products or product improvements;
- regulatory approvals and oversight of clinical and certain non-clinical research and development activities;
- the quality, safety and efficacy of medical and pharmaceutical products and supplies;
- the operation and licensure of manufacturing facilities, laboratories, dialysis clinics and other health care facilities;
- product labeling, advertising and other promotion;
- accurate reporting and billing for government and third-party reimbursement, including accurate and complete medical records to support such billing and, in the U.S., the obligation to report and return overpayments within 60 days of the time that the overpayment is identified and quantified;
- the discounting of reimbursed drug and medical device products and the reporting of drug prices to government authorities;
- the collection, dissemination, access, use, security and privacy of protected health information or other protected data; 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 adverse legal consequences. These include, in particular, loss or suspension of federal certifications, loss or suspension of licenses under the laws of any state or governmental authority from which we generate substantial revenues, monetary and administrative penalties, increased costs for compliance with government orders, complete or partial exclusion from government reimbursement programs, refunds of payments received from government payors and government health care program beneficiaries due to failures to meet applicable requirements 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 medical devices and drug products are subject to detailed, rigorous and frequently changing regulation by the U.S. Food and Drug Administration ("FDA"), and numerous other national, supranational, federal and state authorities. 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 research, 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, they could be subject to significant adverse administrative and judicial enforcement actions in the future. These possible enforcement actions could include warning letters, injunctions, civil penalties, seizures of the Company's products, and criminal prosecutions as well as dissemination of information to the public about such enforcement actions. 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 impact on our business, financial condition and results of operations. For a discussion of our open FDA warning letter, see "Item 4B. "Information on the Company - Business Overview - Regulatory and legal matters - FDA warning letters."

The Company operates many facilities and engages with other business associates to help it carry out its health care activities. 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 and its business associates. We rely on 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, recklessly or inadvertently fail to adhere to these regulations, then our authority to conduct business could be terminated and our operations could be significantly curtailed. Any such terminations or reductions could materially reduce our revenues. If we fail to identify in our diligence process or to promptly remediate any non-compliant business practices in companies that we acquire, we could be subject to penalties, claims for repayment or other sanctions. Any such terminations or reductions could materially reduce our revenues, with a resulting material adverse impact on our business, financial condition and results of operations.

By virtue of this regulatory environment, our business activities and practices are subject to extensive review by regulatory authorities and private parties, and continuing audits, subpoenas, other inquiries, claims and litigation relating to the Company's compliance with applicable laws and regulations. We may not always be aware that an inquiry or action has begun, particularly in the case of "qui tam" or "whistle-blower" actions brought by private plaintiffs under the False Claims Act, which are initially filed under seal. We are the subject of a number of governmental inquiries and civil suits by the federal government and private plaintiffs. For information about certain of these pending investigations and lawsuits, see note 22 of the notes to our consolidated financial statements included in this report.

In addition, there may be future legislative or regulatory changes that affect procedures or decision making for approving medical device or drug products. Any such legislation or regulations, if enacted or promulgated, could result in a delay or denial of regulatory approval for our products. If any of our products do not receive regulatory approval, or there is a delay in obtaining approval, this also could have a material adverse impact on our business, financial condition and results of operations.

If we are unable to protect our information technology security systems and rely on our third-party service providers to protect their systems against cyber attacks or prevent other privacy and data security incidents that result in privacy and data breaches that disrupt our operations or result in the unintended disclosure and access of sensitive personal information or proprietary or confidential information, we could be exposed to significant regulatory fines or penalties, liability or reputational damage, or experience a material adverse impact on our business, financial condition and results of operations.

We routinely process, store and transmit large amounts of data in our operations, including sensitive personal information as well as proprietary or confidential information relating to our business or third-parties. We may be subject to breaches of the information technology security systems we use both internally and externally with third-party service providers.

A cyber-attack may penetrate our security controls and result in the misappropriation or compromise of sensitive personal information or proprietary or confidential information, including such information which is stored or transmitted on the systems used by certain of our products, to create system disruptions, cause shutdowns, or deploy viruses, worms, and other malicious software programs that attack our systems. We handle the personal information of our patients and beneficiaries, Patient Personal Data ("PPD"), throughout the United States and other parts of the world. On occasion, we or our business associates may experience a breach under the U.S. Health Insurance Portability and Accountability Act Privacy and Security Rules, the EU's General Data Protection Regulation and/or other similar laws ("Data Protection Laws"), including the following events:

- impermissible use, access, or disclosure of unsecured PPD,
- a breach under the Data Protection Laws when the Company or its business associates neglect to implement the required administrative, technical and physical safeguards of its electronic systems and devices, or
- a data breach that results in impermissible use, access or disclosure of personal identifying information of its employees, patients and beneficiaries.

We have redesigned the policies and procedures for internal reporting of privacy incidents or breaches and external reporting of privacy breaches to comply with the Data Protection Laws and regulations across the world. These policies and procedures are intended to help ensure (i) our compliance with the strict reporting deadlines set by Data Protection Laws and any regulation and (ii) swift remediation of any process defect.

As we increase the amount of sensitive personal information that we store and share digitally, our exposure to these privacy and data breaches and cyber-attack risks increases, including the risk of undetected attacks, damage, loss or unauthorized disclosure or access, and the cost of attempting to protect against these risks also increases. We have implemented security technologies, processes and procedures to protect sensitive personal information and proprietary or confidential information; however, there are no assurances that such measures will be effective against all types of breaches. Any failure to keep our information technology systems and our patients' and customers' sensitive information secure from attack, damage, loss or unauthorized disclosure or access, whether as a result of our action or inaction or that of our third-party business associates or vendors that utilize and store such personal information on our behalf, could adversely affect our reputation and operations and also expose us to mandatory public disclosure requirements, litigation and governmental enforcement proceedings, material fines, penalties and/or remediation costs, and compensatory, special, punitive and statutory damages, consent orders and other adverse actions, any of which could have a material adverse impact on our business, financial condition and results of operations.

We operate in many different jurisdictions and we could be adversely affected by violations of the U.S. Foreign Corrupt Practices Act and similar worldwide anti-corruption laws.

The U.S. Foreign Corrupt Practices Act ("FCPA") and similar worldwide anti-corruption laws generally prohibit companies and their intermediaries from making improper payments to public officials for the purpose of obtaining or retaining business. Our internal policies mandate compliance with these anti-corruption laws. We operate many facilities throughout the United States and other parts of the world. Our decentralized system has thousands of persons employed by many affiliated companies, and we rely on our management structure, regulatory and legal resources and effective operation of our compliance program to direct, manage and monitor the activities of these employees and their agents. Despite our training, oversight and compliance programs, we cannot assure you that our internal control policies and procedures always will protect us from deliberate, reckless or inadvertent acts of our employees or agents that contravene the Company's compliance policies or violate applicable laws. Our continued expansion, including in developing countries, could increase the risk of such violations in the future. Violations of these laws, or allegations of such violations, could disrupt our business and result in a material adverse impact on our business, financial condition and results of operations. Beginning in 2012, the Company received certain communications alleging conduct in countries outside the United States that might violate the Foreign Corrupt Practices Act or other anti-bribery laws. The Company's Supervisory Board, through its Audit and Corporate Governance Committee, conducted investigations with the assistance of independent counsel. In a continuing dialogue, the Company voluntarily advised the Securities and Exchange Commission and the United States Department of Justice (collectively and interchangeably the "government") about these investigations. The government also conducted its own investigations, in which the Company cooperated. In the course of this dialogue, the Company identified and reported to the government, and took remedial actions including employee disciplinary actions with respect to, conduct that resulted in the government seeking monetary penalties and other remedies against the Company and disgorgement of related profits revolving principally around conduct in the Company's products business in a limited number of countries outside the United States. The Company recorded charges of €200 M in 2017 and €77 M in 2018 encompassing estimates for the government's claims for profit disgorgement, penalties, certain legal expenses, and other related costs or asset impairments believed likely to be necessary for full and final resolution, by litigation or settlement, of the claims and issues arising from the investigation. The increase recorded in 2018 took into consideration preliminary understandings with the government on the financial terms of a potential settlement. Following this increase, which takes into account incurred and anticipated legal expenses, impairments and other costs, the provision totals €224 M as of December 31, 2018. The Company has reached an agreement in principle with the government agencies encompassing the terms understood to be necessary for settlement. The Company believes that the previously-recorded charge appropriately accounts for the consequences of the resolution as related to its financial statements. The agreement in principle remains subject to memorialization in fully integrated documents and final approval by authorized officials of the government and the Company. The Company continues to implement enhancements to its anti-corruption compliance program, including internal controls related to compliance with international anti-bribery laws. The Company continues to be fully committed to compliance with the Foreign Corrupt Practices Act and other applicable anti-bribery laws. See "Item 15B. Management's annual report on internal control over financial reporting" and note 22 of the notes to our consolidated financial statements included in this report.

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

A number of the dialysis clinics and health care centers that we operate are owned, or managed, by joint ventures in which one or more hospitals, physicians or physician practice groups hold an interest. Physician owners, who are usually nephrologists, may also provide medical director services and physician owners may refer patients to those centers or other centers we own and operate or to other physicians who refer patients to those centers or other centers we own and operate. Because our relationships with physicians are governed by the federal and state anti-kickback statutes, we have structured our joint venture arrangements to comply with many of the criteria for safe harbor protection under the U.S. Federal Anti-Kickback Statute; however, 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, the Stark Law or other similar laws worldwide, we could be required to restructure or terminate them. We also could be required to repay to Medicare, Medicaid as well as other federal health care program amounts pursuant to any prohibited referrals, and we could be subject to criminal and monetary penalties and exclusion from federal and state healthcare programs. Imposition of any of these penalties could have a material adverse impact on our business, financial condition and results of operations. See note 22 of the notes to our consolidated financial statements included in this report.

If we are unable to secure appropriate reimbursement arrangements for the pharmaceuticals we provide in our dialysis clinics, our business could be adversely affected.

We receive reimbursement for the treatment of Medicare patients based upon the ESRD PPS rates as determined by CMS. CMS subjects a base ESRD PPS payment rate to case-mix adjustments that take into account individual patient characteristics. The annually adjusted rates may not provide fully compensating reimbursement for the services or products consumed during service. Pharmaceuticals included within the bundled rate are subjected to increased reimbursement pressure in comparison to the pharmaceuticals currently reimbursed outside the bundle. In some cases, pharmaceuticals that were reimbursed outside of the bundle are transitioned for inclusion within the bundle. Recently, CMS clarified that once any non-oral ESRD-related drug in a category previously considered oral only is approved by the U.S. Food and Drug Administration ("FDA"), such category of drugs will cease to be considered oral only. As a result of this determination, reimbursement for calcimimetics is now included in the ESRD PPS, effective as of January 1, 2018, subject to CMS's payment a "transitional drug add-on payment adjustment" for two years. During this transition period, CMS will not pay outlier payments for these drugs. If we are unable to secure appropriate reimbursement arrangements for the pharmaceuticals we provide in our dialysis clinics, we could experience a material adverse effect on our operating results.

Further, an increased utilization of bundled pharmaceuticals or decreases in reimbursement for pharmaceuticals outside the bundled rate may result in a material adverse impact on our results of operations. We are also subject to audits and reviews by enforcement authorities, including the FDA, for compliance with applicable drug regulations. These audits or reviews may impact our participation in Medicare and Medicaid programs, the imposition of potential fines or penalties as well as oversight or recalibration of processes and procedures which may have a material adverse impact on our business and results of operations.

Risks relating to our business

If we fail to estimate, price for and manage our medical costs in an effective manner, the profitability of our value-based products and services could decline and could materially and adversely affect our results of operations, financial position and cash flows.

Through our value-based agreements and health insurance products, we assume the risk of both medical and administrative costs for certain patients in return for fixed periodic payments from governmental and commercial insurers. Our participation in various value-based programs includes the Centers for Medicare and Medicaid Services ("CMS") Comprehensive End-Stage Renal Disease ("ESRD") Care initiative and capitation or shared savings agreements with commercial insurers in which FMCH receives a fixed fee to cover all or a defined portion of the medical costs of a defined population of patients. We previously participated in the CMS Bundled Payments for Care Improvement ("BPCI") program until we divested our controlling interest in Sound Inpatient Physicians, Inc. ("Sound") on June 28, 2018. We also participated in Medicare Advantage chronic special needs plans, until December 31, 2018. For information

on the value-based programs in which we participate, see Item 4B. "Information on the Company - Business overview - Care Coordination - health plan services."

CMS relied on authority granted by the ACA to implement the Comprehensive ESRD Care Model, which seeks to deliver better health outcomes for ESRD patients while lowering CMS' costs. Although Congress's efforts to date to repeal the ACA have been unsuccessful, further efforts to repeal or revise the ACA, the posture of CMS in the Trump Administration toward projects of this sort and litigation seeking the termination of the ACA may affect the project's future prospects in ways which we currently cannot quantify or predict.

The reserves that we establish for health insurance policy benefits and other contractual rights and benefits are based upon assumptions and judgments concerning a number of factors, including trends in health care costs, expenses, general economic conditions and other factors. To the extent the actual claims experience is less favorable than estimated based on our underlying assumptions, our incurred losses would increase and future earnings could be adversely affected.

Our profitability in our value based agreements and insurance products is dependent in part upon our ability to contract on favorable terms with hospitals, physicians and other health care providers. The failure to maintain or to secure cost-effective health care provider contracts may result in a loss of beneficiaries or higher medical costs, which could adversely affect our business.

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.

Healthcare 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. Healthcare products may also be subject to recalls and patent infringement claims which, in addition to monetary penalties, may restrict our ability to sell or use our products. We cannot assure that such claims will not be asserted against us; for example, 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 impact on our business, financial condition and results of operations. While personal injury litigation involving the Company's acid concentrate product was substantially resolved by settlement consummated in November 2017, the Company and certain of its insurers are in litigation against each other relating to such insurers' coverage obligations under applicable policies. See note 22 of the notes to consolidated financial statements included in this report.

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, or that our insurance carriers will not dispute their coverage obligations. 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 for which we are self-insured or in excess of the limits of our insurance coverage could have a material adverse impact on our business, financial condition and results of operations. Liability claims, regardless of their merit or eventual outcome, also may have a material adverse effect on our business and result in a loss of customer confidence in us or our products, which could have a material adverse impact on our business, financial condition and results of operations.

Our growth depends, in part, on our ability to continue to make acquisitions and develop de novo dialysis clinics and health care centers.

The health care industry experiences continuing consolidation particularly among health care providers. This development could adversely affect the Company's ability to find suitable acquisition targets and to increase future growth and product sales. Additionally, the ability to make future acquisitions as well as develop de novo dialysis clinics and health care centers depends, in part, on the availability of financial resources and the current restrictions imposed by competition laws as well as existing credit agreements. The integration of acquired businesses may cause problems, e.g., by assuming unknown liabilities, underperformance subsequent to integration, associated requirements from competition authorities, or non-compliant business practices not disclosed by the seller or not uncovered during due diligence. We also

compete with other health care companies in seeking suitable acquisition targets and developing de novos. Any or all of these factors generally could adversely affect future growth, including growth of our product sales.

We face specific risks from international operations.

We operate dialysis clinics in around 50 countries and sell a range of products and services to customers in around 150 countries. Our international operations are subject to a number of risks, including but not limited to the following:

- the economic situation in certain 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;
- some countries or economic unions may impose charges or restrictions, such as local content requirements, which restrict the importation of our products;
- potential increases in tariffs and trade barriers that could result from withdrawal by the United States or other countries from unions, including the exit from major multilateral trade agreements;
- transportation delays or interruptions.

International growth and expansion into emerging markets could cause us difficulty due to greater regulatory barriers than in the United States or Western Europe, the necessity of adapting to new regulatory systems, and problems related to entering new markets with different economic, social, legal and political systems and conditions.

Any one or more of these or other factors relevant to international operations could increase our costs, reduce our revenues, or disrupt our operations, with possible material adverse impact on our business and financial condition.

We could be adversely affected if we experience shortages of goods or material price increases from our suppliers, or an inability to access new and improved products and technology.

The Company's business is dependent on the reliable supply of several raw materials for production and service purposes. If we are unable to counteract the risk of bottleneck situations at times of limited availability of goods and other materials in spite of our purchasing strategy in combination with ongoing monitoring of market developments, this could result in delays in production and hence have an adverse effect on our results of operation. Similarly, price increases by suppliers and the inability to access new products or technology could also adversely affect the Company's results of operations.

Our purchasing strategy is aimed at developing partnerships with strategic suppliers through long-term contracts and at the same time ensuring, where reasonably practicable, that we have at least two sources for all supply and price-critical primary products (dual sourcing, multiple sourcing). To prevent loss of suppliers, we monitor our supplier relationships on a regular basis. Suppliers which are integral to our procurement functions are also subject to performance and risk analyses as well as continuous supply chain monitoring. Through constant market analyses, a demands-based design of supplier relationships and contracts, as well as the use of financial instruments, we seek to mitigate disruptive goods shortages and potential price increases and provide access to new product and technology developments.

If physicians and other referral sources cease referring patients to our health care service businesses and facilities or cease purchasing or prescribing our products, our revenues would decrease.

In providing services within our health care business, we depend upon patients choosing our health care facilities as the location for their care. Patients may select a facility based, in whole or in part, on the recommendation of their physician. Physicians and other clinicians typically consider a number of factors when recommending a particular dialysis facility, pharmacy, physician practice, vascular surgery center or urgent care center to an ESRD patient, including, the quality of care, the competency of staff, convenient

scheduling, and location and physical condition. Physicians may change their recommendations, which may result in the movement of new or existing patients to competing facilities, including facilities established by the physicians themselves. At most of our dialysis clinics, a relatively small number of physicians often account for the referral of all or a significant portion of the patient base. We have no ability to dictate these recommendations and referrals. If a significant number of physicians or other referral sources cease referring their patients to our facilities or stop purchasing or prescribing our dialysis products, this would reduce our health care revenue and could materially adversely affect our overall 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. The expiration or loss of patent protection for one of our products, 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, which could materially and adversely affect our business, financial condition and results of operations. See note 22 of the notes to consolidated financial statements included in this report.

Our competitors could develop superior technology or otherwise take advantage of new competitive developments that impact our sales.

We face numerous competitors in both our health care services business and our dialysis products business, some of which may possess substantial financial, marketing or research and development resources. Competition from new and existing competitors, and especially new competitive developments such as increasing disruption in the health care industry, and innovations in technology and care delivery models 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 or services by competitors could render one or more of our products or services less competitive or even obsolete, which could also affect the Company's sales and distribution of pharmaceuticals for which, to some extent, the Company is obligated to make certain minimum annual royalty payments.

Global economic conditions as well as further disruptions in financial markets may have an adverse effect on our businesses.

We are dependent on the conditions of the financial markets and the global economy. In order to pursue its business, the Company is reliant on capital, as are its renal product customers and commercial health care insurers. Limited or more expensive access to capital in the financial markets could adversely affect our business and profitability. Among other things, the potential decline in federal and state revenues may create additional pressures to contain or reduce reimbursements for our services from public payors around the world, including Medicare, Medicaid in the United States and other government sponsored programs in the United States and other countries around the world.

Increasing job losses or changes in the unemployment rate in the United States may result in a smaller percentage of our patients being covered by an employer group health plan and a larger percentage being covered by lower paying Medicare and Medicaid programs. To the extent that payors are negatively impacted by a decline in the economy, we may experience further pressure on commercial rates, a further slowdown in collections and a reduction in the amounts we expect to collect.

Devaluation of currencies and worsening economic conditions, including inflationary cost increases in various markets in connection with deteriorating country ratings also increase the risk of a goodwill impairment, which could lead to a partial or total goodwill write-off in the affected cash generating units.

In addition, uncertainty in the financial markets could adversely affect the variable interest rates payable under certain of our credit facilities or could make it more difficult to obtain or renew such facilities or to obtain other forms of financing in the future. Any or all of these factors, or other consequences of the continuation, or worsening, of domestic and global economic conditions which cannot currently be predicted, could continue to adversely affect our businesses and results of operations.

Any material disruption in federal government operations and funding could have a material adverse impact on our business, financial condition and results of operations.

A substantial portion of our revenues is dependent on federal healthcare program reimbursement, and any disruptions in U.S. government operations could have a material adverse impact on our business, financial condition and results of operations. If the U.S. government defaults on its debt, there could be broad macroeconomic effects that could raise our cost of borrowing funds, and delay or prevent our future growth and expansion. Any future federal government shutdown, U.S. government default on its debt and/or failure of the U.S. government to enact annual appropriations could have a material adverse impact on our business, financial condition and results of operations. Additionally, disruptions in U.S. government operations may negatively impact regulatory approvals and guidance that are important to our operations, and create uncertainty about the pace of upcoming health care regulatory developments.

If we are unable to attract and retain skilled medical, technical and engineering personnel, or if legislative, union, or other labor-related activities or changes result in significant increases in our operating costs or decreases in productivity, we may be unable to manage our growth or continue our technological development.

Our continued growth in the health care business will depend upon our ability to attract and retain skilled workforce, including highly skilled nurses and other medical personnel. Competition for those employees is intense and shortages for these sought-after employees, such as nurses, or skilled engineers and research and development personnel, may increase the Company's personnel and recruiting costs and/or impair our reputation for production of technologically advanced products. 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 employees of or consultants to our health care services businesses.

Our health care products business depends on the development of new products, technologies and treatment concepts to be competitive. Additionally, in recruiting, employing and retaining personnel we may be exposed to risks relating to various labor laws, legislative, union, or other labor-related activities or changes. Further, these factors could preclude us from integrating acquired companies into our operations, which could increase our costs, decrease our productivity and prevent us from realizing synergies from acquisitions. If we are unable to manage the risks above, then our growth and results of operations could be adversely impacted.

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

We are subject to ongoing tax audits in the U.S., Germany and other jurisdictions. We could potentially receive notices of unfavorable adjustments and disallowances in connection with certain of these audits. If we are unsuccessful in contesting unfavorable determinations we could be required to make additional tax payments, which could have a material adverse impact on our business, financial condition and results of operations in the relevant reporting period. See Item 5, "Operating and financial review and prospects - IV. Financial position."

A dependency on the payment behavior and decision-making of our business partners can affect the collectability of accounts receivable.

Our health care product business, as well as our dialysis services business outside the U.S. differs across the regions in which we operate. In many cases, our products and services are paid, either directly or indirectly, by government institutions. We believe the risk of default from a government payor is lower in comparison to the commercial payors worldwide. On a country level, the payor base is characterized by distinct customer or payor groups which can range in volume from a few customers to a considerable amount of customer types which have varying levels of risk associated with default or non-payment of receivables as well as risks for dependencies based upon the competition within low volume customer base environments. In certain cases, a resulting dependency on the payment behavior and decision-making of our business partners can affect the collectability of accounts receivable and can adversely affect our business, results of operations and financial condition. We continuously seek to mitigate these risks by actively negotiating long-term contracts with major customers, targeted marketing activities, developing new product and pricing models as well as improving the quality of our services and products.

Unforeseeable events could affect our services and our ability to deliver in a limited time and place.

Fresenius Medical Care operates dialysis facilities or manufacturing facilities in many regions of the world, with diverse geographic, societal and economic conditions. Unforeseeable events such as natural disasters,

terrorist attacks or political instability, could affect our services and our ability to deliver those services in a limited time and place.

Through forward-looking planning and prevention programs, Fresenius Medical Care is trying to prevent or mitigate the negative impact of such potential future events. In addition, to maintain operations in the event of an onset and to reduce potential impact on our patients and the organization, we have spare capacity and safety stock of certain resources as well as emergency and recovery plans in place. Some risks may be mitigated by our insurance programs.

There are significant risks associated with estimating the amount of healthcare service revenues that we recognize that could impact the timing of our recognition of revenues or have a significant impact on our operating results and financial condition.

There are significant risks associated with estimating the amount of revenues from healthcare services that we recognize in a reporting period.

- The billing and collection process is complicated due to a number of factors including insurance coverage changes, geographic coverage differences, differing interpretations of plan benefits and managed care contracts, and uncertainty about reimbursement from payers with whom we are not contracted.
- Laws and regulations governing Medicare, Medicaid and other federal programs are extremely complex, changing and subject to interpretation.
- Determining applicable primary and secondary coverage for an extensive number of patients at any point in time, together with the changes in patient coverage that occur each month or changes in plan benefits, requires complex, resource-intensive processes. Errors in determining the correct coordination of benefits may result in refunds to payors.
- The complexity of estimating revenues from a primary payor also brings complexity to estimating revenues from secondary payors and patients.
- Collections, refunds and payor retractions typically continue to occur for up to three years or longer after services are provided.

If our estimates of revenues are materially inaccurate, it could impact the timing and amount of our recognition of revenues and have a significant impact on our operating results and financial condition.

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, 2018, we had consolidated debt of €7,546 M and consolidated total shareholders' equity of €12,902 M. 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.

In October 2012, we entered into a syndicated Credit Agreement, which was amended in November 2014 as well as in July 2017 (the "Amended 2012 Credit Agreement"). Our Amended 2012 Credit Agreement, the indentures relating to our senior notes (generally referred to as "Bonds" in this report and in our consolidated financial statements) and our accounts receivable securitization program (the "A/R Facility" or the "Accounts Receivable Facility") include covenants that require us to maintain certain financial ratios or meet other financial tests. Under our Amended 2012 Credit Agreement and the A/R Facility, we are obligated to maintain our consolidated leverage at or below an established maximum ratio of consolidated net funded debt to consolidated EBITDA ("Net Leverage Ratio") as these terms are defined in the respective financing agreements.

Our Amended 2012 Credit Agreement and the indentures related to our Bonds include other covenants which, among other things, restrict or could 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 30.75% of our outstanding shares, excluding treasury shares that we held, as of February 11, 2019. Fresenius SE also owns 100% of the outstanding shares of Management AG, the General Partner of the Company. As the sole shareholder of the General Partner, Fresenius SE has the sole right to elect the supervisory board of the General Partner which, in turn, appoints the General Partner's Management Board. 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 Company and precludes a takeover or change of control of the Company without Fresenius SE's consent, either or both of which could adversely affect the price of our shares. Our Articles of Association require that the General Partner or a parent company of the General Partner hold more than 25% of our share capital. The Articles of Association also provide that the General Partner ceases to be the general partner if the shares of the General Partner are acquired by a person who does not make an offer to acquire the shares of the Company's other shareholders within three months of the acquisition of the General Partner. In either case, the necessity for such a significant investment in connection with an acquisition of the General Partner could also discourage or preclude a change of control through acquisition of the General Partner, which also could adversely affect the price of our shares.

Because we are not organized under U.S. law, we are subject to certain less detailed disclosure requirements under U.S. federal securities laws, and we are exempt from most of the governance rules of the New York Stock Exchange.

Under the pooling agreement that we have entered into for the benefit of public holders of our 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 SEC and to file information with the SEC with respect to annual and general meetings of our shareholders. As of June 2016, the pooling agreement provides that we may prepare such financial statements in accordance with U.S. Generally Accepted Accounting Principles ("U.S. GAAP") or IFRS and, commencing with our report for the first quarter of 2017, we prepare our quarterly and annual financial statements in accordance with IFRS with the euro as our reporting currency. The pooling agreement also requires that the supervisory board of Management AG, our General Partner, include at least two members who do not have any substantial business or professional relationship with Fresenius SE, Management AG or FMC-AG & Co. KGaA and its affiliates and requires the consent of those independent directors (currently, Mr. Rolf A. Classon and Mr. William P. Johnston, to certain transactions between us and Fresenius SE and its affiliates.

We are a "foreign private issuer," as defined in the SEC's regulations, and consequently we are not subject to all of the same disclosure requirements applicable to domestic companies. We are exempt from the SEC'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 Exchange Act. We are also generally exempt from most of the governance rules applicable to companies listed on the New York Stock Exchange ("NYSE"), including the requirement that our board have a majority of independent directors (as defined in those rules) and the obligation to maintain a compensation committee of independent directors. We are required to maintain an audit committee in accordance with Rule 10A - 3 under the Exchange Act and to provide annual (and, if required, quarterly) affirmations of our compliance. We must also disclose the significant ways in which the governance standards that we follow differ from those applicable to U.S. companies under the NYSE governance rules. Exemptions from many governance rules applicable to U.S. domestic issuers may adversely affect the market prices for our securities. See Item 16G, "Corporate governance."