Part I

Item 1.Identity of directors, senior management and advisors

Not applicable

Item 2. Offer statistics and expected timetable

Not applicable

Item 3. Key information

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 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 4 p.m. Central European Time (CET).

Exchange rates

	December 31, 2023 spot exchange rate in €	December 31, 2022 spot exchange rate in €	2023 average exchange rate in €	2022 average exchange rate in €	2021 average exchange rate in €
1 U.S. dollar	0.90498	0.93756	0.92484	0.94962	0.84549

B. Capitalization and indebtedness

Not applicable

C. Reasons for the offer and use of proceeds

Not applicable

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 affect the outcome of forward-looking statements included in this report and/or 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 legal and 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 health care 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 health care system. In the U.S., there have been efforts to pursue significant changes to existing health care programs, including efforts to repeal or replace the ACA which, while unsuccessful to date, continue. On June 17, 2021, the U.S. Supreme Court reversed lower court rulings that declared the ACA to be unconstitutional, holding that the states and other plaintiffs in the case did not have standing to challenge the law. If future efforts to limit or repeal the ACA are successful, such efforts could have significant effects on our businesses, both positive and negative, but the outcomes are impossible to predict.

In October 2017, the Trump administration discontinued making cost-sharing reduction (CSR) reimbursements to insurers, arguing that Congress failed to appropriate funding. In response, many state departments of insurance either allowed or required insurers to mitigate their losses by increasing the 2018 premiums on their ACA plans. Many insurers also mitigated the impact to themselves by “silver loading,” a practice whereby the premiums for silver-level plans were increased to offset the loss of CSR payments. Silver loading may also have mitigated the impact of premium increases to some low-income consumers by increasing their premium tax credits. In 2019 and 2020, all states either permitted or required silver loading. In 2017, several insurers sued the U.S. federal government to reinstate CSR payments. On June 21, 2021, the U.S. Supreme Court denied requests from multiple insurers to review lower court decisions that held they were not entitled to full unpaid CSR payments. As a result, insurers are entitled to the unpaid CSRs, but the total amount they are owed must be offset by any excess premium tax credits received from premium increases for 2018 and beyond. The Biden administration’s budget request to the Congress for the fiscal year (FY) 2023 included appropriations for CSR payments, although the Consolidated Appropriations Act of 2023, which will fund the federal government during FY 2023, did not include specific CSR appropriations and we cannot predict the extent to which silver-loading will continue or how the ongoing litigation over the U.S. federal government’s obligation to pay the CSRs might be resolved. While the Biden administration again requested appropriations for CSR payments in its FY 2024 budget request, the Congress has yet to finalize any of its FY 2024 appropriations bills as of January 2024. As a result, a reduction in the availability of insurance through insurance exchanges established by the ACA could reduce the number of our commercially insured patients and shift such patients to Medicare and Medicaid. In addition, the United States Supreme Court’s recent ruling in Marietta Memorial Hospital Employee Health Benefit Plan, et al. v. DaVita Inc. et al. 142 S. Ct. 1968 (2022) (Marietta) will make it easier for health plans to design plan benefits for Medicare eligible ESRD patients in a way that makes private health insurance relatively less attractive to ESRD patients and Medicare relatively more attractive. In the Marietta case, the questions presented involved whether the health plan violated the Medicare Secondary Payor Act (MSPA) by “taking into account” that plan beneficiaries are eligible for Medicare and/or by “differentiating” between the benefits that the plan offers to patients with dialysis versus others. On June 21, 2022, the United States Supreme Court reversed the Sixth Circuit decision and held that the EGHP for Marietta Memorial Hospital did not violate the MSPA.

In December 2023, six bipartisan members of the House reintroduced the Restore Protections for Dialysis Patients Act (H.R. 6860), which would address the Marietta decision. The bill includes updated language which would restore the understanding of the Medicare Secondary Payer Act prior to the Marietta decision and ensure that patients cannot be discriminated against because of their need for dialysis. However, we cannot predict whether the U.S. Congress will enact this or any other proposed legislation that would reverse the potential effects of the Marietta decision. Because Medicare and Medicaid reimbursement rates are generally lower than the reimbursement rates paid by commercial insurers, a shift of commercially insured patients to Medicare and Medicaid could have a material adverse impact on our business, financial condition and results of operations. The Marietta ruling may also result in certain EGHPs reducing the benefits offered for dialysis, which could, depending on the number of patients impacted, have a material and adverse impact on our business, financial condition and results of operation. See “Changes in reimbursement, payor mix and/or governmental regulations for health care could materially decrease our revenues and operating profit” below.

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

We receive reimbursement for our health care 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 programs in the U.S. For the fiscal years ended December 31, 2023 and 2022, approximately 25% and 26%, 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, namely a $1.2 trillion sequester (across-the-board spending cuts) in discretionary programs, took effect on April 1, 2013, and continues in force. The 2% sequestration was temporarily suspended several times subsequent to May 1, 2020 as part of the U.S. government's efforts to address the COVID-19 pandemic. In March 2021, President Biden signed the American Rescue Plan Act of 2021 (the American Rescue Plan Act) which resulted, according to Congressional Budget Office estimates, in budget deficits that required a 4% reduction in Medicare program payments for 2022 under the Statutory Pay-As-You-Go Act of 2010 (Statutory PAYGO). In December 2021, Congress passed and President Biden signed into law the Protecting Medicare and American Farmers from Sequester Cuts Act impacting payments for all Medicare Fee-for-Service claims and extending the sequestration suspension through March 31, 2022 with a 1% reduction effective thereafter from April 1 to June 30, 2022 and a return to the full 2% sequester on July 1, 2022. The Protecting Medicare and American Farmers from Sequester Cuts Act deferred until 2023 the 4% reduction in Medicare program payments that would have been triggered by Statutory PAYGO as a result of the budgetary impact of the American Rescue Plan Act. However, the Consolidated Appropriations Act of 2023 again suspended Statutory PAYGO reductions for 2023 and 2024. Spending cuts pursuant to U.S. sequestration have adversely affected our operating results in the past and, with the suspension having been lifted, will continue to do so. 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, have been proposed or considered from time to time. Changes in payment methodologies and funding or payment requirements of (without limitation) the End-Stage Renal Disease Prospective Payment System (ESRD PPS), 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 may also experience changes in the interpretation of government regulations by the courts. We have very little opportunity to influence or predict the magnitude of many of those changes. For further information regarding Medicare and Medicaid reimbursement, including new payment models proposed by executive order in July 2019 which are intended to encourage identification and earlier treatment of kidney disease as well as increased home dialysis and transplants, see Item 4B, "Information on the Company — Business Overview — Regulatory and Legal Matters — Reimbursement" and Item 5, "Operating and Financial Review and Prospects — II. Financial condition and results of operations — Overview."

Our patients make decisions about their insurance coverage among options that, depending on their personal circumstances and location, may include Medicare, Medicaid, employer group health coverage, exchange plans and other commercial coverage. As of January 1, 2021, for the first time, all ESRD patients are eligible to enroll in Medicare Advantage plans. As a result, some patients with commercial coverage, and other patients with Medicare coverage, may elect to move to Medicare Advantage plans. Government reimbursement programs, including Medicare and Medicaid, generally pay less than commercial insurance, and Medicare Advantage plans generally pay less than other commercial plans. In addition, we may experience higher write-offs of Medicare deductibles and other cost-sharing amounts due to secondary 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. For further information, 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."

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 rejections of or reductions in reimbursement from private payors, including, for example, through their use of lower allowed charges rather than rates based on our billed charges;

- we may experience a reduction in our ability to obtain and retain commercially insured patients to utilize our health care services;

- efforts by private payors to continue to control the cost of and/or the eligibility for access to health care services, including relative to insurance products on and off the health care exchanges established by the ACA and potential efforts by employer group health plans and commercial insurers to limit benefits or reduce reimbursement for our services or eliminate reimbursement for some of our services;

- 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;

- if legislative or regulatory efforts or litigation to restrict or eliminate the charitable funding of patient insurance premiums are successful, our patients with coverage under publicly funded programs like Medicare may be unable to continue to pay the premiums for that coverage and may become uninsured for dialysis services. In addition, a portion of our patients who are currently covered by private insurers may be unable to continue to pay the premiums for that coverage and may become uninsured for dialysis services or 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;

- termination of the public health emergency originally declared in January 2020 with respect to the COVID-19 pandemic, which occurred on May 11, 2023 and, commencing April 1, 2023, state termination of Medicaid coverage that was expanded during the public health emergency, either or both of which, among other consequences, could reduce Medicaid coverage for many Americans, resulting in an increase in the uninsured patient population including dialysis patients; or

- 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. An increased utilization of bundled pharmaceuticals, as part of the ESRD PPS, or decreases in reimbursement for pharmaceuticals outside the bundled rate may result in a material adverse impact on our results of operations.

For further information, see Item 4B, “Information on the Company — Business Overview — Regulatory and Legal Matters — Reimbursement.”

In addition to the foregoing factors, the health care insurance industry is experiencing continuing consolidation among insurers and pharmacy benefit managers, including increasing buyer power and impacts on referral streams. Such consolidation could have a material adverse effect on 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 health care 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 “whistleblower” 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 R&D activities;

- the quality, safety and efficacy of medical and pharmaceutical products and supplies;

- the operation and licensure of manufacturing facilities, laboratories, dialysis clinics, ambulatory surgery centers 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;
- limits on our ability to make acquisitions or certain investments and the terms of those transactions;
- 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, product recalls, 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.

Our medical devices and drug products are subject to detailed, rigorous and frequently changing regulation by numerous national, supranational, federal and state authorities. In addition, our facilities and procedures and those of our suppliers are subject to periodic inspection by various regulatory authorities which may suspend, revoke, or adversely amend the authority necessary for research, manufacture, marketing or sale of our products and those of our suppliers. We and our suppliers must incur expense and spend time and effort to ensure compliance with these complex regulations, and if such compliance is not maintained, we and our suppliers 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 our 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 our business practices and operations; refunds; a total or partial shutdown of production while the alleged violation is remedied; and recalls, withdrawals or suspensions of current products from the market. Any of these events, in combination or alone, could disrupt our business and have a material adverse impact on our business, financial condition and results of operations.

We operate many facilities and engage with other business associates to help carry out our health care activities. In such a widespread, global 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 their business associates. We rely on our management structure, regulatory and legal resources and the effective operation of our compliance programs to direct, manage and monitor our operations, including the activities of our employees and their agents, to comply with government regulations. We cannot assure that our internal control policies and procedures will always protect us from intentional or inadvertent acts of our employees or agents that contravene our compliance policies or violate applicable laws. 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. See also “Risks relating to internal control and compliance — 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,” below.

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 our compliance with applicable laws and regulations. We may not always be aware that an inquiry or action has begun, particularly in the case of “qui tam” or “whistleblower” 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 governmental and private plaintiffs. For information about certain of these pending investigations and lawsuits, see note 25 of the notes to our consolidated financial statements included in this report.

In addition, future legislative or regulatory changes could affect procedures or decision making for approving medical devices or pharmaceuticals. 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.

Cyber-attacks or other privacy and data security incidents could disrupt our business and expose us to significant losses, liability and reputational damage.

We and our third-party service providers 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.

Cyber-attacks may penetrate our and our third-party service providers' 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 or their products, to create system disruptions, cause shutdowns (including disruptions to our production plants), or deploy viruses, worms, ransomware, denial-of-service attacks and other malicious software programs that attack our systems. We and our third-party service providers handle the personal information of our patients and beneficiaries, Patient Personal Data (PPD), throughout the U.S. and other parts of the world. 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 Data Protection Laws when we or our 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 our employees, patients and beneficiaries.

Our IT systems have been attacked in the past, resulting in certain patient data being illegally published. For information regarding our cybersecurity risk management and governance, as well as a cybersecurity incident that we incurred in September 2023, see Item 16K. "Cybersecurity."

When appropriate, we have filed complaints against the unknown attackers with the relevant authorities and we contacted the patients who were affected by the illegal data publication as well as other relevant regulatory agencies and stakeholders. While there has not been any material impact to our financial condition and results of operations as a result of these attacks, future cyber-attacks against our IT systems may result in a loss of financial data or interruptions of our operations that could have a material adverse impact on our business, financial condition and results of operations in the future. The Ukraine War has increased the risk of cyber-attacks against our systems and data.

As we increase the amount of sensitive personal information or financial data that we store and share digitally, our exposure to these privacy and data breaches and cyber-attack risks increases (particularly as medical records are a high-value target), 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. The 2022 Physician Fee Schedule issued by CMS has extended coverage of certain Medicare telehealth services through calendar year 2023 and the Consolidated Appropriations Act of 2023 further extended such coverage through December 31, 2024. In addition, the Consolidated Appropriations Act, 2022, an omnibus funding bill signed by President Biden on March 15, 2022, temporarily extended certain Medicare telehealth flexibilities, which are central to enabling Medicare beneficiaries' access to a broad range of services via telehealth from any location, for 151 days beginning on the first day after the end of the "public health emergency" period established for COVID-19, which occurred on May 11, 2023, and the CMS Physician Fee Schedule for calendar year (CY) 2023 further extended the availability of telehealth services for Medicare beneficiaries through December 2024. While the availability of telehealth services is convenient and improves access to medical care, increased reliance on, and utilization of, telemedicine for delivery of health care services could also increase the risk of privacy violations and our vulnerability to data breaches and cyber-attacks. There are no assurances that our security technologies, processes and procedures that we or our outside service providers have implemented to protect sensitive personal information and proprietary or confidential information and to build security into the design of our products will be effective. Any failure to keep our information technology systems, financial data 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 materially adversely affect our reputation and ability to continue normal operations, 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.

If certain of our investments or value and risk-based care programs with health care organizations and health care providers are found to have violated 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 entities 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. We also have arrangements with physician practices to collaborate on our value and risk-based care programs with public and private payors. In the past, certain parties have attempted to utilize our disclosure of these arrangements as the basis for qui tam proceedings under the Anti-Kickback Statute and the Stark Law. Such attempts have not been successful to date. Because our relationships with physicians are governed by the federal and state anti-kickback statutes and other state fraud and abuse laws, we have structured our arrangements to comply with many of the criteria for safe harbor protection and waivers under the Anti-Kickback Statute; however, these arrangements do not always satisfy all elements of applicable safe harbors. While we have established comprehensive compliance policies, procedures and programs to ensure ethical and compliant business operations, if one or more of our arrangements, including value and risk-based care programs, were found to be in violation of the Anti-Kickback Statute, the Stark Law, analogous state laws, or other similar laws worldwide, we could be required to restructure or terminate them. We could also 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 health care programs. Imposition of any of these penalties could have a material adverse impact on our business, financial condition and results of operations. See note 25 of the notes to our consolidated financial statements included in this report.

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, statutory or regulatory shipping holds and intellectual property rights (for example patents or trademarks) 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, or, for example, that significant adverse verdicts will not be reached against us 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 intellectual property rights 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 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. We and certain of our insurers are in litigation against each other relating to such insurers' coverage obligations under applicable policies. 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. For information about certain of these pending investigations and lawsuits, see note 25 of the notes to our consolidated financial statements included in this report.

Risks relating to internal control and compliance

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. 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 U.S. and other parts of the world. Our widespread, global operations have 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 third-party intermediaries. On March 29, 2019, we entered into a non-prosecution agreement (NPA) with the U.S. Department of Justice (DOJ) and a separate agreement with the SEC in connection with its Cease and Desist Order (SEC Order) intended to resolve fully and finalize the U.S. government allegations against us arising from DOJ and SEC investigations into conduct in countries outside the U.S. that violated the FCPA or other anti-bribery laws, and we agreed to the appointment of an independent compliance monitor (the Monitor). The Monitor certified to our implementation of an effective anti-corruption compliance program on December 30, 2022, and submitted her final certification report on January 31, 2023. The DOJ and SEC have accepted the Monitor's certification and the NPA and SEC Order expired on March 1, 2023 and March 29, 2023, respectively. While we continue to make significant investments in our compliance and financial controls and in our compliance, legal and financial organizations (including certain remaining recommendations of the Monitor), and are fully committed to compliance with the FCPA and other applicable anti-bribery laws, we cannot ensure that our internal control policies and procedures always will protect us from deliberate, reckless or inadvertent acts of our employees or third-party intermediaries that contravene our 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.

In 2015, we self-reported to the German prosecutor conduct with a potential nexus to Germany and continued to cooperate with government authorities in Germany in their review of the conduct that prompted our and the United States government investigations.

For further information, see note 25 of the notes to our consolidated financial statements included in this report.

Risks relating to our business activities and industry

We are subject to risks associated with public health crises and epidemics/pandemics, such as the global COVID-19 pandemic.

Our global operations expose us to risks associated with public health crises and epidemics/pandemics, such as the global COVID-19 pandemic. Given the already compromised health condition of our typical dialysis patients, our patients represent a heightened at-risk population, particularly, but not limited to, during a public health crisis such as the COVID-19 pandemic which has led to increases in mortality rates in our patient population resulting in an adverse impact on our operations. The COVID-19 pandemic, specifically, has resulted in a material deterioration of the conditions for the global economy and financial markets have been materially affected, all of which have adversely affected and are expected to continue to adversely affect our business, results of operations and financial condition. See "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" below. Going forward, the prolonged effects attributable to the COVID-19 pandemic on the macroeconomic and operational environment may continue to have an adverse impact on our operations and increase our expenses, including as a result of impacts associated with preventive and precautionary measures that we, our suppliers, customers and other businesses or governments continue to implement or impose on a local, regional, national or international level.

As noted above, our patients represent a heightened at-risk population. Our in-center and home hemodialysis (HHD) patients must receive their life-saving dialysis treatment several days a week for three to four hours at a time, and our peritoneal dialysis patients must dialyze daily, which presents unique challenges for patients and their care teams. During the height of the COVID-19 pandemic, we experienced negative impacts on employee absenteeism, turnover and the recruiting cycle for new employees, which adversely affected our production and clinical services operations and could continue to do so. In our dialysis clinics we are challenged to maintain sufficient clinical staff, including nurses, social workers, dietitians, care technicians and available space to treat all of our patients, including those who are or may be infected with COVID-19, in a manner that does not unnecessarily expose our care teams or other patients for whom we provide dialysis services and have experienced clinical personnel shortages. We have incurred, and expect to continue to incur, extra costs in establishing isolated treatment areas for actual and suspected COVID-positive patients, implementing expanded personal protective equipment protocols and other precautions as well as identifying, containing and addressing the impact of COVID-19 infections on our staff and patients. It appears that COVID-19 has resulted in an increase in persons experiencing temporary renal failure in many areas in which we operate. We expect to continue to experience additional staffing shortages as well as incur additional staffing costs required to meet the resulting increased demand for dialysis treatment and/or to provide equipment and medical staff needed for emergency treatments, for example in hospitals. Increased mortality rates in either the pre-ESRD patient population or in our ESRD patient population, compared to their historical averages, have and could continue to materially and adversely affect our operating results. Patients suffering from ESRD generally have co-morbidities that often place them at increased risk with COVID-19 and the COVID-19 pandemic has resulted in more of our dialysis patients requiring hospitalization, a trend which could continue as new variants arise, which could materially and adversely affect our financial results, including those of our value-based and shared risk products and services.

As a result of these and potentially other factors, and given the evolving nature of the virus, as exemplified by the development and proliferation of several variants of the virus, the COVID-19 pandemic could further negatively affect our results. For further information, see Item 5. “Operating and financial review and prospects — II. Financial condition and results of operations — Company Structure,” below. It is uncertain how COVID-19 will further affect our global operations generally if these impacts persist or are exacerbated over an extended period of time. Any of these impacts could have a continued material adverse effect on our business, financial condition and results of operations.

In addition, to the extent that the COVID-19 pandemic adversely affects our business, net assets, financial condition and results of operations, it could also have the effect of heightening many of the other risks described in this report.

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, dialysis home program, pharmacy, physician practice, vascular surgery center, or cardiac catheterization 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 and home programs, 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 and home programs or stop purchasing or prescribing our dialysis products, this would reduce our health care revenue and could materially adversely affect our overall operations.

As a company with operations spanning 150 countries, we face specific risks from our global operations.

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

- the economic and political situation in certain countries or regions could deteriorate, become unstable, or lead to armed conflict, as exemplified by the Ukraine War;

- geopolitical factors could intensify fluctuations in exchange rates, currency devaluations, and/or material increases in interest rates (for example, as a reaction from central banks to high inflation), any of which could adversely affect profitability and all of which have been heightened by the Ukraine War;

- sovereign rating agency downgrades coupled with an economic downturn in various regions or as a result of geopolitical conflicts in certain regions (for example, the Ukraine War) could result in impairment of our goodwill, investments or other assets due to decreases in the recoverable amount of those assets relative to their book value;

- 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 or give local manufacturers an advantage in tenders or provide large discounts to providers for certain purchases of our products;

- potential increases in tariffs and trade barriers could occur upon any withdrawal by the U.S. or other countries from multilateral trade agreements or the imposition of sanctions, retaliatory tariffs and other countermeasures in the wake of trade disputes and geopolitical conflicts and wars in certain regions (for example the Ukraine War);

- we could experience transportation delays or interruptions or higher energy costs or energy shortages, such as Russia's restriction of energy exports to Europe imposed in connection with the Ukraine War;

- growth and expansion into emerging markets could cause us difficulty due to greater regulatory barriers than in the U.S. 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; and

- we may not prevail in competitive contract tenders.

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

Certain countries in which we market, manufacture or sell our products do not have laws which protect our intellectual property to the same degree as those in the U.S. or elsewhere and our competitors may gain market position by designing products that infringe upon our intellectual property rights. An inability to protect our intellectual property in these countries could have an adverse effect on our business, results of operations and financial condition.

We conduct humanitarian-related business and provide life-sustaining health care products and services directly or indirectly in sanctioned countries, such as Russia, Belarus, Iran and Syria. We believe our humanitarian-related business is permitted by applicable sanctions regimes (or, in some cases is excluded from such regimes), and in light of the humanitarian nature of our products and services and the patient communities that benefit from our products, we expect to continue such activities, provided they continue to be permissible under or excluded from applicable export control and economic sanctions laws and regulations. Life-sustaining health care products are usually not subject to trade sanctions/export controls. However, as a result of the escalation of EU, U.S. and other countries' trade sanctions targeting Russia and Belarus, certain spare parts and components for our products fall under product categories subject to restrictions. Sanctions programs often, but do not always, provide for certain exemptions or availability of licensure for medical or pharmaceutical purposes. Furthermore, product registration procedures may be affected in case technology/technical information on products or components to be submitted in such procedures is or becomes subject to export or transfer restrictions for a relevant country and in case relevant licenses cannot be obtained, which ultimately may also have an impact on marketability of affected products. At this time, we expect that such risk would mostly be limited to product registration procedures in Russia and Belarus as a result of the escalation of EU, U.S. and other countries' trade sanctions targeting Russia and Belarus, but it may also affect Eurasian Economic Union (EAEU) product registration procedures in other EAEU member states in case these involve an information exchange with Russian/Belarusian authorities of restricted technology/technical information and in case relevant licenses cannot be obtained. A violation of applicable economic sanctions or export controls laws and regulations could subject us to enforcement actions. Possible enforcement actions vary between jurisdictions and depend on the factual circumstances of the given violation, but could include criminal penalties, imprisonment of responsible individuals, administrative or civil penalties, restricted access to certain markets and reputational harm, among others. Our internal control policies and procedures may not protect us from deliberate, reckless or inadvertent acts of our employees or agents that contravene our compliance policies or violate applicable laws.

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

Through our value and risk-based care programs, we assume the risk of both medical and administrative costs for certain patients in return for fixed periodic payments or potential reimbursement based on our achievement against set benchmark targets from governmental and commercial insurers. Specifically in the U.S., our participation in various value and risk-based care programs includes the CMS CKCC model and capitation, risk-based or shared savings agreements with commercial insurers in which FMCH receives fixed periodic payments or set benchmark targets to cover all or a defined portion of the medical costs of a defined population of patients. For information on the value-based programs in which we participate, see Item 4B, "Information on the Company — Business overview — Other health care services — Value and risk-based care programs."

Our profitability in our value-based agreements and risk products depends in part upon our ability to negotiate favorable financial terms, to manage a patient's care, to collaborate with our payor partners, to coordinate with other health care providers, to accurately document patients' health conditions for risk adjustment, and to find cost efficient, medically appropriate sites of service for our patients. Any failure to do so would limit our ability to improve the quality of patient care and health outcomes and to reduce medically unnecessary costs, which could lead to poorer performance under value and risk-based care programs.

The reserves that we establish in connection with the operation of our value and risk-based care programs are based upon assumptions and judgments concerning a number of factors, including trends in health care costs, expenses, patient hospitalization rates 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.

CMS relied on authority granted by the ACA to implement the CKCC model and seeks to deliver better health outcomes for ESRD patients while lowering CMS' costs. Efforts to repeal or replace the ACA, while unsuccessful to date, continue. See "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." We applied, and were accepted, for participation in CMS' Comprehensive Kidney Care Contracting model. The implementation period for the CKCC model began on October 15, 2020, on a no-risk basis, and we began participation in the first performance year of the CKCC model on January 1, 2022, at which time each participating entity assumed financial risk. We do not yet know whether we and our partners will be able to deliver better health outcomes while lowering CMS' costs through participation in the CKCC model. See Item 4B, "Information on the Company — Business Overview — Regulatory and Legal Matters — Reimbursement — Executive order-based models."

Our sales and earnings growth depends, in part, on our ability to develop and expand our core kidney care business, efficiently manage costs and execute our portfolio optimization plan to exit non-core and dilutive assets, as well as realize anticipated cost savings within our expected timeframe.

The health care industry experiences continuing consolidation, particularly among health care providers, as well as pressure on reimbursement and increasing costs, which requires us to identify both growth opportunities and efficiencies in the way we operate. Continuing consolidation in our industry could adversely affect our ability to find suitable acquisition targets and to increase future growth and product sales.

We also compete with other health care companies in seeking suitable acquisition targets and developing our core health care businesses. Our ability to make future acquisitions as well as develop our core kidney care business depends, in part, on the appropriate strategic target selection, the availability of financial resources and the current restrictions imposed by competition laws. 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, any or all of which may result in our incurring unanticipated costs.

In order to respond to our rising costs, especially in the face of economic downturns and rising inflation, and to improve growth, we announced the next stage in the implementation of our strategy in November 2021: the transformation of our operating model into a significantly simplified future structure of two global operating segments embodying a more centralized approach; Care Enablement, the consolidation of our previously decentralized health care products business (including R&D, manufacturing, supply chain and commercial operations as well as supporting functions, such as regulatory and quality management) under a global medical technology umbrella, and Care Delivery, combining our global health care services businesses. The new global operating model enables the further consolidation of general and administrative functions in our Company.

Our strategy also includes reviewing our business portfolio, specifically with a view to exiting unsustainable markets and non-core businesses and the cessation of certain R&D programs to enable more focused capital allocation towards areas in our core business that are expected to have higher profitable growth. For additional information regarding the impacts from strategic divestitures identified during the review of our business portfolio, see Item 5. “Operating and financial review and prospects” and note 5 f) of the notes to the consolidated financial statements included in this report. While we believe the FME25 Program and Legacy Portfolio Optimization (as defined in Item 4. “Information on the Company — A. History and development of the Company,” below) will provide us with a more efficient way of both managing and growing the business in the future, the amounts of anticipated cost savings and anticipated expenses related thereto described above are based on our current estimates, and involve risks, uncertainties, assumptions and other factors that may cause the timing of actual results, performance or achievements to be materially different from the anticipated timing described herein. Assumptions relating to the FME25 Program and the achievement of the aforementioned cost savings within the specified timeframe involve subjective decisions and judgments with respect to, among other things, the estimated impact of certain operational adjustments, labor management and labor relations (including our commitment to consultation with works councils and other workplace representatives in good faith), and other cost and savings adjustments, as well as future economic, competitive, industry and market conditions, impacts from the COVID-19 pandemic and possible unanticipated effects from acquisitions, all of which are inherently uncertain and may not be completely within the control of our management. Although the Company’s management believes these estimates and assumptions related to the timing of these savings to be reasonable, there can be no assurance that the estimates described herein will prove to be accurate, result in anticipated operational efficiencies or be implemented according to our previously announced timing. We expect that our security holders, investors and other stakeholders will monitor both whether we achieve our anticipated FME25 Program cost savings at our anticipated implementation cost levels and whether we meet our announced timing in doing so. Failure to realize the expected cost savings from the FME25 Program within our announced timeframe described above could adversely impact the market for our securities and availability of financing, which, in addition, could limit our future growth, including growth in either our revenues or earnings within our health care services and products businesses. Any or all of these factors generally could have an adverse effect on our business, financial condition and results of operations. For further discussion on the impacts to our business in 2023 (see Item 5. “Operating and financial review and prospects — III. Results of operations, financial position and net assets”).

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 25 of the notes to the 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 whom may possess substantial financial, marketing or R&D resources. Competition from new and existing competitors, and especially new competitive developments such as pharmaceuticals that reduce the progression of chronic kidney disease, and innovations in technology and care delivery models could materially adversely affect the future pricing and sale of our products and services. In 2023, a study on one such type of pharmaceutical, glucagon-like peptide 1 (GLP-1) receptor agonists, regarding its effectiveness in treating CKD experienced by diabetic patients was terminated early as a result of the study having met certain prespecified clinical endpoints. Although there is only limited available information currently, the ability to delay CKD or ESRD progression and cardiovascular mortality improvements as a result of the use of these pharmaceuticals could have an impact on our patient population in the future (further information regarding the impact of certain pharmaceuticals that reduce the progression of chronic kidney disease and our analysis of their impact on our cash flow projections and goodwill sensitivity assessments can be found in note 2 a) of the notes to the consolidated financial statements included in this report). 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 qualify them for certain additional payments for new and innovative equipment or render one or more of our products or services less competitive or even obsolete, which could also affect, among other items, our sales and distribution of pharmaceuticals for which, to some extent, we are obligated to make certain minimum annual royalty payments.

Global economic conditions as well as disruptions in financial markets could 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 our business, we are reliant on capital markets, as are our 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 in a prolonged economic slowdown or recession could create additional pressures to contain or reduce reimbursements for our services from public payors around the world, including Medicare and Medicaid in the U.S. and other government sponsored programs in the U.S. and other countries around the world. Devaluation of currencies such as the impact from hyperinflationary economies as well as fluctuations in currencies as a result of the Ukraine War, unfavorable interest rate changes and worsening economic conditions, uncertainty arising from the Ukraine War (and other geopolitical conflicts) regarding a possible deterioration of the global macroeconomic outlook, including inflationary cost increases in various markets in connection with deteriorating country credit ratings increase the risk of a goodwill impairment, which could lead to a partial or total goodwill write-off in the affected cash generating units, or have a negative impact on our investments and external partnerships. In addition, uncertainty as well as volatility in global financial markets, including the banking sector, and inflation could adversely affect the valuations of certain of our investments, interest rate-sensitive assets or liabilities or variable interest rates payable under 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 should access to these capital markets become restricted. Inflationary cost increases have also had and may continue to have an unfavorable effect on our business, especially if the prices and reimbursement rates for our products and services remain unchanged or do not adequately track against cost increases. Most recently, the global spread of the COVID-19 pandemic has resulted in a material deterioration of the conditions for the global economy and financial markets have been materially and adversely affected which has and could continue to have adverse effects on our financial condition and our liquidity.

In the past, we have seen challenges in the labor market, in particular in the U.S., resulting in staff shortages, high turnover rates and meaningfully higher costs, which have and could continue to impact our growth, specifically in U.S. health care services where labor constraints affected our ability to increase treatment volumes. These impacts, combined with uncertainty in the macroeconomic environment, driving inflationary cost increases and supply chain constraints, have had a materially adverse effect on our results of operations. The current uncertainty in the macroeconomic environment has also intensified the risk that price increases and restricted access related to energy commodities, including the costs of oil, gas and electricity, may occur. Our cost monitoring and cost savings initiatives in this area, including inventory management, alternative sourcing, and existing and future long-term contracting may not offset a significant increase in prices and could result in an adverse effect on our results of operations going forward.

Job losses or increases in unemployment rates could result in a smaller percentage of our patients being covered by employer group health plans and a larger percentage being covered by lower paying government reimbursement programs. Unemployment rates in some countries have been negatively impacted by the COVID-19 pandemic, which adversely affected the global economy and our operating results. The extent to which the COVID-19 pandemic continues to impact our business, results of operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted. To the extent that our commercial 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 are able to collect. 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 have a material adverse effect on our businesses and results of operations.

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.

Our business is dependent on the reliable supply of several raw materials and finished components for production and service purposes. If we are unable to obtain sufficient quantities of these materials at times of limited availability of such materials, this could result in delays in production or loss of sales and hence have an adverse effect on our results of operations. Similarly, price increases by suppliers (including from the impact of inflation) and the inability to access new products or technology could also adversely affect our results of operations. The Ukraine War has increased both the likelihood and potential impact of these risks and exposures to varying degrees. In particular, the lingering macroeconomic inflationary environment, including material increases in energy prices, has resulted in and could continue to lead to, among other consequences, material increases in costs for energy, supplies and transportation. A continued disruption or discontinuation of energy supplies from Russia may increase these impacts and could have additional material adverse effects on our business such as a potential closure of certain of our production sites or significantly increased costs incurred due to a switch to alternative energy sources. These disruptions in supply, coupled with labor shortages, labor cost increases, and heightened COVID-19-related employee absenteeism and turnover, have resulted and could continue to result in a negative impact on our business. All of these factors introduce additional risk to our operations and exposure to legal liability in the delivery of our goods and services.

Our procurement risk mitigation efforts include (i) the development of partnerships with strategic suppliers through framework contracts, (ii) where reasonably practicable, at least two sources for all supply and price-critical primary products (*dual sourcing, multiple sourcing*), and (iii) measures to prevent loss of suppliers, such as risk analyses as well as continuous supply chain monitoring. Any failure of these measures to mitigate disruptive goods shortages and potential price increases or to allow access to favorable new product and technology developments could have an adverse impact on our business and financial condition. In some cases, for reasons of quality assurance, cost effectiveness, or availability, certain components or raw materials needed to manufacture our products are obtained from a sole supplier. A failure of any of our single-source suppliers to fulfil their contractual obligations in a timely manner or as a result of regulatory noncompliance or physical disruption at a manufacturing site could adversely affect our ability to manufacture and distribute our products in a timely or cost-effective manner, and our ability to make product sales. Due to the stringent regulations and requirements of regulatory agencies, including the U.S. FDA, regarding the manufacture of our products, we may not be able to quickly establish additional or replacement sources.

Any material disruption in 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 depends on government health care program reimbursement, and any disruptions in government operations could have a material adverse impact on our business, financial condition and results of operations. If the governments with which we do business default on their debts, 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 government shutdown (which may have a greater likelihood due to a political party split in control of the U.S. Congress), government default on debt, decline in government revenues during a prolonged economic slowdown and/or failure of governments to enact annual appropriations could have a material adverse impact on our business, financial condition and results of operations. Additionally, material disruptions in 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, engineering or key strategic personnel, or if legislative, union, other labor-related activities or changes or employee absenteeism and turnover (including impacts from COVID-19 or other illnesses and factors) result in significant increases in our operating costs or decreases in productivity, we may be unable to manage our growth, continue our technological development or execute our strategy.

Our continued growth in the health care business will depend upon our ability to attract and retain a skilled workforce, including highly skilled nurses, technicians and other medical personnel. Our health care products business depends on the development of new products, technologies and treatment concepts to be competitive, and for that we need to attract the best and most talented people, especially in R&D. Competition for those employees is intense and shortages for these sought-after employees, such as nurses, or skilled engineers and R&D personnel, as well as increased reliance on contracted nurses and other personnel, have increased our personnel and recruiting costs and may continue to do so, and/or could impair our reputation for production of technologically advanced products. In recent years, we experienced and may continue to experience, greater employee absenteeism and turnover and longer recruiting cycles which negatively impact our ability to produce and deliver the goods and services that we provide to our customers and our patients, as well as increased personnel 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 employees of or consultants to our health care services businesses. In addition, effective execution of our strategy will depend upon our ability to attract suitable candidates for leadership roles, including open positions in our executive leadership team.

Additionally, in recruiting, employing and retaining personnel, we may be exposed to increasing risks relating to various labor and staffing laws, legislative, union, or other labor-related activities or changes. These factors could also impact the integration of 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.

We need to develop new internal functions to perform certain business services that Fresenius SE provided to us prior to the Conversion.

Prior to the Conversion, as part of the Fresenius SE Group, we received certain essential capabilities that we did not then and currently do not independently have (either in full or in part) including information technology, insurance and treasury functions, payroll and other human resources functions, including with respect to pensions, as well as tax audit and tax support as well as leases of our principal offices and manufacturing facilities and facility management. In addition, we also provide certain functions and services for the Fresenius SE Group.

As a result of our deconsolidation through the Conversion, we separated from the Fresenius SE Group, and both the Company and the Fresenius SE Group are required to set up or provide the aforementioned functions and services on their own. The provision of some of these services to each other is no longer legally permissible after the Conversion.

As part of the Conversion process, we entered into a series of transitional services agreements with Fresenius SE at a cost that we consider to be comparable to the costs we incurred for such services prior to the Conversion. The agreements have various durations, depending on the services covered under the particular agreement, with the agreement for information technology services having the longest term. We cannot guarantee that we will be able to establish or procure these functions after the transitional services period without experiencing material adverse effects on our business, financial condition and results of operations.

If we are unable to meet applicable legal requirements and/or market expectations with respect to sustainability, both our business and our reputation could suffer. We could be subject to fines and other financial burdens associated with global environmental, social and governance (ESG) regulations and laws, and we could alienate our patients, employees, customers, partners, investors and the communities we serve. Furthermore, if we do not meet investors' or certain markets' ESG standards, the market for our securities could be adversely impacted.

Companies' ESG activities are facing increased scrutiny from stakeholders such as institutional and other investors, regulatory bodies and non-governmental organizations (NGOs). Failure to effectively identify, carry out and manage the necessary sustainability and related reporting activities as required or expected, as well as effectually manage the impact of factors beyond our control, could cause us to incur additional costs or damage our brand. We could also be subject to financial and other penalties imposed by the respective authorities in the jurisdictions in which we do business. For example, a rise in prices of carbon emission rights stemming from the requirements of European climate regulations could increase our production costs. Such cost increases could have an adverse effect on our operations and results if we do not accurately plan for, and effectively implement, necessary sustainable business practices.

In addition to environmental risks, we also face several social risks. High staff turnover is a risk, not only due to the expense associated with hiring and training new staff, but also because it could affect our ability to serve our patients. For further information on personnel risks, see the risk factor "If we are unable to attract and retain skilled medical, technical, engineering or key strategic personnel, or if legislative, union, other labor-related activities or changes or employee absenteeism and turnover (including impacts from COVID-19 or other illnesses and factors) result in significant increases in our operating costs or decreases in productivity, we may be unable to manage our growth, continue our technological development or execute our strategy." above. Furthermore, companies are increasingly expecting their suppliers to share their commitment to sustainability and demonstrate sustainable business practices across their supply chains, including the ability to identify and mitigate risks related to human rights in their entire value chain in connection with the requirements of the German Supply Chain Due Diligence Act (*Lieferkettensorgfaltspflichtengesetz*) and other regulations. If we fail to comply with our legal obligations related to supply chain due diligence, we could face significant fines and be excluded from public tenders and contracts. We could also suffer reputational damage, especially given that our performance in this area is closely monitored by NGOs, investors and others.

In light of these expectations, among other aspects, we have incorporated sustainability as a performance target for the compensation of our Management Board. Should management fail to meet these outcomes, investors and/or debt providers may not deem us the correct fit for their investment or financing purposes, thereby negatively impacting our share price or our ability to source funding through debt financing. Our €2 billion syndicated multicurrency sustainability-linked revolving credit facility agreement (Syndicated Credit Facility), which serves as a backup facility, includes a sustainability component, pursuant to which the credit facility's margin for any outstanding borrowings will rise or fall depending on our sustainability performance.

A heightened focus on ESG topics may result in more extensive regulatory requirements aimed at mitigating the effects of climate change and other current and future ESG concerns. Should further regulation (such as the SEC's proposed disclosure requirements regarding climate-related risks, see Item 16.G, "Corporate Governance"), or stakeholder expectations be more stringent in the future, we may experience increased compliance burdens and costs to meet regulatory obligations and we cannot currently estimate what impact existing and future regulations will have on our business, financial condition and results of operations.

Risks relating to taxation and accounting

There are significant risks associated with estimating the amount of health care 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 health care 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 payors 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 insurance 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 may 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. For further information regarding our revenue recognition policies, see note 1 k) of the notes to the consolidated financial statements included in this report.

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

We are subject to ongoing tax audits in Germany, the U.S. 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." For further information on the German tax authorities' objections to our previously filed tax returns, see note 25 of the notes to the consolidated financial statements included in this report.

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 and our dialysis services business differ across the regions in which we operate. In many cases, our products and services are paid for, either directly or indirectly, by government institutions. We believe the risk of default from a government payor is generally low to moderate worldwide which could, however, prove to be wrong, particularly in the event of a government shutdown which could result in significant payment delays even if it does not create a default. 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. Our measures aiming 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, could be insufficient or ineffective.

Risks relating to our financial condition and our securities

Our indebtedness may prevent us from fulfilling our debt-service obligations or implementing certain elements of our business strategy.

At December 31, 2023, we had consolidated debt (including lease liabilities as well as debt and lease liabilities included within liabilities directly associated with assets held for sale) of €12,187 M and consolidated total shareholders' equity of €14,827 M. Our debt could jeopardize the successful execution of our business strategy, increase our vulnerability to general adverse economic conditions, limit our ability to obtain necessary financing to fund future working capital needs, capital expenditures, payment of dividends and other general corporate requirements, 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 other purposes, limit our flexibility in reacting to changes in our business and the industry in which we operate, place us at a competitive disadvantage compared to our competitors that have less debt, limit our ability to pursue possible future acquisitions and sell assets, make it more difficult for us to satisfy our obligations under our debt securities, and limit our ability to borrow additional funds. Additionally, a deterioration of our current rating could lead to a reintroduction of financial covenants, could limit our financial flexibility, increase our financing costs or limit access to funding.

Our leverage makes us vulnerable to a downturn in the operating performance of our business, larger than normal fluctuations or volatility in our cash flow, or a downturn in economic conditions. Our ability to make payments on and to refinance our indebtedness will depend on our ability to generate cash in the future, which is dependent on various factors. These factors include governmental and private insurer reimbursement rates for medical treatment and general economic, financial, competitive, legislative, regulatory, and other factors that are beyond our control. If our cash flow is not sufficient to meet our debt service and principal payment requirements, we could be required to refinance our obligations or to dispose of assets in order to meet such requirements. In addition, from time to time we need to refinance our existing debt as and when it matures. In either case, there is no guarantee that we will be able to refinance our existing indebtedness on terms comparable to those governing our existing indebtedness. If our cash flow is not sufficient to meet our debt service and principal payment requirements, or if we are unable to refinance our existing indebtedness on acceptable terms, it could have a material adverse effect on our business, financial condition, or results of operations. For information about our outstanding indebtedness, see note 16 and note 17 of the notes to our consolidated financial statements included in this report.

On July 1, 2021, we entered into our Syndicated Credit Facility. Our Syndicated Credit Facility and certain of our other financing instruments include covenants which, among other things, restrict or could have the effect of restricting our ability to dispose of assets and create liens, and restrict the indebtedness of our subsidiaries. These covenants may otherwise limit our activities as well. The breach of any of the covenants could result in a default and acceleration of the indebtedness under the respective financing agreements, 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.

Despite our existing indebtedness, we may still be able to incur significantly more unsecured debt in the future. The covenant in our 4.75% bonds due 2024 limiting our ability to incur unsecured debt is currently suspended and will remain so as long as two of the three credit ratings assigned to these bonds by S&P Global Ratings Europe Limited (S&P), Moody's Deutschland GmbH (Moody's) and Fitch Ratings Ireland Limited (Fitch) are at least BBB- or Baa3 (as the case may be) or higher, or, in each case, the equivalent investment grade rating of the rating categories of any rating agencies substituted for S&P, Moody's or Fitch. On February 24, 2023, Standard & Poor's downgraded the Company's corporate credit rating from BBB to BBB- and revised the outlook from stable to negative. On February 27, 2023, Moody's confirmed the Company's corporate credit rating and revised the outlook from stable to negative. On August 25, 2023, Fitch affirmed the Company's corporate credit rating, removed the rating watch negative and assigned a negative outlook. Nevertheless, should we lose our investment grade rating, we may still be able to incur substantial unsecured debt in compliance with that covenant if we maintain an interest coverage ratio (as defined in the indenture for our 4.75% bonds due 2024) of at least 2.0 to 1.0, as is presently the case, or as otherwise permitted by that covenant, regardless of our credit rating or interest coverage ratio, including under our Syndicated Credit Facility and our accounts receivable securitization program (Accounts Receivable Facility). Upon repayment of our 4.75% bonds due 2024, we will no longer be subject to any covenant that limits our ability to incur unsecured debt, regardless of our credit rating. If additional debt is added to our current debt levels, the related risks that we now face from our indebtedness could intensify.

After the Conversion, Fresenius SE no longer controls our Company through ownership of 100% of the shares in the General Partner of our Company. However, due to its significant share of ownership and certain provisions of our Articles of Association, Fresenius SE retains significant influence over the management of the Company.

Fresenius SE owns 32.2% of our outstanding shares as of February 8, 2024. Under our Articles of Association, Fresenius SE has the right to appoint two of the six shareholder representatives to our Supervisory Board for as long as it holds 30% or more of the Company's share capital and the right to appoint one of the six shareholder representatives to the Supervisory Board for as long as it holds at least 15% (but less than 30%) of the Company's share capital, and to dismiss those shareholder representatives. The Chair of our Supervisory Board is one of the Fresenius SE representatives. In the case of a tie in the AG Supervisory Board, the Chair has two votes in a new vote on the same matter if this also results in a tie. Under our Articles of Association, certain matters requiring a resolution at our general meeting of shareholders require a qualified majority of 75% of the share capital represented at the time of the vote, including capital increases and decreases, the creation of authorized and conditional capital, the issuance of convertible bonds, corporate measures such as mergers or spin-offs, the conclusion of intercompany agreements (*Unternehmensverträge*) such as domination and/or profit and loss transfer agreements (*Beherrschungs- und/oder Gewinnabführungsverträge*), amendments to the Articles of Association, dissolution of the Company, mergers, a change in the legal form of the stock corporation and other fundamental changes. By virtue of its ownership of approximately 32.2% of our share capital, Fresenius SE therefore has a de facto veto right over any such resolution or resolutions in and when proposed for adoption by our shareholders. In addition, the Conversion and deconsolidation of the Company from the Fresenius SE Group resulted in the termination of certain voting restrictions on Fresenius SE's shares in the Company, including a restriction on voting in the election of members of the Company's Supervisory Board and members of Fresenius SE's management board are now eligible to seek election to and serve on the Company's Supervisory Board. The present Fresenius SE designees on our Supervisory Board are the Chief Executive Officer and Chief Financial Officer, respectively, of Fresenius SE. As a result of its share ownership, its de facto veto right over shareholder votes requiring a qualified majority and its representation on our Supervisory Board (including the Chair), Fresenius SE will continue to have the ability to exercise significant influence over the management of our Company in its form as an AG, and the interests and rights of Fresenius SE could deviate from the interests of the Company and its public shareholders.