

OPPORTUNITIES AND RISK REPORT

The Fresenius Group is exposed to a number of risks due to the complexity and the dynamics of its business. These risks are inevitable consequences of entrepreneurial activities.

Opportunities can only be exploited when there is a willingness to take risks.

As a provider of products and services for the severely and chronically ill, we are relatively independent of economic cycles. The diversification into four business segments, which operate in different segments of the health care market, and the global footprint further minimize the Group's risk profile. Our experience, as well as our strong market position, serve as a solid basis for a reliable assessment of risks.

At the same time, we will continue to take advantage of the wide-ranging opportunities for sustainable growth and expansion that the health care market offers to the Fresenius Group.

OPPORTUNITIES MANAGEMENT

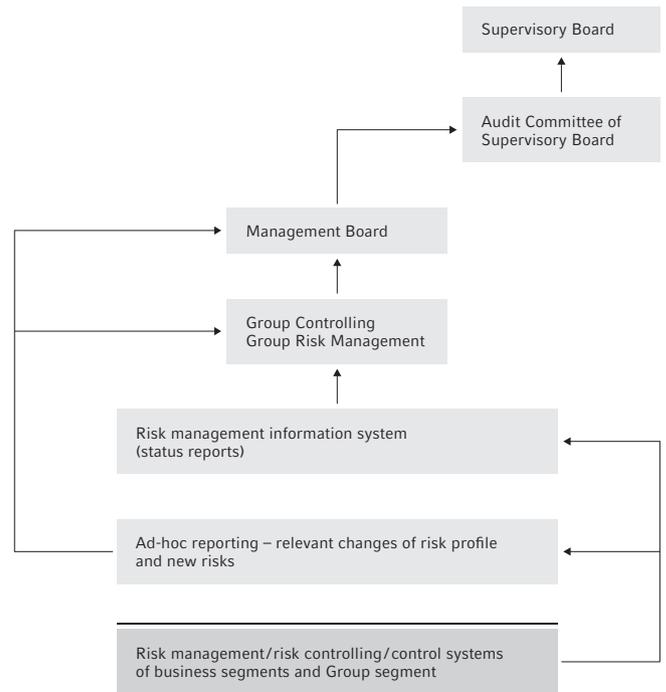
Managing opportunities is an ongoing, integral part of corporate activity aimed at securing the Company's long-term success. In this way, we can explore new prospects and consolidate and improve on what we have already achieved. The organization and management of the Fresenius Group have a decentralized, regional structure. This enables us to recognize and analyze trends, requirements, and opportunities in the often fragmented markets and to focus our actions accordingly. We maintain regular contact and dialogue with research groups and scientific institutions, and keep a close watch on markets and competitors in order to identify opportunities. Within the Group, opportunities and synergies can be exploited through continuous communication involving the exchange of information and know-how between the business segments. Anticipated future opportunities for the Fresenius Group are discussed in the **Outlook** starting on page 70.

RISK MANAGEMENT

FRESENIUS RISK MANAGEMENT SYSTEM

Risk management is a continuous process. Identifying, controlling, and managing risks are key tools of solid corporate governance. The **Fresenius risk management system** is closely linked to its corporate strategy. Opportunities are not recognized in the risk management system.

STRUCTURE OF THE FRESENIUS RISK MANAGEMENT SYSTEM



Markets are kept under constant observation and close contact is maintained with customers, suppliers, and institutions. These policies allow us to swiftly identify and react to changes in our business environment.

Using standardized processes, risk situations are evaluated regularly and compared with specified requirements. If negative developments emerge, responses can be initiated at an early stage.

Responsibilities for the **risk management processes** and the **monitoring of risks** in the business segments have been assigned as follows:

- ▶ The business areas and their operational business units are responsible for identifying, assessing, and managing risks.
- ▶ The managers responsible are required to report any relevant changes in the risk profile to the Management Board without delay.
- ▶ The Management Board of the Fresenius Group has overall responsibility for effective risk management and regularly discusses the current risk situation.
- ▶ The audit committee of the Supervisory Board monitors the quality and effectiveness of the risk management system every six months.

The risk management system is supported both at Group level and in the business segments by our **risk controlling measures** and our **management information system**. Detailed monthly and quarterly reports are used to identify and analyze deviations of actual versus planned business development. In addition, the risk management system includes a **control system** that consists of organizational safeguarding measures, as well as internal controls and audits, with which we can identify significant risks at an early stage and counteract each one individually.

The functionality and effectiveness of our risk management system is reviewed regularly by the Audit Committee of the Supervisory Board, the Management Board and the Internal Audit department. Conclusions arising from the audits are taken into account in the ongoing refinement of the system, to allow prompt reaction to changes in our environment. This system has thus far proved effective. The control system is also regularly reviewed by the Management Board and the Internal Audit department. Moreover, the external auditor reviews whether the control system set up by the Management Board is suitable for the early identification of risks that would put the continued existence of the Company in danger. The insights gained from the audit regarding the internal financial reporting controls are also taken into account in the continued development of the system.

Fresenius has ensured that the scope and focus of the organizational structure and systems for identifying, assessing, and controlling risks, and for developing countermeasures and for the avoidance of risks, are aligned suitably with the Company-specific requirements and that they are properly functional. However, there can be no absolute certainty that this will enable all risks to be fully identified and managed.

INTERNAL FINANCIAL REPORTING CONTROLS

Numerous measures and internal controls assure the correctness and reliability of accounting processes and financial reporting, and thus preparation of annual financial statements, consolidated financial statements, and management reports

in compliance with applicable principles. Our **four-tier reporting process** especially promotes intensive discussion and ensures control of the financial results. At each reporting level, i. e.,

- ▶ the local entity,
- ▶ the region,
- ▶ the business segment, and
- ▶ the Group,

financial data and key figures are reported, discussed, and compared on a regular monthly basis with the prior-year figures, budget, and latest forecast. In addition, all parameters, assumptions, and estimates that are of relevance for the externally reported Group and segment results are discussed intensively with the department responsible for preparing the Group's consolidated financial statements. These matters are also reviewed and discussed quarterly by the Supervisory Board's Audit Committee.

Control mechanisms, such as automated and manual reconciliation procedures, are further precautions put in place to assure that financial reporting is reliable and that transactions are correctly accounted for. All consolidated entities report according to Group-wide standards, which are determined at the head office. These are regularly adjusted to allow for changes made to the accounting regulations. The consolidation proposals are supported by the IT system. In this context, reference is made to the comprehensive consolidation of internal Group balances. To prevent abuse, we take care to maintain a strict separation of functions. **Management control and evaluations** also help to ensure that risks with a direct impact on financial reporting are identified and that controls are in place to minimize them. Moreover, changes in accounting principles are monitored and employees involved in financial reporting are instructed regularly and comprehensively. External experts and specialists are engaged if necessary. The Treasury, Tax, Controlling, and Legal departments are involved in supporting the preparation of the financial statements. Finally, the information provided is verified once again by the department responsible for preparing the consolidated financial statements.

Fresenius Medical Care is subject to the controls of Section 404 of the **Sarbanes-Oxley Act**.

RISK AREAS

OVERALL ECONOMIC RISKS AND RISKS DUE TO THE OPERATING FRAMEWORK

At present, the **development of the global economy** presents no significant risk to the Fresenius Group. In 2019, we expect overall economic growth to continue. Moreover, Fresenius is affected only to a small extent by general economic fluctuations. We expect demand for our life-saving and life-sustaining products and services to continue to grow. Furthermore, Fresenius is striving for the firm balance of its business in the main regions and between established and emerging markets.

The risk situation for each business segment depends in particular on the development of its relevant markets. **Country-specific political, legal, and financial conditions** are therefore monitored and evaluated carefully, particularly in the current macroeconomic environment. This applies, for example, to countries with budget problems as a result of their debt burden, in particular with regard to our accounts receivable. This also applies to the possible impact on our business activities resulting from the decision by the United Kingdom to leave the European Union and the continuing uncertainty about the exit conditions. This further applies to Catalonia's quest for independence from Spain.

And it applies in particular to any initiatives by the U.S. administration with regard to potential changes to the current health care programs.

RISKS IN THE HEALTH CARE SECTOR

Risks related to changes in the health care market are of major importance to the Fresenius Group. The main risks are the financing of health care systems and the corresponding reimbursement systems, as well as the development of new products and therapies.

Financing of health care and reimbursement systems

In our largely regulated business environment, **changes in the law** – also with respect to reimbursement – can have a major impact on our business success. This applies especially in the United States, where a large portion of our sales are

generated, and where changes in the government **reimbursement system**, in particular, for example in the reimbursement of dialysis treatments, could have a considerable impact on our business. In 2018, approximately 33% of Fresenius Medical Care's sales in the United States were attributable to U.S. federal health care benefit programs, such as **Medicare** and **Medicaid (CMS)**. A reduction in reimbursement rates or reimbursed services could result in significantly lower sales and operational results.

Medicare has implemented an end-stage renal disease (ESRD) **prospective payment system (ESRD PPS)**, which expanded the scope of the products and services covered by a bundled rate. Due to pressure to reduce health care costs, increases in the reimbursement rate by the U.S. government have been limited.

As part of the PPS, our dialysis clinics in the United States participate in the **Quality Improvement Program (QIP)**. Medicare reimbursement benefits can be reduced by up to 2% based on the previous year's benefits if clinics do not meet the quality standards of the QIP. Underlying quality measures are reviewed, extended, and amended annually by the CMS. A material failure by Fresenius Medical Care to achieve the minimum client quality standards under the QIP could materially and adversely affect its business, financial condition, and results of operations.

In addition, Fresenius Medical Care participates in various value-oriented compensation programs under which we receive fixed compensation to cover all or a defined amount of treatment costs for a defined number of patients:

- ▶ Under CMS's Comprehensive ESRD Care Model, dialysis providers and physicians can form entities known as ESRD Seamless Care Organizations (ESCOs) as part of a new payment and care delivery model that seeks to deliver better health outcomes for Medicare ESRD patients while lowering CMS' costs. ESCOs that achieve the program's minimum quality thresholds and generate reductions in costs of care above certain thresholds for the ESRD patients covered by the ESCO will receive a share of the cost savings, which is adjusted based on the ESCO's performance on certain quality metrics. ESCOs that include dialysis chains with more than 200 facilities are required to share in the risk of cost increases and reimburse CMS a share of any such increases if actual costs rise above set thresholds.

- ▶ Bundled Payment for Care Improvement (“BPCI”) is a CMS pilot initiative, extended through September 30, 2018, with bundled payments for the individual services furnished to Medicare beneficiaries during a single episode of illness or course of treatment, including acute inpatient hospital services, physician services, and post-acute services. We commenced participation in several markets under the BPCI in April 2015 through our majority-owned subsidiary, Sound Inpatient Physicians, Inc. (“Sound”). On June 28, 2018, we divested our controlling interest in Sound. Under the BPCI, we had the ability to receive additional payments if we were able to deliver quality care at a cost that was lower than certain established benchmarks, but also had the risk of incurring financial penalties if we were unsuccessful in doing so.
- ▶ Furthermore, Fresenius Medical Care provided Medicare Advantage Chronic Special Needs Plan (MA-CSNP) products until December 31, 2018. MA-CSNPs are Medicare health plans offered by private companies that contract with Medicare to provide Medicare benefits to special needs individuals with specific severe or disabling chronic conditions such as ESRD, with a focus on improving the coordination of care. As an MA-CSNP, Fresenius Medical Care provided health care services and received set payments from CMS for the complete care of ESRD patients who enrolled in our MA-CSNP.
- ▶ In addition, Fresenius Medical Care has entered into sub-capitation and other risk-based and value-based arrangements with certain payers to provide care to Medicare Advantage ESRD patients.

Inadequate pricing of products or an unsuitable cost estimate for the service portfolio for beneficiaries and ineffective cost management may have a material adverse effect on our financial position, net assets, and operational results.

Fresenius Medical Care mitigated the impact of the referenced reimbursement models and other legislative initiatives by two broad measures:

- ▶ First, Fresenius Medical Care works with medical directors and treating physicians to generate options for efficiency increases consistent with QIP and good clinical practice and negotiates cost savings on the purchasing of pharmaceuticals;

- ▶ Second, Fresenius Medical Care introduces new initiatives in order to achieve efficiency increases and better patient outcomes by increasing patient care upon initiation of dialysis, increasing the percentage of patients using home therapies, and generating additional cost reductions in its clinics.

The U.S. administration has publicly announced its intention to pursue significant changes to existing health care insurance programs, especially programs in connection with the Affordable Care Act. In addition, options to restructure the Medicare program in the direction of a defined-contribution, “premium support” model and to shift Medicaid funding to a block grant or per capita arrangement, with greater flexibility for the states, are also likely to be considered.

The U.S. administration also announced its decision to end subsidies, known as cost-sharing reduction (CSR) payments, to health insurance companies to help pay out-of-pocket costs of low-income Americans. Some commercial insurers have stated that they will need much higher premiums and may withdraw from the insurance exchanges created under the Affordable Care Act if the subsidies were eliminated. As a result, significant increases in insurance premiums and a reduction in the availability of insurance through such exchanges could reduce the number of Fresenius Medical Care’s commercially insured patients and shift such patients to Medicare and Medicaid. Because Medicare and Medicaid reimbursement rates are generally lower than the reimbursement rates paid by commercial insurers, a shift of commercially insured patients to Medicare and Medicaid could have a material adverse impact on the business, financial conditions, and result of operations of Fresenius Medical Care.

Further federal or state legislation or regulations may be enacted in the future through a public referendum process in the United States that could substantially modify or reduce the amounts paid for services and products offered by us and our subsidiaries and/or implement new or alternative operating models and payment models that could present more risk to our health care service operations. For example, the ballot initiatives introduced at the state level could result in further regulation of clinic staffing requirements, state inspection

requirements, and margins on commercial business. State regulation at this level would introduce an unprecedented level of oversight and additional expense at the clinic level that could have a material adverse effect on the business of Fresenius Medical Care in the impacted states.

In addition, a portion of dialysis treatment in the United States is reimbursed by **private health insurance companies** and **integrated care organizations**, with reimbursements generally higher than the reimbursements provided by the government health care program. As a result, payments from private health insurers contribute a significant portion to Fresenius Medical Care's profits. In 2018, approximately 34% of Fresenius Medical Care's sales from health care services were attributable to private health insurance companies in the North American segment. If these organizations in the United States manage to push through a reduction in the reimbursement, or the share of reimbursements by private health insurers, it would significantly reduce the revenues and operating earnings for the products and services of Fresenius Medical Care.

A portion of Fresenius Medical Care's patients who are currently covered by private insurers may elect to transition to government-funded reimbursement programs that reimburse us at lower rates for our services if efforts to restrict or eliminate the charitable funding of patient insurance premiums are successful.

Changes in reimbursement from government and private insurers for our entire product and service portfolio in the United States could have a material adverse effect on our business and operating results.

The same applies to the hospital market in Germany, where the **DRG system** (Diagnosis-Related Groups) is intended to increase the efficiency of hospitals while reducing health care spending. Patients are largely assigned to hospitals by the public health and pension insurers. It is therefore important for Helios Germany that the contracts between its hospitals and the insurers and health care institutions are maintained. We not only monitor legislative changes intensively, but also work together with governmental health care institutions.

As a result of the Act to Enhance Nurse Staffing Levels (PpSG), the nursing costs will be excluded from the DRG from 2020. Instead, the costs for patient-oriented nursing care will be fully reimbursed by the health insurance funds via separate nursing budgets. As early as 2019, each additional or increased care place at the bed will be completely refinanced by the cost bearers.

In the German market, Helios Germany sees a general trend towards outpatient treatment, which could lead to lower growth in the number of inpatient cases. To counter this trend, Helios Germany is expanding outpatient services offerings in a separate division. If Helios Germany does not succeed in sustainably adapting its business model through suitable measures, this could lead to a decline in the number of cases and have a material adverse effect on our business, financial condition, and result of operations.

Quirónsalud, our private chain of clinics in Spain, operates hospitals through **PPP contracts (public-private partnership)**, among others methods. These are part of the public health system in Spain. The company has thus been given responsibility in certain areas of health care for the citizens of Spain with statutory health insurance. Quirónsalud receives compensation for its services in the form of a per capita lump sum or remuneration for the specific service rendered. If Quirónsalud were to lose the concession to operate hospitals with PPP contracts or renegotiations with public or private insurance companies resulted in worse conditions for doing so, or if hospitals are not able to compensate for lower reimbursement rates by cutting costs, this could have a material adverse effect on our net assets, financial position, and results of operations.

Reductions in health care spending could also negatively affect the pricing of Fresenius Kabi products.

Changes in the law, the reimbursement method, and the health care program could affect the scope of payments for services, as well as for insurance coverage and the product business. This could have a significant adverse impact on the assets and liabilities, financial position, and results of operations. Generally, our aim is to counter such possible regulatory risks through enhanced performance and cost reductions.

Development of new products and therapies

The **introduction of new products and services**, or the development of new technologies by competitors, could render one or more of our products and services less competitive or even obsolete, and thus have a significant negative impact on future sales, the prices of products, and our range of services. This includes the introduction of generic or patented drugs by competitors, which may have an impact on sales and operational results.

Cooperation with medical doctors and scientists allows us to identify and support relevant technological innovations and to keep abreast of developments in alternative treatment methods. These enable us to evaluate and adjust our corporate strategy if necessary.

OPERATING RISKS

Our operational business around the world is exposed to a number of **risks** and to extensive **regulation**, which include, among others:

- ▶ the quality, safety, and efficacy of medical and pharmaceutical products, supplies, and therapies;
- ▶ the operation and licensing of hospitals, other health care facilities, manufacturing facilities, and laboratories;
- ▶ the planning, construction, equipment, and management of pharmaceutical and medical-technological production facilities;
- ▶ the planning, construction, equipment, and management of health care facilities;
- ▶ permits from public authorities and monitoring of clinical and non-clinical research and development activities;
- ▶ product releases and approvals for new products and product modifications;
- ▶ the rate of, and accurate reporting and billing for, government and third-party reimbursement;
- ▶ the labeling and designation of pharmaceutical products and their marketing;
- ▶ attracting qualified personnel;
- ▶ compensation of medical directors and other financial arrangements with physicians and other referral sources;
- ▶ access to, collection, publication, use, and security of health information and other protected data.

If Fresenius fails to comply with laws or regulations, this may give rise to a number of consequences, including monetary and administrative penalties, increased compliance costs, exclusion from governmental programs, or a complete or partial curtailment of our authorization to conduct business, any of which could have a material adverse effect on our business reputation, financial condition, or results of operations.

Significant risks of operations for the Fresenius Group are described in the following sections.

Production, products, and services

Compliance with **product and manufacturing regulations** is ensured by our quality management systems, which are, inter alia, structured in accordance with the internationally recognized **quality standards ISO 9001 and ISO 13485**, taking into account relevant national and international regulations. These are implemented by internal standards such as quality and work procedure manuals. Regular internal and external audits are carried out at the Group's production sites, distribution companies, and dialysis clinics. These audits test compliance with regulations in all areas – from management and administration to production and clinical services and patient satisfaction. Our production facilities comply with the Good Manufacturing Practice (GMP) of the markets they supply. Our facilities are audited by local public health authorities such as the U.S. Food and Drug Administration (FDA) or the European Medicines Agency (EMA) and other authorities. If an authority detects any deficiencies, Fresenius will immediately take appropriate rectifying measures, as, for example, following the inspections of our production facilities in India in 2017.

Non-compliance with the requirements of these authorities in our production facilities or at our suppliers could lead to regulatory actions, such as warnings, product recalls, production interruptions, monetary sanctions, or delays in new product approvals. Any of these regulatory actions could adversely affect our business reputation and our ability to generate sales and result in significant expenses.

In addition, **production** could be adversely affected by events such as natural disasters, infrastructure disruptions, regulatory rulings, or supply disruptions, e. g., of raw materials, or technical failures.

Potential risks arising from the **start-up of new production sites or the introduction of new technologies** are countered through careful planning, regular analysis, and continual progress reviews.

Performing **medical treatments** on patients in our hospitals, rehabilitation clinics, and dialysis clinics is subject to inherent risks. For example, disruptions to processes, also due to causes such as natural disasters or technical failures, involve risks for patients and the clinic. In addition, there are operational risks, for example regarding hygiene. We counteract these risks with strict operating procedures, continual personnel training, and patient-oriented working procedures. Furthermore, we are constantly striving to improve the standard of patient treatment through our quality management systems.

Performance risks associated with Fresenius Vamed's **project business** are countered through professional project management and control, and with a proven system tailored to each business activity for identifying, evaluating, and minimizing these risks. This system consists of organizational measures, such as standards for pricing-in risks when preparing quotations. Risks are assessed even before accepting orders and are subsequently updated during regular project controlling. To avert the risk of default, financial measures are taken, such as checking creditworthiness and, as a rule, safeguarding through prepayments, letters of credit, and secured credits.

Procurement

On the **procurement side**, we counter risks – which mainly involve possible price increases and the availability of raw materials and goods – by appropriately selecting and working together with our suppliers through long-term framework agreements in certain purchasing segments and by bundling volumes within the Group.

We counter the risk of poor-quality purchased raw materials, semi-finished products, and components mainly by requiring our suppliers to meet strict quality standards. This

includes a structured qualification process, which comprises audits, document and advance sample inspections, as well as regular quality controls of deliveries. We only purchase high-quality products with proven safety and suitability from qualified suppliers that conform to our specifications and standards.

Competition

Growing **competition**, among other things induced by the reentry of competitors into the U.S. market for generic IV drugs after production halts, could materially affect the future pricing and sale of our products and services adversely. The introduction of generic or patented drugs by competitors may have an impact on the sales and operational results of our products.

Generally, the health care markets are characterized by price pressure (including from tenders), competition, and efforts to contain costs. These factors could result in lower sales and adversely affect our business, our financial position, and our operational results.

In the United States, almost all Fresenius Kabi injectable pharmaceutical products are sold to customers through arrangements with **group purchasing organizations (GPOs)** and distributors. The majority of hospitals undertake contracts with GPOs of their choice for their purchasing needs. Currently, three GPOs control the large majority of sales in the United States to hospital customers. Fresenius Kabi derives a large percentage of its revenue in the United States through a small number of GPOs and has purchasing agreements with the most important of them. To maintain these business relationships, Fresenius Kabi needs to be a reliable supplier of a comprehensive and high-quality product line, remain price-competitive, and comply with the regulations of the U.S. Food and Drug Administration (FDA). The GPOs also have purchasing agreements with other manufacturers and the bidding process for products is highly competitive. Most of the agreements Fresenius has with GPOs in the United States can be terminated at short or medium notice. If Fresenius Kabi does not succeed in fulfilling and maintaining its existing contracts or if new contracts are concluded on less favorable terms, this could have an adverse effect on our sales, financial position, and operational results.

The main customers in the area of transfusion technology are plasma companies and blood centers. There are four major plasma companies serving the United States. Blood centers in the United States are consolidating in response to blood-saving efforts at hospitals, which is having an effect on pricing. We are countering this pricing development with efficiency improvements and cost reductions.

Referrals from physicians

Our hospitals, rehabilitation clinics, and dialysis clinics are dependent on patients selecting them for their medical treatment. To a large extent, patients rely on the recommendation of their attending physician. Physicians make their recommendations based on various factors, including the quality of the medical treatment and the competence of the hospital staff, as well as the distance to the hospital, and the availability of appointments for treatment. If we are unable to meet these criteria, physicians may recommend fewer or no patients at all to our clinics. In addition, Fresenius Helios could receive fewer referrals from physicians because they increasingly perceive Fresenius Helios' outpatient services as competition or because they no longer take specialized hospitals with a certain medical focus into account when making their choice. These factors could result in lower sales and adversely affect our business, our financial position, and our operational results.

Payment default

As a rule, we assess the creditworthiness of new customers in order to limit the risk of **late payment and defaults** by customers. We also conduct follow-up assessments and review credit lines on an ongoing basis. We monitor receivables outstanding from existing customers, and assess the risk of default. This particularly applies to countries with budgetary problems and countries exposed to political risks. In 2018, we again worked on the status of our receivables, by taking measures such as factoring.

Personnel

The Company addresses **potential shortages of qualified personnel** through appropriate measures for employer branding, as well as recruitment, development, and retention of qualified staff.

In order to increase the awareness and attractiveness of the Fresenius Group, our employer branding relies on a mix of university marketing, company-internal events (such as the Fresenius Career Day "Meet the Board" involving our top management), and digital employer branding (e. g., by expanding our career website and our presence on social media channels).

To ensure a sustainable supply of qualified staff, we offer, for example, targeted programs for young academic talents with subsequent retention programs, as well as comprehensive apprenticeships for students.

With more than 4,000 apprentices and dual students, Fresenius is one of the biggest training companies in Germany. In order to meet the manifold demand for qualified personnel, we offer 1,300 apprenticeship places in more than 50 professions and dual study programs every year. We provide information about our apprenticeship and study program offers on our career website, as well as at our locations through various marketing activities and vocational orientation offers (e. g., vocational information days, Night of Apprenticeship, student internships, Apprentices' Navigation System).

Furthermore, we offer young academic talents the opportunity to gain initial practical experience and to establish contacts within our company in the context of internships before or during their studies or in the context of their final papers.

Depending on their customer and market structure, our business segments adopt different approaches and measures for personnel development. We strengthen employee loyalty to our company by offering our employees attractive development opportunities and fringe benefits and variable compensation and work time models. In addition, we promote international and interdisciplinary cooperation.

By using target-group-specific measures, Fresenius addresses the overall shortage of specialized hospital personnel. We thereby aim to recruit qualified and dedicated personnel, thus ensuring our high standard of treatment quality.

Effective January 1, 2019, the German hospital market will also be subject to the "Verordnung zur Festlegung von Personaluntergrenzen in pflegeintensiven Bereichen in Krankenhäusern" (PpUGV – Ordinance on the Minimum Requirements for Nursing Personnel in Hospitals). This ordinance stipulates minimum staffing levels for nursing personnel in certain areas of the hospital. Most of the hospitals of Helios Germany already meet these requirements. Further planned statutory regulations on minimum personnel levels in additional hospital departments with beds may further intensify competition for qualified nursing staff. Helios Germany is therefore working intensively on additional measures to make it particularly attractive as an employer for nursing staff. These include the compatibility of family and career (e.g., through childcare facilities at hospital sites or the possibility of part-time work), attractive further and advanced training opportunities, occupational risk prevention, and career opportunities.

Additional information on our measures to recruit and develop qualified personnel and to retain employees can be found in our Group Non-financial Report from page 113 onwards.

FINANCIAL RISKS

Currency and interest-rate risks

The international operations of the Fresenius Group expose us to a variety of **currency risks**. In addition, the financing of the business exposes us to certain **interest rate risks**. We use derivative financial instruments as part of our risk management to avoid any possible negative impacts of these risks. However, we limit ourselves to non-exchange-traded, marketable instruments, used exclusively to hedge our operations and not for trading or speculative purposes. The majority of our transactions are conducted with banks that have a high rating.

The Fresenius Group's **foreign exchange risk management** is based on a policy approved by the Management Board that defines the targets, organization, and handling of the risk management processes. In particular, the guidelines assign responsibilities for currency risk determination, the execution of hedging transactions, and the regular reporting of risk management. These responsibilities are coordinated with the management structures in the residual business processes of the Group. Decisions on the use of derivative financial instruments in **interest rate management** are taken in close consultation with the Management Board. Hedging transactions using derivatives are carried out by the Corporate Treasury department of the Fresenius Group – apart from a few exceptions in order to adhere to foreign currency regulations. These transactions are subject to stringent internal controls. This policy ensures that the Management Board is fully informed of all significant risks and current hedging activities.

The Fresenius Group is protected, to a large extent, against **currency and interest rate risks**. As of December 31, 2018, approximately 64% of the Fresenius Group's debt was protected against increases in interest rates either by fixed-rate financing arrangements or by interest rate hedges; 36% was exposed to interest rate risks. A sensitivity analysis shows that a rise of 0.5 percentage points in the reference rates relevant for Fresenius would have an impact of approximately 1.0% on Group net income.

As a global company, Fresenius is widely exposed to translation **effects due to foreign exchange rate fluctuations**. The exchange rate of the U.S. dollar to the euro is of particular importance because of our extensive operations in the United States. Translation risks are not hedged. A sensitivity analysis shows that a one cent change in the exchange rate of the U.S. dollar to the euro would have an annualized effect of about €120 million on Group sales, about €22 million on EBIT, and about €7 million on Group net income.

As a globally active company, we have production facilities in all the main currency areas. In the service businesses, our revenue and cost base largely coincide. The Fresenius Group uses a Cash-Flow-at-Risk (CFaR) model in order to estimate and quantify such **transaction risks** from foreign currencies. The foreign currency cash flows that are reasonably expected to arise within the following 12 months, less any hedges, form the basis for the analysis of the currency risk. As of December 31, 2018, the Fresenius Group's cash flow at risk was €66 million. Hence, with a probability of 95%, a potential loss in relation to the forecast foreign exchange cash flows of the next 12 months will not be higher than €66 million. Further details on financial risks can be found on pages 235 to 246 in the Notes.

Recoverability of assets

Financial risks that could arise from acquisitions and investments in property, plant and equipment and in intangible assets are assessed through careful and in-depth reviews assisted by external consultants. The amount of intangible assets, including goodwill, product rights, trade names, and management contracts, represents a considerable part of the total assets of the Fresenius Group. Goodwill and other intangible assets with an indefinite useful life carried in the Group's consolidated balance sheet are **tested for impairment** each year. A significant deterioration in our prospects for the future or in the general economic environment could result in additional depreciation being necessary. Further information can be found on pages 203 ff. of the Notes.

Taxes and duties

As a global corporation, Fresenius is subject to numerous **tax laws and regulations**. Risks arising therefrom are identified and evaluated on an ongoing basis. The Fresenius Group's companies are subject to regular tax audits. Any changes in tax regulations or resulting from tax audits and additional import duties could lead to higher tax payments.

Debt and liquidity

Fresenius' debt was €18,984 million as of December 31, 2018. The **debt** could limit the Company's ability to pay dividends, arrange refinancing, be in compliance with its credit covenants, or implement the corporate strategy. If the conditions on the relevant financial markets deteriorate significantly, financing risks could arise for Fresenius. We reduce these risks through a high proportion of mid- and long-term funding with a balanced maturity profile.

Some of our major financing agreements contain covenants requiring us to comply with certain financial ratios and additional financial criteria. Non-compliance with these covenants could result in a default and acceleration of the debt

under the respective agreements. We counteract this risk by taking the relevant performance indicators into account in our Group planning and continuously monitoring their development. This enables us to take countermeasures at an early stage.

Additional information on conditions and maturities can be found on pages 208 ff. of the Notes and on pages 62 ff. of the Group Management Report.

Inflation risks

As an international company, we are exposed to varying **inflation rates and price developments**. We are also active in high-inflation countries such as Argentina. Due to the development of inflation in Argentina, our subsidiaries operating there have applied IAS 29, Financial Reporting in Hyperinflationary Economies, since July 1, 2018. For the fiscal year 2018, this resulted in an effect on net income (net income attributable to the shareholders of Fresenius SE & Co. KGaA) of -€12 million. Furthermore, as of December 31, 2017, there was an effect on the equity of the shareholders of Fresenius SE & Co. KGaA of €15 million.

RISKS ASSOCIATED WITH RESEARCH AND DEVELOPMENT AND PRODUCT APPROVAL

The **development of new products and therapies** always carries the risk that the ultimate goal might not be achieved, or it might take longer than planned. This is particularly true for the Fresenius Kabi biosimilar products. The development of biosimilar products entails additional risks, such as significant development costs and the still-developing regulatory and approval processes. Regulatory approval of new products requires comprehensive, cost-intensive preclinical and clinical studies. Furthermore, there is a risk that regulatory authorities either do not grant, or delay, product approval, or withdraw an existing approval. In addition, adverse effects of our products that may be discovered after regulatory approval or

registration may lead to a partial or complete withdrawal from the market, either as a result of regulatory actions or our voluntary decision to stop marketing a product.

In January 2018, for example, the Coordination Group for Mutual Recognition and Decentralized Procedures – human (CMDh) at the European Medicines Agency (EMA) recommended that drugs containing hydroxyethyl starch (HES) be withdrawn from the market. This position was not taken unanimously and has therefore been referred to the European Commission for a decision. In April 2018, the Standing Committee of the European Commission referred the matter back to the Pharmacovigilance Risk Assessment Committee (PRAC) of the EMA. The PRAC maintained its recommendation to suspend regulatory approvals. As a result, the CMDh of the EMA took the position in July 2018 that regulatory approvals would be maintained under the condition that risk-minimizing measures are implemented. These include controlled distribution to accredited hospitals/centers, training and direct communication with health care professionals, and warnings on the packaging. In July 2018, the European Commission approved this position. Similar measures could also be taken by authorities in non-EU countries.

The Fresenius Group spreads its risk widely by conducting development activities in various product segments. We also counteract risks from research and development projects by regularly analyzing and assessing development trends and examining the progress of research projects. We also strictly comply with the legal regulations for clinical and chemical-pharmaceutical research and development.

With IV drugs, it is also crucial that new products are continually brought to the market in a timely manner. Therefore, we monitor the development of new products on the basis of detailed project plans and focus on achieving specific milestones. In this way, we can take countermeasures if defined targets are called into question.

RISKS FROM ACQUISITIONS

The **acquisition and integration** of companies carries risks that can adversely affect the assets and liabilities, financial position, and results of operations of Fresenius. Acquisition processes often include closing conditions, including but not limited to antitrust clearance, fulfillment of representations and warranties, and adherence to laws and regulations. Non-compliance with such closing conditions by either party to an acquisition could lead to litigation between the parties or with others and thus claims against Fresenius.

Following an acquisition, the acquired company's structure must be integrated while clarifying legal questions and contractual obligations. Marketing, patient services, and logistics must also be unified. During the integration phase, key managers can leave the company and both the course of ongoing business processes and relationships with customers and employees can be harmed. In addition, change-of-control clauses may be claimed. The integration process may prove more difficult or require more time and resources than expected. Risks can arise from the operations of the newly acquired company that Fresenius regarded as insignificant or was unaware of. An acquisition may also prove to be less beneficial than initially expected. **Future acquisitions** may be a strain on the finances and management of our business. Moreover, as a consequence of an acquisition, Fresenius may become directly or indirectly liable towards third parties, or claims against third parties may turn out to be non-assertable. We counter risks from acquisitions through detailed integration roadmaps and strict integration and project management, so that countermeasures can be initiated in good time if there are deviations from the expected development.

INFORMATION TECHNOLOGY RISKS

The Company's processes are growing ever more complex as a result of the Fresenius Group's steady growth and increasing internationalization. Correspondingly, **the dependence on information and communication technologies**, and on the systems used to structure procedures and – increasingly – harmonize them internationally, intensifies. A failure of these systems could temporarily lead to an interruption of other parts of our business and thus cause serious damage. Fresenius counters these risks with various security measures, controls, and audits. In addition, we counter these risks with constant investment in hardware and software, as well as by improving our system know-how. Potential risks are covered by a detailed contingency plan, which is regularly improved and tested. Redundant systems are maintained for all key systems, such as IT systems or communications infrastructure.

The loss of sensitive data or the **non-compliance with data protection laws**, regulations, and standards could damage our competitive position, our reputation, and the entire company. To comply with these requirements, we have implemented comprehensive data protection management systems, which provide the appropriate technical and organizational measures and controls for the protection of personal data. Fresenius SE & Co. KGaA and all business areas maintain data protection organizations, including a data protection officer, based on their corporate structure. Data protection guidelines describe the binding requirements for data protection and data handling in all business areas. Further information about our Data Protection Management Systems can be found in the Group Non-financial Report on pages 104 ff.

In addition, the increased integration of IT systems and the use of new technologies such as cloud computing within our business processes means that **cyberattacks** could penetrate our internal and external systems, and attackers could cause damage or gain sensitive information. The existing IT security architecture, with various security measures at different levels, protects the systems in our data centers. Access to sensitive or critical data from outside the protected data center network is prevented by the use of secure

protocols and cryptographic measures. In addition, annual penetration tests are carried out for applications with critical data (for example, patient or personnel data).

A comprehensive access protection system, for example procedures to assign and monitor authorizations and password guidelines, is in place to minimize organizational risks, such as tampering or unauthorized access. In addition, there are company guidelines regulating the granting of access authorization, and compliance with these rules is monitored. We also conduct operation- and security-related audits.

COMPLIANCE AND LEGAL RISKS

Compliance risks

Fresenius is subject to comprehensive government regulation and control in nearly all countries. In addition, Fresenius must comply with general rules of law, which differ from country to country. There could be far-reaching legal repercussions or reputation damage should Fresenius fail to comply with these laws or regulations.

We must comply with these rules and regulations, which particularly monitor the safety and effectiveness of our medical products and services. Corruption is a core risk area across all business segments. Antitrust law, data protection, money laundering, sanctions, and human rights are further significant risk areas. Therefore, it is of special importance to us that our **compliance programs** and guidelines are adhered to. Through compliance, we aim to meet our own expectations and those of our partners, and to orient our business activities to generally accepted standards and local laws and regulations.

At Fresenius, we have implemented worldwide risk-oriented **Compliance Management Systems** in all business segments worldwide. These systems take into account the respective markets in which Fresenius operates. They are tailored to the specific requirements of each business segment. Furthermore, we at Fresenius assess compliance risks using a standardized methodology.

Each business segment has appointed a Chief Compliance Officer to oversee the development, implementation, and monitoring of the relevant business segment's Compliance Management System. Business segments have established compliance responsibilities in line with their organizational and corporate structure. The Corporate Compliance depart-

ment of Fresenius SE & Co. KGaA supports the compliance officers in each business segment with standardized instruments, processes, and methods, and reports to the Chief Compliance Officer of Fresenius SE & Co. KGaA – the member of the Management Board for Legal Affairs, Compliance, and Human Resources.

Our compliance programs set binding rules of conduct for our employees. We believe that we have taken adequate measures to ensure that national and international rules are observed and complied with.

Further information about our Compliance Management Systems can be found in the Group Non-financial Report on pages 109 ff.

Legal risks

Risks that arise from **legal disputes** are continually identified, analyzed, and communicated within the Company. Companies in the health care industry are regularly exposed to actions for breach of their duties of due care, product liability, breach of warranty obligations, patent infringements, treatment errors, and other claims. This can result in high claims for damages and substantial costs for legal defense, regardless of whether a claim for damages is actually justified. Legal disputes can also result in an inability to insure against risks of this kind at acceptable terms in future. Products from the health care industry can also be subject to recall actions. This could have a negative effect on our reputation and on the assets and liabilities, financial position, and results of operations of the Group.

The Fresenius Group is routinely involved in claims, lawsuits, investigations and other legal matters arising, for the most part, in the ordinary course of its business of providing health care services and products. The outcome of litigation and other legal matters is always difficult to predict accurately. However, we do not expect any material adverse effect on our business, results of operations, and financial condition from the legal matters currently pending.

Further information regarding legal matters and the FCPA review at Fresenius Medical Care can be found on pages 225 to 234 of the Notes.

OTHER RISKS

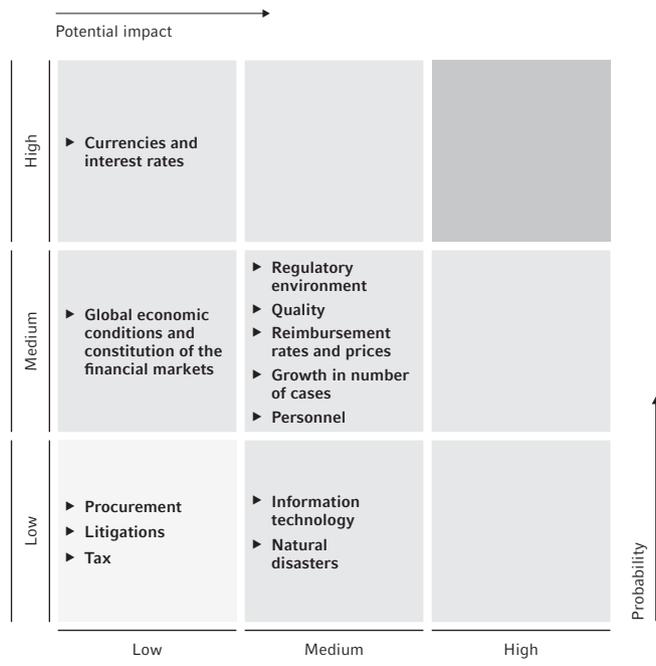
Our international orientation also gives rise to the following risks, which could have an adverse effect on our business and thus on our financial position, and operational results.

- ▶ Political, social, or economic instability, especially in developing and emerging countries,
- ▶ civil unrest, armed conflict, outbreaks of disease,
- ▶ natural disasters, terrorist attacks, and other unforeseen events,
- ▶ different labor law conditions and difficulties in meeting the global demand for qualified personnel,
- ▶ different and less stable regulations protecting intellectual property,
- ▶ delays in the transport and delivery of our products.

More detailed information on environmental management at Fresenius and on assistance in the event of natural disasters and other crises can be found in the Group Non-financial Report on pages 121 ff. and/or 98 f. and 102.

Risks involving management and control systems, were, based on our established risk management and controlling processes, not considered to be significant.

RISKS AFFECTING THE ONE-YEAR FORECAST PERIOD



ASSESSMENT OF OVERALL RISK

The basis for evaluating overall risk is the risk management that is regularly audited by management. Potential risks for the Group include factors beyond its control, such as the evolution of economies, which are constantly monitored by Fresenius. Risks also include factors immediately within its control, such as operating risks, which the Company anticipates and reacts to appropriately, as required. There are currently no recognizable risks regarding future performance that appear to present a long-term and material threat to the Group’s assets and liabilities, financial position, and results of operations. We have created organizational structures that provide all the conditions needed to rapidly alert us to possible risk situations and to be able to take suitable countermeasures.

RISKS AFFECTING THE ONE-YEAR FORECAST PERIOD

The chart on page 90 shows the significant risks that could lead to deviations from the expected business performance within the one-year forecast period. Compared to the previous year, the risk in connection with the recruitment of qualified personnel, especially given the background of regulatory requirements on the minimum level of nursing staff in hospitals, and the risk of possible lower growth in the number of cases in the German hospital market, were also included. Apart from that, no changes have occurred in the grouping and the potential effects of risks. Within the regulatory environment, due to possible initiatives by the U.S. administration, we are exposed to risks relating to changes to the existing health care programs. With regard to reimbursement rates, possible changes to patient structures in the United States increase the risk with regard to reimbursements by private health insurance schemes.

In classifying risk, qualitative assessments are applied first of all, followed by quantitative factors. The scales for classification of potential impact and probabilities are shown in the following two tables:

Potential impact	Description of impact
High	Significant negative impact on the one-year forecast
Medium	Moderate negative impact on the one-year forecast
Low	Insignificant negative impact on the one-year forecast

Probability	Classification
High	≥ 66% to 100%
Medium	≥ 33% to < 66%
Low	0% to < 33%

EFFECTS ON OUR MEDIUM-TERM GOAL

Fundamentally, all the risk areas and risks listed in the risk report could lead to our failing to achieve our medium-term target. We believe the following will be particularly important for this:

- ▶ Risks relating to the quality, safety, and effectiveness of our products and services (Operating risks, see page 82 ff.);
- ▶ Risks arising from the financing of health systems and potential changes in reimbursement systems (Risks in the health care sector, see page 79 ff.);
- ▶ Risks arising from the regulatory environment and compliance with laws and regulations (General economic risks and risks in the general operating framework, see page 79).