3.D Risk factors

Our businesses face significant risks and uncertainties. You should carefully consider all of the information set forth in this Annual Report and in other documents we file with or furnish to the SEC, including the Form 20-F filed with the SEC by our subsidiary Alcon Inc. in connection with our planned spin-off of the Alcon business, as well as the following risk factors, before deciding to invest in or to maintain an investment in any Novartis securities. Our business, as well as our financial condition or results of operations, could be materially adversely affected by any of these risks, as well as other risks and uncertainties not currently known to us or not currently considered material.

Risks facing our business

Our products face losses of intellectual property protection.
Major products of our Innovative Medicines Division, as well as certain products of our Sandoz and Alcon Divisions, are protected by patent and other intellectual property rights, which provide us with exclusive rights to market the products, and give us an opportunity to recoup our investments in research and development. However, the strength and duration of those intellectual property rights can vary significantly from product to product and country to country, and they may be successfully challenged by third parties or governmental authorities. Loss of market exclusivity for one or more important products has had, and can be expected to continue to have, a material adverse effect on our results of operations.

The introduction of generic competition for a patented branded medicine typically results in a significant and rapid reduction in net sales and operating income for the branded product because generic manufacturers typically offer their unpatented versions at sharply lower prices. Such competition can occur after successful challenges to intellectual property rights or the regular expiration of the term of the patent or other intellectual property rights. Such competition can also result from the entry of generic versions of another medicine in the same therapeutic class as one of our drugs or in another competing therapeutic class, from a Declaration of Public Interest or the compulsory licensing of our drugs by governments, or from a general weakening of intellectual property laws in certain countries around the world. In addition, generic manufacturers sometimes take an aggressive approach to challenging intellectual property rights, including conducting so-called “launches at risk” of products that are still under legal challenge for infringement, before final resolution of legal proceedings.

We also rely in all aspects of our businesses on unpatented proprietary technology, know how, trade secrets and other confidential information, which we seek to protect through various measures, including confidentiality agreements with licensees, employees, third-party collaborators, and consultants who may have access to such information. If these agreements are breached or our other protective measures should fail, then our contractual or other remedies may not be adequate to cover our losses.

Some of our best-selling products have begun or are about to face significant competition due to the end of market exclusivity resulting from the expiry of patent or other intellectual property protection.

- Our former top-selling products *Gleevec/Glivec, Diovan* and *Exforge* all face continued and increasing generic competition in major markets.

- Patent protection for the marketed forms of our *Sandostatin* products has expired. Generic versions of *Sandostatin* SC are available in the US, the EU and Japan. While there is currently no generic competition in the US, the EU or Japan for *Sandostatin* LAR, the long-acting version of *Sandostatin* that represents the majority of our *Sandostatin* sales, such generic competition may arise in the future.

- Intellectual property protecting a number of additional major products is either being challenged or will expire at various times in the coming years, raising the possibility of generic competition. Among these products that may begin to face generic competition in one or more major markets during the next three years are *Gilenya*, our everolimus products (*Afinitor/Votubia* and *Zortress/Certican*), *Exjade* and *Jadenu*, and *Lucentis*.

For more information on the patent and generic competition status of our Innovative Medicines Division’s products, see “Item 4. Information on the Company—Item 4.B Business overview—Innovative Medicines—Intellectual property.”

In 2019, we expect a potentially significant impact on our net sales from products that have already lost intellectual property protection, as well as products that will lose protection during the year. Because we typically have substantially reduced marketing and research and development expenses related to products that are in their final years of exclusivity, the initial loss of intellectual property protection for a product during the year could also have an impact on our 2019 operating income in an amount corresponding to a significant portion of the product’s lost sales. The magnitude of the impact of generic competition on our income could depend on a number of factors, including the time of year at which the generic competitor is launched; the ease or difficulty of manufacturing a competitor product and obtaining regulatory approval to market it; the number of generic competitor products approved, including whether, in the US, a single competitor is granted an exclusive marketing period; whether an authorized generic is launched; the geographies in which generic competitor products are approved, including the strength of the market for generic pharmaceutical products in such geographies and the comparative profitability of branded

pharmaceutical products in such geographies; and our ability to successfully develop and launch profitable new products to replace the income lost to generic competition. See also "—Our research and development efforts may not succeed," below, with respect to the development and launch of new products.

Clearly, with respect to major products for which the patent terms are expiring, the loss of exclusivity of these products could have a material adverse effect on our business, financial condition, or results of operations. In addition, should we unexpectedly lose exclusivity on additional products as a result of patent litigation or other reasons, this could also have a material adverse effect on our business, financial condition, or results of operations, both due to the loss of revenue and earnings, and the difficulties in planning for such losses.

Our financial performance depends on the commercial success of key products.

Our financial performance, including our ability to replace revenue and income lost to generic and other competition and to grow our business, depends heavily on the commercial success of our products. If any of our major products were to become subject to problems such as changes in prescription growth rates, unexpected side effects, loss of intellectual property protection, supply chain issues or other product shortages, regulatory proceedings, changes in labeling, publicity affecting doctor or patient confidence in the product, material product liability litigation, or pressure from new or existing competitive products, the adverse impact on our revenue and profit could be significant. In addition, our revenue and profit could be significantly impacted by the timing and rate of commercial acceptance of key new products.

See also "—Our business is affected by pressures on pricing and reimbursement for our products," below, with regard to the impact of pricing and reimbursement issues on the commercial success of our products.

All of our businesses face intense competition from new products and technological advances from competitors, and physicians, patients and third-party payers may choose our competitors' products instead of ours if they perceive them to be safer, more effective, easier to administer, less expensive, more convenient or more cost-effective. Products that compete with ours are launched from time to time. We cannot predict with accuracy the timing of the introduction of such competitive products or their possible effect on our sales. However, products significantly competitive to our major products – including *Cosentyx, Lucentis, Gilenya, Sandostatin, Tasigna, Afinitor, Kisqali* and *Kymriah*– are on the market, and others are in development. In addition, numerous companies from around the world are seeking to enter the healthcare field to take advantage of their expertise in digital and other new technologies.

See "—We may fail to develop or take advantage of transformational technologies and business models," below.

Such competitive products could significantly affect the revenue from our products and our results of operations. This impact could also be compounded to the extent such competition results in us making significant additional investments in marketing and sales, or in research and development.

For example, our US Sandoz business has suffered significant declines in sales and profits in recent years due, at least in part, to increased competition in its product segments. There can be no certainty that Sandoz US sales will recover in the coming years. In any event, such competition and the costs of our efforts to improve the business's performance, as well as other factors, can be expected to affect the business, financial condition, or results of operations of this organization, at least in the near term. In addition, despite the devotion of significant resources to our efforts to improve the performance of Sandoz US, those efforts may ultimately prove insufficient. Should our efforts fail to accomplish their goals, or fail to do so in a timely manner, it could have a material adverse impact on our business, financial condition, or results of operations beyond the near term, as well.

See also "—Our research and development efforts may not succeed," and "—Competition and failure to successfully develop biosimilars and other differentiated products may impact the success of our Sandoz Division," below.

Our research and development efforts may not succeed.

We engage in extensive and costly research and development activities, both through our own dedicated resources and through collaborations with third parties, in an effort to identify and successfully and cost-effectively develop new products that address unmet and changing medical needs, are accepted by patients and physicians, are reimbursed by payers, and are commercially successful. Our ability to continue to maintain and grow our business; to replace sales lost due to competition, entry of generics or other reasons; and to bring to market products and medical advances that take advantage of new and potentially disruptive technologies, depends in significant part upon the success of these efforts. However, developing new healthcare products and bringing them to market is a highly costly, lengthy and uncertain process. In spite of our significant investments, there can be no guarantee that our research and development activities will produce commercially successful new products that will enable us to replace revenue and income lost to generic and other competition and to grow our business. See also "—We may not successfully achieve our goals in transactions or reorganizations," below, with regard to our efforts to reorganize our Innovative Medicines product development organization.

Using the products of our Innovative Medicines Division as an example, the research and development process for a new product can take up to 15 years, or even longer, from discovery to commercial product launch – and with limited available intellectual property protections, the longer it takes to develop a product, the less time there may be for us to recoup our research and development costs. New products must undergo intensive preclinical and clinical testing, and must be approved by means of highly complex, lengthy and expensive approval processes that can vary from country to country.

During each stage, there is a substantial risk that we will encounter serious obstacles that will further delay us and add substantial expense, that we will develop a

product with limited potential for commercial success, or that we will be forced to abandon a product in which we have invested substantial amounts of time and money. These risks may include failure of the product candidate in preclinical studies, difficulty enrolling patients in clinical trials, clinical trial holds or other delays in completing clinical trials, insufficient clinical trial data to support the safety or efficacy of the product candidate or to differentiate our product candidate from competitors, delays in completing formulation and other testing and work necessary to support an application for regulatory approval, adverse reactions to the product candidate or other safety concerns, an inability to manufacture sufficient quantities of the product candidate for development or commercialization activities in a timely and cost-effective manner, and failure to obtain, or delays in obtaining, the required regulatory approvals for the product candidate or the facilities in which it is manufactured.

In addition, following the "Brexit" vote in the UK, the EU decided to move the headquarters of the EU's health authority, the EMA, from the UK to the Netherlands by March 2019. It is expected that a significant percentage of the current employees of the EMA will decide not to make the move to the Netherlands. This raises the possibility that new drug approvals in the EU could be delayed as a result.

Further, in recent years, in order to achieve approvals of new products and new indications, governmental authorities around the world have increasingly required more clinical trial data than they had in the past, the inclusion of significantly higher numbers of patients in clinical trials, and more detailed analyses of the trials. In addition, in order for a product to be reimbursed and to be commercially successful, payers and prescribers have increasingly required additional data that differentiates the product from other drugs on the market. As a result, despite significant efforts by health authorities such as the FDA to accelerate the development of new drugs, the already lengthy and expensive process of obtaining regulatory approvals and reimbursement for pharmaceutical products has in many cases become even more challenging.

Similarly, the post-approval regulatory burden has also increased. Approved drugs are subject to various requirements such as risk evaluation and mitigation strategies (REMS), risk management plans, comparative effectiveness studies, health technology assessments, and requirements to conduct post-approval Phase IV clinical trials to gather additional safety and other data on products. These requirements have the effect of making the maintenance of regulatory approvals for our products increasingly expensive, and further heightening the risk of recalls, product withdrawals, loss of market share, and loss of revenue and profitability.

There is also the risk that we may fail to identify significant new product candidates for development or potentially disruptive new technologies, and so may fail to take advantage of a potential new wave of innovation.

Our Alcon Division faces similar challenges in bringing new products to market, including both the products and components that have been developed in house, as well as those that have been acquired from third parties. Alcon's Surgical and Vision Care products face medical device development and approval processes that are often similarly as difficult as those faced by our Innovative Medicines Division. For example, in 2017 the EU published a new EU Medical Devices Regulation, which has introduced substantial changes to the requirements for medical device manufacturers bringing new products to the EU market, including with respect to clinical development, labeling, technical documentation and quality management systems. The regulation has a three-year implementation period. Further, the FDA is also pursuing various efforts to modernize its regulation of devices, including potential changes to existing regulatory approval pathways that could impact our device approval efforts. Alcon has taken steps to increase its innovation power and the success of its research and development efforts. But these efforts are costly and require extensive efforts over time. There can be no certainty that Alcon will be successful in these efforts, in either the short term or the long term, and if Alcon is not successful, there could be a material adverse effect on the success of the Alcon Division.

In addition, our Sandoz Division has made, and expects to continue to make, significant investments in the development of biotechnology-based, "biologic" medicines intended for sale as bioequivalent or "biosimilar" versions of currently marketed biotechnology products, as well as other differentiated, "difficult-to-make" generic products. While the development of such products typically is significantly less costly and complex than the development of the equivalent originator medicines, it is nonetheless often significantly more costly and complex than that for non-differentiated generic products. In addition, many countries do not yet have fully developed legislative or regulatory pathways to facilitate the development of biosimilars and permit biosimilars to be sold in a manner in which the biosimilar product would be readily substitutable for the originator product. Further delays in the development and completion of such regulatory pathways, or any significant impediments that may ultimately be built into such pathways, or any other significant difficulties that may arise in the development or marketing of biosimilars or other differentiated products, could put at risk the significant investments that Sandoz has made, and will continue to make, in the development of differentiated products in general, and in its Biopharmaceuticals business in particular. Sandoz also achieves significant revenue opportunities when it secures and maintains exclusivity periods granted for generic products in certain markets – particularly the 180-day exclusivity period granted in the US by the Hatch Waxman Act for first-to-file generics. Failure to obtain and maintain such exclusivity periods or to successfully develop and market biosimilars and differentiated generic products could have a material adverse effect on the success of the Sandoz Division and the Group as a whole.

See also "—Competition and failure to successfully develop biosimilars and other differentiated products may impact the success of our Sandoz Division," below.

Further, in all of our divisions, our research and development activities must be conducted in an ethical and compliant manner. Among other things, we must be concerned with patient safety, data privacy, Good Clinical Practices requirements, data integrity requirements, the fair treatment of patients in developing countries, and animal welfare requirements. Should we fail to properly

manage such issues, we risk injury to third parties, damage to our reputation, negative financial consequences as a result of potential claims for damages, sanctions and fines, and the potential that our investments in research and development activities could have no benefit to the Group.

If we are unable to maintain a flow of successful, cost-effective new products and new indications for existing products that will sustain and grow our business, cover our substantial research and development costs and the decline in sales of older products that become subject to generic or other competition, and take advantage of technological and medical advances, then this could have a material adverse effect on our business, financial condition, or results of operations.

For a further description of the approval processes that must be followed to market our products, see the sections headed “Regulation” included in the descriptions of our operating divisions under “Item 4. Information on the Company—Item 4.B Business overview.”

Our business is affected by pressures on pricing and reimbursement for our products.

Our businesses are operating in an ever more challenging environment, with significant pressures on the pricing of our products and on our ability to obtain and maintain satisfactory rates of reimbursement for our products by governments, insurers and other payers. The growth of overall healthcare costs as a percentage of gross domestic product in many countries means that governments and payers are under intense pressure to control healthcare spending even more tightly than in the past. These pressures are particularly strong given the increasing demand for healthcare resulting from the aging of the global population and associated increases in noncommunicable diseases, and the resulting impact on healthcare budgets. These pressures are further compounded by significant controversies and intense political debate and publicity about prices for pharmaceuticals that some consider excessive, including government regulatory efforts, funding restrictions, legislative proposals, policy interpretations, investigations and legal proceedings regarding pharmaceutical pricing practices.

See also “—Ongoing consolidation among our distributors and retailers is increasing both the purchasing leverage of key customers and the concentration of credit risk,” below, with regard to the impact of the consolidation among our customers on our pricing; “—Our products face losses of intellectual property protection,” above, with regard to the impact of the loss or risk of loss of intellectual property protections on our pricing; and “—Political and economic instability may impact our results,” below, with regard to the impact of economic conditions on our pricing.

As a result, in addition to ongoing public and political pressures to limit the prices we charge for our products, we face numerous cost-containment measures imposed by governments and other payers, including government-imposed industrywide price reductions, mandatory pricing systems, reference pricing systems, payers limiting access to treatments based on cost-benefit analyses, imports of drugs from lower-cost countries to higher-cost countries, shifting of the payment burden to patients through higher co-payments, limiting physicians’ ability to choose among competing medicines, mandatory substitution of generic drugs for the patented equivalent, growing pressure on physicians to reduce the prescribing of patented prescription medicines, increasing pressure on intellectual property protections, and requirements for increased transparency on pricing. For more information on such price controls, see “Item 4. Information on the Company—Item 4.B Business overview—Innovative Medicines—Price controls.”

We expect these challenges to continue and to increase in 2019 and following years as political pressures mount, and healthcare payers around the globe, including government-controlled health authorities, insurance companies and managed care organizations, step up initiatives to reduce the overall cost of healthcare, restrict access to higher-priced new medicines, increase the use of generics and impose overall price cuts. These factors may materially affect our ability to achieve an acceptable return on our investments in the research and development of our products, may impact our ability to invest in the research and development of new products, and could have a material adverse impact on our business, financial condition, or results of operations, as well as on our reputation.

We could be impacted by new laws and regulations, and by failures to comply with law, legal proceedings and government investigations.

We are obligated to comply with the laws of all of the countries around the world in which we operate and sell products with respect to an extremely wide and growing range of activities. Such legal requirements can vary from country to country, and new requirements may be imposed on us from time to time as a result of changing government and public expectations regarding the healthcare industry, and acceptable corporate behavior generally.

For example, we are faced with increasing pressures, including new laws and regulations from around the world, to be more transparent with respect to how we do business, including with respect to our interactions with healthcare professionals and organizations. These laws and regulations include requirements that we disclose payments or other transfers of value made to healthcare professionals and organizations, as well as information relating to the prices for our products. Such measures, including any additional such measures that may be put in place, could have a material adverse impact on our business, financial condition, or results of operations.

In addition, companies and executives in our industry continue to face significant government investigations, legal proceedings and law enforcement activities, both in the US and in countries around the world. Increasingly, such activities can involve criminal proceedings, and can retroactively challenge practices previously considered to be legal. A number of our subsidiaries across each of our divisions are, or may in the future be, subject to various investigations and legal proceedings,

including proceedings regarding sales and marketing practices, pricing, corruption, trade regulation and embargo legislation, product liability, commercial disputes, employment and wrongful discharge, antitrust matters, securities, insider trading, occupational health and safety, environmental matters, tax, cybersecurity, data privacy and intellectual property.

Our Sandoz Division may from time to time seek approval to market a generic version of a product before the expiration of patents claimed by the marketer of the patented product. We do this in cases where we believe that the relevant patents are invalid or unenforceable, or would not be infringed by our generic product. As a result, affiliates of our Sandoz Division frequently face patent litigation, and in certain circumstances, we may elect to market a generic product even though patent infringement actions are still pending. Should we elect to proceed in this manner and conduct a "launch at risk," we could face substantial damages if the final court decision is adverse to us.

For information on significant legal matters pending against us, see "Item 18. Financial Statements—Note 19. Provisions and other non-current liabilities" and "Item 18. Financial Statements—Note 27. Commitments and contingencies." See also "—Our reliance on outsourcing key business functions to third parties heightens the risks faced by our businesses," below.

To help us in our efforts to comply with the many requirements that impact us, we have a significant global ethics and compliance program in place, and we devote substantial time and resources to efforts to ensure that our business is conducted in a lawful and publicly acceptable manner. Nonetheless, despite our efforts, any actual or alleged failure to comply with law or with heightened public expectations could lead to substantial liabilities that may not be covered by insurance, or to other significant losses, and could affect our business, financial position and reputation.

Such proceedings are inherently unpredictable, and large judgments sometimes occur. As a consequence, we may in the future incur judgments that could involve large cash payments, including the potential repayment of amounts allegedly obtained improperly, and other penalties, including treble damages. In addition, such legal proceedings and investigations, even if meritless, may affect our reputation, may create a risk of potential exclusion from government reimbursement programs in the US and other countries, and may lead to civil litigation. As a result, having taken into account all relevant factors, we have in the past and may again in the future enter into major settlements of such claims without bringing them to final legal adjudication by courts or other such bodies, despite having potentially significant defenses against them, in order to limit the risks they pose to our business and reputation. Such settlements may require us to pay significant sums of money and to enter into corporate integrity or similar agreements, which are intended to regulate company behavior for extended periods.

Any such judgments or settlements, and any accruals that we may take with respect to potential judgments or settlements, could have a material adverse impact on our business, financial condition, or results of operations, as well as on our reputation.

The manufacture of our products is highly regulated and complex.

The manufacture of our products is complex and heavily regulated by governmental health authorities around the world, including the FDA. Whether our products and the related raw materials are manufactured at our own dedicated manufacturing facilities or by third parties, we must ensure that all manufacturing processes comply with our own quality standards, as well as with current Good Manufacturing Practices (cGMP) and other applicable regulations.

The technically complex manufacturing processes required to manufacture many of our products increase the risk of production failures and product recalls, and can increase the cost of producing our goods. Many of our products require a supply of highly specialized raw materials. For some of our products and raw materials, we may rely on a single source of supply. In addition, we manufacture and sell a number of sterile products, biologic products and products involving advanced therapy platforms, such as CAR-T therapies, gene therapy and radioligand therapy products, all of which are particularly complex and involve highly specialized manufacturing technologies. As a result, even slight deviations at any point in their production process or in material used may lead to production failures or recalls. For example, for our new CAR-T therapy product *Kymriah,* manufacturing-related issues have impacted the product's sales. In sum, because the production process for some of our products is complex and sensitive, the cost of production of these products can be high, and the chance of production failures, lengthy supply interruptions, product recalls or voluntary market withdrawals is increased.

In addition, due to the inherent complexities of our production processes, we are required to plan our production activities well in advance. If we should suffer from raw material shortages, or if we should underestimate market demand for a product, or should fail to accurately predict when the product would be approved for sale, then we may not be able to produce sufficient product to meet demand. Alternatively, if we overestimate the quantity or timing of product to be produced, then we may be required to dispose of excess product, which would result not only in the loss of the product but also in the resources spent to produce it.

These complex production processes are also heavily regulated by health authorities around the world. And in recent years, these health authorities have substantially intensified their scrutiny of manufacturers' compliance with such requirements. Any significant failure by us or our third-party suppliers to comply with these requirements, or with the health authorities' expectations, may cause us to shut down the production facilities or production lines and recall previously shipped products. Alternatively, we may be forced to do so by a government health authority, or could be prevented from importing our products from one country to another. In addition, health authorities have in some cases imposed significant penalties for such failures to comply with cGMP. A failure to comply fully with cGMP could also lead to a delay in the approval of new products to be manufactured at the impacted site.

Further, because our products are intended to promote the health of patients, for some of our products, a

supply disruption or other production issue could endanger our reputation and subject us to lawsuits or to allegations that the public health, or the health of individuals, has been harmed.

In sum, complex production processes and compliance with regulatory requirements can increase our cost of producing our products, and any significant disruption in the supply of our products could impact patient health and our sales, which could have a material adverse effect on our business, financial condition, or results of operations, as well as our reputation.

See also "—We may not successfully achieve our goals in transactions or reorganizations," below, with regard to our efforts to reorganize our product manufacturing organization, and "—Climate change, extreme weather events, earthquakes and other natural disasters could adversely affect our business," below.

We devote substantial time and resources to meeting these challenges. However, there can be no guarantee as to the success of our efforts, or that we or our third-party suppliers will not face significant manufacturing issues, or that we will successfully manage such issues when they arise. Such issues could lead to shutdowns, to product shortages, or to our being entirely unable to supply products to patients for an extended period of time. Such shortages or shutdowns have led to, and could continue to lead to, significant losses of sales revenue and to potential third-party litigation.

We may not successfully achieve our goals in transactions or reorganizations.

As part of our strategy, from time to time we acquire and divest products or entire businesses in order to expand or complement our existing businesses, or to enable us to focus more sharply on our strategic businesses. For example, we recently completed the acquisitions of AveXis, Inc., a gene therapy company, and Endocyte, Inc., a radioligand therapy company, as well as the divestment of our stake in the GSK consumer healthcare joint venture. We also announced plans to spin off our Alcon Division and to divest the Sandoz US dermatology business and US oral solids portfolio.

Despite expending significant efforts and resources in this area, we cannot ensure that we will identify products or businesses that are suitable for acquisition. In addition, acquisition activities can be thwarted by governmental regulation, including market concentration limitations, political interference, overtures from competitors for the targeted assets, potentially increasing prices demanded by sellers, and other issues. Once an acquisition is agreed upon with a third party, we may not be able to complete the acquisition in the expected form or within the expected timeframe, or at all, due to a failure to obtain required regulatory approvals or a failure to achieve contractual or other required closing conditions. Further, after an acquisition, efforts to develop and market acquired products or to integrate the acquired business may not meet expectations, or may otherwise not be successful, as a result of difficulties in retaining key personnel, customers and suppliers; difference in corporate culture, standards, controls, processes and policies; the price at which we acquired the business; or other reasons. Acquisitions and divestments can also divert management's attention from our existing businesses, and could result in the existing businesses failing to achieve expected results, or in liabilities being incurred that were not known at the time of acquisition, or the creation of tax or accounting issues.

Similarly, we cannot ensure that we will be able to successfully divest or spin off businesses or other assets that we have identified for this purpose. Neither can we ensure that we will correctly select businesses or assets as candidates for divestment or spin-off, that we will be able to successfully complete any planned divestments or spin-offs, or that any completed divestment or spin-off will achieve the expected strategic benefits, synergies or opportunities, or that the divestment or spin-off will ultimately maximize shareholder value.

In addition, as part of our strategy, from time to time we reassess the optimal organization of our business, such as our ongoing efforts to centralize and optimize our manufacturing and business services organizations, in order to better align our organization with the capabilities and expertise required for competitive advantage. But the expected benefits of such reorganizations may never be fully realized or may take longer to realize than expected. There can be no certainty that the businesses and functions involved will be successfully integrated into the new organizations or that key personnel will be retained. Disruption from the reorganizations may make it more difficult to maintain relationships with customers, employees or suppliers; could result in shortfalls in program oversight; and may result in the Group not achieving the expected productivity and financial benefits.

Both with respect to the transactions and reorganizations previously announced, and to potential future transactions and reorganizations, if we fail to successfully address these risks, or to devote adequate resources to them, we may fail to achieve our strategic objectives, including our growth strategy, or otherwise may not realize the intended benefits of the acquisition, divestiture, spin-off or reorganization.

Significant breaches of information security and the use of electronic communications technologies could adversely affect our business and expose people's personal information.

We are heavily dependent on critical, complex and interdependent information technology systems, including internet-based systems, to support our business processes. In addition, we rely on internet and social media tools and mobile technologies as a means of communications and to gather information, which can include people's personal data. We also increasingly seek to develop technology-based products such as mobile applications and other digital health products that go "beyond the pill" to improve patient welfare in a variety of ways, which could also result in us collecting personal information about individual patients and others.

The size, age and complexity of our information technology systems make them potentially vulnerable to external and internal security threats; outages; malicious intrusions and attacks; cybercrimes, including state-sponsored cybercrimes; malware; misplaced or lost data; programming or human errors; or other similar events. Although we have devoted and continue to devote significant resources and management attention to cybersecurity, information management and business

continuity efforts, like many companies, we have experienced certain of these events and expect to continue to experience them in the future, as the external and internal information security threat continues to grow. We believe that the information security incidents we have experienced to date have yet to result in significant disruptions to our operations, and have not had a significant adverse effect on our results of operations, or on third parties. However, we may not be able to prevent future outages, security incidents or other breaches in our systems from having a material adverse effect on our business, financial condition, results of operations, or reputation.

A significant information security or other such event could negatively impact important business processes, such as the conduct of scientific research and clinical trials, the submission of the results of such efforts to health authorities in support of requests for product approvals, the functioning of our manufacturing and supply chain processes, our compliance with legal obligations, communication between employees and with third parties, and other key business activities. Information technology issues could also lead to the compromise of trade secrets or other intellectual property that could be sold and used by competitors to accelerate the development or manufacturing of competing products; to the compromise of personal financial and health information that could be misused for fraud and identity theft; and to the compromise of information technology security data such as usernames, passwords and encryption keys, as well as security strategies and information about network infrastructure, which could allow unauthorized parties to gain access to additional information on our systems. In addition, malfunctions in software or medical devices that make significant use of information technology, including our Alcon surgical equipment, could lead to a risk of direct harm to patients.

In addition, our routine business operations increasingly involve our gathering personal information (including sensitive personal information) about patients, vendors, customers, employees, collaborators and others, through the use of information technologies such as the internet, social media, mobile technologies and technology-based medical devices. Breaches of our systems or those of our third-party contractors, or other failures to protect such information, could expose such people's personal data to unauthorized persons. Any event involving the substantial loss of personal data could give rise to significant liability, reputational harm, damaged relationships with business partners, and potentially substantial monetary penalties under laws enacted or being enacted around the world. Such events could also lead to restrictions on our ability to transfer personal data across country borders.

We also use internet, social media and mobile tools as a means to communicate with the public, including about our products or about the diseases our products are intended to treat. However, such uses create risks, such as potential violations of rules regulating the promotion of prescription medicines and the potential loss of trade secrets or other intellectual property. In addition, there continues to be significant uncertainties as to the rules that apply to such communications, and as to the interpretations that health authorities will apply in this context to the rules that do exist. As a result, despite our efforts to comply with applicable rules, there is a significant risk that our use of internet, social media and mobile technologies for such purposes may cause us to nonetheless be found in violation of them.

Our dependence upon information technology, including any breaches of data security, technology disruptions, privacy violations, or other impacts from the use of interconnected technologies, could give rise to the loss of trade secrets or other intellectual property, to the public exposure of personal information, and to interruptions to our operations, and could result in enforcement actions or liability, including potential government fines, claims for damages, and shareholders' litigation. Any significant events of this type could require us to expend significant resources beyond those we already invest to remediate any damage, to further modify or enhance our protective measures, and to enable the continuity of our business, and could have a material adverse effect on our business, financial condition, results of operations, and reputation.

We may fail to develop or take advantage of transformational technologies and business models.

Rapid progress in medical and digital technologies and in the development of sometimes radical new business models is substantially transforming numerous industries around the world, creating new businesses and new opportunities for revenue and profit, while sometimes quickly rendering established businesses uncompetitive or obsolete. Such transformations, both positive and negative, may impact the healthcare industry, and numerous companies from the digital technology and other industries are seeking to enter the healthcare field.

To take advantage of these opportunities, Novartis has embarked upon a digital transformation strategy, with the goal of making Novartis an industry leader in leveraging advanced analytics and other new technologies. As part of this effort, we have created a new role of Chief Digital Officer, reporting directly to the CEO, charged with creating and executing a Companywide digital strategy, to be led by the Executive Committee of Novartis.

In order to reach our goal, we expect to invest substantial resources into efforts to improve the way we use data in drug discovery and development; to improve the ways we engage with patients, doctors and other stakeholders; and to automate business processes. With our commitment to using innovative science and digital technologies to help create transformative treatments for patients, together with our expertise and the extensive data we have and continue to amass, we believe that we have an opportunity to transform our business model using digital technologies.

There is no guarantee that our efforts toward a digital transformation will succeed, or that we will successfully transform our business model, or that we will be able to do so at any particular cost or any particular time. In order to succeed, we will be required to encourage a cultural change among our employees, attract and retain employees with appropriate skills and mindset, and successfully innovate across a variety of technology fields.

At the same time, other companies with specialized expertise or business models are entering the

healthcare field, from research and development to pharmaceutical distribution, potentially disrupting our relationships with patients, healthcare professionals, customers, distributors and suppliers, with unknown potential consequences for us. For example, companies such as Amazon, which acquired PillPack; IBM, with its Watson project; Alphabet, with its subsidiaries Verily and Calico; and Amazon, Berkshire Hathaway and JPMorgan, with their healthcare joint venture, as well as other established technology companies and specialized startup organizations, are aggressively seeking to move forward in this field. In addition, we face new competitors from different regions of the world, including China, which is moving aggressively to expand its role in the sciences and in many industries. Such new competitors may successfully impact our share of the healthcare value chain, or even develop products or technologies that could make our products uncompetitive or obsolete.

In an effort to maintain and advance our position as a leader in healthcare and related technology, we have made significant efforts to develop and to collaborate with other organizations in the development of advanced therapy platforms, including CAR-T therapy, developed in collaboration with the University of Pennsylvania; gene therapy, through our acquisition of AveXis and the licensing of *Luxturna* outside the US from Spark Therapeutics; and radioligand therapy, through our acquisitions of Advanced Accelerator Applications and Endocyte, Inc.

If we should fail in our efforts at a digital transformation of our Company, or in bringing advanced therapy platforms to market, then there is a risk that we may fail to create the innovative new products, tools or techniques that the new medical and digital technologies may make possible, or may fail to create them as quickly and efficiently as such technologies may enable. We may also lose opportunities to engage with our stakeholders and to profit from improved business processes, and may lose the resources devoted to these efforts to transform our business. At the same time, should third parties successfully enter the healthcare field with disruptive new technologies or business models, then we potentially may see our business supplanted in whole or in part by these new entrants. Any such events could have a material adverse effect on our business, financial condition, or results of operations.

Environmental, social and governance matters may impact our business and reputation.

Increasingly, in addition to the importance of their financial performance, companies are being judged by their performance on a variety of environmental, social and governance (ESG) matters, which are considered to contribute to the long-term sustainability of companies' performance.

A variety of organizations measure the performance of companies on such ESG topics, and the results of these assessments are widely publicized, including, for example, MSCI, Sustainalytics, the Dow Jones Sustainability Index and, in the healthcare industry, the Access to Medicine Index. In addition, investment in funds that specialize in companies that perform well in such assessments are increasingly popular, and major institutional investors, such as BlackRock, have publicly emphasized the importance of such ESG measures to their investment decisions. Topics taken into account in such assessments include the company's efforts and impacts on climate change and human rights, ethics and compliance with law, and the role of the company's board of directors in supervising various sustainability issues. In addition to the topics typically considered in such assessments, in our healthcare industry, issues of the public's ability to access our medicines are of particular importance.

We actively manage a broad range of such ESG matters, taking into consideration their expected impact on the sustainability of our business over time, and on the potential impact of our business on society. For a description of our activities on such topics, see "Item 4. Information on the Company—Item 4.B Business overview—Overview—Corporate responsibility." However, in a rapidly changing world, there can be no certainty that we will manage such issues successfully, or that we will successfully meet society's expectations as to our proper role. Any failure or perceived failure by us in this regard could have a material adverse effect on our reputation and on our business, financial condition, or results of operations, including the sustainability of our business over time.

See also "—Our reliance on outsourcing key business functions to third parties heightens the risks faced by our businesses," and "—Climate change, extreme weather events, earthquakes and other natural disasters could adversely affect our business," below.

Intangible assets and goodwill on our books may lead to significant impairment charges.

We carry a significant amount of goodwill and other intangible assets on our consolidated balance sheet, primarily due to acquisitions, including, in particular, substantial goodwill and other intangible assets obtained as a result of our acquisitions of Alcon and of certain oncology assets from GSK. As a result, we may incur significant impairment charges in the future if the fair value of the intangible assets and the groupings of cash-generating units containing goodwill would be less than their carrying value on the Group's consolidated balance sheet at any point in time.

We regularly review for impairment our long-lived intangible and tangible assets, including identifiable intangible assets, investments in associated companies, and goodwill. Goodwill, intangible assets with an indefinite useful life, acquired research projects not ready for use, and acquired development projects not yet ready for use are subject to impairment review at least annually. Other long-lived assets are reviewed for impairment when there is an indication that an impairment may have occurred. Impairment testing under IFRS may lead to impairment charges in the future. Any significant impairment charges could have a material adverse effect on our results of operations and financial condition. In 2018, for example, we recorded intangible asset impairment charges of USD 1.2 billion.

For a detailed discussion of how we determine whether an impairment has occurred, what factors could result in an impairment, and the impact of impairment charges on our results of operations, see "Item 5. Operating and Financial Review and Prospects—Item 5.A Operating results—Critical accounting policies and

estimates—Impairment of goodwill, intangible assets and property, plant and equipment" and "Item 18. Financial Statements—Note 1. Significant accounting policies" and "Item 18. Financial Statements—Note 10. Goodwill and intangible assets."

Political and economic instability may impact our results.

Unpredictable political conditions currently exist in various parts of the world, including a backlash in certain areas against free trade, anti-immigrant sentiment, social unrest, fears of terrorism, and the risk of direct conflicts between nations. In the US, the presidential administration's imposition of tariffs and opposition to free-trade agreements could have a negative impact on international trade. Similarly, there is a risk that barriers to free trade and the free movement of people may rise in Europe as a result of the UK's "Brexit" efforts and the rise of nationalist, separatist and populist sentiment in various countries, sometimes exacerbated by large-scale migration flows. Furthermore, significant conflicts continue in parts of the Middle East, including conflicts involving Saudi Arabia and Iran, and with respect to places such as Russia, Ukraine and North Korea. Collectively, such difficult conditions could, among other things, disturb the international flow of goods and increase the costs and difficulties of international transactions.

In addition, local economic conditions may adversely affect the ability of payers, as well as our distributors, customers, suppliers and service providers, to pay for our products, or otherwise to buy necessary inventory or raw materials, and to perform their obligations under agreements with us. Although we make efforts to monitor these third parties' financial condition and their liquidity, our ability to do so is limited, and some of them may become unable to pay their bills in a timely manner, or may even become insolvent, which could negatively impact our business or results of operations. These risks may be elevated with respect to our interactions with fiscally challenged government payers, or with third parties with substantial exposure to such payers. See also "—Our reliance on outsourcing key business functions to third parties heightens the risks faced by our businesses," below.

Financial market issues may also result in a lower return on our financial investments, and a lower value on some of our assets. Alternatively, inflation could accelerate, which could lead to higher interest rates, increasing our costs of raising capital. Uncertainties around future central bank and other economic policies in the US and EU, as well as high debt levels in certain other countries, could also impact world trade. Sudden increases in economic, currency or financial market volatility in different countries have also impacted, and may continue to unpredictably impact, our business or results of operations, including the conversion of our operating results into our reporting currency, the US dollar, as well as the value of our investments in our pension plans.

For further information on such risks, see "—Foreign exchange fluctuations may adversely affect our earnings and the value of some of our assets," and "—Any inaccuracy in the assumptions and estimates used to calculate our pension plan obligations could substantially increase our pension-related expenses," below. See also "—Our business is affected by pressures on pricing and reimbursement for our products," above, and "Item 5. Operating and Financial Review and Prospects—Item 5.B Liquidity and capital resources—Effects of currency fluctuations."

There is also a risk that countries facing local financial difficulties, including countries experiencing high inflation rates and highly indebted countries facing large capital outflows, may impose controls on the exchange of foreign currency. Such exchange controls could limit our ability to distribute retained earnings from our local affiliates, or to pay intercompany payables due from those countries.

See also "Item 5. Operating and Financial Review and Prospects—Item 5.B Liquidity and capital resources—Condensed consolidated balance sheets," and "Item 18. Financial Statements—Note 14. Trade receivables" and "Item 18. Financial Statements—Note 28. Financial instruments—additional disclosures."

Similarly, increased scrutiny of corporate taxes and executive pay may lead to significant business disruptions or other adverse business conditions, and may interfere with our ability to attract and retain qualified personnel. See "—Changes in tax laws or their application could adversely affect our results of operations" and "—An inability to attract and retain qualified personnel could adversely affect our business," below.

To the extent that economic and financial conditions directly affect consumers, then our Innovative Medicines and Sandoz Divisions may be impacted. Given the requirements in certain countries that patients directly pay an increasingly large contribution toward their own healthcare costs, there is a risk that consumers may cut back on prescription drugs to help cope with rising costs. In addition, the elective surgical and contact lens businesses of our Alcon Division may be particularly sensitive to declines in consumer spending.

At the same time, significant changes and potential future volatility in the financial markets, in the consumer and business environment, in the competitive landscape, and in the global political and security landscape make it increasingly difficult for us to predict our revenues and earnings into the future. As a result, any revenue or earnings guidance or outlook that we have given or might give may be overtaken by events, or may otherwise turn out to be inaccurate. Though we endeavor to give reasonable estimates of future revenues and earnings at the time we give such guidance, based on then-current knowledge and conditions, there is a significant risk that such guidance or outlook will turn out to be, or to have been, incorrect.

Separately and collectively, such factors may have a material adverse effect on our revenues, results of operations, financial condition and, if circumstances worsen, our ability to raise capital at reasonable rates.

Our indebtedness could adversely affect our operations.

As of December 31, 2018, we had USD 22.5 billion of non-current financial debt and USD 9.7 billion of current

financial debt. Our current and long-term debt requires us to dedicate a portion of our cash flow to service interest and principal payments and, if interest rates rise, this amount may increase. As a result, our existing debt may limit our ability to use our cash flow to fund capital expenditures, to engage in transactions, or to meet other capital needs, or otherwise may place us at a competitive disadvantage relative to competitors that have less debt. Our debt could also limit our flexibility to plan for and react to changes in our business or industry, and increase our vulnerability to general adverse economic and industry conditions, including changes in interest rates or a downturn in our business or the economy. We may also have difficulty refinancing our existing debt or incurring new debt on terms that we would consider to be commercially reasonable, if at all.

Our reliance on outsourcing key business functions to third parties heightens the risks faced by our businesses.
We outsource the performance of certain key business functions to third parties, and invest a significant amount of effort and resources into doing so. Such outsourced functions can include research and development collaborations, manufacturing operations, warehousing and distribution activities, certain finance functions, marketing activities, data management and others. We may particularly rely on third parties in developing countries, including for the sales, marketing and distribution of our products, and to obtain the intermediate and raw materials used in the manufacture of our products.

Our reliance on outsourcing and third parties for the research and development or manufacturing of our products may reduce the potential profitability of such products.

In addition, governments and the public are increasingly placing pressure on major corporations, including Novartis, to take responsibility for compliance with human rights and appropriate environmental practices, as well as other actions, of their third-party contractors around the world. Examples of this include the Conflict Minerals rule in the US, and the UK Modern Slavery Act.

We place strict contractual requirements on such contractors to comply with law and with our high standards. We also expend significant resources on efforts to screen out inappropriate contractors, to monitor the activities of those we have retained, and to seek their compliance with the law and with our expectations. Nonetheless, many of these companies have limited resources, and, in particular, do not have internal compliance resources comparable to those within our organization.

Ultimately, if the third parties fail to meet their obligations to us, we may lose our investment in the collaborations and fail to receive the expected benefits. In addition, should any of these third parties fail to comply with the law or should they act inappropriately in the course of their performance of services for us, there is a risk that we could be held responsible for their acts, that our reputation may suffer, and that penalties may be imposed upon us. Any such failures by third parties could have a material adverse effect on our business, financial condition, results of operations, or reputation.

Competition and failure to successfully develop biosimilars and other differentiated products may impact the success of our Sandoz Division.
Our Sandoz Division faces intense competition from companies that market patented pharmaceutical products, which sometimes take aggressive steps to delay the introduction of generic and biosimilar medicines, to limit the availability of exclusivity periods or to reduce their value. At the same time, Sandoz faces strong competition from other generic and biosimilar pharmaceutical companies, which aggressively compete for market share, including through significant price competition. Such competitive actions by other patented, generic and biosimilar pharmaceutical manufacturers may increase the costs and risks associated with our efforts to introduce and market such products, may delay the introduction or marketing of such products, and may further limit the prices at which we are able to sell these products and impact our results of operations. In particular, in the US in recent years, industrywide price competition among generic pharmaceutical companies and consolidation of buyers have significantly hurt Sandoz sales. Expecting these trends to continue, we agreed to sell the Sandoz US dermatology business and generic US oral solids portfolio to Aurobindo Pharma USA Inc.

In addition, Sandoz has invested heavily in the development of biosimilar drugs and other differentiated products, with the expectation that such products offer the potential for higher profitability than less complex products. Sandoz has invested in the development of such products despite the fact that their development is more difficult and expensive than the development of standard generic drugs, and despite the fact that regulations concerning the approval, marketing and sale of biosimilars in certain countries, including in the US, are still under development or not entirely clear. If Sandoz should fail in its efforts to develop and market biosimilars or other such differentiated products, or if the developing biosimilars regulations do not ultimately favor the development and sale of such products, or if we are unable to sell our biosimilar products for a sufficient price, then this could have an adverse effect on the success of our Sandoz Division, and we may fail to achieve expected returns on the investments by Sandoz in the development of biosimilars and other differentiated products.

See also “—Our research and development efforts may not succeed” above, with regard to the risks involved in our efforts to develop biosimilars and differentiated generic products and to obtain exclusivity periods; and “—Ongoing consolidation among our distributors and retailers is increasing both the purchasing leverage of key customers and the concentration of credit risk,” below, with respect to the impact of such consolidation on our pricing.

Any inaccuracy in the assumptions and estimates used to calculate our pension plan and other post-employment obligations could substantially increase our pension-related expenses.
We sponsor pension and other post-employment benefit plans in various forms. These plans cover a significant portion of our current and former associates. While most of our plans are now defined contribution plans, certain of our associates remain participants in defined benefits

plans. For these defined benefits plans, we are required to make significant assumptions and estimates about future events in calculating the present value of expected future plan expenses and liabilities. These include assumptions used to determine the discount rates we apply to estimated future liabilities and rates of future compensation increases. Assumptions and estimates used by Novartis may differ materially from the actual results we experience in the future, due to changing market and economic conditions, higher or lower withdrawal rates, or longer or shorter life spans of participants, among other variables. For example, in 2018, a decrease in the interest rate we apply in determining the present value of expected future defined benefit obligations of one-quarter of 1% would have increased our year-end defined benefit pension obligation for plans in Switzerland, the US, the UK, Germany and Japan, which represent 94% of the Group total defined benefit pension obligation, by USD 0.8 billion. Any differences between our assumptions and estimates and our actual experience could require us to make additional contributions to our pension funds. Further, additional employer contributions might be required if plan funding falls below the levels required by local rules. Either such event could have a material effect on our results of operations and financial condition.

For more information on obligations under retirement and other post-employment benefit plans and underlying actuarial assumptions, see “Item 5. Operating and Financial Review and Prospects—Item 5.A Operating results—Critical accounting policies and estimates—Retirement and other post-employment benefit plans” and “Item 18. Financial Statements—Note 24. Post-employment benefits for associates.” See also “—Political and economic instability may have a material adverse effect on our results,” above.

Changes in tax laws or their application could adversely affect our financial results.

Our multinational operations are taxed under the laws of the countries and other jurisdictions in which we operate. However, the integrated nature of our worldwide operations can produce conflicting claims from revenue authorities in different countries as to the profits to be taxed in the individual countries, including potential disputes relating to the prices our subsidiaries charge one another for intercompany transactions, known as transfer pricing. The majority of the jurisdictions in which we operate have double tax treaties with other foreign jurisdictions, which provide a framework for mitigating the impact of double taxation on our revenues and capital gains. However, mechanisms developed to resolve such conflicting claims are largely untried, and can be expected to be very lengthy.

In recent years, tax authorities around the world have increased their scrutiny of company tax filings, and have become more rigid in exercising any discretion they may have. As part of this, the Organization for Economic Co-operation and Development (OECD) has proposed a number of tax law changes under its Base Erosion and Profit Shifting (BEPS) Action Plans to address issues of transparency, coherence and substance.

At the same time, the European Commission is finalizing its Anti Tax Avoidance Directive, which seeks to prevent tax avoidance by companies and to ensure that companies pay appropriate taxes in the markets where profits are effectively made and business is effectively performed. The EU also adopted a new Directive on Administrative Cooperation (DAC6) in 2018, which seeks additional reporting. In addition, the European Commission continues to extend the application of its policies seeking to limit fiscal aid by member states to particular companies, and the related investigation of the member states’ practices regarding the issuance of rulings on tax matters relating to individual companies.

These OECD and EU tax reform initiatives also need local country implementation, including in our home country of Switzerland, which may result in significant changes to established tax principles. Although we have taken steps to be in compliance with the evolving OECD and EU tax initiatives, and will continue to do so, significant uncertainties remain as to the outcome of these efforts.

Switzerland is in the process of considering the implementation of corporate tax reform, which could become effective as early as the first quarter of 2019. However, the outcome of these efforts remains subject to change and could be enacted in a materially different form from what is currently proposed, or could be administered or implemented in a manner different from our expectations. There is also a risk that the EU may not be satisfied with the outcome of Switzerland’s tax reform efforts, and take steps to seek further changes. Accordingly, there can be no assurance that Swiss corporate tax reform will not adversely affect our business or financial condition.

In addition, in the US, the Tax Cuts and Jobs Act, enacted at the end of 2017, included substantial changes to the US taxation of individuals and businesses. Although the law substantially decreased tax rates applicable to corporations in the US, we do not yet know what all of the consequences of this new statute will be, including whether the law will have any unintended consequences. In particular, significant uncertainties remain as to how the US government will implement the new law, including with respect to the tax qualification of interest deductions, the concept of a territorial tax regime, royalty payments and cost of goods sold.

In general, such tax reform efforts, including with respect to tax base or rate, transfer pricing, intercompany dividends, cross-border transactions, controlled corporations, and limitations on tax relief allowed on the interest on intercompany debt, will require us to continually assess our organizational structure against tax policy trends, and could lead to an increased risk of international tax disputes and an increase in our effective tax rate, and could adversely affect our financial results.

Counterfeit versions of our products could harm our patients and reputation.

Our industry continues to be challenged by the vulnerability of distribution channels to illegal counterfeiting and the presence of counterfeit products in a growing number of markets and over the internet. Counterfeit products are frequently unsafe or ineffective, and can potentially be life-threatening. To distributors and patients, counterfeit products may be visually indistinguishable from the authentic version. Reports of product

ineffectiveness or adverse reactions to counterfeit drugs, or increased levels of counterfeiting could affect patient confidence in our authentic products, and could harm our business or lead to litigation. In addition, it is possible that a lack of efficacy or adverse events caused by unsafe counterfeit products could mistakenly be attributed to the authentic product. If a product of ours was the subject of counterfeits, we could incur substantial reputational and financial harm.

Foreign exchange fluctuations may adversely affect our earnings and the value of some of our assets.
Changes in exchange rates between the US dollar, our reporting currency, and other currencies can result in significant increases or decreases in our reported sales, costs and earnings as expressed in US dollars, and in the reported value of our assets, liabilities and cash flows.

In addition to ordinary market risk, there is a risk that countries could take affirmative steps that could significantly impact the value of their currencies. Such steps could include "quantitative easing" measures and potential withdrawals by countries from common currencies. In addition, countries facing local financial difficulties, including countries experiencing high inflation rates and highly indebted countries facing large capital outflows, may impose controls on the exchange of foreign currency. Such exchange controls could limit our ability to distribute retained earnings from our local affiliates, or to pay intercompany payables due from those countries. See "—Political and economic instability may have a material adverse effect on our results," below.

Despite measures undertaken to reduce or hedge against foreign currency exchange risks, because a significant portion of our earnings and expenditures are in currencies other than the US dollar, including expenditures in Swiss francs that are significantly higher than our revenue in Swiss francs, any such exchange rate volatility may negatively and materially impact our results of operations and financial condition, and may impact the reported value of our net sales, earnings, assets and liabilities. In addition, the timing and extent of such volatility can be difficult to predict. Further, depending on the movements of particular foreign exchange rates, we may be materially adversely affected at a time when the same currency movements are benefiting some of our competitors.

For more information on the effects of currency fluctuations on our consolidated financial statements and on how we manage currency risk, see "Item 5. Operating and Financial Review and Prospects—Item 5.B Liquidity and capital resources—Effects of currency fluctuations," "Item 11. Quantitative and Qualitative Disclosures About Market Risk," and "Item 18. Financial Statements—Note 28. Financial instruments—additional disclosures."

Ongoing consolidation among our distributors and retailers is increasing both the purchasing leverage of key customers and the concentration of credit risk.
Increasingly, a significant portion of our global sales is made to a relatively small number of drug wholesalers, retail chains and other purchasing organizations. For example, our three most important customers globally are all in the US, and accounted for approximately 16%, 13% and 7%, respectively, of Group net sales in 2018. The largest trade receivables outstanding were for these three customers, amounting to 12%, 10% and 6%, respectively, of the Group's trade receivables at December 31, 2018. The trend has been toward further consolidation among distributors and retailers, both in the US and internationally. As a result, we may be affected by fluctuations in the buying patterns of such customers, and these customers are gaining additional purchasing leverage, increasing the pricing pressures facing our businesses. These pressures can particularly impact our Sandoz Division, the generic products of which can often be obtained from numerous competitors. Moreover, we are exposed to a concentration of credit risk as a result of this concentration among our customers. If one or more of our major customers experienced financial difficulties, the effect on us would be substantially greater than in the past, and could include a substantial loss of sales and an inability to collect amounts owed to us. Such events could have a material adverse effect on our business, financial condition, or results of operations.

An inability to attract and retain qualified personnel could adversely affect our business.
We highly depend upon skilled personnel in key parts of our organization, and we invest heavily in recruiting, training and retaining qualified individuals, including significant efforts to enhance the diversity of our workforce. The loss of the service of key members of our organization – including senior members of our scientific and management teams, high-quality researchers and development specialists, and skilled personnel in developing countries – could delay or prevent the achievement of major business objectives.

Our future growth will demand talented associates and leaders, yet the market for talent has become increasingly competitive. In particular, Emerging Growth Markets are expected to continue to be an important source of growth, but in many of these countries there is a limited pool of executives with the training and international experience needed to work successfully in a global organization like Novartis.

In addition, shifting demographic trends are expected to result in fewer students, fewer graduates and fewer people entering the workforce in the Western world in the next 10 years. Moreover, many members of younger generations around the world have changing expectations toward careers, engagement and the integration of work in their overall lifestyles.

The supply of talent for certain key functional and leadership positions is decreasing, and a talent gap is visible for some professions and geographies – engineers in Germany, for example. Recruitment is increasingly regional or global in specialized fields such as clinical development, biosciences, chemistry and information technology. In addition, the geographic mobility of talent is expected to decrease in the future, with talented individuals in developed and developing countries anticipating ample career opportunities closer to home than in the past. This decrease in mobility may be worsened by anti-immigrant sentiments in many countries, and laws discouraging immigration. See "—Political and economic instability may impact our results," above.

In addition, our ability to hire qualified personnel also depends on the flexibility to reward superior performance and to pay competitive compensation. Laws and regulations on executive compensation, including legislation in our home country, Switzerland, may restrict our ability to attract, motivate and retain the required level of qualified personnel.

We face intense competition for an increasingly limited pool of qualified individuals from numerous pharmaceutical and biotechnology companies, universities, governmental entities, other research institutions, other companies seeking to enter the healthcare space, and companies in other industries. As a result, despite significant efforts on our part, we may be unable to attract and retain qualified individuals in sufficient numbers, which could have an adverse effect on our business, financial condition, or results of operations.

Environmental liabilities may adversely impact our financial results.
The environmental laws of various jurisdictions impose actual and potential obligations on us to remediate contaminated sites, in some cases over many years. While we have set aside substantial provisions for worldwide environmental liabilities, there is no guarantee that additional costs will not be incurred beyond the amounts for which we have provided in the Group consolidated financial statements. If environmental contamination related to our facilities or products adversely impacts third parties, if we fail to properly manage the safety of our facilities and the environmental risks, or if we are required to further increase our provisions for environmental liabilities in the future, this could have a material adverse effect on our business, financial condition, results of operations, and reputation.

See also “Item 4. Information on the Company—Item 4.D Property, plants and equipment—Environmental matters” and “Item 18. Financial Statements—Note 19. Provisions and other non-current liabilities.”

Climate change, extreme weather events, earthquakes and other natural disasters could adversely affect our business.
In recent years, extreme weather events and changing weather patterns such as storms, flooding, droughts and temperature changes have become more common. As a result, we are potentially exposed to varying natural disaster or extreme weather risks such as hurricanes, tornadoes, droughts or floods, or other events that may result from the impact of climate change on the environment, such as sea level rise. For example, some of our production facilities that depend on the availability of significant water supplies are located in areas where water is increasingly scarce. Other facilities are located in places that, because of increasingly violent weather events, sea level rise, or both, are increasingly at risk of substantial flooding. As a result, we could experience increased production or other costs, business interruptions, destruction of facilities, and loss of life, all of which could have a material adverse effect on our business, financial condition, or results of operations.

In addition, our corporate headquarters, the headquarters of our Innovative Medicines Division, and certain of our major Innovative Medicines Division production and research facilities are located near earthquake fault lines in Basel, Switzerland. Other major facilities are located near major earthquake fault lines in various locations around the world. In the event of a major earthquake, we could experience business interruptions, destruction of facilities, and loss of life, all of which could have a material adverse effect on our business, financial condition, or results of operations.

Risks related to our ADRs

The price of our ADRs and the US dollar value of any dividends may be negatively affected by fluctuations in the US dollar/Swiss franc exchange rate.
Our American Depositary Shares (ADSs), each representing one Novartis share and evidenced by American Depositary Receipts (ADRs), trade on the NYSE in US dollars. Since the shares underlying the ADRs are listed in Switzerland on the SIX Swiss Exchange (SIX) and trade in Swiss francs, the value of the ADRs may be affected by fluctuations in the US dollar/Swiss franc exchange rate. In addition, since dividends that we may declare will be denominated in Swiss francs, exchange rate fluctuations will affect the US dollar equivalent of dividends received by holders of ADRs. If the value of the Swiss franc decreases against the US dollar, the price at which our ADRs trade may – and the value of the US dollar equivalent of any dividend will – decrease accordingly.

Holders of ADRs may not be able to exercise pre-emptive rights attached to shares underlying ADRs.
Under Swiss law, shareholders have pre-emptive rights to subscribe for issuances of new shares on a *pro rata* basis. Shareholders may waive their pre-emptive rights in respect of any offering at a general meeting of shareholders. Pre-emptive rights, if not previously waived, are transferable during the subscription period relating to a particular offering of shares and may be quoted on the SIX. US holders of ADRs may not be able to exercise the pre-emptive rights attached to the shares underlying their ADRs unless a registration statement under the US Securities Act of 1933 is effective with respect to such rights and the related shares, or an exemption from this registration requirement is available. In deciding whether to file such a registration statement, we would evaluate the related costs and potential liabilities, as well as the benefits of enabling the exercise by ADR holders of the pre-emptive rights associated with the shares underlying their ADRs. We cannot guarantee that a registration statement would be filed, or, if filed, that it would be declared effective. If pre-emptive rights could not be exercised by an ADR holder, JPMorgan Chase Bank, N.A., as depositary, would, if possible, sell the holder’s pre-emptive rights and distribute the net proceeds of the sale to the holder. If the depositary determines, in its discretion, that the rights could not be sold, the depositary might allow such rights to lapse. In either case, the interest of ADR holders in Novartis would be diluted and, if the depositary allowed rights to lapse, holders of ADRs would not realize any value from the pre-emptive rights.