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 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.

Pressures on pricing and reimbursement for our products affect our business and may impact our future financial results.
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. Global pressures on pricing may negatively impact, in parallel, both our product pricing and our market access.

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 and co-pay accumulator programs, limiting physicians' ability to choose among competing medicines, mandatory substitution of generic drugs for the patented equivalent, pressure on physicians to reduce the prescribing of patented prescription medicines, increasing pressure on intellectual property protections, and growing 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 2020 and beyond, 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.

Significant breaches of information security or disruptions of our information technology systems could adversely affect our business.
We are heavily dependent on critical, complex and interdependent information technology systems, including internet-based systems, some of which are managed by third-party service providers, to support our business processes. We routinely experience cybersecurity attacks and incidents on such networks and systems, and while to date none of these incidents have been material to us, like many companies, we expect to continue to experience similar cybersecurity threats and attacks in the future. Cybersecurity threats and attacks take many forms and 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. While we have devoted and continue to devote significant resources and management attention to cybersecurity, information management and business continuity efforts, 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 event, such as a disruption or loss of availability of one or more of our information technology systems, could negatively impact important business processes, such as the conduct of scientific research and clinical trials, the submission of data and information to health authorities, our manufacturing and supply chain processes, our shipments to customers, our compliance with legal obligations, and communication between employees and with third parties. 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; 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 systems or data. In addition, mal-

functions in software or other medical devices that make significant use of information technology could lead to a risk of direct harm to patients.

For business reasons we have outsourced significant parts of our IT infrastructure to third-party providers, and we currently use these providers to perform business-critical IT services for us. We are therefore vulnerable to service interruptions by these providers and we may experience interruptions, delays or outages in IT service availability in the future due to a variety of factors outside of our control. Outages and capacity constraints could arise from a number of causes such as technical failures, natural disasters, fraud or security attacks. Interruptions in the service provided by these third parties could affect our ability to perform critical tasks.

In addition, we face potential difficulties in integrating the IT systems of the businesses that we acquire, including replacing, integrating or working with separate IT systems used by such companies, and transferring relevant data from such separate systems and their third-party providers. See also "—We may not successfully achieve our goals in transactions or reorganizations," below.

Our dependence upon information technology, breaches of data security, technology disruptions, or other impacts from the use of interconnected technologies, could disrupt our business operations and result in enforcement actions or liability, including potential government fines and penalties, 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.

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

Our financial performance, including our ability to replace revenue and income lost to generic, biosimilar and other competition and to grow our business, depends heavily on the commercial success of our key 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, data integrity issues, 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. The commercial success of our key products and launches in the face of increasing competition and pressures on pricing requires significant attention and focus from members of our key management. See also "—Pressures on pricing and reimbursement for our products affect our business and may impact our future financial results," above, 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. We cannot predict with accuracy the timing of the introduction of products that compete with ours or the related effect on our sales. However, products significantly competitive to our major products – including *Cosentyx, Lucentis, Gilenya, Tasigna, Kisqali, Kymriah, Entresto* and *Beovu* – 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 research and development, or in marketing and sales.

Our products face losses of intellectual property protection.

Major products of our Innovative Medicines Division, as well as certain products of our Sandoz Division, are protected by patent and other intellectual property rights, which provide us with exclusive rights to market those products for a limited time 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. The resulting 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 or biosimilar 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 or biosimilar manufacturers typically offer their versions at sharply lower prices. Such competition can occur after successful challenges to intellectual property rights or the regular expiration of the patent term or other intellectual property rights. Such competition can also result from the entry of generic or biosimilar versions of another medicine in the same therapeutic class as one of our drugs or in a 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 and governing laws in certain countries around the world. In addition, generic or biosimilar manufacturers may sometimes conduct so-called "launches at risk" of products that are still under legal challenge for infringement, or whose patents are still under legal challenge for validity, 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, or from successful or otherwise resolved challenges to patent protection.

- Our former top-selling product *Gleevec/Glivec* continues to face generic competition in major markets.

- Patent protection for *Exjade* in the US has expired. Generic versions of *Exjade* are available in the US.

- In the US, for *Afinitor*, we have resolved patent litigation. Generic versions of the three lower dosage strengths of *Afinitor* are available in the US; additional generic competition may start in mid-2020. We have resolved patent litigation relating to *Afinitor Disperz*.

- 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 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. Generic versions of *Sandostatin LAR* are available in some EU markets.

- Intellectual property protection for 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 or biosimilar competition. Among these products that may begin to face generic or biosimilar competition in one or more major markets during the next three years are our remaining everolimus products or their remaining dosage strengths (*Afinitor/Votubia* and *Zortress/Certican*), *Jadenu*, *Lucentis* and potentially *Gilenya*. 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 2020, we expect a potentially significant impact on our net sales from products that have already lost intellectual property protection, as well as products that may 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 operating income for that year in an amount corresponding to a significant portion of the product's lost sales. The magnitude of the impact of generic or biosimilar competition on our income could depend on a number of factors, including the time of year at which the generic or biosimilar competitor is launched; the ease or difficulty of manufacturing a competitor product and obtaining regulatory approval to market it; the number of generic or biosimilar 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 or biosimilar competitor products are approved, including the strength of the market for generic or biosimilar 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 or biosimilar competition.

With respect to major products for which the patents are expiring or are successfully challenged, 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 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 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 grow our business; to replace sales lost due to branded 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 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.

Research and development of new products of our Innovative Medicines Division can take approximately 10 to 15 years, from discovery to commercial product launch. Failure can occur at any point in the process, including in later stages after substantial investment. 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.

Further, to achieve approvals of new products and new indications, regulatory authorities continue to establish new and increasingly rigorous requirements in the already lengthy and expensive process of obtaining regulatory approvals and reimbursement for pharmaceutical products.

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 potential new innovations.

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. While the development of such products typically is significantly less costly and complex than the development of the equivalent originator medicines, it is nonetheless significantly more costly and complex than that for typical small-molecule generic products. In addition, many countries do not yet have fully developed legislative or regulatory pathways to facilitate the development of biosimilars and permit their sale in a manner in which they are readily substitutable for the originator product. Further delays or difficulties that may arise in the development or marketing of biosimilars could put at risk the significant investments that Sandoz has made, and will continue to make, in its Biopharmaceuticals business. 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 could have a material adverse effect on the success of the Sandoz Division and the Group as a whole.

Further, 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, Current Good Clinical Practices (cGCP) requirements, data integrity, the fair treatment of patients, 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 Innovative Medicines and Sandoz Divisions under “Item 4. Information on the Company—Item 4.B Business overview.”

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

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

For example, we are faced with new laws and regulations requiring more transparency in 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 costs and 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 worldwide, and various US, federal and state, and international laws and regulations, including those pertaining to government benefit programs, reimbursement, rebates, price reporting and regulation, and healthcare fraud and abuse. Such activities can involve criminal proceedings, and can retroactively challenge practices previously considered to be legal. There is also a risk that governance for our medical and patient support activities, and our interactions with patient organizations, may be inadequate or fail, or that we may undertake activities based on improper or inadequate scientific justification. Our failure to comply with applicable requirements for such activities could result in adverse regulatory or legal action, damage our reputation, and have a significant negative impact on our financial results.

The laws and regulations relevant to the healthcare industry are broad in scope and are subject to change and evolving interpretations, which could require us to incur substantial costs associated with compliance or to alter one or more of our sales or marketing practices. In addition, violations of these laws, or allegations of such violations, could disrupt our business and result in a material adverse effect on our business and results of operations. A number of our subsidiaries across each of our divisions are, or may in the future be, subject to var-

ious 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.

In addition, our use of the internet, social media and mobile tools also carries risks related to potential violations of rules regulating the promotion of prescription medicines and the potential loss of confidential information, trade secrets or other intellectual property. There continue 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, and as a result, despite our efforts to comply with applicable rules, there is a risk that our use of the internet, social media and mobile technologies may cause us to be found in violation of applicable regulations.

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 make the business decision to market a generic product even though patent infringement actions are still pending. Should we elect to do so and conduct a so-called “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 20. Provisions and other non-current liabilities” and “Item 18. Financial Statements—Note 28. Commitments and contingencies.”

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. 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.

Legal proceedings and investigations are inherently unpredictable, and large judgments sometimes occur. As a consequence, we may in the future incur judgments that could involve large 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.

Our reliance on outsourcing key business functions to third parties heightens the risks faced by our businesses.
For business reasons, we outsource the performance of certain key business functions to third parties, and invest a significant amount of effort and resources into doing so, including to manage and oversee such third parties. 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. Some of these third parties do not have internal compliance resources comparable to those within our organization.

Our reliance on outsourcing and third parties for the research and development or the manufacturing of our products poses certain risks, including misappropriation of our intellectual property, failure of the third party to comply with regulatory and quality assurance requirements, unexpected supply disruptions, breach of the research and development or manufacturing agreement by the third party, and the unexpected termination or nonrenewal of the agreement by the third party.

In addition, governments and the public expect major corporations, including Novartis, to take responsibility for and report on compliance with various human rights, responsible sourcing and environmental practices, as well as other actions of their third-party contractors around the world. Examples of this include the conflict minerals disclosure requirements in the US, and the UK Modern Slavery Act.

Ultimately, if third parties fail to meet their obligations to us, we may lose our investment in the collaborations or fail to receive the expected benefits of our agreements with such third parties. In addition, should any of these third parties fail to comply with the law or our standards, or should they otherwise 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.

Compliance with data privacy laws and regulations is complex and could expose us to a variety of risks.
We operate in an environment that relies on the collection, processing, analysis and interpretation of large sets

of patients' and other individuals' personal information, including via social media and mobile technologies, and that also, in many situations, requires that data to freely flow across borders of numerous countries in which there are different, and potentially conflicting, data privacy laws in effect. For example, the EU General Data Protection Regulation (GDPR), which took effect in May 2018, and the California Consumer Privacy Act, which took effect in January 2020, impose stringent requirements on how we and third parties with whom we contract collect, share, export or otherwise process personal information, and provide for significant penalties for noncompliance. Breaches of our systems or those of our third-party contractors, or other failures to protect the data we collect from misuse or breach by third parties, could expose such personal information to unauthorized persons.

Any event involving the substantial loss of personal information or other privacy violations 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 use personal information and/or transfer personal information across country borders.

The manufacture of our products is complex and highly regulated.

The manufacture of our products relies on technically complex processes and, in some cases, highly specialized raw materials, and is highly regulated. Deviations, difficulties or delays in production, or failure to obtain specialized raw materials, have in the past resulted in some of the following, and may in the future result in: shut-downs, work stoppages, approval delays, voluntary market withdrawals, product recalls, penalties, supply disruptions or shortages, increased costs, product liability or reputational harm. In addition, 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 current Good Manufacturing Practices (cGMP) and other applicable regulations. Failure to comply with cGMP requirements have in the past resulted in some of the following legal or regulatory actions, and may in the future result in possible legal or regulatory actions, such as warning letters, suspension of manufacturing, seizure of products, injunctions, voluntary recall of products, failure to secure product approvals, or debarment. Any of these events could have a material adverse effect on our business, financial condition and results of operations.

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, such as cell lines, tissue samples, bacteria, viral strains and radioisotopes. For some of our products and raw materials, we rely on a single source of supply for ingredients or relevant components. 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 therapies and radioligand therapies, all of which are particularly complex and involve highly specialized manufacturing technologies. As a result, even slight deviations at any point in their production processes or in material used may lead to production failures or recalls. 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 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. 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. Our success in these efforts will depend on many factors, including a cultural change among our employees, attracting and retaining employees with appropriate skills and mindsets, and successfully innovating across a variety of technology fields. However, there is no guarantee that these efforts will succeed, that we will successfully transform our business model, or that we will be able to do so at any particular cost or in the necessary time frame.

At the same time, other companies with specialized expertise or business models and substantial resources 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. In addition, we face new competitors from different regions of the world, including China, which is aggressively expanding 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.

If our digital transformation efforts, or our efforts to bring advanced therapy platforms to market, should fail, 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 that we 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 we 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.

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, and enter into strategic alliances and collaborations. For example, we previously announced plans to divest the Sandoz US dermatology business and US oral solids portfolio, and we recently completed the spin-off of our Alcon Division, the acquisition of the assets associated with *Xiidra*, and the acquisition of The Medicines Company.

Our alliances and acquisitions are a significant source of our growth, yet our efforts may be impacted by our ability to identify products or businesses that are suitable for acquisition; by governmental regulation, including market concentration limitations; and by overtures from competitors that may increase the prices of potential targets. Once an acquisition is agreed upon with a third party, we may not be able to complete the acquisition in a timely manner or at all, nor can there be assurance that pre-acquisition due diligence will have identified all possible issues that might arise with regard to an acquisition. Our efforts on acquisitions and divestments can also divert management's attention from our existing businesses.

Further, after an acquisition, efforts to develop and market acquired products, to integrate the acquired business or to achieve expected synergies may not meet expectations, or may otherwise not be successful, as a result of difficulties in retaining key personnel, customers and suppliers, or differences in corporate culture, standards, controls, processes and policies. Acquisitions can also result in liabilities being incurred that were not known at the time of acquisition, or the creation of tax or accounting issues. Acquired businesses are not always in full compliance with legal, regulatory or Company standards, including, for example, cGMP or cGCP standards, requiring remediation efforts that could be costly and time-consuming. Also, our strategic alliances and collaborations with third parties may not achieve their intended goals and objectives in any particular time frame, or at all.

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, or that any completed divestment or spin-off will achieve the expected strategic benefits, operational efficiencies 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. 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, that key personnel will be retained, or that we will be able to attract talent during ongoing transformations and reorganizations. Disruption from reorganizations may make it more difficult to maintain relationships with customers, employees or suppliers; could result in shortfalls in program oversight; could negatively impact our reputation; and may result in the Group not achieving the expected productivity and financial benefits.

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, strategic alliance, spin-off or reorganization.

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. In addition, investment in funds that specialize in companies that perform well in such assessments are increasingly popular, and major institutional investors have publicly emphasized the importance of such ESG measures to their investment decisions. Topics taken into account in such assessments include, among others, 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 the potential impact of our business on society and the environment. However, in light of investors' increased focus on ESG matters, 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, share price, 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," above, and "—Climate change, extreme weather events, earthquakes and other natural disasters could adversely affect our business," below.

Falsified products could harm our patients and reputation.
Our industry continues to be challenged by the vulnerability of distribution channels to falsified medicines

(which includes counterfeit and stolen medicines under the definition of the World Health Organization). The presence of falsified medicines is growing in terms of the markets affected and on the internet. Falsified medicines pose patient safety risks and can be seriously harmful or life-threatening. They are often visually indistinguishable from genuine medicines and usually require a forensic authentication process of the packaging and/or the actual medicine to ascertain their falsified nature and determine their likely impact on patient safety. Reports of adverse events related to falsified medicines and increased levels of falsified medicines in the healthcare system affect patient confidence in our genuine medicines and in healthcare systems in general. These events could also cause us substantial reputational and financial harm, and potentially lead to litigation if the adverse event from the falsified medicine is mistakenly attributed to the genuine one. Thefts of our genuine products from warehouses or plants, or while in-transit, which are then not properly stored and are later sold through unauthorized channels, could adversely impact patient safety, our reputation and our business. Further, there is a direct financial loss when, for example, falsified medicines replace sales of genuine medicines, or genuine medicines are recalled following discovery of falsified products.

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, anti-corporatist sentiment, social unrest, fears of terrorism, and the risk of direct conflicts between nations. In the US, for example, the presidential administration's imposition of tariffs and opposition to free-trade agreements, including the recent tariffs imposed by the US and China, and the possibility of additional tariffs or other trade restrictions relating to trade between the US and other countries, could have a negative impact on international trade in general and our business in particular. Given that the status of trade negotiations remains subject to change, we cannot be certain of the nature or extent of the potential impact on our business. For example, if tariffs on pharmaceutical products or active pharmaceutical ingredients (APIs) were increased, this could impact the profitability of our products. Furthermore, significant conflicts continue in certain parts of the world. Collectively, such unstable conditions could, among other things, disturb the international flow of goods and increase the costs and difficulties of international transactions, which could significantly impact time to market and our ability to supply our products to patients in an un-disrupted fashion, and further erode reimbursement levels for innovative therapies.

As a result of the UK's Brexit vote, the British government has been in the process of negotiating the terms of the UK's future relationship with the EU, requiring us to make certain contingency plans for scenarios in which the UK and the EU do not reach a mutually satisfactory understanding as to that relationship. We cannot predict whether there will be any such understanding, or if such an understanding is reached, whether its terms will vary in ways that result in greater restrictions on imports and exports between the UK and EU countries, and increased regulatory complexities that could materially adversely impact our business operations in the UK.

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.

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 and other post-employment obligations could substantially increase our pension-related expenses," below. See also "Item 5. Operating and Financial Review and Prospects—Item 5.B Liquidity and capital resources—Effects of currency fluctuations," "Item 5. Operating and Financial Review and Prospects—Item 5.B Liquidity and capital resources—Condensed consolidated balance sheets," "Item 18. Financial Statements—Note 15. Trade receivables" and "Item 18. Financial Statements—Note 29. 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 financial results" and "—An inability to attract and retain qualified personnel could adversely affect our business," below.

Our business may be impacted by economic and financial conditions directly affecting consumers. Given the requirements in certain countries that patients directly pay an increasingly large portion of their own healthcare costs, there is a risk that consumers may cut back on prescription drugs to help cope with rising costs.

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 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, 2019, we had USD 20.4 billion of non-current financial debt and USD 7.0 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.

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 including *Xiidra*, Endocyte, AveXis, AAA, and 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 2019, for example, we recorded intangible asset impairment charges of USD 1.1 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,” “Item 18. Financial Statements—Note 1. Significant accounting policies” and “Item 18. Financial Statements—Note 11. Goodwill and intangible assets.”

Competition, failure to adapt to changing business conditions, and complexities in the development of biosimilars may impact the success of our Sandoz Division.

Sandoz faces intense competition from companies that market patented pharmaceutical products as well as strong competition from other generic and biosimilar pharmaceutical companies, which aggressively compete for market share, including through significant price competition. Such competitive actions 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 past years, industrywide price competition among generic pharmaceutical companies and consolidation of buyers caused significant declines in sales and profits of Sandoz. In light of this, we agreed to sell the Sandoz US dermatology business and generic US oral solids portfolio to Aurobindo Pharma USA Inc. This transaction is expected to be completed in the first quarter of 2020 pending regulatory approval. There is no certainty that the remaining Sandoz US business will be commercially successful. Sandoz has also announced a refined strategy, with the objective of being an industry leader as a focused generics company, which bears risk in a competitive environment in which other generics companies strive to also launch first and in which originators rigorously defend the exclusivity of their products. The refined strategy touches many fundamental areas of the Sandoz organization, including portfolio strategy, resource allocation, production, development, sales and governance. These changes may fail to achieve their intended goals, and may negatively affect the motivation of employees in certain parts of Sandoz.

In addition, Sandoz has invested heavily in the development of biosimilar drugs, with the expectation that such products offer the potential for higher profitability. If Sandoz should fail in its efforts to develop and market biosimilars, due to the fact that their development is more difficult and expensive than the development of standard generic drugs, 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.

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.

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 2015 Agenda) Action Plans to address issues of transparency, coherence and substance. In addition, in 2019 the OECD launched a new initiative on behalf of the G20 to minimize profit shifting by working toward a global tax framework that ensures that corporate income taxes are paid where consumption takes place and also introduces a global standard on minimum taxation combined with new tax dispute resolution processes. The respective principles are currently being evaluated.

Most of the rules of the EU 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, apply as of January 1, 2019. 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.

In Switzerland, the Basel-Stadt Cantonal Tax Reform was approved by voters in February 2019, with parts retroactive from January 1, 2019. In May 2019, Swiss voters approved the Swiss Federal Tax Reform. With the enactment of this tax reform, new elements were introduced into law as of January 1, 2020. These include the abolishment of special taxed regimes, notional interest deduction, and an implementation of a Patent-Box, which provides tax advantages on income generated from intellectual property rights. Some of the new elements as well as the transition rules for the Swiss tax reform might be regarded as not completely aligned with OECD and EU regulations, and might require subsequent amendments, the need for and impact of which are difficult to predict.

In the US, the Tax Cuts and Jobs Act, enacted at the end of 2017, included significant changes to US corporate income tax law. Though we continue to monitor regulations and other guidance issued by the US Department of the Treasury, it is uncertain whether the application of new guidance, particularly with respect to the tax limitation of interest deductions and qualification of base erosion payments, will have a material effect on our financial position and results of operations.

In general, such tax reform efforts will require us to continually assess our organizational structure against tax policy trends, 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.

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. In Argentina, for example, where we have subsidiary operations, the government authorized currency exchange controls in 2019. Currency 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 impact our results," above.

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” and “Item 18. Financial Statements—Note 29. 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 23%, 17% and 10%, respectively, of net sales in 2019. The largest trade receivables outstanding were for these three customers, amounting to 14%, 12% and 7%, respectively, of the Group’s trade receivables at December 31, 2019. The trend has been toward further consolidation among distributors and retailers, particularly in the US. 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 personnel – 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. Emerging Growth Markets, in particular China and India, 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, we are undertaking a cultural transformation to an “inspired, curious and unbossed” organization, which is a core organizational imperative. Inability to successfully implement this cultural change may result in cynicism and disengagement of our associates, as well as impede our ability to retain key talent in strategically important areas. This risk is augmented by ongoing organizational changes, as well as changes to our culture and leadership expectations that may conflict with some leaders’ preferred leadership styles. Consequently, we may fail to retain key talent, who may possess capabilities that are rare and highly sought in the marketplace, unless they are appropriately engaged, motivated and incentivized. The departure of key talent could have a material adverse effect on our business performance, results of operations and reputation.

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 near future. 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. 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, including in connection with activities in the past by businesses that are no longer part of Novartis. In some cases, these remediation efforts may take 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 contam-

ination 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 20. 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.

The potential impacts of climate change may also include increased operating costs associated with additional regulatory requirements and investments in reducing energy, water use and greenhouse gas emissions.

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 2019, 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 95% 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 25. Post-employment benefits for associates.”

Holders of ADRs may not be able to exercise pre-emptive rights attached to shares underlying ADRs.

If a capital increase is approved, then our shareholders would generally have certain pre-emptive rights to obtain newly issued shares in an amount proportional to the nominal value of the shares they already hold. These pre-emptive rights could be excluded in certain limited circumstances with the approval of a resolution adopted at a general meeting of shareholders by a supermajority of two thirds of the votes. Pre-emptive rights, if not excluded, 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 that, if filed, 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.