

Exchange Rates

The following table shows, for the years and dates indicated, certain information concerning the rate of exchange of US dollar per Swiss franc based on exchange rate information found on Bloomberg Market System. The exchange rate in effect on January 20, 2016, as found on Bloomberg Market System, was CHF 1.00 = \$0.998.

<u>Year ended December 31, (\$ per CHF)</u>	<u>Period End</u>	<u>Average⁽¹⁾</u>	<u>Low⁽²⁾</u>	<u>High⁽²⁾</u>
2011	1.06	1.13	1.06	1.25
2012	1.09	1.07	1.02	1.12
2013	1.12	1.08	1.05	1.12
2014	1.01	1.09	1.01	1.13
2015	1.01	1.04	0.97	1.08
<u>Month</u>				
August 2015			1.02	1.07
September 2015			1.02	1.04
October 2015			1.01	1.05
November 2015			0.97	1.01
December 2015			0.97	1.02
January 2016 (through January 20, 2016)			0.99	1.01

(1) Represents the average of the exchange rates on the last day of each month during the year.

(2) Represents the lowest, respectively highest, of the exchange rates on the last day of each month during the year.

3.B Capitalization and Indebtedness

Not applicable.

3.C Reasons for the offer and use of proceeds

Not applicable.

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 on Form 20-F 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.

Risks Facing Our Business

Our products face important patent expirations and significant competition.

The products of our Pharmaceuticals and Alcon Divisions, as well as certain key products of our Sandoz Division, are generally protected by patent and other intellectual property rights, which are intended to provide us with exclusive rights to market the products. However, those intellectual property rights have varying strengths and durations. 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 medicine typically results in a significant and rapid reduction in net sales and net income for the patented 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 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 patents, conducting so-called "launches at risk" of products that are still under legal challenge for patent 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, 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.

- We already face generic competition in Japan and some EU countries for our best-selling product *Gleevec/Glivec* (cancer). In the US, we have resolved patent litigation with certain generic manufacturers. We have licensed one generic manufacturer to market a generic version of *Gleevec* in the US as of February 1, 2016. In the EU, our *Glivec* intellectual property rights also are being challenged by generic manufacturers.
- *Diovan* and *Co-Diovan/Diovan HCT* (high blood pressure), which had long been our best-selling product, has generic competitors for *Diovan* in the US, EU and Japan and for *Co-Diovan/Diovan HCT* in the US and EU. In Japan, Novartis has resolved patent litigation with a generic manufacturer. Patent protection for *Co-Diovan* will expire in Japan in 2016. In addition, valsartan, the active ingredient in *Diovan*, is also used in the single-pill combination therapies *Exforge/Exforge HCT* (high blood pressure), and despite the existence of separate patents covering the product, *Exforge* faces generic competition in the US. Our *Exforge* patents also face challenges in the EU.
- Patent protection for octreotide acetate, the active ingredient in *Sandostatin*, has expired. Generic versions of *Sandostatin* SC are available in the US, EU and Japan. A US patent protects *Sandostatin LAR*, the long-acting version of *Sandostatin* which represents a majority of our *Sandostatin* US sales. This patent is expected to expire in 2017. Patents protecting the *Sandostatin LAR* formulation in the EU and Japan have expired. There is currently no generic competition for *Sandostatin LAR* in the US, EU or Japan.
- Patent protection on rivastigmine, the active ingredient in *Exelon*, has expired and *Exelon* capsules are subject to generic competition in major markets, including the US, Japan and all of Europe. We hold additional patents with respect to *Exelon* Patch, which makes up a substantial portion of our *Exelon* sales, but generic versions of *Exelon* Patch are on the market in the US and most EU countries.
- Certain patents and extensions protecting our top-selling products, *Afinitor* and *Gilenya* will begin to expire in 2018 and 2019, and some of the patents protecting these products are being challenged in the US.

For more information on the patent status of our Pharmaceuticals Division's products see "Item 4. Information on the Company—Item 4.B Business Overview—Pharmaceuticals—Intellectual Property" and "Item 18. Financial Statements—Note 20".

In 2016, we expect an impact on our net sales of approximately \$3.2 billion as a result of the loss of intellectual property protection for our products, including *Gleevec/Glivec*. Because we typically have substantially reduced marketing and research and development expenses related to products that are in their final year of exclusivity, we expect that this loss of intellectual property protection also will have an impact on our 2016 operating income in an amount corresponding to a significant portion of the products' lost sales. The magnitude of the impact of generic competition could depend on a number of factors, including the time of year at which such exclusivity would be lost; 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, and whether an authorized generic is launched; and 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.

Clearly, with respect to major products for which the patent terms are expiring, the loss of exclusivity of these products can be expected to have a material adverse effect on our business, financial condition and 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 and results of operations, both due to the loss of revenue and earnings, and the difficulties in planning for such losses.

Similarly, all of our businesses are faced with intense competition from new products and technological advances from competitors, including new competitors from other industries such as Google and IBM that are entering the healthcare field. Physicians, patients and third-party payors 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, including products competing against some of our best-selling products, 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 *Lucentis*, *Gilenya* and *Afinitor* have been launched. Such products, and other competitive products, could significantly affect the revenues from our products and our results of operations.

Similarly, our Alcon Division, a leader in the eye care industry, has recently suffered declining growth rates due in part to increased competition for its products, across all of its business franchises. To counter this, we are taking steps to accelerate growth to improve the division's sales and profits. Our efforts under this plan are expected to take time to succeed. As a result, such competition and other factors can be expected to affect Alcon's business, financial condition or results of operations in the near term. In addition, despite the implementation of the growth acceleration plan, our efforts to improve Alcon's performance may prove insufficient. Should our growth acceleration efforts fail to accomplish its 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 the discussion of Alcon's new product development efforts in "Our research and development efforts may not succeed in bringing new products to market, or may fail to do so in a cost-efficient manner, or in a manner sufficient to grow our business, replace lost revenues and income and take advantage of new technologies" below.

Our research and development efforts may not succeed in bringing new products to market, or may fail to do so in a cost-efficient manner, or in a manner sufficient to grow our business, replace lost revenues and income and take advantage of new technologies.

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 our research and development activities in identifying, and successfully and cost-effectively developing

new products that address unmet medical needs, are accepted by patients and physicians, and are reimbursed by payors. To accomplish this, we commit substantial effort, funds and other resources across our divisions to research and development, both through our own dedicated resources and through collaborations with third parties. Developing new healthcare products and bringing them to market, however, 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 viable new products that will enable us to grow our business and replace revenues and income lost to generic and other competition.

Using the products of our Pharmaceuticals 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 will 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 which 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, 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, insufficient clinical trial data to support the safety or efficacy of the product candidate, 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 a series of widely publicized issues, health regulators have increased their focus on product safety. Governmental authorities and payors around the world have also paid increased attention to whether new products offer a significant benefit over other products in the same therapeutic class. These developments have led to requests for more clinical trial data, for the inclusion of a significantly higher number of patients in clinical trials, and for more detailed analyses of the trials. As a result, the already lengthy and expensive process of obtaining regulatory approvals and reimbursement for pharmaceutical products has become even more challenging.

For the same reason, 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 and of achieving reimbursement for our products increasingly expensive, and further heightening the risk of recalls, product withdrawals, loss of revenues or loss of market share.

Our Alcon Division faces similar challenges in developing new products and bringing them to market. Alcon's Ophthalmic Pharmaceuticals products must be developed and approved in accordance with essentially the same processes as our Pharmaceuticals Division. Alcon's Surgical and Vision Care products face medical device development and approval processes that are often similarly difficult. Alcon is taking steps to accelerate its growth, and this can be expected to be costly and to require extensive efforts over time. There can be no certainty that Alcon will be successful in these efforts, in either the short- or the long-term, and if Alcon is not successful, there could be a material adverse effect on the success of the Alcon Division, and on the Group as a whole. See also the discussion of Alcon in "—Our products face important patent expirations and significant competition" above.

In addition, our Sandoz Division has made, and expects to continue to make, significant investments in the development of differentiated, "difficult-to-make" generic products, including biotechnology-based, "biologic" medicines intended for sale as bioequivalent or "biosimilar" generic 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 for non-differentiated generic products. In addition, despite significant efforts by us and others, to date many countries do not yet have a fully-developed legislative or regulatory pathway which would 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, and could have a material adverse effect on the long-term success of the Sandoz Division and the Group as a whole.

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, 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 cost-effectively maintain an adequate flow of successful new products and new indications for existing products sufficient to maintain 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 description of the approval processes which 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 for our products.

The growth of overall healthcare costs as a percentage of gross domestic product in many countries means that governments and payors are under intense pressure to control healthcare spending even more tightly. These pressures are particularly strong given the persistently weak economic and financial environment in many countries and the increasing demand for healthcare resulting from the aging of the global population and the prevalence of behaviors that increase the risk of obesity and other chronic diseases. In addition, in certain countries, governments, patients, healthcare providers and the media are increasingly raising questions about healthcare pricing issues. As a result, our businesses and the healthcare industry in general are operating in an ever more challenging environment with very significant pricing pressures. These ongoing pressures affect all of our divisions, and involve a number of cost-containment measures, such as government-imposed industry-wide price reductions, mandatory pricing systems, reference pricing systems, payors limiting access to treatments based on cost-benefit analyses, an increase in 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, and growing pressure on physicians to reduce the prescribing of patented prescription medicines. For more information on such price controls see "Item 4. Information on the Company–Item 4.B Business Overview–Pharmaceuticals–Price Controls."

As a result of such measures, we faced downward pricing pressures on our patented and generic drugs in countries around the world in 2015. These pressures ranged from efforts by many governments and proposals by politicians to reduce the amounts we would be paid for our medicines, intense publicity regarding the pricing of pharmaceuticals, including publicity and pressure resulting from prices charged by competitors and peer companies for new products as well as price increases by competitors and peer companies on older products that the public deemed excessive, and government investigations into pharmaceutical pricing practices.

We expect these challenges to continue and possibly increase in 2016 as political pressures mount, and healthcare payors 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. Such pressures could have a material adverse impact on our business, financial condition or results of operations, as well as on our reputation.

Failure to comply with law, legal proceedings and government investigations may have a significant negative effect on our results of operations.

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 government and public expectations regarding acceptable corporate behavior change. For example, there are new laws in the US and in other countries around the world that require us to be more transparent with respect to our interactions with healthcare professionals. 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 and reputation.

In particular, in recent years, there has been a trend of increasing civil and criminal government investigations, litigations and law enforcement activities against companies operating in our industry, both in the US and in an increasing number of countries around the world. A number of our subsidiaries across each of our divisions are, or may in the future be subject to various investigations and legal proceedings that arise or may arise from time to time, such as proceedings regarding sales and marketing practices, pricing, corruption, trade regulation and embargo legislation, product liability, commercial disputes, employment and wrongful discharge, antitrust, securities, insider trading, health and safety, environmental, tax, cybersecurity and data privacy, and intellectual property matters, and are increasingly challenging practices previously considered to be legal.

Such proceedings are inherently unpredictable, and large judgments sometimes occur. As a consequence, we may in the future incur judgments or enter into settlements of claims that could involve large cash payments, including the potential repayment of amounts allegedly obtained improperly, and other penalties, including treble damages. In addition, such proceedings may affect our reputation, create a risk of potential exclusion from government reimbursement programs in the US and other countries, may lead to civil litigation and otherwise subject us to monetary penalties. Further, judgments and settlements sometimes require companies to enter into corporate integrity or similar agreements, which are intended to regulate company behavior for a period of years. Any such resolutions could have a material adverse impact on our business, financial condition or results of operations, as well as on our reputation.

Our businesses are and have been subject to a number of these types of cases and governmental investigations, including the following:

- In 2014, the Tokyo District Public Prosecutor Office indicted our Japanese affiliate, Novartis Pharma K.K. (NPKK), as well as a former NPKK employee on certain charges relating to the alleged manipulation of data in certain clinical trials. The charges against NPKK are subject to a maximum total fine of JPY 4 million. Trial in this matter commenced in December 2015. In addition, in February 2015, the Japanese Ministry of Health, Labor and Welfare (MHLW) issued a business suspension order for failure to report adverse events, which required NPKK to halt manufacturing and sales in Japan for the period from March 5 to 19, 2015. NPKK is implementing a corrective and preventive action plan in response to a business improvement order and instruction issued by the MHLW in the fourth quarter of 2015 regarding additional instances of delayed adverse events reporting.
- In 2013 and 2014, the US government and certain states filed civil charges against our US affiliate, Novartis Pharmaceuticals Corporation (NPC) in federal court in the Southern District of New York, asserting federal False Claims Act and state law claims related to alleged unlawful contractual discounts and rebates to specialty pharmacies in connection with certain of our products. The US government alleged substantial damages, including treble damages and civil penalties of up to \$11,000 per claim, which according to the government could exceed \$2 billion. In the second half of 2015, NPC reached a settlement with all plaintiffs, including the United States Department of Justice, 45 states (made up of the eleven intervening states, as well as all the other states which were either part of the relator's complaint, or which reimbursed prescriptions of *Myfortic* and *Exjade* during the relevant time period), the District of Columbia and the qui tam relator. This resolves all the above-described claims related to *Myfortic*, *Exjade*, *Tasigna*, *Gleevec* and *TOBI*. As part of the settlement, NPC agreed to pay \$390 million plus additional legal expenses to plaintiffs, and agreed with the Office of Inspector General of the US Department of Health & Human Services on an amendment and extension of its current Corporate Integrity Agreement until 2020.

A number of significant legal matters remain pending against us. For more detail see "Item 18. Financial Statements–Note 20." See also "–Our reliance on outsourcing and third parties for the performance of key business functions heightens the risks faced by our businesses" below.

In addition, 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, 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.

Adverse judgments or settlements in any of the significant investigations or cases against us could have a material adverse effect on our business, financial condition, results of operations and reputation.

The manufacture of our products is highly regulated and complex, and may result in a variety of issues that could lead to extended supply disruptions and significant liability.

The manufacture of our products is heavily regulated by governmental health authorities around the world, including the FDA. Whether our products 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, as well as with our own high quality standards. In recent years, health authorities have substantially intensified their scrutiny of manufacturers' compliance with such requirements. If we or our third-party suppliers fail to comply fully with these

requirements and the health authorities' expectations, then we could be required to shut down our production facilities or production lines, or could be prevented from importing our products from one country to another. This could lead to product shortages, or to our being entirely unable to supply products to patients for an extended period of time. And such shortages or shut downs have led to and could continue to lead to significant losses of sales revenue and to potential third-party litigation. 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.

Like many of our competitors, we have faced significant manufacturing issues in recent years. As a result of such issues, we were unable to supply certain products to the market for significant periods of time, and suffered significant losses in sales and market share. In October 2015, the FDA issued a warning letter to our Sandoz Division concerning their sites in Kalwe and Turbhe, India, relating to documentation practices in Kalwe and sterile manufacturing practices in Turbhe that were identified during an inspection in August 2014. Though we have taken steps to respond to the warning letter, there can be no guarantee that FDA's concerns will be met.

In order to meet increasing health authority expectations and our own high quality standards, we are devoting substantial time and resources to remediate issues, improve quality and assure consistency of product supply at our manufacturing sites around the world. Ultimately, there can be no guarantee of the outcome of these efforts. Nor can there be any guarantee that we will not again face significant manufacturing issues, or that we will successfully manage such issues when they arise.

In addition to regulatory requirements, many of our products involve technically complex manufacturing processes or require a supply of highly specialized raw materials. For some products and raw materials, we may rely on a single source of supply. In particular, a significant portion of our portfolio are "biologic" products. Unlike traditional "small-molecule" drugs, biologic drugs or other biologic-based products cannot be manufactured synthetically, but typically must be produced from living plant or animal micro-organisms. As a result, the production of biologic-based products which meet all regulatory requirements is especially complex. Even slight deviations at any point in the production process may lead to production failures or recalls. In addition, because the production process is based on living plant or animal micro-organisms, the process could be affected by contaminants that could impact those micro-organisms. As a result, the inherent fragility of certain of our raw material supplies and production processes may cause the production of one or more of our products to be disrupted, potentially for extended periods of time.

Also as part of the Group's portfolio of products, we have a number of sterile products, including oncology products, which are technically complex to manufacture, and require sophisticated environmental controls. Because the production process for such products is so complex and sensitive, the chance of production failures and lengthy supply interruptions is increased.

Finally, in addition to potential liability for government penalties, because our products are intended to promote the health of patients, for some of our products, any 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, a disruption in the supply of certain key products—whether as a result of a failure to comply with applicable regulations or health authority expectations, the fragility of the production process, inability to obtain product or raw materials from a sole source of supply, natural or man-made disasters at one of our facilities or at a critical supplier or vendor, or our failure to accurately predict demand—could have a material adverse effect on our business, financial condition or results of operations, as well as our reputation. See also "—Earthquakes and other natural disasters could adversely affect our business," below.

The persistently weak global economic and financial environment in many countries and increasing political and social instability may have a material adverse effect on our results.

Many of the world's largest economies and financial institutions continue to be impacted by a weak ongoing global economic and financial environment, with some continuing to face financial difficulty, liquidity problems and limited availability of credit. In addition, we continue to see weak economic growth or a slowing of economic growth rates in certain emerging growth markets, such as China, Russia, Brazil and India. It is uncertain how long these effects will last, or whether economic and financial trends will worsen or improve. In addition, these issues may be further impacted by the unsettled political conditions currently existing in the US and Europe, as well as the difficult conditions existing in parts of the Middle East and places such as Ukraine, as well as the ongoing refugee crisis, anti-immigrant activities, social unrest and fears of terrorism that have followed in many countries. Such uncertain times 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. For example, financial weakness in certain countries has increased pressures on those countries, and on payors in those countries, to force healthcare companies to decrease the prices at which we may sell them our products. See also "Item 4. Information on the Company—Item 4.B Business Overview—Pharmaceuticals—Price Controls."

Concerns continue that payors in some countries, including Greece, Italy, Portugal and Spain, may not be able to pay us in a timely manner. Certain other countries are experiencing high inflation rates and have taken steps to introduce exchange controls and limit companies from distributing retained earnings or paying intercompany payables due from those countries. The most significant country in this respect is Venezuela, where we are exposed to a potential devaluation loss in the income statement on our total intercompany balances with our subsidiaries there, which at December 31, 2015 amounted to \$0.3 billion. In November 2015, one of our Venezuelan subsidiaries agreed with Venezuelan authorities to settle a substantial part of our existing intercompany trade payables dated on or before December 31, 2014 in a transaction that, in turn, required us to use a significantly devalued US dollar/Venezuela bolivar exchange rate for consolidation of the financial statements of our Venezuela subsidiaries. The use of the new exchange rate resulted in a \$211 million loss from the re-measurement of the intra-Group and third party liabilities. Ongoing conditions in Venezuela and other such countries could continue to lead to further devaluations of their currencies, which could in turn result in significant additional financial losses to the Group in the future. See also "Item 5. Operating and Financial Review and Prospects—Item 5.B Liquidity and Capital Resources—Effects of Currency Fluctuations" and "—Condensed Consolidated Balance Sheets," and "Item 18. Financial Statements—Notes 15 and 29."

Current economic conditions may adversely affect the ability of our distributors, customers, suppliers and service providers to obtain the liquidity required to pay for our products, or otherwise to buy necessary inventory or raw materials, and to perform their obligations under agreements with us, which could disrupt our operations, and could negatively impact our business and cash flow. 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 and results of operations. These risks may be elevated with respect to our interactions with third parties with substantial operations in countries where current economic conditions are the most severe, particularly where such third parties are themselves exposed to payment risks from business interactions directly with fiscally-challenged government payers. See also "—Our reliance on outsourcing and third parties for the performance of key business functions heightens the risks faced by our businesses" below.

In addition, the varying effects of difficult economic times on the economies, currencies and financial markets of different countries has impacted, and may continue to unpredictably impact, our business and 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. See "—Foreign exchange fluctuations may adversely affect our earnings and the value of some of our assets," below, and "—If any of numerous

key assumptions and estimates in calculating our pension plan obligations turn out to be different from our actual experience, we may be required to increase substantially our contributions to pension plans as well as our pension-related costs in the future," below. In addition, the financial situation may also result in a lower return on our financial investments, and a lower value on some of our assets. Alternately, inflation could accelerate, which could lead to higher interest rates, which would increase our costs of raising capital.

To the extent that the economic and financial conditions directly affect consumers, some of our businesses, including the elective surgical business of our Alcon Division, may be particularly sensitive to declines in consumer spending. In addition, our Pharmaceuticals and Sandoz Divisions, and the remaining businesses of our Alcon Division, may not be immune to consumer cutbacks, particularly given the increasing requirements in certain countries that patients pay a larger contribution toward their own healthcare costs. As a result, there is a risk that consumers may cut back on prescription drugs and medical devices to help cope with rising costs and difficult economic times.

At the same time, significant changes and 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 which 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.

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 operation" and "An inability to attract and retain qualified personnel could adversely affect our business" below.

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 2015, the US dollar continued its significant increase in value against most currencies. In particular, the average value of the euro, the Japanese yen and emerging market currencies (especially the ruble) decreased in 2015 against the US dollar. However, in January 2015, following an announcement by the Swiss National Bank that it was discontinuing its minimum exchange rate with the euro, the value of the Swiss franc increased substantially. In addition, in 2015, China took steps to devalue its currency, and the value of its currency against the US dollar has continued to decline.

There is a risk that other countries could also take 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, certain countries are or may experience periods of high inflation. This could lead these countries to devalue their currencies, and to set exchange controls, as, for example, Venezuela has done. Such steps taken by Venezuela have impacted our financial results. See "The persistently weak global economic and financial environment in many countries and increasing political and social instability may have a material adverse effect on our results" above. Ongoing conditions in Venezuela and other such countries could continue to lead to further devaluations of their currencies, which could in turn result in significant additional financial losses to the Group in the future.

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 revenues in Swiss francs, such exchange rate volatility may negatively and materially impact the Group's business, 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, the Group 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 29."

We may not successfully achieve our goals in strategic transactions or reorganizations, including the portfolio transformation transactions, the strategic reorganizations we announced in January 2016, and the formation of Novartis Business Services.

As part of our strategy, from time to time we evaluate and pursue potential strategic business acquisitions and divestitures to expand or complement our existing businesses, or to enable us to focus more sharply on our strategic businesses. We cannot ensure that suitable acquisition candidates will be identified. Acquisition activities can be thwarted by overtures from competitors for the targeted assets, potentially increasing prices demanded by sellers, governmental regulation (including market concentration limitations) and replacement product developments in our industry. 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 time frame, 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 integrate the business may not meet expectations, or may otherwise not be successful, as a result of corporate cultural differences, difficulties in retention of key personnel, customers and suppliers, coordination with other products and processes, or other reasons. Also, acquisitions and divestments could 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 suitable buyers will be identified for businesses or other assets that we might want to divest. Neither can we ensure that we will correctly select businesses or assets as candidates for divestiture, that we will be able to successfully complete any agreed upon divestments, or that any expected strategic benefits, synergies or opportunities will arise as a result of any divestiture.

In 2015, we completed a series of transactions intended to transform our portfolio of businesses. In these transactions, we acquired GSK oncology products and certain related assets; created a joint venture with GSK in consumer healthcare of which Novartis owns 36.5%; divested our vaccines business (excluding the influenza vaccines business) to GSK; divested our Animal Health business to Lilly; and divested our influenza vaccines business to CSL. In 2014, we had also divested the blood transfusion diagnostics unit to Grifols S.A. that had been part of our former Vaccines and Diagnostics Division. In agreeing to these transactions, we expect to achieve certain strategic benefits, synergies and opportunities, including certain financial results, but there can be no certainty that such expected benefits will be fully realized or that they will be realized at any particular time.

In addition, as part of our strategy, from time to time we reassess the optimal organization of our business, including the allocation of products by division and the level of centralization and simplification of certain functions across the Group, to better align those products and functions with the capabilities and expertise required for competitive advantage. As an example of this, in January 2016 we announced a series of strategic actions intended to further focus our divisions, including focusing our Alcon Division on its Surgical and Vision Care franchises, strengthening our ophthalmic medicines business by transferring Alcon's Ophthalmic Pharmaceuticals products to our Pharmaceuticals Division, and shifting selected

mature pharmaceutical products from our Pharmaceuticals Division into Sandoz. We also announced steps to increase Group-wide coordination of drug development, and to improve efficiency with an integrated manufacturing operation and more shared commercial and medical services at the country level. We expect these actions to further strengthen our competitive position, enable us to maintain our leading position in research and development, and free resources for our growth priorities. But the expected benefits of this reorganization may never be fully realized or may take longer to realize than expected. There can be no certainty that the numerous businesses and functions involved will be successfully integrated into the new organizations and that key personnel will be retained. Disruption from the reorganizations may make it more difficult to maintain relationships with customers, employees or suppliers, and may result in the Group not achieving the expected productivity and financial benefits, including potential sales declines and lost profits.

Similarly, in 2014 we created a shared services organization, Novartis Business Services (NBS). NBS consolidates a number of business support services previously spread across divisions, including Information Technology, Financial Reporting and Accounting Operations, Real Estate & Facility Services, Procurement, Payroll and Personnel Administration and the Pharmaceuticals Global Business Services. This reorganization was designed to improve profitability and free up resources that could be reinvested in growth and innovation, and to allow our divisions to focus more on customer-facing activities. But the expected benefits of this reorganization may never be fully realized or may take longer to realize than expected. There can be no certainty that the numerous business functions involved will be successfully integrated into a single organization and that key personnel will be retained. Disruption from the reorganization may make it more difficult to maintain relationships with customers, employees or suppliers, 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 timely recognize or 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 or reorganization.

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

We carry a significant amount of goodwill and other intangible assets on our consolidated balance sheet, primarily due to acquisitions. As a result, significant impairment charges may result in the future if the expected fair value of the goodwill and other intangible assets would be less than their carrying value on the Group's consolidated balance sheet at any point in time.

We regularly review our long-lived intangible and tangible assets, including identifiable intangible assets, investments in associated companies and goodwill, for impairment. Goodwill, acquired research and development, 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 2015, for example, we recorded intangible asset impairment charges of \$347 million. For a detailed discussion of how we determine whether an impairment has occurred, what factors could result in an impairment and the increasing 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—Notes 1 and 11."

Our indebtedness could adversely affect our operations.

As of December 31, 2015 we had \$16.3 billion of non-current financial debt and \$5.6 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. In addition, our

existing debt may limit our ability to engage in transactions or otherwise may place us at a competitive disadvantage relative to competitors that have less debt. 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 and third parties for the performance of key business functions heightens the risks faced by our businesses.

We invest a significant amount of effort and resources into outsourcing and offshoring certain key business functions with third parties, including research and development collaborations, manufacturing operations, warehousing, distribution activities, certain finance functions, marketing activities, data management and others. Our reliance on outsourcing and third parties for certain functions, such as the research and development or manufacturing of products, may limit the potential profitability of such products. In addition, despite contractual relationships with the third parties to whom we outsource these functions, we cannot ultimately control how they perform their contracts. Nonetheless, we depend on these third parties to achieve results which may be significant to us. If the third parties fail to meet their obligations or to comply with the law, 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 in the course of their performance of services for us, there is a risk that we could be held responsible for such violations of law, as well and that our reputation may suffer. Any such failures by third parties could have a material adverse effect on our business, financial condition, results of operations or reputation.

In particular, in many countries, including many developing markets, we rely heavily on third party distributors and other agents for the marketing and distribution of our products. Many of these third parties do not have internal compliance resources comparable to those within our organization. Some of these countries are plagued by corruption. If our efforts to screen our third party agents and detect cases of potential misconduct fail, we could be held responsible for the noncompliance of these third parties with applicable laws and regulations, which may have a material adverse effect on our reputation and on our business, financial condition or results of operations.

We may not be able to realize the expected benefits of our significant investments in Emerging Growth Markets.

At a time of slowing growth in sales of healthcare products in industrialized countries, many emerging markets have in recent years experienced proportionately higher sales growth and an increasing contribution to the industry's global performance. In 2015, our Continuing Operations generated \$12.4 billion, or approximately 25% (2014: 26%) of our net sales from Emerging Growth Markets—which comprise all markets other than the Established Markets of the US, Canada, Western Europe, Japan, Australia and New Zealand—as compared with \$37.0 billion, or approximately 75% (2014: 74%) of our net sales, in the Established Markets. However, combined net sales in the Emerging Growth Markets grew 7% in constant currencies in 2015, compared to 4% sales growth in constant currencies in the Established Markets during the same period. As a result of this trend, we continue to take steps to increase our activities in the Emerging Growth Markets, and have been making significant investments in our businesses in those countries.

In the past year, however, certain of these Emerging Growth Market countries, including Brazil, India, China and Russia, have experienced economic slowdowns. As a result, there can be no guarantee that our efforts to expand our sales in these countries will succeed, or that these countries will once again experience growth rates significantly in excess of the world's largest markets. In particular, some Emerging Growth Market countries may be especially vulnerable to the effects of the persistently weak global financial environment, may have very limited resources to spend on healthcare or may be susceptible to political and social instability. See "—The persistently weak global economic and financial environment in many countries and increasing political and social instability may have a material adverse effect on our results" above. Many of these countries are subject to increasing political and social pressures, including

from a growing middle class seeking increased access to healthcare. Such pressures on local government may in turn result in an increased focus by the governments on our pricing, and may put at risk our intellectual property. See "Our business is increasingly affected by pressures on pricing for our products," and "Our products face important patent expirations and significant competition" above.

These countries also may have a relatively limited number of persons with the skills and training suitable for employment at an enterprise such as ours. See "An inability to attract and retain qualified personnel could adversely affect our business" below. In some Emerging Growth Market countries, a culture of compliance with law may not be as fully developed as in the Established Markets—China's investigations of the activities of multinational healthcare companies, for example, have been well publicized—standards of acceptable behavior may be lower than such standards in Established Markets, or we may be required to rely on third-party agents, in each case putting us at risk of liability and reputational damage. See "Failure to comply with law, and resulting investigations and legal proceedings may have a significant negative effect on our results of operations," and "Our reliance on outsourcing and third parties for the performance of key business functions heightens the risks faced by our businesses," above.

In addition, many of these countries have currencies that may fluctuate substantially. If these currencies devalue significantly against the US dollar—as happened in China and Russia, among others, in the past year—and we cannot offset the devaluations with price increases, then our products may become less profitable, or may otherwise impact our reported financial results. Currency devaluation risk may also exist in countries with high inflation economies. Should these countries take steps that cause their currencies to be devalued, we may realize a significant financial loss. See "The persistently weak global economic and financial environment in many countries and increasing political and social instability may have a material adverse effect on our results" and "Foreign exchange fluctuations may adversely affect our earnings and the value of some of our assets," above. Ongoing conditions in such high inflation countries could continue to lead to further devaluations of their currencies, which could in turn result in significant additional financial losses to the Group in the future.

For all these reasons, our sales to Emerging Growth Markets carry significant risks. A failure to continue to expand our business in Emerging Growth Markets could have a material adverse effect on our business, financial condition or results of operations.

Failure to obtain marketing exclusivity periods for new generic products, or to develop biosimilars and other differentiated products, as well as intense competition from patented and generic pharmaceuticals companies, may have an adverse effect on the success of our Sandoz Division.

Our Sandoz Division 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—and when it is able to develop biosimilars and other differentiated products with few, if any, generic competitors. Failure to obtain and maintain these market opportunities could have an adverse effect on the success of Sandoz.

In addition, the division faces intense competition from companies that market patented pharmaceutical products, which sometimes take aggressive steps to prevent or delay the introduction of generic medicines, to limit the availability of exclusivity periods or to reduce their value, and from other generic pharmaceuticals companies, which aggressively compete for exclusivity periods and for market share of generic products that may be identical to certain of our generic products. These activities may increase the costs and risks associated with our efforts to introduce generic products and may delay or entirely prevent their introduction.

Sandoz has also invested heavily in the development of biosimilar drugs, despite the fact that regulations concerning their marketing and sale in certain countries, including in the US, are still under development or not entirely clear. If, despite ongoing efforts by us and others to encourage the

development of such regulations, such regulations do not ultimately favor the development and sale of biosimilar products, then 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 in bringing new products to market, or may fail to do so cost-efficiently enough, or in a manner sufficient to grow our business and replace lost revenues and income" above, with regard to the risks involved in our efforts to develop differentiated generic products.

If any of numerous key assumptions and estimates in calculating our pension plan obligations turn out to be different from our actual experience, we may be required to increase substantially our contributions to pension plans as well as the amount we pay toward pension-related expenses in the future.

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 under 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 expenses and liabilities related to these plans. These include assumptions used to determine the discount rates we apply to estimated future liabilities and rates of future compensation increases. In addition, our actuarial consultants provide our management with historical statistical information such as withdrawal and mortality rates in connection with these estimates. Assumptions and estimates used by Novartis may differ materially from the actual results we experience due to changing market and economic conditions (including the effects of the persistently weak global financial environment, which, to date, have resulted in extremely low or negative interest rates in many countries), higher or lower withdrawal rates, or longer or shorter life spans of participants, among other variables. For example, a decrease in the interest rate we apply in determining the present value of expected future defined benefit obligations of one-quarter of one percent would have increased our year-end defined benefit pension obligation for plans in Switzerland, US, UK, Germany and Japan, which represent about 95% of the Group total defined benefit pension obligation, by \$0.8 billion. Any differences between our assumptions and estimates and our actual experience could have a material effect on our results of operations and financial condition. Further, additional employer contributions might be required if plan funding falls below the levels required by local rules. 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". See also "The persistently weak global economic and financial environment in many countries and increasing political and social instability may have a material adverse effect on our results" above.

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

The integrated nature of our worldwide operations enables us to achieve an attractive effective tax rate on our earnings because a portion of our earnings are earned in jurisdictions that tax profits at more favorable rates. In recent years, tax authorities around the world have increased their scrutiny of company tax structures, and have become more rigid in exercising any discretion they may have. As a result, companies' flexibility to optimally structure their organizations for business and tax purposes may be significantly reduced. In addition, the public is increasingly taking an interest in what the tax burden of multinational companies should be. Any changes in tax laws or in the laws' application that may result from this, including with respect to tax base or rate, transfer pricing, intercompany dividends and cross-border transactions, controlled corporations, and limitations on tax relief allowed on the interest on intercompany debt, could increase our effective tax rate and 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 adverse reactions to counterfeit drugs or increased levels of counterfeiting could materially affect patient confidence in the authentic product, and harm the business of companies such as ours or lead to litigation. In addition, it is possible that 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.

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 are 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 14%, 11% and 5%, respectively, of Group net sales in 2015. The largest trade receivables outstanding were for these three customers, amounting to 13%, 9% and 6%, respectively, of the Group's trade receivables at December 31, 2015. The trend has been toward further consolidation among distributors and retailers, both in the US and internationally. As a result, our customers are gaining additional purchasing leverage, which increases the pricing pressures facing our businesses. 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. This could have a material adverse effect on our business, financial condition and 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. 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 emerging markets—could delay or prevent the achievement of major business objectives.

Future economic growth will demand talented associates and leaders, yet the market for talent has become increasingly competitive. In particular, emerging markets are expected to be a driving force in global growth, but in countries like Russia and China 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 emerging 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.

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 and results of operations.

Significant breaches of data security or disruptions of information technology systems, including by cyber-attack or other security breach, and breaches of the privacy rights of third parties could adversely affect our business.

Our business is heavily dependent on critical, complex and interdependent information technology systems, including Internet-based systems, to support business processes. In addition, Novartis and our employees rely on internet and social media tools and mobile technologies as a means of communications, and to gather information. We are also increasingly seeking to develop technology-based products such as mobile applications that go "beyond the pill" to improve patient welfare in a variety of ways, which could result in us gathering information about patients and others electronically.

The size and complexity of our information technology systems, and, in some instances, their age, make them potentially vulnerable to external or internal security breaches, breakdowns, malicious intrusions 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 the protection of our data and information technology, like many companies, we have experienced such events and expect to continue to experience them in the future. We believe that the data security breaches we have experienced to date have not resulted in significant disruptions to our operations, and will not have a significant adverse effect on our current or future results of operations. However, we may not be able to prevent breakdowns or breaches in our systems that could have a material adverse effect on our business, financial condition, results of operation or reputation.

Any such events 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 and other key business activities. Such potential information technology issues could lead to the loss of important information such as trade secrets or other intellectual property and could accelerate development or manufacturing of competing products by third parties. In addition, malfunctions in software or devices that make significant use of information technology, including our Alcon surgical equipment, could lead to a risk of harm to patients.

Our use of information technologies, including internet, social media, mobile technologies, and technology-based medical devices, as well as other routine business operations, sometimes involve our gathering personal information (including sensitive personal information) regarding our patients, vendors, customers, employees, collaborators and others. Breaches of our systems or other failures to protect such information could expose the personal information of third parties to unauthorized persons. Any such information or other privacy breaches could give rise to significant potential liability and reputational harm. In addition, we make substantial efforts to ensure that any international transfers of personal data are done in compliance with applicable law. Any restrictions that may be placed on our ability to transfer such data could have a material adverse effect on our business, financial condition, results of operations and reputation.

In addition, to the extent that we seek as a company to use internet, social media and mobile tools as a means to communicate with the public about our products or about the diseases our products are intended to treat, 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 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 social media and mobile technologies for such purposes may cause us to nonetheless be found in violation of them.

Any such breaches of data security or information technology disruptions or privacy violations 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 liability or enforcement actions, which could require us to expend significant resources to continue to modify or enhance our protective measures and to remediate any damage. Such events could have a material adverse effect on our business, financial condition, results of operations and reputation.

Environmental liabilities may adversely impact our results of operations.

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 caused by us adversely impact 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 on our reputation. See also "Item 4.D Property, Plants and Equipment–Environmental Matters" and "Item 18. Financial Statements –Note 20."

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, drought, and temperature changes, appear to have become more common. We operate in countries around the world. As a result, we are potentially exposed to varying natural disaster or extreme weather risks like hurricanes, tornadoes or floods, or other events that may result from the impact of climate change on the environment. As a result of such events, 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 and results of operations.

In addition, our corporate headquarters, the headquarters of our Pharmaceuticals Division, and certain of our major Pharmaceuticals 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 and results of operations. See also "–The manufacture of our products is highly regulated and complex, and may result in a variety of issues that could lead to extended supply disruptions and significant liability," above.

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 preemptive rights attached to shares underlying ADRs.

Under Swiss law, shareholders have preemptive rights to subscribe for issuances of new shares on a *pro rata* basis. Shareholders may waive their preemptive rights in respect of any offering at a general meeting of shareholders. Preemptive 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 preemptive 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 preemptive 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 preemptive rights could not be exercised by an ADR holder, JPMorgan Chase Bank, N.A., as depositary, would, if possible, sell the holder's preemptive 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 preemptive rights.