# **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 22, 2014, as found on Bloomberg Market System, was CHF 1.00 = \$1.10.

Year ended December 31,				
(\$ per CHF)	Period End	Average <sup>(1)</sup>	Low	High
2009	0.97	0.92	0.84	1.00
2010	1.06	0.96	0.86	1.07
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
<u>Month</u>				
August 2013			1.07	1.09
September 2013			1.06	1.10
October 2013			1.09	1.12
November 2013			1.08	1.10
December 2013			1.10	1.13
January 2014 (through January 22, 2014)			1.10	1.12

<sup>(1)</sup> Represents the average 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 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 deemed to be 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 key products from our other divisions, are generally protected by patent rights, which are intended to provide us with exclusive rights to market the patented products. However, those patent rights are of varying strengths and durations. Loss of market exclusivity for one or more important products have 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 result from the regular expiration of the term of the patent. 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, or 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 frequently 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 remedies may not be adequate to cover any 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 protection.

- The patent on valsartan, the active ingredient of <code>Diovan/Co-Diovan/Diovan HCT</code> (high blood pressure), which was long our best-selling product, expired in the major countries of the EU in November 2011, and generic competitors have launched there. In addition, patent protection expired in the US in September 2012, and generic versions of <code>Diovan HCT</code> have launched in the US. Generic versions of <code>Diovan</code> monotherapy have not yet launched in the US but could potentially launch at any time. In addition, patent protection for <code>Diovan</code> expired in Japan in 2013, and will expire in 2016 for <code>Co-Diovan</code> (including patent term extensions). The active ingredient valsartan is also used in the single-pill combination therapies <code>Exforge</code> and <code>Exforge HCT</code> (high blood pressure). While market exclusivities for <code>Exforge/Exforge HCT</code> will remain in the EU and Japan due to regulatory exclusivities and to a valsartan patent extension for <code>Exforge</code> in Japan until 2015, there is a risk that generic manufacturers may circumvent regulatory exclusivity and gain approval of a combination valsartan-amlodipine product in Europe. In the US, under a license agreement with a generics manufacturer, <code>Exforge</code> is expected to face generic competition beginning in October 2014.
- The patent on zoledronic acid, the active ingredient in Zometa (cancer), as well as in Reclast/Aclasta (osteoporosis), expired in 2013 in the US and in other major markets, and generic versions of these products have launched.
- Patent protection for octreotide acetate, the active ingredient of Sandostatin, has expired. Generic versions of Sandostatin SC are
  available in the US and elsewhere. Patents protecting the Sandostatin LAR formulation, the long-acting version of Sandostatin which
  represents a majority of our Sandostatin sales, expired in 2010 in key markets outside the US, and will expire in 2014 and beyond in
  the US.
- Patent protection on rivastigmine, the active ingredient in Exelon, expired in 2011 and 2012 and Exelon capsules are subject to
  generic competition, including in the US and all of Europe. We hold certain formulation patents with respect to Exelon Patch, which
  makes up a substantial portion of our Exelon sales. These patents have been challenged. Generic patches were launched in Germany and
  certain other EU countries in 2013.
- The patent on the active ingredient in <code>Gleevec/Glivec</code> (cancer) will expire in 2015 in the US, in 2016 in the major EU countries and in September 2014 for the main indications in Japan. However, the product is protected by additional patents claiming innovative features of <code>Gleevec/Glivec</code>. Generic versions of <code>Gleevec/Glivec</code> have already been launched in Turkey, Brazil, Canada, China, India, Russia and for a minor indication in Japan.

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 2014, the impact of generic competition on our net sales is expected to be as much as \$3.0 billion. Because we typically have substantially reduced marketing and research and development expenses related to a product in its final year of exclusivity, it is expected that the loss of patent protection will have an impact on our operating income which can be expected to correspond to a significant portion of the product's lost sales. The magnitude of such an impact 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, and whether, in the US, a single competitor is granted an exclusive marketing period; and the geographies in which generic competitor products are approved, including the strength of the market for generic 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. 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 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* and *Gilenya* have recently been launched. Such products, and other competitive products, could adversely affect the revenues from our products and our results of operations.

Our research and development efforts may not succeed in bringing new products to market, or to do so cost-efficiently enough, or in a manner sufficient to grow our business and replace lost revenues and income.

Our ability to continue to grow our business and to replace sales lost due to competition or to other sources 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 all 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 lost revenues and income.

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 a limited available patent life, the longer it takes to develop a product, the less time there will be for us to recoup our development costs. New products need not only undergo intensive preclinical and clinical testing, but also 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 which will further delay us and add substantial expense, that we will only 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 or delays or clinical trial holds at clinical trial sites; delays in completing formulation and other testing and work necessary to support an application for regulatory approval; adverse reactions to the product candidate or indications 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, FDA and other governmental health authorities have recently intensified their scrutiny of pharmaceutical companies' clinical development activities, both with respect to compliance with regulations related to the conduct of clinical trials, and with respect to their interpretations of the clinical trial requirements necessary to support a product submission. This has added to the obstacles and costs we face in bringing new products to market.

Our other divisions face similar challenges in developing new products and bringing them to market. Alcon's Ophthalmic Pharmaceuticals products, Vaccines and Diagnostics' Vaccine products, and the products of our Animal Health Division all must be developed and approved in accordance with essentially the same processes as faced by our Pharmaceuticals Division. Nearly all of our other products face similarly difficult development and approval processes. At Alcon, management has announced significant investments in research and development to develop new eye care products to replace sales that may be lost to generic competition and to grow its business. Vaccines and Diagnostics has, and continues to expend considerable time and resources to fully develop and bring to market new vaccines, including Bexsero, to combat serogroup B meningococcal disease. Our Animal Health Division seeks to bring new products to market from time to time. If these efforts do not bear significant fruit, they could have a material adverse effect on the medium to long-term success of these divisions, and of the Group as a whole.

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 can be significantly less costly and complex than the development of the equivalent originator medicines, it can often be significantly more costly and complex than for non-differentiated generic products. In addition, to date, many countries do not yet have a fully-developed legislative or regulatory pathway which would permit biosimilars to be brought to market or sold in a manner in which the biosimilar product would be readily substitutable for the originator product. Significant impediments in the development of differentiated products, further delays in the development of such regulatory pathways, or any significant impediments that may ultimately be built into such pathways, 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 biotechnology operations in particular, and could have a material adverse effect on the long-term success of the Sandoz Division and the Group as a whole.

If we are unable to cost-effectively maintain an adequate flow of successful new products and new indications for existing products sufficient to cover our substantial research and development costs and the decline in sales of older products that either become subject to generic competition, or are displaced by competing products or therapies, 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 four operating divisions under "Item 4. Information on the Company—Item 4.B Business Overview."

# Increasing regulatory scrutiny of drug safety and efficacy has and is likely to continue to adversely affect us.

Following a series of widely publicized issues in recent years, health regulators are increasingly focusing on product safety. In addition, governmental authorities around the world have paid increased attention to the risk/benefit profile of pharmaceutical products with an increasing emphasis on product safety and on examining whether new products offer a significant benefit over older 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 for pharmaceutical products has become even more challenging.

In addition, for the same reason, the post-approval regulatory burden has been increasing. Approved drugs have increasingly been subject to 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 far more detailed safety and other data on products. These requirements have the effect of making the maintenance of regulatory approvals and achieving reimbursement for our products increasingly expensive, and further heightening the risk of recalls, product withdrawals, or loss of market share.

Like our industry peers, we have been required by health authorities to conduct additional clinical trials, and to submit additional analyses of our data in order to obtain product approvals or reimbursement by government or private payors. We have had REMS and other such requirements imposed as a condition of approval of our new drugs. Because these regulatory developments can increase the costs of, and cause delays in obtaining approvals, and create an increased risk that products either will not be approved, or will be removed from the market after previously having been approved, these regulatory developments could have a material adverse effect on our business, financial condition and results of operations.

## Our business is increasingly 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 global economic and financial environment. In addition, in certain countries, 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 businesses that rely on reimbursement—including Pharmaceuticals, Alcon, Sandoz and Vaccines and Diagnostics. They 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 innovative medicines 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. Such initiatives include the 2010 enactment of the Affordable Care Act in the US, its implementation, and ongoing efforts by the US Government to find additional savings from government healthcare programs.

As a result of such measures, we faced downward pricing pressures on our patented and generic drugs in many countries in 2013. For example, during 2013, the UK's National Institute for Health and Clinical Excellence (NICE) recommended against the UK National Health Service funding the use of our products Jakavi (myelofibrosis) and Afinitor (advanced breast cancer indication). NICE did recommend the funding of the use of our products Xolair (allergic asthma), Lucentis (diabetic macular edema indication), and Jetrea (vitreomacular traction), but only after we offered significant price discounts. Similarly, a German agency, the Gemeinsamer Bundesausschuss (G-BA), is conducting an analysis of the

benefits of drugs previously approved, and as part of that analysis refused to recommend the use of our product *Galvus* to treat type 2 diabetes. In China, the government has imposed significant price cuts on certain of our products. In the US, under the Affordable Care Act, there is a newly created entity, the Independent Payment Advisory Board, which has been granted unprecedented authority to implement broad actions to reduce future costs of the Medicare program. This could include required prescription drug discounts or rebates. In addition, as a result of the ongoing implementation of the Affordable Care Act, some patients may be required to switch from existing commercial health insurance policies to policies offered on the new healthcare exchanges. Should a significant number of patients switch to policies offered on the exchanges that offer lesser benefits than their prior policies, there could be an impact on the sales or pricing of our products.

We expect these efforts to control costs to continue in 2014 as 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. For more information on price controls and on our challenging business environment see "Item 4. Information on the Company—Item 4.B Business Overview—Pharmaceuticals—Price Controls."

# Failure to comply with law, and resulting investigations and legal proceedings 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, as well as with new requirements 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 will 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 compliance with law 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 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 government investigations and litigations against companies operating in the industries of which we are a part, both in the US and in an increasing number of countries around the world. A number of our subsidiaries are, and will likely continue to be, subject to various legal proceedings that arise from time to time, including proceedings regarding product liability, sales and marketing practices, commercial disputes, employment and wrongful discharge, antitrust, securities, health and safety, environmental, tax, privacy, and intellectual property matters. 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 have a material adverse effect on our results of operations or cash flows.

In addition, governments and regulatory authorities around the world have been stepping up their compliance and law enforcement activities in recent years in key areas, including marketing practices, corruption, trade restrictions, embargo legislation, insider trading, antitrust, and data privacy, and are increasingly challenging practices previously considered to be legal. Responding to such investigations is costly, and requires an increasing amount of management's time and attention. In addition, such investigations may affect our reputation, create a risk of potential exclusion from government reimbursement programs in the US and other countries, and may lead to litigation. These factors have contributed to decisions by us and other companies in our industry, when deemed in their interest, to enter into settlement agreements with governmental authorities around the world prior to any formal decision by the authorities. These settlements have involved and may continue to involve large cash

payments, including the potential repayment of amounts allegedly obtained improperly, and other penalties, including treble damages. In addition, settlements of healthcare fraud cases often require companies to enter into corporate integrity agreements, which are intended to regulate company behavior for a period of years. Our affiliate Novartis Pharmaceuticals Corporation is a party to such an agreement, which will not expire until 2015. Also, matters underlying governmental investigations and settlements may be the subject of separate private litigation.

Our businesses are currently subject to a number of these governmental investigations and information requests by regulatory authorities. See "Item 18. Financial Statements—Note 20."

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 and results of operations.

For more detail regarding specific legal matters currently pending against us and provisions for such matters, 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.

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 products we market and sell are either manufactured at our own dedicated manufacturing facilities or by third parties. In either case, 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. The manufacture of our products is heavily regulated by governmental health authorities around the world, including the FDA. In recent years, such health authorities have intensified their scrutiny of manufacturers' compliance with such requirements, and are increasingly challenging practices that were previously considered acceptable. 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. 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 our competitors, we have faced, and continue to face, significant manufacturing issues. For example, in November 2011, we received a Warning Letter from the FDA with respect to three of our Sandoz Division's facilities—in Broomfield, Colorado, Wilson, North Carolina, and Boucherville, Canada. The Warning Letter raised concerns regarding these facilities' compliance with FDA cGMP regulations. It stated that until the FDA confirms that the deficiencies have been corrected, the FDA can recommend that any pending applications or supplements listing Novartis affiliates as a drug manufacturer not be approved. In addition, FDA may refuse requests to issue export certificates to our Sandoz US affiliate, or import certificates to our Sandoz Canada affiliates. The letter further states that other federal agencies may take the Warning Letter into account when considering the award of contracts. In addition, in May 2013 we received a Warning Letter from the FDA concerning the oncology injectables manufacturing

facility in Unterach, Austria. The letter contained two observations which followed an agency inspection at the site in October 2012, and are related to historical visual inspection practices for products manufactured at the site. In the fourth quarter of 2012, the FDA formally notified Sandoz that the compliance status of its Broomfield, Colorado site has been upgraded. In January 2014, the FDA formally notified Sandoz that the compliance status of its Boucherville, Canada site was upgraded. Work continues on closing out committed actions across the sites.

Separately, in December 2011, we suspended operations and shipments from the OTC Division facility located at Lincoln, Nebraska, which also produces certain products for our Animal Health Division. This action was taken to accelerate maintenance and other improvement activities at the site. Subsequently, in 2012 and 2013, we recalled certain OTC Division products that were produced at the Lincoln facility. We have made progress in the remediation of quality issues at Lincoln, and the FDA closed out its October 2013 inspection of the site with zero Form 483 observations. However, we have also outsourced the production of certain Lincoln products, and have discontinued others. As of the date of this Form 20-F, it is not possible to determine when the plant will resume full operations.

In December 2012, our Alcon Division received an FDA Warning Letter following an inspection at the LenSx laser manufacturing site in Aliso Viejo, California. Alcon responded in writing to the FDA, and in February 2013, FDA responded to Alcon acknowledging that the corrective actions described in Alcon's written response appear to address the items identified in the Warning Letter. The FDA will verify these corrective actions during its next scheduled inspection of the site. The items noted in the Warning Letter do not affect the safety or effectiveness of the LenSx laser, or impact Alcon's ability to sell the product.

As a result of such manufacturing issues, we were unable to supply certain products to the market for significant periods of time, and so have suffered and may continue to suffer significant losses in sales and market share. These supply issues have required us to outsource the production of certain key products that were previously manufactured in our own production facilities, which may limit the potential profitability of such products. In addition, to meet health authority and our own high quality standards, we have expended considerable resources to upgrade and remediate issues at our sites. Should we fail to complete the planned improvements at the sites in a timely manner, including those done in agreement with the FDA, then we may suffer significant additional losses in sales and drainage of resources, and we could be subject to legal action without further notice including, without limitation, seizure and injunction.

In addition, to meet increasing health authority expectations, we are devoting substantial time and resources to improve quality and assure consistency of product supply at our other manufacturing sites around the world. Ultimately, there can be no guarantee of the outcome of any of these efforts. Nor can there be any guarantee that we will not face similar issues in the future, 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 also rely on a single source of supply. In particular, a significant portion of our portfolio, including products from our Pharmaceuticals, Alcon, Vaccines and Diagnostics, and Sandoz Divisions, 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 batch 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 which 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 considered to be technically complex to manufacture, and require strict 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 subject us to lawsuits or to allegations that the public health, or the health of individuals, has been endangered.

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, 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. See also "—Earthquakes and other natural disasters could adversely affect our business," below.

# The persistently weak global economic and financial environment 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. 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, Europe and other places. 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, persistent financial weakness in certain countries in Europe 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 some countries, including Greece, Italy, Portugal and Spain, may not be able to pay us in a timely manner. Certain other countries, such as Venezuela have taken steps to introduce exchange controls and limit companies from distributing retained earnings or paying intercompany payables due from those countries.

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, 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 crisis is directly affecting consumers, some of our businesses, including the elective surgical business of our Alcon Division and our OTC and Animal Health Divisions, may be particularly sensitive to declines in consumer spending. In addition, our Pharmaceuticals, Vaccines and Diagnostics, 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 vaccines, as well as consumer health products, 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.

# Foreign exchange fluctuations may adversely affect our earnings and the value of some of our assets.

In the past year, the US dollar, our reporting currency, has significantly increased in value against certain other world currencies. However, in prior years, the US dollar suffered significant decreases in value. In addition, in recent years, unresolved fiscal issues in the US and in many European economies, and investor concerns about the future of the Euro, have led to the flight of investor capital to the perceived safety of the Swiss franc, causing the Swiss franc to rise significantly in value. Because a significant portion of our earnings and expenditures are in currencies other than the US dollar, including expenditures in Swiss francs which are significantly higher than our revenues in Swiss francs, this volatility can have a significant and often unpredictable impact on our reported net sales and earnings. As has happened in the recent past, changes in exchange rates between the US dollar and other currencies can result in increases or decreases in our reported sales, costs and earnings as expressed in US dollars. Fluctuations in exchange rates between the US dollar and other currencies may also affect the reported value of our assets measured in US dollars and the components of shareholders' equity. In addition, there is a risk that certain countries could devalue their currency. If this occurs then it could impact the effective prices we would be able to charge for our products and also have an adverse impact on both our consolidated income statement and currency translation adjustments included in our consolidated equity. For more information on the effects of currency fluctuations on our consolidated financial statements and on how we manage currency risk, see "Item 5.0 Operating and Financial Review and Prospects—Item 5.0 Operating Results—Effects of Currency Fluctuations," "Item 5.8 Liquidity and Capital Resources," "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 acquisitions or divestments of businesses.

As part of our growth strategy, 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 candidates, potentially increasing prices demanded by sellers, governmental regulation (including market concentration limitations) and replacement product developments in our industry. Further, after an acquisition, successful integration of

the venture can be complicated by corporate cultural differences, difficulties in retention of key personnel, customers and suppliers, and coordination with other products and processes. Also, acquisitions could divert management's attention from our existing business, and could result 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 that we wish to divest. Neither can we ensure that we will correctly select businesses as candidates for divestiture, or that any expected strategic benefits, synergies or opportunities will arise as a result of any divestiture. If we fail to timely recognize or address these matters or to devote adequate resources to them, we may fail to achieve our growth strategy or otherwise not realize the intended benefits of any acquisition or divestiture.

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

The amount of goodwill and other intangible assets on our consolidated balance sheet has increased significantly in recent years, primarily due to acquisitions. As a result, impairment testing could lead to material impairment charges in the future.

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 2013, for example, we recorded intangible asset impairment charges of \$116 million. Of this, \$57 million relates to the Alcon Division, and \$59 million to all other divisions. 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 Long-Lived Intangible and Tangible Assets" and "Item 18. Financial Statements—Notes 1 and 11."

#### Our indebtedness could adversely affect our operations.

As of December 31, 2013 we had \$11.2 billion of non-current financial debt and \$6.8 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 may limit our ability to engage in other transactions and otherwise may place us at a competitive disadvantage relative to our competitors that have less debt. We may 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. Any such failures by third parties could have a material adverse effect on our business, financial condition or results of operations.

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 experienced proportionately higher sales growth and an increasing contribution to the industry's global performance. In 2013, we generated \$14.7 billion, or approximately 25% (2012: 24%) of 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 \$43.2 billion, or approximately 75% (2012: 76%) of our net sales, in the Established Markets. However, combined net sales in the Emerging Growth Markets grew 10% in constant currency in 2013, compared to 2% sales growth in constant currency in the Established Markets during the same period. As a result of this trend, we have been taking steps to increase our presence in the Emerging Growth Markets.

There is no guarantee that our efforts to expand our sales in these countries will succeed, or that these countries will continue to experience growth rates in excess of the world's largest markets. 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 are more susceptible to political and social instability. See "—The persistently weak global economic and financial environment 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.

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 have been well publicized—or we may be required to rely on third-party agents, in either case putting us at risk of liability. 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, and we cannot offset the devaluations with price increases, then our products may become less profitable, or may otherwise impact our reported financial results. See "Foreign exchange fluctuations may adversely affect our earnings and the value of some of our assets," above.

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 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—and when it is able to develop 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 patented pharmaceuticals companies, which commonly take aggressive steps 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. See also "—Our research and development efforts may not succeed in bringing new products to market, or to do so cost-efficiently enough, or in a manner sufficient to grow our business and replaced 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. We are required to make significant assumptions and estimates about future events in calculating the present value of expected future expense and liability related to these plans. These include assumptions about 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 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 the funding level determined based on local rules falls below a pre-determined level. 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-empl

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 which tax profits at more favorable rates. Changes in tax laws or in the laws' application, 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. Additionally, it is possible that adverse events caused by unsafe counterfeit products would 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 in the longer term.

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 US 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 10%, 9% and 7%, respectively, of Group net sales in 2013. The largest trade receivables outstanding were for these three customers, amounting to 9%, 7% and 5%, respectively, of the Group's trade receivables at December 31, 2013. 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 will become increasingly competitive. Shifting demographic trends will result in fewer students, fewer graduates and fewer people entering the workforce in the Western world in the next 10 years. The supply of talent for key functional and leadership positions is decreasing, and a talent gap is clearly 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.

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. Moreover, younger generations around the world have changing expectations toward careers, engagement and the integration of work in their overall lifestyles. Geographic mobility is expected to decrease, and talented individuals in emerging countries anticipate ample career opportunities closer to home than in the past.

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 and other research institutions. As a result, 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.

#### 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. 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 we are required to further increase our provisions for environmental liabilities in the future, or if we fail to properly manage the safety of our facilities and the environmental risks, this could have a material adverse effect on our business, financial condition and results of operations. For more detail regarding environmental matters, see "Item 4.D Property, Plants and Equipment—Environmental Matters" and "Item 18. Financial Statements—Note 20."

# Significant disruptions of information technology systems or breaches of data security could adversely affect our business.

Our business is increasingly dependent on critical, complex and interdependent information technology systems, including Internet-based systems, to support business processes as well as internal and external communications. The size and complexity of our computer systems make them potentially vulnerable to breakdown, malicious intrusion, malware and other cyber-attacks, which may result in the impairment of production and key business processes.

In addition, our systems are potentially vulnerable to data security breaches—whether by employees or others—which may expose sensitive data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personal information (including sensitive personal information) of our employees, clinical trial patients, customers and others.

Such disruptions and breaches of data security could have a material adverse effect on our business, financial condition and results of operations.

#### Increasing use of social media and mobile technologies could give rise to liability or breaches of data security.

Novartis and our associates are increasingly relying on social media tools and mobile technologies as a means of communications. To the extent that we seek as a company to use these tools as a means to communicate about our products or about the diseases our products are intended to treat, there are significant uncertainties as to the rules that apply to such communications, and as to the interpretations that health authorities will apply to the rules that 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. In addition, because of the universal availability of social media tools and mobile technologies, our associates may use them in ways that may not be sanctioned by the company, and which may give rise to liability, or which could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personal information (including sensitive personal information) of our employees, clinical trial patients, customers and others. Such uses of social media and mobile technologies could have a material adverse effect on our business, reputation, financial condition and results of operations.

# 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 risks like hurricanes, tornadoes or floods. As a result of these and other potential impacts of climate change on the environment, 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 could be put at risk.

Our corporate headquarters, the headquarters of our Pharmaceuticals and Animal Health Divisions, and certain of our major Pharmaceuticals Division production and research facilities are located near earthquake fault lines in Basel, Switzerland. In addition, other major facilities of several divisions 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.

#### 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.