

NOVARTIS AG
Form 20-F
January 27, 2015

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As filed with the Securities and Exchange Commission on January 27, 2015

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington D.C. 20549

FORM 20-F

o REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR 12(g) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

ý ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 for the fiscal year ended December 31, 2014

OR

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

o SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
Commission file number 1-15024

NOVARTIS AG

(Exact name of Registrant as specified in its charter)

NOVARTIS Inc.

(Translation of Registrant's name into English)

Switzerland

(Jurisdiction of incorporation or organization)

**Lichtstrasse 35
4056 Basel, Switzerland**

(Address of principal executive offices)

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(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered pursuant to Section 12(b) of the Act:

Title of class	Name of each exchange on which registered
American Depositary Shares	New York Stock Exchange, Inc.
each representing 1 share	
Ordinary shares, nominal value CHF 0.50 per share*	New York Stock Exchange, Inc.*
Securities registered or to be registered pursuant to Section 12(g) of the Act:	

None

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:

None

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report:

2,398,626,257 shares

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act (Check one):

Large accelerated filer Accelerated filer Non-accelerated filer

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP International Financial Reporting Standards as issued by the International Accounting Standards Board Other
If "Other" has been checked in response to the previous question indicate by check mark which financial statement item the registrant has elected to follow.

Item 17 Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

*

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Not for trading but only in connection with the registration of American Depositary Shares representing such ordinary shares.

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INTRODUCTION AND USE OF CERTAIN TERMS

Novartis AG and its consolidated affiliates publish consolidated financial statements expressed in US dollars. Our consolidated financial statements found in Item 18 of this annual report on Form 20-F (Form 20-F) are prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB).

Unless the context requires otherwise, the words "we," "our," "us," "Novartis," "Group," "Company," and similar words or phrases in this Form 20-F refer to Novartis AG and its consolidated affiliates. However, each Group company is legally separate from all other Group companies and manages its business independently through its respective board of directors or other top local management body. No Group company operates the business of another Group company. Each executive identified in this Form 20-F reports directly to other executives of the Group company which employs the executive, or to that Group company's board of directors.

In this Form 20-F, references to "US dollars" or "\$" are to the lawful currency of the United States of America, and references to "CHF" are to Swiss francs; references to the "United States" or to "US" are to the United States of America, references to the "European Union" or to "EU" are to the European Union and its 28 member states, references to "Latin America" are to Central and South America, including the Caribbean, and references to "Australasia" are to Australia, New Zealand, Melanesia, Micronesia and Polynesia, unless the context otherwise requires; references to "associates" are to employees of our affiliates; references to the "FDA" are to the US Food and Drug Administration, references to "EMA" are to the European Medicines Agency, an agency of the EU, and references to the "CHMP" are to the Committee for Medicinal Products for Human Use of the EMA; references to "ADR" or "ADRs" are to Novartis American Depositary Receipts, and references to "ADS" or "ADSs" are to Novartis American Depositary Shares; references to the "NYSE" are to the New York Stock Exchange, and references to the "SIX" are to the SIX Swiss Exchange; references to "GSK" are to GlaxoSmithKline plc, references to "Lilly" are to Eli Lilly and Company, and references to "CSL" are to CSL Limited.

All product names appearing in *italics* are trademarks owned by or licensed to Group companies. Product names identified by a "@" or a " " are trademarks that are not owned by or licensed to Group companies.

FORWARD-LOOKING STATEMENTS

This Form 20-F contains certain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Other written materials filed with or furnished to the US Securities and Exchange Commission (SEC) by Novartis, as well as other written and oral statements made to the public, may also contain forward-looking statements. Forward-looking statements can be identified by words such as "potential," "expected," "will," "planned," "pipeline," "outlook," or similar terms, or by express or implied discussions regarding potential new products, potential new indications for existing products, or regarding potential future revenues from any such products; potential shareholder returns or credit ratings; or regarding the potential completion of the announced transactions with GSK and CSL, or regarding potential future sales or earnings of any of the businesses involved in the transactions with GSK, Lilly or CSL, or regarding any potential strategic benefits, synergies or opportunities as a result of these transactions; or regarding potential future sales or earnings of the Novartis Group or any of its divisions; or by discussions of strategy, plans, expectations or intentions. You should not place undue reliance on these statements.

Such forward-looking statements are based on the current beliefs and expectations of management regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect,

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actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that any new products will be approved for sale in any market, or that any new indications will be approved for any existing products in any market, or that any approvals which are obtained will be obtained at any particular time, or that any such products will achieve any particular revenue levels. Nor can there be any guarantee that the announced transactions with GSK and CSL will be completed in the expected form or within the expected time frame or at all. Neither can there be any guarantee that Novartis will be able to realize any of the potential strategic benefits, synergies or opportunities as a result of the transactions with GSK, Lilly or CSL. Neither can there be any guarantee that Novartis or any of the businesses involved in the transactions will achieve any particular financial results in the future. Nor can there be any guarantee that shareholders will achieve any particular level of shareholder returns. Neither can there be any guarantee that the Group, or any of its divisions, will be commercially successful in the future, or achieve any particular credit rating.

In particular, management's expectations could be affected by, among other things:

unexpected regulatory actions or delays or government regulation generally, including an unexpected failure to obtain necessary government approvals for the transactions, or unexpected delays in obtaining such approvals;

the potential that the strategic benefits, synergies or opportunities expected from the announced transactions, including the divestment of our former Animal Health Division to Lilly, may not be realized or may take longer to realize than expected;

the inherent uncertainties involved in predicting shareholder returns or credit ratings;

the uncertainties inherent in research and development, including unexpected clinical trial results and additional analysis of existing clinical data;

our ability to obtain or maintain proprietary intellectual property protection, including the ultimate extent of the impact on Novartis of the loss of patent protection and exclusivity on key products which commenced in prior years and will continue this year;

unexpected manufacturing or quality issues;

global trends toward health care cost containment, including ongoing pricing pressures;

uncertainties regarding actual or potential legal proceedings, including, among others, actual or potential product liability litigation, litigation and investigations regarding sales and marketing practices, government investigations and intellectual property disputes;

general economic and industry conditions, including uncertainties regarding the effects of the persistently weak economic and financial environment in many countries;

uncertainties regarding future global exchange rates, including as a result of recent changes in monetary policy by the Swiss National Bank;

uncertainties regarding future demand for our products;

uncertainties involved in the development of new healthcare products; and

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uncertainties regarding potential significant breaches of data security or disruptions of our information technology systems.

Some of these factors are discussed in more detail in this Form 20-F, including under "Item 3. Key Information 3.D. Risk factors," "Item 4. Information on the Company," and "Item 5. Operating and Financial Review and Prospects." Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described in this Form 20-F as anticipated, believed, estimated or expected. We provide the information in this Form 20-F as of the date of its filing. We do not intend, and do not assume any obligation, to update any information or forward-looking statements set out in this Form 20-F as a result of new information, future events or otherwise.

Table of Contents**PART I****Item 1. Identity of Directors, Senior Management and Advisers**

Not applicable.

Item 2. Offer Statistics and Expected Timetable

Not applicable.

Item 3. Key Information**3.A Selected Financial Data**

The selected financial information set out below has been extracted from our consolidated financial statements prepared in accordance with IFRS as issued by the IASB. Our consolidated financial statements for the years ended December 31, 2014, 2013 and 2012 are included in "Item 18. Financial Statements" in this Form 20-F.

All financial data should be read in conjunction with "Item 5. Operating and Financial Review and Prospects". All financial data presented in this Form 20-F are qualified in their entirety by reference to the consolidated financial statements and their notes.

	Year Ended December 31,				
	2014	2013	2012	2011	2010
	(\$ millions, except per share information)				
INCOME STATEMENT DATA					
Group net sales	57,996	57,920	56,673	58,566	50,624
Net sales from continuing operations	52,419	52,090	51,330	52,195	43,539
Operating income from continuing operations	11,089	10,983	11,507	10,293	10,153
Income from associated companies	1,918	599	549	526	798
Interest expense	(704)	(683)	(724)	(751)	(692)
Other financial (expense)/income	(31)	(92)	(96)	(2)	64
Income before taxes from continuing operations	12,272	10,807	11,236	10,066	10,323
Taxes	(1,545)	(1,498)	(1,706)	(1,381)	(1,266)
Net income from continuing operations	10,727	9,309	9,530	8,685	9,057
Net (loss)/income from discontinuing operations	(447)	(17)	(147)	387	912
Group net income	10,280	9,292	9,383	9,072	9,969
Attributable to:					
Shareholders of Novartis AG	10,210	9,175	9,270	8,940	9,794
Non-controlling interests	70	117	113	132	175
Basic earnings per share (\$)					
Continuing operations	4.39	3.76	3.89	3.59	3.88
Discontinuing operations	(0.18)	0.00	(0.06)	0.16	0.40
Total	4.21	3.76	3.83	3.75	4.28
Diluted earnings per share (\$)					

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Continuing operations	4.31	3.70	3.85	3.54	3.86
Discontinuing operations	(0.18)	0.00	(0.06)	0.16	0.40
Total	4.13	3.70	3.79	3.70	4.26
Cash dividends ⁽¹⁾	6,810	6,100	6,030	5,368	4,486
Cash dividends per share in CHF ⁽²⁾	2.60	2.45	2.30	2.25	2.20

(1) Cash dividends represent cash payments in the applicable year that generally relates to earnings of the previous year.

(2) Cash dividends per share represent dividends proposed that relate to earnings of the current year. Dividends for 2014 will be proposed to the Annual General Meeting on February 27, 2015 for approval.

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	Year Ended December 31,				
	2014	2013	2012	2011	2010
	(\$ millions)				
BALANCE SHEET DATA					
Cash, cash equivalents and marketable securities & derivative financial instruments	13,862	9,222	8,119	5,075	8,134
Inventories	6,093	7,267	6,744	5,930	6,093
Other current assets	10,805	13,294	13,141	13,079	12,458
Non-current assets	87,826	95,712	96,187	93,384	96,620
Assets related to discontinuing operations	6,801	759			
Total assets	125,387	126,254	124,191	117,468	123,305
Trade accounts payable	5,419	6,148	5,593	4,989	4,788
Other current liabilities	19,136	20,170	18,458	18,159	19,870
Non-current liabilities	27,570	25,414	30,877	28,331	28,856
Liabilities related to discontinuing operations	2,418	50			
Total liabilities	54,543	51,782	54,928	51,479	53,514
Issued share capital and reserves attributable to shareholders of Novartis AG	70,766	74,343	69,137	65,893	63,218
Non-controlling interests	78	129	126	96	6,573
Total equity	70,844	74,472	69,263	65,989	69,791
Total liabilities and equity	125,387	126,254	124,191	117,468	123,305
Net assets	70,844	74,472	69,263	65,989	69,791
Outstanding share capital	898	912	909	895	832
Total outstanding shares (millions)	2,399	2,426	2,421	2,407	2,289
Cash Dividends per Share					

Cash dividends are translated into US dollars at the Bloomberg Market System Rate on the payment date. Because we pay dividends in Swiss francs, exchange rate fluctuations will affect the US dollar amounts received by holders of ADRs.

Year Earned	Month and Year Paid	Total Dividend per share (CHF)	Total Dividend per share (\$)
2010	March 2011	2.20	2.37
2011	March 2012	2.25	2.48
2012	March 2013	2.30	2.44
2013	March 2014	2.45	2.76
2014 ⁽¹⁾	March 2015	2.60	2.63 ⁽²⁾

(1) Dividend to be proposed at the Annual General Meeting on February 27, 2015 and to be distributed March 5, 2015

(2) Translated into US dollars at the 2014 Bloomberg Market System December 31, 2014 rate of \$1.010 to the Swiss franc. This translation is an example only, and should not be construed as a representation that the Swiss franc amount represents, or has been or could be converted into US dollars at that or any other rate.

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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 21, 2015, as found on Bloomberg Market System, was CHF 1.00 = \$1.14.

Year ended December 31, (\$ per CHF)	Period End	Average⁽¹⁾	Low	High
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
2014	1.01	1.09	1.01	1.13

Month

August 2014	1.09	1.11
September 2014	1.05	1.09
October 2014	1.03	1.06
November 2014	1.03	1.04
December 2014	1.01	1.04
January 2015 (through January 21, 2015)	0.98	1.16

(1) 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 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 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.

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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 imatinib, the active ingredient in our best-selling product *Gleevec/Glivec* (cancer), will expire in July 2015 in the US, in 2016 in the major European countries and expired in 2014 for the main indications in Japan. Additional patents claiming innovative features of *Gleevec/Glivec* have been challenged in the US. A settlement with one of these generic manufacturers will allow that generic manufacturer to enter the US market on February 1, 2016. Generic versions of *Gleevec/Glivec* have already launched in a number of countries around the world.

The patent on valsartan, the active ingredient in *Diovan/Co-Diovan/Diovan HCT* (high blood pressure), which had long been our best-selling product, has expired in the US, EU and Japan, and generic competitors have launched there. Patent protection for *Co-Diovan* will expire in Japan in 2016. The active ingredient valsartan is also used in the single-pill combination therapies *Exforge/Exforge HCT* (high blood pressure). While separate patents exist in the EU to protect this combination product, they have been challenged. Market exclusivities for *Exforge/Exforge HCT* will remain in the EU due to regulatory exclusivities. However, there is a risk that generic manufacturers may circumvent regulatory exclusivity and gain approval of a combination valsartan-amlodipine product. In the US, *Exforge* already faces generic competition despite the existence of separate patents covering the product.

Patent protection for octreotide acetate, the active ingredient in *Sandostatin*, has expired. Generic versions of *Sandostatin* SC are available in the US and elsewhere. A series of US patents protect *Sandostatin LAR*, the long-acting version of *Sandostatin* which represents a majority of our *Sandostatin* US sales. Some of these US patents have already expired, and the last of these US patents is expected to expire in 2017. Patents protecting the *Sandostatin LAR* formulation in key markets outside the US have expired.

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 and all of Europe. We hold additional patents with respect to *Exelon* Patch, which makes up a substantial portion of our *Exelon* sales, but these have been challenged. Generic versions of *Exelon* Patch are on the market in several European countries.

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".

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In 2015, the impact of generic competition on our net sales is expected to be approximately \$2.5 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, 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 that are entering the healthcare field. Physicians, patients and third-party payers may choose our competitors' products instead of ours if they perceive them to be safer, more effective, easier to administer, less expensive, more convenient, or more cost-effective.

Products that compete with ours, 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 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 may fail 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

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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 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 other divisions face similar challenges in developing new products and bringing them to market. Alcon's Ophthalmic Pharmaceuticals products and the products of our Vaccines Division all must be developed and approved in accordance with essentially the same processes as faced by our Pharmaceuticals Division. Alcon's Surgical and Vision Care products face similarly difficult development and approval processes. Alcon makes significant investments in research and development to develop new eye care products to replace sales that may be lost to generic or other competition and to grow its businesses. Vaccines has, and continues to expend considerable time and resources to fully develop and bring to market new vaccines, including vaccines to combat meningococcal disease. 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 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, 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 difficulties 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

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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 five operating divisions under "Item 4. Information on the Company Item 4.B Business Overview."

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 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, 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 that rely on reimbursement including Pharmaceuticals, Alcon, Sandoz and Vaccines. 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 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.

As a result of such measures, we faced downward pricing pressures on our patented and generic drugs in many countries in 2014. For example, during 2013, a German agency, the Gemeinsamer Bundesausschuss (G-BA), initiated an analysis of the benefits of drugs approved prior to 2011. As part of that analysis the G-BA concluded that our type 2 diabetes medicines *Galvus* and *Eucreas* did not provide an added benefit over certain other medicines indicated for the treatment of that disease. As a result, we were unable to reach agreement with the head organization of the German statutory health insurance funds, GKV-Spitzenverband, on an acceptable price for *Galvus* and *Eucreas*, and, in 2014, we stopped distribution of these products in Germany.

We expect these pressures to continue in 2015 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 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 failure to comply with law or with heightened public expectations could lead to

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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 our industry, 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, such as proceedings regarding sales and marketing practices, product liability, 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 sales and 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 and monetary penalties. 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 in the US and other countries sometimes require companies to enter into corporate integrity or similar 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 is scheduled to expire in 2015. Also, matters underlying governmental investigations and settlements may be the subject of separate private litigation.

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.

Our businesses are currently subject to a number of these cases and governmental investigations, as well as information requests by regulatory authorities. 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. 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.

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

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standards. In recent years, 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, 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 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. 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.

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 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, including products from our Pharmaceuticals, Alcon, Vaccines, 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 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 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 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, 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.

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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. 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 payors in 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. See also, "Item 5. Operating and Financial Review and Prospects Item 5.B Liquidity and Capital Resources," "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, 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, Vaccines, 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

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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.

In addition, increasing political and social instability around the world, including political instability and military action involving Russia, Ukraine and parts of the Middle East, the impacts of the Ebola crisis in western Africa, increased political and religious radicalism in many places, and increasing social unrest, including anti-immigrant activities in many countries may lead to significant business disruptions or other adverse business conditions. 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 "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. This in turn may significantly affect the comparability of period-to-period results of operations. In 2014, the US dollar significantly increased in value against most currencies. In particular, the average value of the Japanese yen and emerging market currencies (especially the ruble) decreased in 2014 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. 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 can have a significant impact on the reported value of our net sales, earnings, assets and liabilities, and the timing and extent of such volatility can be difficult to predict.

In addition, there is a risk that certain countries could take other steps which could significantly impact the value of their currencies. Such steps could include "quantitative easing" measures, potential withdrawals by countries from common currencies or the setting of exchange controls, as Venezuela did. Should such steps significantly change the value of a country's currency, then this could impact the value in US dollars of our sales and earnings in such countries, as well as the 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. 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 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

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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.

On April 22, 2014, we announced that we had reached definitive agreements with GSK and Lilly on a set of transactions intended to transform our portfolio of businesses. In a series of inter-conditional transactions with GSK, Novartis agreed to: (1) acquire GSK oncology products and certain related assets, and was granted a right of first negotiation over the co-development or commercialization of GSK's current and future oncology R&D pipeline, excluding oncology vaccines; (2) create a joint venture with GSK in consumer healthcare, in which Novartis would own 36.5%; and (3) divest its Vaccines Division (excluding the influenza vaccines business) to GSK. In addition, Novartis agreed to divest its Animal Health Division to Lilly. Subsequently, on October 26, 2014, we announced that we had entered into a definitive agreement to divest our influenza vaccines business to CSL.

The transaction with Lilly closed on January 1, 2015. All of the remaining transactions are subject to closing conditions, including regulatory approvals. In addition, the transactions with GSK are inter-conditional. The transactions with GSK are expected to close in the first half of 2015 and the transaction with CSL is expected to close in the second half of 2015.

Because of the need for external approvals and certain other contingencies, the proposed transactions may not be completed in the expected form or within the expected time frame, or at all. If the transactions are completed, then certain milestone and royalty payments may be owed if certain conditions are met. But because of the uncertainties involved, we cannot ensure that any such payments will be made either by us or to us. In addition, in agreeing to these transactions, we expected to achieve certain strategic benefits, synergies and opportunities, including certain financial results, but such expected benefits may never be fully realized or may take longer to realize than expected. With respect to the acquisition of the GSK oncology products and related assets, we cannot be certain that the GSK business will be successfully integrated with ours and that key personnel will be retained. Disruption from these transactions may make it more difficult to maintain relationships with customers, employees or suppliers. Lastly, extensive preparations are needed to complete these transactions, as well as the integration and de-integration of the respective businesses, requiring substantial attention from our management. This diversion of management's attention away from our continuing businesses could result in the continuing businesses failing to achieve expected financial or other results, or in liabilities being incurred that were not known at the time of the transactions, or the creation of tax or accounting issues.

In addition, in April 2014, we announced the creation of a shared services organization, Novartis Business Services (NBS), which became effective on July 1, 2014. NBS consolidated 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.

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

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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.

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 2014, for example, we recorded intangible asset and goodwill impairment charges of \$752 million. Of this, \$334 million was recorded on the announcement of the sale of our influenza vaccines business to CSL. 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, 2014 we had \$13.8 billion of non-current financial debt and \$6.6 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 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

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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 2014, we generated \$15.3 billion, or approximately 26% (2013: 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 \$42.7 billion, or approximately 74% (2013: 74%) of our net sales, in the Established Markets. However, combined net sales in the Emerging Growth Markets grew 11% in constant currencies in 2014, compared to 1% sales growth in constant currencies in the Established Markets during the same period. As a result of this trend, we have been taking steps to increase our activities in the Emerging Growth Markets, and have been making significant investments in our businesses in those countries.

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 in many countries 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.

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 pharmaceutical 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 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

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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. 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. 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 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 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 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 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

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materially affect patient confidence in the authentic product, and harm the business of companies such as ours or lead to litigation. 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.

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 15%, 13% and 6%, respectively, of Group net sales in 2014. The largest trade receivables outstanding were for these three customers, amounting to 11%, 8% and 4%, respectively, of the Group's trade receivables at December 31, 2014. 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. 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. 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, many members of 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, other research institutions, other companies seeking to enter the healthcare space and companies in other industries. 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.

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Significant breaches of data security or disruptions of information technology systems 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 as well as internal and external communications. The size and complexity of these systems make them potentially vulnerable to breakdown, malicious intrusion, malware and other cyber-attacks. While we have invested heavily in the protection of our data and information technology, we may not be able to prevent breakdowns or breaches in our systems that could adversely affect our business.

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. In addition, such potential information technology issues could lead to the loss of important information such as trade secrets or other intellectual property, or personal information (including sensitive personal information) of our employees, clinical trial patients, vendors, customers, collaborators and others, or could expose such important information to unauthorized persons. We also manufacture and sell a number of devices that make significant use of information technology, including our Alcon surgical equipment. Malfunctions in such technology could lead to a risk of harm to patients.

Any such breaches of data security or information technology disruptions 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.

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."

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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 Division, 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. 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.

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Item 4. Information on the Company

4.A History and Development of Novartis

Novartis AG

Novartis AG was incorporated on February 29, 1996 under the laws of Switzerland as a stock corporation (*Aktiengesellschaft*) with an indefinite duration. On December 20, 1996, our predecessor companies, Ciba-Geigy AG and Sandoz AG, merged into this new entity, creating Novartis. We are domiciled in and governed by the laws of Switzerland. Our registered office is located at the following address:

Novartis AG
Lichtstrasse 35
CH-4056 Basel, Switzerland
Telephone: 011-41-61-324-1111
Web: www.novartis.com

Novartis is a multinational group of companies specializing in the research, development, manufacturing and marketing of a broad range of healthcare products led by innovative pharmaceuticals. Novartis AG, our Swiss holding company, owns, directly or indirectly, all of our significant operating companies. For a list of our significant operating subsidiaries, see "Item 18. Financial Statements Note 32."

Important Corporate Developments 2012-2014

2014

- October Novartis announces a definitive agreement with CSL of Australia to divest its influenza vaccines business for \$275 million.
- Novartis announces changes to the Novartis Executive Committee. Three members of the Executive Committee of Novartis, George Gunn, Brian MacNamara and Andrin Oswald, would leave the Company following the completion of the relevant portfolio transactions announced in April 2014, and expected to close in the first half of 2015.
- Novartis announces that it has entered into a collaboration with Bristol-Myers Squibb Company to evaluate three molecularly targeted compounds in combination with Bristol-Myers Squibb's investigational PD-1 immune checkpoint inhibitor, Opdivo® (nivolumab), in Phase I/II trials of patients with non-small cell lung cancer.
- August Novartis appoints a Chief Ethics, Compliance and Policy Officer reporting directly to the CEO.
- July Novartis announces that its Alcon Division has entered into an agreement with a division of Google Inc., to in-license its "smart lens" technology for all ocular medical uses.
- June Novartis announces that the FDA licensed its manufacturing facility in Holly Springs, North Carolina for the commercial production of cell-culture influenza vaccines, with the capacity to significantly increase production in the event of an influenza pandemic.
- May Novartis enters into a licensing and commercialization agreement with Ophthotech Corporation for the exclusive rights to market *Fovista* (OAP030, anti-PDGF aptamer) outside the US.

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April Novartis announces a set of definitive inter-conditional agreements with GSK. Under these agreements, Novartis would acquire GSK oncology products and certain related assets, would be granted a right of first negotiation over the co-development or commercialization of GSK's current and future oncology R&D pipeline (excluding oncology vaccines) and would divest the Vaccines Division (excluding its influenza vaccines business) to GSK. The two companies would also create a joint venture in consumer healthcare, of which Novartis would own 36.5%.

Novartis also announces a definitive agreement with Lilly to divest the Company's Animal Health Division. This divestment was completed on January 1, 2015.

Novartis announces the creation of 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. NBS became effective on July 1, 2014.

February Novartis announces the acquisition of CoStim Pharmaceuticals Inc., a Cambridge, Massachusetts-based, privately held biotechnology company focused on cancer immunotherapy. The acquisition brings to Novartis late discovery stage immunotherapy programs directed to several targets, including PD-1.

Novartis appoints a Global Head, Corporate Responsibility reporting directly to the CEO.

January Novartis implements several changes to its governance structure. These include elimination of the Chairman's Committee of the Novartis AG Board of Directors; transfer of operational responsibilities that previously rested with the Chairman or the Chairman's Committee, such as approval authority for management compensation, to the CEO or the Executive Committee; and establishment of the Research and Development Committee of the Novartis AG Board of Directors to oversee Novartis research and development strategy and advise the Board on scientific trends and activities.

2013

November Novartis announces a \$5.0 billion share buyback. The buyback begins on the date of the announcement and will be executed over two years on the second trading line.

Novartis announces a definitive agreement to divest its blood transfusion diagnostics unit to Grifols S.A. of Spain, for \$1.7 billion. This transaction was completed in January 2014.

Novartis announces that it will co-locate certain scientific resources in order to improve the efficiency and effectiveness of its global research organization. Changes include establishing a respiratory research group in Cambridge, Massachusetts, a proposal to close the Horsham, UK, research site, a plan to exit from the Vienna, Austria research site, consolidation of the US-based component of oncology research from Emeryville, California to Cambridge, Massachusetts, closure of the biotherapeutics development unit in La Jolla, California, and a plan to exit research in topical applications for dermatology.

September Novartis announces that it has entered into an exclusive global licensing and research collaboration agreement with Regenerex LLC, a biopharmaceutical company based in Louisville, Kentucky, for use of the company's novel Facilitating Cell Therapy (FCRx) platform.

August Joerg Reinhardt, Ph.D., assumes role of Chairman of the Board of Directors of Novartis AG on August 1.

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July The Novartis Board of Directors announces a final agreement with its former Chairman, Dr. Daniel Vasella. From the date of the Annual General Meeting held on February 22, 2013, until October 31, 2013, Dr. Vasella was to provide certain transitional services, including select Board mandates with subsidiaries of Novartis and support of the ad-interim Chairman and the new Chairman. For his transitional services during such period, Dr. Vasella would receive cash of CHF 2.7 million, and 31,724 unrestricted shares as of October 31, 2013 (the market value of the shares as of the date of the announcement was approximately CHF 2.2 million). In addition, from November 1, 2013, to December 31, 2016, Dr. Vasella will receive a minimum of \$250,000 per annum in exchange for making himself available to Novartis, at Novartis' request and discretion, to provide specific consulting services, such as the coaching of high-potential associates of Novartis and speeches at key Novartis events at a daily fee rate of \$25,000, which will be offset against the \$250,000 minimum annual payment. During November and December 2013, Dr. Vasella did not provide any coaching to associates and did not receive any compensation for this period.

Novartis announces that it has entered into a development and licensing agreement with Biological E Limited (BioE), a biopharmaceutical company based in India, for two vaccines to protect against typhoid and paratyphoid fevers. The agreement advances the Novartis goal to deliver accessible and affordable vaccines that address unmet medical need in endemic regions.

April Novartis and Malaria No More, a leading global charity determined to end malaria deaths, announce that they are joining forces on the Power of One campaign to help close the treatment gap and accelerate progress in the fight against malaria. Over the next three years, Novartis will support the campaign financially and also donate up to three million full courses of its pediatric antimalarial drug to match the treatments donated by the public, doubling the impact of these donations.

February Novartis announces that the Novartis AG Board of Directors and Dr. Vasella agreed to cancel his non-competition agreement and all related conditional compensation. The agreement was to take effect after Dr. Vasella stepped down as Chairman of the Board at the Novartis Annual General Meeting on February 22, 2013.

January Novartis announces that, at his own wish, Novartis AG Chairman of the Board of Directors Dr. Daniel Vasella will not stand for re-election as a member of the Board of Directors at the Annual General Meeting to be held on February 22, 2013. The Board of Directors proposed the election of, among others, Joerg Reinhardt, Ph.D., as a member of the Board for a term of office beginning on August 1, 2013, and ending on the day of the Annual General Meeting in 2016. The Board announced its intention to elect Joerg Reinhardt as Chairman of the Board of Directors as from August 1, 2013. The Board of Directors further announced its intention to elect its current Vice-Chairman, Ulrich Lehner, Ph.D., as Chairman of the Board of Directors for the period from February 22, 2013, until the new Chairman took office.

2012

September Novartis successfully completes a \$2.0 billion bond offering in two tranches.

August Novartis and the University of Pennsylvania (Penn) form a broad-based Research & Development alliance to advance novel T-cell immunotherapies to treat cancer. Novartis and Penn enter into a multi-year collaboration to study chimeric antigen receptor (CAR) technology for the treatment of cancer. The parties establish a joint Center for Advanced Cellular Therapies at Penn to develop and manufacture CARs. Novartis licenses worldwide rights to the first CAR investigational therapy, CART-19, from Penn, and obtains worldwide commercial rights to products from the collaboration. Novartis will provide an up-front payment to Penn, research funding, funding for the establishment of the CACT and milestone payments for the achievement of certain clinical, regulatory and commercial milestones and royalty payments.

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- May Sandoz announces an agreement to acquire Fougera Pharmaceuticals, based in Melville, New York, for \$1.525 billion, to make Sandoz the number one generic dermatology medicines company globally and in the US, and to strengthen Sandoz's differentiated products strategy. The acquisition was completed in July 2012.
- March Alcon gains exclusive rights outside the US to ocriplasmin, a potential first pharmacological treatment for vitreomacular adhesion. Alcon pays ThromboGenics an upfront payment of EUR 75 million, with potential additional payments based on milestones, and on royalties on sales.
- January Novartis extends its commitment to help achieve the final elimination of leprosy. Our new five-year commitment includes a donation of treatments worth an estimated \$22.5 million, and is expected to reach an estimated 850,000 patients. Novartis will also intensify efforts to build a multi-stakeholder initiative in a final push against leprosy. We have a long history in fighting leprosy, donating medicines and developing programs to support patients, valued at more than \$100 million since 1986.

Novartis announces the restructuring of its US Pharmaceuticals business to strengthen its competitive position in light of the loss of patent protection for *Diovan* and the expected impact on the worldwide sales of *Tekturna/Rasilez* after the termination of the ALTITUDE study. The restructuring of the US General Medicines business results in a reduction of 1,960 positions and leads to an exceptional charge of \$160 million in the first quarter of 2012 and to expected annual savings of approximately \$450 million by 2013.

For information on our principal expenditures on property, plants and equipment, see "Item 4. Information on the Company 4.D Property, Plants and Equipment." For information on our significant investments in research and development, see the sections headed "Research and Development" included in the descriptions of our operating divisions under "Item 4. Information on the Company 4